Chapter 1

ADJUDICATION

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ADMINISTRATIVE LAW OF THE EUROPEAN UNION

ADJUDICATION

CO-REPORTERS ON ADJUDICATION

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How to read this report

This report analyzes administrative adjudicatory procedures in the European Union.[1] The executive summary briefly presents our overall findings. Part I discusses our three most significant findings: adjudicatory procedure differs in each of the six regulatory sectors we studied; Commission's adjudicatory procedures are inquisitorial rather than adversarial in nature; and a strong trend has emerged in favor of requiring Commission decisionmakers to provide procedural protections. Part II presents a brief summary of adjudicatory procedures in the six sectors. A detailed summary of procedures in those six sectors (approximately 120 pages in length) and the full sectoral reports (about 400 pages in length) are available from the co-reporters. Both the detailed summary and the full sectoral reports will be published separately.

Executive Summary

This report considers the adjudicatory procedures of the European Commission and other executive agencies of the European Union. It draws comparisons and distinctions with administrative law in the US and other common law jurisdictions. Sometimes adjudicatory procedures are referred to as "decision-making" procedures and the report uses these terms interchangeably. The report does not consider adjudicatory procedures at the Member State level nor judicial review issues. It refers to decisions of specific rather than general applicability. The report considers adjudicatory procedures in six sectors: competition, trade remedies, trademarks, food safety, pharmaceutical licensing, and state aids (meaning state subsidies or other benefits). These sectors account for most (but not all) of the adjudicatory decision-making at the EU level.

Three overall themes emerge from this study and are discussed in Part I. of the report First, there is no single adjudicatory procedure applicable across all the sectors studied. The procedures in the six sectors differ in numerous respects. Thus EU adjudicatory procedures are quite different from those employed in the US or in other common law jurisdictions such as the UK where there are procedural templates that describe most administrative adjudicatory procedures. (Part I.A.)

Second, EU adjudicatory procedure is "inquisitorial" rather than adversarial. In this respect also, EU procedures differs sharply from most of the administrative procedures employed in the US and UK. This difference manifests itself most clearly in the area of hearings. A notable feature of inquisitorial systems is that hearings are considered part of the investigation, rather than a phase that occurs after the investigation is completed. As a result, there is no separation of functions between staff members engaged in investigation and those who provide adjudicatory hearings. Instead, hearings are conducted by the same personnel who are responsible for the investigation (competition cases are an exception). Rights usually associated with administrative hearings in common law systems (such as the structured presentation of proofs and the cross-examination of adverse witnesses) are not present. The purpose of the hearing is to provide a forum for the presentation of additional information or analysis to facilitate the investigation, rather than a process resulting in a decision separate from the investigation. (Part I.B.)

[1] We are grateful for the research assistance of Gabe Grossman and for the editorial assistance of Nancy Landreville, Jeff Lubbers, and Eleanor Fox and for all the other lawyers and EU officials who have read and offered constructive suggestions. Our sectoral reporters wrote encyclopedic treatments of the procedural aspects of each of their sectors and met all deadlines. We would like particularly to thank Xavier Lewis of the Legal Service for his many generous contributions to this work.

Third, an evolving body of case law from the European Court of Justice (ECJ) and the Court of First Instance (CFI) provides substance to the rights of defense and of good administration. Although these rights arise out of a fundamentally inquisitorial procedure, they are in many respects comparable to US procedural due process or UK natural justice. Indeed, there has been a marked convergence between US and UK procedures, on the one hand, and EU procedures on the other. Thus private litigants enjoy the rights to receive detailed notice of the Commission's position, to inspect the Commission's file, to lodge objections (often in an oral hearing), to receive a decision within a reasonable time, and to receive a statement of reasons for the Commission's action. (Part I.C.)

Finally, Part II. consists of a brief summary of adjudicatory procedures employed in the six sectors we studied.

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I. ADJUDICATION IN THE EUROPEAN COMMUNITY: GENERAL THEMES

Introductory note: This report concerns adjudicatory decisions taken at the European Commission level, not those taken at the Member State level. The great majority of regulatory schemes involving private companies are administered by Member States (in many cases pursuant to legislation adopted at the Community level).

The report is intended as a practical rather than a theoretical account of EU administrative procedure. Its target audience is lawyers who represent clients in adjudicatory procedures before the Commission, particularly lawyers from outside the European Union. The report is written from the perspective of a US practitioner, and uses US administrative procedures as its frame of reference. Where appropriate, the report draws comparisons and distinctions between the processes observed in the EU and those that exist in the US and other common law countries, such as the UK.

For purposes of this report, the term "Commission" includes not only the Commission itself but also European "agencies" empowered by the Council to play key roles in making individualized decisions. These agencies include the Office of Harmonization in the Internal Market (OHIM) which administers the EU trademark law; the European Agency for the Evaluation of Medical Products (EMEA) which plays a key advisory role in pharmaceutical licensing; and the European Food Safety Authority (EFSA) which carries out important functions in food safety regulation.[2]

The report considers adjudicatory procedures at the administrative level, not issues relating to judicial review by Community courts. The emphasis is on procedural protections available to private parties in connection with these proceedings.

The report concerns *decisions of specific applicability* (that is, adjudication) within the six sectors we studied. It does not concern decisions of *general* applicability (that is, rulemaking), although in some cases the Commission's final decision may take the form of a rule (that is, a statement of general application rather than an individualized decision).[3] These decisions involve the application of general norms to particular facts in order to impose legal effects (such as penalties, denial or grant of permissions, changes in legal status, or orders to alter conduct) on parties (usually private parties but sometimes Member States). The report does not consider the impact of the European Constitution since it is presently uncertain whether the Constitution will be ratified and enter into force. If the Constitution does become effective, its provision on administrative justice will likely broaden and constitutionalize procedural rights already recognized in various regulations and court decisions.[4]

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[2] See Geradin 2005.

[3] According to numerous ECJ and CFI cases, the right to a hearing applies only to adjudicatory decisions, not to rulemaking or quasi-legislative decisions. See Craig 2006 316-22.

[4] Art. 41(2) of the Charter of Fundamental Rights of the European Union (2000), which would be embodied in the EU Constitution, provides for a right to "good administration." Good administration means that every person has a right to have his or her affairs handled impartially, fairly, and within a reasonable time; every person has a right to be heard before any measure which would adversely affect him or her is taken; every person has a right of access to his or her file, while respecting the legitimate interests of confidentiality and professional and business secrecy; and the administration is obligated to give reasons for its decision. See Chiti 2004 at 43-44; Craig 2006 at 385-87. While the right to "good administration"

Overview

Part I of this report consists of a discussion of three general themes that emerge from the sectoral reports we have received as well as our own research about European administrative law.

- Commission-level adjudication has no common set of procedures. The procedures are different in each of the six sectors we have studied (Part I. A.) Part II summarizes the key features of the procedures employed in each of the six sectors.

- Commission-level adjudication is inquisitorial in nature rather than adversarial. (Part I. B.)

- While administrative procedure is guided by general principles of Community law (such as the right to defense, the right of good administration, and the duty to state reasons), a trend has emerged in the decisions of Community courts in favor of providing additional procedural protections for private parties engaged in Commission-level adjudication. (Part I. C.)

A. EC adjudicatory procedures in the six sectors differ from each other.

Differences between the sectors.

A striking aspect of the six areas studied was the heterogeneity of processes across the various sectors. In the US and UK, adjudicative processes have evolved around a common model. US administrative law provides an opportunity for a trial type hearing officer in the case of most administrative adjudication involving resolution of disputed facts. In cases covered by the Administrative Procedure Act (APA), [5] this hearing officer is an administrative law judge (ALJ). The hearing officer writes a proposed decision, but the final decision at the agency level is rendered by the agency head or heads.[6] In the UK, multi-member tribunals perform most administrative adjudication. But EC administrative procedure does not fit any pre-established template; there is no Administrative Procedure Act (as in the US), no Tribunals and Inquiries Act (as in the UK). It must be studied sector-by-sector.

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already exists as a general principle of Community law, see Nehl 1999, 13-39, the Constitution would probably extend administrative hearing rights to certain sectors in which they are not yet fully recognized.

[5] The adjudicatory provisions of the US APA come into play "in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing..." 5 USC §554(a). Recent decisions construe this provision quite narrowly, thus sharply constricting the scope of the APA's adjudicatory provisions. *See, e.g., Dominion Energy Brayton Point, LLC v. Johnson,* 443 F.3d 12 (1st Cir. 2006). There is a large universe of hearings required by statute that do not fall under the APA but in which procedures akin to those required by the APA are provided; however, unlike APA proceedings, administrative law judges (ALJs) are not employed as the initial decisionmakers. See Asimow 2005, pp. 1005-08.

[6] Obviously, American adjudicatory procedures vary greatly, particularly the many adjudicatory decisions that are not regulated by federal or state APAs. Nevertheless, most of them cluster around the norm described in the text. Many such proceedings do not employ trial-type procedures such as oral testimony and cross-examination; especially in cases that do not involve disputed factual issues, the parties engage in written presentations followed by oral argument.

