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ADMINISTRATIVE LAW OF THE EUROPEAN UNION

ADJUDICATION

SUMMARY OF SECTORAL REPORTS

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The following material summarizes the information provided in the six sectoral reports concerning EU administrative adjudication. [We assume that this summary will be published with the six sectoral reports in whatever form they are ultimately published] Each summary provides information keyed to the set of questions that were provided to the sectoral reporters. The six reports that are summarized here are:

- Competition (¶a.)
- Trade remedies (¶b.)
- Trademarks (¶c.)
- Food safety (¶d.)
- State aids (¶e.)
- Pharmaceutical licensing (¶f.)

A brief summary of this material is included as Part II in our report on EU administrative adjudication.

Of course, the reports themselves are far lengthier than this summary. The full reports (which are about 700 pages in length) contain much valuable detail, documentation, and footnotes, most of which has been removed from this summaries in order to make this section (and this report) of manageable length.

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1. Substantive background

Part 1 of your report should provide a brief overview of the substantive law and policy in your sector and the range of matters that arise for adjudication. Some of the sectors involve several different types of disputes so you should describe each of them. Identify any major trends or developments on the substantive side that have consequences for the decisional process. Also identify the various participants and institutions that are involved in the decisionmaking process and what role each unit plays in the process. We are seeking only an overview of substantive law, not an extensive treatment, in light of the fact that our project is primarily procedural rather than substantive in nature.

a. *Competition.* The EU rules on competition are found in Articles 81 and 82 of the EC Treaty. Article 81(1) EC prohibits as incompatible with the common market all agreements between undertakings, decisions by associations of undertakings, and concerted practices that may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market. However, Article 81(3) EC provides that the prohibition may be declared inapplicable to certain restrictive agreements that are economically beneficial and justified.

Article 81(1) is broadly construed to catch a wide range of potentially harmful agreements. The Commission or other decisionmakers must examine agreements in their legal and economic context. If a restriction is not capable of appreciably distorting competition, for example because it is trivial or the transaction could not proceed without it, it is not caught by Article 81(1). Analysis under Article 81(3) entails a full assessment of pro-competitive effects and efficiencies as balanced against anti-competitive effects.

Individual exemptions under Article 81(3) may be granted by the Commission or, since modernizing reforms took effect in May 2004, by national competition authorities or national courts. Also the Commission may issue "block exemptions" for agreements that comply with specified conditions. The Commission issues block exemptions for certain common arrangements (such as distribution restraints) and for certain sectors (such as motor vehicles).

Before May 2004, under Regulation 17-1962, the Commission had a monopoly over the grant of exemptions and parties were obliged to notify their agreements to the Commission if they sought an exemption. The Commission found itself seriously burdened by the notification and approval process. Regulation 1/2003 superseded Regulation 17, abolished the notification and prior approval procedure, and decentralized the process of enforcement of Article 81 by authorizing national courts and agencies (as well as the Commission) to grant exemptions.

Article 82 prohibits the abuse of a dominant position. A dominant firm may abuse its position by various predatory, exclusionary, discriminatory, or exploitative conduct. A dominant firm has the opportunity to prove an objective justification for its conduct.

Finally, the EU controls mergers. The Merger Regulation (now Reg. 139/2004) contains the rules for notification of proposed concentrations of Community dimension, establishes the timetable for the merger review proceedings, and specifies the Commission's investigative powers and the rights of the parties. The Merger Regulation applies without regard to whether the parties are domiciled in the Community and whether the transaction will be consummated in

the Community. Thus it is applicable to mergers of firms even if they are not located in the EU as long as they make sufficient sales in the EU to qualify the merger as one of Community dimension.

Competition law enforcement in Europe is the most obvious "success story" of direct enforcement of EU law by the EU organs. While Member States now have a significant and increasing role in enforcing EU competition law, they are far overshadowed by the role of the European Commission. The allocation of enforcement responsibility primarily to the Commission is different from most other areas of EU law, where enforcement lies primarily with national administrative authorities (indirect Community administration) and with national courts.

Private enforcement of EU competition law is a function for the Member States. Even in this area, however, the Commission is contemplating a role for itself in specifying obligations of Member States to provide effective procedural vehicles and sufficient remedies, with a view towards strengthening current weak systems for private resource.

b. *Trade remedies.* When the EU is confronted with competition from imports, it has three main trade remedies at its disposal: anti-dumping, anti-subsidy and safeguards.

The basic EU anti-dumping regulation is the mechanism whereby the EU can combat prices that are, according to the regulation, unfairly low, usually by imposing a duty at the EU border on products from particular companies in particular countries. Indications that prices are unfairly low are when they are lower than the price charged on the home market or where they are loss making. The EU can impose anti-dumping measures where dumped imports cause material injury to the EU industry.

The basic EU anti-subsidy regulation is the mechanism whereby the EU can counteract the effects of government subsidies, which can give foreign competitors an unfair advantage over their EU counterparts. Through the EU's anti-subsidy rules, the EU can impose an extra duty at the EU border on products from particular companies in particular countries. (A duty imposed to counteract a subsidy is known as a countervailing duty or CVD, and the EU's anti-subsidy rules are sometimes referred to as its "CVD" rules.) As in anti-dumping, the EU can impose countervailing duties where subsidized imports cause material injury to the EU industry.

The EU can also take safeguard measures. With safeguards, the EU can provide its industry with temporary relief from competition from abroad, regardless of whether that competition is unfair. The safeguard regulation also provides for the Commission to impose "surveillance" of imports, to monitor their development and perhaps ultimately impose safeguard measures. Different from the anti-dumping and anti-subsidy mechanisms, there are additional requirements for the EU to impose safeguard measures, and the standard of injury is higher: the EU has to prove that the imports cause "serious" rather than "material" injury to the Community industry. Rather than duties, safeguards usually take the form of quantitative restrictions on imports of a particular product, although more recently they have been in the form of higher customs duties. Unlike anti-dumping and anti-subsidy rules, which are directed at particular countries, as a general rule safeguards must restrict imports of the product concerned from all origins. The exception to this rule is China. In the context of China's accession to the WTO, special safeguard provisions allowing the EU to take safeguards against imports from China alone were adopted. They will remain in force until 2013.

Of the three trade remedies, anti-dumping is by far the EU's preferred remedy (in 2005 there were 24 new anti-dumping investigations initiated). Anti-subsidy action is comparatively rare (2 were initiated in 2004), and safeguard action is the rarest of them all (2 investigations initiated in 2004). This is in contrast to the United States, which uses all three trade remedy mechanisms regularly.

The European Commission plays the primary role in investigating, evaluating, quantifying and proposing trade remedies, upon a complaint from the Community industry or representatives thereof, or exceptionally, on its own initiative. The European Commission is also authorized to impose safeguard measures. However, only the Council of the European Union is authorized to actually impose definitive anti-dumping and countervailing measures. The Member State governments of individual countries have a greater role in safeguard actions, because the European Commission will generally only initiate its investigation upon a request from a Member State.

c. *Trademarks.* Trademark law provides protection for any word, symbol or other *distinctive sign* used to distinguish an organization's product or service from those of its competitors. A trademark acts as a "badge of origin" or "badge of quality," which informs the public that the goods or services with which it is associated originate from a certain company and are guaranteed to be of a certain quality. From the trademark owner's perspective, a trademark is also an important tool of recognition and marketing and can represent an important intangible asset.

1. Legal requirements to obtain a trademark. The first requirement for a Community trademark to be valid is that it must be distinctive, meaning that it must be capable of distinguishing the goods or services to which it is applied as those of a particular business. The public may be because it is inherently distinctive—for example, an invented word such as KODAK—or because, although not distinctive in itself, it has through extensive use in fact become associated with a given business. Purely descriptive signs can therefore not be accepted as trademarks. The second requirement is that the trademark must be capable of written description, be it by the spelling of a word, the presentation of the figurative sign, or the writing down of musical notes or color codes.

2. Registration of a trademark. Where a mark is intended to be used in more than one country of the European Union, the owner should seek to obtain a Community Trademark ("CTM") from the Community Trademark office in Alicante, Spain. Contrary to the European patent, the Community trademark has a unitary character. It has equal effect throughout the whole European union. It can only be registered, transferred, be the subject of a decision revoking the rights of the proprietor or declaring it invalid, and its use can only be prohibited, in respect to the whole Community. If a mark is refused as a CTM on the basis of opposition of the owner of a prior conflicting mark, it is possible (on payment of a fee) to convert the application into one or more national applications. The CTM becomes subject to revocation if not used over a five-year period. However, use in any single EU country is sufficient to protect it for the whole of the EU.

It is necessary to register a Community trademark in order for it to be valid. An examination of 'anteriorities' (prior registered identical or similar trademarks for identical or similar activities) will take place before granting the trademark. The trademark owner also benefits from a right of priority that allows him a certain delay after the first registration during which he can register his trademark in other countries.

3. *Challenges by private parties.* Private parties can challenge the CTM application or the CTM as granted by various means: the *opposition*, the application for *invalidity,* and the application for *revocation*.

The *opposition* is available to an earlier trademark owner when the mark applied for is either:

- *identical* with the earlier mark, and the goods or services for which registration is applied for are identical with the goods or services for which the earlier mark is protected; or
- identical or *similar* to the earlier mark and the goods or services covered by the marks are identical or similar in such a way that there exists a *likelihood of confusion* on the part of the public in the territory in which the earlier mark is protected; or
- identical with or similar to the earlier mark and is to be registered for goods or services which are *not* similar to those for which the earlier trademark is registered, where the trademark has a *reputation* in the Community (in the case of an earlier CTM) or in the Member State concerned (in the case of an earlier national mark) and where the use of the mark applied for would take unfair advantage of, or be detrimental to, the distinctive character or the repute of the earlier mark.

The opposition must be notified to the Office within a period of three months following the publication of the CTM application.

Causes for *invalidity* must be distinguished in between *absolute* grounds for invalidity and *relative* grounds for invalidity. Invalidity can be claimed at any time after the Community trademark is *registered*.

Absolute grounds for invalidity are identical to the absolute grounds for refusal such as lack of distinctive character (see point 4.2. above). Another absolute ground for invalidity is the bad faith of the applicant when he filed the application. *Relative grounds for invalidity* include all grounds for opposition as described above. Another relative ground for invalidity occurs when the use of the mark may be prohibited pursuant to another earlier right (under the Community legislation or national law), and in particular a right to a name, a right of personal portrayal, a copyright, or an industrial property right.

The *revocation* of a trademark may be claimed if

- if the trademark has not been put to genuine *use* in the Community in connection with the goods or services in respect of which it is registered within a continuous period of *five years*, when there are no proper reasons for non-use;
- if, in consequence of acts or inactivity of the proprietor, the trademark has become the *common name* in the trade for a product or service in respect of which it is registered;
- if, in consequence of the use made of it by the proprietor of the mark or with his consent in respect of the goods or services for which it is registered, the trademark is liable to *mislead the public*, particularly as to the nature, quality or geographical origin of those goods or services.

d. *Food safety.*

An application process triggers most food safety decisionmaking. See generally Reg. 178/2002 (the General Food Law Regulations). However, in most cases, the ultimate decision does not take the form of a specifically applicable adjudicatory decision. Instead, it takes the form of a legislative decision, taken through the comitology process, whereby the particular food item for which authorization was sought is added to the annex of an existing rule. (See ¶7.7 *infra* for discussion of the rulemaking process). Then any other manufacturer is authorized to market the same item if it meets the description of the approved item.

However, in the case of novel foods and genetically modified foods, the application process results in an adjudicatory decision applicable only to the particular applicant. For that reason, we discuss the application procedures for novel foods below. However, the process of decisions on applications is fundamentally the same whether the ultimate result is approval through rulemaking or through adjudication. In some cases, a negative decision (rejecting an application) will take the form of an individualized decision (as in the case of smoke flavorings).

A novel food is any food that has not been on the Community market pre-May 15, 1997 and has not been used for human consumption to a significant degree in the Community and meets other requirements for novelty (such as having a new or intentionally modified primary molecular structure or being isolated from micro-organisms, fungi or algae). Novel foods must undergo a pre-market approval procedure; unless it is substantially equivalent to existing foods in which case a notification simultaneous with marketing suffices.

e. State aids

One of the goals of the EU is the establishment of a system ensuring that competition in the internal market is not distorted. The state aid rules aim at protecting competition against one of the threat that a Member State's aid to one of its firms will create barriers to cross-border competition. The state aid rules regulate government support being granted to certain market participants. The antitrust rules are directly addressed to undertakings, whereas state aid rules are addressed mainly to Member States.

1. What is State Aid and when is it permissible

The State Aid rules deal not only with cash subsidies paid by a member state to a particular company. Rather, the term "state aid" is used in the broadest possible sense. Any "gratuitous advantage" (and including non collection of state revenues otherwise due, the granting of guarantees, etc.) at the expense of the state is covered, provided that the advantage is made available to only certain companies, in certain regions or to certain sectors of the economy. Measures that apply indiscriminately to all sectors and regions are typically not state aid.

The EU prohibits such State aid unless it is authorized by the Commission pursuant to certain criteria that is provided for in the EU or secondary legislation. The EU declares certain types of aid compatible with the common market, including, for example, aid to make good the damage caused by natural disasters or exceptional occurrences (but the application of the exceptions is still subject to the supervision of the Commission). The Commission, in its discretion, can declare other types of aid to be compatible with the common market (ranging from

aid to promote the economic development of underdeveloped areas to aid to promote the execution of an important project of common European interest.

Any aid that cannot be authorized on such bases is incompatible with the common market. Member States must not make such aid available to beneficiaries. The Commission will typically order a Member State that granted such aid to recover it from the beneficiaries and may adopt injunctions to stop any further aid payments.

2. Basic distinctions - If a Member States intends to grant State aid it first needs to notify such "new" aid to the Commission for approval. Once the Commission approves the aid, the aid becomes "existing aid," but the Commission can order that it be modified for the future. The difference is important, because only new aid is subject to the standstill obligation and because the Commission retains greater power (including the power to demand restitution) over new aid. The concept of existing aid covers includes aid granted before a Member State acceded to the EC (very relevant for the ten new Member States who joined on May 1, 2004).

State aid may be granted either "ad-hoc" in a particular case to address specific needs, or on the basis of a general aid scheme. An "aid scheme" is a general legislative or administrative measure by which a Member State defines the conditions under which aid may be granted to undertakings that are defined in the scheme in general, abstract terms. Aid that is not granted on the basis of an aid scheme is "individual aid" (sometimes also referred to as "*ad-hoc*" aid). Once an aid scheme has been authorized, individual aid granted pursuant to the scheme does not require individual notification to or approval by the Commission. By contrast individual aid always requires notification and approval by the Commission. In practice most aid is granted on the basis of approved aid schemes.

State aid that is put into effect without having been authorized by the Commission is called "unlawful aid". By contrast, "incompatible aid" is State aid that is "incompatible with the common market" pursuant to Article 87 (1) TEC.

3. Procedural overview

The most important procedural concept is that State aid may be granted only after the Commission has approved it. The underlying "stand-still" obligation for the Member States is provided for in Article 88 (3) TEC. This stand-still obligation can be relied upon by third parties, and enforced by actions requesting national courts to quash decisions of national authorities to grant aid before the Commission has taken a decision.

State aid proceedings are bilateral proceedings between the Commission and the member state concerned, and not between the Commission and the undertaking that received State aid. Undertakings that receive aid, the competitors of the aided undertaking (even in their role as complainants) and the local authorities (within the Member State) that grant the aid only have the statues of "interested parties" in this procedure, and only as of a certain stage in the procedure.

Nevertheless, adverse consequences resulting from the procedure mainly affect the beneficiary. It is the beneficiary that will not receive the State aid deemed to be incompatible with the Common Market, and it is the beneficiary that has to pay back amounts it received if the aid was (illegally) paid prior to an authorization decision by the Commission. This procedural setting

has led to certain difficulties (and criticism) since it limits the procedural position of complainants and aid beneficiaries.

The procedure followed by the Commission in State aid cases can divided into two phases, Phase 1 being a *prima-facie* examination of the aid measure in question, and Phase 2 being the formal investigation procedure.

As soon as the Commission has received a notification of a State aid measure by a Member State, the Commission is obliged to initiate Phase 1. Similarly, the Commission is obliged to examine "without delay" any information it obtains regarding alleged non-notified aid. Often, the source of any such information is a complaint by a private party, but the Commission also monitors press reports regarding instances of State aid being granted by the national authorities.

At the end of Phase 1, the Commission will adopt a decision stating either that

- the measure does not constitute State aid; or
- the measure constitutes State aid and is compatible with the common market;
- or the measure raises doubts as to its compatibility with the State aid rules. In this latter case, the Commission will proceed to Phase. 2.

During Phase 2, the Member State concerned and any other interested parties, including any other Member State and any person, undertaking or association of undertakings whose interests might be affected by the granting of the aid, are invited to submit comments. The Member State concerned has the opportunity to reply to any of the comments submitted to the Commission. The formal investigation procedure is closed by a Commission decision stating that either

- the measure does not constitute State aid; or
- the measure is authorized as it is ("positive decision") or subject to conditions ("conditional decision"); or
- the measure is not authorized ("negative decision"). In this case, the Member State is prohibited from putting the measure into effect and must typically recover any aid already ("unlawfully") granted to the beneficiary.

f. *Pharmaceutical licensing.* The pharmaceutical regime is complex because of the variety of the issues it addresses, many of which involve a delicate scientific and technical assessment based on the available data, and the broader policy principles that underpin the system. Broadly speaking, it involves a scientific evaluation of medicines, based on a benefit-risk assessment and takes into account both the need to protect patients as well as the need to ensure availability of new therapeutic methods. In addition, the regime must strike balances between protecting patients and stimulating innovation and competition.

Only the pharmaceutical regime regulates products in such minute detail, including details on composition, therapeutic indications, prescription status, persons involved in the manufacturing and the regulatory process, method of packaging and package sizes, the wording of the package leaflet and of labeling on the containers, and prescribing information for physicians. Any amendment to this detail is also subject to regulatory review. This, combined with the high variability of products and the significance of many specific characteristics of the products, requires the regime to rely heavily on administrative decision-making. These decisions in general aim at protecting public health but can also have a significant economic impact and adequate procedural guarantees are thus of major significance in this sector.

[The report contains an extensive discussion of the law and legal institutions relating to pharmaceutical regulation; because of space limitations, it is heavily abridged here] Originally, there was no marketing authorization at the EU level; authorizations were carried out by Member States. Pharmaceutical licensing through pre-marketing authorization at the EU level was established by Directive 65/65 in the wake of the thalidomide scandal and expanded and strengthened in 1993 and 2004. The 2004 revision increases manufacturer reporting obligations, provides for further inspections, and improves supervision and enforcement of pharmaceutical rules.

The centralized procedure is administered at the Commission level and applies to biotechnology drugs or other innovative products. The decentralized procedure is administered at the Member State level. It applies to other new drug products. The decision on marketing authorization is made by the reference member state. A Coordinating Group mediates disagreements between Member States under the decentralized procedure. In the event of disagreement, the Committee for Medical Products for Human Use (CHMP) renders an arbitral decision.

The Commission makes the primary decisions such as issuance of marketing authorizations, suspensions or withdrawals. The European Medical Agency (EMEA) provides scientific evaluation of medicines on which Commission decisions are based; EMEA is divided into several committees including Committee for Medical Products for Human Use (CHMP). The Coordination Group, which consists of member state regulators, mediates disputes between member states in the decentralized procedures. The Standing Committee on Medicinal Products for Human Use represents member states and is consulted by the Commission as part of the comitology process.

The key decisions in this sector relate to i) granting of marketing authorizations (usually based on a scientific opinion of CHMP); ii) variations to existing authorizations at request of manufacturers, or iii) variations, suspensions and withdrawals of marketing authorizations based on new scientific evidence that alters the risk-benefit assessment.

2. Narrative. We would like Part 2 of each of your reports to include a narrative or story of how a typical dispute in your sector develops from beginning to end. The narrative could be based on one or more actual cases (for example, a landmark decision in the sector or a case from your own experience) or a hypothetical. If the story is entertaining, it is preferred.

a. *Competition.* Atropine is a leading chemical manufacturer, based in Port Sulphur, Louisiana, which produces a number of specialty products. One of these is atrobenzocarbide (ABC) used in the production of British chocolate, German mattresses and French brake linings. There are few alternatives technically to ABC. There is strong demand for ABC, and only three suppliers, each using a different technology. The process used by Atropine is unique and secret; there are no patents. The Greek company Charon makes ABC of acceptable quality, but with dire consequences for the air quality of the neighbouring region. The German company Gross has tried to make the product as efficiently as Atropine but without success, and would therefore like to sell its business.

In 1975, the boss of Atropine met and enjoyed the company of Mr. Mendoza, the owner of Mendoza S.p.a., a Sicilian plant eligible for generous subsidies from the State and with plenty of space and workers who could turn their talents to making ABC. The parties agreed upon a joint venture: Atropine would supply the secret technology and Mendoza would build the plant

and run it. The deal provided that if Mendoza wanted to build a new plant using the technology, a fresh license from Atropine would need to be negotiated.

In 1999, the technology is still secret and still unique. Atropine is having some business problems but Mendoza is doing well and wants to expand and build new plants on Elba, the Isle of Skye and Crete, thus diversifying geographically and culturally. Mendoza asks for a licence to use the technology. Atropine refuses to grant a licence to the new plants.

Mendoza says that refusing to grant a licence is a violation of Articles 81 and 82 EC. Atropine denies this, and to demonstrate its confidence in its own legal position, files a notification with the European Commission, asserting refusing to grant a "site license" of technology to one plant of known capacity is not restrictive of competition within the meaning of Article 81(1) EC. Mendoza files a simultaneous complaint. The notification and complaint are registered by DG COMP's antitrust registry and are then attributed to the respective Directorate that appears to be responsible for the matter.

Both documents land on the desk of Charlotte, the case-handler in Directorate X. She is a Danish national who studied law in Denmark and at Tulane University in New Orleans, after which she passed the competitive examination to become a civil servant of the European Commission in 1995. She works with five colleagues, from Italy, Finland, France, Germany and Portugal. She works under a head of unit, Ms. O'Sullivan (an economist from Ireland), who has 17 years' seniority, and is responsible, among others, for the sector of the economy that this case concerns. Ms. O'Sullivan's Director is Mr. Ramirez (a former Spanish government official who became the head of cabinet of a Spanish Commissioner and now with the arrival of the new Commission was made director of Directorate X).

Charlotte the Dane decides that the complaint presents important points of principle, and agrees to meet Mendoza's counsel. He explains to her all the mysteries of technology and convinces her that the provision calling for the negotiation of a fresh licence is actually the prohibition of exploitation of licensed technology elsewhere in the EU. By trying to limit the production of its licensee, Atropine seems to be infringing Article 81 EC. Article 82 EC may also be a problem.

Charlotte the Dane starts drafting a note for her head of unit in which she proposes to issue a request for information addressed to Atropine, Charon, Gross and Mendoza. Charlotte has already prepared the necessary questionnaires and submits them together with her note to Ms. O'Sullivan, her head of unit. Since Ms. O'Sullivan agrees with Charlotte's analysis of the case she signs the questionnaires, which then go out to the companies.

After having received the information from the questionnaires, Charlotte analyzes the information submitted by the companies. Since she sees a need for further clarification with respect to some of the answers given by some of the companies she proposes further questions to Atropine and Gross. These are duly signed by Ms. O'Sullivan and sent to the companies. After having received the additional information, Charlotte completes her analysis and comes to the conclusion that the Commission should issue a statement of objections because she believes that the refusal by Atropine to grant the license to Mendoza constitutes an infringement of Article 81 EC.

She therefore prepares a note to the Commissioner which shortly summarizes the facts and her analysis of the case. As a conclusion she proposes to the Commissioner to issue a statement of objections. This note is to be signed jointly by Charlotte and the Director General

before it is send to the Commissioner's Cabinet where it needs to arrive a number of days before the weekly meeting between the Commissioner and DG COMP. Before the Director General signs the note to the Commissioner, also Charlotte's hierarchy needs to sign the so-called "signataire," a kind of circular by which Charlotte's hierarchy is informed concerning the note in order to approve it before submission to the Director General and subsequently the Cabinet. As there were some questions concerning the concrete facts and Charlotte's approach by Mr. Ramirez and also the Director General's personal assistant, Charlotte needs to make some amendments to the note which means postponing it by one week.

Once the note is signed by the Director General and sent to the Cabinet a copy of it is also submitted to the Commission's Legal Service that also participates in the weekly meeting between the Commissioner and DG COMP. The Legal Service also has some questions concerning the note and therefore asks for it to be made a point for discussion, a so called "B-point" (meaning that it will be actually discussed in the meeting). In the meeting Mr. Ramirez, assisted by Ms. O'Sullivan and Charlotte, presents the case to the Commissioner. The Legal Service then explains that they have some concerns that the some of the arguments that Charlotte presents for issuing the statement may need to be formulated differently. The Commissioner therefore approves issuance of the statement of objections under the condition that Charlotte resolves the drafting issues in cooperation with the Legal Service before issuing the statement.

After consulting the Legal Service, Charlotte prepares another signataire with the draft-statement of objections for the signature of the Commissioner. Charlotte's hierarchy must approve it: Ms. O'Sullivan and Mr. Ramirez and the Director General in the same manner as the first draft, before it is presented to the Commissioner for her approval. The Commissioner signs the statement of objections and it is sent to Atropine. A non-confidential version of the statement of objections is mailed to Mendoza. Atropine is given six weeks to reply to the statement of objections. Mendoza is invited to submit observations on the Commission's statement of objections within the same period.

Atropine, outraged with the allegations that it infringes competition law, requests access to the Commission's file to verify the evidence on which Commission's case is based. The Commission services send Atropine a CD-ROM containing digital versions of documents constituting the Commission's file. This includes a non-confidential version of Mendoza's complaint and evidence submitted by Mendoza.

In the reply to the statement of objections, Atropine's lawyers raise a number of arguments undermining both factual and legal grounds on which the Commission's statement of objections and Mendoza's complaint are based. In addition, they submit documentary evidence undermining certain facts on which the Commission's objections are based and a legal opinion of Professor Simonides, a well-known authority in the field of EC competition law, stating that the legal interpretation adopted by the Commission is not in line with ECJ case law. Atropine's lawyers request an oral hearing to be held.

Mendoza submits its comments to the Commission statement of objections and also requests to participate in an oral hearing before the Commission. In addition, it submits an economic study from VERITAS, a reputable Brussels-based consultancy that provides advice on economic aspects of EC competition law. The VERITAS study shows that Atropine's refusal to license will have serious anticompetitive effects on the EU ABC market. Mendoza also informs Matratzen GmbH, a German producer of mattresses that buys ABC from Mendoza and Atropine, about the proceedings before the Commission. Matratzen GmbH decides to intervene in the case and sends to the Commission a letter stating that Atropine's refusal to license has adverse effects

on the German mattresses market. In its submission, Matratzen GmbH requests an opportunity to present its arguments during the oral hearing.

The applications from the parties requesting an oral hearing are forwarded to Ms. Lopez, a hearing officer. Ms. Lopez had a 15 years long carrier with the Directorate General for Competition before she being named a hearing officer. Her sole function is to organize hearings and make sure that the parties' right to be heard is respected. She does not otherwise participate in the proceedings before the Commission.

Ms. Lopez must invite Atropine to the hearing, but it is in her discretion to invite other parties to the oral hearing. She thinks that it would be helpful to hear Mendoza, but decides not to invite Matratzen GmbH to the oral hearing, as she deems it sufficient that their arguments are presented in writing. Ms. Lopez sets the date of the oral hearing in two months time. She sends a letter to Atropine and Mendoza informing them on the date of the hearing, asking them to provide her with an overview of the arguments they want to present at the hearing and to name any equipment they may like to use during the hearing. She also invites the parties to an informal meeting in two weeks time at which the schedule of the hearing will be discussed. At this informal meeting lawyers of Atropine and Mendoza and the representatives of the Commission agree on the schedule of the hearing.

At the day of the oral hearing, just before the hearing is commenced, Atropine asks Ms. Lopez to admit additional evidence to be presented at the hearing. Atropine explains that it is a crucial piece of evidence that they were not able to supply at an earlier stage. Ms. Lopez agrees to allow the evidence to be presented at the hearing and Atropine provides the copy of the documents on which it relies to all parties participating in the hearing.

Ms. Lopez formally opens the hearing and invites Mr. Ramirez, who is representing the Commission, together with Ms. O'Sullivan and Charlotte, to present the Commission's case. Then Atropine's lawyers present arguments purporting to rebut allegations in the Commission's case as well as the new documentary evidence undermining Commission's case. Ms. O'Sullivan asks a number of questions relating to the new evidence submitted by Atropine during the hearing. In addition, a representative of a German competition authority, who is present at the hearing, raises certain points relating to the German mattress market. The hearing continues for a second day during which Mendoza presents its arguments. The questions from the Commission follow. After the questions from the Commission Ms. Lopez invites Atropine, the Commission and Mendoza to make concluding remarks.

After the hearing Ms. Lopez prepares an interim report on the hearing and on the observance of the right to be heard. The report also summarizes the Commission's case and the arguments put forward by the parties and third parties as well as any developments at the hearing. In Ms. Lopez's view, some of the legal arguments made by the Commission are not supported by ECJ case law. She points out that the Commission must be particularly meticulous in explaining such developments in its enforcement policy. Her report is given to Mr. Ramirez, Ms. O'Sullivan and Charlotte, and the Director General. Although Ms. Lopez's report has no binding force, Charlotte takes it very seriously in drafting the decision. She and Ms. O'Sullivan make sure that the statement of reasons in the decision carefully discusses the new interpretation adopted by the Commission.

When a preliminary draft of the decision is ready, Charlotte drafts a note to the Director General and the Commissioner summarizing the facts and their assessment in the light of EC competition law. She concludes that Atropine's refusal to license constitutes an abuse of

Atropine's dominant position in the EU market. Charlotte proposes adopting a decision obliging Atropine to grant a license to Mendoza and imposing a fine of EUR 20 million on Atropine. Charlotte's hierarchy is informed of the draft decision and the note before submission to the Director General and subsequently the Commissioner's Cabinet. Before the draft decision is presented to the Commissioner for her approval, Ms. O'Sullivan, Mr. Ramirez and the Director General must endorse it. In addition, Charlotte's senior colleague, Mr. Lewandowski from Directorate A is consulted. He raises some objections concerning the legal reasoning adopted in Charlotte's draft decision and Charlotte needs to make some amendments to the draft decision and the note. Finally, the note is signed by the Director General and sent to the Commissioner's Cabinet. A copy of it is also submitted to the Commission's Legal Service and to DG Enterprise that is responsible for industrial policy concerning ABC. Legal Services and DG Enterprise do not raise any objections as to the proposed decision. At this stage also Ms. Lopez prepares her final report, in which she comments solely on the observance of the right to be heard.

After internal consultations within the Commissions are completed, a draft of the decision is sent to the Member States' national competition authorities and discussed at a meeting of the Advisory Committee composed of representatives of the Member States competition authorities. The Advisory Committee suggest that certain amendments be made to the draft decision. Charlotte drafts a new version of the draft decision including the amendments proposed by the Advisory Committee. The final draft of the decision, after the approval by Charlotte's hierarchy, is submitted for consideration to the College of Commissioners. The opinion of the Advisory Committee and Ms. Lopez's final report are attached to the draft decision. The College of Commissioners adopts the decision after a short presentation of the case is given by Mr. Ramirez. The decision is sent to Atropine. A non-confidential copy of the decision is forwarded to Mendoza. At the same time, the Commission services inform the public on the Commission decision in a short press-release.
Atropine's lawyers decide to file an appeal from the Commission decision to the CFI. They are aware of the fact that it would probably take more than two years before the Court decides on the case. Thus, they apply to the President of the Court for an order suspending the implementation of the Commission's decision until the appeal is decided by the Court.

b. *Trade remedies.* This narrative is intended to offer a general view of the way the process works in practice. It is based on personal experience of one of the authors in a particular case, in which he assisted exporters/producers of a foreign country targeted by an anti-dumping investigation. This case is not atypical as far as the process is concerned.

The exporters/producers sought the help of a lawyer at a rather late stage, i.e. after the notice of initiation of the anti-dumping investigation had been published. It was then too late to try to avert initiation, by attempting to convince the Commission that there was no or insufficient *prima facie* evidence of dumping and/or injury or by contacting delegates in the Advisory Committee from those EU Member States whose industries use the products allegedly dumped. Exporters/producers in foreign countries sometimes know earlier that an anti-dumping complaint will be or has been filed, but often they do not. Yet the authorities of the exporting country are informed when a complaint has been filed. They can inform their producers/exporters of the existence of a complaint; some do so, some not.

Such attempts to prevent initiation are difficult to make anyway, as the Commission is not permitted by the Basic Regulation to disclose to exporters and importers that a complaint even exists before the initiation of an investigation, ditto for Members of the Advisory Committee. Lawyers for complainants have no ethical obligation to give a copy of the complaint

to lawyers for exporters/producers targeted in the complaint and generally consider that they owe their clients a duty not to do so.

After the initiation, lawyers for exporters/producers were given a copy of the non-confidential version of the complaint. Based on the non-confidential information contained in it (which typically does not include some important relevant data), the lawyers argued that this complaint could not justify initiating an investigation. The lawyers for the exporters/producers made these comments more to reserve their clients' rights in a possible subsequent court proceeding against the anti-dumping measures. There is normally no possibility to obtain a court injunction against the initiation. As a practical observation, the Commission currently applies significantly higher standards in assessing the admissibility of complaints than it did in the case that is the basis of this narrative.

Much work was dedicated to assisting the exporters/producers who had received Commission questionnaires in their responses within the short time available.

The lawyers of the exporters/producers inspected the non-confidential file of the Commission containing the responses of the EU producers to the Commission questionnaire and their submissions. Particularly on injury, they concluded and argued to the Commission that the required non-confidential summary of the confidential data contained in these responses and submissions was less than meaningful. These arguments fell on deaf ears at the Commission. However, it should be noted that recently the Commission has become more insistent in requiring meaningful non-confidential summaries.

On their own initiative, the lawyers for the exporters/producers sought and obtained the reports to the annual shareholders' meetings of the complainants that were public companies. Interestingly, not only did most of these reports showed that these companies turned a profit during the period under investigation, but also—and more importantly—none of them referred to the impact of dumped imports on the like product of these complainants.

Subsequently, the lawyers of the exporters/producers filed a submission with the Commission contesting the dumping and injury calculations in the complaint. In addition, their submission argued (a) that the product exported by the exporters/producers in the foreign country was not "like" the product manufactured by the EU industry, showing that the former was not substitutable for the latter, which was sold to a very different downstream industry and (b) that the imported product could not have caused injury to the EU producers as it was sold in a completely different market.

A hearing was sought, granted and held prior to imposition of the provisional duty, in which the lawyers for the exporters/producers further developed these arguments. The Head of the Mission of the exporting country to the EU participated in the hearing. The Head made several arguments. First, the Head argued that the imposition of anti-dumping duties would distort the competition between the exporters/producers of his country and exporters/producers of other countries, some of which were not targeted by the investigation. Second, the Head argued that the anti-dumping duties would very significantly lower the volume of his country's exports to the EU of a product that represented a high proportion of his country's export earnings. The Commission Head of Unit and his team listened carefully and politely, but gave rather technical and not very convincing reasons why provisional anti-dumping duties should/would be imposed.

A short time thereafter the Commission submitted to the Advisory Committee a report on the investigation. The lawyers of the exporters/producers of the foreign country tried to obtain a copy of this report but failed, as under the rules the Commission staff and the members of the Advisory Committee may not disclose such information, let alone the report. The lawyers were hamstrung in their efforts to persuade members of the Advisory Committee to oppose the imposition of provisional duties.

After the imposition of provisional duties, a "disclosure document" was sent to the exporters/producers explaining, in some more detail than the recitals of the Commission Regulation imposing the provisional duties, the way dumping had been calculated and the injury findings. The lawyers for the exporters/producers duly commented on the "disclosure document", contesting, as may be expected, the various findings.

The Commission staff then collected some additional information and reviewed the findings on dumping and injury, with a view to drafting a regulation to impose definitive anti-dumping duties. Such a draft regulation is adopted by the Commission as a proposal that is then submitted to the Council of Ministers for adoption of a definitive regulation imposing anti-dumping duties.

In the meantime, in light of the Commission's expected failure to change the assessment in light of exporters'/producers' legal arguments, the lawyers of the exporters/producers recommended to the authorities of the exporting country to put some political counter-pressure on the EU authorities, including Member States. They were advised to collect information on pending negotiations with EU industries on major contracts for the supply of equipment to the exporting country. The recommendation was that they let it be known to these EU industries that the negotiations would have to be put on hold in view of the impending adoption by the EU of definitive anti-dumping duties. In other words, such duties would have severe consequences on the exports of the exporting country and on its ability to generate sufficient foreign currency to pay for the equipment to be supplied by EU industries.

Whether or not these recommendations were followed can be left aside, the fact is that in the Council of Ministers there was no (at that time required) simple majority in favor of the Commission proposal to impose definitive anti-dumping duties and the whole case was dropped. This was not a typical outcome, as the Council adopts most of the definitive anti-dumping measures proposed by the Commission to the Council of Ministers.

This case, among others, was one of the motivations for an amendment of the basic Anti-Dumping Regulation. It provided that definitive anti-dumping measures are considered to be adopted by the Council of Ministers unless a simple majority of Member States in the Council rejects the Commission proposal within one month after its submission. Indeed, it is not certain that under the new voting rules the proposal could have been defeated.

e. State aids

1. Investment Aid

A typical example of state aid is the granting of investment aid. Aid might be granted in order to support an undertaking's initiative to set up a production plant in an economically disfavored region to create new employment for the local population or to support investments in new infrastructure.

Any undertaking that wishes to receive such investment aid will have to turn to the competent national authorities that administer the aid scheme. The national authorities will then initiate their proceedings pursuant to their national procedural rules. Part of this procedure will be the notification to the Commission of the plan to grant aid to a certain undertaking. The notifying Member State can only pay the aid to the undertaking concerned once the Commission has authorized this aid. If the Member State decides to award the aid nonetheless, this aid will be illegal under Community law. If a Member State intends to award aid prior or without the Commission's authorization, competitors of the recipient undertaking may file an application with national courts seeking an injunction against the award of the aid before the Commission's authorization.

When an undertaking wishes to be granted investment aid, legal advice might be necessary at various stages: The undertaking might need assistance to determine which national scheme or which type of aid it might be eligible for. This will very often involve negotiations between the undertaking and the national authorities, particularly where the undertaking plans to make very large investments, which will have many collateral effects. In such cases it will be necessary to convince the national authorities that the investment will be of considerable importance to the local or regional economic development and that aid is appropriate. Particularly, where also other undertakings or the general public as a whole will benefit from an investment, the authorities will be much more inclined to contribute public money. Legal advice will then often be needed in order to determine the maximum amount of permissible aid. This assessment usually involves interplay between national rules on aid schemes and the relevant Community legislation and Community frameworks on various types of aid.

In the notification process advisers have to watch out that the Member State concerned complies with the Community rules on State aid as otherwise the prospective recipient of the aid might face the risk to be obliged to pay back the aid. Even though the undertaking will not be a party in the proceeding before the Commission—only the Member State concerned enjoys this privilege—the undertaking has also certain limited procedural rights, like the right to be informed of various procedural steps or to submit observations. Here, representation by legal advisers will often be useful and necessary.

Undertakings not receiving aid might also be in need of legal guidance if they wish to prevent a competitor from receiving aid. They might wish to lodge a complaint with the Commission, so that the Commission will initiate a State aid investigation, or they might wish to rely on national procedures and ask a national court to order a stay of payment of aid.

2. Public private partnerships

In 2002, the UK government implemented its plan to modernize and partly privatize London's underground rail system through a Public Private Partnership (the "PPP"). To implement this plan, the London underground was divided into an operating company, London Underground Limited ("LUL"), responsible for providing transport services to the public, and three infrastructure companies (the "Infracos") responsible for maintaining and upgrading the underground's rail network on the basis of 30-year contracts signed between LUL and each of the three Infracos and selected by a bidding process. All four companies were originally established as public entities within the public sector but a public tendering procedure transferred ownership

in the Infracos in 2002 to private investors. Control over LUL was transferred in 1999 to a public body called Transport for London ("TfL"), which is controlled by the elected Greater London Authority and chaired by the Mayor of London.

The Greater London Authority and TfL were highly critical of the PPP proposed by the UK government. In particular the Mayor of London, Ken Livingston, was a vociferous opponent of the plan. In February 2002, TfL, backed by Mr. Livingston, submitted a complaint to the European Commission claiming that the PPP arrangements infringed EU rules on State aid. The UK government formally notified its plans to set up this PPP to the Commission also in February 2002 in order to obtain confirmation that the proposed arrangement did not infringe EU rules on State aid.

Finally, in October 2002, the Commission decided that the PPP arrangement did not involve the granting of State aid to the parties acquiring the Infracos. In reaching this conclusion, the Commission relied on the observation that

> "after the observance of an open, transparent and non-discriminatory procedure, it is, in principle, presumed that the level of any public sector support can be regarded as represent the market price for the execution of a project. This conclusion should lead to the assumption that, in principle, no State aid is involved."

The Commission found that the bidding procedure conducted by LUL fulfilled these criteria. The award of the PPP contracts had been advertised and adhered to the procedure provided for in the relevant public procurement directive, which allowed the narrowing down to a limited number of preferred bidders and to enter into negotiations with only a limited number of bidders ("negotiated procedure"). The Commission rejected the claim that the modification of the contract terms after the selection of the preferred bidders had been discriminatory. All bidders had known the possibility of post-selection changes and the complex nature of the infrastructure contracts required a flexible approach. The changes made did not affect the scope and characteristics of the PPP beyond what had originally been communicated to the interested bidders in the advertisements. The reasons that triggered the changes like affordability constraints, an improved understanding of the requirements of London Underground, and changes in circumstances—the Commission notably referred to the "events of September 11, 2001"—were all "factors which would have had an impact not only on the bids of the preferred bidders, but also on the bids of the non-preferred bidders if those bids had remained in the competition." For these reasons the Commission concluded that the tendering procedure had been open, transparent and non-discriminatory which meant that the PPP contracts reflected a market price and thus did not involve elements of State aid.

f. *Pharmaceutical licensing.* This narrative concerns anorectic medicines (appetite suppressants). In 1995, Germany triggered a Community interest referral (under Art. 12 of Directive 75/319, now Art. 31 of the Human Use Directive) to obtain a binding Community conclusion "on the risks and benefit of chemically defined, centrally acting anorectics and on their authorization status." The referral resulted from concerns about the risk of patients developing primary pulmonary hypertension when using anorectic agents for treatment of obesity.

The CPMP (Committee for Proprietary Medicinal Products, renamed in 2004 to CHMP—Committee for Human Medicinal Products) issued initial opinions (separately for each

substance type) on 15 February 1996. The opinions proposed amendments to the SmPCs (Summary of Product Characteristics which is the main information for prescribing physicians and is similar to the U.S. package insert). Some of the marketing authorization holders appealed the opinions and, as a consequence, the CPMP modified its proposal for amending the SmPCs. However, during these reviews, the positive risk-benefit assessment of the medicines involved was not generally questioned. Based on the CPMP's final opinions, the Commission adopted two decisions on 9 December 1996 that required Member States to impose the relevant changes to the SmPCs on marketing authorization holders.

In 1998, Austria and other Member States requested a new Community Referral for the substances in question, because of safety concerns after the occurrence of several cases of cardiac valve disorders. The procedure was initiated pursuant to Article 15a of Directive 75/319 (now Art. 36 of the Human Use Directive), which governs products whose approval status has already been determined by a Community procedure. The request generally questioned the risk-benefit balance of anorectic products in light of new guidelines on the efficient treatment of obesity.

The first report of the pharmacovigilance working party to the CPMP in 1998 came to the conclusion that the risk-benefit assessment of other anorectic products remained unchanged, but a later report concluded that the substances do not fulfill the criteria of effective therapy in obesity treatment as clinical evidence showed only that they were effective in short term treatment and clinical evidence on their long-term effect was unavailable. This was based on the new CPMP Note for Guidance (issued in 1997) and new national guidelines, which required a long-term weight loss effect in the treatment of obesity. Based on these findings, the CPMP issued opinions recommending the withdrawal of the marketing authorizations for these anorectic medicines because the risk-benefit balance of the products was now considered negative. Some marketing authorization holders appealed but were not successful. Based on the final CPMP opinions, the Commission adopted three decisions on 9 March 2000, ordering the Member States to withdraw the marketing authorizations for the products concerned. Several marketing authorization holders sought judicial review before CFI, which annulled the decisions.

CFI ruled that the 2000 decisions were invalid because the Commission did not have the powers to adopt the contested decisions of 9 March 2000 that ordered the withdrawal of marketing authorizations granted for anorectic medicines. It held that the Article 12 procedure in 1996 cold not result in binding Commission decisions, and that the marketing authorizations for the anorectic products were not harmonized, so that there could be no valid referral under Article 15a. Furthermore, it held the decision was illegal because it did not meet the substantive requirements for withdrawing marketing authorizations. The Court stated that a competent authority can at any time re-evaluate the risk-benefit balance and may take appropriate action, particularly in cases of scientific uncertainty. The latter is an application of the precautionary principle, a general principle of Community law that allows actions to protect public health early on in the procedure without changing the general burden of proof.

However, the withdrawal of a marketing authorization cannot be based on mere changes in the scientific criteria for the assessment if no new data underpin a revised assessment of the risk-benefit balance of a product. In addition, the CPMP did not refer to new products available on the market with a better risk-benefit balance, which would have had an impact on the evaluation of the products in question. As a result, the decisions were also unlawful with regard to their content, as they were not based on any new data that was not available at the time of the first review in 1996. (The ECJ affirmed CFI on the issues relating to the regulations and avoided decision on the key substantive issue.) [The report has two additional narratives that have been omitted because of space concerns. The narrative on third generation oral contraceptives discusses the process of re-evaluating approved drugs because of new evidence about health

effects. The narrative on Ferriprox, a drug that treats iron overload, led to a CFI decision holding that the administrative process in drug cases is solely between the Commission and the applicant for marketing authorization. While the CHMP must consider observations made by a third party (in this case a researcher who disagreed with the applicant), the third party has no standing to participate and no standing to seek judicial review.]

3. The difference between adversary and inquisitorial administrative process.

EU law and practice is more inquisitorial and less adversarial than American or British models of administrative law. The "hearings" that are provided for in some of the sectors are very different from those that occur in the U. S. or Britain. Even though the concepts of "due process" or "natural justice" sometimes appear in descriptions of EU law and practice, these concepts have quite a different meaning than in the U. S. or Britain. The inquisitorial approach used in Commission proceedings is an adaptation of the inquisitorial process used in the civil and criminal justice systems of continental member states. EU practice also incorporates elements from the administrative law systems of continental member states (though not, for example, the conseil d'etat in France).

Under the adversarial model of administrative adjudication, there is a separation between the investigatory and adjudicatory phases. After the investigation is concluded, an independent decisionmaker provides a trial-type hearing at the agency level (this is quite distinct from the judicial review that is provided later). This decisionmaker is often called an administrative law judge (ALJ) in the U.S.; in Britain an independent tribunal often provides the hearing. In connection with that hearing, agency staff members who have played investigatory, prosecutorial, or advocacy roles in the particular case cannot serve as adjudicatory decisionmakers or make ex parte communications to those decisionmakers (we call this "separation of functions"). In the U. S., the heads of an agency usually have responsibility for the final agency decision (which can differ from the proposed decision of the ALJ), but separation of functions continues to apply at the agency head level. The decisionmakers at both the ALJ and agency head level take personal responsibility for their decisions. (This description is obviously oversimplified and some U.S. administrative processes are more inquisitorial and less adversarial than as described above).

In contrast, under the inquisitorial model of administrative adjudication, there is no separation between investigation and adjudication, no separation of personnel between different functions. Instead, all administrative procedures are considered to be phases of the investigation. The "hearing" is an opportunity for the party being investigated to advocate its side of the case, not a real trial before an independent decisionmaker. Thus the hearing is viewed as a phase of the investigatory process, not as a separate adjudicative process. The final Commission decision is collective and institutional in nature, not a decision for which particular persons take personal responsibility.

The fundamental distinction between adversary and inquisitorial systems is essential to understanding the law and practice of the Commission. That law and practice will baffle American and British lawyers until they understand this basic distinction. We would welcome your comments on the adversary-inquisitorial distinction. You can comment specifically on it in section 1 of your report or you can intersperse comments about it throughout the report—or both. (There are some more specific questions that touch on this distinction in the portion of the guidelines relating to hearings). Does the above brief description of the inquisitorial approach correctly describe the practice in your

sector? Are there elements of the adversary system in that practice? Is the inquisitorial process in EU law different from or similar to the administrative law of member states that you're familiar with? As a policy matter, should the practice change in the direction of the adversary system? Whatever comments or observations you might offer on this fundamental distinction will be very helpful to us in preparing our synthesis.

a. *Competition.* Proceedings before the EC are inquisitorial rather than adversarial. The Community administrative and judicial structure is influenced to a substantive extent by continental as opposed to common law models. The Communities started after all as a continental project and the accession of the UK did not change this legal reality. Particular emphasis should be placed on the influence of French administrative law, which is far more inquisitorial than the American or British models. In fact, the inquisitorial approach used in Commission proceedings is an adaptation of the inquisitorial process used in the judicial systems of continental Member States. Thus, the "hearings" that are provided for in the antitrust area may be very different from those that occur in the U.S. or Britain. Even though the concepts of "due process" or "natural justice" appear in descriptions of EU law and practice, these concepts may have quite a different meaning.

Nevertheless, the above description must be qualified in two ways: First, while in principle the EU administrative enforcement system remains inquisitorial, many adversarial elements have been introduced, particularly in Commission antitrust proceedings. The strengthening of the role of the hearing officer falls under this trend. This may be due to sociological reasons, most prominently to the dominance of British and U.S. law firms in the Brussels legal scene. Second, one must never lose sight of the role of the European Courts, especially the CFI.

b. *Trade remedies.* The administrative process followed in the EU in the trade remedies area is essentially inquisitorial. There is no separation between the investigatory and adjudicatory phases. The investigation is carried out by a European Commission department (DG TRADE), and that same department drafts the decision to be taken by the European Commission on a proposal by the Member of the Commission responsible for trade policy, where the Commission has the authority to act (provisional anti-dumping and countervailing duties, provisional and definitive safeguard duties). DG TRADE also drafts the decision to be proposed by the Commission to the Council of the European Union where the Council has the authority to act (definitive anti-dumping and countervailing duties, countermeasures against foreign countries under the Trade Barriers Regulation.

There are nonetheless some adversarial features in the administrative process for certain trade remedies, in the sense that interested parties have an input in the investigation and have the possibility to defend their interests and views, as will be illustrated in the relevant parts of this report. One interesting feature is the consultation by the Commission of an advisory committee consisting of representatives of EU Member States, at the initiation of the investigation and subsequently on the results of the investigation and on the measures contemplated by the Commission staff. Interested parties often contact members of such advisory committee directly on an informal basis to defend their interests and views. Yet, the process remains essentially inquisitorial. There is no equivalent of an administrative law judge as in the U.S., though it should be noted that the U. S. administrative process in the trade remedies area does not provide for an ALJ either.

From a policy perspective, in view of the checks and balances that exist— within the Commission and in the advisory committees—there does not appear to be a need to switch from the inquisitorial process to an adversarial one. There is no indication that an inquisitorial system like the EU results in more trade remedies being imposed than an adversarial system like the U.S.

From a legal perspective, these checks and balances ought, however, to be complemented by an additional counterweight designed to allow private parties to better defend their interests, where they do not coincide with the various public policy interests that come into play. Creating a hearing officer function would go some way towards remedying this. Such function already exists in the framework of the enforcement of competition rules by the Commission. The task of such hearing officer should, however, not be limited to ensuring that procedural rules have been complied with, as has been the experience in the area of EU competition rules. He or she could also query the substantive aspects of the case.

f. *Pharmaceutical licensing.* Administrative decisions in the pharmaceutical sector are taken on the basis of a mainly investigational or inquisitorial procedure and not pursuant to an adversary process. There is no clear separation between an investigational phase and an adjudicatory step by an independent decision maker.

To a great extent, the investigatory procedure is based on data provided by the interested party, rather than on independent fact finding by the authorities. In all cases the authorities take into account other data that are available and the Community pharmaceutical system is also based on a pooling of regulatory and scientific expertise from throughout Europe at the European Medicines Agency (EMEA).

The new system of sanctions in pharmaceutical cases (taking effect in 2005) offers an opportunity for introduction of a more adversary system of adjudication. A proposed version of the Commission Regulation on sanctions envisages a two-step procedure, where the EMEA conducts the main investigation and the Commission assesses this review in light of the relevant legal provisions and takes the final decision. It is unclear whether there will be an adversary procedure for imposing sanctions.

4. Application or investigation phase

4.1 Application phase: If the administrative process you are describing begins with an application for a particular benefit, license, or permission, please describe the application process. What information must be disclosed? What forms are filed? To whom is the application directed? Is it filed in a member state—and if so, which member state—or with the Commission? Are competitors or the general public notified of the application and, if so, how and when? Is there a pre-filing meeting where counsel can find out if the staff sees any problems with the application? Is there a time limit on the Commission's consideration of the application? If the application is denied, what form does the denial take?

a. *Competition.*

Abolition of notification system. Under Regulation 1/2003, the previous system of notification and administrative authorization was abolished. Therefore, with the exception of merger control (discussed below), it is no longer appropriate to speak of an "application for a particular benefit, license, or permission." Indeed, the very idea of the new system of enforcement of Articles 81 and 82 EC is diametrically opposed to such an application and relies on rigorous "self-assessment."

National competition laws. However, the system of notification and administrative authorization survives in the national competition laws in certain Member States, though the global trend in the EU Member States is to amend their competition laws and follow the EU example, by introducing a system of legal exception. As long as the old system survives nationally, one must take into account that restrictive agreements or practices may still have to be notified nationally in some Member States.

Guidance letters. Even at the Community level, there may be instances where the Commission may still receive an application for a "benefit." Undertakings may approach the Commission informally in order to seek guidance. This compensates to a certain extent for the loss of legal certainty as a result of the abolition of the notification system. These informal channels of co-operation are most necessary in difficult cases. However, companies are not entitled to obtain such opinions and this informal mechanism does not re-introduce a notification system from the back door. A guidance letter is without prejudice to the Commission's powers as to the subsequent assessment of the same issues and cannot bind national courts, although such Commission statements can be of persuasive value before national courts.

In order for the Commission to issue a guidance letter, five cumulative conditions must be satisfied: (a) the question involved cannot be clarified by reference to existing sources of law; (b) clarification of the novel question is useful, taking into account its economic importance or a widely spread market practice; (c) the guidance letter can be issued on the basis of information provided to the Commission; (d) the questions involved are not identical or similar to questions pending before CFI or ECJ; (e) the specific practice concerned is not subject to proceedings pending before the Commission, a national competition authority, or a national court.

Merger control. In contrast to the application of Article 81 and 82 EC, the EC merger control system is based on prior notification and authorization. Notification is required for mergers with a Community dimension, i.e. for mergers that reach the Community thresholds (the thresholds are based on the sales of the two companies worldwide and in the EU). The aim of such notification is to obtain clearance of the merger from the Commission, i.e. a Commission decision declaring the merger compatible with the common market and allowing its implementation.

The application process starts with pre-notification contacts with the Commission and proceeds to the filing of a notification form (Form CO for a normal merger). A notification must contain the information (including documents), specified in the appropriate application forms. The form mainly refers to the parties (with specific information on turnover, subsidiaries, activities, ownership and control, any link between the parties, etc.) and to the "affected market." It must normally be submitted by the merging parties or the parties acquiring joint control. However, the person or company acquiring control of all or part of one or more companies may also submit it. If representatives of persons or companies sign the notification, the signatories must provide written proof that they are authorized to act. In the case of joint notifications, there must be a joint representative authorized to transmit and receive documents on behalf of all notifying parties.

It is necessary to submit one original and 35 copies of Form CO and the supporting documents (originals or copies of the originals) to DG COMP. The notification must be submitted in one of the official languages of the Community (which will be the language of the proceedings), except for original documents, which must be submitted in their original language (if they are not in an official language already, they will have to be translated into one of the

official languages). If the Commission finds that the notified concentration falls within the scope of the Merger Regulation, it will then publish in the Official Journal the facts of the notification, including information on the companies concerned (names, country of origin) and about the nature of the concentration and the economic sectors involved.

Pre-notification contacts take place with the Commission in the vast majority of merger cases. They normally consist of one or two meetings (usually two weeks before the filing of the notification form) between DG COMP and the parties. To launch pre-notification contacts, the merging parties should provide the Commission with a memorandum giving a brief background to the transaction and some general information. The meetings aim mainly at discussing jurisdiction and other legal issues, at preparing the upcoming Commission investigation (if a notification form is actually filed) and at preventing incomplete notification forms. In cases in notifications have been found to be incomplete, there were usually no or very limited pre-notification contacts. Such contacts are always held in strict confidence and secrecy. DG COMP advises holding them in an open and cooperative atmosphere, in order to have a fruitful pre-notification phase. The first pre-notification meetings would normally need a draft Form CO in order to facilitate a detailed discussion. In any event, whether or not pre-notification meetings have occurred, the merging parties should provide DG Competition with a substantially complete draft Form CO before filing a formal notification.

The time-limit within which the Commission must decide on the concentration starts once a formal notification is submitted and the Commission considers it complete. In any case, once the Commission receives a draft notification form during the pre-notification contacts, it will require at least 5 working days to review it. However, the Commission will have to decide within 25 days on a Member State's request for a referral of the case. This period starts to run once the Commission has received the reasoned submission from the Member State.

c. *Trademarks.*

1. *Where to file application*. A Community trademark is obtained by registration at the Office for Harmonization in the Internal Market (hereinafter OHIM or the "Office"). The trademark applicant can choose to file his/her application either directly at the Office in Alicante or at the central industrial property office of any EU Member State. In the latter case, the national office must forward the application to the Office in Alicante within two weeks after filing.

2. *How to file an application.* A CTM may be applied for at the Office by mail, fax or online, using the "e-filing" system. The Office makes the application form available. A copy of the application form can also be downloaded from the Office's website: http://oami.eu.int/en/mark/marque/pdf/demande.pdf. Online application for a CTM is also available from the Office's webpage: http://oami.eu.int/en/mark/marque/efentry.htm The e-filing allows the applicant to complete an electronic application form and provide the requested attachments and complete the payment details online. This system provides for real-time confirmation and online verification to assure error-free filing and secure a filing date. An applicant applying online should receive his CTM number within three days.

It is not compulsory to be represented before the Office in order to *file* a CTM application. However, 'non European based' applicants will normally have to be represented before the Office in *all other proceedings* regarding the CTM. Representation of natural or legal persons before any legal practitioner may only undertake the Office qualified in one of the Member States and having his place of business within the Community. The representative must also be registered on the list maintained by the Office. European-based applicants can be

represented by an employee of the applicant (who can also represent non-European based affiliates of the European based applicant).

3. *What information must the application contain?* The application must contain (a) a request for the registration of the mark as a CTM, (b) information identifying the applicant (and its representative, if any) (c) a list of the goods or services in respect of which the registration is requested, and (d) a representation of the trademark.

The list of the goods or services for which the mark is to be registered must be made using the common classification referred to in the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks of 15 June 1957, as revised and amended. The list must classify each item in only one class of the Nice Classification. The goods and services must in principle be grouped according to these classes, each group being preceded by the number of the class to which that group of goods or services belongs and presented in the order of the classes under that Classification.

In the event colors and/or graphic features are claimed, the mark shall be reproduced on a separate sheet of paper. The text application shall contain an indication that the mark is reproduced separately and may contain a description of the mark. Where registration of a three-dimensional mark is applied for, the representation shall consist of a photographic reproduction or a graphic representation of the mark.

Where the priority of a previous application, the exhibition priority or the seniority of one or more earlier trademarks is claimed, the application further contains a declaration to that effect and gives the appropriate information of dates and places.

4. *Language of application.* The CTM application must specify the language in which the application is filed, and the second language the use of which the applicant accepts as a possible language of proceedings. The application may be filed in any of the official languages of the European Community. The indication of a second language is necessary even when the language used in the application is an official language of the Office. If the application was filed in a language, which is not one of the languages of the Office, the Office shall arrange to have the application translated into the language indicated by the applicant.

The choice of the language of the application and the designation of the second language cannot be changed once the application is filed. The choice of languages can further be used as a strategic tool for future proceedings before the Office. In *ex parte* proceedings (i.e. the examination by the Office of the CTM application, where the applicant is the sole party), the language of the proceedings shall be the language used for filing the application. In *inter partes* proceedings (opposition, revocation and invalidity proceedings) however, if the language used in the application is not an official language of the Office, and unless otherwise agreed upon by the parties, the language of the proceedings shall be the one designated as the second language in the application. If both the language of the application and the second language are official languages of the Office, the opponent or the party who is applying for revocation or invalidity may choose the language of the proceedings.

The choice of language should not possibly assist a potential competitor (while keeping things relatively easy for the applicant). For instance, if you think that your trademark application is likely to be opposed by a French company, you may want to choose a Dutch/ German combination, or an English/ Italian combination, but you should avoid the

English/French combination. This is of course highly dependent on facts and on the language abilities of the applicant and its counsels.

For English-speaking applicants (or applicants for which it is advantageous to have the CTM proceedings in English) the following options may be considered:

- File the CTM application in English and choose a second language that does not ease the proceedings for potential opponents: e.g. an English/ Italian combination.
  The advantage of this combination is that all communications with the Office in *ex parte* proceedings will be in English, as well as all official correspondence and documents (e.g. certificate of registration). The disadvantage is that there is a risk that the *inter partes* proceedings might be in Italian.
- File the CTM application in a relatively not current EU language, and designate English as a second language: e.g. a Hungarian/English combination. This solution has the advantage that the *inter partes* proceedings will in any case occur in English, which is the only official language of the Office in the above-mentioned combination. The attacking party will consequently not be given the opportunity to choose the language of the proceedings. This solution however presents the disadvantage that *ex parte* proceedings as well as all official documentation from the Office may be in Hungarian. This drawback is nevertheless lessened by the fact that in the event the language of the application is not a language of the Office, the latter may, in *ex parte* proceedings, send written communications in the second language indicated by the applicant.

4. *Fees.* A CTM application is subject to the payment of a basic application fee and of a class fee for each class exceeding three to which the goods or services belong.

5. *Is there a time limit on the Office's consideration of the application?* There is no specific time limit mentioned in the Regulations. The Office is however expected to act *"without delay"* in most circumstances. Conversely, the Office can specify time limits to be met by the applicant for the various steps of the proceedings. Such period cannot be less than one month for European-based applicants and cannot be less than two months in other cases. In all cases, it cannot be more than six months, although extensions of time can be granted if requested and when this is appropriate under the circumstances.

d. *Food safety.* In the area of food safety, the grant of approval for the introduction of most new food products is in the form of a rule. The exceptions are novel foods and genetically modified foods. (See ¶¶1 for definition of novel foods and 7.7 for summary of the comitology process.) Individual applications that trigger rulemaking include authorization of a food additive, food decontaminant, food contact material, color, or flavoring. In some cases, rejection of an application takes the form of an individualized decision (such as smoke flavorings).

Regardless of whether the ultimate approval comes through rulemaking or adjudication, the products and ingredients being authorized go through a similar regulatory and scientific assessment procedure. Depending on the applicable legal instrument, the applicant files an application either at Member State level or with the Commission. European Food Safety Agency (EFSA) performs an initial scientific assessment. Such procedure would take anywhere between one (in exceptional cases) and five years, with a majority of cases in the two to three year range. The newer legislative instruments usually provide deadlines for the scientific assessment and for most of the following administrative procedure. However, the deadlines are often suspended by requests for further scientific and technical information from the applicant, potential re-

submission to EFSA because of new information received (also from third parties) to be assessed, and because of the interplay between the Commission and the Regulatory Committee (see ¶7.7).

We concentrate here on novel foods because both the approval and rejection of novel food and genetically modified food applications produce an individualized decision rather than a rule. See the Novel Foods Reg., 258/97. In the case of novel foods, the procedure begins with submission of an application to a member state in which the product is to be put on the market. A copy of the application is forwarded to the Commission. The Scientific Committee for Food has provided guidance on the structure and content of the application in several opinions.

Companies wishing to pursue a novel food application usually do some forum shopping when it comes to a decision on the Member State in which the application should be filed. Indeed, it is quite easy to decide on the place where the "novel food is first put on the market". Companies would either have a preference for the Member State in which they have their main business operations or their seat; or a Member State which they believe is easily accessible (for example for language); or a Member State they believe has a good understanding of novel foods (technical expertise required and already several files processed in a reasonable time frame). Accordingly, of the fourteen novel foods authorized to date, 5 files had their initial assessment in the United Kingdom, 4 in the Netherlands, 2 each in France and Finland, and 1 in Denmark.

e. *State aids*. Treaty Article 88(3) obliges Member States to inform the Commission of any plans to grant or alter aid and to not implement such aid before the Commission has taken a decision. In the notification the Member State must provide all necessary information in order to enable the Commission to assess the conformity of the aid with the State aid rules. Existing aid need not be notified to the Commission, but alterations to existing aid must be notified. Notifications can also be made voluntarily for the avoidance of doubt because whether a Member State is granting state aid or not can be difficult to determine.

Notifications of new aid are made on specific notification forms set out in Annex I to Regulation 794/2004. Notifications are addressed to the Secretary General of the Commission and transmitted to the Commission by the Permanent Representative of the Member State concerned. From January 1, 2006, notifications should only be transmitted to the Commission electronically. Neither the general public, competitors nor other Member States are informed of the notification. Only the Member State that submitted the notification will receive an acknowledgement of receipt. In more complex cases of individual aid, Member States, the beneficiary and the Commission engage in pre-notification discussions, typically aimed at identifying the information that the Commission is likely to focus on in its analysis.

f. *Pharmaceutical licensing*. This discussion concerns marketing authorizations (and variations of authorizations applied for by the manufacturer). Under Art. 8 (3) of Directive 2001/83/EC, the applicant for a marketing authorization has to provide comprehensive information about the product, including manufacturing method, therapeutic indications and contraindications as well as adverse reactions, pharmaceutical form, dose, route of administration, precautionary and safety measures, description of control methods, results of pharmaceutical, preclinical and clinical trials (which is the core part of the dossier), a proposed SmPC etc. This information has to be provided in the form of the so-called Common Technical Document (CTD). See (http://pharmacos.eudra.org/F2/eudralex/vol-2/home.htm) which contains implementation guidance.

For some types of applications, such as abridged applications (the main approval route for generic medicines), or applications for biosimilar products (which are follow-on products of biological medicines), different dossier requirements apply. Abridged applications, for example, are exempted from the requirement to provide pre-clinical and clinical studies. For biosimilar products, however, generally more data must be provided due to the specific nature of such products.

Applications in the centralized procedure have to be sent to the EMEA in London. The EMEA has set up a Q&A document, dealing with the formal and substantial parts to be dealt with until submission (http://www.emea.eu.int/htms/human/presub/list.htm), which also contains information about electronic submission, number of copies, timing aspects, etc. Third parties are generally not notified about the lodging of marketing authorization applications. However, the EMEA posts positive opinions of the CHMP on its web site. Pending applications are from that time on made public.

The EMEA requests a pre-filing announcement at least six months in advance so as to organize the workload of the members of the committees and to allow for an efficient review of the application. In addition, applicants typically engage in a pre-submission meeting with EMEA approximately six months prior to the anticipated date of submission to obtain procedural, regulatory and legal advice from the EMEA. At the pre-filing meeting, an applicant can discuss legal and procedural steps, including preferences for Rapporteurs and the appointment of "project managers" within the EMEA. The project manager, who is appointed in the pre-filing phase has a crucial role in the organization of the application and evaluation procedure and serves as a contact point for the parties involved in the process. The pre-filing meeting is also intended to help the applicant in preparing the application, in accordance with the legal requirements, and so as to allow prompt validation. Furthermore, EMEA offers scientific advice through its working parties if guidelines on a specific topic are not sufficient, or if the company wants to deviate from them. Scientific advice can be obtained at all stages during the process of development of the product and typically is requested well in advance of an actual application because it is used to steer the development of the data package. Scientific advice is not binding for the final decision about a marketing authorization application.

Before an evaluation procedure starts, the application first needs to be validated. The validation of an application should normally be complete ten days after the EMEA has sent an acknowledgement of receipt to the applicant. However, if further information or clarification is needed, the validation phase may take longer. The evaluation procedure begins after the Rapporteur and Co-Rapporteur confirm that they have received a dossier. It should be completed and an opinion issued within 210 days, but there are various steps where that period is suspended (so-called clock stops).

4.2 Applications—investigatory phase. What happens to an application after it is filed? Please describe the process by which an application is processed and considered including referral to scientific committees.

a. *Competition.* As explained above, companies apply to the Commission for the conferral of a certain benefit only in the context of merger control. Once the merging parties submit to the merger registry a "Form CO" (i.e. a formal notification) and if the Commission considers this complete, the latter will examine it "as soon as it receives it" and start a Phase I investigation. The notification will be allocated to the appropriate merger unit inside every Directorate in DG COMP. The merger unit will be chosen based on the industry sector to which the merger notified corresponds or where it is believed to cause a major impact. The Commission

will also publish a notice in the Official Journal including the name of the parties and the nature of the concentration.

The Commission will have a maximum of 25 working days either (i) to conclude that the notified transaction does not fall within the Merger Regulation, or (ii) to adopt a decision declaring the concentration as being compatible with the common market, or (iii) to conclude that the concentration raises serious doubts as to its compatibility with the common market and therefore to initiate proceedings. These proceedings will conclude with the adoption of a decision either clearing (with or without conditions) the merger or prohibiting it.

The initial period of 25 working days may be extended to 35 working days where (i) the competent authority in a Member State makes a request for referral of the case, or (ii) if the parties present commitments in order to render the concentration compatible with the common market thus avoiding the initiation of proceedings. This extension allows the parties to discuss the commitments presented to the Commission in order to render the decision compatible with the common market. It is possible for a Member State to request a referral of the case if it considers that the concentration threatens to affect significantly market competition within that Member State. The Commission will then have, if it has not started proceedings, 25 working days to decide whether to refer the case, or 65 working days if it has started proceedings. The Commission's investigatory powers are described below (¶4.7.2).

When the Commission takes any of the decisions mentioned above at the end of a Phase I investigation, it will publish a short notice in the Official Journal (together with a press release on the DG COMP website). In case the notified concentration "raises serious doubts as to its compatibility with the common market," it will then start a Phase II investigation. The Commission will have to issue a decision within 90 working days, either clearing the merger or prohibiting it. This can be extended to 105 days if the parties present commitments before the 65th day of investigation. Moreover, within 15 working days after the initiation of Phase II the parties can request an extension (only once) of 20 working days.

When the Commission decides to either block the merger, or impose a fine or periodic penalty payment, it must send the parties a statement of objections, usually one month after the initiation of Phase II, which the parties can respond to in writing. This statement of objections will be the basis of a future decision. After the issuance of the statement of objections, the merging parties can access the file. Later, the Commission will hold a hearing with the merging parties and any third parties that have played an active role in the proceedings. On this basis the case team will reach a view on the transaction, report to the Competition Commissioner and give the parties a last chance to offer better commitments.

Before adopting the final decision, the Commission must consult the Advisory Committee taking "utmost account" of its opinion. If an agreement on commitments is reached, the Commission will issue a decision approving the merger, with or without being subject to commitments. However, if no agreement can be reached, DG COMP will propose that the Commission block the deal as being incompatible with the common market, and the parties may not proceed with the merger. This decision, which is taken by the "College" of the EU Commissioners as a whole, may be appealed to the CFI by the merging parties, or by third parties with a legitimate interest.

c. *Trademarks.*

1. *Examination of the conditions of filing:* There is no such thing as a 'pre-filing meeting' where counsel can find out if the Office's staff sees any problems with the application. However, the Office notifies the applicant in writing if any conditions for registration are not fulfilled. The applicant is then given a certain period of time in order to remedy the deficiencies mentioned.

The Office first examines whether the CTM application contains the required information and whether the basic fee has been paid. If these requirements are not met, the Office notifies the applicant that a date of filing cannot be accorded. The applicant then has the opportunity to remedy these deficiencies within two months. If the applicant does so, the date on which all the deficiencies are remedied shall determine the date of filing. If the deficiencies are not remedied before the time limit expires, the application shall not be dealt with as a CTM application and any fees paid will be refunded. The office then examines whether the other requirements are met (requirements concerning the applicant's representative, the claims of priority or seniority, and other information requested in the form) and whether the payment of additional class fees has been made. If not, the Office invites the applicant to remedy the deficiencies noted within such period as it may specify. If the deficiencies concerning the other requirements are not remedied before the time limit expires, the Office shall reject the application.

2. *Examination as to absolute grounds for refusal:* The Office examines whether the trademark consists of a sign capable of being represented graphically, whether this sign is capable of distinguishing the goods or services of one undertaking from those of other undertakings, whether the sign does not consist exclusively of indications that may serve, in trade, to designate the kind, quality, quantity, purpose or other characteristics of the goods/services, or which have become customary in the current language or in the trade practices, and whether there exist no other absolute grounds for refusal.

If such grounds for refusal exist, the trademark cannot be registered. The Office shall notify the applicant of these grounds specifying a period within which the applicant may withdraw or amend the application or submit his observations. Where the applicant fails to overcome the ground for refusing registration or to submit the requested statement within the time limit, the Office shall refuse the application entirely or partially.

3. *Informal oral hearings.* Informal oral hearings can take place with the Examiner on request of the applicant in order to discuss the CTM application and to better explain its background and characteristics to the Office members. These meetings are generally held with the team of the Examiners, the CTM applicant and/or the applicant's representative and attorneys. The Office is well prepared for these meetings and its members are cooperative. These sessions often consist of professional presentations.

4. *The search report:* Once the Office has accorded a date of filing to a CTM application and has established that the applicant is entitled to be the proprietor of the mark, it shall draw up a Community search report. This search report cites those earlier CTMs or applications discovered which are identical or similar to the CTM applied for and which may be invoked as *relative* grounds for refusal against the registration of the CTM applied for (see below under "Opposition"). National offices may also operate a search in their own register of trademarks in respect of CTM application if they have beforehand informed the Office of their decision to do so. The Office then transmits without delay to the applicant the Community search report and the national search reports received within the time limit (3 months). It is then up to the CTM applicant whether to maintain, amend or withdraw its application.

The search report does not have any legal consequences in itself. An applicant should not amend or withdraw its application solely on the basis of the information provided in the report. Further investigations have to be initiated to decide whether the reported mark will be a real obstacle or not (for example, whether it has been used). In addition, it is not known whether the owner of the prior mark will file an opposition. To be on the safe side and in order to avoid unnecessary filing costs, the question whether there are any identical or similar prior trademarks should be treated well in advance of the filing of the application by conducting availability searches in the various countries.

5. *Withdrawal, restriction, amendment and division of the application:* The applicant may at any time withdraw its CTM application or restrict the list of goods or services contained therein. Where the application has already been published, the withdrawal or restriction shall also be published. Amendments to a CTM application may only be made to correct minor errors; the amendment cannot substantially change the mark or extend the list of goods or services. The applicant may also decide to divide his application by declaring that some of the goods or services included in the original application will be the subject of one or more divisional applications.

6. *Publication and information of third parties:* The general public is informed of the application through its publication. 'Competitors' (i.e. owners of earlier similar trademarks) are further notified of the application by the Office. The application shall be published in Part A of the Community Trademarks Bulletin (available free of charge on http://oami.eu.int/en/office/diff/default.htm). This publication may not take place before the expiry of a period of one month from the date on which the Office transmits the search report to the applicant.

d. *Food safety.* The Member State where an application for permission to market a novel food is filed determines a body that will carry out the "initial assessment." This assessment must be carried out within three months. In practice, the deadline may be suspended if the assessment body requires additional data or studies from the applicant. There is usually regular and informal contact between the applicant and the assessment body during this three months period. (In the case of most food applications, however, the application is filed with the Commission and the initial assessment is carried out by EFSA). Practitioners report that EFSA is becoming more formalized and contacts between applicants and scientific panel members are strongly discouraged.

The initial assessment of a novel food application is forwarded to the Commission, which will forward it to the other Member States for comments or reasoned objections with a 60-day deadline. The comments and objections will be recirculated. Member States may also ask applicants to provide pertinent information. Some applicants will, depending on the resources and contacts they have available, make contact with the other Member States during the 60 days period, others won't. Some applicants will also have informal contacts with the Commission before they file their application at the Member State of choice. No records would be maintained and any opinions issued by Commission desk officers on the individual issues discussed would not be binding.

If no additional assessment is required by EFSA and no Member State raises objections, theoretically the novel food could be marketed. In practice, no novel food has ever been lucky enough to get on the market at this stage. In all cases, the Member States have raised comments

or objections that were classified as "reasoned objections." In such case, a formal authorization decision is required. This decision is taken under the comitology procedure (see ¶7.7 *infra).*

The regulations provide no deadline for this second part of the procedure once the 60-day comments period for Member States has lapsed. The quickest-ever novel food file (potato proteins) managed to get through the entire procedure in roughly one year. Usually, the process takes about two to three years. Some applications were discussed several times in the Regulatory Committee before the Commission decided to proceed to a vote (see discussion of comitology in ¶7.7).

Applicants commonly maintain informal contact with at least those Member States that have raised objections and provide them with information in order to ensure that these States will not object once the file is voted in the Regulatory Committee. For small and medium sized companies, this can be quite a cumbersome exercise. On the other hand, if there were no EU authorization procedure for novel foods, going through a large number of national approvals would surely be worse. To date, two novel food applications have been refused authorization, and several applicants withdrew their applications during the course of the procedure. There have been no legal challenges to any refusals or authorizations issued despite this being possible as the authorization decisions are addressed to individuals and may therefore be challenged at the CFI.

f. *Pharmaceutical licensing.* The project manager organizes the evaluation process of the application. He is appointed in the pre-submission phase and will assist the applicant before the actual filing of an application. After the filing, the project manager coordinates the validation, the assessment by the Rapporteurs as well as the CHMP participation and involvement of scientific advisory groups and experts, etc. He must make sure that the time frames are observed.

Following validation (which involves a check on whether the application is complete and satisfies the formal legal requirements), the crucial part of the application procedure begins— the evaluation of whether the medicine fulfills the criteria of safety, efficacy and quality and can therefore be authorized. The CHMP will appoint a Rapporteur and Co-Rapporteur for the assessment of the application. They evaluate the application on basis of the dossier and provide the CHMP with a preliminary assessment. The CHMP can request scientific advisory committees to provide scientific input on basis of the assessment of the Rapporteur and/or Co-Rapporteur.

The preliminary assessment is discussed within the Committee and will normally lead to the drafting of a list of questions and a recommendation to be provided to the applicant together with the scientific discussion. The recommendation might state that i) the product could be approvable provided satisfactory answers are given to questions (or amendments as outlined in the list of questions are implemented) or ii) that the product is unlikely to be satisfactory since there are "major objections" which have been identified in the detailed questions.

The applicant has up to 6 months to answer the CHMP questions and provide additional information. During this time, the clock for the evaluation of the application is stopped. The applicant can liaise with the project manager, the Rapporteur and Co-rapporteur in order to clarify issues concerning the questions and the further processing of the application. It can also withdraw the application with a view to re-lodging it at a later stage.

On the basis of the applicant's response, both Rapporteurs will draft a joint response and provide it to the CHMP and the EMEA, which then may comment on it. The applicant will also receive it for information purposes. The CHMP may at that point decide to request oral explanations from the applicant and therefore, stop the clock again. If not, the final draft of the SPC, package leaflet, etc. is provided and finally, at day 210 the latest CHMP opinion together

with the assessment report is issued on basis of scientific consensus. If no consensus can be reached, the majority vote will prevail and the diverging opinions have to be reflected in the assessment report.

In case of an unfavorable opinion, the applicant has to be informed immediately and provided with the CHMP assessment report. In these cases, the applicant may request in writing (within 15 days after the receipt of the opinion) that the opinion is reassessed. The request has to be supported by a written explanation within 60 days after the receipt of the opinion. The CHMP then has to reassess its opinion within 60 days after the receipt of the written explanation through newly appointed Rapporteurs. However, the review is restricted to the questions raised by the applicant in its appeal and may only be based on scientific information that had already been provided to the CHMP when issuing its first opinion. The applicant may also request involvement of a scientific advisory committee at that point. The CHMP must draft a final opinion, which includes the conclusions of the reassessment. The CHMP opinion together with the assessment report will then be provided to the Member States, the applicant and Commission for the adoption of a decision.

4.3 Complaints—pre-complaint phase. If the administrative process you are describing begins with a complaint, is there a pre-complaint phase in which the representatives of private parties have an opportunity to discuss the matter with Commission staff before an investigation begins or a complaint is issued? What occurs at such meetings?

a. *Competition.* In EU procedure, a person may "complain" to the Commission that another person is engaged in conduct that violates competition law. The Commission may also act on its own initiative. In either case, it may initiate an investigation. Usually the investigation precedes the decision to bring charges. If it decides to bring charges, the Commission issues a "statement of objections" to the companies concerned. The statement consists of a factual description of the allegedly illegal conduct and a legal assessment. During the investigation phase, the companies being investigated have extensive formal and informal contacts with the Commission.

Companies may approach the Commission informally even before any investigation is carried out. This can be the case of whistleblowers that avail themselves of the possibilities offered by the Leniency Notice and give the Commission information on a cartel to avoid fines for violation of EC competition law. Under the 2002 Leniency Notice complete immunity or a reduction in the amount of a fine may be granted to companies that provide the Commission with evidence on a cartel. Firms wishing to benefit from leniency in a cartel case apply to DG-COMP which will treat all information supplied confidentially. The Commission official will then proceed to a preliminary assessment of the situation and inform the company if immunity from fines would be available to it for a suspected infringement.

Under the EC merger control system, as indicated above (see ¶4.1), the parties are encouraged to contact DG-COMP at an early stage of the procedure, before any notification is submitted. Moreover, during both Phase I and Phase II investigations, the notifying parties usually have several meetings and other contacts with Commission staff, during which both sides can discuss the issues arising from the transaction. In particular, at any stage of the procedure, the Commission may give the notifying parties the opportunity to express their views orally.

The Commission will also hold during Phase II investigations "State of Play" meetings chaired by senior DG-COMP management to facilitate exchanges of information between DG-

COMP and the notifying parties. In practice, the first meeting would be offered to the parties within two weeks following the initiation of proceedings, a second meeting would be offered before the issuance of the statement of objections, and a third meeting is to be offered to the parties following their reply to the statement of objection and/or the oral hearing.

e. State aids. Many proceedings are triggered by complaints. A complaint can be submitted by anyone and may relate to both new aid and misuse of existing aid schemes. Nevertheless only complainants that fall within the definition of an "interested party" under the Regulation (generally competitors of aided undertakings) are entitled to the procedural benefits offered to complainants.

Prospective complainants often establish contacts with the Commission informally, prior to submitting a complaint, because the complainant prefers to remain anonymous (at least vis-à-vis the beneficiary and the Member State in question). Informal contacts provide the Commission with the relevant information for it to act on its own motion, and in a number of cases no "formal" complaint is ever brought, even though the informal discussions have had a similar effect. The drawback of an anonymous complaint is that the complainant loses the procedural benefits resulting from making a formal complaint. Another reason for informal pre-complaint contacts is to determine what information and supporting documents the Commission is most interested in. The Commission is generally open to discussions of this kind.

The risk sometimes associated with making pre-complaint contacts is "the-genie-is-out-of-the-bottle" problem. The Commission is entitled to act on its own motion, and often does so, so that initial contacts may trigger an investigation. A complainant cannot "control" the further process by not submitting the formal complaint (or by withdrawing it, if it was filed).

A formal complaint must be submitted to the Commission in writing. The complaint should be submitted on the basis of the Commission's published form. A complainant is free to provide additional information to the Commission in the form of a memorandum or by attaching relevant documents. The complaint should be addressed to the Directorate-General competent to deal with the complaint (i.e. DG COMP in most cases, DG AGRI in agricultural cases and DG TREN in transport cases).

The complaint should include the following information:

- information on the complainant, i.e., name, contact details, a brief description of how the aid award affects the complainant's interest, and information on the complainant's representative including a proof of authorization to act;
- indication of which Member State is concerned and at which level of government the alleged unlawful State aid has been granted;
- information on the alleged aid measure complained of;
- the grounds of the complaint;
- information on other procedures, like national court proceedings, that are pending with regards to the same aid measures;
- any supporting documents.

The complainant can decide to remain anonymous. It can also submit a complaint in such a way that it will identify itself to the Commission, but request that its identify be withheld from the Member State and the beneficiary in question.

If the Commission obtains information on new aid that is unlawful aid, it is required to examine such information without delay and the complaint will trigger a Phase 1 investigation. At the initial stage of this procedure, the Commission addresses an information request to the Member State concerned, and the Member State would submit the equivalent of the notification form under Regulation 794/2004. If an "interested party makes the complaint" the Commission must act on such complaint. Such complainants have the right to be informed if the Commission intends not to act on the complaint and on any other decision the Commission takes on the substance of the case. Interested parties include in particular the beneficiary of the aid, as well as competing undertakings and trade associations. The Commission has two months to complete the Phase I investigation.