The administrative procedure that is provided in each of the six sectors has little in common with the others.[7] Each has its own foundation in the Treaty or in statutes, each is administered by a separate bureaucratic structure, each has its own procedural regulations, each has its own historical development, each has a different relationship with decision-making processes in the Member States. Nevertheless, as pointed out in Part I.C., decisions of the European courts have prompted a certain amount of procedural convergence between the sectors.

This sub-section describes the wide differences between the adjudicatory procedures in the six sectors we studied: competition, trade remedies, trademarks, food safety, pharmaceutical licensing, and state aids. Part II of this report briefly summarizes what we have learned about the adjudicatory procedures in the six sectors we have studied.[8]

EU adjudicatory procedures vary depending on whether they are triggered by an initial application for a benefit (merger applications, trademark applications, food licensing, pharmaceutical licensing, state aids) or whether they are triggered by administrative action that could lead to a sanction or deprivation of an existing status (competition, trade remedies, trademark oppositions, changed circumstances or sanctions in pharmaceutical cases). In two areas (state aids, food licensing), the decisional process seems more political rather than adjudicatory in nature.

Each sector follows its own investigative procedure which enables the relevant directorate of the Commission to inform itself about the facts and circumstances of a dispute.[9] In certain competition cases, the Directorate General for Competition (DG COMP) conducts an intrusive investigation that can include unannounced site visits and inspections of non-business premises including residences.[10] In other cases, such as trade remedies, food safety, state aids, and pharmaceutical licensing, the Commission or independent agencies such as EFSA conduct an active investigation based primarily upon documents furnished by the parties or by experts in the field. In the trademark area, OHIM conducts an initial trademark search and thereafter relies on

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[7] The six sectors described herein do not exhaust all the areas of adjudication and dispute settlement that involve the Commission. For example, the "clearance of accounts" process concerns disputes between Member States and the Commission about agricultural subsidies. Each year, the Commission seeks to recover improper payments and Member States frequently dispute its conclusions. Prior to seeking relief in the Community courts, Member States and the Commission resort to a conciliation procedure. The Conciliation Body hears the dispute and seeks to "reconcile the divergent positions of the Commission and the Member State." At the conclusion of the process, the Body draws up a non-binding report on the outcome of its efforts, including making remarks on the unresolved points of dispute. See Reg. 442/94, Art. 1.

[8] A detailed summary of procedures in those six sectors (approximately 140 pages in length) is available from the co-reporters. Similarly, the much lengthier full sectoral reports (about 400 pages in length) are available from the co-reporters. These documents will be published separately from the present volume.

[9] Generally in American administrative law, an agency has broad powers to subpoena documents as part of an investigation. While subpoenas must be judicially enforced, the agency needs only to show that the documents in question are relevant to a subject the agency is authorized to investigate. See American Bar Association 2003 pp. 47-57.

[10] In American administrative law, an agency generally must secure a warrant to inspect business premises, but the requirements for obtaining such warrants are much less demanding than in criminal cases. Marshall v. Barlow's Inc., 436 US 307 (1978).

complaining parties or Member States to provide the necessary data. In the area of state aids, the Commission's investigation consists primarily of requesting information from Member States.

Rights of access to the Commission's file also vary widely. In some areas, such as competition and trademarks, the parties have broad access to all documents in the Commission's file, other than material protected by confidentiality (such as informers or business secrets) or internal Commission documents.[11] However, non-parties (such as complainants) have more limited access to files. In other areas, the parties have access only to non-confidential versions of the documents in the files (trade remedies). In state aids, neither Member States nor private parties have access to the Commission's file.

Another significant area of variation relates to oral hearings. Hearings involving oral testimony are routinely allowed upon request in some areas (competition, trade remedies, pharmaceutical licensing), occur rarely in some areas (trademarks), and are never held in other areas (food safety,[12] state aids). In contrast, oral hearings are the norm in US administrative law.[13] In many cases, a written, rather than an oral exchange, furnishes all the process a party receives. In state aid cases, there is an opportunity for interested parties to submit written comments (to which Member States can reply)[14] and to engage in informal meetings with the staff, but there is no oral hearing.

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[11] In American administrative law, neither the APA nor due process requires agencies to provide discovery of documents in their files (in other words, the broad provisions for discovery applicable in civil cases do not apply to administrative litigation). See American Bar Association 2003, ¶4.03. However, many agencies have adopted rules permitting parties to discover material in the agency's files. Alternatively, such information is available on demand to anyone (including third parties) under the Freedom of Information Act (FOIA). However, under FOIA exceptions, an agency is not required to disclose pre-decisional intra- or inter-agency memoranda. 5 USC §552(b)(5); see NLRB v. Sears, Roebuck & Co., 421 US 132 (1975). In addition, under FOIA, an agency is not required to disclose various documents compiled for law enforcement purposes, such as those that might disclose the identity of a confidential source. 5 USC §552(b)(7).

[12] In the area of genetically engineered foods and novel foods, applications are filed at the Member State level and it would be necessary to survey Member State procedures to ascertain whether any hearings are granted. We have not undertaken such a survey.

[13] US administrative adjudication normally calls for oral presentation of testimony by witnesses followed by cross-examination. See Administrative Procedure Act, 5 USCA 556(d) which provides: "A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts." Nevertheless, relying on the last clause of the provision just quoted, the courts allow agencies to dispense with cross-examination when credibility is not at stake, such as in cases involving only differences of expert testimony. See American Bar Association 2003, ¶5.08. An oral hearing can be denied entirely if there are no disputed issues of fact. See, e.g., Weinberger v. Hynson, Westcott & Dunning, Inc., 412 US 609 (1973) (upholding summary judgment procedure at Food & Drug Administration). An oral hearing can also be denied in cases involving claims for money or benefits or initial licensing when "a party will not be prejudiced thereby." APA §556(d), last sentence. .

[14] Reg. 659/1999, Arts. 6(1), 20(1).

In cases where they do occur, oral hearings are usually conducted by the team of case handlers who are investigating the matter (either the application or the proposed sanction).[15] The exception is in competition cases, where the hearing is held by the case handlers under the supervision of a hearing officer who specializes in conducting hearings (and dealing with data requests and confidentiality issues), but does not conduct investigations.[16] Hearing officers in competition cases are responsible to the Commission, not to DG COMP. In general, the case handlers who conduct hearings do not write proposed decisions. In competition cases, however, the hearing officer files a report on whether the procedural rules have been observed which may also contain substantive observations on the Commission's internal draft decision. Since the introduction of independent hearing officers is a relatively recent development, it is unclear what impact this innovation will have on decision-making.[17]

The ultimate Commission decision generally takes the form of an individualized decision addressed to the parties. However, in some cases (such as trade remedies and most food safety cases) the decision may take the form of a broadly applicable rule.[18] An individualized decision must state reasons that are sufficient to allow for judicial review and must contain discussion of both law and facts, but the necessary detail of the statement of reasons varies with the circumstances of the case.[19]

Generally there is no opportunity for administrative reconsideration. However, in trade remedy cases, after one year parties may apply for an interim review of the definitive measures

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[15] As discussed in Part I.B., in American practice, adjudicatory hearings are generally subject to separation of functions. This means that the hearing officer has not played any adversary role in respect to the pending case. In cases covered by the APA, the hearing officer (referred to as an ALJ) engages exclusively in hearing cases and never conducts investigations. ALJs cannot receive ex parte communications from other agency staff members with respect to "facts in issue." ALJs work for the agencies for which they decide cases but cannot be supervised by staff members who engage in adversary functions. See American Bar Association 2003, ¶¶10.05, 10.10. Many agencies to which the APA's adjudication provisions do not apply employ a large staff of hearing officers who perform no tasks other than hearing cases; in other agencies that provide fewer hearings, any staff member can be designated as the hearing officer, but customarily that person will not have participated in the investigation in the case under consideration.

[16] We have been informed that a similar practice may soon be instituted by DR TRADE in certain trade remedy cases.

[17] The use of hearing officers in competition proceedings was introduced by the Commission decision of May 23, 2001, on the terms of reference of hearing officers in certain competition proceedings (OJ L 162, 19.6.2001, p. 21). Since that time, hearing officers have issued a number of reports on hearings over which they have presided, which are restricted to observations on procedural issues and conclude that the right to be heard was respected. *See e.g.*, Final Report of the Hearing Officer in Case COMP/32/448 and 32/450 – Compagnie Maritime Belge, OJ C 162/2, 2.7.2005. The authors are unaware of any case in which the hearing officer has made substantive observations or findings.

[18] In American practice, adjudicatory disputes are resolved by a decisional document produced by the agency heads or heads. The decision is individualized and addressed to the parties. APA §556(b).

[19] In American practice, the APA requires a statement of findings of fact, conclusions of law, and reasons for discretionary decisions. APA §557(c); American Bar Association 2003, ¶6.021. So-called post-hoc rationalizations (reasons supplied by agency counsel at the judicial review stage are not allowed). Due process also requires a statement of reasons even though the APA does not apply. Id. ¶6.021 n.7.

imposed by the Commission. In trademark cases, OHIM provides a board of appeals to reconsider the agency's initial decisions.