The decision to initiate an investigation on its own motion can also relate to existing aid. Where the Commission considers that an existing individual aid is not (or no longer) compatible with the common market, it will usually be unable to do very much, because legitimate expectations of the beneficiary will typically prevent it from requiring changes. In cases however, in which Commission approval has been obtained as a result of fraud or by providing wrong or misleading information, the Commission may withdraw its original approval decision.

Where the Commission considers that an existing aid scheme is not or no longer compatible with the TEC, the Commission it can issue a recommendation to the Member State in which it will propose appropriate measures. To prepare for such a recommendation, the Commission can open proceedings and request, interalia, information from the Member State concerned.

The Commission must keep the Member States' systems of existing aid under constant review. If a complaint relates to existing aid, the Commission will inform the Member State concerned and request information. Eventually, it will inform the Member State of its preliminary views and give it the opportunity to submit comments. The Member State should respond within one month, but the Commission may extend this time limit. In the case of existing aid, a complainant has no procedural rights to force the Commission to look into the matter. The reason for the differentiation is that such aid has been previously approved; as a result the Commission's powers are generally limited to request the Member State to make future changes. More importantly, the Commission enjoys discretion as regards the question whether it wants to reopen past approvals (or to raise an issue as regards state aid that existed before a Member State joined the EC).

f. *Pharmaceutical licensing.* In the pharmaceutical licensing sector, complaint procedures are generally not foreseen. However, some procedures are triggered by Member States or the Commission because of safety concerns and comprise an investigation of a product. This involves imposed variations as well as community referral procedures. Furthermore, the latest review of pharmaceutical law has provided for a new mechanism of enforcement for infringements of pharmaceutical rules on Commission level, which will have the nature of a complaint procedure.

Before a decision to initiate an infringement procedure is taken by the Agency, the Commission informs the marketing authorization holder concerning the alleged infringement.

Thus, the target of such a complaint procedure gets the chance to provide a statement with regard to the allegations before he is confronted with a formal investigation procedure. In addition, the Agency has to notify in writing its decision to start an infringement procedure. The notification is addressed to the marketing authorization holder and the concerned Member States and includes the allegations and relevant facts for the substantiation together with a request to stop the infringement.

4.4 Opening of investigation

4.4.1 How is an investigation triggered? Through a notification or application? By a third party complaint or information from another government agency or a court case? Or by information identified by the Commission staff itself?

a. *Competition.* In EU procedure, a person may "complain" to the Commission that another person is engaged in conduct that violates competition law. The Commission may also act on its own initiative. Or a matter can be transferred from one of the national competition authorities. In any of these situations, the Commission may initiate an investigation if it feels the alleged violation affects the Community's public interest. The Commission may also investigate whether a company has failed to comply with a prior Commission decision applicable to that company. Commission investigations are often triggered by an application for leniency.

Generally the first investigative step is an on-the-spot inspection, which can result either from a simple authorization or a formal decision taken by the Commission. With a formal decision, Commission staff is entitled to enter the premises, examine business records, make copies, and question the company staff on matters relating to the inspection. With a simple authorization, the staff can only enter the premises with the permission of the company, but it is often—and advisedly—granted, since a formal decision authorizing entry can ensue in short shrift. National officials may assist the Commission staff in carrying out these inspections. In certain circumstances, the staff can inspect non-business (domestic premises). This can occur in the case of serious violations and reasonable suspicion that records are being kept in other premises, including homes of the managers. A domestic inspection requires a reasoned decision and prior judicial authorization.

The Commission may request information or adopt a formal decision requiring information to be furnished. The request must be in writing and must identify a suspected infringement and identify the information sought as precisely as possible. There is no legal requirement that the companies comply with the request (but there are penalties for supplying incorrect or misleading information). Companies may seek to clarify the nature of the information that has been requested. If the Commission issues a formal decision requiring information to be furnished, the request can be challenged before the CFI and failure to supply the information can result in a fine. The Commission also has power to take statements from any person who consents to be interviewed. In addition, a whistleblower can approach the Commission seeking leniency for its participation in a cartel.

In the context of merger control, an investigation is triggered mainly by the merging parties' filing of a completed Form CO notification. When Form CO has been filed and the announcement of the filing has been published in the Official Journal, the Commission proceeds to Phase I. If a proposed merger falls within the jurisdiction of three or more Member States, the merging parties may request the Commission, during the pre-notification phase, to take over the responsibility for examining it. Equally, once a merger has been notified in one or more Member

States, those Member States may request the Commission to conduct the examination of the transaction. In either of these two situations, the investigation will be triggered by the referral of the case to the Commission, either during the pre-notification phase or once it has been notified nationally. There is one further situation which may trigger a Commission investigation: when the parties implement a merger with a potential Community dimension without having previously notified their intentions to the Commission. In this case the Commission will conduct an *ex-officio* investigation, and if it confirms that the transaction had a Community dimension and was not notified, it will require the companies to dissolve the concentration.

b. *Trade remedies. Starting the process: the complaint:* Anti-dumping and anti-subsidy proceedings generally begin with the submission of a written complaint by a person or an association on behalf of the Community industry. The Commission also has the power to start investigations on its own initiative. Complaints are submitted to the Complaints Office of DG TRADE or to a Member State who will forward it to the Commission. A complaint must contain evidence of dumping or subsidization, injury, and a causal link between the allegedly dumped or subsidized imports and the alleged injury. There is no specific form for anti-dumping or anti-subsidy complaints, but the regulations contain indications of what must be included in a complaint and the EU has prepared two non-binding guides on preparing complaints.

A request for safeguards can only be lodged by an EU member state with the Commission (or the Commission can open a safeguard investigation on its own initiative). In practical terms, companies usually submit their requests for safeguard action on the national level, with a request that the government bring the matter to the Commission. The choice of which Member State to approach is primarily driven by which Member State or States is/are the primary seat of the threatened industry. There is no form for asking for safeguard relief, but the regulation says that the Member State (usually aided by the requesting industry) is to provide the Commission with "evidence available" about volume and price of imports and the impact on community producers.

Pre-complaint meetings: Before formally lodging an anti-dumping or anti-subsidy complaint, companies usually consult informally the Complaints Office of DG TRADE, sometimes several times, normally on the basis of draft complaints. Companies then have the opportunity to try to fill in any gaps and address problems before submitting a formal complaint. Commission policy is presently to be more demanding as to the quality of the complaint. It may take months of work to draft and re-draft a complaint that will satisfy the Complaints Office. Companies also glean from these pre-meetings whether they have a viable complaint—they might decide not to lodge a complaint at all if it is unlikely to be accepted.

In safeguard cases, unless the EU is prepared to act on its own initiative, companies first have to convince a Member State government to take the matter to the EU. Therefore, there are generally (possibly numerous) meetings with the Member State government prior to the Member State taking the issue to the EU. The Member State might also have informal contacts with the Commission regarding the case before officially putting the EU on notice and starting the clock running. On the other hand, if the Member State wishes to accelerate the process, it might launch the process immediately, without pre-meetings.

Time limits for considering complaints and initiation: For anti-dumping and anti-subsidy matters, from the moment that a complaint is officially lodged, the Commission has 45 days to examine it and to determine whether the companies that submitted it had the standing to do so and whether it makes out a *prima facie* case of dumping or subsidization, material injury, and causation. During this time, the Commission cannot publish any notice that it has received or is

considering a complaint, nor can it respond to any inquiries about such complaints. It must notify the government of the exporting country concerned after receipt of a properly documented complaint and before proceeding to initiate an investigation.

The Complaints Office is required to investigate the "representativeness" of the complaint—that is, whether it has been filed on behalf of a major proportion of the Community industry. The Commission is required to assess the degree of support for, or opposition to, the complaint expressed by Community producers of the like product. It cannot proceed if more than half of those expressing an opinion oppose the opening of an investigation. It also cannot proceed if the Community producers expressly supporting the complaint account for less than 25 % of total production of the like product produced by the Community industry. If the Commission is satisfied that the complaint was submitted on behalf of the Community industry and that it provides a *prima facie* case, it will, after written consultation of the Advisory Committee, proceed to open an investigation.

A Commission decision opens the investigation. Initiation is made public by means of a "Notice of Initiation" published in the Official Journal of the European Communities. The Notice announces the initiation of the investigation, indicates the product and countries concerned, gives a summary of the information received, and asks all interested parties come forward to make themselves known, ask for a hearing, and submit information. The Commission sets strict time limits within which interested parties must do so, generally 10 days from initiation to make oneself known and 40 days from initiation to ask for a hearing and make submissions, including responses to questionnaires. This is very brief in view of the amount of data to be supplied in the questionnaire response. The Commission will advise the exporters, importers and representative associations of importers or exporters known to it to be concerned, as well as the country of origin and/or export and the complainants, of the initiation of the proceedings.

Procedures in safeguard cases are different from those in anti-dumping and anti-subsidy cases. For safeguards, the process begins when a Member State informs the Commission that trends in imports appear to call for surveillance or safeguard measures, providing "all evidence available." The Commission immediately passes this information on to all the Member States. Within eight working days of the Commission's receipt of the information, and in any event before the introduction of any Community surveillance or safeguard measure, consultations are held in an Advisory Committee made up of representatives of each Member State with a representative of the Commission as chairman. After consultations, the Commission must decide whether or not to initiate an investigation within one month, counting from the date of receipt of the abovementioned information from the Member State.

If the Commission decides to initiate a safeguards investigation, it publishes a notice to that effect in the Official Journal of the European Communities. The notice contains a summary of the information received, and stipulates that all relevant information and requests to be heard have to be communicated to the Commission within certain time limits.

c. *Trademarks.*

1. *CTM applications*. The investigatory powers of the Office are limited to the examination of absolute grounds for refusal and to the search report it conducts about earlier trademarks. As seen above (point 4.2.), when an application is filed, the Office first verifies whether the sign is capable of distinguishing the goods or services and whether there exist no other absolute grounds for refusal. If not, the application is accepted and is given a date of filing. The Office will then conduct a search report regarding earlier trademarks (see point 4.2. above).

These "investigations" made by the Office of its own motion however always occur as a result of the filing of the CTM application with the Office.

Beside the examination for absolute grounds for refusal and the search report, there is *stricto sensu* no investigation by the Office regarding an application for a Community trademark or for a Community trademark already granted. The Office indeed has no investigatory powers regarding possible violation of laws in the trademark area. This "investigatory role" is left to private parties who will then submit the result of their researches to the Office, which will then take a decision in regard of the information gathered by the parties. Private parties can challenge the CTM application or the Community trademark as granted by various means. These means are the opposition, the application for invalidity and the application for revocation (see point 1 above).

2. Third party challenges. The opposition procedure is triggered by a 'notice of opposition' addressed to the Office. The notice of opposition must be filed within three months following the publication of the CTM application against which the opposition is directed and the appropriate fee paid. The opposition and must specify the grounds on which it is made and contains a range of additional information. The opponent can submit facts, evidence and arguments in support of the opposition within a period fixed by the Office. "Non European based" persons must be represented by a qualified legal practitioner or a professional representative in order to file an opposition. Where the notice of opposition is not filed in the language of the CTM application (if that language is one of the Office's languages), or in the second language indicated in the application, the opposing party must file a translation of the notice of opposition in one of those languages within a period of one month from the expiry of the opposition period.

A Community trademark shall be declared *invalid* (on absolute or relative grounds) on application to the Office or on the basis of a counterclaim in infringement proceedings. Similarly, the rights of the proprietor of a CTM shall be declared to be *revoked* on application to the Office or on the basis of a counterclaim in infringement proceedings if the conditions set out under point 1 above are met. Such counterclaims can be raised before national courts designated by the Member States to perform the functions of CTM courts.

e. *State aids*. A phase I investigation can be triggered by

- a notification of an aid measure to the Commission by a Member State;
- a complaint to the Commission by any person or company; or
- by the Commission out of its own motion.

A phase II investigation is opened by a formal Commission decision ("decision to initiate the formal investigation procedure"). The Commission must initiate the formal investigation procedure:

- where, after the preliminary examination of new aid, the Commission concludes that there are (at least) doubts as to the compatibility of the measure with the common market;
- where, in cases of misuse of aid, the Commission concludes after the preliminary examination of the information in its possession that there are (at least) doubts as to whether there is a misuse of aid;

- where the Commission considers that existing aid is not compatible with the common market and the Member State concerned does not accept the Commission's proposals to abolish or alter the aid in question; or
- where the Commission decides to revoke a decision because the decision was based on incorrect information provided during a previous examination or investigation procedure.

The decision to open Phase II sets forth the reasons for the Commission's doubts and concerns, and it will provide a summary of the facts and the legal consequences to be drawn from the facts. It will invite interested parties to submit comments.

The full decision to open the Phase 2 investigation is published in the C-series of the Official Journal only in its authentic language version, coupled with the publication of a summary in the other official Community languages.

f. *Pharmaceutical licensing.*

a) Variations: Variations can be triggered by the introduction of an urgent safety restriction, either on initiative of the marketing authorization holder or the Commission. An urgent safety restriction is an interim change to product information due to new information having a bearing on the safe use of the medicinal product. The urgent safety restriction may be imposed by the marketing authorization holder or by the competent authorities and it needs to be followed by an application for a variation to formally implement the urgent measure to the marketing authorization.

New information leading to the implementation of urgent safety restrictions can arise from different sources. Marketing authorizations are subject to continuous review by the EMEA and the authorities of the Member States. This is not only reflected in the right to ask the marketing authorization holder for data to be able to assess whether the risk-benefit-balance of a product remains positive but also by the installation of a pharmacovigilance system, which imposes information/notification obligations on the marketing authorization holder, allows for the systematic collection and reporting of adverse events, and ensures the proper exchange of information across the border on basis of an agreed terminology. New information may also be gained through new studies conducted with the medicine, new therapeutic options in the treatment of a disease, etc.

With new information, the risk-benefit-assessment may clearly become negative with the consequence of a marketing authorization withdrawal. However, there are other possibilities to keep the risk-benefit assessment positive, such as the changing of information (warnings, contraindications, etc) or to limit the indications, etc. While the urgent safety restriction allows implementing the measure quickly to protect public health, the variation procedure then formally implements the measure and provides for a scientific assessment of the situation.

b) Community Referral. The Member States, the Commission, the applicant or the marketing authorization holder in cases can trigger a Community Interest Referral where the Community interest is at stake. The Community interest has a very broad meaning and covers not only public health issues but also internal market issues or consumer protection tasks. However, the referrer must demonstrate the Community interest. The body or person, who triggers the referral, must refer the matter to the CHMP (using the official notification form) and clearly identify the question, which is referred to the CHMP together with a detailed explanation.

c) Penalties regulation. The Agency can initiate an infringement procedure on its own initiative; on initiative of a Member State's competent authority, or on initiative of the Commission. The Commission must always be informed. In addition, the agency shall request

information about the allegations from the marketing authorization holder. For further details on the scope of the Penalties Regulation see the part on "Enforcement action" (point 9).

4.4.2 Are there checks on the investigation process? Any requirements that probable cause be established before investigations take place or any other protective requirements? How about requirements of approval (such as the requirement that lower level staff get higher-level approval in order to proceed)?

a. *Competition.* The Commission has unchecked discretion whether to take up a case. It will do so if the Commission is "well placed" to act. It is well placed where a particular practice has effects in more than three member states or in cases involving new issues.

The decision to investigate is generally taken at the level of head-of-unit within DG Competition (hereinafter "DG COMP") level. The alleged infringement must be a priority, either because of its seriousness, harm done to consumers, or precedential value. The availability of resources is also considered. There is an internal review of the decision to start an investigation by a control unit within DG COMP. The case is allocated to individual case-handlers or a team of case-handlers depending on complexity of the case. The case-handlers will propose further actions to be taken such as the issuance of a statement of objections.

With regard to mergers, the Commission does not enjoy discretion as to whether to initiate proceedings or not. Indeed, when a merger is considered to have a Community domension, the Commission is bound to take up the case and issue a decision as to the compatibility or otherwise of the merger with the common market (unless the notifying parties withdraw the notification).

b. *Trade remedies.* In anti-dumping and anti-subsidy cases the Commission is required before opening an investigation to, as far as possible, examine the accuracy and adequacy of the evidence provided. It cannot initiate an investigation if the complaint is not "representative," as described above, and the regulation provides that a complaint must be rejected where there is insufficient evidence to justify proceeding with the case. The decision to initiate is made by the Commission normally by written procedure.

Individual case handlers do not make their own decisions. A team of four case handlers, supervised on a day-to-day basis by a Head of Section and Head of Unit, typically carries out the investigation. Subsequently, proposals for formal action are vetted by the Director and ultimately by the Director-General of DG TRADE, before they are submitted to the entire Commission (for provisional anti-dumping or countervailing measures, which can only be imposed by means of a Commission regulation) or by the Commission to the Council (in the case of a proposal for definitive anti-dumping or countervailing measures, which can only be imposed by means of a Council regulation).

The requirements for initiating and conducting a safeguards investigation are, on paper, less stringent. Member States can inform the Commission of trends in imports that "appear" to call for surveillance or safeguard action. Subsequently consultations take place and the Commission can initiate an investigation when "it is apparent that there is sufficient evidence to justify the initiation of an investigation." As for the investigation itself, the regulation provides only that the Commission is to "seek all information it deems to be necessary" and, where it considers it "appropriate" to endeavor to check this information with importers, traders, agents, producers, trade associations and organizations.

Safeguard investigations are assigned to a team of case handlers in DG TRADE, supervised on a day-to-day basis by a Head of Section and Head of Unit, with proposals for formal action being vetted by the Director and ultimately by the Director-General of DG Trade. Formal action under the safeguard regulation, such as a decision to impose quantitative restrictions on imports, is taken by a vote of all the Commissioners. If a Member State disagrees with the Commission decision, it can refer the matter to the Council, which acting by a qualified majority may confirm, amend or revoke that decision. Alternatively, the Council can itself take safeguard action, voting by qualified majority on the basis of a Commission proposal.

c. *Trademarks.* In the case of third party oppositions or applications for invalidity or revocation, the Office makes a first verification of the applications that could be assimilated to a sort of requirement of probable cause.

e. *State aids.* [This portion not completed. Authors treat time limits and manpower limitations as checks on initiating Phase I. They mention the need for a formal decision initiating Phase II and involvement of the hierarchy and the Commissioner and his cabinet, the need to summarize initial findings and legal analysis, and the need to consult legal service, as well as the political attention drawn by initiating Phase II.]

f. Pharmaceutical *licensing.* Generally, the EMEA´s Code of Conduct requires EMEA to take certain measures to ensure that proper administrative procedures are observed. However, the Code's requirements are of a general nature and do not provide for specific safeguards on the investigative process in the event that EMEA seeks a variation to a marketing authorization.

The referral procedures generally require a clear identification of the issues and questions that are being referred to the CHMP. In case of an Article 31 referral, the referring party must establish that a Community interest is involved, but there seems to be limited review, especially when an authority makes the referral. There are no further checks or protective measures that specifically limit or control the investigative measures that the EMEA may employ.

The Draft Penalties Regulation requires the EMEA to disclose details of the alleged infringements together with the available evidence showing the infringement when it notifies the marketing authorization holder, the Commission and other authorities of the beginning of the infringement proceeding. This requirement to disclose the factual basis for an infringement is designed to ensure that procedures are not initiated without sufficient prima facie evidence to support the allegations. It can therefore be regarded as a protective mechanism. However, there is no need for prior approval by the Commission or another Community Organization.

4.4.3 Are there ways by which a private party can push forward or expedite Commission action on an application or with respect to a complaint against a competitor? How about ways to slow down an investigation?

a. *Competition:* Companies can influence the speed of the investigation by cooperating with requests for information or by delaying them through grudging cooperation, giving incomplete answers or asserting privileges. A third party that has complained to the Commission about an alleged infringement but has received no action can complain to the CFI, but only in rare situations do they have an enforceable right to do so. Lobbying does occur, though much less than in the state-aid field.

In the merger field, the Commission is subject to strict deadlines to decide the case but the merging companies can agree on extending the deadlines by offering commitments. The deadlines also do not apply where the company submits incomplete notification or fails to provide the Commission with the requested information within the time limits set by the Commission.

The only way in which the parties can expedite merger proceedings is through pre—notification meetings. Indeed, before submitting the formal notification, the Commission and the parties very often hold several pre-notificaiotn contacts (see ¶4.1). As a result of these pre-notification contacts, the Commission gathers a great amount of information by the time it initiates Phase I proceedings. This allows it to assess the notified merger in greater detail from the very beginning and to identify any competition issue at an earlier stage. It also allows the parties to submit commitments addressing these concerns earlier and favors the possibility of a clearance before the end of Phase I.

On the other hand, the whole merger clearance procedure may slow down when the investigation during both Phase I and Phase II is suspended. Suspension may occur when the Commission issues a decision requiring a party to supply information or issues a decision to conduct an investigation. This may occur because one of the notifying parties has not provided requested information, refuses to cooperate with an inspection, or fails to inform the Commission of material changes in the information contained in the notification. Where the Commission decides to require the supply of information, without first proceeding by way of a simple request for information, the time limits will also be suspended if such a request is owned to circumstances for which one of the merging parties is responsible.

b. *Trade remedies:* In anti-dumping and anti-subsidy proceedings, the time limits for the consideration of a complaint are fairly brief; thus it would be difficult for a private party to obtain action earlier than within the 45 days that the Commission has for the consideration of the complaint and required consultation of the Advisory Committee.

The overall timing of anti-dumping and anti-subsidy investigations is explicitly specified in the regulations at maximum fifteen months and thirteen months respectively, so it is not possible to slow the process beyond those maximum limits. As for accelerating, the conduct of investigations is very "routinized," and Commission officials regularly comment that the time frame is tight for them to accomplish everything they need to, such as studying questionnaire replies, conducting verification visits in Europe and abroad, holding hearings, providing access to the file, making provisional and definitive conclusions and taking into account the submissions of interested parties. It would be difficult to convince the Commission to deviate from its regular practices in order to expedite the process. However, complainants can, by choosing the date to file their complaint, determine the "period of investigation," i.e. the reference period for establishing dumping, and thus the period where dumping is highest.

Safeguard action is less "routinized" and consequently, there is more room for flexibility in the timing. However, the regulation sets a time limit for a safeguard investigation of nine months, extended by a maximum of two months, limiting the possibility of delay. As for accelerating the process, urgent action by imposing immediate surveillance or provisional safeguard measures is possible under the safeguard rules. However, only a Member State can request urgent action. According to the safeguard regulation, urgent measures, in the form of an immediate increase in the existing level of customs duty, can be taken in "critical circumstances," where delay would cause damage which would be difficult to repair, and where a preliminary determination provides "clear evidence" that increased imports have caused or are threatening to cause serious injury. The duration of such measures cannot exceed 200 days.

c. *Trademarks.* A party can push forward the proceedings by refusing the extensions of time requested by the other party. Indeed, extensions of time to file observations before the Office are only granted if both parties agree to it. Refusing to agree will mean that no further extensions will be granted and the proceedings will consequently be expedited.

Conversely, slowing down the proceedings will only be possible by way of filing extensions of time or filing a suspension of the proceedings, and if the counterpart agrees with it. The Office may suspend any opposition proceedings where the circumstances are such that a suspension is appropriate.

If an opponent wants to slow down the opposition proceedings, he might file the notice of opposition in another language than the one used to file the CTM application (or the one designated as a second language in the application). He will then be given one additional month from the expiry of the opposition period (3 months) to file a translation of the notice in the appropriate language. The same rule applies to the evidence submitted by the opposing party.

e. *State aids*. Parties have limited opportunity to speed up or slow down the initiation of an investigation. Member States can determine the timing of their notification, and are known to have sped up notifications to avoid the application of newly enacted frameworks or guidelines. Complaints will typically filed as early as possible, but there have been instances were complaints were carefully timed to maximize their impact. Thus in large rescue and restructuring aid cases, the filing of a complaint (and leaking the information to the press) may be a powerful tool to influence or complicate the refinancing of the company in difficulty that counts on a partial state bail out. The timing of own initiative investigations cannot normally be influenced by parties, except in case of "informal" complaints.

4.5 Personnel and committees:

4.5.1 Describe the organization of the staff on the Commission side during the application and the investigation phase. What is the division of responsibilities between staff members and supervisors?

a. *Competition.* The Commission (consisting of 25 members) is responsible for the implementation of policy. Many of its decisions must be delegated to individual commissioners or to DG-COMP. However, the ECJ decided that only everyday management matters can be delegated; matters involving infringement of competition law cannot be delegated.

DG-COMP is headed by a Director General and consists of nine directorates. There are three Deputy Directors General and a Chief Competition Economist. Each directorate is divided into units that correspond to a specific economic sector. A unit consists of a head of unit and case handlers that conduct investigation and propose measures to be taken in individual cases. The Commission's Legal Service is its in-house lawyer. The Legal Service acts independently of the directorates and the Commissioners and is responsible to the President of the Commission. Legal Services must give an opinion about each formal act taken by the Commission. If Legal Services does not approve of the proposed measure, the members of the Commission must decide the matter.

Case teams head individual cases. A team consists of a case manager (who is a senior DG COMP official) and 2-3 case handlers. Case handlers conduct the investigation and propose measures to be taken. These proposals are monitored internally before being considered by the Competition Commissioner.

The merger enforcement process was reorganized in 2004, partly as the result of accession of new Member States and partly because of recent CFI rulings overturning Commission decisions prohibiting certain mergers. The main element in the reorganization is the integration of the Merger Task Force ("MTF") into the directorates dealing with specific sectors of the economy. MTF was replaced by a coordination unit reporting to a Deputy Director General who oversees consistency of procedure and policy. This means that each unit in each sectoral directorate will deal with any type of case in its allotted industrial sector, i.e. cartels, mergers, and abuses of dominance.

As a more direct attempt to improve its economic approach when assessing concentrations, the Commission has appointed a Chief Competition Economist (CCE) in DG COMP. The chief economist is supported by a team of some 10 economists who will provide case-handlers with economic and econometric input and conduct a critical examination of the case team's conclusions. He reports directly to the Director General for Competition. The Commission also convenes *ad hoc* panels, including officials from other DGs, to offer the case team an independent internal review and test the Commission's conclusions at different stages during the procedure.

b. *Trade remedies.* In the case of anti-dumping or anti-subsidy procedures, once the Complaints Office has finished its work and has advised that the complaint meets the requirements for initiation of an investigation, and the case is initiated, it passes to the other units of the directorate responsible for anti-dumping and anti-subsidy investigations within DG TRADE.

DG TRADE assigns separate teams to investigate the existence of dumping or subsidization and to investigate the existence of injury and causation. Generally, the team is made up of one Head of Section, aided by two case handlers to assess dumping/subsidization, and one Head of Section aided by two case handlers to investigate injury. In practice, the four case handlers conduct the investigation, for example carrying out verifications. The case handlers report orally and in writing to their Heads of Section on "missions." The Heads of Section bear the overall responsibility for the case, usually attending the hearings and overseeing the drafting of all documents in the case. Higher up in the hierarchy are the Heads of Unit, the Director, and the Director General of DG TRADE. A proposal for provisional or definitive measures will be scrutinized by these higher levels of the hierarchy, and the proposal for a Commission regulation (in the case of provisional measures) and the proposal for a Council regulation (in the case of definitive measures) will be finally vetted by the Commissioner's cabinet and the Commissioner him or herself. It will also usually be scrutinized by other DGs of the EC, such as DG-Enterprise or DG-COMP.

Safeguard investigations are the responsibility of people of the same directorate and as the case may be of the same people that handle anti-dumping or anti-subsidy investigations, and hence are staffed and proceed in roughly the same way. However, safeguard investigations are characterized by more political involvement than anti-dumping or anti-subsidy investigations because complaints can only be filed by the EU Member States and are more politically sensitive.

c. *Trademarks.* There are no division of responsibilities between staff and supervisors and decisions are taken collegially in the name of the Office. This can create some difficulties in practice as the members of departments and units come from the various EU jurisdictions. They are bringing in their ideas, which means that in some cases it is difficult to come to a decision by common consent.

In application cases, an examiner is responsible for taking decisions on behalf of the Office. Opposition Divisions are responsible for taking decisions on oppositions to CTM applications. The Opposition Divisions generally consist of three persons, among which at least one must be legally qualified. Cancellation divisions are responsible for taking decisions in relation to applications for revocation or declarations of invalidity of Community trademarks. The Cancellation Divisions also consist of three-member groups, where at least one member must be legally qualified.

e. *State aids*. Upon notification to a specific DG, a case team will be formed usually comprising one or two case handlers who report to their Head of Unit. The case team conducts the investigation and drafts a first proposal for a decision to be adopted by the Commission. The officials of the Member State concerned, as well as the complainants or any persons submitting comments will be in direct contact with the members of the case team. The Commission's services consult internally on a draft decision. Legal Service also reviews any proposal.

During the preliminary examination of notified aid, there is no obligation of the Commission to consult other Member States or interested parties, including complainants. Nevertheless, in accordance with its duty of good administration, the Commission may engage in talks with the notifying State or with third parties in an endeavor to overcome, during the preliminary procedure, any difficulties encountered. However, it is not required to do so. In *Commission v. Sytraval and Brink's France*, the ECJ noted that the Commission is not obliged to examine on its own initiative any potential objections, which a complainant might have raised had it been given the opportunity of taking cognizance of the information obtained by the Commission in the course of its investigation. However, the Court went on to say that this

> does not mean that the Commission is not obliged, where necessary, to extend its investigation of a complaint beyond a mere examination of the facts and points of law brought to its notice by the complainant. The Commission is required, in the interests of sound administration of the fundamental rules of the Treaty relating to State aid, to conduct a diligent and impartial examination of the complaint, which may make it necessary for it to examine matters not expressly raised by the complainant.

The final decision is taken be the entire college of Commissioners. The proposal will be adopted if a majority of the total number of Commissioners – not of the number of Commissioners present in the meeting – votes in favor of the proposal. In exceptional cases the Council can also approve state aid. The Council may, upon application by a Member State, unanimously authorize State aid if this "is justified by exceptional circumstances." If prior to the Member State's application to the Council, the Commission has already initiated an investigation procedure, the Member State's application to the Council will suspend the Commission's investigation. If the Council has not made its attitude known within three months of the Member State's application, the Commission will again retain competence to adopt a decision on that case.

f. *Pharmaceutical licensing.*

a) EMEA. Under the centralized procedure, the CHMP is in charge of the evaluation of human medicines. The members are appointed for a renewable period of three years by the Member States after consultation with the EMEA's Management Board. They must be selected on the basis of their experience in the evaluation of medicines. They represent the national authorities but are required to base their findings on the requirements of public health and should not serve as points of influence for the interests of national authorities. For the evaluation of a medicine, an EMEA official is normally appointed as project manager in the pre-application phase. The CHMP appoints one of its members as rapporteur and another one as co-rapporteur. In case of a required re-evaluation of an opinion, different members have to act as rapporteur and co-rapporteur. Depending on the medicine to be reviewed, the CHMP may involve additional groups or experts in the evaluation of a product including standing or temporary working parties and scientific advisory groups.

b) Coordination Group. Since October 30, 2005, the Coordination Group has been an official part of the decentralized process for marketing authorizations. The Coordination Group aims to reach agreements among Member States when there are dissenting opinions concerning marketing authorization applications or variation applications and thereby avoid formal arbitration proceedings.

c) Commission. DG Enterprise's Unit F2 deals with pharmaceuticals regulation. The Head of the Unit is Dr. Martin Terberger. The Unit is structured into the following five subgroups: i) Legal, Economic and Horizontal Affairs, which covers decision making procedures, pediatrics, penalties, orphan regulation, pharmacovigilance, enlargement, borderline products, etc. ii) Decision Making Process, which covers marketing authorizations, designation of orphan medicine status, etc. iii) Medicinal Products for Human Use, which covers the decision making process for human medicines, coordination with the different bodies involved in the authorization process, clinical trials, Notice to Applicants, pharmaceutical law review, etc. iv) Veterinary Medicinal Products. v) Telematics, which covers the EUDRA system, IT standardization, Pharmacos websites.

d) Standing Committee on Medicinal Products for Human Use
The Standing Committee on Medicinal Products for Human Use comprises representatives of the Member States and is chaired by the Commission. It plays a role in the decision making process in accordance with Article 121 Directive 2001/83 and Article 87 of Regulation No. 726/2004, which allows input from Member States into the adoption of a Commission decision under a typical comitology procedure (see below).

4.5.2 Is there any requirement of consultation with advisory committees or other parts of the Commission? Does the comitology process come into play here? How about consultation with member states or agencies of member states?

a. *Competition.* The Chief Competition Economist (CCE) sometimes becomes involved in cases that involve complex economic analysis. A CCE team member becomes a member of the case team but reports back to the CCE. The Legal Service must give its opinion before a Statement of Objections is sent, a case is formally rejected, or in case of other decisions. After approval of a proposed measure by Legal Service, the Competition Commissioner endorses the measure. It is also subject to consultation with other DGs responsible for regulation of some aspects of the product market that is subject to the decision.

In some cases, the Commission must consult with the Advisory Committee on Restrictive Practices and Dominant Positions. That committee is composed of representatives of the competition authorities of the member states. Consultation with this committee precedes the taking of infringement interim measures and alterations of block exemptions. Consultation also occurs in the case of decisions by the Commission to investigate sectors of the economy or types of agreements. The Commission must take "utmost account of the opinion delivered by the Advisory Committee" and must inform the latter how its opinion has been taken into account. If the opinion of the Committee is given in writing, it must be attached to the draft proposed decision to be considered by the Commissioners.

In merger cases, the Commission is assisted by an Advisory Committee for the adoption of provisions implementing the Merger Regulation. The Advisory Committee is composed of representatives of the Member States and the Commission will consult it before adopting decisions ending Phase II proceedings or imposing fines and periodic penalty payments. These consultations must take place at meetings chaired and convened by the Commission, to be held no later than 10 days after a convocation notice has been sent. The Advisory Committee then delivers an opinion on the provision proposed by the Commission (if necessary by voting), and the Commission will take full account of this opinion. In complex merger cases, DG Competition may also consult and set a debate with other DGs.

b. *Trade remedies.* There is an Anti-dumping and Anti-subsidy Advisory Committee, composed of representatives of Member States with a representative of the Commission as chairman. This Advisory Committee is consulted by the Commission at various stages in the investigation, notably at the stage of initiation of the investigation and of any reviews, before termination, before the Commission imposes provisional measures, and before the Commission proposes that the Council adopt definitive measures. The Advisory Committee's positions do not compel the Commission in any way. That being said, considering that the Advisory Committee contains Member State representatives and the Council composed of Member State representatives can only impose definitive measures, the opinion of the Advisory Committee is generally taken seriously.

DG TRADE consults other DGs of the Commission, notably DG ENTERPRISE, as well as the Legal Service, before a proposal for provisional measures or a draft of a Commission proposal for definitive measures is submitted to the Commission. On a formal basis, provisional anti-dumping or anti-subsidy duties can only be imposed by means of a Commission regulation, which has to be adopted by the college of Commissioners, voting by simple majority.

In safeguards, consultations take place in an Advisory Committee (whose members may or may not be the members of the AD or AS Advisory Committees) made up of representatives of each Member State with a representative of the Commission as chairman. These consultations are held at the start of the proceedings, eight working days after the Commission has received information from a Member State about suspect import trends. Consultation of the Advisory Committee is also called for during the application of surveillance or safeguard measures, to determine their efficacy and continued necessity.

e. *State aids.* Besides the fairly restricted obligation to consult with Member States and complainants mentioned above, there are no additional obligations to consult with committees established within the Community framework. The Advisory Committee on State aid is not consulted on individual decisions, either during the preliminary examination or at any later stage of the procedure.

f. *Pharmaceutical licensing.* The CHMP can involve standing or temporary working groups to provide scientific advice if required in the evaluation of an individual product.

The comitology procedures are relevant for the pharmaceutical decision making process. The body involved in the comitology procedure is the Standing Committee on Medicinal Products for Human Use Standing Committee. The comitology process provides the Member States' agencies the possibility to influence the decision making process. They can issue written remarks to the draft decision of the Commission and ask for an oral hearing in the Standing Committee. While the comitology process is an instrument to integrate Member States in the decision making process of the Commission and to balance the fact that they will be bound by the decision issued by the Commission, to our knowledge the Comitology procedure has never become crucial in the adoption of decisions in the pharmaceutical sector.

4.6 Notice

4.6.1 Is a complaint issued before an investigation begins or does investigation precede the complaint?

a. *Competition.* The investigation precedes the decision to initiate proceedings. Usually proceedings are initiated by issuance of a statement of objections when the Commission contemplates taking an infringement or interim measures decision. Proceedings are also initiated by issuance of a "preliminary assessment," when the Commission expresses concerns to companies that then offer commitments, or by the publication of a notice in the Official Journal. Initiation of proceedings stops the limitation periods on the imposition of penalty payments and it prevents national competition authorities from dealing with the same case.

As regards merger control, if, during Phase II and after the parties have presented their commitments, the Commission still thinks that the merger would significantly impede effective competition, it will issue a statement of objections, to which the parties may respond. Thus the statement of objection is issued only after the Commission's investigation has been initiated and only in those cases where the investigation runs into a second phase. Indeed, it is usually sent around four weeks after Phase II begins.

b. *Trade remedies.* See discussion under ¶4.4.1b.

e. *State aids*. A Member State that notified State aid to the Commission would receive an acknowledgment of receipt of the notification. The preliminary examination of the notification begins as soon as the Commission, and the Member State received the notification or any other interested party is not specifically notified of this fact. If the Commission's investigation has been triggered by a complaint, the Commission will inform the Member State concerned of this complaint and will usually address a request for information to this Member State. Similarly, if the Commission initiated its investigation by its own motion, it will inform the Member State concerned of this fact and will also address a request for information to this Member State.

f. *Pharmaceutical licensing.* The draft penalties regulation foresees a written notification of the target when the Agency takes the decision to start an infringement procedure against it. In the notification, the Agency must disclose the details of the allegations against the marketing authorization holder and any element of fact and law, on which such allegations are founded. In addition, the notification must include the information that penalty payments may be imposed together with a request to terminate the infringement.

4.6.2 What are the requirements of notifying the target of a pending investigation or of the decision to issue a complaint? What information is conveyed in the notice? How specific must the notice be?

a. *Competition:* The statement of objections is the key document that notifies companies that proceedings will be commenced against them. Since the investigation precedes issuance of this document, the companies are normally well aware of the legal situation. The statement of objections informs the parties concerned of the objections raised against them. It sets a time limit in which the parties may inform the Commission of their views. The parties can set out the facts relevant to their defense and attach relevant documents to prove those facts. They can also propose that the Commission hear persons corroborating the facts set out in their submission.

A Commission decision need not be an exact replica of the statement of objections; the Commission may take account of information or argument it receives subsequent to issuing the statement. However, there is an infringement of the right of defense if the final decision alleges infringements other than those referred in the statement of objections or takes different facts into consideration. It is not sufficient merely to identify points of difference between the statement of objections and the decision; the target must explain precisely why each of the differences that are unfavorable to it constitutes a new complaint on which they were not given the opportunity to comment.

As regards merger control, the statement of objections must in writing, and must set a time limit within which the notifying parties may provide the Commission with their written comments in writing. In general, the Commission will set out in the statement of objections the facts that led it to conclude what the relevant markets are and how the notified transaction would significantly impede effective competition within the common market or a substantial part of it, in particular as a result of the creation or strengthening of a dominant position. Also included is the documentary evidence that the Commission obtained through its own investigation or from third parties, and on which it bases its objections. In any case, the future decision of the Commission will be based only on information on which the parties have had the opportunity to submit comments. Therefore, if the Commission desires to raise any other objections, this must be done through a separate statement of objections.

c. *Trademarks.* In the case of an opposition, the opposing party does not notify the applicant. The Office communicates the opposition to the applicant and shall invite him to file his observations within such period as it may specify. There are three deadlines:

- A two-month "cooling off" period begins from the applicant's receipt of the opposition in order for the parties to assess their case before the investigation actually begins and to allow them to find an amicable solution.
- The opponent files arguments and documents in support of the opposition within the time limit indicated by the Office. All these materials are is communicated to the applicant.
- The applicant files arguments against the opposition within the time limit indicated by the Office. All time limits can be extended upon mutual agreement.

In case of an application for revocation or invalidity, the Office shall communicate such application to the proprietor of the CTM and shall request him to file his observations within such period as it may specify. These are also communicated to the CTM proprietor.

e. *State aids.* Should the Commission decide to initiate Phase II, the formal investigation procedure, the decision will be notified to the Member State concerned (the addressee of the decision). Moreover, this decision is published in the Official Journal (albeit often with a significant delay) and therefore accessible to anyone who is interested. The decision to initiate the formal investigation procedure must summarize the relevant issues of fact and law, include a preliminary assessment as to the character of the measure, and set out the Commission's doubts as to the compatibility with the common market. The decision calls upon the Member State concerned and upon other interested parties to submit comments to the Commission within a period prescribed by the Commission, which should normally not exceed one month (in duly justified cases, this period can be extended by the Commission.) Because the decision is published, third parties are not specifically notified. However, the Commission is required to send a copy of the decision to interested parties who supplied information concerning unlawful aid. The publication ensures that all persons who may be concerned are notified and given an opportunity of putting forward their arguments in order to defend their interests, and to obtain from these persons all information required for the guidance of the Commission's future action.

f. *Pharmaceutical licensing.* If a Member State or the Commission starts a referral procedure, the applicant or marketing authorization holder must be informed about the referral and the questions identified by the referring party (Commission or a Member State). Under the draft penalties regulation, a target company must be notified in writing when EMEA decides to start an infringement procedure. In the notification, EMEA must indicate the details of the allegations against the marketing authorization holder and any factual and legal elements on which such allegations are based. On the basis of a report from EMEA, the Commission will issue a statement of objections, which must include a description of the alleged infringement and the supporting evidence as well as a warning that penalties may be imposed. The Commission also has the authority "where appropriate" to include in its statement of objections an order that the target company stop the alleged infringement.

4.6.3 Are third parties notified of such action? What public notice is provided? Are complaints confidential?

a. *Competition:* Although not legally required, the Commission usually publishes a short notice on the DG-COMP website describing what a new case is about. The target company must be informed in advance of this publication.

In the merger control procedure, third parties involved in the case are also informed in writing of the Commission's objections. However, in the majority of cases, third parties do not receive the statement of objections as such, but only information about the main objections of the Commission. Once the Commission initiates Phase II proceedings, or decides to send to the parties a statement of objections, it will publish a notice in the Official Journal and a press release in its web site, giving information on the competition concerns that led it to initiate Phase II or to issue the statement of objections. As to the confidentiality of the statement of objections, in general, any information, including documents, used during merger clearance proceedings that contain business secrets or other confidential information, as may be the case for the statement of objections, will not be made accessible by the Commission when the Commission considers that their disclosure is not necessary.

b. *Trade remedies:* The first public announcement of trade remedies case comes with the publication of a notice of initiation in the Official Journal of the European Communities. If the

Commission services rejected the complaint, no public announcement is made. The notice of initiation is brief, generally two to three pages. It announces the initiation of the investigation, indicates the product and the countries concerned, gives a summary of the information received and provides that all relevant information must be communicated to the Commission within particular time limits.

In anti-dumping and anti-subsidy proceedings, the Commission must advise the exporters, importers and representative associations of importers or exporters it knows to be concerned, as well as representatives of the exporting country and the complainants of the initiation of the investigation. Although the Commission makes an effort to notify interested parties directly, publication of the notice is considered notice of the initiation of the investigation and interested parties are expected to take the initiative to make them known. Very often, interested parties find out about the investigation too late, because their own authorities failed to inform them and the failed to notice publication; in such a case, the Commission is generally unsympathetic, because the overall procedure is subject to strict deadlines that cannot be extended to accommodate companies who have come forward too late.

In safeguard proceedings, the Commission has no obligation to endeavor to inform interested parties of its investigation, beyond the publication of the notice of initiation in the Official Journal of the European Communities.

c. *Trademarks.* The fact that a CTM application is under opposition appears in the Office's database "CTM online": http://oami.eu.int/en/database/ctm-online.htm. All relevant information is included in the database. Third parties are informed of the existence of an *application* or a *counterclaim* for revocation or for a declaration of invalidity through the mention of the date of submission of the application or of the filing of the counterclaim in the Register of Community Trademarks. These entries made in the Register will further be published in the Community Trademarks Bulletin.

f. *Pharmaceutical licensing.* Generally, third parties are not notified of actions taken against a company. However, in cases where public health is at stake, the EMEA or Member State authorities may inform the public about measures taken. In addition, the EMEA web site contains a section with "Product Safety Announcements," where information about safety concerns together with information for physicians and patients can be found.

4.7 Conduct of the investigation

4.7.1 Are there time limits on completing investigation? Where no time limits are specified, are there general requirements? What happens if time limits are exceeded?

a. *Competition.* Commission investigations under Articles 81 and 82 are not subject to any time limit and sometimes drag on for years. While no specific time limits exist, general principles of Community law oblige the Commission to complete its investigations within the time limits of reasonableness. An unduly unreasonable duration must be owed to some specific exceptional reasons for the Commission to escape the European Courts' censure. Of relevance is also the right to good administration in Article 41 of the Charter of Fundamental Rights of the European Union, now reflected in Article II-101 of the Treaty establishing a Constitution for Europe, which refers to the right of every person "to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions, bodies, offices and agencies of the Union".

As described above, in merger control proceedings, the Commission must complete its investigation within given time limits. These may be extended in certain circumstances. If the Commission does not take any decision within the time limits, the consequence is that the transaction will be deemed to be compatible with the common market. If the parties do not present their commitments within the time limits, the Commission will not take the commitments into account when deciding on the compatibility of the transaction with the common market.

b. *Trade Remedies.* The time limits for completing anti-dumping and anti-subsidy investigations are strict: provisional measures in maximum nine months, a regulation for imposition of definitive measures must be adopted fifteen months from initiation for anti-dumping, thirteen months for anti-subsidy proceedings, which means that the investigation has to be finished and the proposal submitted one month prior to the expiration of this deadline. The regulation does not allow the authorities any flexibility; if the deadlines are not respected, duties cannot be imposed.

According to the safeguard regulation, if the Commission considers that Community surveillance or safeguard measures are necessary, it shall take the necessary decisions no later than nine months from the initiation of the investigation. In exceptional circumstances, this time limit may be extended by a further maximum period of two months. However, if those time limits are not respected, nothing in the regulation seems to prevent a Member State from later asking the Commission to take action, in which case it must take a decision within five working days of receipt of the request. The regulation does not impose time limits for action to be taken by the Council, acting by qualified majority on a proposal from the Commission if that route is taken, which never happens.

c. *Trademarks.* There is no time limit indicated for the Office in the CTM Regulation to complete the investigation. The Office indicates periods of time within which the parties have to reply or fulfil the Office's requests. The sanctions applying when these time limits are not fulfilled are described under the appropriate sections. A procedure exists by which any party to proceedings before the Office who, in spite of all due care, was unable to observe a time limit *vis-à-vis* the Office shall, upon application, have his rights re-established if the non-observance in question has the direct consequence of causing the loss of any right or means of redress.

e. *State aids.*

Phase 1 investigations: Decisions following the notification of State aid to the Commission must be taken within two months of the day following the receipt of a complete notification. The decision that must be taken within these two months can either be a decision (i) that the notified measure does not constitute aid, or (ii) that the measure notified is compatible with the common market and that, therefore, no objections are raised, or (iii) that the Commission will initiate formal investigations.

A notification will be considered as complete if within two months from its receipt, or from the receipt of additional information requested, the Commission does not request any further information. The period within which the Commission is obliged to take its decision can be extended if both the Commission and the Member State concerned agree on such an extension. The Commission also has the power to fix shorter time limits unilaterally, where this is "appropriate".

If the Commission fails to take a decision within two months after a "complete" notification was submitted, there is a presumption that the Commission has authorized the aid. For this presumption to have an effect, the Member State must give the Commission prior notice of its intention to implement the aid in question, and upon receipt of this notice, the Commission has another 15 working days to take a decision (i.e. to open a phase 2 investigation).

Because the time limit starts to run after the notification is complete, the Commission could extend the time limit by asking further questions. There are three reasons, which make it difficult for the Commission to abuse these powers:

- The Court has held that the Commission cannot extend the time limit by repeatedly asking the exact same question.
- The procedural Regulation provides that a Member State must in principle respond to requests for information from the Commission, and that if it does not respond, the notification will be deemed to have been withdrawn.
- To counterbalance that, the Member State has the right to explain to the Commission (in a reasoned statement) that either the Commission is already in possession of the information requested or that it is not possible for the Member State to provide the information. The Member state can state that the Commission is in possession of all the information it needs, and the 2-month time limit starts one day after the Commission received such statement. Further questions will no longer interrupt the 2-month period (but the Member State and the Commission will retain the possibility to extend the 2 month period by mutual consent).

In the examination of unlawful (i.e., non-notified) aid or if the Commission initiates a phase 1 investigation on its own motion, the Commission is not bound by any express time limits (as opposed to the examination of notified aid, where strict time limits apply). Nonetheless, the Commission may not prolong the investigation of non-notified aid indefinitely as it is bound to take a decision within a reasonable time limit. In practice, irrespective of theoretical time limits, there is a lot of back and forth, the Commission asking questions and the Member State answering them. In practice this delays the first phase investigations much beyond the 2-month time limit.

The Court has suggested, in its case law, that if there are too many rounds of questions and answers, that the resulting delay may be an indication that the Commission faces "serious doubts" as regards the compatibility of the aid, and that the Commission may be required at that point to initiate the Phase 2 investigation.

The preliminary examination can lead to three different outcomes: i) The Commission might find that the notified measure does not constitute aid; ii) it might find that no doubts are raised as to the compatibility of the notified measure with the common market; iii) It might open a Phase 2 investigation. The preliminary examination can never result in a decision that the new aid in incompatible with the Common market. Such a negative decision can only be adopted after the formal investigation procedure has been conducted.

Phase 2 investigations. Phase 2 investigations rarely take less than one year. The delay is caused by many factors, including the delay in publishing the initiation decision in the Official Journal.

The time the Commission may need to reach a final decision is partially regulated by three criteria: First, a decision closing the formal investigation procedure has to be taken as soon as the doubts that prompted the Commission to initiate the procedure have been removed. Second, the Commission should endeavor—as far as possible—to adopt a decision within a period of 18 months from the opening of the procedure. This time limit may be extended by common agreement between the Commission and the Member State concerned. Third, general principles of law (such as estoppel or the protection of legitimate expectations) will prevent the Commission's from dragging out a phase II investigation indefinitely.

What constitutes a reasonable length of time depends on the particular circumstances of the case and, in particular, its context, the complexity of the case and its importance to the parties involved.

If the Commission has initiated a formal investigation into an aid scheme, which has already been implemented, subsequent amendments to this aid scheme by the Member State do not affect the time limit with regard to the original scheme. Instead of taking the amendments into account in the ongoing procedure, the Commission can decide to open a separate procedure dealing with the aid scheme in its amended version.

Once the time limit of 18 months has expired, and if the Member State concerned so requests, the Commission must take its decision within two months on the basis of the information available to it. Where the information available is not sufficient to establish compatibility of the aid with the common market, the Commission will typically take a (partially) negative decision declaring the aid in question as incompatible with the common market.

When the Commission is investigating possible unlawful aid, the Commission is not bound by this time limit. *Mutatis mutandis* this also applies to investigations of alleged misuse of aid. The time limit, however, applies if the Commission ordered the provisional recovery of unlawful aid by means of a recovery injunction and the unlawful aid has effectively been recovered by the Member State concerned. In such a case, the Commission is bound to take the final decision within the time limits applicable to notified aid. It is unclear if the Commission is also bound by the time limits if the Member State concerned recovers the aid even without a prior recovery injunction being issued by the Commission.

A Phase II investigation is closed by a Commission decision stating that either

- the measure does not constitute State aid; or
- the measure is authorized as it is ("positive decision") or subject to conditions ("conditional decision"); or

the measure is not authorized ("negative decision"). In this case, the Member State is prohibited from putting the measure into effect and must recover any aid already granted to the beneficiary.

The initiation of the formal investigation procedure usually excludes legitimate expectation by the Member State authority granting the aid or the beneficiary that the aid measure in question was compatible with the TEC. The Commission's investigation is suspensory in nature, and therefore, it is only once such a decision has been adopted by the Commission, and the period for bringing an action against that decision has expired, that a legitimate expectation as

to the lawfulness of the aid concerned can be pleaded. The mandatory nature of the supervision of State aid by the Commission is a further reason to normally exclude legitimate expectations that aid granted in violation of the stand-still obligation was lawful. In that regard, the case law affirms that a "diligent businessman should normally be able to determine whether that procedure has been followed."

However, in the case of unlawful (i.e. non-notified) aid, the Commission (perhaps as a result of the political unpopularity of the decision it ought to take) might stop actively pursuing a case. The Court has therefore held that if the Commission remains inactive for a long period of time after it opened the formal investigation procedure, the beneficiary may rely on the Commission's failure to diligently pursue the matter, and the European Courts can protect his expectations that the aid will not be questioned. In RSV the Court held, that by waiting 26 months after it had opened proceedings before

The recovery of State aid by the Commission is subject to a 10 year limitation period. The limitation period begins to run on the day that the unlawful aid is awarded to the beneficiary. Any action taken by the Commission or by a Member State with regard to unlawful aid interrupts the limitation period. The term "any action" is interpreted widely by the Community courts, e.g., a formal request to provide information is sufficient. After each interruption, the limitation period starts to run afresh. Moreover, the period is suspended while appeals are pending in the Community Courts concerning the aid in question. Aid, in relation to which the limitation period has expired, is deemed to be existing aid.

f. *Pharmaceutical licensing.* [The report contains a detailed treatment of the various steps involved in the investigation and decisionmaking of both applications]

4.7.2 What are the techniques whereby the Commission can investigate private parties and learn the facts of disputed transactions? Required periodic reports? Subpoenas (or equivalent process such as Art. 11) to compel persons to show up and give testimony? Subpoenas to require the submission of documents? Physical inspections of business premises or private homes? Inspection of required records? What are the consequences of failing to comply with compulsory process?

a. *Competition.* Regulation 1/2003 provides for an array of investigatory measures that the Commission can take in the context of the enforcement of the Treaty competition rules. Firstly, the Commission may seek to obtain information not only from the companies suspected of violating the competition rules, but also from third parties. The Commission may exercise this power either by making a "simple request" or alternatively by adopting a "formal decision requiring information."

The "simple request" for information must be made in writing, state the legal basis and its purpose(which means that the Commission must identify a suspected infringement) and identify the information sought as precisely as the circumstances permit. There is no legal obligation to reply to a simple request. The companies are, however, subject to substantial fines in case of supplying incorrect or misleading information. At this stage the company may seek legal advice and/or contact the Commission directly to clarify the questions or the scope of information that the Commission seeks to obtain. A "formal decision requiring information" is challengeable

before the CFI. If the addressee of that decision fails to provide the required information within the time limit set by the Commission, it may be subject to fines or periodic penalty payments.

In most cases a request for information would follow an on-the-spot inspection, which is likely to be the first contact that the company will have with the Commission in the course of the proceedings. In some cases companies are informed of the inspection in advance, usually by phone or fax. The Commission will previously consult the national competition authority of the Member State in whose territory the inspection is to be conducted. Officials of national competition authorities may also assist the Commission officials in carrying out these inspections. An inspection may include entering business premises, examining books and business records, taking copies, and asking for oral explanations. The regulations also provide for the sealing of business premises and books or records, for asking representatives or members of staff of undertakings for explanations and for recording their answers.

There is a distinction between voluntary and mandatory inspections. For a voluntary inspection a simple authorization suffices, whereas the Commission may arm itself with a formal decision to which companies are required to submit. In case of mandatory investigations, when an undertaking opposes an inspection ordered by Commission decision, the delicate problem of the co-operation with national judicial authorities arises. Under an ECJ decision (*Roquette Frères)* the national courts' purview is limited to determining whether the Commission decision is authentic and whether the coercive measures sought are arbitrary or excessive. For this purpose the national courts can address questions to the Commission. National courts may not substitute their own assessment of the need for the investigations ordered for that of the Commission. The lawfulness of the Commission's assessments of fact and law is subject only to review by the Community judicature.

Failure to submit to a mandatory inspection may lead to fines and periodic penalty payments. Fines may also be imposed when the companies concerned produce the required books or other records in incomplete form, when they are responsible for breaking seals affixed by Commission officials, or when they give incorrect or misleading answers or otherwise fail to provide complete answers on facts relating to the subject-matter and purpose of a mandatory inspection.

Regulation 1/2003 empowers the Commission to order the inspection of non-business (domestic) premises. Such inspections can occur if the violation of Articles 81 and 82 EC is "serious" and a "reasonable suspicion" exists that books or other records related to the business and to the subject-matter of the inspection are being kept in such premises. To that end a reasoned decision is required, along with the prior authorisation of a national judicial authority. The latter's purview covers the authenticity of the Commission decision and the non-arbitrariness and non-excessiveness of the specific measure. The national court may ask for more detailed explanations of the Commission but once more it may not substitute its own assessment for that of the Commission and without requesting the whole file to be transmitted to it. The Commission also has a power to take statements from any person who consents to be interviewed for the purpose of collecting information relating to the Commission's investigation. However, no fine or penalty is provided for incorrect or misleading information offered at an interview.

In EC merger control proceedings, the Commission start early in the procedure to gather details of the market affected by the transaction. Form CO is the first source of information, but the Commission also requests information from the merging parties and sometimes from other corporations or associations. It may ask for this information by simple request or by decision. The Commission may also request competent authorities of the Member States to provide it with

information. It may interview any person by telephone or other electronic means, if that person gives his consent. The Commission may also investigate private parties, and may request the authorities in the Member States to conduct an investigation according to their national law.

The Commission's specific powers of investigation under the Merger Regulation are very similar to its powers of investigation in antitrust proceedings, the main difference being that in merger proceedings, unlike in antitrust proceedings, Commission officials cannot conduct searches in private homes. In general, the Commission is authorized to conduct all necessary inspections of business premises.

The consequences for failing to comply with compulsory requests for information or submission to investigation are fines of up to 1% of the aggregate turnover of the undertakings or associations of undertakings. In particular, the Commission may impose such fines (i) when the demandees supply incorrect, incomplete or misleading information; or do not supply information within the required time limit; or (ii) the demandees produce the required records in incomplete form during inspections, or simply refuse to submit to an inspection ordered by decision; or (iii) a representative gives an incorrect or misleading answer, or fails to rectify such an answer by a certain deadline; or (iv) seals fixed during the investigation have been broken. The Commission may also impose periodic penalty payments not exceeding 5% of the average daily aggregate turnover of the undertakings or associations of undertakings concerned for each working day of delay in cases (i) and (ii) above.

b. *Trade remedies:* To prove the existence of dumping or subsidization, the Commission sends questionnaires to exporters and to the governments. The Commission officials then conduct on-site verification visits in order to ensure that the information provided in the questionnaire replies was true and accurate. Questionnaires ask for a transaction-by-transaction report of all domestic sales (for normal value) and export sales (for export price) that occurred during the year-long investigation period. For subsidization, they will investigate in the company's books what payments it received from government; the Commission will also ask the government about payments to companies. On the basis of such data, the Commission can evaluate the dumping or subsidization margin. For injury, the Commission also relies on questionnaire replies, this time from the Community industry and importers. The analysis of injury involves primarily a determination of the amount of price underselling or price undercutting. These questionnaire replies are also verified on-site. In addition to the questionnaire replies, which are the Commission's primary source of data, the Commission also gathers information from the complainants and through the hearings.

Providing information to the Commission in the course of trade remedies investigations is entirely voluntary; the Commission has no power whatsoever to compel answers. However, interested parties often participate in the investigation, because if they do not, or if the Commission deems their cooperation insufficient, the Commission can proceed on the basis of "non-cooperation" (see below), or, in the absence of cooperation of the Community industry, decide that there is no or insufficient evidence of injury.

The regulations empower the Commission to proceed on the basis of "facts available" or the "best information available" in case of non-cooperation. The "best information available" often turns out to be the *worst* information available from the perspective of the "target," for example, figures provided by the complainants. That being said, the Commission is admonished in the regulations to make an effort to crosscheck this "best information" against other independent sources, particularly when best information is used to establish normal value.

The other independent sources could be published price lists, official import statistics and customs returns, or information obtained from other interested parties. That being said, the Commission is only asked to do so "where practicable and with due regard to the time limits of the investigation." In addition, since the Commission does not want to encourage non-cooperation, so in using the "facts available", it usually errs on the side of caution, meaning prefers the information that shows the greatest margin of dumping and/or injury.

Thus, non-cooperation has consequences, and the regulations explicitly say that "[i]f an interested party does not cooperate, or cooperates only partially, so that relevant information is thereby withheld, the result may be less favorable to the party than if it had cooperated." The consequences of non-cooperation can be so negative in fact that the regulations place some limits on the Commission's ability to call "non-cooperation" and move to the "facts available." For example, the regulations say that failure to provide a computerized response does not necessarily constitute non-cooperation, and information that is not "ideal in all respects" should not simply be disregarded. Rather, companies should be given a reasonable chance to complete any deficiencies. Finally, if evidence or information is not accepted, the entity that provided the information is to be informed and given an opportunity to provide further explanations. If the explanations are deemed unsatisfactory, the reasons must be disclosed in published findings.

c. *Trademarks.* The trademark area does not require as deep investigations as other administrative proceedings before the Commission. In most of the cases, it is the private parties that will submit evidence as they have a direct interest are supporting their own cases. The investigation means and techniques may therefore not be as developed as those in other proceedings. Nevertheless, the Office can examine the facts of its own motion. However, in proceedings relating to *relative* grounds, the Office is restricted in its examination to the facts, evidence and arguments provided by the parties and the relief sought. Also the Office may disregard facts or evidence which are not submitted in due time.

In order to learn about the facts, the Office can issue requests for information or decide to hold oral proceedings when it considers that it would be expedient. If the Office considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. The parties shall be informed of the hearing of a witness or expert before the Office and shall have the right to be present and to put questions to the witness or expert. The relevant department of the Office may commission one of its members to examine the evidence adduced.

As for the parties to the proceedings, they also can require that oral proceedings be held (if considered expedient by the Office) or issue a request for information. Other means to submit evidence in support of their case or to obtain evidence are the production of documents and items of evidence, the submission of opinions by experts, or of statements in writing sworn or affirmed or having a similar effect under the law of the State in which the statement is drawn up.

e. *State aids.* As the investigation of State aids by the Commission is construed as a procedure between the Commission and one or more Member States, the investigative instruments at the Commission's disposal are in principle directed against Member States, not against private parties.

In investigation procedures, the Commission can request all necessary additional information from the Member State concerned. Where the Member State does not respond within the period specified by the Commission or provided incomplete information, the Commission

must first send a reminder, allowing an appropriate additional period of time for the provision of the additional information.

If the Member States fails to comply with this reminder, the notification is deemed withdrawn if the information is not provided within the prescribed period. If alleged unlawful aid is the subject of the investigation and a Member State does not reply to a reminder, the Commission can require the information by means of a formal decision (a so-called "information injunction"). If the Member State fails to comply also with this injunction, the final decision can be taken on the basis of the information available to the Commission.

The Commission does not have competence to directly investigate the beneficiary of alleged unlawful aid because the procedure relating to non-notified aid is technically confined to the Member State concerned and the Commission. Nevertheless, in practice, the central administration of the Member State in question often consents to the beneficiary taking a somewhat active role in the proceeding. Most questions of fact can typically not be answered by the administration of the Member State concerned and require the involvement of the beneficiary. Rather than channeling all questions through the Member States' administration, Member States allow factual issues to be discussed directly with the beneficiary and beneficiaries typically are interested in direct contact with the Commission, as is the Commission. The tricky part in practice is linked to the question that Member States insist on controlling the process, because they insist that beneficiaries not contradict the legal position (and the practice as regards the level of information provided) the Member state wishes to take generally in its dealings with the Commission.

The only area where the Commission is entitled to take investigative actions that directly involve private parties concerns compliance monitoring (i.e. after aid was authorized and granted). The Commission can make on-site monitoring visits on premises of an undertaking concerned. Where the Commission has serious doubts as to whether its decisions with regard to individual aid are complied with, the Member State concerned must allow the Commission to undertake on-site monitoring visits. Before the on-site monitoring visit is conducted, the Commission must inform the Member State concerned in good time and in writing and must also inform it of the identities of the authorized officials and experts. If the Member State has duly justified objections to the Commission's choice of experts, new experts must be appointed in common agreement between the Commission and the Member State. After the visit, the Commission has to prepare a report, a copy of which it must provide to the Member State concerned.

f. *Pharmaceutical licensing.* This section provides an overview on the information sources available to the EMEA and Commission. Generally, it must be borne in mind that the supervision of the pharmaceutical sector, as far as manufacturing, importing, distribution, advertising, etc. is concerned, lies within the competence of the Member States which have extensive investigative powers that are not discussed here.

i) *Central marketing authorization applications:*

Application. The main information measure in the application procedure is the application itself and particularly the dossier on the medicine, which needs to be evaluated to check whether the requirements for issuing a marketing authorization as set out in Article 12 of Regulation 726/2004 (safety, efficacy and quality of the medicine) are met. In addition, the

CHMP may ask the applicant to supplement the provided documents, which it may do in writing or with oral explanations.

Furthermore, the CHMP will normally produce a list with questions to the application after the initial assessment by the Rapporteur and Co-rapporteur. The applicant may answer these questions in writing and, if need be, also in an oral hearing before the CHMP. While the applicant prepares for the answers, there will be a clock stop for the evaluation of the medicine, which should not be longer than 6 months.

Laboratory Check of Medicines. The CHMP can request that a laboratory check the medicine, its starting materials, intermediate products or other compounds in order to assure the validity of the control methods applied in the manufacture of the product.

GMP-Inspection. If it is necessary for the evaluation of the medicine, the Committee will ask for an GMP inspection of the manufacturing plant. Information about the manufacturer or importer may also be obtained from Member States upon written request by the CHMP.

Scientific Committees. The CHMP can ask for scientific advice from its standing or temporary working groups, which consist of scientific experts.

ii) Existing authorizations

Information from a referrer: The referrer must provide the Committee with all available information relating to the matter in question. The question limits the review conducted by the Agency.

Periodic Safety Update Reports (PSURs). The marketing authorization holder is obliged to provide periodic reports about the safety of its product to the Agency and the Member States either on request or after specific time periods clarified in the law. PSURs need to include a scientific risk-benefit-assessment.

Specific Data Request. The Agency can ask the marketing authorization holder to supply it with data that allow the checking that the risk-benefit assessment remains positive.

Notifications of adverse events. The marketing authorization holder must report adverse events to the Member States and the Agency, dependent on the event involved (expected or unexpected serious events, within the Community or in third countries).

Information generated through pharmacovigilance system: Member States are obliged to install a functioning pharmacovigilance system and to ensure information exchange with other Member States and the Agency. Pharmacovigilance systems had been in place in individual Member States before and involved specific reporting schemes from health care professionals or pharmacovigilance centers for the collection of reports. Today's system provides for harmonized institutional requirements in the Member States, electronic data exchange and a European Database for Pharmacovigilance information. These sources of obtaining information about medicines are important for signal generation concerning drug risks and may be further used in the re-assessment of a medicine.

Scientific Material, Studies. In addition, new scientific material, publications of studies in specialized journals, new studies conducted by the company or competitors may provide information that requires the re-assessment of the authorization of the medicine.

Expert Advice. The CHMP may call for expert advice on specific questions. In that case the Committee must specify the questions to be answered by the expert.

Written and Oral Explanations. The applicant or marketing authorization holder may provide written or oral explanations before the Committee adopts its opinion.

Information from third parties. The Committee may request information from third parties. Third parties may also, on their own initiative, approach the Agency and supplement information about a medicine. In the *Ferriprox* case, CFI held that the Agency must take all information into account that concerns the evaluation of a medicine since it is bound by the purpose to serve public health.

iii. *Draft penalty regulation.* The Agency has the right to ask for (i) written or oral explanations; (ii) the submission of particular documents; (iii) the testing of a medicinal product; and the cooperation of national competent authorities (such as request for inspections, conduct of supervisory measures).

The Commission may ask the marketing authorization holder, the Agency or national authorities to provide information on the issue at stake. It may also hear other natural or legal persons on the issue. The Commission may also decide to send the matter back to the Agency, if it considers that additional information is needed to issue a decision.

4.8 Rights and duties of target

4.8.1 What privileges are available to the target of investigation? Attorney client? Self-incrimination? Work product?

a. *Competition.* The target of a competition law investigation enjoys certain rights and privileges. First and foremost, the Commission is bound to respect human rights, which are general principles of Community law and apply to any form of action or inaction of the Community institutions. Courts draw inspiration from the constitutional traditions common to the Member States and from the guidelines supplied by international treaties for the protection of human rights on which the Member States have collaborated or of which they are signatories, most notably from the European Convention on Human Rights.

In EC competition law proceedings regard must be had in particular to the rights of defense, a principle whose fundamental nature has been stressed on numerous occasions judgments of the European courts. More specifically, the courts have pointed out that the rights of defense must be observed in administrative procedures which may lead to the imposition of penalties. That protection extends also to "preliminary inquiry procedures including, in particular, investigations which may be decisive in providing evidence of the unlawful nature of conduct engaged in by undertakings and for which they may be liable."

In addition, the Commission action is subject to the principle of proportionality. Thus, the courts have held that inspections and requests for information must be necessary and proportionate to the objective pursued by the Commission. Proportionality limitations are, indeed, expressly provided for in the text of Regulation 1/2003.

More specifically, the target of the Commission's investigation is entitled to claim legal professional privilege, which covers lawyer-client communications made for the purpose and in the interest of the client's right of defense. The privilege covers only documents emanating from an independent lawyer–not documents produced by an in-house lawyer. The target has also the right to avoid self-incrimination, which is, however, limited by an obligation on the part of a company to cooperate with the Commission. Thus, the Commission is not entitled to require the target of its investigations to answer questions if an answer to the question would be equivalent to the admission of an infringement. On the other hand, the Commission can reward a company that pleads guilty by reducing its fine.

4.8.2 Is there a duty on the part of private parties to cooperate in the investigation? What is the nature and source of this duty and does it vary as between sanction cases and application cases?

a. *Competition.* Companies that are the target of a specific investigatory measure by the Commission must cooperate fully with the latter. The Commission enjoys wide powers to make investigations and to obtain information, in order to bring to light infringements of Articles 81 and 82 EC and it is for it to decide, for the purposes of an investigation, whether particular information is necessary. More particularly, in on-the-spot investigations, the company concerned must be responsive rather than passive. Merely making records available in a general way is insufficient. A company must co-operate in finding specific records when the Commission so requests.

b. *Trade remedies.* Since cooperation with the investigation is voluntary, parties can refuse access to any information for whatever reason, subject always to the threat by the Commission of being deemed "uncooperative" and having the Commission make decisions on the basis of the "facts available". However, providing a justification for refusal, for example, legal privilege can help to avoid a conclusion by the Commission that the refusal is evidence of lack of cooperation.

e. *State aids.* A *general* duty on Member States to cooperate in good faith with the Commission arises from Article 10 TEC, which imposes, on Member States the duty to facilitate the achievement of the Community's tasks and to abstain from any measure that could jeopardize the attainment of the objectives of the TEC. In addition to this, Treaty Article 88 requires Member States to cooperate with the Commission in the constant review of existing systems of aid and to inform the Commission of any plans to grant or alter aid. Regulation 659/1999 elaborates on these treaty provisions and lays down more detailed rules on the Member States' obligation to cooperate, and specifically, to provide information to the Commission.

However, the Commission has no power to directly enforce its requests against a Member State that does not comply with its duty to cooperate. If a Member State does not comply with a request to provide information even after the Commission has used all its procedural instruments at its disposal to induce the Member State to comply—i.e. the issuance of a reminder or the adoption of an information injunction—the only possibility for the Commission is to resort to the procedure available under Article 226 TEC. Under this procedure, the Commission first has to deliver a reasoned opinion and give the non-complying Member State an opportunity to submit observations. Only if the Member State does not comply with this opinion within the period specified by the Commission can the matter be taken to the Court.

Other Member States are bound by the general obligation to cooperate with the Community institutions. They must not hinder the Commission's investigation of State aid granted by other Member States, and would also be bound to provide the Commission with any useful information they have in regard to investigations relating to other Member States.

Regulation 659/1999 does not lay down any specific duties on private parties to cooperate. It is for the Member State concerned, based on the powers under its administrative

law, to ensure cooperation of the beneficiary with the Member State. The Commission's inability to force private third parties to provide evidence also extends to complainants and other parties (such as trade associations), which often have valuable information (such as statistics, or raw data on which statistics are based). The lack of powers of compulsion of the Commission in this regard causes difficulties in practice, because the Member State concerned will have similarly limited powers vis-à-vis non-beneficiary third parties.

f. *Pharmaceutical licensing.* In the pharmaceutical sector, the marketing authorization holder has plenty of obligations to cooperate with the authorities. As described earlier, the marketing authorization holder must provide PSURs, notify adverse events, and provide data needed for the risk-benefit assessment of a medicine if requested by the agency. In addition, there are obligations to cooperate with national authorities responsible for the supervision of the manufacturing, distribution, etc. of medicines imposed on the marketing authorization holder. The different procedures provide for the authorities, particularly the CHMP, to request further information, inspections, etc., which the marketing authorization holder needs to comply with. The draft penalties regulation explicitly includes a cooperation requirement of the marketing authorization holder towards the Agency and the Commission during the investigation procedure.

4.8.3 Must the target be notified when third parties are questioned regarding the target?

a. *Competition:* The target is not notified when third parties are questioned regarding the target. In the proceedings before the Commission, the target does not have the right to be present when third parties are questioned regarding the target or to cross-examine the witnesses. If the Commission relies on statements made by third parties as evidence against the target, such statements will be referred to in the statement of objections. Transcripts of oral submissions made by third parties are included in the Commission's file, and the parties are allowed to comment on such submissions during the hearing and/or in written submissions to the Commission in the course of the procedure.

b. *Trade remedies.* Parties need not be notified when the Commission interviews third parties about them, but if the Commission intends to rely explicitly on information provided orally, interested parties have a right to comment on it. In such a case, a non-confidential summary of the remarks would have to be prepared for the file, probably by the private party upon the request of the Commission. All written submissions must be accompanied by a non-confidential version, which is made available to interested parties as part of the non-confidential file.

However, oral submissions to the Commission are often not "relied upon" as such, but can have a significant influence on the case handlers. For example, during the on-site verification visits, the Commission officials invariably ask questions of persons in the companies they visit. Responses are recorded in the mission report of the case handlers, never provided to other interested parties. Where these statements do not contain business secrets, it is a lacuna in the legal protection of interested parties that oral submissions do not have to be recorded or reported in the file that is available for inspection.

f. Pharmaceutical licensing. Under the Community Referral Article 31 of Directive 2001/83, the CHMP may call upon any other person to provide information relating to the referral (Article 32 (3)). However, the law does not impose any specific notification requirements on the applicant or marketing authorization holder. Under the Draft Penalties Regulation, the

Commission may hear any legal or individual person who can provide information on the alleged infringement. The draft does not impose a specific obligation to notify the target concerned if the Commission questions a third party.

4.8.4. What are the mechanisms whereby the target can raise issues about pending investigations?

a. *Competition:* The situation of the target changes in the course of the proceedings. Certain rights of the defense relate only to the contentious proceedings which follow the delivery of the statement of objections, while other rights, such as the right to legal representation and the privileged nature of correspondence between lawyer and client must be respected as from the preliminary-inquiry stage.

At the preliminary investigation stage the Commission obtains the information and documentation necessary to check the actual existence and scope of a specific factual and legal situation. Before the statement of objections is issued, the investigated company has no particular rights, other than those related to particular actions taken by the Commission in the course of preliminary investigation. It may claim legal professional privilege, invoke its right for privacy with regard to premises, or the right to necessary legal representation. At this stage the Commission may take a number of actions without granting the target the right to be heard or even giving it a notice of its action. For example, the Commission is not obliged to hear the parties prior to issuing a decision to search company's premises or a decision requiring information.

A company that receives a statement of objections becomes a party to the proceedings and acquires a number of rights, such as the right to be informed of the objections raised against it, or the right to access the Commission's file. Such company will have a number of formal and informal contacts with the Commission officials in the course of the proceedings. It will have an opportunity to raise issues about pending investigation at this stage.

In EC merger control proceedings, the main mechanism whereby the notifying parties can raise issues about pending investigations is their response to the statement of objections sent them by the Commission during the Phase II investigation. Indeed, parties to whom the statement of objections is addressed, or who have been informed of the objections in the SO, must submit their comments on the objections to the Commission in writing. Their comments must set out all facts and matters known to them that are relevant to their defense, and must include any relevant document as evidence of the facts set out. They may also suggest that the Commission should hear persons who can corroborate those facts. The other main possibility for private parties to raise issues about the pending investigation is during the oral hearing, if so requested by the notifying parties in their written comments. However, it is also possible for the notifying parties to raise these issues orally at other stages of the investigation procedure.

b. *Trade remedies.* The target of an investigation is allowed to make written submissions, provided that they arrive within the time limits set in the notice of initiation of the investigation. Generally, the target will make written comments on the complaint in the first instance; exporters will also often take the opportunity to reply to the Commission's questionnaire by making further written comments. The target will also have an opportunity for one or two oral hearings. Most substantively, the target receives disclosure of the details underlying the essential facts and considerations on the basis of which provisional measures are imposed, likewise for the essential facts and considerations on the basis of which it is intended to

recommend the imposition of definitive measures, and it has the opportunity to submit comments on disclosure.

These opportunities are not expressly provided for in the case of a safeguard proceeding. However, in a recent case the targets, i.e. the authorities of the exporting countries and even the exporters that had made them known, did receive disclosure documents following the imposition of provisional measures.

d. *Food Safety*. Some recently adopted regulations provide for an undefined appellate process to the Commission from any act or omission by EFSA. However, this process as yet unused and its impact cannot be assessed. There are serious uncertainties surrounding the procedure. See Food Contact Material Reg. 1935/2004, Art. 14.

f. *Pharmaceutical licensing.* Generally the marketing authorization holder can provide information on its product at any time. In the context of an infringement procedure, the draft penalties regulation foresees an opportunity for the marketing authorization holder to provide oral or written explanations during the first stage of the investigation. The Commission, during the second stage, has to provide the possibility to written explanations and / or an oral hearing to its statement of objection. In addition, the target may raise issues, when asked for information by the Commission. (Art. 12 of the draft regulation). Article 16 of the draft regulation enshrines the rights of participation of the target and allows it to submit any documents, books or records, or copies, etc.

4.8.5. Are there any defenses against investigation? Harassment? Selective complaints (that is, Commission has picked on one party but not others)? Excessive burden of demand for information?

a. *Competition:* The case law of the European Community Courts indicates that the Commission has a wide sphere of discretion as to how to conduct its investigation. Only final acts of the Commission are subject to appeal; acts adopted in the course of the procedure are not subject to judicial review. In particular, the ECJ has ruled that neither the initiation of a procedure nor a statement of objections may be challenged before the Community Courts. The Commission has also wide power of discretion as to the choice of the companies it subjects to its enforcement actions. It is entitled, in order effectively to ensure the application of Community competition rules, to give differing degrees of priority to the complaints brought before it by reference to their Community interests.

With respect to requests for information it does not seem that excessive burden of the request could be a valid argument to raise against the Commission. In the context of Commission's investigations on company's premises, the CFI held that the excessive volume of documents, which the Commission copied, couldn't in itself constitute a defect in the conduct of the investigation. As explained above, a company to which the Commission directed a simple request for information is not obliged to comply with this request. On the other hand, if the Commission issues a decision requiring information, the addressee is obliged to answer and may be subject to fines if he fails to do so. There are limited reasons, such as legal professional privilege, that may be invoked to refuse to provide with the Commission with information it has requested by means of a formal request for information.

Instances of administrative irregularities, unfairness, discrimination or violations of the Code of Good Administrative Behaviour by the Commission officials may be complained of to

the Ombudsman. Defenses against investigation may also be raised in the appeal to the Court of First Instance, if the Commission issues a final decision in the case.

b. *Trade remedies.* In anti-dumping and anti-subsidy proceedings, in principle, if the Commission opens an investigation on the basis of a properly filed and substantiated complaint, it is not a defense to cry harassment or to argue that others ought to be investigated too. The company might be able to convince the Commission to look into imports from another source in addition, on the basis of the general principle of non-discrimination. Furthermore, if the products of others are causing problems, they can be raised in the course of the investigation as a possible "other factor" causing injury.

Safeguard proceedings must be initiated against all countries exporting the "like" or "directly competitive" products to the EU, except in the case of a special safeguard against China. With safeguards, where imports of a product have already been subject to a safeguard measure, no new measure can be applied to that product until a period equal to the duration of the previous measure has elapsed. Such period shall not be less than two years. However, a safeguard measure of 180 days or less may be re-imposed for a product if at least one year has elapsed since the date of introduction of a safeguard measure on the import of that product and such a safeguard measure has not been applied to the same product more than twice in the five-year period immediately preceding the date of introduction of the measure.

c. *Trademarks.* There is no real 'investigation' on the merits conducted by the Office in the trademark area so the various questions under ¶¶4.8 are inapplicable. Rather, the proceedings must be considered as private interests proceedings, where only the parties can investigate the other party's trademark and field of activities. As in other 'private' proceedings, attorney-client privilege and self-incrimination privilege are available to the CTM applicant. The applicant will generally cooperate as it is in his own interest to prove his case. He is however not obliged to cooperate and help the other party to establish facts that would have adverse effects for him.

Once an opposition is communicated to the applicant, the latter shall file his observations within the period specified by the Office. Any submission of facts or evidence by the opposing party shall be communicated to the applicant who shall be given an opportunity to reply within a period specified by the Office. The observations filed by the applicant shall be communicated to the opposing party who shall be called upon by the Office, if it considers it necessary to do so, to reply within a period specified by the Office.

The Office shall invite the parties, as often as necessary, to file observations, on communications from the other parties or issued by itself (article 43 Regulation 40/94). Further, the CTM applicant can request that the opposing party (or an applicant for invalidity or revocation) submit proof *of use* of its own mark. The proprietor of an earlier CTM or national mark who has given notice of opposition will then have to furnish proof that, during the period of five years preceding the date of publication of the Community trademark application, the earlier mark has been put to genuine use in connection with the goods or services in respect of which it is registered.

f. Pharmaceutical licensing. There are no specific defenses against investigation foreseen in the pharmaceutical legislation since investigations are triggered for public health reasons. However, the EMEA's code of conduct, which is an implementation of good administrational behavior, lays down some principles that have to be respected by the agents when carrying out an assessment of a medicine. The code of conduct particularly deals with discrimination and abuse

of powers. As to discrimination, "the Agency shall ensure that the principle of equality of treatment is respected. Members of the public who are in the same situation shall be treated in a similar manner...The agent or other servant of the Agency shall in particular avoid any unjustified discrimination between members of the public based on nationality, sex, racial or ethnic origin, religion or belief, disability, age, or sexual orientation. As to abuse of power, "powers shall be exercised solely for the purposes for which they have been conferred by the relevant provisions. The agent or other servant of the Agency shall in particular avoid using those powers for purposes which have no basis in the law or which are not motivated by any public interest."

4.9 Access to information in Commission files

4.9.1 What are the rights of access to information in the Commission's files by the target or a rejected applicant? Everything in the files or only selected information? If the latter, who decides what information is to be provided? Is access given to member states but not private parties?

a. *Competition:* Access to Commission files is a procedural guarantee that is necessary for effective exercise of the rights of defense and to be heard. CFI cases have held that the Commission must turn over to the parties to whom it addressed a statement of objections all documents obtained in the course of the investigation, not merely grant selective access. However, the Commission will not disclose business secrets and other confidential information, internal documents of the Commission (or competition authorities of the member states), and correspondence between the Commission and the competition authorities of member states. The Commission will also disclose the relevant parts of other parties' replies if these contain new evidence pertaining to the allegations in the statement of objections (normally this information will be included in a supplementary statement of objections). The Commission may not disclose business secrets and other confidential information but ma exchange this information with the competition authorities and courts of member states in cases of cooperative enforcement.

In the field of merger control, the Commission must grant to the parties to whom the SO is addressed access to the file, with the aim of enabling them to exercise their defense rights. Access is subject only to the legitimate interest of companies in the protection of their business secrets. The procedure for access to the file in merger proceedings is very similar to the procedure followed under the application of Articles 81 and 82 EC. The SO addressees may also review documents that the Commission did not attach to the statement of objections, such as observations from competitors or customers. The Commission must also grant such access to other parties involved who have been informed of the Commission's objections, if this is necessary for those parties to prepare comments on the statement of objections. However, the right to access the file does not extend to (i) confidential information, (ii) internal documents of the Commission or the competent authorities of the Member States, or (iii) correspondence between the Commission and the competent authorities of the Member States or between the latter. Finally, the Commission must also grant access to the file to the authorities of a Member State to which the Commission has referred a case.

c. *Trademarks.* The CTM Regulation does not provide specific provisions concerning access; both applicants and challenges have access to all information in the relevant file. Access is also given to national courts and national industrial property officers.

e. *State aids.* Even though there is no such express provision in Regulation 659/1999, the Members State concerned is in a position to rely on a right to participate in an adversarial

procedure with the Commission, which comprises certain rights of access to the file. In practice the Commission will inform the Member State of relevant information it has on file, it will however not permit the Member State physical access to the entire file. Private parties have no right of access to the file, although in practice the Commission will (as a matter of courtesy, but not as a matter of right) discuss with the beneficiary the issues it considers relevant and the factual information it has on file supporting its concerns. Other interested parties do not have an explicit right to access to the file, but the Commission will make certain information available to third parties. During a Phase 1 investigation the Commission will normally not provide any information. However, in the case of complainants the Commission may provide them with an opportunity to clarify their submission and/or discuss the matter. The information provided to the complainants will generally be limited to what the Commission considers useful for its investigation, the information is not provided in response to a right of the complainant.