The relationship between decisions at the Community level (Commission-level adjudication and judicial review in Community courts) and decisions at the Member State level (Member State administrative agencies and courts) varies as between the six sectors. In each case, the comitology process provides input opportunities for Member States even if they are not formally engaged in the decisional process. Thus in the competition area, enforcement is divided between the Commission and competition authorities in the Member States, although Member States must follow the law established at the EU level. In pharmaceutical licensing, under the centralized process, licensing occurs at the Commission level, but under the decentralized process it occurs at the Member State level. In trademarks, licensing of community trademarks occurs at the Commission level but Member States license trademarks enforceable within that State. A large amount of trademark litigation occurs in courts of the Member States. In the case of food safety, most regulation is at the Commission level. In the case of novel foods, however, applications are lodged in a Member State which performs the initial assessment, though the final decision occurs at the Commission level. In the areas of trade remedies and state aids, decisionmaking is lodged exclusively at the Community level.

Reasons for differences between sectors

There are several reasons why adjudicatory procedures have developed in such a diverse manner across the various segments of operation of the Commission and its agencies. These include differences in the history of direct Commission involvement in the particular sector, the involvement of Member States in the area, the different types of parties affected by the procedures, and the development of separate agencies outside the Commission.

First, administrative procedures appear to have developed in each of the sectors independently and in tandem with the development of Community's regulatory role in the particular areas. The Commission's competence in various sectors of economic activity has developed and expanded greatly since the establishment of the European Community in 1957. The Commission began to function in each of the areas studied at different times, and procedures were developed as necessary to address the growing scope of Commission involvement. Over time, procedures were honed and expanded by practical experience, as well as through guidance from the ECJ and later the CFI as parties appealed Commission decisions.

Competition law provides a clear case in point. Competition was one of the earliest fields in which the Commission had competence, dating back to 1962 when it was granted broad powers to enforce the competition rules contained in the 1957 Treaty of Rome.[20] Accordingly, the Commission's current adjudicatory practices in the competition area have a long history. Although the Commission did not have specific authority to review and investigate merger transactions until 1990, with the introduction of the first Merger Regulation,[21] the Directorate General of Competition (DG COMP) applied many of the adjudicatory procedures developed in antitrust cases to merger reviews, so procedures are relatively consistent across the range of competition enforcement. By contrast, in the area of pharmaceutical licensing, although

[20] Council Regulation 17/62 of February 6, 1962, First Regulation implementing Articles 85 and 86 of the Treaty. OJ 13, 21.2.1962.

[21] Council Regulation (EEC) No. 4064/89 of December 21, 1989, on the control of concentrations between undertakings. OJ L 395 30.12.1989.

Commission pharmaceutical legislation dates from as early as 1965,[22] a centralized procedure directly involving the Commission was not introduced until 1995. Similarly, the European Food Safety Authority (EFSA) was not established until 2002,[23] and has had a correspondingly short time to accumulate sufficient experience to review and develop its practices.

Second, as noted above, in some areas the Commission shares the field with regulatory bodies of the Member States, while in other areas the Commission has sole competence. One example is customs cases, which the Commission co-administers with local Member State customs authorities. Where the Commission reviews a customs matter after full adjudication on the merits at the Member State level, it is questionable whether the time and resources required to give additional procedural protections at the Commission level are necessary or desirable.[24] The varying involvement of Member States in the different areas studied is one possible cause of variations in procedure.

Third, adjudicatory procedures have developed differently to address the needs of the different types of entities involved in Commission actions. For example, in the state aid field, the parties to the proceeding are the Commission and the Member State granting the aid. Beneficiaries of the aid or their competitors are not parties. The participation of a Member State as a party in the adjudicatory process raises very different questions concerning the need for access and procedural fairness than if the procedure involved only private parties (although, as described below, rights of access developed in competition cases have since been extended to Member States in state aids cases). Further, the involvement of a Member State injects a political element into the process, potentially raising issues beyond the scope of the particular investigation in question. In trade cases, the Commission investigates an entire industry; remedies are often duties or restrictions imposed on certain imports from some foreign country or countries. In such cases, certain procedural rights, such as the right to inspect the file, may be extended to any person with some interest in the industry—manufacturers, exporters and importers, industry associations, users and consumer organizations. By contrast, in other areas such as trademarks, and pharmaceutical licensing, Commission decisions typically only affect private parties or corporations and the procedural protections are more tailored to private parties.

Fourth, it has been suggested that procedures have developed differently, not only due to the specific demands of the various sectors, but also because of the establishment of specialist bodies with a defined range of functions, such as the OHIM, EFSA and EMEA.[25] Since such bodies are specially constituted and are not actually part of the Commission, they have considerable freedom to establish administrative procedures within their specific mandates. The OHIM, EFSA and EMEA are independent agencies with their own professional staff, and may not have any institutional preference for particular procedures. The OHIM, for example, is the only institution studied that provided for an internal appeal process (the Board of Appeal) before parties seek judicial review. In addition, the OHIM imposes a form of separation of functions,

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[22] Directive 65/65 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products of January 1965.

[23] Regulation EC No. 178/2002 of the European Parliament and of the Council of January 28, 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31/1, 1.2.2002.

[24] See discussion of customs remission and repayment cases in Part I. C.

[25] For discussion of EU independent agencies, see Gatto 2006, 505-08.

with different officials working at different stages of the proceedings.[26] At the other end of the spectrum, the EFSA has very limited procedural protections for private parties, possibly partly as a reflection of the hybrid adjudicatory/rulemaking nature of EU food safety regulation; similarly, the EMEA perceives its role as an independent, scientific (as opposed to political) body. Interestingly, the EMEA has developed procedures for party involvement in its review of pharmaceutical licensing applications, even though it is technically only an advisory body to the Commission and has no decision-making authority of its own.

In light of the above, it is questionable whether harmonization of processes across the various sectors is a realistic or desirable goal. It certainly has not been a focus of Commission attention, possibly in part due to resource constraints. There are many demands on Commission resources, in particular due to the active involvement of Member States and the need to devote significant resources to translation. Certain aspects of adjudicatory procedure can require significant resources, such as the need for extensive hearings in cases where many parties have an interest,[27] and for this reason may be disfavored in some areas. Further, substantial development and convergence of decision-making processes has taken place (and continues to do so) in an incremental manner at the operating (Directorate General) level and through development of administrative law through the CFI. For these reasons, there does not appear to be any impetus within the Commission or from the wider legal community for a complete overhaul of the existing systems at this time.

B. Commission procedures are inquisitorial rather than adversarial.

In the US model of agency decision-making, the investigative stage and the adjudicative stage *are separate*. First, the agency staff conducts an investigation and decides to issue a complaint (in the case of violations of law) or to reject an application (in cases that have been triggered by an application for a benefit or status). Then the target of the complaint (or the rejected applicant) is furnished a *hearing before an impartial and previously uninvolved hearing officer*[28] followed by a final decision made by the agency head or heads.[29] The administrative

[26] Officials working on an opposition cannot have worked on the application; members of the cancellation division cannot have participated in application or opposition proceedings; members of the Board of Appeal cannot have participated in any prior proceedings.

[27] In one antidumping investigation in the footwear industry, Commission staff in DG Trade gave hearings to approximately 70 interested parties.

[28] In cases covered by the federal Administrative Procedure Act, the hearing officer is an administrative law judge (ALJ). An ALJ works for the agency for which the ALJ decides cases, but is hired according to a strictly defined procedure administered by the Office of Personnel Management. The independence of ALJs is protected by a variety of statutory provisions. See American Bar Association 2003, ch. 10.

[29] See APA §557(b); American Bar Association 2003, ¶6.03.

hearing is *adversarial in nature* and is similar to a judicial trial.[30] Judicial review on the administrative record is almost always available, but the reviewing court's powers are constrained. In the UK, a tribunal (the members of which were not previously involved in the case) provides the hearing at which a party can challenge an administrative determination. The tribunal is independent of the agency that made the adverse decision; judicial review is on the record and judicial power is constrained.[31]

The US model generally provides for *separation of functions*, meaning that persons who have functioned in adversary roles (prosecutors, investigators, or advocates) are not permitted to serve as decisionmakers (either hearing officer or agency head).[32] In addition, neither outsiders nor adversary staff members are permitted to engage in ex parte communications either with the hearing officer or the agency heads. Separation of functions is not complete since, in most cases, hearing officers are employees of the agency that has conducted the investigation.[33] However, hearing officers are organizationally separated from adversaries and generally have considerable de facto independence.

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[30] Some large systems of US administrative adjudication do not fit the adversary model. In adjudications conducted by the Social Security Administration adjudication (mostly concerning disputes about disability) the SSA is not represented by counsel. The ALJ is responsible for representing the agency, safeguarding the interests of the applicant (especially if the latter is not represented by counsel), and then deciding the case. This inquisitorial approach was approved by the US Supreme Court in Richardson v. Perales, 402 US 389 (1971). Similarly, the Court upheld a provision prohibiting the payment of more than $10 to an attorney for a claimant for veterans' benefits, stating that Congress was not required to follow adversarial procedures, at least in cases of benefit determinations. Walters v. Ntl. Ass'n of Radiation Survivors, 473 US 305 (1984). In addition, administrative adjudication is often much less adversarial than civil or criminal litigation. For example, hearing officers are not supposed to serve as umpires while the lawyers run the hearing. Instead, hearing officers are expected to play an active role in structuring issues and questioning witnesses or assisting unrepresented parties, whereas such actions are quite problematic for trial judges.