When the Commission adopts a decision to open a Phase 2 investigation, this decision is published in the Official Journal. The publication has to be accompanied by a case summary in all other Community languages. The Commission considers that the information it provides in describing the case and its initial assessment suffices to satisfy third parties legitimate interests in knowing about the content of the file. The Court seems to support that position. A restriction on the amount of information that can be provided to interested parties results from the Commission's and the Member States' obligation to safeguard professional secrecy.

Private parties may rely on Treaty Article 255 (and Reg. 1049/2001) which provides that "any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, shall have a right of access to European Parliament, Council and Commission documents," subject to general principles and limits on grounds of public or private interest. Member States cannot rely upon Article 255 TEC, as they are not included in its scope. It is important to note that the right of access is limited to documents emanating from the Community institutions and does not extend to documents prepared by Member States, the beneficiary or other third parties (although such other documents usually make up to bulk of the case file). Also excluded from the right to access are draft documents (like draft decisions and comments thereon). Hence, only Regulation 1049/2001 covers a small portion of the case file.

f. *Pharmaceutical licensing.* Access to Commission documents is subject to Regulation 1049/2001 on public access to documents of the European Parliament, the Council and the Commission. [Information on public access is contained in the Transparency report and is not summarized here]. The Pharmaceutical Unit of the EC provides for access to its decision through the Community Register of Medical Products http://pharmacos.eudra.org/F2/register/index.htm. This register comprises marketing authorization approvals, refusals, variation decisions, withdrawals, suspensions, decisions in the decentralized procedures, etc. However, documents may only be accessed if they do not contain confidential information.

As to access to Commission files by directly involved parties: The draft Commission decision will be made available to the applicant or marketing authorization holder at the same time as it is send to the Member States and therefore access is granted automatically. However, access to the written remarks of the Standing Committee is not explicitly granted in the law and could be restricted on the grounds that the document is for internal use and no decision on the issue has been taken yet. In addition, if several marketing authorization holders are concerned, confidentiality issues amongst them may arise and therefore, the information disclosed to the different companies may have to be separated. Internal documents are not excluded from being

accessed and therefore, an involved party can access such documents on basis of the rules on access if no restriction applies in the individual case.

As to access to EMEA files by directly involved parties:

Rapporteur reports: The initial assessment report is made available to the applicant. The EMEA will send this report to it even though it is a preliminary conclusion only.

List of questions and overall conclusions of the CHMP: After a first discussion of the rapporteur reports, the CHMP adopts a list of questions and overall conclusions, which is made available to the applicant.

Joint Response Assessment Report (Rapporteur / Co-rapporteur) : The joint report will also be provided to the applicant, again with the disclaimer that it serves information purposes only.

Final opinion and assessment report: These documents will be sent to the applicant as well within 15 days after the adoption.

Access to reports when more than one company is involved: Access to reports can be problematic, when, for instance in a class review, the reports discuss different medicines and the commercial secrets of the individual companies are included. In such cases, access must also be restricted between the different companies. The fact that competitors are subject to the same review procedure does not entitle them to access business secrets.

As to EMEA documents: Access to the files by third parties

EPAR: The EPAR is published by the EMEA on its web site and publicly available. However, the EPAR does not contain material that is commercially confidential. Before an EPAR is published, the applicant may comment on what he considers to be confidential. The project manager will then prepare a draft EPAR, which must be decided upon by the CPMP.

Access to documents in general: The "Rules on the Implementation of Council Regulation (EC) No. 1647/2003 on "Access to EMEA Documents" provide details on accessing EMEA documents that are produced by the Agency or that it has received or has in its possession unless access is restricted. Access may be refused in order to protect commercial interests of a person including intellectual property, etc. or if disclosure would seriously undermine the decision-making process.

4.9.2 How is this right exercised & when must it be exercised? When must the information be provided?

a. *Competition:* Access to file is granted after notification of the statement of objections at the request of the addressee thereof. Documents are scanned and digitally recorded so that they can be supplied electronically. The file can also be provided in paper form or by inspection at the Commission's premises.

In the context of leniency applications, the Commission developed the practice of taking oral statements primarily to limit the documents that would be available for discovery purposes in private action litigations in the U.S. in particular. Its practice in this area is evolving and most probably not uniformly applied. The current practice is that oral statements made by leniency applicants (which the Commission tries to keep short and exclude business secrets and confidential information to avoid the need for editing) are routinely recorded by the Commission, transcribed and signed by leniency applicants (or at least the Commission requests a signature but considers it immaterial whether the transcript is signed or not; the danger of signing a transcript is

that this document could potentially be seen as an admission of liability by the company). The Commission has to date always relied on these tapes in the statement of objections, and included the tapes and the transcripts of the tape-recorded presentations in the file. The need for some kind of "investigation privilege" for such statements has been raised, but not accepted by the Commission to date. Some officials believe the Commission no longer will routinely make transcripts of tape recordings (the number of leniency applications has doubled in the past year, and DG-COMP is under-resourced to deal with these) – but the tape recordings will still be made available as part of the file, and other parties can listen to them and make notes.

In EC merger control proceedings, once the notifying parties receive the statement of objections, they must prepare a written response that includes a request for access to the file. Other parties involved in the procedure that have been informed of the Commission's objections must request access to the file if that is necessary for the preparation of their observations. The procedure for obtaining access to the file is supervised by the Hearing Officer. Although the Commission's Best Practice Guidelines state that it will grant access to "key documents" obtained by the Commission as soon as Phase II of the investigation is initiated, i.e. before notifying the statement of objections and granting formal access to the file, the Implementing Regulation refers to access to the file only after the statement of objections is issued. The Commission has been much criticized on this point, as it would substantially improve the parties' defense rights if they had access to the file before they receive the statement of objections.

e. *State aids.* In practice, access to the file is granted in a rather informal way by making copies of certain documents available or by summarizing their substance. Moreover, the Commission would inform the Member State concerned of any complaints filed and would provide the Member State with copies of any observations submitted by third parties in Phase 2 proceedings. A physical inspection of the Commission's substance file is not permitted.

f. *Pharmaceutical licensing.* As to Commission documents, the Commission's rules of procedure provide that third parties must make a written application for access to documents (by mail, e-mail, or fax). The applicant does not have to provide reasons but it must specifically identify document it wishes to access. Access can be provided in the form of hard copies, electronic versions, or access to a file where the document is stored. If access is refused, the Commission must provide reasons. The Commission must also inform the applicant about the possibility of having the application reconsidered by the Commission. This second application is called a confirmatory application and follows the same procedure as the initial application. If access is denied again, the Commission must inform the applicant about the right to appeal to the CFI and the European Ombudsman complaints procedure. If the document originates from a third party, the latter must be consulted before access can be granted as any objections by such third party must be taken into account.

As to EMEA, third parties may request access to documents by lodging a written or electronic application to the executive director of the EMEA identifying the particular document sought. The procedure within the EMEA is essentially the same as the Commission's (as described above). EMEA documents, such as the rapporteur and co-rapporteur report and the draft assessment report, will be sent to an applicant or marketing authorization holder directly without any requirement to apply for it. .

4.9.3 Can affected third parties such as competitors have access to Commission's files? How about people representing the public interest?

a. *Competition:* Complainants may obtain limited access to documents in the file. They can ask for a non-confidential version of the statement of objections. If the complaint is rejected, the complainant may request access to the documents on which the Commission bases its assessment. However, complainants do not have unlimited access to documents. There is provision for intervention if the interveners show a "sufficient interest" in the case.

c. *Trademarks.* Third parties may *inspect* the files relating to a CTM application and the resulting mark. The same applies for opposition files and invalidity/revocation files. These third parties who can be competitors or even people representing the public interest must show no special well-founded interest. The files relating to applications that have not yet been published are available for inspection without the consent of the applicant. Third parties must file a request for inspection of the files with the Office. A fee must be paid.

e. *Pharmaceutical licensing:* Pharmaceutical law does not contain any specific rules granting to third parties access to documents that affect a party to a procedure. The general rules of access to Commission or EMEA documents (see above) apply. Article 4 of Regulation 1049/2001 allows the Commission to refuse access if disclosure would undermine (i) the protection of the public interest, privacy and integrity of an individual, or the commercial interests of natural or legal persons, including intellectual property; (ii) court proceedings or legal advice; or (iii) inspections, investigations or audits, unless there is an overriding interest in favor of disclosure. In addition, access may be restricted when the internal documents concerned relate to a matter on which a decision has not yet been taken. If the document comes from a third party, the latter must be consulted before a access is granted. The same principles apply to EMEA documents. However, after a marketing authorization is granted, the EPAR is publicly available without any confidential material. In addition, the EMEA may provide information to the public, such as the refusal to grant a marketing authorization together with its reasons or pharmacovigilance information.

4.9.4 What information in the files is unavailable, for example because of trade secrets [Art. 287]? Unavailable because of confidentiality, informant protection, or state secrets? Unavailable because they are staff advisory memos or preliminary decisional documents? (These question may overlap the project on transparency and data protection).

a. *Competition:* Where business secrets or other confidential information are necessary to prove the infringement, the Commission must assess whether the need to disclose the information is greater than the harm that might result from disclosure. "Business secrets" are those that, if disclosed, could result in serious harm to the company whose business activity is described in the information. "Other confidential information" would significantly harm some person or other company, such as persons who wish to remain anonymous or who communicated in confidence to the Commission. Submitters of the information must indicate materials they consider confidential, with reasons, and must submit a separate non-confidential version of the information.

Under what is known as the *Akzo* procedure, where the Commission intends to disclose information, and the company that provided it wants such information to be treated as a business secret or confidential, the Commission must inform the company of its intention and the reasons for it. If the company objects to disclosure, but the Commission finds that the information is not protected and may be disclosed, that finding shall be stated in a reasoned decision. The decision has to be notified to the company concerned, which must have an opportunity to challenge the

decision in the CFI. The information may not be disclosed before one week after the decision has been notified.

c. *Trademarks.* There is little or no issue of trade secrets or of confidential information in the trademark area. As a consequence, almost all documents submitted to the Office by the CTM applicant or holder should be available for inspection. However, if the party concerned showed a special interest in keeping parts of the file confidential before the application for inspection of the files was made, these parts shall be withheld from inspection, unless inspection of such parts of the file is justified by overriding legitimate interests of the party seeking inspection.

Other documents in the Office' files may be withheld from inspection. These documents are (a) documents relating to objection to participation of members of the Office in proceedings for instance due to their personal interest in a case and (b) draft decisions and opinions of the Office, and all other internal documents used for the preparation of decisions and opinions.

e. *State aids*. According to Article 287 TEC, the Commission and its officials are not allowed to disclose information of the kind covered by the obligation of professional secrecy. Regulation 659/1999 extends this obligation to Member States and their officials. In State aid proceedings, the Commission, the Member States, their officials and other servants, including independent experts appointed by the Commission, must not disclose information that is covered by the obligation of professional secrecy. It follows that third parties are not entitled to receive documents containing business secrets.

The publication of the final State aid decision must not lead to the disclosure of information covered by professional secrecy either. Prior to publication, the decision must therefore be notified to the Member State concerned which must be given the opportunity to indicate to the Commission which information it considers to be covered by professional secrecy.

In addition, access to documents can be refused where disclosure would undermine the protection of the public interest or privacy and the integrity of the individual, and also where disclosure would undermine the protection of, *inter alia*, commercial interests of a natural or legal person, or the purpose of inspections, investigations and audits, unless there is an overriding public interest. Apart from these general limitations to the right to access to documents, there are further limitations: Access to documents, drawn up by the Commission for internal use or received by it, which relate to a matter where the decision has not been taken by the Commission, can "be refused if disclosure of the document would seriously undermine the institution's [i.e., the Commission's] decision-making process, unless there is an overriding public interest in disclosure." Under the same conditions, access to documents containing opinions for internal use as part of deliberations and preliminary consultations within the Commission can be refused even after the decision has been taken.

Member States, moreover, have the right to request the Commission not to disclose a document originating from them without their prior agreement. This limitation seems to be of particular relevance in State aid proceedings as in such proceedings many documents presumably originate from Member States.

f. *Pharmaceutical licensing.* The restrictions on disclosure, as set forth in The Citizen's Guide on the Access of European Commission Documents are discussed in the Transparency

Report and not separately summarized here. Since the EMEA's rules on access to documents contain the same restrictions, the information should apply analogously to its documents. The draft penalty regulation restricts the target's right to access documents relating to the infringement procedure if the documents or material is deemed to be confidential with regard to third parties or to the Agency, Commission or national competent authority.

4.9.5 Consequences if Commission fails to provide access to information? Does it make the subsequent decision illegal? Only if the failure to provide information was prejudicial?

a. *Competition:* Annulment of a Commission decision because of a failure to disclose documents is not automatic. Annulment occurs only if the access is insufficient to enable to the defendant to exercise the right to be heard. In the case of inculpatory documents, the target must show that the Commission would have decided the case differently if the document were disallowed as evidence. The burden is less in the case of an exculpatory document; the defense only needs to show that it could have used the document in its defense and it might have had some influence, at least as regards the gravity and duration of the charged conduct and the level of the fine.

b. *Trade remedies.* In anti-dumping and anti-subsidy cases, the complainants, importers and exporters and their representative associations, users and consumer organizations, plus representatives of the exporting country have a right to inspect all information made available by any party to an investigation. The general public has no inspection rights.

All written submissions made by interested parties, in order to be considered by the Commission, must be accompanied by a non-confidential version. The same applies to questionnaire replies, which are required to be submitted in a "limited" and "non-limited" version. The non-confidential versions of all documents are placed in the file, for inspection by interested parties. These versions may not always contain summaries of confidential information that are meaningful enough to allow other interested parties to defend themselves properly. No disclosure of confidential information to lawyers under a protective order is possible.

Information is passively placed in the file and it is the interested parties' responsibility to come check its contents periodically. The Commission does not notify interested parties when new documents enter the file. As a result, an interested party could be unaware of the arrival of an important document in the file, missing the opportunity to comment on it. Although it is an admittedly unsatisfactory solution, lawyers generally stay in contact with the Commission officials in charge of the case, calling them frequently in order to check the status of the file to determine when a visit to the file is called for.

Interested parties are not allowed to see the Commission's internal memos and mission reports. These internal working papers do not make up part of the file and are virtually never disclosed.

The Commission summarizes its conclusions for the first time in a provisional disclosure letter. This is produced at the same time as the provisional regulation, and it is provided to interested parties as a matter of course. Other parties can make a written request for a copy of this letter, which is meant to be "disclosure of the details underlying the essential facts and considerations on the basis of which provisional measures have been imposed." The provisional disclosure letter also contains an individualized part addressed to individual companies only, in

which the Commission analyzes specific confidential information (such as prices) pertaining to that company.

A final disclosure letter precedes definitive duties. This letter contains final disclosure of the essential facts and considerations on the basis of which it is intended to recommend the imposition of definitive measures, or the termination of an investigation or proceedings without the imposition of measures. Final disclosure is normally made not less than one month before the definitive regulation, and interested parties have at least 10 days to comment.

Provisions for access to the file are conspicuously absent from the safeguard regulation. However, in practice, access is granted along the same lines if the exporting country's authorities so request.

e. *State aids.* If the Commission fails to grant access to relevant information received from third parties, this may vitiate the Commission's final decision and may lead to its annulment by the Court of Justice on the basis of Article 230 TEC. The decision will however only be annulled if the applicant can establish that absent this infringement the outcome of the procedure might have been different. This is not the case, for example, if the Member State had no opportunity to submit comments on observations submitted by third parties, where these observations did not contain any new information.

f. *Pharmaceutical licensing.* If the Commission or the EMEA fail to provide information, the applicant is entitled to bring the matter before the CFI or lodge a complaint with the European Ombudsman.

4.10 Settlement or compromise. What opportunities exist to settle or compromise a dispute before formal proceedings are instituted or after they are instituted but before decision? What obligation is imposed on the Commission to conduct settlement negotiations in good faith? If there are conflicting private parties, what is the process whereby complaints by private parties are settled or compromised?

a. *Competition.* Companies can settle their cases with the Commission by making commitments to change or abandon the agreement or practice under investigation. The Commission then issues a preliminary assessment instead of a statement of objections and adopts a decision making the commitments binding. Such decisions close the proceeding but do not bind national authorities or courts as to the applicability of Articles 81 and 82 EC.

The commitments can be behavioral or structural and either limited or unlimited in time. Companies that do not comply with their commitments are subject to significant penalties. Third parties are notified of a settlement and are invited to submit comments. In theory third parties can apply for annulment of the settlement decision in the CFI, but it is likely that the Commission has wide discretion in this area.

In the merger field, the Commission may attach either conditions or obligations to which the merging companies have consented. A condition refers to measures that structurally change the market, while an obligation refers to behavioral measures. In the case of breach of an obligation, the Commission may revoke its approval decision. In the case of the failure of a condition, the approval decision is considered void ab initio. The Commission can impose heavy fines or can order the merged assets unscrambled. In other cases, commitments by the parties are merely "taken note of" in the approval decision without being treated as conditions or obligations.

b. *Trade remedies.* A common means of "settling" an anti-dumping or anti-subsidy investigation is by means of an undertaking. Once a provisional affirmative determination of dumping or subsidization and injury is made, the Commission can accept a voluntary undertaking offer, after specific consultation of the Advisory Committee. In dumping, the undertaking is usually a price undertaking, where the company commits itself to charge at least a certain amount for the product in the future. In anti-subsidy cases, the undertaking would be from the government, promising to cease subsidization, or from particular companies, agreeing to cease exports or to charge at least a certain price for them.

In return, the Commission agrees to waive the anti-dumping or anti-subsidy duty for that company. If undertakings are accepted, the investigation of dumping and injury is normally still completed. If a negative final determination is made, the undertakings automatically lapse, except where the negative final determination is basically due to the existence of the undertaking. (In that case, the undertaking may be required to be maintained for a reasonable period.) If an affirmative final determination of dumping/subsidization and injury is made, then the undertaking stays in place and its duration is as long as the underlying anti-dumping or anti-subsidy regulation. If undertakings are accepted from all the companies concerned, then the investigation is terminated (barring objection from the Advisory Committee).

The offer of an undertaking has to be timely, generally at the latest at the time that the comments on final disclosure are due. A non-confidential version of the undertaking offer must be provided, to allow other interested parties to comment on it.

Undertakings have the advantage that the amount of the price increase is kept by the company, rather than being paid as an anti-dumping or anti-subsidy duty into the Community budget. However, undertakings have the disadvantage of anti-competitively fixing prices at a certain level, even though the regulations do caution that price increases should not be more than necessary to offset the amount of dumping/subsidization or injury, whichever is the lowest.

In addition, compliance with undertakings is difficult to monitor, and sometimes the offer of an undertaking is rejected as impracticable. It can be difficult for the Commission to discover breaches of undertakings, so when undertakings are accepted, the Commission requires exporters, or in the case of subsidies, countries, to provide periodic reports of compliance. It also requires companies/governments to accept verification of pertinent data.

In case of breach, the benefit of a price undertaking is quickly and easily (in procedural terms) withdrawn, and any interested party is entitled to submit *prima facie* evidence of a breach, which the Commission is required to investigate. Failure to comply with reporting obligations or any suspicion of a breach of an undertaking tends to result in a wholesale withdrawal of its benefits, after consultation with the Advisory Committee and after the exporter/country has been given the opportunity to comment. Where the acceptance of the undertaking is withdrawn, the provisional or definitive duty automatically applies.

As for settling a safeguard action, the taking of safeguards is an intensely political matter, and the EU might drop its action upon reaching a political compromise with the foreign government or governments in question. For example, although the WTO Safeguards Agreement prohibits "voluntary" restraints imposed by a foreign government, the Chinese government recently announced its intention to impose export quotas for textiles, in order to ward off safeguard and other trade remedy actions upon expiration of the WTO Agreement on Textiles and Clothing in the beginning of 2005.

c. *Trademarks*: In the case of opposition proceedings, we already mentioned the period of cooling off that gives an opportunity for the parties to negotiate and find an agreement as to the scope of their trademarks (see point 4.6.2.). Another opportunity of reaching a compromise exists after the proceedings have begun. In opposition proceedings as well as revocation and invalidity proceedings, the Office may, if it thinks fit, invite the parties to make a friendly settlement. In general, the content of the compromise is based on mutual negotiations between the parties. It is also possible that the Examiner gives in an informal way (e.g. during a phone call) his opinion on how to reach an agreement. The parties may as well at any time put an end to the proceedings by notifying the Office that they desire to do so.

The possibility further exists that a CTM proprietor surrenders his Community trademark in respect of some or all the goods or services for which it is applied or registered, which will put an end to the proceedings regarding the same trademark in relation to the same goods or services. Finally, the applicant for or proprietor of a Community trademark may request the conversion of his CTM application or Community trademark into a national trademark application, for instance if the CTM ceases to have effect. According to the circumstances, this conversion may remove the conflict exists between the parties.

e. *State aids.* The procedural rules do not provide for a formal settlement opportunity, but in practice the Commission and the Member State concerned almost invariably seek to reach a compromise solution. In fact, the delay in many cases arises from settlement negotiations. The political nature of many cases and the stakes involved for the Member States is such that considerable time and energy is spent on finding a compromise in difficult cases, both at a political and at a "technical" level. What constitutes a compromise is difficult to describe in abstract terms, but a reduction of aid or aid intensity, a deferral of aid payments until justifying subsequent events have occurred, etc. are typical elements of "solutions".

Only in extreme cases will a notification be withdrawn. Where the Commission has already initiated the formal investigation procedure, it must close that procedure by a formal decision. There is obviously no possibility of withdrawal when the Commission is investigating alleged instances of unlawful aid and misuse of aid. As investigations into unlawful aid and misuse of aid are *ex officio* procedures, there is no notification or application by the Member State concerned that could be withdrawn.

When the Commission is investigating existing aid because it considers an existing scheme no longer compatible with the common market, the procedure facilitates a settlement. In such cases the Commission "shall issue a recommendation proposing appropriate measures to the Member State concerned." This non-binding recommendation allows the state to discuss the matter, or to accept the recommendation only in part and the Commission can react to that reaction, all within the framework of a first phase investigation.

f. *Pharmaceutical licensing:* An applicant for a marketing authorization who faces a denial of its application, or a marketing authorization holder whose product is subject to review and whose marketing authorization may be suspended or withdrawn, may avoid such negative outcome by agreeing on changes to the marketing authorization application or the issued marketing authorization. As far as safety is concerned, amendments concerning the indication of the product, as well as contraindications, special warnings and precautions, etc. may balance such concerns and render the risk-benefit assessment positive.

5. The individualized/generalized (or adjudicative-legislation) distinction

Are there procedural distinctions between situations in which an individual party is affected on grounds particular to that party (individualized or quasi-adjudicative action) and situations in which a large number of different persons are affected in the same way (generalized or quasi-legislative action)? For example, in the case of generalized action, are the rules relating to investigation, hearings, and decisions different than in the case of adjudication? If there are such distinctions, how is this line between individualized and generalized action drawn in practice?

a. *Competition:* The Commission can adopt block exemption regulations and soft law instruments (such as notices, guidelines and communications). It can also investigate sectors of the economy or types of agreements.

Competition is one of the few areas of Community competence where the Commission enjoys extensive legislative powers. The Commission has been given the power by the Council to adopt secondary legislation not only in the procedural field, but also substantively. As to substance, the Commission has been adopting block exemption regulations since 1965. These are acts that apply Article 81(3) EC to categories of agreements. Usually, the adoption of a block exemption regulation is a rather dramatic event that acquires a substantial degree of publicity and is preceded by an extensive stage of public consultations. Nevertheless, the Commission's discretion in the adoption of those instruments is absolute (if they are not *ultra vires).*

The Commission has issued vast numbers of soft law instruments, such as Notices, Communications, Guidelines, Green and White Papers, in both the competition field and in other areas of regulation. Like block exemption regulations, the Commission conducts public consultations before adopting these soft law instruments. In practice they are published in draft form in the C series of the Official Journal, while third parties submit their comments, which are usually published in the website of DG COMP.

Soft law instruments are not considered legally binding but have proved quite influential in practice. These texts purport to be codes of conduct, not prescriptive rules. But, like the old block exemption regulations, their effect in reality is different. The effect of Guidelines and Notices is likely to be robust and constraining, not very soft at all. The European courts refer to them frequently, and Commission decisions often invoke them as do national authorities and courts. As discussed later (¶11.5), the Commission is bound by these instruments.

The third instance of generalized action by the Commission is the investigation into sectors of the economy and into types of agreements. Such investigations occurred rarely in the past but several are now ongoing. The Commission may request companies to communicate to it all agreements, decisions and concerted practices. In this case, there is no target of proceedings as such, although the companies that are the addressees of a request for information and subject to investigations are under the same duties as those that are the specific target of an antitrust proceeding.

b. *Trade remedies:* In trade remedies cases, final decisions are in the form of regulations, which are of general application. In anti-dumping and anti-subsidy cases measures provided by them are individualized together with a measure of general application.

d. *Food safety*. In EU food law, the distinction between adjudication and rulemaking seems artificial and arbitrary. In many cases, the form of rulemaking is used to decide very specific factual circumstances. Adjudication is used very rarely (individualized approval decisions occur only in the cases of novel foods and genetically modified foods). In some cases (such as smoke flavorings) rejection of an application comes in the form of an individualized decision. Decisions taken through rulemaking cannot be challenged before CFI because of the standing rules.

e. *State aids.* State aid investigation proceedings on the basis of Treaty Articles 87 and 88 are administrative rather than legislative: They only involve one party—the Member State concerned—in relation to which the Commission is called to decide whether the State aid measure that this Member State grants or intends to grant is compatible with the Treaty. The procedure is bilateral and adversarial; it will always result in the adoption of an individual decision binding upon the Member State concerned, but not in a general legislative measure.

The Commission has a policy to adopt guidelines or frameworks explaining how it intends to apply the State aid rules with regard to certain industrial sectors or certain specific types of potential State aid measures. Such guidelines are not formulated in individualized terms, but are intended to cover a broader category of potential State aid measures. The Commission would submit such State aid guidelines or frameworks to Member States for their acceptance. If a Member State refuses to adhere to such guidelines or frameworks, the Commission could always commence a formal investigation against this Member State, which in the end would be bound to succumb to the Commission's guidelines or frameworks on the basis of the outcome of the investigation.

Certain differences relate to the nature of the aid reviewed by the Commission. The review of individual aid (i.e. concrete instances in which aid may be granted) is clearly an administrative function, in which the Commission assesses the consequences of a particular aid against a well-defined, rather concrete factual background. When assessing aid schemes, the Commission is faced with a different type of analysis since the scheme is designed to be applied in many future cases, in various sectors of the economy, and approval decision takes on a different character, because the prognostic element and the underlying general policy objectives play a very different role. Moreover, it is much less common that third parties intervene in proceedings relating to aid schemes because the beneficiaries and the competitors are (normally) not yet known in the course of the procedure.

f. *Pharmaceutical licensing.* The distinction between an adjudication and a legislative decision is not always clear. An example (from outside the human medicines sector) is presented by the CFI case T-13/99 *Pfizer Animal Health SA v. The Council of the European Union*. That case concerned an application for annulment of a Council Regulation that contained provisions for the withdrawal of the authorization to use certain antibiotics as additives in feeding stuffs. This authorization procedure can appear to relate to one company while formally relating to the inclusion of a substance in a legislative list regarding additives that can be used in feeding stuffs and has effect erga omnes. Nevertheless, the Court held that Pfizer had standing because it was the only producer of virginiamycin and had gone through the specific and detailed regulatory approval procedure.

6. Hearing phase

6.1 Rights to an administrative hearing

6.1.1 Is there a right to one or more hearings in your sector? In which type of dispute is an opportunity for hearing provided?

a. *Competition.* The ECJ has ruled that the Commission is under an obligation to observe the rights of defense during administrative proceedings leading to imposition of fines or other adverse actions for violation of EC competition law. The rights of defense comprise the right to be heard, the right of access to the file and the principle of sound administration. This is a fundamental principle of Community law which must be guaranteed even in the absence of rules governing the procedure in question.

The Commission's case must be made known to the companies concerned and they must have the right to make known their views on the truth and relevance of facts and circumstances alleged and on the documents used by the Commission to support its claim that there has been an infringement of the Treaty. Article 27(1) of Regulation 1/2003 obliges the Commission to give the companies an opportunity to be heard on the matters to which the Commission has taken objection, before taking a decision on finding of infringement, interim measures, imposition of a fine or a periodic penalty payment. This list is non-exhaustive.

In most cases there would be one hearing that follows the adoption of a statement of objections by the Commission. However, the statement of objections is not final: it can be amended, parts of it may be dropped or additions may be made by the Commission in the light of evidence that transpires at a later stage. If there is a material alteration in the evidence of the contested infringements, the Commission must give the companies concerned an additional opportunity to be heard. Similarly, where the Commission has left out of the statement of objections an objection which it wishes to include later in its decision, or it wishes to impose on the parties a fine that has not been mentioned in its original statement of objections, it should serve a supplementary statement of objections and give the parties an opportunity to be heard.

In EC merger control proceedings, the Commission must grant notifying parties (and other parties that have so requested in their written comments) the opportunity to develop their arguments at a formal oral hearing, at least in the following stages of the procedure:

(i) when the Commission intends to take a decision declaring a proposed merger incompatible with the common market; or

(ii) when, after deciding that the proposed merger did not fall within the scope of the Regulation or was not incompatible with the common market, the Commission decides to revoke that decision because it was based on incorrect information for which one of the companies is responsible or that the companies concerned did not comply with an obligation attached to the decision; or

(iii) when the Commission orders the parties to dissolve a concentration that has been implemented by the parties and the merger has been declared incompatible with the common market, or the parties have implemented a concentration in contravention of a condition attached to a clearance decision;

(iv) when the Commission takes interim measures appropriate to restore or maintain conditions of effective competition against a concentration that has been implemented before a decision as to its compatibility with the common market has been taken, or in contravention to a condition in a clearance decision, or when the merger has been declared incompatible with the common market.

Parties may also be given the opportunity to express their views orally at other stages in the proceedings.

The Commission must also grant the parties on which it proposes to impose a fine or periodic penalty payment the same opportunity to develop their arguments in a formal oral hearing before adopting such a decision, though it may also give them the opportunity to express their views orally at other stages in the proceedings.

Although, as explained above, there is a right to only a single formal oral hearing at the end of the investigation process, it is possible for the parties (notifying parties and third parties) to express their views orally during other stages of the procedure at informal hearings, for example at the "State of Play" meetings (see answer to question 4.3 above) or during the "triangular meetings" between the notifying parties and third parties. The opportunity to hold an oral hearing does not depend on the type of dispute, but only on a written request by the parties to the Commission.

b. *Trade remedies:* Interested parties have a right to be heard in anti-dumping and anti-subsidy procedures, at least once. In many cases, when parties request it, they are permitted a second or even third hearing. However, additional hearings are granted at the discretion of the Commission officials in charge of the case.

The ECJ, which was responsible for trade remedies cases prior to the creation of the CFI, has specifically said that the right to a fair hearing in anti-dumping investigations is a fundamental principle protected by Community law:

> "Those requirements must be observed not only in the course of proceedings which may result in the imposition of penalties, but also in investigative proceedings prior to the adoption of anti-dumping regulations which, despite their general scope, may directly and individually affect the undertakings concerned and entail adverse consequences for them."

For safeguards, interested parties also have a right to be heard orally by the Commission where they have made a written application showing that they are actually likely to be affected by the outcome of the investigation and that there are special reasons for them to be heard orally.

c. *Trademarks:* The proceedings before the Office are mainly written and the procedure is organized so as to allow the parties to submit their observations and evidence in writing without having to appear. Oral hearings are not very common before the Office and the only experience we have with hearings are the informal hearings held with the Examiner during the CTM application process (see point 4.2. above). However, if the Office considers that oral proceedings would be expedient they shall be held either at the instance of the Office or at the request of any party to the proceedings. This is true for every proceedings described above (application, opposition, invalidity and revocation). An oral hearing is nevertheless not a right of the parties as it is the Office that eventually decides whether these oral proceedings could be useful or not.

d. *Food safety.* No hearings are provided for in connection with food safety applications. The lack of a hearing and other basic adjudicatory protections was the subject of criticism by the Advocate General. *The Queen v. Secretary of State for Health*, Joined cases C-154/04 and C-155/05, involved a regulation that concerned which food supplements containing vitamins could be sold in the Community. The decision whether to add a product to the list was made under comitology procedures without any opportunity for a hearing or a reasoned decision or a requirement of decision within a reasonable time. The Advocate General wrote:

> In short, this procedure, in so far as it may exist and in so far as it may deserve this title, has the transparency of a black box: no provision is made for parties to be heard, no time-limits apply in respect of decision-making; nor, indeed, is there any certainty that a final decision will be taken. The procedure therefore lacks essential guarantees for the protection of the interests of private applicants.
>
> ...The representative of the Council, responding to a question, remarked that the decisions on the composition of the positive lists are of general application and that it was not necessary, therefore, to accord procedural rights to individual interested parties at the preparatory stage. That position, it would appear to me, is based on a misunderstanding.
>
> Even though decisions relating to the extension or the shortening of the positive lists have effect erga omnes, plainly they may also affect the vital interests of individual parties. In order to ensure that these interests are taken into account in the decision-making process in a manner, which is open to judicial scrutiny, the basic legislative act ought for that purpose to provide for the minimal guarantee of an adequate procedure. [The Advocate General analogized food safety requirements to trade remedies, where decisionmaking protections are provided even though the ultimate decision is in the form of a regulation].

There is no explicit discussion of the Advocate General's submission in the *Alliance for Natural Health* decision and the procedures were sustained. Nevertheless, dictum in the decision suggests that the Court may, in the future, be more receptive to claims that comitology procedure is not sufficient in cases involving individualized interests. The court said:

> In that regard, a measure which, like that at issue in the main actions, includes a prohibition on marketing products containing substances not included on the positive lists laid down in the applicable legislation must be accompanied by a procedure designed to allow a given substance to be added to those lists and the procedure must comply with the general principles of Community law, in particular the principle of sound administration and legal certainty.
>
> Such a procedure must be accessible in the sense that it must be expressly mentioned in a measure of general application which is binding on the authorities concerned. It must be capable of being completed within a reasonable time. An application to have a substance included on a list of authorized substances may be refused by the competent authorities only on the basis of a full assessment of the risk posed to public health by the substance, established on the basis of the most reliable scientific data available and the most recent results of international research. If the procedure results in a refusal, the refusal must be open to challenge before the courts...
>
> The absence of any such provisions cannot, however, be regarded as such as to jeopardize the proper functioning of the procedure for modifying the positive lists within a reasonable time. It is none the less the responsibility of the Commission, by virtue of the implementing powers conferred on it by Directive 2002/46 concerning, inter alia, the way the procedure is operated, to adopt and make accessible to interested parties, in accordance with the principle of sound administration, the measures necessary to ensure generally that the consultation stage with the European Food Safety Authority is carried out transparently and within a reasonable time.

The Queen on the Application of Alliance for Natural Health v. Secretary of State for Health, Joined cases C-154/04 and C-155/05 ¶¶72, 73, 82 (July 12, 2005).

e. *State aids.* The Phase 1 investigative procedure does not provide for a formal hearing of the Member State concerned or any other interested parties. However, the Member State concerned and interested parties are entitled to submit comments. Indeed, the ECJ ruled that the Commission is obliged to allow the undertakings concerned to submit their comments in the context of the examination pursuant to Article 88(2) TEC.

A Member State can submit comments to the Commission once the Commission opens the Phase 2 investigation. The Member State also has an opportunity to reply to any comments submitted to the Commission by interested parties. In addition, a Member State can submit comments when the Commission decides to revoke a positive or conditional State aid decision because the decision was based on incorrect information provided to the Commission. Finally, the Commission will invite the Member State concerned to submit comments where it is of the view that an existing aid is not, or is no longer, compatible with the common market.

Interested parties may submit comments after the Commission adopted a decision to initiate a Phase 2 investigation. Any comments that the Commission receives from an interested party will be transmitted to the Member State concerned. An interested party can request that its identity be withheld from the Member state concerned in case it fears damage from its identity being revealed. The Member State concerned will have the possibility to reply to such comments from interested parties, normally within a time period of one month, which may be extended by the Commission. In practice, the Commission often accepts comments after the original deadlines have long expired, in particular in cases, which continue for a long time after the procedure, was imitated.

f. *Pharmaceutical licensing:* Both applicants for marketing authorization and targets of enforcement action have an opportunity to furnish written or oral explanations to decisionmaking bodies. However, these "hearings" form part of the investigation process and are conducted together with the scientific evaluation of a medicine. In the case of centralized marketing applications, CHMP must provide applicants with the ability to make oral or written explanations about their submissions while the application is still under consideration by CHMP. The CHMP has also issued a guidance paper on the conduct of hearings, which contains specific and practical information about carrying out such hearings, as well as a schematic overview of the different steps and pictures of the hearing facilities. Applicants, who are subject to a hearing, should prepare for the hearing in accordance with these recommendations. See http://www.emea.eu.int/pdfs/human/regaffair/239001en.pdf.

Under Art. 9 of Reg. 726/2004, if the CHMP opinion is negative or not entirely positive, the applicant may within 15 days after the receipt of the opinion, notify the Agency that it requests a re-evaluation of the opinion. It must supplement this request within 60 days (after receipt of opinion) with comprehensive reasoning. The re-assessment may, again, include an oral explanation if required to clarify the issues that were raised in the appeal. Under Art. 20(2), if a centrally approved product is under review, the marketing authorization holder should be given the possibility to provide oral or written explanation concerning the questions raised.

Under Arts. 8(2), 11, and 16 of the draft Penalties Regulation, a marketing authorization holder has the right to be heard by the Agency during the investigation procedure to present its defense. In addition, the draft Regulation also foresees a right for the marketing authorization

holder to request an oral hearing in its written explanations on the Commission's statement of objections. At the hearing, third persons may participate at the request of the marketing authorization holder. The hearing will be conducted by the Commission on its premises and is not open to the public.

As a general rule, the CHMP may request information from third parties if it considers it necessary to carry out the scientific evaluation of the medicine. This was confirmed in the *Ferriprox* case, when the court held that the Commission indeed had to take into account information obtained from third persons, even though third persons had no right on their own to participate in the CHMP hearing.

6.1.2 Who is entitled to a hearing in the case of a prospective adverse decision? In addition to parties who would be subject to sanctions, or parties whose applications are denied, is anyone else is entitled to a hearing? Competitors who could be harmed by the grant of favorable treatment by the Commission to an applicant? Persons claiming to protect the public interest?

a. *Competition:* The addressees of a decision are always entitled to an oral hearing before the Commission if they request it in their written submissions given in response to the Commission's statement of objections. Where appropriate, complainants may also be heard at the oral hearing, if they have so requested in their written comments to the statement of objections.

The Commission *may* hear such third persons, as it deems necessary or as the competition authorities of the Member States request. The Commission has a margin of discretion with respect to hearing third parties. Such third parties may include witnesses that could give an account of the infringement, or evidence relating to the facts about the relevant market. Third parties may also apply to be heard and their applications will be granted if they show a sufficient interest. An example of a third party that has a sufficient interest in the outcome of the proceedings is a consumer association, where the proceedings concern products or services used by the end-consumer or products or services that constitute a direct input into such products or services. The Commission informs such persons in writing of the nature and subject matter of the procedure and sets a time-limit for giving written submissions. The right to be heard is exercised in writing. The Commission has a discretionary power to invite these third parties to present their arguments at the oral hearing of the parties to whom a statement of objections has been addressed. In addition, competition authorities of the Member States, as well as officials and civil servants of other authorities of the Member States, may be invited to participate in the hearing.

Under EC merger control proceedings, the persons entitled to an oral hearing are:

(i) the notifying parties,

(ii) other individual parties (parties to the proposed concentration other than the notifying parties, such as the seller and the corporation which is the target of the concentration), and

(iii) third parties, including customers, suppliers and competitors that can demonstrate a sufficient interest, in particular managers or employees of the corporations concerned or consumer associations.

b. *Trade remedies*. As mentioned above, in order to have a right to be heard, interested parties must make themselves known in writing within the time limits set by the notice of initiation. This written manifestation of interest has to show that the party is an interested party "likely to be affected by the result of the proceeding" and that there are "particular" or "special reasons" why they should be heard. As a matter of practice, it can be observed that the

Commission interprets these provisions liberally, usually granting a hearing to anyone who asks for one (as long as they can make out a reasonable interest).

c. *Trademarks.* Oral hearings may only be available to the *parties* to proceedings before the Office, subject to the Office's green light as explained above. In the event of proceedings concerning revocation or declaration of invalidity based on absolute grounds, parties include any person and any group that represents the interests of manufacturers, producers, suppliers of services, traders or consumers, which under the terms of the law governing it has the capacity in its own name to sue and be sued. In the event of proceedings based on relative grounds, only the persons entitled to file an opposition may be parties to the proceedings.

The Office may issue a summons to the person concerned to appear before it. The issues which, in the Office' view, need to be discussed must be indicated in the summons. The summons must be of at least one-month notice unless the parties agree for a shorter period. In its summons, the Office must draw the attention of the parties on the fact that if they do not appear despite having been duly summoned, the proceedings may continue without them.

6.1.3 If several private parties are involved, will there be separate hearings or just one hearing?

a. *Competition:* In principle there would be one oral hearing for all co-defendants and other interested parties (including complainants). It is possible for the parties attending the oral hearing to be heard *in camera* when business secrets are under discussion.

In EC merger proceedings the Commission may grant the opportunity to hold separate oral hearings depending on the parties involved, i.e., there might be an oral hearing for the merging parties and another for third parties. This makes it possible to raise confidential information during the oral hearings.

c. *Trademarks.* There will generally be one hearing during which the parties (or witnesses or experts) summoned by the Office will be able to orally present their cases or statements to the Office in presence of all the other parties to the proceedings. If the length of the hearing requires it, a second date for hearing may possibly be fixed by the Office. Again, however, oral hearings do not play an important part during proceedings before the Office.

6.1.4 Can other interested parties intervene in the hearing? How else can they participate (for example, is there a practice of filing amicus briefs?

a. *Competition:* As already explained, the right to be heard is primarily exercised in writing. If third parties are invited to attend the oral hearing, they are entitled to present their arguments at the hearing.

In EC merger control, if the Commission or other competent authorities of the Member States deem it necessary, they may also hear other natural or legal persons. Indeed, on application, natural or legal persons showing a sufficient interest, especially members of the administrative or management bodies of the corporations concerned or the recognized representatives of their employees, are entitled to be heard. Once these third parties apply in writing to be heard, the Commission must inform them in writing of the nature and subject matter of the procedure, and must set a time limit within which they may make known their views.

b. *Trade remedies*: Generally, interested parties each have their own individual hearing and other persons are not informed nor invited to attend. Often, after a hearing, the interested party will submit a confidential and non-confidential copy of its presentation, which is then available for perusal and comment by other interested parties.

The Commission officials may attempt, in the interest of saving time and avoiding repetition, to group interested parties with similar concerns, such as importers, so as to have one long hearing instead of several shorter ones. However, if parties object to being "grouped", the Commission will usually, as far as practicable, try to accommodate them by granting them individual hearings.

The amount of time allocated to the hearings and whether or not interested parties can have individual hearings depends to a very large extent on the discretion of the individuals in charge of the case and on the number of parties involved who request a hearing. Some officials are very strict, insisting that the hearing be no more than one hour, for example, while others are willing to allow the hearing to continue as long as necessary in order to allow the interested party to address all its concerns.

c. *Trademarks.* From our experience, no other person but the parties to the proceedings can intervene or participate in any way in the hearing. There is no practice such as filing amicus briefs in the proceedings before the Office.

6.1.5 At what point in time is a private party entitled to a hearing? Before or after the Commission has taken legally effective action? At any point during the investigatory process? Before a benefit is terminated or after it has been terminated?

a. *Competition:* The parties to whom the proposed decision is addressed are given the opportunity to be heard after the Commission has adopted the statement of objections, and before the Commission formally adopts a decision in the case. The Commission should provide these parties the right to be heard before consulting the Advisory Committee on Restrictive Practices and Dominant Positions. It appears that the regulations do not provide for a hearing in case of a Commission decision withdrawing the benefit of a block exemption. This gap is, however, filled by reference to the general principle of Community law, referred to above, that individuals should be heard before any adverse decision is taken.

In EC merger control proceedings, a private party is entitled to a formal hearing after the issuing of the statement of objections, but before the Commission adopts a final decision. See ¶6.1.1. However, it is common practice for the formal oral hearing to take place a few working days after the deadline for responding to the statement of objections. In any event, the Commission may if appropriate grant the opportunity for informal oral hearings at any time during the merger clearance proceedings.

b. *Trade remedies.* In general, in anti-dumping and anti-subsidy matters, the first hearing takes place after verification and before the provisional regulation. By having a hearing at that moment, interested parties hope to have an impact on the Commission's thinking before it is consecrated into a regulation.

However, interested parties may consider that they have more to say once they have seen the provisional regulation and provisional disclosure of the essential facts and considerations that were the basis for the provisional regulation. At that point the Commission has disclosed its

preliminary point of view; up until that point, the Commission does not inform interested parties of its conclusions or inclinations. Therefore, some interested parties prefer to be heard (or heard again) at that stage.

Whether or not the Commission will accommodate requests to be heard at different moments or to have a second hearing depends very much on the discretion of the individual Commission officials involved in the case. Their obligation is simply to hear interested parties—when and how often is not specified.

Similarly, the safeguard regulation does not go into specifics about the right to be heard, beyond saying that interested parties have such a right, if they ask within the time limits and show that they are actually likely to be affected by the outcome of the investigation and that there are special reasons for them to be heard orally.

c. *Trademarks.* A party to the proceedings can request an oral hearing at any time during the proceedings, as long as the debate between parties is not closed in order for the division of the Office to decide on the case. Oral hearings, if any, always take place before the Office decides on the case. It is most likely that if oral hearings are provided, these will take place once the parties have exchanged their written observations and submitted their evidence in writing with the Office.

6.1.6 How serious does the proposed action have to be to trigger a right to a hearing? (We note different adverbs being used such as "perceptibly affected" or "gravely affected") Is there a right-privilege distinction? Doctrine of legitimate expectations? Are discretionary decisions treated differently from non-discretionary decisions? Are decisions to take away an existing benefit (or to prohibit certain actions) treated differently from applications for a new benefit or for permission to take action?

a. *Competition:* The right to be heard is triggered irrespective of the seriousness of the proposed Commission's action. Under the general principles of Community law, a right to be heard exists in all proceedings that are likely to result in a decision adversely affecting a party, whether or not provided for in secondary legislation. The ECJ seems to treat somewhat differently decisions taken by the Commission in exercise of its investigatory powers, such as a decision ordering an inspection or requesting information from a company. The Court denied the parties the right to be heard in such cases. Though, undeniably, the interests of a company may be adversely affected by such decisions, the Court held that a distinction should be drawn between decisions relating to the gathering of information by the Commission and those relating to the substance of the case. Only the latter change the status of the party. Similarly, companies under investigation are not entitled to be heard before the Commission adopts a statement of objections against them.

In EC merger control, the right to an oral hearing does not depend on the seriousness of the proposed action (though it would normally take place during Phase II investigations). It depends exclusively on whether the Commission either intends to adopt a decision as explained above (see ¶6.1.1), or when it considers it appropriate for a third party to have an oral hearing (in both cases if so requested).

c. *Trademarks.* According to the CTM Regulation, oral proceedings must be considered to be *"expedient"* by the Office in order to be held at its own instance or at the request of a party. This criterion is applicable for any type of proceedings. The decision of holding oral proceedings

will probably depend on the complexity of the case and on whether there is a clear-cut case or not. The importance of testimony of witnesses or of reports by experts may also come into consideration as to hold oral pleadings or not.

6.1.7 As to what issues is person entitled to a hearing? Only if there are disputed facts? Is there a distinction between "adjudicatory facts" (that is, facts about the parties) and "legislative facts" (that is, generalized facts that don't concern the specific parties)? Where discretionary action is at stake? Where party wishes to argue for a new legal interpretation or for an exception to existing precedents? How about the situation in which a rule (delegated legislation) has already resolved the issue that the person wishes to raise—is there still entitlement to a hearing? Where Commission has discretionary powers, can it constrain that power by adopting generally applicable rules?

a. *Competition:* These distinctions are not entirely relevant under EC antitrust procedure. The parties may make written and oral submissions relating to all aspects of the case. The exercise of the right to be heard entails that parties have an opportunity to make known their views on the truth and relevance of facts and circumstances alleged and on the documents used by the Commission to support its claim that there has been an infringement of the Treaty.

The Commission may, indeed, constrain its discretionary powers by adopting generally applicable soft law instruments. Thus it limited its discretion in setting the amount of fines in antitrust cases by adopting the fining guidelines and the leniency notice. Such soft law instruments bind the Commission by creating legitimate expectations and the European Courts have recognised that the Commission may not depart from rules which it has imposed on itself. In particular, whenever the Commission adopts guidelines for the purpose of specifying, in accordance with the Treaty, the criteria which it proposes to apply in the exercise of its discretion, there arises a self-imposed limitation of that discretion inasmuch as it must then follow those guidelines.

In the merger control field, the oral hearing is a right of the parties and does not depend on the issues to be discussed. However, when a third party asks the Commission for an oral hearing, the Commission will grant the hearing if it considers it appropriate. The issues to be raised during an oral hearing concern mainly the arguments of the parties on objections raised by the Commission.

b. *Trade remedies:* There are no rules regulating or indicating appropriate topics for a hearing. Interested parties are entitled to come to present whatever they feel is relevant to the Commission officials. Commission officials will often say "this is *your* show" to interested parties who come for a hearing, emphasizing that the Commission officials are there to listen to whatever the interested party considers relevant, but refusing to enter into a dialogue with the interested party at the hearing.

c. *Trademarks.* If found 'expedient' by the Office, oral proceedings may be required as to any issue relevant to the case and where a discussion before the Office and in the presence of the parties may be useful to decide this case. There is no distinction between "adjudicatory facts" and "legislative facts," although an oral hearing will probably rather be ordered to discuss "adjudicatory facts" proper to the parties. Oral hearings may also be useful to discuss some legal interpretations or rules that were decided in prior cases in view of the case at stake. As Community trademark issues must predominantly be decided on a case-by-case basis, there is always a possibility that a prior rule or interpretation does not apply to a new situation. When

taking decisions, the Office will generally limit the scope of the decision to the case taken into consideration. The Office may however formulate general rules as well on that occasion.

6.2 Hearing officer or officers

6.2.1 who is the hearing officer or officers? How are those persons qualified and trained? Is the person a full-time hearing officer or does he/she have other tasks? How many hearing officers are present at a hearing (that is, is there just one hearing officer or is there a panel of hearing officers)?

a. *Competition.* A hearing officer is a high-ranking Commission official who serves as a guardian of the procedural rights of the parties in the proceedings before the Commission. The powers of the hearing officer were significantly strengthened in 2001, when the Commission adopted a Mandate on that subject. Hearing officers are appointed solely to serve in this capacity. The Mandate contains special rules governing the appointment and tenure of the hearing officer. At present, there are two hearing officers, who, before their appointment as hearing officers, held positions as high-ranking officials in DG COMP. There is one hearing officer present at a hearing.

b. *Trade remedies.* In trade remedy cases, there is not a "hearing officer;" the Commission officials in charge of the particular case are the persons who conduct and attend the hearing. In general, the case handlers and their immediate superiors (Heads of Section) will attend the hearing. Sometimes, a Head of Unit, higher in the hierarchy, will attend the hearing. It would be rare to see the Head of Unit's superior, the Director attend a hearing. In other words, the persons who attend the hearing are not specialized in hearings; the hearing is simply one of the stages of a proceeding that takes place in every case. The case handlers and their superiors are responsible for every aspect of the particular case to which they are assigned, the hearing included.

c. *Trademarks.* The hearing officers are the same persons as those responsible for taking decisions in relation to a CTM application, an opposition, or an application for revocation or for declaration of invalidity. They are specifically trained in trademark issues and their full-time function is to acquire knowledge of the cases presented to them, to hold hearings if necessary, and to make decisions as to these cases. Generally, in application cases, there is only one examiner present at the hearing. In opposition proceedings or in revocation/invalidity proceedings, there is normally a panel of three hearing officers (although in straightforward cases, only one hearing officer will be present).

f. *Pharmaceutical licensing.* Oral explanations are before the CHMP. No specific hearing officer is appointed and no specific training is given to the persons conducting the hearing.

6.2.2 What is the role of the hearing officer or officers? To serve as independent administrative judges (as would occur in an adversarial system) or as officials gathering information as part of an administrative investigation (as would occur in an inquisitorial system). [See part 3 of these guidelines for further background on this distinction] Or do they serve some other function or functions?

a. *Competition*. The regulations provide that the hearing officer should conduct the hearing in full independence. The hearing officer is not a member of DG COMP and, for

administrative purposes, responds directly to the Competition Commissioner. He has direct access to the Competition Commissioner and can comment on any aspect of a case at any time.

The role of the hearing officer is to make sure that the parties' rights of defense are respected in the course of the administrative proceedings before the Commission. The primary responsibility of the hearing officer is to be the guarantor of the proper conduct of the oral hearing. In addition, he exercises a variety of functions relating to the right of defense, such as deciding on the applications by third parties to be heard or resolving disputes between the parties and the Commission concerning access to file and confidentiality issues. He can also serve as mediator between DG COMP staff and the parties. Senior members of DG COMP are obliged to keep the hearing officer informed about the developments in the case up to the point when a draft decision is submitted to the Competition Commissioner.

The hearing officer reports to the Director General for Competition and to the director responsible on the procedural issues of the case and on whether the right to be heard has been respected. In addition, he may make observations and suggestions on the further progress of the proceedings. On the basis of the draft decision the hearing officer prepares a final report assessing whether parties' rights of defense have been respected and whether due account has been taken in the draft decision of all the relevant facts, whether favourable or unfavorable to the parties concerned. The final report is submitted to the Competition Commissioner, the Director General for Competition, and the director responsible. It is attached to the draft decision submitted to the Commission for consideration. The final report is also delivered with the decision to the addressees of the decision.

b. *Trade remedies:* Hearings are part of the information gathering of the investigation. As mentioned above, the Commission officials generally listen passively and do not engage in a debate. They generally begin the hearing with a statement that the hearing is the interested party's opportunity to state its concerns; the Commission official will generally warn the participants that it will not answer questions or enter into a debate on the merits of the case. While the officials usually do not answer questions themselves, they often pose questions to the company being heard. However, the Commission's questions are generally related to the topics that the company has chosen to focus on or topics that crop up in the course of the hearing.

c. *Trademarks.* The system established before the Office is closer to an inquisitorial model than to an adversarial model. It must however be reminded that there is no 'investigation' *stricto sensu* by the Office, in the sense that the Office does not have the powers to gather information or to run investigations about Community trademarks and applications. Rather, this process is left to private parties and companies that have an interest in opposing the grant of a CTM. This being said, there is no separation of functions between the 'research phase' ('investigation by the parties') and the 'decision phase.' Both phases are part of the same proceeding and there is no separation of personnel between these different functions. As a result, the hearing officers are also the ones receiving and examining the information gathered by the parties to the proceedings and deciding on the case presented before them.

6.2.3 In adversarial systems, there are various rules intended to safeguard the independence of hearing officers in administrative proceedings. Perhaps none of these rules apply to the inquisitorial proceedings conducted by the Commission. Is there any law or practice in your sector that provides protection to private interests similar to the following:

6.2.3.1 Could decision makers be disqualified for any form of bias? For example, what about a financial conflict of interest? Is there a transparency system in which officials must disclose any financial interests? How about clear evidence that a decisionmaker has prejudged the issues? If any such bias issues can be raised, how do you raise them and when must you raise them?

a. *Competition:* There are no specific rules that apply to Commission officials making decisions in competition cases and this is an area where the law is not developed. Commission officials are, however, subject to a Code of Good Administrative Behavior that applies to all members of the Commission staff. The Code obliges Commission staff to always act objectively and impartially, in the Community interest and for the public good, while their decisions should not be influenced by personal or national interest or political pressure. It is also possible for decisionmakers to disqualify themselves in cases of conflict of interests or any other instance that impairs or might seen to impair their objectivity.

If the Commission official fails to act objectively during the procedure, the party concerned may lodge a complaint with the Secretariat General of the Commission. The complaint will be forwarded to the Director General or Head of Department whose conduct is questioned. They have two months to answer to the complaint. Afterwards the complainant has one month to apply to the Secretary-General of the Commission to review the outcome of the complaint. In addition, bias on part of the decisionmaker may constitute a reason to invalidate the decision for misuse of powers in the appeal to the CFI.

c. *Trademarks.* Members of the divisions of the Office or the Boards of Appeal may not take part in any proceedings if they have *any* personal interest therein, including financial conflict of interest. The same rule applies if they have previously been involved as representatives of one of the parties. There is an obligation of disclosure. If a member of the office or a Board of Appeal considers, for one of these reasons or for any other reason, that he should not take part in any proceedings, he shall inform the Division or Board accordingly.

Any party to the proceedings may also object to decisionmakers for one of the reasons stated above or if suspected of partiality. It is especially provided however that no objection may be based upon the nationality of examiners or Office members. An objection must be made in writing to the Office as soon as the party is aware of the facts on which it is based. An objection shall not be admissible if, while being aware of a reason for objection, the party has already taken a procedural step.

In the event of a disclosure of a conflict of interest, the Divisions and the Boards of Appeal shall decide as to the action to be taken without the participation of the member concerned. For the purposes of taking this decision, his alternate shall replace the member who withdraws or has been objected to in the Division or Board of Appeal. The Division or Board of Appeal shall then take a decision as to the disqualification or not of the member concerned (article 132.4. Regulation 40/94).

e. *State aids.* The Commission is under a duty to examine a case diligently and impartially and to apply certain "principles of sound administration," which is one of the general principles that are "observed in a State governed by the rule of law and are common to the constitutional traditions of the Member States." Moreover, Treaty Article 213(2) states that the Members of the Commission shall, in the general interest of the Community, be completely independent in the performance of their duties. Regarding Commission staff, the Rules of

Procedure of the Commission, in the Code of Good Administrative Behavior, which are attached to the Rules of Procedure as an Annex, require Commission staff to "always act objectively and impartially, in the Community interest and for the public good." However, there is no express rule providing for disqualification of officials involved in the preparation of a State aid decision.

If it can be shown that an official involved in the preparation of a State aid decision or a Member of the Commission did not abide by the obligation of complete impartiality, the resulting State aid decision will be flawed and subject to judicial review. A violation of the obligation to impartiality is a serious infringement of the principle of sound administration. As a consequence, it should be expected that the State aid decision challenged on the ground of a violation of the principle of impartiality will be annulled by the Community Courts.

f. *Pharmaceutical licensing.* Regulation 726/2004 provides rules on how to handle conflicts of interest. Article 63 requires that Members of the administrative body, the Committees, Rapporteurs and experts must not have any financial interests in the pharmaceutical industry, which could impact their neutrality. They are obliged to act in the public interest and in order to ensure this they need to disclose information about their financial interests annually. This information is publicly available on request but can only be accessed in the premises of the Agency. In addition, members of administrative bodies, or of the Committees or Rapporteurs and experts need to clarify any interests they may have concerning the topics of individual meetings. The Agency's Code of Conduct contains further provisions in this respect:

> Integrity and high standards of professional conduct by members of the Management Board, scientific committees and working parties, European experts and EMEA staff are crucial for the independence of the EMEA and for its reputation vis-à-vis the public regarding its execution of European Union policy in the field of public health.

The Code requires the agents to be impartial and independent. It clarifies who should declare interests and defines direct and indirect interests as financial interests, work carried out for the pharmaceutical industry, other links with pharmaceutical industry and links with other industries relevant to the nature of the work. It also provides for details on the procedure of declaring interests and its evaluation, as well as forms for the declaration of interests.

In addition, the EMEA has issued a "EMEA policy on the handling of conflicts of interests for EMEA scientific committees members and experts" further detailing its handling of conflicts of interests and specifically the criteria and procedure for assessing risk levels when interests are involved. Dependent on this assessment, it will be determined if and to what extent a person can participate in a procedure (such as the drafting of general guidelines, or the scientific assessment of a medicine either as a member of the CHMP or a working group or acting as rapporteur, etc.). The EMEA has a special body, the "Declaration of Interests Assessment Group" (DIAG) to deal with these assessment and determination.

6.2.3.2 Are there any limitations on off-the-record ("ex parte") communications between the decision makers parties outside the Commission?

a. *Competition:* There are no specific limitations on off-the-record communications between the decisionmakers and by parties outside the Commission. The Code of Good Administrative Behaviour provides some general guidelines as to the scope and contents of communications with the Commission. In addition, the Commission is obliged to protect confidential information it has obtained from the parties in the course of the proceedings.

c. *Trademarks.* Beside purely administrative informational communications, ex parte communications between the parties and the Office are not allowed. All other communications made by a party to the Office will be communicated to the other parties to the proceedings.

6.2.3.3 Is there any separation of functions of Commission staff members? In other words, can persons who have played roles as investigators, prosecutors, or advocates serve as hearing officers or advisers to hearing officers?

a. *Competition:* As already explained, the hearing officers are independent of DG COMP and play exclusively the role of the hearing officer in the proceedings. Their participation in the proceedings is limited to the functions described above. The hearing officers also resolve matters relating to access to documents and confidentiality of information.

c. *Trademarks.* There is a relative separation of functions between the different proceedings brought before the Office (CTM application, opposition and invalidity/revocation): two of the three members of an Opposition Division may not have taken part in examining the application. Members of the Cancellation Divisions may not take part in any proceedings regarding invalidity or revocation if they have participated in the final decision on the case in the proceedings for registration or opposition proceedings. Similarly, members of the Boards of Appeal may not take part in appeal proceedings if they participated in the decision under appeal.

The member(s) concerned is under the same obligation of disclosure and withdrawal as when he has a conflict of interest. Any party may also raise an objection to this member in the same conditions as described under point 6.2.3.1. The same procedure as to the disqualification decision will take place.

There is however no separation of functions within the same proceeding. For instance, the members of an Opposition Division will receive the observations filed by the parties, examine their content, decide whether oral hearings would be expedient, possibly hold oral hearings, and finally decide on the case.

e. State aids. There are no specific internal rules attributing certain specific functions to the various officials working in a Directorate-General.

6.2.3.4 Are there any rules prohibiting or relating to legislative or political pressure on decision makers?

a. *Competition:* There are no explicit rules that apply to lobbying. The EC Treaty, however, obliges the Commissioners to be completely independent in the performance of their duties. The Commissioners may not take instructions from a government, the Council or any other body. They may not behave in a manner that would be incompatible with their duties. Member States are obliged to respect this principle and not to seek to influence the Members of the Commission in the performance of their tasks. The Code of Good Administrative Behaviour imposes similar duties on the members of the Commission staff.

b. *Trade remedies.* Because the hearings are informal, there is no hearing officer; they are inquisitorial and very rarely adversarial. Concerns about the impartiality of the Commission officials conducting the hearing generally do not arise. There are no provisions for objecting on the basis of bias.

c. *Trademarks.* Besides the staff regulations of officials of the EU, which apply to the OHIM members, there are no specific rules relating to legislative or political pressure on decisionmakers.

e. *State aids.* The Commission and its officials have to perform their duties in complete independence. They are not allowed to succumb to any such pressure from third parties. If they do, the Commission's decision will be flawed due to a violation of the principle of sound administration.

f. Pharmaceutical licensing. Art 61 of Regulation 726/2004 prohibits the Member States from influencing the work of the Agency and its Committees by giving orders to the national representatives, which could conflict with their duties and tasks within the Agency. In addition, it requires the opinion to be science based. In general, the EMEA has the task to provide scientific input and not to take political decisions. On judicial review, the courts have stressed that decisions in the pharmaceutical sector have to be taken on public health grounds, which implies that they need to be free from political considerations and influence as well as economic interests.

6.3 Conduct of hearing

6.3.1 Hearing or conference? Is the "hearing" a meaningful step in the decisionmaking process or merely a relatively useless informal conference with Commission officials? Please explain.

a. *Competition:* Although the procedure before the Commission in antitrust cases is predominantly a written procedure, the importance of the oral hearing must not be underestimated. The oral hearing gives the companies subject to Commission investigation as well as third parties the opportunity to present their arguments before the Commission. It is an opportunity to clarify certain matters not settled in the written procedure and to emphasise the main line of the case. It also enables the parties to comment on written replies of other parties. It is not infrequent after the oral hearing for the Commission to change its mind and this explains the occasional divergences between the statement of objections and the actual final Commission decision in many cases.

c. *Trademarks.* Because the proceedings before the Office are designed to be mainly written proceedings, oral proceedings are rare. The hearing consists in an opportunity for the parties to convey their arguments through pleadings and/or to highlight the evidence they submit to the Office. It also allows the Office to obtain further information about the case to be examined and to ask questions directly to the parties, witnesses or experts.

e. *State aids.* As explained above, there is no formal hearing, but a possibility for the Member State concerned and interested parties to submit comments. If meetings are organized they are informal in that the Commissions' case team (or one of its members) meets with the representatives of a Member State or any other interested party. Such meetings are possible at any time during the procedure.

6.3.2 What is the order of events at the hearing? For example, does the prosecution open with a statement of its position?

a. *Competition:* The hearing is opened by the hearing officer. The basic order of the procedure to be followed during the hearing is not established by the law, but, typically, the procedural steps in an oral hearing are the following:

1) Presentation of the Commission's case by the DG COMP case handler; in practice this is often a short and formal step.

2) The parties are heard and third parties are given the opportunity to speak on the subject-matter of the case. The statements of the companies may deal with any factual, legal or economic point raised by the Commission's statement of objections.

3) The hearing officer invites the representatives of the competent authorities of the Member States to ask questions to the parties present at the hearing; normally this will be at the end of a party's presentation; if a presentation is particular long, questions may be invited after each speaker.

4) The hearing officer or members of the Commission staff present at the hearing ask their questions; these questions usually relate to the arguments made during the oral presentation. The Commission may invite the party to clarify or expand points an argument it used.

5) The hearing officer may invite the present parties to make concluding remarks before he formally closes the hearing. The closing remarks should be concise and, in principle, address only the issues that have arisen since the party made its own presentation.

The agenda of the hearing in practice is discussed beforehand by the hearing officer with the lawyers representing the parties to be heard. In preparation for the hearing the hearing officer may, after consulting the director responsible for the case, hold a meeting with the parties participating in the hearing. If no agreement on co-ordination of the procedure is made, the hearing officer allocates and polices time-limits for the parties making their submissions.

c. *Trademarks.* The order of events will generally follow the agenda and points to be discussed that were stated by the Office in its summons issued to inform the persons concerned of the hearing. When evidence is taken orally, the hearing will be conducted according to the evidence to be submitted.

f. *Pharmaceutical licensing.* Oral explanations are provided at the request of either the applicant or the CHMP. According to EMEA's instructions, an applicant seeking to present an oral explanation should present a written request to the CHMP preferably one month before the anticipated date of the oral explanation and certainly prior to Day 180. The CPMP may also invite the applicant to provide oral explanations on aspects of the dossier requiring clarification. A list of outstanding issues, to be addressed at the oral explanation will be adopted by the CHMP (usually at Day 180) and sent to the applicant. The applicant would then liaise with the Rapporteur and the EMEA project manager regarding details of the presentation.

In order to maximize the benefit of an oral explanation, it is important that applicants preparing for and attending oral explanations bear in mind that they are held to only allow clarification of outstanding issues. Oral proceedings of the CPMP are in English. Slide projectors, overhead projectors and computerized systems are available at the EMEA. Applicants should consult in advance with the EMEA project manager on the facilities they would like to use.

Any written explanation which the applicant wishes to present in order to support and elaborate on outstanding issues to be addressed during the oral explanation should be received by the EMEA project manager and all CHMP members at least 14 days before the CHMP meeting. Copies of any audio/visual aid material, including paper copies of projector slides/overheads, should be sent to the CPMP Secretariat and the EMEA project manager in advance or be brought to the meeting, for distribution prior to the oral explanation. At least one week before the oral explanation, the applicant should provide the project manager with the definitive list of names and a short curriculum vita of the persons who will be attending the oral explanation. The applicant's delegation attending the hearing should be limited to a maximum of 10 persons

Oral explanations will usually be conducted in the following sequence: The Chairman will invite the applicant's representatives to briefly introduce themselves; to confirm that all pertinent data have been submitted to the CPMP, whether favorable or unfavorable to the case and whether there is any further or additional information to be given to the CPMP. The Chairman will invite the applicant representatives to make their presentation (usually not more than 30 minutes) and will then ask the Rapporteur to put any outstanding questions to the applicant. An opportunity will also be given to all members of the CPMP to add supplementary questions or comments. At the conclusion of the oral explanation, the representatives of the applicant will be invited to withdraw while the CPMP discusses its recommendations on the application.

6.3.3 Do witnesses present testimony at the hearing? If so, who selects the witnesses—the hearing officer or the lawyers? Who frames the issues? Who decides on the order in which witnesses testify? Who puts questions to the witnesses? Can the hearing officer engage his own experts? If he does, can the parties present their own experts?

a. *Competition:* The right to submit witness testimony is part of the right to be heard. It is for the parties to select the witnesses and to frame the issues that will be subject to the witnesses' testimony. Witnesses may be called upon to confirm the line of argument made during the hearing. Expert witnesses may also be used to respond to the questions put by the members of Commission staff after they have an opportunity to consider the evidence. If witnesses or expert witnesses are produced, the companies in principle provide the Commission with a statement of what they will say and details of their qualifications.

b. *Trade remedies.* As mentioned above, hearings in trade remedy cases are informal. In fact, it is almost a misnomer to call them "hearings" because they are so informal and unstructured. They generally take place in a meeting room near the offices of the case handlers in charge of the case, with the participants sitting around a table. A hearing is an opportunity for interested parties to have the attention of the officials responsible for the case, so although in many cases it is not a "meaningful" event, it does provide some opportunity to ensure that the case handlers are aware of certain issues.

In terms of "witnesses," the interested party can bring whatever persons it deems fit to its hearing, and the Commission officials may very well ask questions. It is for this reason that interested parties must be careful about who they bring to a hearing, must brief them as to the issues of the case, and must know in advance what they plan to say and would say if asked specific questions. Individuals do not have an obligation to answer questions, but refusal makes a very negative impression on the officials in charge of the case. In such situations, it is better not to bring certain persons along to the hearing at all rather than have them be faced with questions they do not want to answer.

c. *Trademarks.* In oral hearings occurring because the Office finds it necessary, the Office selects the witnesses and frames the issues. It does so in the decision it takes to that end, stating the means by which it intends to obtain evidence, the relevant facts to be proved and the date, time and place of hearing. An extract from this decision, indicating in particular the date, time and place of the hearing ordered and stating the facts regarding which the witnesses are to be heard, is included in the summons given by the Office to said witnesses.

When a party requests the hearing, this party selects the witnesses and frames the issues. The party must make known to the Office the names and addresses of the witnesses within the time limit set by the Office in its decision to hear oral evidence. The Office will then summon said witnesses for the date and time of hearing it determines.

The parties are informed of the hearing of a witness before the Office and have the right to be present at the hearing. Both the Office and the parties to the proceedings can put questions to the witnesses. The same rules apply for the hearing of experts. The period of notice given in the summons of a witness or expert to give evidence must be of at least one month, unless they agree otherwise. Together with the extract of the Office's decision to hear oral evidence, the summons contains the names of the parties to the proceedings and particulars of the rights, which the witnesses or experts may invoke.

6.3.4. Presentation of proof. Assuming that the hearing is more than an informal conference but is actually an opportunity to present proofs, how are proofs presented? Oral or written? Audio-visual? Expert testimony? Qualification of experts? Any rules of evidence? Burden of proof rules?

a. *Competition:* There are no specific rules relating to the presentation of proof; it is discussed and agreed on with the hearing officer. If a party has any special requirements for its presentation, such as the use of a video recorder or an overhead projector, it should inform the hearing officer beforehand. In addition, copies of documents that will be referred to during the hearing should be supplied in advance, either with the reply to the statement of objections, or in good time before the hearing.

The Commission bears the burden of proving all elements of an infringement of Article 81(1) EC. However, if the party claims the benefit of exemption under Article 81(3), that party must prove that all requirements for application of Article 81(3) have been fulfilled. An intriguing issue is the burden of proof in Article 82 EC. While it would seem from the regulation that the Commission has the burden to prove all the conditions of Article 82 EC, Commission officials argue that the effectiveness of competition law enforcement requires that the defendant should at least prove those facts that are within its own knowledge and that tend to exculpate him. Thus, they argue, this should be the case of defenses of efficiency or defenses based on objective justification.

c. *Trademarks:* The general rule regarding burden of proof is that each party must prove what it claims. For instance, an opposing party must prove that the CTM application filed by an applicant is likely to cause confusion in the public's mind with the earlier trademark of the opponent. Proofs are generally presented in writing, but can also be presented orally if considered useful by the Office. Audiovisual means can also be used during oral hearings if appropriate. It is also possible to have recourse to experts where appropriate.

Only the parties to the proceedings may present evidence and argument. The Office itself may however engage experts if it deems it appropriate. It is however unlikely that the Office will engage experts in *ex parte* proceedings due to the liability for the costs of the expertise. A distinction must be drawn between an opinion poll filed by a party to the proceedings and the opinion poll initiated by the Office. Only the latter is considered as an expert opinion. When appointing an expert—on its own motion or on request of a party—the Office must decide in what form the expert report will be submitted. The terms of reference of the expert must include a precise description of his task and the time limit within which the expert must submit his report. A copy of any written expert report must be submitted to the parties. The parties may object to an expert on grounds of incompetence or on the grounds of conflict of interest.

6.3.5 Does the Commission staff present evidence or argument or only the private party or parties?

a. *Competition*: As explained above, the hearing starts with a presentation of the summary of the Commission's case. The Commission may also ask questions relating to the evidence and arguments presented by the parties during the hearing.

6.3.6 Is there one continuous hearing or are the proceedings carried on discontinuously from time to time?

a. *Competition:* There is one continuous hearing. In most cases, an oral hearing lasts one or two days, but in more complex cases it can go on for more than two weeks.

6.3.7 Confrontation. Can one side (private or Commission) contradict the proofs or arguments introduced by the other side? How? Cross-examination?

a. *Competition:* The principal purpose of the hearing is to allow the parties to present their case and comment on the evidence used by the Commission in the statement of objections. The parties do not have the right to cross-examine the Commission, other parties (co-defendants), or third persons whose testimony is heard at the hearing. The Commission does not cross-examine the parties, but it may, after the presentation, question the parties with respect to their oral submissions. The Commission is by no means obliged to comment on the parties' arguments immediately; the final assessment of the parties' arguments during the hearing is reflected in the Commission decision, which represents the final pronouncement of the Commission on the case.

b. *Trade remedies:* There is provision in the anti-dumping and anti-subsidy rules for confrontational hearings, where importers, exporters, representatives of the government of the exporting country and the complainants can meet those parties with adverse interests, so that opposing views may be presented and rebuttal arguments offered. No party is obliged to attend such a meeting however, and the regulation specifically says that failure to do so shall not be prejudicial to that party's case. As a practical observation, such confrontational hearings are exceedingly rare.

c. *Trademarks.* The evidence presented by one party can always be contradicted by the other parties in writing and/or orally. The Office communicates all evidence and proof to that end to the other parties. This communication always takes place before the hearing if any. The Office has not as such the power to contradict evidence, although it may, especially during oral hearings, confront the parties with the evidence submitted from both sides. According to

experience, examination of witnesses and/or experts does not play an important role in practice. If it nevertheless takes place, a sort of cross examination of witnesses and/or experts is possible due to the facts that parties can put questions to them.

6.3.8 Is there any requirement that persons responsible for making a decision have achieved personal familiarity with the issues or can the decision be purely institutional in nature?

a. *Competition:* As explained above, the ECJ has ruled that compliance with the principle of collegiate responsibility requires that decisions are actually taken by the college of Commissioners and correspond exactly to its intention. The college of Commissioners alone is responsible for adopting both the operative part and the statement of reasons, in accordance with that principle. The Court has also confirmed that Commission decisions finding infringement of EC competition rules cannot, without violating the principle of collegiate responsibility, be the subject of a delegation to the Member of the Commission responsible for competition policy.

c. *Trademarks:* Due to the intrinsic case-by-case nature of any trademark issue put before the Office, it is impossible to render a decision without having a comprehensive understanding of the facts and circumstances of the case to be decided. The decision to be made is always an individual one and highly depends on the situation of the case.

6.3.9 To what extent are criminal law standards followed in cases of serious sanctions such as a requirement that the Commission prove fault or intent? Is there a requirement that legal standards be clearly defined? How does one distinguish whether the administrative law or criminal law standards are applied?

a. *Competition:* The Commission proceedings are not considered to be criminal in nature. No proof of fault or intent is necessary to find a violation of Articles 81 or 82 EC; however, imposition of a fine requires at least a showing of negligence. There is no requirement of a certain standard of proof to be satisfied by the Commission, although this is a theme that is constantly debated in common law Member States. The European Courts refer quite often to the "*requisite legal standard*," yet this term does not seem to indicate a predetermined legal standard of proof, at least in the sense used in common law systems.

6.3.10 Time limits on making the decision? How long is a "reasonable time"?

a. *Competition:* Apart from merger cases, where the Commission is subject to strict time limits for making a decision, there are no particular time limits for the Commission to adopt its decision in Article 81 and 82 EC cases. The Commission is, however, bound by general principles of Community law to bring its proceedings to an end and produce its decision within a reasonable time.

The reasonableness requirement is rather fluid. On the analogous question of delays in deciding cases before CFI, ECJ has held that: "the reasonableness of such a period must be appraised in the light of the circumstances specific to each case and, in particular, the importance of the case for the person concerned, its complexity and the conduct of the applicant and of the competent authorities." In this respect, the Court of Justice has considered numerous precedents of the European Court of Human Rights, albeit "*by analogy.*"

Of relevance is also the right to good administration in Article 41 of the Charter of Fundamental Rights of the European Union, now reflected in Article II-101 of the Treaty establishing a Constitution for Europe, which refers to the right of every person "to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions, bodies, offices and agencies of the Union."

c. *Trademarks:* There is no time limit imposed on the Office to render a final decision. Delays may be extended or shortened according to the number of observations and evidence submitted by the parties, as well as to the language in which these documents are submitted. The time limit within which decisions are taken also depends on the workload of the responsible teams.

Generally, the publication of a Community trademark application happens within approximately nine months of its filing if there are no major discussions at stake. This delay includes the translation of the application within the 20 languages of the European Union. This time limit must be extended if discussions (e.g. regarding the distinctiveness of the trademark) take place. Opposition proceedings, if no settlement is found, generally last for 13 months. The Office believes this period of time can be reduced by the end of the year 2005. It must however be taken into account that the period of cooling off already lasts for two months and that six months are allowed for filing of the statement of grounds and observations in reply. A decision in appeal is generally taken within 12 months from the filing of the appeal, although this again strongly depends on the workload of the Office.

6.3.11 How is the record of the hearing maintained? Is there a verbatim transcript? What goes into the record and to what degree can decisionmaker rely on material outside the record? Can decisionmaker rely on his/her own expertise? Can decisionmaker rely on material in Commission's files? Can the decisionmaker take official notice of facts that have not been proved and what is the procedure for doing so?

a. *Competition:* Regulation 1/2003 provides that statements of each party made during a hearing must be recorded and shall be made available, upon request, to the parties attending the oral hearing. The record of the oral hearing is made in an audio recording. The Commission used to prepare written minutes of the oral hearing. This procedure, however, gave rise to problems resulting from delays in transcription or translation and in number of instances the parties challenged the Commission decision on the grounds of some error in the production of the minutes. The new procedure does not give rise to such problems.

b. *Trade remedies:* There is no transcript of the hearing made. The officials may take notes of what is presented, but in general interested parties that make a presentation provide the Commission after the fact with a confidential and non-confidential version of it.

c. *Trademarks.* A first way to keep track of hearings consists of minutes of oral proceedings or of the taking of evidence. The minutes contain the essentials of the oral proceedings or of the taking of evidence, the relevant statements made by the parties, and the testimony of the parties, witnesses or experts. The minutes of the testimony of a witness, expert or party is first read out or submitted to him so that he may examine them. It is noted in the minutes that this formality has been carried out and that the person who gave the testimony approved the minutes. Where his approval is not given, his objections are noted. The minutes are signed by the employee who drew them up and by the employee who conducted the oral proceedings or the taking of evidence. Each party is provided with a copy of the minutes.

Recordings of the hearing are also made in order to keep an exact track of what was said during the hearing. Upon request, the Office shall make available to the parties verbatim transcripts of recordings of the oral proceedings, in typescript or in any other machine-readable form. The Office in making such transcript subject to the payment of the costs incurs this release.

The Office members making the decision can only rely on the documents submitted by the parties in the case at stake and on the records of the hearing. They can of course also rely on their own expertise to the extent that it can be applicable to the case and is helpful to solve it.

7. Decisional phase

a. *Competition:* The Commission proceeding culminates with the adoption of a decision, which is addressed to specific persons. Decisions are enforceable under national procedural law. The decision represents the Commission's final pronouncement on the case and is challengeable before the CFI. An appeal to the ECJ is possible only on points of law.

7.1 Are we correct in assuming that the officials who conducted the hearing do not write a "proposed" decision? Our assumption is that there is only a single final decision at the conclusion of the process, not a series of tentative decisions.

a. *Competition.* The proposed decision is drafted by the case handlers and is approved by senior Commission officials who may suggest changes. The hearing officer is solely responsible for organizing the hearing and ensuring that the parties' rights of defense are respected during the proceedings before the Commission.

The hearing officer is not involved in drafting the Commission decision in the case, although he is one of the senior officials who comment on it, which may result in changes in the draft decision. In particular, after the oral hearing, the hearing officer prepares an interim report on the hearing and on the procedural issues with respect to the observance of the right to be heard. The observations in this report may deal also with questions of substance, summarizing the main arguments made by the Commission in the statement of objections, arguments put forward by the parties and third parties as well as any developments at the hearing. The hearing officer may also give his own legal assessment of the case and his provisional conclusions from the hearing. He may also make suggestions relating to the further progress of the proceedings. This interim report, which is not disclosed to the parties, is given to the Director-General for Competition and to the director of the operational directorate of DG COMP responsible for handling the case. Although it has no binding force, this report is taken very seriously by the case handlers drafting the decision, in particular if the report identifies shortcomings in the Commission's case.

After a preliminary draft of the decision is ready, the hearing officer prepares his final report, which is shorter. This report is sent to the Commissioner, the Director General for Competition and the director of the directorate that handled the case. In this report he comments solely on the observance of the right to be heard.

The preliminary draft decision is then sent to the Legal Service for review. Subsequently, it is presented for consultation to the Advisory Committee, where representatives of the Member States' competition authorities discuss the proposed decision and make comments thereupon. On the basis of this consultation, the Commission officials will proceed to the adoption of a final

draft decision that is then sent, together with the final report of the hearing officer and the opinion of the Advisory Committee, to the College of Commissioners for approval.

b. *Trade remedies:* No decision is made pursuant to the hearing.

In anti-dumping and anti-subsidy cases, the first decision that the Commission emits is the provisional regulation, which is adopted by it maximum nine months after initiation of the procedure. (The Commission could also decide to terminate the procedure at any point, after consultation and if no objection is raised in the Advisory Committee.)

Where the facts as finally established show that there is dumping or countervailable subsidies and injury caused thereby, and the Community interest calls for intervention, a definitive anti-dumping or countervailing duty shall be imposed by the Council, acting on a proposal submitted by the Commission after consultation of the Advisory Committee. The Council adopts the proposal unless it decides by a simple majority to reject the proposal, within a period of one month after its submission by the Commission. The regulations specify that the amount of the anti-dumping or countervailing duty shall not exceed the margin of dumping or subsidization established but it "should" be less if such lesser duty would be adequate to remove the injury to the Community industry. The "should," reflects the terminology of the WTO Anti-Dumping Agreement. Under EU law as interpreted by the EU Courts, it means "must" pursuant to the proportionality principle.

In safeguard cases, the Commission can decide preliminarily to take provisional measures, which can stay, in place for 200 days, while it is conducting its investigation. Definitively the Commission can decide, within maximum nine months of the initiation of the investigation, to terminate the investigation with no surveillance or safeguard measures, after consultation of the Advisory Committee. Termination is to take place within maximum one month of the consultation. If the Commission considers that Community surveillance or safeguard measures are necessary, it makes the necessary decisions no later than nine months (exceptionally extended for two further months) from the initiation of the investigation. Any decision taken by the Commission can be challenged by a Member State, which refers the decision to the Council. Then the Council, acting by a qualified majority, may confirm, amend or revoke that decision. If, within three months of the referral of the matter to the Council, the Council has not taken a decision, the decision taken by the Commission shall be deemed revoked. The Council also has the power, acting by a qualified majority on a proposal from the Commission, to take safeguard measures. However, this power has heretofore not been used.

c. *Trademarks.* It is correct that there is only a single and final decision at the conclusion of the proceedings. The practice of writing a series of "proposed" decisions do not exist before the Office.

f. *Pharmaceutical licensing.* The CHMP as the body that scientifically evaluates a medicine and also conducts the hearing of an applicant will render an opinion on a marketing authorization and for the assessment report for the medicine together with a draft summary of the product characteristics (SPC); any conditions affecting the authorization; details of any recommended conditions or restrictions on the safe and effective use of the medicinal product and the proposed labeling and package leaflet text. The final decision is drafted by the Commission, which will also attach the abovementioned documents attached to the CHMP opinion.