[31] See Wade & Forsyth, ch. 23.

[32] APA §554(d). Note, however, that the APA does not require separation of functions in initial licensing. APA §554(d)(A). In practice, however, agencies frequently separate functions in initial licensing. Many federal adjudicatory schemes are not covered by the APA but the general rules of separation of functions are observed in practice in non-APA adjudication. Due process may require separation of functions in some instances, but the case law is sketchy. See American Bar Association 2003, ¶7.061 n. 76.

[33] In some situations (involving industrial injuries and mine safety, among others) federal law provides for two separate agencies, one engaged in rulemaking, investigation and prosecution, another engaged in investigation. Scholars who have studied these independent adjudicating agencies have not assessed them positively. See Gifford 1991.

EU administrative adjudication does not follow this adversarial model.[34] The procedures are also quite different from *droit administratif* countries (such as France, Germany, or Italy). In the latter countries, the law provides for relatively little formal procedure at the administrative level, but specialized administrative courts furnish in-depth review of the administrative action.[35] Instead the model resembles that of the inquisitorial or civil-law criminal justice system.[36] Inquisitorial criminal law systems vary greatly among the civil law countries, but generally a magistrate judge supervises the investigation by the police and prosecutors and assembles a dossier. The magistrate can dismiss the case at any time. If a criminal case is not dismissed, a judge conducts a trial. The trial is based primarily on the written materials contained in the dossier. There may be oral testimony by witnesses and by the accused, but the judge controls the proceedings and the lawyers who have relatively little to do. *The trial is viewed as the end point of the investigation, not as a separate phase from the investigation.*

EU administrative procedure in the sectors examined resembles the inquisitorial criminal law model. The specialized staff members of the relevant directorate of the Commission conduct an investigation of a proposed enforcement action or of an application for a benefit. The investigation concludes with a notice to the target or applicant setting forth the Commission's tentative findings.

At some point in the investigation, a hearing may take place, but the nature of that hearing is quite different from those that typically occur in the US or UK. The same case handlers who conducted the investigation also conduct the hearing. The hearing is viewed as an opportunity for the investigated party to state its side of the case. There is no cross-examination or confrontation of adverse witnesses. In competition cases, however,[37] the hearing is supervised by an independent officer who specializes in presiding at hearings and who has not been involved in the investigation and whose job is to make sure the target's procedural rights are respected.[38] Whether the hearing is provided by case handlers or an independent hearing officer, the persons who make the ultimate decision (such as the college of commissioners in competition cases) never attend the hearings.

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[34] See Craig 2006 at 370-72. Craig observes that the European courts have tersely dismissed claims by litigants that the lack of an independent administrative tribunal in EU regulatory cases violates §6(1) of the European Convention on Human Rights. This section mandates that in the determination of civil rights or obligations, "everyone is entitled to a fair and pubic hearing within a reasonable time by an independent and impartial tribunal established by law." Craig speculates that the fairly intensive judicial review provided by CFI could properly be viewed as the independent and impartial tribunal referred to by §6(1), especially in conjunction with the array of administrative procedural rights discussed in Part I.C. below.

[35] Bignami 2005, 260, 266-69. The administrative courts generally receive new evidence and entertain new objections to the administrative decision. Nevertheless, the administrative courts tend to be quite deferential to the administration.

[36] See Langer 2004; Damaŝka 1986 for discussions of inquisitorial systems and a comparison to adversarial systems. The term "inquisitorial" carries unfortunate connotations, suggesting to some readers a connection with the Spanish inquisition. Of course, the inquisitorial approach utilized by civil law countries has nothing in common with the Spanish inquisition. It might be better to employ some term like "inquiry" or "investigational" rather than "inquisitorial." Nevertheless, this report sticks with the term "inquisitorial" since it is in common use.

[37] We have been informed that independent hearing officers will soon be introduced in trade remedy cases.

[38] See earlier discussion of hearing officers in competition cases in Part I. A. above.

An exception to the generally inquisitorial mode of decision-making occurs in trademark opposition cases; here the responsible agency (OHIM) functions as an impartial arbiter in a dispute between an applicant for a Community trademark and the holder of an existing mark that alleges the new mark would be infringing.[39] Most of the investigation in these cases is left to the parties and the Office resolves the dispute based on the submissions of the opposing party.

C. The trend in favor of providing procedural protections for private parties and Member States in disputes with the European Commission.

1. **Overview.** While the adjudicatory procedures of the European Union remain solidly within the domain of the inquisitorial system, an important evolutionary process has occurred over the last three decades. During that period, there has been a steady accretion of procedural protections for private litigants and Member States who are engaged in adjudicatory disputes with the European Commission. These rights relate to investigations, access to Commission files, adequate notice, provision of a hearing (oral or written), decision within a reasonable time, and a statement of reasons. These rights are derived from several different sources: i) provisions in the Treaty, ii) regulations applicable to specific sectors, and iii) a body of European Court of Justice (ECJ) and Court of First Instance (CFI) case law that has catalyzed the process of procedural norm creation.[40] The case law seems similar to the case-by-case evolution of the standards of US procedural due process[41] and of UK natural justice.[42] As a result, there has been a convergence between procedural norms governing adjudication in the EU on the one hand and the US and UK on the other.[43]

2. **Early procedural protections and UK accession**. The "right of defense" for parties who are targets of administrative action has long been recognized in the law of Member States, particularly France, and was recognized in Community law as well. However, in earlier years, the rights of defense were rather sketchy by the standards of US or UK law. For example, in competition cases, a target company had a right to notification of the Commission's objections; received a summary of the contents of the Commission's file; had an opportunity to make known its views and provide exculpatory evidence; and had a right to statement of reasons sufficient for the parties and reviewing courts to understand whether a decision was lawful.[44]

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[39] Trademark cases also include a form of separation of functions in that officials who participated in one phase of the trademark process (such as an opposition) cannot be the same officials who worked on the earlier application. Members of the Board of Appeals cannot have participated in any prior proceedings.

[40] Scott & Sturm 2007; Craig 2006 ch. 10-11; Schwarze 2004, pp. 969-76; Lenaerts & Vanhamme 1997; Nehl 1999.

[41] See American Bar Association 2003, ch. 2.

[42] See Wade & Forsyth 2004, ch. 12-14.

[43] Of course, as in any country, the expansion of the rights of defense of private parties in Community adjudication has both benefits and costs. The costs of providing oral hearings, for example, in complex cases such as competition and trade remedies can be quite substantial, since there may be many parties who wish to be heard and highly complex economic issues to be resolved. The Commission may lack the financial and human resources needed to conduct such elaborate proceedings.

[44] Bignami 2005, 259-65.

These rights have evolved over time, largely through judicial consideration of competition cases. Some commentators believe this was a natural evolution.[45] Others argue that the judicial decisions are, in part, attributable to the UK's accession to the EU treaty in 1973. British commentators criticized Community procedures in competition cases because they fell short of satisfying UK standards of "natural justice." Natural justice is the British analogue to due process. It includes an unbiased decisionmaker as well as the right to notice, right to know the government's case, and an appropriate, usually oral, hearing.[46] In order to respond to these objections, the EU expanded the target's rights. These changes were reflected first in critical reports by an EU Advocate General (who was British); by critical reports of a Select Committee of the House of Lords; and then in a series of ECJ decisions.[47]

3. **Development of the right of defense through competition cases: *Transocean* and *Hoffman-La Roche*.** In the *Transocean* case,[48] the ECJ considered the complaint of an association of marine paint manufacturers that had earlier received a five-year exemption under Article 85(3) of the Treaty for various anti-competitive practices embodied in its agreement. The Commission renewed the exemption but inserted a new condition requiring the members to report any common managers or directors between the members and non-member paint companies. The association objected to this condition. It also objected to the fact that the Commission had imposed it without giving the association notice and an opportunity to be heard.

The Commission had notified the association that it would impose conditions on the renewal, including required disclosure of "any change in the participatory relationships of the members." The association argued that they could not infer from this statement that the Commission intended to impose the actual disclosure requirement, to which they would have strongly objected if they had been so notified.

The Court decided that the failure to give notice of the precise condition violated the requirements of notice and hearing in the competition regulations. "It is clear, however, both from the nature and objective of the procedure for hearings...that this Regulation...applies the general rule that a person whose interests are perceptibly affected by a decision taken by a public authority must be given the opportunity to make his point of view known. This rule requires that an undertaking be clearly informed, in good time, of the essence of conditions to which the Commission intends to subject an exemption and it must have the opportunity to submit its observations to the Commission...."[49] Thus *Transocean* construed the regulations implementing

[45] See generally Nehl 1999.

[46] Bignami 2005, 269-72. See generally Wade & Forsyth 2004, chapters 12-14.

[47] Bignami 2005, 272-79, observing that Community officials were concerned that UK national courts might not enforce decisions that failed to meet the standards of natural justice. Others attribute the evolutionary development of defense rights to the establishment in 1989 of the CFI which sees itself as an administrative court. Still others attribute the development to concerns within the EU that constitutional courts in Member States such as Germany might question the Community's decisionmaking procedures.

[48] Transocean Marine Paint Assoc. v. Commission, Case 17/74, 1974 ECR 1063.

[49] *Id*. at 1079-80. The Advocate General in *Transocean* was English and had strongly argued that the principles of natural justice applied before European courts. For discussion of the evolution of the right to appropriate notice, see Craig 2006, pp. 363-65.

the competition law broadly to assure that a party subject to adverse action is entitled both to adequate notice and to an opportunity to make its objections known.

Transocean might be viewed as based on an interpretation of the regulations. However, in *Hoffmann-La Roche*, the ECJ generalized the requirements of procedural fairness articulated in *Transocean* into broad principles of Community law, at least in cases involving a sanction.[50] In sweeping dictum, the Court declared: "Observance of the right to be heard is in all proceedings in which sanctions, in particular fines or penalty payments, may be imposed, a fundamental principle of Community law which must be respected even if the proceedings in question are administrative proceedings....The undertakings concerned must have been afforded the opportunity during the administrative procedure to make known their views on the truth and relevance of the facts and circumstances alleged and on the documents used by the Commission to support its claim that there has been an infringement of Article 86 of the Treaty."[51] However, the Court found there had been no breach of this obligation since the target company had seen and inspected all of the documents on which the Commission relied.[52]

4. **Subsequent competition cases—the right to inspect the file.** Decisions by European courts vindicate the right of the parties in competition cases to inspect all non-confidential documents in the file.[53] Clearly, the right to inspect the file is an essential aspect of the right of defense, particularly given the inquisitorial, document-based approach taken in EU cases.

For example in *Hercules*,[54] the target complained that only selected documents in the Commission's file had been disclosed prior to the hearing. The Court of First Instance said that the Commission was bound by its own regulations to disclose all of the information in the file (other than business secrets or internal Commission documents or information disclosed to the Commission under a promise of confidentiality). However, the failure to disclose the responses of other targets to the statement of objections was not prejudicial since disclosure could not have led to a different result.[55]

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[50] Hoffmann-La Roche & Co. v. Commission, Case 85/76, 1979-1 ECR 461.

[51] *Id*. at 511-12.

[52] A recent application of the right of defense in a competition case occurred in a merger case. The Commission breached the right of defense of one of the merger partners (which still exists as a separate entity) by failing to permit it to defend itself. The Commission allowed the merged entity to submit observations but was obliged to allow the constituent company to submit objections also. Thyssenkrupp Stainless GmbH v. Commission, Cases C-65/02P and &C-73/02P, [2005] CMLR 16.

[53] For detailed discussion of cases involving access to Commission files, including the application of the access right in complex multi-party cases, see Craig 2006 at 365-69; Lenaerts & Vanhamme 1997 at 541-49. For discussion of the general right of access to all EU-agency documents (the EU equivalent of the US Freedom of Information Act) see Craig 2006 at 350-60.

[54] S.A. Hercules Chemicals N.V. v. Commission, Case T-7/89, [1991] II-1711, 1739-40, ¶¶53-54. Cases with II before the page number are decisions of the Court of First Instance (CFI), whereas cases with I- before the page number are decisions of the European Court of Justice (ECJ). Similarly, cases with a T-number are CFI decisions; cases with a C- number are ECJ decisions.

[55] *Id*. at 1740, ¶56.

Similarly, in the *Soda Ash* cases,[56] the CFI used the phrase "equality of arms" to describe the target's need for broad access to possibly exculpatory documents in the file.[57] "It is sufficient for it to be established that the non-disclosure of the documents in question might have influenced the course of the procedure and the content of the decision to the applicant's detriment...if the documents in question might...have had a significance which ought not to have been disregarded."[58] "It cannot be for the Commission alone to decide which documents are of use for the defense. Where, as in the present case, difficult and complex economic appraisals are to be made, the Commission must give the advisers of the undertaking concerned the opportunity to examine documents which may be relevant so that their probative value for the defense can be assessed."[59] "Having regard to the general principle of equality of arms, which presupposes that in a competition case the knowledge which the undertaking concerned has of the file used in the proceeding is the same as that of the Commission, the Commission's view cannot be upheld in such a situation, [that is, the Commission decides what documents are exculpatory] the rights of defense which the applicant enjoys during the administrative procedure would be excessively restricted in relation to the powers of the Commission, which would then act as both the authority notifying the objections and the deciding authority, while having more detailed knowledge of the case-file than the defense."[60]

Of course, the right of access to the file must be balanced against the obligation to maintain the confidentiality of the business secrets of other undertakings, a right protected by the Treaty. This requires a delicate balancing of the right of defense against the right of confidentiality.[61]

The most recent iteration of the competition regulation builds on these judicial decisions. The regulation provides that the Commission shall base its decision only on objections on which the parties concerned have been able to comment.[62] "The rights of defense of the parties concerned shall be fully respected....They shall be entitled to have access to the Commission's file." However, access rights are subject to protection of business secrets, confidential information, internal documents of the Commission and correspondence between the Commission and Member States.[63]

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[56] Solvay SA v. Commission, Case T-30/91, 1995 II-1775.

[57] *Id*. at 1802, ¶59, quoting *Hoffmann-La Roche*.

[58] *Id*. at 1806 ¶68.

[59] *Id*. at 1811-12 ¶81.

[60] *Id*. at 1812, ¶83.

[61] *Id*. ¶88, allowing access to documents with narrow deletions to preserve confidentiality. See Lenaerts & Vanhamme 1997, at 541-49 for discussion of balancing access to documents against confidentiality. See also Sison v. Council of the European Union, Cases T-110/03, T-150/03, T-405/03, [2005] 2 CMLR 29 (CFI) (individual whose assets were frozen as part of the fight against terrorism did not have right of access to his file nor to names of states that furnished information about him).

[62] Reg. 1/2003, Art. 27, ¶1.

[63] *Id*. ¶2.1

5. **Expansion of the right of defense in competition cases to other sectors**

Subsequent decisions by European courts have expanded the rights of defense to regulatory sectors other than competition.

a. **Trade remedies.** In *NTN Toyo Bearing Co.*,[64] the Advocate General (who was British) urged that the principles of disclosure of files developed in competition law should apply in the area of trade remedies as well, regardless of the absence of regulations that required it. In *Al-Jubail Fertilizer,*[65] the views of the Advocate General were endorsed by the Court and became Community law. In that case, the ECJ overturned an anti-dumping duty because of a failure to disclose critical information to a target exporter. The undisclosed material included information on European costs of production and prices of fertilizer, which had served as the basis for concluding that the domestic industry had been injured. Although the regulations only required disclosure of information relevant to the defense of the exporters' interests or that the Commission used in the investigation, the Court declared that "fundamental rights form an integral part of the general principles of law, whose observance is ensured by the Court. Consequently, it is necessary when interpreting... the regulation to take account in particular of the requirements stemming from the right to a fair hearing, a principle whose fundamental character has been stressed on numerous occasions in the case-law of this court...Those requirements must be observed not only [in penalty cases] 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."[66]

b. **State Aids.** The Treaty provides for a notice and comment procedure in the area of state aids that is open not only to Member States but to beneficiaries of the aid and to competitors of the aided industry.[67] That provision has been supplemented by regulations that require the Commission to provide an opportunity for comments in doubtful cases.[68]

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[64] Case 113/77, NTN Toyo Bearing Co. v. Council, 1979 ECR 1185. See report of the Advocate General at 1261-65.

[65] Al-Jubail Fertilizer Co. v. Council, Case C-49/88, 1991 ECR I-3187.

[66] *Id.* at I-3241. This decision reflected the views of the Advocate General that *Hoffmann-La Roche* applied to anti-dumping cases. Id. at I-3221-22.

[67] Art. 88(2): "If, after giving notice to the parties concerned to submit their comments, the Commission finds that aid granted by a State or through State resources is not compatible with the common market..." The ECJ held that this provision must be followed in all cases in which the Commission finds that a state-aid scheme presents difficulties of deciding whether it is compatible with the common market. As the result, the Court annulled a Commission decision that declined to challenge an aid scheme because a competitor of the aided industry was not invited to submit comments. Cook v. Commission, Case C-198/91, 1993 ECR I-2487, 2529-31.

[68] Reg. 659/1999, Art. 6(1).

In the *Netherlands* case,[69] the statement of objections to a state-aid scheme was not sufficiently specific. In addition, the Netherlands was not given an opportunity to make known its position on the consultations the Commission had conducted with organizations of persons that competed with the aided company. As a result, the Member State's right of defense was infringed.[70] Similarly, PTT, the direct beneficiary of the aid in question, was also entitled to be heard by the Commission since the contested decision related directly to it and the economic consequences directly affected it. It was entitled to receive a specific statement of objections and a right to be heard.[71] In addition, competitors of an aided entity have a right to a statement of reasons for the Commission's determination that no state aid exists.[72]

c. **Customs duties.** Although most decisions relating to customs duties are administered at the Member State level, certain customs disputes are considered by the Commission. In the *Technische Universität München* decision,[73] the Court determined that in making determinations relating to exemption from customs duties, the competent institutions have a duty to examine carefully and impartially the relevant aspects of the individual case, and the person concerned has a right to make his views known and to have an adequately reasoned decision. In that case, all three of these obligations were infringed.