In case of disagreement between the Commission and the Standing Committee on the Commission's draft decision, the Council would become the body competent to take the decision

(see Comitology procedure above). If the Standing Committee raises new questions concerning the safety, efficacy or quality of the product, the Commission may also stop the decision making process and refer the issue back to the CHMP for further evaluation. A prominent example for the latter is the *Ferriprox* case (mentioned in the narrative section above), where the Commission after having obtained the new data from Dr. Olivieri decided to refer the application back to the CHMP. Another example is the *OMNITROP* case in which the Commission disagreed with the CHMP's finding on the "essential similarity" of the products concerned (biological products). Currently, Sandoz is challenging this decision in CFI.

Generally, the Commission will only issue one decision. However, in cases of the review of a whole product class comprising different substances and different products, the Commission may issue several decisions even if they are in content the same or similar, as in the Anorectics case (mentioned in the narrative above).

7.2 What is the nature of the decision-maker's obligation to find facts (how detailed must fact findings be)? Must the decisionmaker provide and justify legal interpretations and conclusions? Must the decision-maker furnish reasons for discretionary decisions? How detailed a statement of reasons must be provided? [Art 253] Must the statement of reasons cover all of the factors that the agency is required to consider?

a. *Competition:* Article 253 EC obliges the Commission to state reasons on which its decisions are based. The European Courts' jurisprudence clarifies the scope of this duty: the statement of the reasons must make it possible for the Court to exercise its supervisory function and for the parties to ascertain the matters justifying the measure adopted, so that they can defend their rights and verify whether the decision is well founded. Whether the statement of reasons is sufficient must be assessed in the circumstances of a particular case, including the context of a particular decision and the interests of the addressee in obtaining an explanation.

The Court has held that the statement of reasons should include both factual and legal grounds on which the Commission bases its decision. There is a line of case law indicating that if a Commission adopts in its decision a new legal interpretation, the decision may need to be more fully reasoned. This is also the case when the Commission departs from an administrative practice followed over many years. For reasons of proper administration, foreseeability and transparency it must give full reasons for that change in its administrative practice. The same is true when the Commission departs from its own Guidelines or Communications, such as in the case of fines.

The Commission bears the burden of proving the infringements so it must mention in its decision sufficiently precise and coherent proof to support its allegations. The Commission may rely on hearsay evidence, and may prove a course of conduct by sufficiently clear and numerous examples.

The Court has always stressed the importance of the statement of reasons: without the statement of reasons the full effects of the decision may be difficult to ascertain. Thus, failure to include adequate reasoning will result in the decision being annulled. The requirement of reasoning covers not only final decisions bringing the proceedings to an end, but also decisions on procedural matters, such as on requests for information and investigations. The Commission must state reasons by specifying the subject-matter and purpose of the measures ordered. As the Courts have held, "this is a fundamental requirement, designed not merely to show that the

proposed entry onto the premises of the undertakings concerned is justified but also to enable the undertakings to assess the scope of their duty to cooperate whilst at the same time safeguarding their rights of defense."

b. *Trade remedies:* In anti-dumping and anti-subsidy proceedings, to take action the Commission must have proof that the constituent elements empowering the institutions to impose anti-dumping or anti-subsidy measures are present: dumping or subsidization, material injury, and causation. Furthermore, they are required to determine that imposing measures would not be against the Community interest. In theory, on this point, the EU rules differ much from U.S. rules that provide for measures once dumping / subsidization and resulting injury are established. In practice, cases in which no measures are adopted on the ground that they are not in the Community interest are very rare.

In general, the Community institutions are required by Article 253 EU Treaty to state the reasons on which any decision is based, to enable judicial review of their decisions.

With regard to safeguards, a decision to take action requires proof that there is serious injury or a threat of serious injury to Community producers resulting from imports. In addition, although it is not mentioned in the EU legislation, WTO dispute settlement has also made it clear that serious injury or a threat of serious injury must be the result of "unforeseen developments."

"Serious injury" is defined by the EU regulation as a significant overall impairment in the position of Community producers, and "threat of serious injury" is defined as serious injury that is "clearly imminent." Proof that imports are causing or threatening to cause serious injury is provided by evidence that there has been a significant increase, either in absolute terms or relative to production or consumption in the Community, in the volume of imports and that there has been significant price undercutting by imports as compared with the price of a like product in the Community. Proof of serious injury is provided by evidence of the impact on Community producers as indicated by trends in certain economic factors like production, capacity utilization, stocks, sales, market share, prices (i. e. depression of prices or prevention of price increases which would normally have occurred), profits, return on capital employed, cash flow and employment.

In terms of a positive obligation to gather evidence itself, the safeguard regulation is relatively lax, simply calling on the Commission to seek all information it deems to be "necessary" and, "where it considers it appropriate", to endeavor to check this information with importers, traders, agents, producers, trade associations and organizations.

c. *Trademarks.* The Office has no powers to investigate the facts on its own. It belongs to the parties to state the relevant facts of their case and to bring evidence of these facts and statements. Because the other parties to the proceedings can contradict these facts and evidence, they are considered to be accurate enough in order for the Office to make a decision based on these facts and allegations.

The examiner or member of the Division or Board of Appeal must provide the legal interpretations and reasoning on which his decision is made. His statement of reasons must be detailed enough and must respond to all arguments submitted by the parties. When one or more of these arguments constitute a sufficient basis to justify the decision, however, the Office does not have to consider all the following arguments alleged by the parties.

e. *State aids.* A decision usually has four parts: a heading, the reasoning (setting out the procedure, the factual background and the legal analysis), the operative part (i.e. the "holding" of the decision) and the signature line setting forth who acted in adopting the decision. The Commission is obliged to impartially and diligently examine the facts of the case. According to Article 253 TEC, the Commission must state the reasons on which its decisions are based. The obligation to state reasons comprises the obligation to clearly and coherently indicate the principal issues of fact on which the decision is based. According to the ECJ, the statement of reasons gives an opportunity to the parties to defend their rights, to the court to exercise its supervisory functions, and to Member States and to all interested nationals to ascertain the circumstances in which the Commission has applied the Treaty. The Commission must also explain the legal basis for the operative part of the decision based on the facts of the case.

f. *Pharmaceutical licensing*. The regulations require that all decisions to grant, refuse, vary, suspend, withdraw or revoke a marketing authorization which are taken in accordance with these regulations shall state in detail the reasons on which they are based. Commission decisions must therefore discuss the reasons of the decision in detail. If the Commission wants to deviate from the CHMP opinion in its final decision, the law explicitly requires a detailed explanation of the reasons for the differences.

The CHMP is obliged to provide for reasons underlying its conclusions. The EMEA's code of conduct requires that "[e]very decision or recommendation of the Agency which may adversely affect the rights or interests of a private person shall state the grounds on which it is based by indicating clearly the relevant facts and the legal basis of the decision, the agent or other servant shall avoid making decisions which are based on brief or vague grounds or which do not contain individual reasoning." The Code also requires officials of the agency to act according to law and to be objective, meaning that they "shall take into consideration the relevant factors (only) and give each of them its proper weight in the decision, whilst excluding any irrelevant element from consideration."

7.3 Is there a duty of care imposed on decisionmaker to consider and respond to all relevant submissions by the parties (a dialogue requirement)?

a. *Competition.* The requirement that the decision should be adequately reasoned implies the duty of the Commission to comment on both inculpatory and exculpatory evidence, as well as to address all major arguments made by the parties. The Commission is not, however, required to discuss all the matters of fact and law raised by every party or dealt with during the proceedings. Neither is it required to refute all the arguments made by the parties.

b. *Trade remedies:* According to the Court in *Ajinomoto Co. and NutraSweet Co.*: "In any event, the undertakings concerned should have been placed in a position during the administrative procedure in which they could effectively make known their views on the correctness and relevance of the facts and circumstances alleged and on the evidence relied on by the Commission in support of its allegation concerning the existence of dumping and the resultant injury.

In anti-dumping and anti-subsidy cases, the regulations impose on the Community institutions the obligation to disclose "the details underlying the essential facts and considerations" on the basis of which provisional measures have been adopted and at the time that the Commission makes a proposal for definitive measures or the termination of an investigation or proceedings without the imposition of measures. Interested parties have an

opportunity to comment on disclosure, and the Commission will, where it considers it necessary, respond to their submissions in the regulations it proposes for adoption to the Council.

e. *State aids.* The Court has consistently held that the Commission "is not required to discuss all the issues of fact and law raised by every party during the administrative proceedings." Therefore, the Commission is not obliged to enter into a genuine "dialogue" with the parties. The unwillingness of the Court to accept a fully fledged dialogue requirement, moreover, may be based on the concern that such a requirement would lead to a "more and more cumbersome administrative process because the parties will be encouraged to raise more and more arguments to which the agency will have to respond." Even though there is no "dialogue requirement," the Commission is obliged to consider all relevant submissions by the Member State and any other parties to a State investigation. At the same time, the reasons given must be at least so comprehensive to allow the Court to exercise its function of judicial review.

f. *Pharmaceutical licensing.* The evaluation of medicines must be based on the conditions for granting marketing authorization as laid down in law. The CHMP and the Commission must take account of all relevant information provided by the company—and also relevant information coming from third parties as shown by the *Olivieri* case. In the case, however, of appeal against a CHMP opinion, the review is limited to data that were already available in the original review.

7.4 Is there a reasonableness requirement imposed on discretionary decisions? If so, how is it stated? Misuse of power? Failure to consider all relevant factors? Manifest error? Is there a requirement of proportionality? How defined?

a. *Competition:* Article 230 EC entitles the CFI to review Commission decisions "on grounds of lack of competence, infringement of an essential procedural requirement, infringement of this Treaty or of any rule of law relating to its application, or misuse of powers" The ECJ has held that its role is to verify whether the relevant rules on procedure and on the statement of reasons have been complied with, whether the facts have been accurately stated and whether there has been any manifest error of appraisal or misuse of powers.

The standard applied to review the Commission's discretionary decisions, in particular its economic assessment of the case, is whether the Commission committed a manifest error of assessment. Thus, in *Van den Bergh Foods*, the Court stressed with regard to the Commission's assessments on the basis of Article 81(1) EC: "Judicial review of Commission measures involving an appraisal of complex economic matters must be limited to verifying whether the relevant rules on procedure and on the statement of reasons have been complied with, whether the facts have been accurately stated and whether there has been any manifest error of assessment or a misuse of powers."

In *Airtours*, a merger case, the Court also reviewed whether the decision was based on convincing evidence and whether the Commission proved its case to the requisite legal standard. This suggests that the Commission may be reversed in its findings, not only in the case of clear contradictions or ignoring of evidence, but also for less serious errors.

Misuse of powers, understood as the exercise of powers for improper purpose rather than lack of power to act, has never been successfully invoked in any competition case. The CFI standard to annul the decision on this ground is that it would have to be apparent on the basis of

objective, relevant and consistent factors that the sole or main purpose of the decision was other than stated.

The Court's competence to review Commission decisions is broader with respect to fines. The Court has unlimited jurisdiction to review Commission decisions imposing fines or periodic penalty payments; in particular the Court may cancel, reduce or increase the fine or periodic penalty payment. Thus, in reviewing the fines imposed by the Commission, the Court may take into account all relevant aspects of the case and all relevant questions of law and fact.

b. *Trade remedies:* The Community institutions can be sanctioned for unreasonable exercise of their discretion by the European Courts, on the basis of lack of competence, infringement of an essential procedural requirement, infringement of the EU Treaty or of any rule of law relating to its application or misuse of power. In terms of "reasonableness", respect of the EU Treaty also means that the Community institutions must respect fundamental principles of Community law, one of which is proportionality, in coming to their decisions. However, it can be commented that the standard of review in trade remedies cases tends to grant the Community institutions a great deal of latitude.

c. *Trademarks.* As the decisions taken by the Office inevitably involve an exercise of judgment, this exercise requires reasonableness and proportionality. These requirements are however not stated as such but flow from the procedural structure, which allows various recourses against a decision that would not be reasonable or proportionate (or against partial decisionmakers). Besides being subject to appeal, the decision can also be put into question (legal aspects only) before the CFI or ECJ.

As for manifest error, a specific rule allows that "obvious mistakes" (together with linguistic errors and errors of transcription) be corrected by the department which took the decision, acting of its own motion or at the request of an interested party. Further, if an "obvious procedural error" is made by the Office in a decision (or in an entry in the Register), the Office must ensure that the decision is revoked (or the entry cancelled). Revocation is determined either *ex officio* or at the request of one of the parties to the proceedings, by the department, which took the decision. This revocation must be determined within six months from the date on which the decision was taken, after consultation with the parties to the proceedings and any proprietor of rights to the CTM in question.

e. *State aids.* Treaty Article 87(3) confers a wide margin of discretion on the Commission to allow aid by way of derogation from the general prohibition laid down in Article 87(1) TEC, inasmuch as the determination in such cases of whether State aid is compatible with the common market raises problems which make it necessary to examine and appraise complex economic facts and conditions. The Court accepts that review is restricted in cases where a complex economic appraisal is involved. In such a case the Court is prepared not to encroach upon the Commission's economic appraisal and does not substitute its economic assessment for that of the Commission. Rather, the Court limits its judicial scrutiny to checking that the procedural rules have been complied with, that the facts are materially accurate, and that there has been no manifest error of assessment and no misuse of powers.

f. *Pharmaceutical licensing.* The EMEA's code of conduct requires acting in accordance with the principle of proportionality. Art. 6 of the conduct reads: "When taking decisions, the agent or other servant of the Agency shall ensure that the measures taken are proportional to the aim pursued. The agent or other servant shall in particular avoid restricting the rights of the

citizens or imposing charges on them, when those restrictions or charges are not in a reasonable relation with the purpose of the action pursued. When taking decisions, the agent or other servant of the Agency shall strike a fair balance between the interests of private persons and the general public interest."

This is relevant when restrictions are imposed on the marketing of a medicine, for instance, by limiting the approved indications or by strengthening the warnings, or when a marketing authorization is suspended or withdrawn. In these contexts, the authorities can also rely on the precautionary principle. Decisions relating to medicines have to be taken on the basis of the public health criteria that are contained in the legislation, and thus unavoidably allow for a broad margin of assessment. Only rarely will there be a black and white situation from a scientific point of view. This margin of assessment does not, however, mean that the CHMP and the Commission have discretionary powers. The exact limits of the powers of the authorities are not yet clearly defined.

7.5 What remedies are available to the Commission? Cease and desist orders? Divestiture? Invalidation of intellectual property? Declaratory relief? Civil money penalties? Restitution? License revocation? Other sanctions?

a. *Competition:* Antitrust enforcement pursues three schematically different, yet substantively interconnected, objectives. The first one is injunctive, i.e. to bring the infringement of the law to an end, which may entail not only negative measures, in the sense of an order to abstain from certain delinquent conduct, but also positive ones ensuring that that conduct ceases in the future. The second objective is restorative or compensatory, i.e. to remedy the injury caused by the anti-competitive conduct. The third one is to punish the perpetrator of the illegal acts in question and also to deter him and others from future transgressions.

Public enforcement may pursue all three objectives. The injunctive objective is served with cease and desist orders and negative or positive injunctions. The restorative-compensatory objective is primarily served by private enforcement although public enforcement may still have a role to play. Finally, public enforcement is predominant in the pursuing the penal objective. Regulation 1/2003 allows the Commission to adopt a variety a variety of measures/remedies when it finds an infringement of EC competition rules. What follows is a brief summary of those measures.

As to declaratory relief: The Commission may declare that an infringement has been committed in the past without imposing fines, if it has a legitimate interest in doing so. Such a decision may be of use to litigants before national courts adjudicating damages claims for antitrust injury.

As to cease and desist orders (injunctions): The Commission may order the companies concerned to terminate the infringement. This power of the Commission is quite broad and may extend to any behavioural or structural remedies that are necessary to bring the infringement to an end. An important limitation on the Commission's power stems from the freedom of contract. In one case, CFI ruled that the Commission could not compel a party to enter into a contractual relationship where it had other means available to end an infringement. In the Commission's view such purely positive measures may be more justifiable in Article 82 EC cases.

The Commission has no right to decide on the validity of intellectual property rights. The Court has held, however, that the Commission may in exceptional cases control the way intellectual property rights are exercised. In *Magill*, the ECJ upheld the Commission's decision

requiring certain broadcasting companies to make available their TV listings and to permit their reproduction subject to payment of reasonable royalties. In *IMS Health*, which was a preliminary reference case, the Court again confirmed that the exercise of intellectual parties was not immune from antitrust. Most recently, the Commission obliged Microsoft to disclose to its competitors detailed descriptions of the communications protocols by which Microsoft's operating systems communicate with one another—referred to as "specifications"—and then to license competitors to use those specifications for the purpose of developing their own products.

As to interim measures: The *Camera Care* case empowered the Commission to adopt interim or interlocutory measures in urgent cases, in order to avoid a situation likely to cause serious and irreparable damage to a complaining party or to harm to the public interest.

As to fines: The Commission may impose fines on companies who intentionally or negligently infringe EC competition law. The fine may not exceed 10% of the total turnover of the fined company in the business year preceding the decision. The regulations require the Commission to consider the gravity and the duration of the infringement in fixing the amount of the fine. The Commission has issued Guidelines that set out the methodology used by the Commission in setting the amount of fines. Of particular importance is also the Commission's Leniency Notice that provides for no fines for cartel whistleblowers and for reduced fines for companies that co-operate with the Commission in unearthing cartels.

As to periodic penalty payments: The Commission may impose on a company a periodic penalty payment to compel it to terminate an infringement in accordance with the decision finding an infringement of EC competition law. The penalty may not exceed 5% of the average daily turnover in the preceding business year.

In the merger control area, the term "remedies" refers to modifications in the merger agreement, proposed through commitments given by the merging parties to the Commission, that are intended to satisfy the Commission's concerns about the compatibility of the proposed merger with the common market. Such commitments may propose "structural remedies," i.e. measures giving rise to the structural change of the market (for example that a business is to be divested), or "behavioral remedies" (such as a promise to license somebody on fair and reasonable terms). These remedies are not imposed by the Commission unilaterally but are rather proposed by the merging parties to the Commission which may accept or reject them. When the Commission accepts such remedies, it may further transform them into conditions or obligations in its clearance decision.

With this caveat in mind, the Commission can unilaterally take the following measures in the context of its merger enforcement powers:

Dissolution of the merger: In case of a Commission decision declaring a merger's incompatibility with the common market, if the parties have already implemented the merger, the Commission may order the dissolution of the merger or the disposal of all the shares or assets acquired, or any other appropriate measure.

Interim Measures: The Commission may take interim measures appropriate to restore or maintain conditions of effective competition where a concentration has been implemented and is declared incompatible with the common market.

Fines: As in the antitrust field, the Commission may also impose fines up to 10% of the aggregate turnover of the undertakings concerned where, either intentionally or negligently, they (a) fail to notify a merger to the Commission; (b) implement a merger before it has been declared compatible with the common market by the Commission; (c) implement a merger that has been

declared incompatible with the common market or do not comply with an order of dissolution issed by decision of the Commission; (d) fail to comply with a condition or an obligation imposed by decision. Lower fines up to 1 % of the aggregate turnover of the undertakings concerned may be imposed for procedural infringements, such as failing to comply with a Commission request for information, taken by decision, for supplying incorrect or misleading information, or for refusing to submit to an inspection ordered by decision.

Periodic penalty payments: The Commission may also impose periodic penalty payments not exceeding 5% of the average daily aggregate turnover for each working day of delay in order to compel an undertaking (a) to supply complete and correct information which it has requested by decision; (b) to submit to an inspection which it has ordered by decision; (c) to comply with an obligation imposed by decision or (d) to comply with any measures of dissolution ordered by decision.

b. *Trade remedies:* No remedies other than those in the basic anti-dumping, anti-subsidy, or safeguard regulations can be imposed.

c. *Trademarks.* The only remedies/decisions available to the Office concern the grant or invalidation of the intellectual property rights vested in the Community trademark. The Office cannot issue any cease and desist order or order any money penalties.

f. *Pharmaceutical licensing.* As discussed above, the Commission may withdraw, suspend or amend marketing authorizations if required for public health reasons. In addition, it may now issue penalties in cases of infringements by marketing authorization holders of their legal obligations and compel the marketing authorization holder to comply with the measures of inquiry imposed by the EMEA. In addition, the Commission may ask Member States to conduct investigations.

7.6 Is the full decision publicly available? How is it publicized?

a. *Competition:* The regulations require that Commission decisions be published. The publication requirement covers decisions finding an infringement, ordering interim measures, making commitments binding, inapplicability decisions, and decisions imposing fines and periodic penalty payments. The published decision must state the names of the parties, the main content of the decision and the penalties imposed. The public version of the decision is purged of business secrets of the parties and other confidential information. The Commission does not publish its procedural decisions, such as decisions ordering on-site inspections or requesting information.

Publication takes place in the Official Journal of the European Union (in the L series). Nowadays the Commission publishes only abridged versions of the decisions in the Official Journal, but makes the full text of the decision available on Commission's website. The full version of the decision is made available only in the authentic language of the decision and in the Commission's working languages (English and French, sometimes German).

In the merger control area, the Commission must publish in the Official Journal all Phase II decisions and all decisions imposing fines and periodic penalty payments, ordering the dissolution of an unduly implemented merger, or ordering interim measures. The opinion of the Advisory Committee must also be published in the Official Journal. The publication shall state the names of the parties and the main content of the decision and shall have regard to the legitimate interest of undertakings in the protection of their business secrets. Phase I decisions,

however, are not published in the Official Journal. These are published in the web site of DG-COMP.

b. *Trade remedies:* In anti-dumping and anti-subsidy cases, both the provisional regulations and the definitive regulations are published in full in the Official Journal of the European Communities. While the safeguard regulation does not specifically require publication in the Official Journal of the European Communities of formal action, such publication does occur, in the same way as in anti-dumping and anti-subsidy cases.

c. *Trademarks.* The decision is first notified to the parties. Where oral proceedings are held before the Office, the decision may be given orally, in which case the decision in writing shall be notified subsequently to the parties. The decision is then published in the Community Trademarks Bulletin, available at http://oami.eu.int/bulletin/ctm/ctm_bulletin_en.htm.

A CTM is recorded in the Register of Community trademarks. The entries made in the Register indicate the date of registration and the registration number and contain information as to the application, the applicant, and the mark applied for. The Register is maintained in the form of an electronic database 'CTM Online' available free of charge through the OHIM's website at: http://oami.eu.int/en/database/ctm-online.htm. The registration is then published in the Community Trademarks Bulletin.

A decision refusing a CTM application as a result of successful opposition proceedings is published upon becoming final in the Community Trademarks Bulletin and contains the following information: filing number, date of the former publication, date of the refusal and remaining goods and/or services in case of partial refusal. A record of the Office's decision on the application for revocation of rights or for a declaration of invalidity is entered in the Register once it becomes final and then be published in the Community Trademarks Bulletin.

e. *State aids.* The official gazette for publication of legal acts in the EU is the Official Journal. The Official Journal is organized in two "series": the L-series, where legally binding acts are published (particularly directives, regulations and decisions), and the C-series for legally non-binding acts (e.g. recommendations or Commission notices). There is a separate edition of the Official Journal in each official Community language. Unless explicitly provided otherwise, publication must be effectuated in all language versions.

Decisions that close a formal investigation must be published in the Official Journal in full and in all official languages of the EU. For all other decisions, the significant administrative burden to publish the full text of these decisions in all language versions is alleviated. Decisions after Phase 1 investigation that a measure does not constitute aid or that the measure can be exempted need only be published in the form of a summary notice. Copies of the decision in full text in the authentic language version or versions may be obtained upon request and are, moreover posted on the Internet.

Recommendations for appropriate measures are published in the form of a summary notice once they have been accepted by the Member State concerned. The recommendation is then posted on the Internet (in the language of the procedure only). If the recommendation is not acceptable the Commission can decide to open a formal investigation procedure. Decisions to open Phase 2 investigation procedure must be published in full in the authentic language version,

but only "a meaningful summary" must be published in the Official Journal in the other official languages.

Regulation 659/1999 does not specify when the respective decisions have to be published. In practice, it is not uncommon that decisions are published only months after the actual date of their adoption. Article 20 of Regulation 659/1999 helps to remedy this shortfall as it gives interested parties the right to obtain a copy of Commission decisions even before their publication in the Official Journal. These delays have serious repercussions on the legal position of the beneficiary of the state aid. It will only have legal certainty that no one instituted proceedings for annulment before the Community Courts when the two months deadline for an action for annulment, which is triggered by publication of the decision in the Official Journal, has expired.

The Commission is obliged to send a copy of its decision ending the formal procedure to any interested party who has submitted comments and to any beneficiary of individual aid. In addition any interested party—even those who did not submit comments—has the right to request a copy of State aid decision. These rules should enable parties who are entitled to appeal a decision before the Community courts to have a proper document upon which to base their appeals.

Apart from the Official Journal, there are other sources of information about EU State aid policy and the Commission's activities: the Annual Reports on Competition Policy, the State Aid Scoreboard, and the State Aid Register. The Commission publishes Annual Reports on Competition Policy, which cover all aspects of European competition policy, ranging from Treaty Articles 81 and 82 to merger control, and to State aid. The so-called State Aid Scoreboard, first launched by the Commission in 2001 and updated twice a year, gives information on the overall situation of State aid in the EU and on the Commission's current State aid activities. Finally, the State Aid Register also provides information on State aid cases. Part I of the State Aid Register presents aggregated data on all cases under preliminary examination that were registered after January 1, 2000 in tabular form, and Part II contains information on cases which have been the object of a final Commission decision since January 1, 2000 and group exemption cases published in the Official Journal.

f. *Pharmaceutical licensing.* Decisions about the granting, variation or refusal of marketing authorizations are publicly available on the Commission web site (http://dg3.eudra.org/F2/register/index.htm). The web site grants access to all decisions relating to a specific product and including the Annexes to the decisions, which comprise the CHMP assessment reports, the SPC, specific conditions for the marketing authorization as well as labeling and package leaflet in all languages. In case of a refusal to grant a marketing authorization, only the CHMP report and the statement of reasons for the refusal annex the decision. Art. 13 (3) obligates the Agency to publish the assessment report and the reasons for the opinion in favor of granting a marketing authorization. This publicly available document, which does not contain confidential information, is called European Public Assessment Report (EPAR).

The EMEA web site (http://www.emea.eu.int/index/indexh1.htm) also contains a register with the EPARs of authorized products, which comprises information about the procedural steps taken before the marketing authorization was issued as well as a listing of the steps taken later. In

addition, the site also provides for access to product safety announcements and for public statements of the EMEA concerning suspensions or withdrawals issued by the Commission.

Under the draft penalties regulations, the Commission's decision to ask for ending an infringement and to impose fines on a marketing authorization holder is to be published. The published data will include the names of the marketing authorization holders, the amount of the fine and the reasons for taking the decision.

7.7 Process resulting in a rule: We recognize that Commission proceedings sometimes result in an individualized decision and sometimes in a rule of general application. Does the process in your sector sometimes result in adoption of a rule rather than a decision? If so, please provide additional information about when and how this might occur.

a. *Competition:* With exception of sector investigations under Article 17 of Regulation 1/2003, proceedings before the Commission always result in an individualized decision. Commission decisions are binding on the addressees of these decisions, but have no binding effects on any third parties. Sector investigations are not limited to the activities of any one or a group of companies, but extend to a particular sector of an economy or particular type of agreements. Following such investigations, the Commission may issue a report presenting the results of the Commission's inquiry. Sector investigations may disclose particular violations of EC competition law, in which case the Commission commences procedure against a particular company or a group of companies.

b. *Trade remedies.* In trade remedies cases, final decisions are in the form of regulations, which are of general application. In anti-dumping and anti-subsidy cases measures provided by them are individualized together with a measure of general application.

d. *Food safety*. In food safety cases, the EU usually regulates through the adoption of generally applicable rules, even though such rules are adopted in response to an individual application for permission to market a particular food product. Applications concerning novel foods and genetically modified foods are resolved through an individualized rather than a generalized decision, but the actual procedures are the same whether the outcome is a rule or an individual decision. Consequently, food safety is covered in detail in the rulemaking project rather than the adjudication project. We include at this point an abbreviated summary of the detailed treatment of rulemaking procedure provided in the sectoral report.

There are two principal forms of rulemaking in EU food safety regulation. General legislation is adopted under the general legislative procedure (Article 251 ECT); implementing legislation is passed under the comitology procedure. We concentrate here on the implementing legislation whereby specific food products are approved for sale. The Commission forwards its proposal to a Regulatory Committee (in the case of food safety, this is SCFCAH as mentioned above) consisting of high-level representatives of the Member States who vote on the proposal. If the Committee approves by a qualified majority, the Commission must approve the proposal. If the proposal does not command a qualified majority, the file is transferred to the Council. The Commission is not entitled to amend its proposals at any time before the file is assessed by the Council.

It is in the Commission's interest to present a proposal that is likely to receive the required qualified majority. For this reason, the Commission usually holds a vote on a "draft" proposal to see where the issues are. Sometimes also, the Commission proceeds to a straw vote if majorities are close. Once a qualified majority is expected, a final proposal is formally presented

for a vote. Many EU law practitioners and stakeholders criticize these practices because the Commission is said to bow to political pressure from the Member States rather than to present a proposal based on its merits. There are a number of rather fundamental differences between the normal legislative procedure and the comitology procedure, which indicate that the latter falls short on transparency and accountability grounds.

- The members of the Regulatory Committee are high-level national officials from the respective Ministries; hence there is little overall political control and balancing of the issues at stake at national level as far as their voting is concerned – it often goes unnoticed.
- There is little if any public knowledge on the discussion and voting in the Regulatory Committee.
- As they are not known, the members of the Regulatory Committee are generally not exposed to European level advocacy, they are often just exposed, if at all, to national advocacy actions.
- Draft measures referred to the Regulatory Committee are not published.

8. Administrative reconsideration

8.1 Is there an opportunity to seek reconsideration of the Commission's decision? If so, how is reconsideration requested? Please describe the process of reconsideration. For example, who considers the reconsideration decision and how is the decision to reconsider made?

a. *Competition:* Administrative reconsideration is possible under Regulation 1/2003 with respect to interim measures, which can only be granted by the Commission for a specified period of time. The decision to renew interim measures is an opportunity for the Commission to reconsider its case and take into account changes that took place after the adoption of the decision. Similarily, a Commission decision making commitments binding on a company may be adopted for a specified period of time. The Commission is entitled to reopen the proceedings in a case concluded by a decision on commitments where there has been a material change in the facts on which the decision was based, the companies concerned acted contrary to their commitments, or where the decision was based on incomplete, incorrect or misleading information supplied by the parties. While Regulation 1/2003 is silent on the matter, the addressee of a Decision making commitments binding may apply to the Commission to vary or withdraw the binding effect of the previously-given commitments. Typically, this will be the case after some time has lapsed and the conditions of competition in the market have changed so that the commitments no longer correspond to the exigencies previously identified.

Although, there have been cases in which the Commission has amended or withdrawn its final decision, in principle the only recourse against the Commission's decision is to appeal it to CFI. If this is not done, the decision becomes definitive against its addressee. Even if the proceedings brought by the parties at a later stage result in a finding that the Commission's decision has been adopted in error, the Commission is not under an obligation to withdraw the decision as against parties which failed to challenge it.

As regards EC merger control, the Commission's decision on the compatibility or incompatibility of a proposed merger with the common market is definitive though it can be challenged before CFI. It is possible, however, that the same parties might resubmit a proposed merger agreement to the Commission after the lapse of some time, when the conditions of

competition may have changed and there are valid hopes that the Commission might take a more favorable view of their agreement.

b. *Trade remedies:*

Interim reviews: In anti-dumping and anti-subsidy cases, interested parties may apply to the Commission for an interim review, provided that at least one year has elapsed since the imposition of the definitive measure. Such reviews can be initiated earlier, on the initiative of the Commission or at the request of a Member State. In an "interim review", the Commission examines the need for the continued imposition of measures, on the argument that they are no longer necessary to offset dumping and/or that the injury would be unlikely to continue or recur if the measure were removed or varied. An interim review can also consider the need to increase the measures, because the existing measure is not, or is no longer, sufficient to counteract the dumping which is causing injury. While an interim review is going on, the measures remain in force. The outcome of an interim review can be to repeal, confirm or modify (up or down) the measures.

Newcomer reviews: A new exporter (a company which did not export the product during the investigation period) can also ask for a newcomer review for the purpose of determining its individual margin of dumping, if any. A newcomer has to prove to the Commission that it is not related to any of the exporters or producers in the exporting country currently subject to the measures, in order to avoid that the newcomer review is simply used as a means of getting around the measures. The Commission also requires, before it enters into the review, that the newcomer prove that it has or definitely will export the product to the EU. During the newcomer review, the duty is suspended for that exporter and his imports are registered, so that once a duty (if any) is established for him, it can be applied retroactively.

Expiry reviews: Definitive anti-dumping and anti-subsidy measures expire five years from their imposition, or five years from the date of the conclusion of the most recent review which has covered both dumping and injury, unless it is determined in an expiry review that expiry would be likely to lead to a continuation or recurrence of dumping and injury.

At an "appropriate time" in the final year of the period of application of the measures, the Commission publishes a notice of impending expiry in the Official Journal of the European Communities. An expiry review can be initiated on the initiative of the Commission, or upon request made by or on behalf of Community producers, and the measure remains in force pending the outcome of such review. The Community producers must lodge a review request no later than three months before the end of the five-year period.

An expiry review is initiated where the request contains "sufficient evidence" that the expiry of the measures would be likely to result in a continuation or recurrence of dumping and injury. The exporters, importers, the representatives of the exporting country and the Community producers are given the opportunity to amplify, rebut or comment on the matters set out in the review request, and conclusions must take "due account" of all relevant and duly documented evidence presented in relation to the question as to whether the expiry of measures would be likely, or unlikely, to lead to the continuation or recurrence of dumping and injury. The measures remain in force during the expiry review. The outcome of an expiry review can only be to repeal or maintain the measures as they are, not modify them.

Procedure for reviews: The procedures that apply to the main investigations, except the time limits, also apply to reviews. With regard to time limits, interim and expiry reviews are

supposed "normally" to be concluded within twelve months of the date of initiation of the review. In anti-dumping, the regulation goes further, saying that in no event should these reviews take longer than fifteen months (for expiry reviews, for any review initiated after 20 March 2004; for interim reviews, for those initiated after 13 March 2006).

In anti-dumping, newcomer reviews must in all cases be concluded within nine months of the date of initiation (for those initiated after 13 March 2006), while in anti-subsidy, although newcomer reviews are supposed to be "accelerated", they are subject to the same twelve month time limit as other reviews.

c. *Trademarks.* There is no way to seek reconsideration independently from lodging an appeal. However, when an appeal is lodged against a decision of the Office (see point 8.2. below), after the statement of the grounds of appeal is filed with the Office and before the case goes before the Board of Appeal, the Division that took the contested decision may revise and rectify this decision.

If the party, which has lodged the appeal, is the sole party to the procedure, and if the department whose decision is contested considers the appeal to be admissible and well founded, the department shall rectify its decision. This process is called revision of decision in *ex parte* cases. If the decision is not rectified within one month after receipt of the statement of grounds, the appeal shall be remitted to the Board of Appeal without delay, and without comment as to its merit. Revision of decision in *interspartes* cases may occur where the party, which has lodged the appeal, is opposed by another party. In this event, if the department whose decision is contested considers the appeal to be admissible and well founded, it shall rectify the decision accordingly. In *inter* partes cases, however, the decision may only be rectified if the department whose decision is contested notifies the other party of its intention to rectify it, and that party accepts it within two months of the date on which it received the notification.

e. *State aids.* Regulation 659/1999 does not provide for reconsideration of the Commission's decision. This holds true for decisions after the preliminary examination as well as decisions to close the formal investigation procedure. However, the Community Courts have ruled that an unlawful administrative act may be revoked even if there is no explicit statutory basis for this possibility, as long as certain legitimate expectations of the addressee are respected. In contrast to this, the revocation of a lawful administrative acts is possible only in exceptional cases, because this would allow the Community institutions to take away vested rights from individuals, which would be contrary to the protection of legitimate expectations and legal certainty.

Regulation 659/1999 allows the Commission to revoke certain decisions where the decision was based on incorrect information provided during the procedure, under the condition that this information was "a determining factor" for the decision. The decisions that might be revoked are decisions to close the preliminary examination and decisions to close the formal investigation procedure. Before revoking a decision, the Commission must give the Member State concerned the opportunity to submit comments and must open the formal investigation procedure.

f. *Pharmaceutical licensing*. In one case, the Commission issued a decision ordering Member States to amend the listed marketing authorizations to produce a harmonized summary of product characteristics for the medicine Capoten and associated names. This decision was

contested in CFI but the proceeding was stopped as the Commission revoked its prior decision, conceding that it had failed to provide proper reasons. This may serve as an example of administrative reconsideration. There is, however, no general rule in pharmaceutical law that the Commission has to reconsider its decision. However, as far as access to documents is concerned, the rules provides for reconsideration of administrative decisions to deny access to documents at both the Commission and EMEA level.

8.2 Administrative appeal: is there any opportunity to appeal the decision to another administrative decisionmaker before seeking judicial review in court (CFI or ECJ)?

a. *Competition:* There is no such possibility in the EU competition law enforcement system.

b. *Trade remedies:* Once the Community institutions have made a decision to impose measures, the only appeal is to the CFI, which is charged with anti-dumping cases. However, in anti-dumping and anti-subsidy cases interested parties may apply to the Commission for a "review."

c. *Trademarks.* A possibility of appeal lies from decisions of the examiners (CTM application), Opposition Divisions (opposition), and Cancellation Divisions (invalidity/ revocation). The decision must be final in order to be appealed. The appeal shall have suspensive effect. Any party to proceedings adversely affected by a decision may appeal. Any other parties to the proceedings shall be parties to the appeal proceedings as of right.

The appealing party must file a notice of appeal in writing at the Office within two months after the date of notification of the decision appealed from. The notice of appeal must contain the name and address of the appellant, the name and business address of his representative where applicable, and a statement identifying the decision, which is contested, and the extent to which amendment or cancellation of the decision is requested. The notice must be filed in the language of the proceedings in which the decision subject to the appeal was taken. The notice of appeal shall be deemed to have been filed only when the fee for appeal has been paid. Within four months after the date of notification of the decision subject to appeal, a written statement setting out the grounds of appeal must be filed.

If the appeal meets the formal requirements for an appeal, the Board of Appeal shall examine whether the appeal is allowable. In the examination of the appeal, the Board of Appeal shall invite the parties, as often as necessary, to file observations, within a period to be fixed by the Board of Appeal, on communications from the other parties or issued by itself. The Board of Appeal may either exercise any power within the competence of the department, which was responsible for the decision appealed, or remit the case to that department for further prosecution. As a reminder, actions may be brought before the European Court of Justice (Court of First Instance, and Court of Justice for appeal) against decisions of the Boards of Appeal. These actions do however not belong to the administrative field but concern judicial review and are therefore not included in the present contribution.

e. *State aids.* There is no possibility to appeal any decision in the field of state aid to another administrative body before seeking judicial review before the Community Courts.

f. *Pharmaceutical licensing.* A CHMP opinion can be "appealed" (to the same body) by filing a "request for reexamination" within 15 days. Regarding access to documents, the law provides for reconsideration of administrative decisions of both the Commission and the EMEA. There are no other formal appeal procedures.

9. Enforcement actions. When the dispute arises out of enforcement by the Commission of a previous decision or order, are there differences in the process of investigation, hearing or decision from cases not arising out of the enforcement of a previous decision or order?

a. *Competition.* Under Art. 256 of the EC Treaty, Commission decisions imposing a pecuniary obligations on persons other than States are enforceable. Enforcement is governed by the rules of civil procedure of the State in which the enforcement is carried out. Consequently, disputes relating to collecting fines imposed by the Commission are governed by national civil procedures. The order of enforcement is appended to the Commission decision by the national authority which the government of the Member State has designated for that purpose. No other formality than verification of the authenticity of the decision is envisaged. Where the Commission issued a decision imposing non-pecuniary obligations, i.e. making structural or behavioral commitments binding on the parties, the Commission may reopen the proceedings if it concludes that the company concerned acts contrary to its commitments. In such case the procedure before the Commission will not be different than that in the original proceedings.

b. *Trade remedies:* Following adoption of an anti-dumping or anti-subsidy regulation, customs officials of EU Member States will begin applying the duties at the border. However, sometimes the Community industry complains that it has not seen any or a sufficient increase in prices. They might consider that the exporters, rather than letting the impact of the duties be felt, have lowered their prices even more or have compensated their importers otherwise, "absorbing" them. Or, the Community industry might complain that the companies targeted by the anti-dumping or anti-subsidy regulation are "circumventing" it by sending their products from another country. Both absorption and circumvention are addressed in the rules.

For absorption, the rules for anti-dumping are more elaborate than those on anti-subsidy. In anti-dumping, the Community industry, any other interested party, a Member State, normally within two years from the entry into force of the measures, can ask the Commission to conduct an absorption review by submitting "sufficient information" showing that, after the original investigation period and prior to or following the imposition of measures, export prices have decreased or that there has been no movement, or insufficient movement in the resale prices or subsequent selling prices of the imported product in the Community. The Commission can self-initiate such "absorption" investigation. The investigation may, after consultation, be reopened to examine whether the measure has had effects on the abovementioned prices. Where the investigation shows that this has indeed been the case, export prices are reassessed and dumping margin is recalculated. Where the insufficient movement in prices is due to a fall in export prices that occurred after the original investigation period, dumping margins may be recalculated to take account of such lower export prices. Where the reinvestigation shows increased dumping, the measures can be amended by the Council, up to twice the amount of duty imposed initially by the Council. The regulation specifies that an absorption investigation is to be carried out "expeditiously": it should normally be concluded within six months but in any event must be concluded within nine months (for absorption reviews initiated after 13 March 2006). An absorption investigation is meant to focus on export price; any alleged changes in normal value

are only part of the investigation where complete information on revised normal values, duly substantiated by evidence, is made available to the Commission within the time limits.

As to absorption in anti-subsidy cases, an absorption review can only be launched if countervailing duties imposed were less than the amount of countervailable subsidies found. The review can be launched by request of the Community producers; any interested party, a Member State, or on the Commission's own initiative. Like in anti-dumping, the request generally has to come within two years from the entry into force of the measures. The Community producers or other interested parties have to provide sufficient evidence that, after the original investigation period and prior to or following the imposition of measures, export prices have decreased or that there has been no movement, or insufficient movement, of resale prices of the imported product in the Community. If the investigation bears this out, countervailing duties can be increased to achieve the price increase required to remove injury. However, the regulation specifies that the increased duty level shall not exceed the amount of the countervailable subsidies.