The issue was whether an electron microscope similar to that which the University wanted to import from Japan was manufactured within the Community. If not, the instrument could be imported duty-free from Japan. A committee of experts that was not shown to be qualified made the decision. "The right to be heard in such an administrative procedure requires that the person concerned should be able, during the actual procedure before the Commission, to put his own case and properly make his views known on the relevant circumstances and, where necessary, on the documents taken into account by the Community institution."[74]

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[69] Kingdom of the Netherlands v. Commission, Joined Cases C-48/90 and C-66/90, 1992 ECR I-565, I-638-40.

[70] *Id*. ¶¶44-49

[71] *Id*. ¶¶50-53.

[72] Commission v. Chambre Syndicale Nationale des Enterprises de Transport de Fonds et Valeurs (Sytraval and Brink's France), Case C-367/95 P, 1998 ECR I-1719, ¶¶58-59, 64. In Union Francais de l'Express (UFEX) v. Commission, Case T-613/97, 2006 ECR II-1531 (June 7, 2006), CFI set aside a Commission decision in a state aid case because of an inadequate statement of reasons. The issue was whether assistance given by the French Post Office to SFMI was state aid and this turned on whether the price charged SFMI covered variable costs and was an adequate contribution to fixed costs. The Commission failed to explain how various approximations of variable cost were made. The court required the Commission to furnish a summary of its analytical accounting calculations. For discussion of the Commission's obligation to exercise due care in considering state aid complaints, see Craig 2006 at 376-78.

[73] Hauptzollamt München-Mitte v. Technische Universität München, Case C-269/90, 1991 ECR 5495. See Schwarze, 2004b at 94-96. For discussion, see Scott & Sturm 2007 [manus. at 18-19]. These authors note: "[T]he court is seeking to promote a process whereby Commission-appointed scientific experts into enter discussions with other parties in possession of information which may reasonably be thought to be indispensable in answering the question with which they have been presented."

[74] Id. at 5501.

Certain cases in which importers seek remission or repayment of customs duties are also decided at the Commission level. The Court of First Instance held that "respect for the rights of the defence in all proceedings which are initiated against a person and are liable to culminate in a measure adversely affecting that person is a fundamental principle of Community law which must be guaranteed, even in the absence of any rules governing the procedure in question." As a result, the Commission had to provide an opportunity for a party seeking remission or repayment of customs duties to effectively make its views known and to provide full access to non-confidential material in the Commission's file (not merely to material that the Commission considered relevant).[75]

d. **Other regulatory functions.** The community courts have generalized the rights of defense that have evolved in specific sectors of regulation. They apply in any area of Commission regulation, regardless of whether procedural rights are provided for in regulations or even if the regulations purport to negative hearing rights.

For example, in *Lisrestal*,[76] a case involving a claim by the European Social Fund (ESF) for the repayment of a subsidy to a Portuguese training facility because of irregularities in the application process, ECJ said: "Observance of the right to be heard is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of Community law which must be guaranteed even in the absence of any rules governing the proceedings in question. . . .That principle requires that the addressees of decisions which significantly affect their interests should be placed in a position in which they may effectively make known their views." *Lilrestal* is notable because the responsibility for enforcement of the conditions of the grant was shared between ESF and a Portuguese agency, but the latter had followed the decision of ESF without providing any procedural protection to the recipient of the subsidy. Thus CFI could have placed responsibility for providing a hearing on the Member State agency, but it chose not to do so.

Similarly, *Air Inter SA v. Commission*[77] involved the Commission's decision to open up particular air routes in France to new competition. The existing carrier that would be damaged by the new competition was entitled to claim the rights of defense. CFI noted: "It must be observed that the application of the fundamental principle of the rights of the defence cannot be excluded or restricted by any legislative provision. Respect for that principle must therefore be ensured both where there is no specific legislation and also where legislation exists which does not itself take account of that principle."

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[75] Eyckeler & Malt v. Commission, Case T-42/96, 1998 ECR II-401. ¶¶ 77-80; Primex Produkte Import-Export GmbH & Co. v. Commission, Case T-50/96, 1998 ECR II-3773, ¶¶57-64. However, CFI did not accord the applicant an oral hearing in a remission/repayment case, in the absence of a showing of why a written presentation of the issues was inadequate. Common Market Fertilizers v. Commission, Case T-134/03 and 135/03, 2005 ECR II-3923 ¶¶ 105-09. In the *Suproco* case, discussed in text at notes --, CFI based its decision in a customs case entirely on the Commission's failure to state the reasons for its decision in sufficient detail for the court to review the decision and the parties to understand the reason why their petition was rejected. .

[76] Lisrestal v. Commission, Case C-32/95, 1996 ECR I-5373, ¶21, affirming a CFI decision, T-450/93, 1994 ECR II-1177. Similarly, see Fiskano v. Commission, Case C-135/92, 1994 ECR I-2885, ¶38, holding that the right of defense applies where the Commission sent a letter to the government of Sweden imposing sanctions on the owner of a fishing boat accused of fishing without a license. The vessel owner has a right of defense even though it was also penalized by Sweden.

[77] Case T-260/94, 1997 ECR II-997, ¶60.

6. **Other procedural rights: Attorney-client privilege, confidentiality, decision within a reasonable time, and statement of reasons.**

a. **Attorney-client privilege.** The Court recognized that a limited form of attorney-client privilege applies to investigations undertaken by the Commission.[78] The privilege applies to written communications between lawyer and client but with two important conditions: i) the communications are made for the purposes and in the interests of the client's right of defense;[79] and ii) they emanate from independent lawyers registered with an EU bar (that is, lawyers who are not bound to the client by a relationship of employment).[80] Whether attorney-client privilege should extend to employed lawyers remains undecided.[81]

b. **Confidentiality.** Article 287 of the Treaty provides that Community personnel "shall be required...not to disclose information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components." The right to confidentiality often calls for a delicate balance between the rights of the target to examine documents in the file and the confidentiality rights of those who have submitted information to the Commission.[82]

In the *Adams* case,[83] the ECJ held that this obligation runs to individuals as well as to undertakings and applies to information supplied voluntarily by an informant to the Commission under a request for confidentiality. The Commission probably breached the duty by supplying photocopies of redacted documents to the target company from which it was able to deduce the identity of the informant who had supplied the Commission with the documents. However, this issue was left undecided. The Court held that the Commission breached its duty by failing to warn the informant that he was in serious danger of prosecution by the Swiss authorities for business espionage if he returned from Italy to Switzerland.

The *Akzo* procedure[84] applies in cases where the Commission proposes to disclose information provided to the Commission by a company that wants it to be treated as confidential.

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[78] Australian Mining & Smelting Europe Ltd. v. Commission, Case 155/79, 1982 ECR 1575, 1611 ¶21-28.

[79] This means that privilege applies to "all written communications exchanged after the initiation of the administrative procedure" though it may be extended to "earlier written communications which have a relationship to the subject matter of that procedure." *AM&S* ¶23.

[80] See Gippini-Fournier 2005 for an extensive discussion of attorney-client privilege in Community law.

[81] In Commission v. Akzo Nobel Chemicals Ltd., Case C-7/04 P(R) (Sept. 27, 2004), this issue was raised before ECJ but was not decided because the Court refused to grant interim relief. *Akzo Nobel* also involved the issue of whether an investigatory memorandum prepared by a corporate executive in preparation for consulting an attorney was protected by privilege. This issue was also left undecided.

[82] See Lenaerts & Vanhamme 541-49.

[83] Adams v. Commission, Case 145/83, 1985 ECR 3539, 3585-91. See Schwarze, 2004b at 96.

[84] See Akzo Chemie BV and Akzo Chemie UK Ltd. v. Commission (1986) ECR p., 1965, ¶29; Art. 9, Commission Decision, May 23, 2001, OJ L 162, 19.6.2001, p. 21.

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 company concerned must be notified of the decision and has an opportunity to challenge the decision in the CFI. The information may not be disclosed prior to one week after the decision has been notified.

c. **Decision within a reasonable time.** Both the investigatory phase and the administrative decision phase must be completed within a reasonable time.[85] The reasonableness of a particular delay is appraised in light of the circumstances specific to each case. In particular, the court should weigh the importance of the case for the person concerned, its complexity, and the conduct of the applicant and of the competent authorities.[86]

d. **Statement of reasons.** Art. 253 of the Treaty established the right to a statement of reasons,[87] a right frequently enforced by the Community courts.[88] In *Suproco,* [89] the CFI's decision annulling the Commission's decision was based entirely on the Commission's failure to state its reasons in sufficient detail for the court to review the decision and for the parties to understand the basis for the Commission's rejection of their petition for customs relief. The decision in question (which related to whether imported sugar products from Curaçao qualified for tariff relief and which involved highly technical regulations) indicated the Commission's conclusion but not its reasoning.

The *Suproco* court said: "According to settled case-law, the statement of reasons required by Article 253 EC must be appropriate to the measure at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the competent Community Court to exercise its power of review."

The Commission is not required to furnish all the details of the factual and legal aspects of every decision. In *Suproco,* the court noted: "The requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining

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[85] See Lenaerts & Vanhamme 567.

[86] Limburgse Vinyl Maatschappij NV v. Commission, Joined Cases C-238-99 etc., 2002 ECR I-8375, 8685 ¶193-94. In the latter case, the court held that an investigation lasting four years and 10 months was not excessive, given the complexity of the case, the amount of documents that had to be considered, and the large number of parties. In addition, the ten-month period of adjudication could not be considered excessive.

[87] "Regulations, directives and decisions adopted jointly by the European Parliament and the Council, and such acts adopted by the Council or the Commission, shall state the reasons on which they are based and shall refer to any proposals or opinions which were required to be obtained pursuant to this Treaty." See Lenaerts & Vanhamme 562-66.

[88] See Craig 2006 at 378-81.

[89] Suproco NV v. Commission, Case T-101/03, 2005 ECR II-3839 ¶20.

explanations."[90] Thus the reasons for a decision that follows a well-established line of authority may be given in summary fashion by reference to the prior decisions, but the Commission must give an explicit account of its reasoning if the decision goes appreciably further than the previous decisions.[91] .

7. **Procedural protections in application cases**

The law relating to the procedural rights of persons who have applied for benefits is less well developed than the law relating to parties who are subject to some kind of sanction or other loss of status. *Technische Universität München,* discussed above, involved an application to import a scientific instrument into the Community without payment of duty. The ECJ held that the applicant had procedural rights, including a right to make its objections known to the Committee which made the decision. In the trademark area, rejected applicants are entitled under the regulations to a right to file observations (and in unusual cases to an oral hearing) even when no opposition has been filed.[92] In the area of pharmaceutical licensing, there is a right to submit written observations and to an oral hearing before the members of the Committee for Medical Products for Human Use (CHMP) who are processing an application. There is also a right to have the CHMP opinion reviewed by the Commission.

In *Windpark,*[93] the applicant applied for financial aid to construct a wind park under a program whereby various recipients of energy projects could receive aid. There were about 700 proposals. The applicant was not selected to receive support but was placed on the reserve list. Later, in response to a letter, the Commission stated that available funds had been exhausted. In this situation, there was no right to a detailed statement of reasons for the decision rejecting the application for financial support, including comparative information on the competing projects that were selected. The reason for the making an exception to the normal requirement of stating reasons is that the rejected applicant's legal position remained unchanged. Its sole entitlement was to an objective examination of the application.[94]

In *Windpark,* the Court also decided that the rejected applicant was not entitled to a hearing, because that right arises only where the Commission contemplates the imposition of a penalty or adoption of a measure likely to have an adverse effect on that person's legal position. In addition, the fact that there were hundreds of applicants militates against giving any of them a hearing. However, this decision would not resolve the issue of whether there is a right to hearing in connection with the rejection of an application for a license or permission to market a food or

[90] *Id.* See also Windpark Groothusen GmbH & Co. Betriebs KG v. Commission, Case C-48/96 P, [1998] ECR I-2873, 2909 ¶34-35; Société Française des Biscuits Delacre v. Commission, Case C-350/88, 1990 ECR 395, 422 ¶15.

[91] Delacre, ¶17-19. *Delacre* held that the Commission was not required to explain the details for setting a subsidy level for butter. The subsidy is adjusted every two weeks and the industry is familiar with the process for setting the price.

[92] Reg. 40/94, Art. [check #s, is it 56(1), 37(2), 38(3)]

[93] Windpark Groothusen GmbH & Co. Betriebs KG v. Commission, Case C-48/96 P [1998] ECR I-2873 (affirming Case T-109/94, 1995 ECR II-3007 (CFI))

[94] Id. I-2909-10, ¶¶ 34-39.

drug or reject a trademark application (as opposed to an application for funding where only some of the applicants can be funded).

II. SUMMARY OF ADMINISTRATIVE PROCEDURE IN THE SIX SECTORS

The following brief summary of the adjudicatory practice in the six sectors of EU administration that we studied is based upon the detailed reports contributed by our sectoral reporters. These reports total about 400 pages in length and contain a wealth of detail, documentation, and footnotes. We have prepared a summary of the reports (about 135 pages in length). Both the full sectoral reports and our detailed summary thereof are available on request from the adjudication reporters or the sectoral reporters (email addresses can be found on the title page of this report). Ultimately both the full sectoral reports and the detailed summary thereof will be published but the exact mode of publication (whether in hard copy or on the internet) has not yet been determined.

A. *Competition*.[95]

Article 81(1) of the Treaty prohibits various anti-competitive practices that are incompatible with the common market. Broadly speaking, this provision parallels section 1 of the US Sherman Act. Article 81(3) provides that the prohibition of Article 81(1) may be declared inapplicable to certain restrictive practices that are found to be economically beneficial and justified.

Under regulation 1/2003, which went into effect in 2004, the Commission no longer has a monopoly on granting such exemptions; they can now be granted by Member States. Courts of the Member States can adjudicate cases arising out of both public and private enforcement of the competition articles of the Treaty. The prior practice of requiring parties to notify the Commission of anti-competitive practices has been abolished (although it still exists in some Member States). Article 82 of the Treaty prohibits abuse of a dominant position and thus roughly parallels the monopolization provision of Section 2 of the US Sherman Act. Finally, the Commission regulates mergers that have a Community dimension.

The Directorate General for Competition (DG COMP) may initiate an investigation of a possible violation of Articles 81 and 82 in response to a complaint, or on its own initiative (often having been informed by an application for leniency) or by a referral from a Member State. A team headed by a DG COMP case manager and consisting of several case handlers conducts the investigation. The investigation usually includes an on-the-spot inspection. The investigators may seek additional information informally or through a formal decision requiring information to be furnished. In some cases, non-business premises can be searched.

If DG COMP decides to proceed further (with the approval of Legal Services and the Competition Commissioner and, in some cases, approval of an advisory committee of competition authorities from Member States), it issues a "statement of objections" (SO) consisting of a factual description of the conduct involved and a legal assessment. If a compromise is reached, however, the Commission issues a "preliminary assessment" which contains commitments by the companies involved.

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[95] For a thorough discussion of the administrative process in competition cases, see Van Beel & Bellis 2005 at 857-76 (mergers), 1021-1166 (competition). For a brief summary, see Craig 2006 at 387-91

In merger cases, the process is initiated by prior notification to the Commission of a proposed merger in order to obtain clearance of the merger. Generally pre-notification contacts occur between the applicants and Commission staff. The Commission conducts a Phase I investigation of the proposed merger and may grant clearance at that stage. If it concludes that the proposed concentration raises serious doubts as to its compatibility with the Common Market, it initiates a Phase II investigation and issues an SO. "State of play" meetings occur during Phase II to facilitate exchange of information.

The SO (in both antitrust and merger cases) informs the target companies of the charges against them (or the Commission's doubts about a proposed merger) and sets a time limit within which they can inform the Commission of their views. They can file written objections and attach relevant documents or can request a hearing. The Commission must provide full access to all documents in its file to the target companies, other than business secrets or other confidential information or internal Commission documents. Complainants (as opposed to targets) have access only to the non-confidential version of these documents.

While the right to be heard is primarily exercised through filing written materials, the Commission must provide an oral hearing on request in antitrust and merger cases. At the hearing, the targets (or merger applicants) have the right to make their views known about the facts and circumstances alleged against them and to support their claim that they have not infringed the Treaty. The hearing follows a detailed order of presentation and may include both the testimony of live witnesses and experts. There is no right of cross-examination or confrontation, but the Commission officials may question any witness who appears. If the SO is significantly amended, an additional hearing must be provided. Complainants may also be heard but this is discretionary with the Commission.

The hearing officer is a high-ranking Commission official who has not previously been involved in the investigation. Hearing officers report to the Competition Commissioner and organizationally are not part of DG COMP. The hearing officer conducts hearings and manages access to documents and resolves claims of confidentiality. The role of the hearing officer is to make sure the parties' rights of defense are respected. The hearing officer reports to DG COMP on the procedural issues in the case and whether the right to be heard was respected. In addition, the hearing officer can make observations on the further progress of the proceedings. After the preliminary decision is prepared by the case handlers, the hearing officer prepares a final report on the procedural aspects of the case and whether due account has been taken in the preliminary decision of all relevant facts.

The case handlers draft the preliminary decision. The preliminary decision is reviewed by the Commission's Legal Service and presented for consultation to the Advisory Committee (consisting of Member State representatives).[96] The final decision is made by the College of Commissioners. The hearing officer does not make a substantive (as opposed to a procedural) decision. However, the hearing officer may comment on the preliminary decision. Such comments are not made available to the parties.

[96] We are informed that the Legal Service provides an important checking role in the process of Commission consideration of preliminary decisions. When the full Commission makes the decision, it can override a negative opinion of the Legal Service. However, in many situations, the Commissioners decide a case by written procedure without discussion or the decision is delegated to a single member of the Commission. In the latter two situations, the act can be adopted only if the opinion of the Legal Service is favorable.

The final decision must contain a sufficient statement of reasons, so that a reviewing court may exercise its supervisory function and the parties can ascertain whether the decision is well founded. The statement of reasons must include both the factual and legal grounds on which the decision is based, including comment on the evidence. It must be more fully reasoned if it states a new legal interpretation.