As to circumvention, the anti-dumping rules and the anti-subsidy rules are more in line with each other, although they are not identical. These rules provide that anti-dumping or countervailing duties (in the "residual" amounts) may be extended to imports from third countries, of the like product, whether slightly modified or not; or to imports of the slightly modified like product from the country subject to measures; or parts thereof, when circumvention of the measures in force is taking place. Circumvention is defined as a change in the pattern of trade between third countries and the Community or between individual companies in the country subject to measures and the Community, which stems from a practice, process or work for which there is insufficient due cause or economic justification other than the imposition of the duty, and where there is evidence of injury or that the remedial effects of the duty are being undermined in terms of the prices and/or quantities of the like product, and where there is evidence of dumping in relation to the normal values previously established for the like product, or where in the case of subsidization, the imported like product and/or parts thereof still benefit from the subsidy. The anti-dumping rules on circumvention go into more detail than the anti-subsidy rules on when an "assembly operation" is considered circumvention.

Anti-circumvention investigations must be initiated, after consultation of the Advisory Committee, on the initiative of the Commission or at the request of a Member State or any interested party on the basis of sufficient evidence regarding the existence of circumvention by a Commission Regulation which may also instruct the customs authorities to make imports subject to registration or to guarantees while the investigation is going on, so that duties can be imposed retroactively. The regulations specify that anti-circumvention investigations shall be concluded within nine months. When circumvention is proven, the Council, acting on a proposal from the Commission, after consultation of the Advisory Committee, can extend the duties.

e. *State aids.* The Commission has no competence to enforce a decision against a Member State. If a Member State does not comply with a Commission decision declaring aid incompatible with the common market, this does not affect the procedure in other State aid cases involving the same Member State. Subsequent State aid procedures are not linked and stand on their own because the effects of the State aid in issue needs to be assessed in each case individually.

The situation can be different if aid is granted subsequently to the same beneficiary: It might be that in one instance the aid granted will be found incompatible with the common market while in a subsequent instance the aid granted in addition will be found compatible with the

common market. If the incompatible aid has already been paid out to the beneficiary, the Commission will oblige the Member State to recover this aid. If the aid has not yet been recovered when the second decision approving the additional aid is adopted, the Commission will oblige the Member State to suspend payment of the difference between the aid to be recovered and the aid authorized by the subsequent decision. Payment will have to be suspended until the Member State has complied with the previous decision to recover the incompatible aid.

Where the Commission adopted a negative decision with regard to non-notified aid, it will also decide that the Member State concerned must take all necessary measures to recover the aid from the beneficiary (a "recovery decision"). The Commission is not authorized to take a recovery decision if the recovery of the aid would be contrary to a general principle of Community law. The aid to be recovered pursuant to a recovery decision includes interest at an appropriate rate fixed by the Commission. The modalities of the recovery are (in principle) governed by the national law of the Member State concerned. However, rules of national law must be interpreted in such a way as to not prevent that enforcement can be actually effected. The Member State concerned is obliged recover the unlawful aid without delay and to take all necessary steps which are available in its legal system, including provisional measures.

The Commission can adopt injunctions (interim orders) as regards unlawful aid or misuse of aid, but not regarding normally notified aid and existing aid. Two types of enforcement injunctions are provided for in Regulation 659/1999: suspension injunctions and recovery injunctions. If the Commission decides that a Member State may intend to grant unlawful aid, it may adopt a "suspension injunction," which requires the Member State concerned to suspend any unlawful aid or aid that is being misused until the Commission has taken a decision on the compatibility of the aid with the common market. The Commission can also adopt a "recovery injunction" to require the Member State to provisionally recover any unlawful aid until the Commission has taken a decision on the compatibility of the aid with the common market. The Commission is only authorized to order provisional recovery of unlawful aid, not of aid that is allegedly being misused. A recovery injunction can only be adopted if the following cumulative criteria are fulfilled: (i) there must be no doubt about the aid character of the measure in question; (ii) there must be an urgency to act; and (iii) there must be a "serious risk of substantial and irreparable damage to a competitor". No such recovery injunction has been adopted to date.

If a Member State does not observe a suspension or recovery injunction, the Commission may refer the matter to the *ECJ* direct and apply for a declaration that the failure to comply constitutes an infringement of the TEC. If a Member State fails to comply with a decision of the Community Courts holding that it failed to comply with the Treaty, the Commission can refer the matter to the Court a second time. In such a case the Court can impose periodic penalty payments until the Member state complies.

f. *Pharmaceutical licensing.* The enforcement of pharmaceutical law and of compliance with the conditions of the marketing authorization by the marketing authorization holder is mainly executed on Member State level. The Commission or the EMEA are therefore generally not directly involved in such enforcement actions. Both may, however, get involved, either to adopt regulatory measures concerning the marketing authorization itself or–in future–to issue penalties for the infringement of obligations by the marketing authorization holder.

As already mentioned above, when Member States notify the CHMP and the Commission that manufacturers or importers have not fulfilled their obligations, or when Member States or the Commission itself consider that enforcement measures should be adopted, the CHMP on Commission request must issue an opinion, which serves as a basis for preliminary and final decisions of the Commission concerning the referred issue. The CHMP and the Commission may also become involved in decentralized procedures if a Member State considers it appropriate to suspend, withdraw or amend an existing marketing authorization. In this case, the CHMP has to assess the issue and provide for an opinion on the intended measure. In such cases, the Member States and the Commission can order preliminary measures to safeguard public health.

In future, the draft Penalties Regulation will provide for a special enforcement measure for the Commission for centrally approved products. If infringement with specific requirements of the pharmaceutical rules occurs, the Commission can order a company to pay penalties. The scope of issuing penalties concerning centrally approved products as proposed will be very broad. The Commission may impose two types of penalties onto the infringer: fines (lump sums) for the infringement of obligations connected to the marketing authorization and periodic penalties for the enforcement of measures of inquiry and of decisions finding the existence of an infringement. In addition, the Commission's competence to issue penalties does not hinder the Member States from enforcing infringements themselves and it could therefore come to parallel enforcement of the same infringements. To avoid this, the draft Regulation foresees communication obligations and a coordination mechanism between the Member States, the Agency and the Commission.

The draft Penalties Regulation foresees a two-step procedure for the imposing of penalties: first, a stage of inquiry conducted by the Agency; and second, a decision-making stage conducted by the Commission. The Explanatory memorandum to the draft regulations explains:

- . The decision to initiate an infringement procedure under the implementing Regulation shall be taken by the Agency, having informed the Commission and national competent authorities.

- . The Agency will equally conduct an inquiry, and to that effect it shall be empowered to require such information to be supplied as is necessary to detect any infringement and to rely on the cooperation of national competent authorities.

- The decisions by the Commission imposing penalties under this Regulation will be based on the opinion of the Agency, following the inquiry, the observations by the marketing authorization holder concerned and, where appropriate, other information submitted to it.

- When carrying out an infringement procedure, the Agency and the Commission will ensure the respect of the rights of defense and of the principle of the confidentiality of the infringement procedure."

10. Strategic concerns

If not discussed elsewhere, this is the place to discuss strategy and tactics. For example, do you have a choice of which country to file in or which language to employ? How do you make this decision? Are there ways to speed up a process or slow it down? To preempt Commission action with a declaratory judgment action in a member state? To use public relations tactics?

b. *Trade remedies:* In terms of strategy, anti-dumping and anti-subsidy investigations tend to proceed without interference once they have been set on the rails. Because of the legal time limits for action, the Commission has a schedule for the conduct of an investigation that it will follow. It is difficult to try to ask the Commission to act more quickly, and it cannot act more slowly without falling afoul of the legal deadlines for action.

There is some room for strategic maneuver in convincing the Commission to initiate a case, at the complaint stage. In terms of language, all anti-dumping and countervailing duty procedures are carried out in English. Although one can submit a complaint in any Community language, submitting in a language other than English will not likely be appreciated, as the Commission is still bound to respect the 45 days from the lodging of a complaint to a decision on initiation. An interested party can also request a copy of the questionnaire and answer it in any one of the Community languages. However, doing so may also be strategically unwise. While the Commission cannot call it "uncooperative" to answer in a Community language other than English, submitting remarks in another language may mean that they must be translated for the case handlers to be able to read them. That may mean that they are too late to have any real impact.

The Commission cannot impose definitive duties; only the Council can do so. Therefore, there is some room for political lobbying of the members of the Council Working Group responsible for trade remedies. Often the same persons are on the Advisory Committee as in the Council Working Group, or at least they work in close collaboration with each other. Each Member State has one vote when it comes to trade remedies, and it takes a simple majority of Member States opposed to block a Commission proposal to impose anti-dumping or countervailing duties.

e. *State aids.* Notifications of State aid measures have to be made to the Commission (not to Member State authorities), so there are no strategic issues as to where to file a notification. The question of whether or not a notification should be made or not does not give rise to such issues either because the obligation to notify State aid does not allow for discretion. A notification can be made in any of the official Community languages and naturally, a Member State will choose its own official language. The choice of the language is of no strategic concern because the language chosen will not have an influence on how the Commission deals with a case or which staff members will handle the case.

Although not set forth in legislation or judicial decisions, in practice informal contacts with the Commission prior to notification of the intended measure are encouraged by the Commission and do actually take place. These contacts allow the Commission a better understanding of the specific circumstances of the case at issue and will result in a more rapid and effective decision-making process after the formal notification has been filed. These first contacts can take the form of correspondence in writing or pre-notification meetings with the Commission.

Undertakings might turn to the Commission and complain about State aid granted to other undertakings that they think was not compatible with the Treaty rules. They can also initiate proceedings before national courts on the basis of the standstill obligation in Article 89(3) TEC. According to this standstill obligation, a Member State is barred from putting into effect State aid before the Commission has taken a decision authorizing the aid. The standstill obligation is directly applicable, which means that it can be enforced directly by Member State

authorities, including courts. A competitor of the beneficiary could try to obtain an injunction before a national court in order to prevent the actual payment of the aid until the Commission has adopted its decision. Likewise, the competitor could ask a national court to declare aid granted before the adoption of a Commission decision unlawful and to order the recovery of this aid.

f. *Pharmaceutical licensing.* Because pharmaceutical law is guided by the general principle of public health, in providing advice, lawyers should also put the principle of public health first.

Companies must ensure the safety of their product. This not only applies to the marketing application phase but also is equally relevant after the marketing of the product starts. The authorities may not only request follow-up information on the product to allow for a continued risk-benefit assessment of the product but companies are themselves responsible for the safety of their product and cannot refer to an issued marketing authorization to avoid civil or criminal liability.

It is therefore crucial that a company shows responsibility for its product and with this demonstrates reliability and credibility, which will build confidence on the regulators part. Responding to regulators questions in an honest and frank way, as well as open cooperation with them on issues raised, will create an environment that allows for a smooth life-cycle management of a medicine together with the regulators.

However, in order to also protect companies' interests, they should stress the importance of procedure and insist on their rights within the procedure in order to be provided with a fair assessment of its medicines.

11. Related questions

11.1 Is there a doctrine of exhaustion of administrative remedies so that a party must raise all issues at the agency level in order to raise them on judicial review? Must a party request reconsideration of decision before seeking judicial review?

a. *Competition.* The law on the question of exhaustion of administrative remedies is not developed. There is no absolute rule, as such, regarding the raising of new pleas in the time between the Commission decision and the CFI judicial review. The parties must have an "legitimate interest" to raise a new plea. While the Commission ought not to be able to add new elements that the applicant did not have the chance to rebut, the position of private parties does not appear to be so rigid. Especially in Article 82 EC cases (and in mergers) where Commission-ordered remedies will be by definition onward-looking and positive, applicants should have a right to produce new evidence that discredits the Commission's approach. Besides, admitting a principle of exhaustion would in essence be equivalent to imposing a duty upon companies to reply to the Commission's accusations during the administrative stage of the proceedings, which is not really the case. Both Regulation 1/2003 and Regulation 773/2004 view the participation in the proceedings by companies that are the target of an investigation only as the exercise of a right and not as the compliance to a duty. Indeed, this seems to be the approach of CFI in *Hilti*, where the Court rejected the argument of the Commission that new pleas that Hilti had made in the judicial review proceedings were inadmissible, because it had not put them forward in the administrative proceedings. The Court held that the applicable rules of procedure "cannot be construed as compelling the undertaking concerned to reply to the statement of objections sent to it ... Although [these rules] seem to be based on a presumption of cooperation on the part of undertakings, cooperation which is desirable from the point of view of compliance with competition law, no obligation to reply to the statement of objections may be inferred in the

absence of any express legal provision to that effect. It should be added that such a duty would, at least in the absence of any legal basis, be difficult to reconcile with the fundamental principle of Community law safeguarding the rights of litigants. The approach for which the Commission argues would in practice create difficulties for an undertaking which, having failed for whatever reason to reply to a statement of objections, wished to bring an action before the Community courts."

c. *Trademarks.* Yes. A party must first exhaust all 'administrative' recourses and go on appeal before the Board of Appeal of the Office in order to possibly bring an action before CFI. Besides, both CFI and ECJ can only review legal findings of the Office, not factual findings.

f. *Pharmaceutical licensing.* There is no specific exhaustion of administrative remedies doctrine that requires a party to raise all issues at the agency level in order to be able to raise them in judicial review proceedings. As a practical matter, however, all relevant information should be made available in due time so that it can be taken into account during the scientific review. In addition, procedural irregularities are best objected to during the procedure so as to allow the institutions to take corrective action. Finally, although a request for reconsideration of an initial CHMP opinion is not a prerequisite for seeking judicial review of the final decision, it is clearly advisable to request a reconsideration if judicial review will be based on issues that can be adequately addressed during such reconsideration.

11.2 If a party raises an argument during the investigation or the hearing and the Commission fails to respond to it, could this failure be an issue on judicial review?

a. *Competition.* The Commission is under an obligation to prove its case, in particular it must produce sufficiently precise and coherent proof to support its allegations and must sufficiently show the facts and assessment on which the decision is based. Both inculpatory and exculpatory evidence must be considered in the Commission's decision and the Commission may not conceal exculpatory evidence from the parties. The Commission's duty does not include full and impartial discovery of all relevant facts.

b. *Trade remedies:* The mere failure to discuss one of the issues that an interested party raised is not *ipso facto* reversible error. However, it can subsequently become an issue before the Court, for example as an allegation that the Community institutions made a manifest error of assessment, evinced by the fact that they did not address an issue of importance which an interested party raised.

c. *Trademarks.* The failure to respond to an argument raised by a party during proceedings before the Office may only be an issue on judicial review to the extent that no more procedural recourse are available before the Office and that, by not responding to the argument raised, the Office has failed to comply with its obligation to state the reasons on which its decision is based. The grounds for an action before the courts are limited to: lack of competence, infringement of an essential procedural requirement (such as lack of motivation of its decision by the Office), infringement of the Treaty, of Regulation, or of any rule of law relating to their application or misuse of power.

f. *Pharmaceutical licensing.* In line with the general principles of Community law, failure to address a relevant argument can render the decision void for lack of adequate reasoning. This will, however, not automatically be the case and will depend on the circumstances.

11.3 Is a duty of care imposed on the Commission to fully and impartially discovers all of the relevant facts?

b. *Trade remedies:* The Community institutions tend to view their obligations as passive rather than active. They consider it the interested parties' responsibility to communicate all relevant information to them, which they receive and process. Should parties fail to supply relevant information, the Commission feels free to proceed on the basis of the "facts available."

There are some indications in the regulations that the Community institutions have some duty to actively inquire. For example, the anti-dumping and anti-circumvention regulations say that if determinations are made on the basis of the "facts available," including the information supplied in the complaint, the Commission is supposed, "where practicable and with due regard to the time limits of the investigation" to check that information by reference to information from other independent sources which may be available, such as published price lists, official import statistics and customs returns, or information obtained from other interested parties during the investigation. This obligation is also stated, albeit in even more aspirational language, in the safeguards regulation. The Commission shall seek all information it deems to be necessary and, where it considers it appropriate, after consulting the Committee, endeavor to check this information with importers, traders, agents, producers, trade associations and organizations.

However, it is submitted that the Community institutions have a more active duty to seek and check information than they generally perceive. They, after all, have to meet their burden of proof that the requisite factors permitting them to take trade remedies action are present. They should not content themselves with the information submitted to them, but should actively crosscheck the information at their disposal and seek any information that is lacking.

c. *Trademarks.* No. As already stated above, the Office has no powers to discover the facts. Rather, it belongs to the parties to search about the facts and to present evidence as to these facts. The Office is required to take into account only those facts as alleged and presented by the parties. The only situation where the Office can discover 'facts' is when it makes the search report (see point 4.2. above). A duty of care is then imposed on the Office to fully and impartially search for the earlier Community trademarks or Community trademark applications which may be invoked as *relative* grounds for refusal against the registration of the Community trademark applied for. This duty of care does however not extend to the national search reports operated by national offices in their own register of trademarks and communicated to the Office.

f. *Pharmaceutical licensing.* The primary interest that must be taken into account is the protection of public health. The pharmaceutical licensing system is, however, mainly based on applications for marketing authorizations and there is no duty on the EMEA or the CHMP to collect new data on their own. The review is based on data submitted by the applicant and on data that are otherwise available, such as the scientific literature and experience held by regulators (supplemented occasionally with data submitted by third parties).

11.4 Is there a principle of res judicata?

a. *Competition.* The principle of *ne bis in idem* is one of the fundamental principles of Community law. In the context of EC competition law, this principle precludes commencing proceedings against a company anew, if such proceedings would result in the imposition of either a second penalty, in addition to the first, in the event that liability is established a second time, or a first penalty in the event that liability not established by the first decision is established by the

second. However, it does not preclude the resumption of proceedings in respect of the same conduct where the first decision was annulled for procedural reasons without any ruling having been given on the substance of the facts alleged. In such case, fines imposed in the new decision replace the fines imposed in the annulled decision.

The Commission is must also observe the prohibition on double jeopardy if the procedure before the Commission commences after a competition authority or a court in a Member State decided on the same matter and imposed fines. In such case, the sanction imposed by the Commission must take into consideration any prior sanction in order to respect the principle of proportionality. In such cases the Commission may, however, draw inferences from evidence it has gathered and it is not bound by the conclusions reached at the national level.

The position of the ECJ is different in respect of third country regulatory action. The ECJ said in particular that antitrust proceedings before the American authorities and those before the European Commission were essentially different as regards both their object and their geographical emphasis. Thus, the Court concluded that in such situation two sets of proceedings against the same person for the same infringement were justified as long as they pursued different ends. Consequently, the Commission may decline, for the purpose of fixing the fine, to take into account fines imposed in parallel third country proceedings or payment of damages in civil-law actions in third country jurisdictions. This was confirmed in the recent *Amino Acids* case by the CFI. The Court acknowledged that *nonbis in idem* is a general principle of Community law. It then recalled the case-law to the effect that while concurrent sanctions resulting from two sets of parallel proceedings, at EU Member State and Community level, are in principle acceptable because those proceedings pursue different ends, the Commission must, when determining the amount of a fine in such cases, take account of any penalties already imposed under national cartel law on the company in question for the same conduct. The Court reasoned that *a fortiori*, the principle did not preclude concurrent procedures and penalties in the EU and the US, since the two legal systems clearly pursued different ends.

b. *Trade remedies.* In Industrie *des Poudres Sphériques,* the applicant claimed that because the Court had annulled a Council regulation, the Commission was prohibited by the principle of *res judicata* to resume the investigation. The Court disagreed, saying that the Commission could lawfully resume the proceeding on the basis of all the acts in the proceeding, which were not affected by the annulment.

c. *Trademarks. .* The principle of *res judicata* applies to relative grounds for invalidity are concerned. The proprietor of an earlier mark or an earlier right who has previously applied for a declaration of invalidity or made a counterclaim to this end in infringement proceedings may not submit a new application for a declaration of invalidity or lodge a counterclaim on the basis of other rights (and *a fortiori* on the basis of the same rights) which he could have invoked in support of his first application or counterclaim. Similarly, and although this is not expressly stated, the proprietor of an earlier mark or earlier right who brought opposition proceedings and who lost the case in opposition may not further submit an application for a declaration of invalidity or lodge a counterclaim for invalidity on the basis of a right which he could have invoked in the opposition proceedings.

An unsuccessful CTM applicant or a CTM holder whose trademark has been later invalidated will not be able to apply a second time for the same trademark for the same classes of goods or services. The Register of Community trademarks contains a list of the trademarks revoked and refused or invalidated on basis of absolute or relative grounds for refusal or

invalidity. This list is also available in the form of a database with search engine on the following Internet address:
http://oami.eu.int/search/legaldocs/la/en_refused_index.cfm the Office may consult this list in order to check whether a trademark has already been applied for and whether it has already been refused or invalidated.

e. *State aid.* EC administrative law knows the principle of *res judicata*. The principle of *res judicata* extends to matters of fact and law actually or necessarily dealt with by a decision (or a Court judgment). It means that a Member State or a private party that has failed to appeal a Commission decision (or a legislative act open to appeal) within the two months time period can not question the original decision, even indirectly.

The Commission itself can only modify an otherwise unassailable decision, if the conditions for modifying a lawful (or unlawful) administrative act are fulfilled. Moreover, the Commission may reconsider a decision, if new facts come to light that were not dealt with in a previous decision. However, Member States and private parties are not normally entitled to such a review.

A limited exception is contained in Article 88(2) TEC, which provides that the Commission must keep existing aid under constant review. This relates mainly to existing aid schemes, and the interests of legal certainty are safeguarded by the fact, that changes to existing aid apply only for the future.

Moreover, the principle of *res judicata* does not apply where the there is an express provision that allows for the revocation of a decision and the subsequent adoption of a new decision in the same case. Regulation 659/1999 gives the Commission competence to revoke a decision where it was based on incorrect information provided during the procedure, which was a determining factor for the decision.

f. *Pharmaceutical licensing.* In line with the general principles, decisions of the ECJ or the CFI result in *res judicata* and administrative decisions that are not challenged in time by interested parties become definitive towards them. There is, however, no broader principle of *res judicata* by administrative practices or guidelines, which can be tested on their legality each time they are being followed.

11.5 Is there a principle of equitable estoppel? For example, assume a Commission staff member gave a private party erroneous advice, which caused the private party to detrimentally rely on the advice. Any relief in such a case?

a. *Competition.* In the case of Notices/Guidelines/Communications published by the Commission and describing the Commission's policy in certain areas, parties may rely threupon and resist any subsequent action by the Commission that departs from its statements, as contained in those Notices or Communications. This has been accepted by the Commission itself and has been expressly confirmed by the European Courts. Thus, CFI has held that such Notices are legally binding on the Commission, provided they do not depart from the rules in the Treaty and from secondary legislation. As explained also above, the Commission may not depart from rules which it has imposed on itself. This is particularly the case when the Commission limits its discretion.

b. *Trade remedies.* No.

c. *Trademarks.* No. There is no doctrine applicable to the proceedings before the Office preventing a first party to take unfair advantage of a second party when, through false language or conduct, the first party (or also in this case, the Office) has induced the second party to act in a certain way, with the result that this second party has been injured in some way. It belongs to each party to defend their own cases before the Office and to fully comply with the CTM regulations that contain all the restrictive procedural rules applicable in proceedings before the Office. One provision regarding the possibility to lodge an appeal against decisions of the Office actually contemplates this issue and confirms the above. The rules expressly state that the parties may not plead any failure by the Office to communicate the availability of appeal proceedings.

e. State aids. EC administrative law does not recognize the concept of equitable estoppel as such, but there are a number of instances in which similar results are achieved in practice. The clearest examples are cases in which the Commission had qualified, outside a proper proceeding, that a certain measure did not constitute state aid. The Commission's statements made in its annual competition reports and in response to parliamentary questions, could not affect the law and the legal qualification of the measures as (non-notified, new) state aid. When the Commission did open an investigation, it determined that the measures were aid, and that they were both unlawful and incompatible with the common market. Normally that would have required the Commission to order their repayment. The Commission, with reference to its own acts (and referring also to the principle that legitimate expectations must be respected), decided to limit its decision to a finding that the state aid was incompatible with the common market, and expressly did not order recovery. A similar case might have been considered, in an Anglo-Saxon setting, as an example of equitable estoppel.

Another example is a (rather exceptional) decision awarding damages because erroneous advice was given and had corrected immediately. While an incorrect interpretation of a Community regulation by a Commission department and its communication to the applicant does not constitute in itself a wrongful act and therefore does not entail the Community's liability, the Community institution having provided incorrect information is under a duty to rectify that information as soon as it has become aware of its incorrectness. Any "failure to make such a correction is […] of such a nature as to render the Communities liable." The legal basis for such non-contractual liability is Article 288(2) TEC, which obliges the Community to "make good any damage caused by its institutions or by its servants in the performance of their duties."

f. *Pharmaceutical licensing.* It is a clear principle of Community law that legitimate expectations must be respected. However, the primary interest of decisions in the pharmaceutical field is to protect public health and this will override expectations of private parties, even if they result from actions of the EMEA or the Commission. In very clear cases, the latter could give rise to a claim for damages but could not prevent the adoption of measures that are needed to protect public health.

11.6 Is there an obligation of consistency, meaning Commission must follow existing precedent or explain why it has been departed from?

a. *Competition.* The Commission is obliged to follow the jurisprudence of ECJ and CFI but is not bound by the interpretation adopted in its own decisions, although it is required to reason its decision carefully where it has adopted a new legal interpretation.

c. *Trademarks.* The analysis made for each case by the Office is mostly factual, due to the fact that it concerns specific trademarks and specific products or services. As such, the

solution given to one case may not be the same in another case. There is a principle applicable according to which each case must be assessed in view of its own characteristics and merits. This principle is derived from the jurisprudence of appeal Boards of the Office and has as a consequence that the Office is not bound by its own mistakes. Consequently, there is no obligation of consistency as such, although the Office is supposed to motivate its decisions and will thus generally explain why it departs from existing precedent. The lack of motivation of an Office's decision or a departure from established precedents will open the door to appeal before the Board of Appeal or before the ECJ.

e. State aids. The Commission is obliged to adhere to the rules of Regulation 659/1999 and apply the substantive standards enunciated in the Treaty rules on State aid. This in itself should ensure consistency in the Commission's decisional practice. In addition, the Court has developed in its case law the principle of the protection of legitimate expectations: In a situation where the Community authorities have caused an economic actor or any other person to entertain legitimate expectations, the individual has the right to rely on the principle of the protection of legitimate expectations. For example, the publication of guidelines or notices, where the Commission summarizes its past decisional practice and sets out its policy position, will be a source of legitimate expectations. In order to provide guidance, the Commission published a number of guidelines and communications also in the field of State aid.

f. *Pharmaceutical licensing.* In *Dr. Karl Thomae GmbH v Commission*, Case T-123/00, ¶¶77-78, the CFI stressed the need for consistency in the context of allowing different trade names for a centrally approved product.

11.7 Are hearings or other proceedings open to the public?

a. *Competition*. The hearings before the Commission are not open to the public. Members of the public are entitled to attend hearings before CFI and ECJ.

b. *Trade remedies*. No.

c. *Trademarks.* See above point 6.1.2.

e. *State aids.* Proceedings before the Commission are not public, and discussions among the Commissioners are confidential. This is explicitly laid down in the Rules of Procedure of the Commission.

f. *Pharmaceutical licensing.* Hearings are not open to the public because they typically involve discussion of business secrets. Public hearings are sometimes organized by the Commission and the EMEA on broader policy issues.

11.8 Is the Commission obliged to follow its procedural rules even if those rules were not otherwise legally required?

a. *Competition.* The Commission has issued a number Guidelines/ Notices/Communication which state the Commission's understanding of substative law or procedural rules that the Commission will apply. These documents include, *inter alia*, the Guidelines on the method of setting fines and the Leniency Notice. The Commission accepted that it is bound by these documents. and this has been expressly confirmed by the European Courts (see ¶11.5 above).

c. Trademarks. All procedural rules of the OHIM are expressed in the CTM regulations and guidelines. Infringement of these rules may cause an appeal to be lodged against the infringing decision.

f. *Pharmaceutical licensing.* As a rule, the Commission and the EMEA have to follow these rules. There may be exceptions when clearly needed to protect public health.

11.9 Is there a "harmless error" rule with regard to all of the various procedural requirements discussed above? (A "harmless error" rule means that a court will not overturn the administrative decision even though procedural errors were committed if those errors did not affect the result)

a. *Competition.* Only certain procedural irregularities will result in a Commission decision being quashed by the CFI or ECJ. Article 230 of the EC Treaty that specifies grounds for an appeal against a Commission decision refers to "infringement of an essential procedural requirement' and to infringement of 'any rule relating to the application of the Treaty."
It is also settled case-law that a decision will be annulled only if a party appealing a decision on the grounds of procedural irregularity is able to show at least the possibility that the result would have been different, had the Commission did not commit an error complained of.

b. *Trade remedies:* There is no "harmless error" standard written into the regulations requiring a court not to overturn the administrative decision because of procedural errors that did not affect the result. However, a "harmless error" can be read *a contrario* from the Court's judgment in the *NTN/Kyoto Seiko* case: "In the light of those factors and bearing in mind, furthermore, the misleading or inaccurate statements in paragraphs 27, 32, 36 and 37, it is possible that in the absence of those errors of fact and law the Council would not have found that there was a threat of injury. Consequently, the forms of order sought by the applicants should be granted and the contested regulation annulled in so far as it affects them." In other words, one could interpret *NTN/Kyoto Seiko* to mean that in a case where the errors could not have a meaningful effect on the result, they would not result in annulment.

c. *Trademarks.* Such a rule is implied in the sense that indeed, a decision of the Office will not be overturned if the procedural errors committed did not affect the result and if these errors were the only basis for the review sought.

f. *Pharmaceutical licensing.* Procedural errors only invalidate a decision when they concern an "essential procedural requirement" and the error at least potentially affected the outcome of the procedure.

12. Other remedies for private parties

12.1 What remedies exist in the case of alleged mal-administration aside from judicial review?

e. *State aids.* In general, complaints about alleged mal-administration can be lodged with the Secretariat-General of the Commission whenever there has been a violation of the of the principles set out in the "Code of Good Administrative Behavior," which is annexed to the Rules of Procedure of the Commission. The Secretariat-General has to forward the complaint to the

relevant department. Within two months, the Director General or head of Department must reply to the complainant in writing. After this, the complainant can apply to the Secretary-General to review the outcome of the complaint; the Secretariat-General has to reply to this request within one month.

f. *Pharmaceutical licensing.* Judicial review is the main remedy for pharmaceutical companies if they feel that an administrative decision has not been properly performed.

However, the *Capoten* case, in which the Commission withdrew its decision after the company lodged a claim with CFI, shows that there may be remedies outside judicial review. Specific complaint procedures investigating maladministration are not explicitly foreseen in the pharmaceutical rules. But the Codes of Conduct of both, the EMEA and the Commission require these bodies to be in line with good administrative behavior. The Commission's Code of conduct also provides for a complaint procedure to investigate in an alleged misadministration (based on the Code of Conduct). Details of the Code together with practical information on its "enforcement" can be found on the following web site: http://europa.eu.int/comm/secretariat_general/code/index_en.htm. Other than that, an applicant or marketing authorization holder may, in principle, start a new procedure at any time.

12.2 Ombudsman

a. *Competition.* EU citizens and companies are entitled to complain to the European Ombudsman with respect to maladministration in the activities of the Community institutions or bodies. Thus, it is possible to complain to the European Ombudsman about instances of administrative irregularities or unnecessary delay in the work of DG COMP, unfairness, discrimination or violations of the Code of Good Administrative Behaviour by the Commission staff.

b. *Trade remedies:* An interested party may be able to turn to the European Ombudsman regarding maladministration by the Community institutions, if it is a citizen of the Union or any natural or legal person residing or having his registered office in a Member State of the Union. The European Ombudsman is tasked with uncovering maladministration in the activities of the Community institutions and making recommendations with a view to putting an end to that maladministration. If it is no longer possible for the institution concerned to eliminate the instance of maladministration and the instance of maladministration has no general implications, the ombudsman can make a "critical remark" about it.

c. *Trademarks.* Any citizen of the European Union and any natural or legal person residing or having its registered office in a Member state of the Union may file a complaint with the European Ombudsman concerning instances of maladministration in the activity of the Community institutions and of the OHIM in particular.

The Ombudsman (website: http://www.euro-ombudsman.eu.int/home/en/default.htm) conducts inquiries on the basis of complaints (or at its own initiative) and in accordance with his duties, except where the alleged facts are or have been the subject of legal proceedings. Where the Ombudsman establishes an instance of maladministration, he shall refer the matter to the institution concerned, which shall have a period of three months in which to inform him of its views. The Ombudsman shall then forward a report to the European Parliament and the institution concerned. The person lodging the complaint shall be informed of the outcome of such inquiries.

The intervention of the European Ombudsman is expressly provided in the CTM regulation regarding the access to documents of the European institutions. 'Confirmatory' decisions taken by the Office refusing (totally or partially) access to documents by a person requesting it may give rise to the lodging of a complaint to the Ombudsman under the conditions laid down in Articles 195 of the Treaty (or form the subject of an action before the ECJ).

Only citizens of EU Member States, persons residing in those States and businesses, associations or other bodies with a registered office in the Union may complain to the European Ombudsman. Before filing the complaint with the European Ombudsman, the complainant must approach the institution or body concerned. Complaints may be filed only by persons individually affected by the maladministration. The person lodging the complaint may request his complaint to be confidential, but the complaint must allow the identification of the person lodging the complaint and the object of the complaint.

The Ombudsman investigates if the complaint is well grounded. If the Ombudsman establishes an instance of maladministration, he informs the institution concerned and makes a draft recommendation. The institution concerned has three months to give its detailed opinion on the issues raised by the Ombudsman. The Ombudsman then forwards a report to the European Parliament and the institution concerned. The person lodging the complaint is informed of the outcome of such inquiries.

e. *State aids.* Any citizen of the Union and any natural or legal person residing or having its registered office in a Member State have the right to complain to the European Ombudsman. The performance of the Ombudsman's duties is governed by the respective regulations and general conditions (the "Statute of the European Ombudsman") adopted by the European Parliament pursuant to Article 195(4) EC.

The subject of complaints to the European Ombudsman can be "instances of maladministration in the activities of the Community institutions or bodies (other than community courts). The Ombudsman has defined the term "maladministration" as follows: "Maladministration occurs when a public body fails to act in accordance with a rule or a principle binding upon it." In order to determine what is an instance of maladministration, the Ombudsman is called to apply the "Code of Good Administrative Behavior", which is annexed to the Rules of Procedure of the Commission. This "Code of Good Administrative Behavior" sets out certain principles (like lawfulness, proportionality, impartiality and independence, and objectivity) that the Community institutions and bodies must respect.

Following a complaint—but also upon his own initiative—the Ombudsman is obliged to conduct enquiries to clarify any suspected maladministration. He will inform the institution or body concerned thereof, and these are invited to submit any useful comment to the Ombudsman. The institutions and bodies, as well as Member States' authorities, are obliged to supply the Ombudsman with any information he has requested of them and give him access to the file concerned, unless there are "duly substantial grounds of secrecy" or unless such information is covered by laws or regulations on secrecy. The Ombudsman and his staff are obliged not to reveal any information or documents, which they obtain in the course of their inquiries.

As far as possible, the Ombudsman should seek a solution with the institution or body concerned to eliminate the instance of maladministration and to satisfy the complainant. If the

Ombudsman finds that there has been maladministration, he will inform the institution or body concerned and might make draft recommendations. The institution or body concerned then has three months within which to prepare a detailed opinion. Thereafter, the Ombudsman will issue a detailed report and send it to the European Parliament and the institution or body concerned. In this report, the Ombudsman may make pertinent recommendations. The complainant will be informed of the outcome of the inquiries, of the opinion expressed by the institution or body concerned, and of any recommendations made by the Ombudsman.

12.3 Quashing evidence

a. *Competition.*If a decision by the Commission to order an investigation is annulled by the Community judicature, the Commission is prevented from using, for the purposes of proceeding in respect of an infringement of the Community competition rules, any documents or evidence which it might have obtained in the course of that investigation, as otherwise the decision on the infringement might, in so far as it was based on such evidence, be annulled by the Community judicature.

c. *Trademarks.* In order to solve possible quashing evidence issues, the Office may request that further evidence be filed, and proceed with any taking of evidence that is available to it, including hearing of the parties, hearing of witnesses and opinions by experts.

e. *State aids.* The "quashing" of evidence is not a distinct administrative remedy known in Community administrative law. It will of course always be admissible to rebut factual evidence advanced by the Commission in State aid proceedings. As the procedure is one between the Commission and the Member State concerned, it is upon the Member State to demonstrate that the evidence adduced by the Commission is unsound or unconvincing. The undertakings to which the Member State intends to grant aid might assist the Member State in that regard and also submit relevant observations to the Commission. Undertakings might also support the Commission and try to provide it with information that corroborates the Commission's views; particularly, competitors of the undertakings who will be the beneficiaries of the aid granted, will have an incentive to support the Commission in this way.

f. *Pharmaceutical licensing:* There are no specific rules under the pharmaceutical legislation allowing certain evidence to be excluded from regulatory dossiers. On the contrary, there is a general principle that all relevant information should be reviewed, even if certain conditions are not satisfied in relation to certification of the reliability of the data. The situation is different under the proposed Penalties Regulation. Evidence may have to be excluded in order to ensure the fairness of the procedure.

12.4 Damages

a. *Competition.* Under Article 288(2) EC "the Community shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its institutions or by its servants in the performance of their duties." The European Courts' case law in this area is rather conservative and the conditions of the Community's extracontractual liability to arise are very stringent. The possibilities of success of damages actions are rather meagre and in the past forty years cases where applicants were successful against a Community institution have been rare indeed. There are three basic requirements: (a) there must be a wrongful act or omission on behalf of the Community institution (here the Commission), (b) a damage

suffered by the applicant, and (c) a causal link between the two. When the Commission enjoys discretion, as the case here, a sufficiently flagrant violation of a superior rule of law for the protection of the individual must have occurred. Causality must be direct, immediate and exclusive. The damage suffered must be certain and specific, proven and quantifiable. The interpretation of those conditions by the European Courts is very restrictive. However, the CFI has recently held that the Commission may enjoy a margin of appreciation, but this does not mean that it is not bound by the duty to act with due care and the principle of good or sound administration. In particular, it must duly take into account all relevant facts that are indispensable to the exercise of its discretion. Especially when the Commission enjoys a wide margin of appreciation, respect of procedural guarantees conferred by the law upon individuals is of fundamental importance and may lead to an action for damages against the Commission.

c. *Trademarks.* N.A. besides the fact that the losing party in opposition proceedings, proceedings for revocation or for a declaration of invalidity or appeal proceedings, must bear the fees incurred by the other party as well as all costs incurred by him essential to the proceedings, within the limits of the scales set for each category of costs, and unless the parties agree otherwise.

e. State aids: According to Article 288(2) TEC, the Community is obliged to make good any damage caused by its institutions or by its servants in the performance of their duties. Liability of the Community has to be determined alongside the general principles common to the laws of the Member States and requires proof of (i) unlawful conduct on the side of a Community institution, (ii) damage, and (iii) a causal link between the breach of Community law and the damage. In the context of State aid, the Community might incur liability, for example, if the Commission wrongfully approves aid, or if it negligently fails to prosecute the implementation of unlawful aid. If a competitor of the recipient of such unlawful aid can prove damage and to establish a causal link between the Commission's unlawful conduct and damage suffered, the Community will be liable on the basis of Article 288(2) TEC. Where a Member State rather than the Community is guilty of unlawful conduct, competitors may bring an action for damages only in a national court against a Member State and only pursuant to national law.

It is possible that a competitor might also sue the aid recipient for damages under national law. Community law cannot serve as a basis for the recipient's liability because the standstill obligation in Treaty Article 88(3) is directed to Member States and does not impose any specific obligation on the recipient. That does not, however, prejudice the possible application of national law concerning non-contractual liability of the recipient. A national court might hold a recipient of aid paid in breach of the standstill obligation liable if under national law "the acceptance by an economic operator of unlawful assistance of a nature such as to occasion damage to other economic operators" is a valid cause of action.

f. *Pharmaceutical licensing:* In principle, a company can claim damages if it is improperly refused a marketing authorization, variation, suspension or withdrawal. However, the threshold is high and claims for damages against Community institutions are rarely successful. In addition, there are no specific rules relating to liability in the pharmaceutical sector.

The standards for entitlement to damages vary according to whether the act that caused the damage was discretionary. In the case of discretionary acts, liability on the basis of Article 288 of the EC Treaty only arises (among other conditions) if the violation was manifest and grave or sufficiently serious. The courts have a great deal of discretion in determining if there has been a sufficiently serious violation. In relation to non-discretionary acts, a claimant merely needs to show that the act was illegal and caused damages.

12.5 Action for failure to act.

e. State aids. A complaint by the Member State concerned that the Commission has not started investigations against other Member States which maintained or introduced similar measures as the ones the Commission is investigating will in itself not render the investigations against the Member State concerned illegal. Nonetheless, as far as the measures applied by the other Member State, which is not the subject of Commission investigations, the Member State concerned (but also any other Member State and any Community institution) could bring an action against the Commission before the ECJ or CFI for failure to act. An action against the Commission for failure to act is only admissible (i) if there is a duty upon the Commission to act, and (ii) if it has first been called upon to act and it had not defined its position within two months after having been called upon.

The situations where the Commission is obliged to take a decision are defined in Regulation 659/1999. One of these situations is that the Commission is in possession of information about alleged unlawful aid. It has to examine that information without delay and must take a decision either that the measure in question does not constitute aid, that it is compatible with the common market, or that the formal investigation procedure will be opened. The Commission first must be called upon to act. If the Member State, which wishes the Commission to investigate another Members State, has not called upon the Commission to act, the action for failure to act will be declared inadmissible. The applicant in the action for failure to act would have to call upon the Commission to address an act to the applicant.

f. *Pharmaceutical licensing.* Claiming damages for not having authorized a medicine or having delayed the authorization of a medicine, or for having suspended or withdrawn an authorization, which then has caused losses in the return of a company, is in theory an option for a company. However, successful claims concerning damages on EC level are rare in general and have not yet been lodged concerning human pharmaceuticals. The general substantive requirements for lodging a claim for damages are dependent on the nature of the act. In liability for Acts of Community bodies there is a distinction between discretionary and non-discretionary acts.

In case of discretionary acts, liability on basis of Art. 288 of the EC Treaty is dependent on the requirement that the claimant can show a violation of superior rules of law for the protection of individuals; that the violation was manifest and grave, or sufficiently serious; and that the violation has caused damages. The margin of discretion is decisive for the application of the requirement of a sufficiently serious violation. In case of non-discretionary acts a claimant needs to show the existence of illegality, causation, and damage.