B. *Trade remedies.*

Under the law of trade remedies, the Commission can protect Community industry from dumping[97] and from governmental subsidies that give foreign competitors an unfair advantage.[98] In dumping and subsidy cases, the complained-of conduct must cause material injury. Anti-dumping and anti-subsidy cases can result in imposition of additional duties on foreign goods. In addition, the EU can take "safeguard" measures that protect Community industry with temporary relief against foreign competition that causes serious injury. Safeguard cases, which are quite rare, usually result in quantitative restrictions on imports from all countries.[99]

Anti-dumping and subsidy cases usually begin with a written complaint on behalf of Community industry. Safeguard cases usually begin with a complaint by a Member State (which has been prompted by complaints of affected industry). [The following material applies only to dumping and subsidy cases, not to safeguard cases, in light of the rarity of safeguard cases]. Before lodging a complaint, companies tend to engage in informal exchanges with DG Trade in order to address specific legal issues about which the potential applicant has doubts.

During a 45-day period, the Commission evaluates the complaint and the representativeness of the complainants. Thereafter, it publishes a relatively brief notice of initiation of investigation and invites interested parties to come forward (within 10 days) and submit information and request a hearing (within 40 days). The Commission advises particular importers and exporters (and associations thereof) that it knows to be concerned of the initiation of the investigation. If the Commission rejects the complaint, there is no public announcement of the decision.

Separate teams of case-handlers evaluate the existence of dumping or subsidization and of material injury. A Head of Section supervises each team of case handlers. The overall timing of the investigation is short and inflexible: 9 months for provisional remedies, 15 months for dumping and 13 months for subsidy. An advisory committee, consisting of Member State representatives, is consulted at each critical stage. Consultation with other DGs is also routine.

The investigation consists of sending detailed questionnaires to the Community industry, foreign exporters and governments. On-site verification visits generally follow. Furnishing information is voluntary, but companies generally provide it because otherwise the Commission can proceed on the basis of the "facts available" in the case of "non-cooperation." Non-

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[97] A product is considered to be dumped if its export price to the Community is less than a comparable price for the like product established for the exporting country.

[98] The basic anti-dumping regulation is Council Reg. 384/96 (Dec. 22, 1995), as last amended by Council Reg. 2117/2005 (Dec. 21, 2005). The basic anti-subsidy regulation is Council Reg. 2026/97 (Oct. 6, 1997), as last amended by Council Reg. 461/2004 (Mar. 8, 2004).

[99] The basic safeguard rules for WTO members are contained in Council Reg. 3285/94 (Dec. 22 1994), as last amended by Council Reg. 2474/2000 (Nov. 11 2000); for non-WTO members, Council Reg. 519/94 (Mar. 7, 1994), as last amended by Council Reg. 427/2003 (Mar.3, 2003).

confidential versions of all written submissions to the Commission are available to other parties. Oral statements made to case-handlers during on-site verifications can be quite significant; if they are "relied on," a non-confidential summary must be provided to other parties.

Complainants, importers, exporters, and their representative associations, as well as users and consumer organizations, 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 and questionnaire replies must be accompanied by a non-confidential version. The non-confidential version is placed in the file for inspection. There is no disclosure of confidential information or of the Commission's internal memoranda and mission reports. Lawyers generally stay in contact with the Commission officials to find out if a file has been updated.

The Commission summarizes its conclusions in a "provisional disclosure letter" that is provided to the parties at the same time as a regulation imposing provisional measures is adopted. Other interested persons can request a copy. The provisional disclosure letter discloses the facts and considerations on the basis of which provisional measures were imposed. The provisional disclosure letter also contains a part addressed only to individual companies that analyzes confidential information. A final disclosure letter precedes definitive duties and the parties have at least ten days to comment.

Dumping and subsidy investigations can be "settled" after the issuance of the provisional determination if the company or government involved offers an "undertaking" and the Commission accepts it. An undertaking in a dumping case would usually be a promise from the exporter to charge at least a certain amount for the product in the future. In a subsidy case, the government might promise to cease subsidization or particular companies would agree to discontinue exports or charge at least a certain price. After undertakings have been accepted, the EU usually proceeds to adopt a definitive regulation and impose a definitive duty, which would apply to companies that did not conclude an undertaking or that may apply if the undertaking is breached.

Prior to adoption of the provisional regulation, an oral hearing is provided to a target company as a matter of right. Sometimes the officials handling the case exercise discretion to provide additional hearings. These hearings furnish an opportunity for companies to make their views known on the circumstances alleged against them and on the evidence relied on by the Commission. In addition, other interested parties generally are entitled to a hearing on request. After a hearing, a party will often submit a written copy of its presentation in both confidential and non-confidential versions. The officials handling the case may, in their discretion, provide an additional hearing after adoption of the provisional regulation.

Essentially the interested party determines what happens at the hearing. The officials are there to listen but usually will not enter into a dialogue. We are advised that in the near future, independent hearing officers will be supplied for trade remedy hearings (similar to the practice in competition cases). This will be a significant departure from prior practice in which the case handlers presided over the hearing.

The case handlers and their immediate superiors attend the hearing and sometimes ask questions of the company representatives. The hearing is considered part of the information-gathering process and thus is inquisitorial rather than adversarial in nature. Historically, the hearings have been informal and unstructured; their function was to provide an opportunity to bring specific facts, circumstances, or arguments to the attention of the case-handlers. With the introduction of independent hearing officers, however, the hearings may become more structured.

Parties can bring witnesses, but the witnesses are subject to being questioned by the officials and a refusal to answer questions might be viewed negatively. No transcript is made; instead, the officials take notes. A party may provide a written copy of its presentation in confidential and non-confidential form. The regulations contain a provision for a confrontational hearing but these are exceedingly rare.

The hearing is not followed by issuance of a proposed decision. The first decision is the Commission's provisional regulation, which is adopted not later than 9 months after initiation of the procedure. Later the Council imposes the definitive anti-dumping or countervailing duty. The decisions must state reasons and make findings on all relevant issues, including the question of whether imposition of duties is against the Community's interest. The decisions must disclose "the details underlying the essential facts and considerations" on the basis of which duties were imposed. Provisional and final decisions are published. The final decisions are in the form of regulations of general application but these regulations contain individualized as well as generalized measures.

Provisional dumping and subsidy measures are imposed by a Commission regulation (approved by simple majority of the College of Commissioners). Only the Council of the EU imposes definitive measures. Safeguard measures can be taken by a vote of the Commissioners, but if a Member State objects, it can refer the matter to the Council for approval by qualified majority.

After the expiration of a one-year period after definitive measures are imposed, interested parties may apply for an interim review in which the Commission examines the need for continued imposition of measures or whether the measures ought to be changed. There is also provision for a newcomer review on behalf of a company that was not exporting the product during the investigation period. Definitive anti-dumping and anti-subsidy measures expire after 5 years unless it is determined in an expiry review that they should be continued. The procedures that apply to investigations also apply to these various forms of post-adoption review. There is also provision for reviews on the part of Community industry in the event that the exporters have "absorbed" the additional duties or "circumvented" the measures previously imposed.

C. *Trademarks*

A Community trademark (CTM) provides Community-wide protection for distinctive signs used to distinguish a product or service from those of competitors.[100] A CTM must be registered with the Office (Office for the Harmonization in the Internal Market or OHIM) in Alicante, Spain. OHIM is an agency outside the European Commission that is responsible for enforcing Community trademark law. Private parties can challenge a CTM by means of an "opposition" filed by an earlier trademark owner complaining of a likelihood of confusion as well as by an application for "invalidity" or for "revocation" (in the event of nonuse or that the mark has become generic). Member States also register trademarks which provide protection in that state only. Litigation about the validity of trademarks can be conducted both before Community courts and courts in Member States.

An application for a CTM is filed with OHIM either in writing or on line. European lawyers must represent non-European based applicants. The application must contain a list of the goods or services in respect of which registration is requested using the classification system in the Nice Agreement. A CTM application must be filed in any of the official languages of the

[100] The basic regulation concerning trademarks is Reg. 40/94.

Community and a second language must also be specified; the choice of languages can be used as a strategic tool. After filing, OHIM considers whether the application meets all requirements and whether any grounds for refusal are present. It is possible to conduct informal meetings with the examiner to discuss a CTM application. OHIM then conducts a Community search to discover earlier identical marks that may be invoked as grounds for refusal to register the mark in an opposition proceeding. After the search report is communicated to the applicant, the general public is informed of the application through publication in the Community Trademarks Bulletin.

OHIM has no investigatory powers other than those already mentioned. Further investigation is left to private parties who may choose to file a "notice of opposition" within 3 months after the application has been published. Opponents can also file an application to hold a CTM invalid or file a counterclaim in Member-State infringement proceedings. A 2-month cooling-off period applies after an opposition petition is filed. Thereafter the opponent files arguments and documents within the times set by OHIM and the applicant files responding documents. The files arising out of an application or an opposition are open to inspection. However, some material may be made unavailable either because it is confidential or because it is an internal OHIM document. Settlements of trademark disputes are possible during the cooling off period or after proceedings have begun. Examiners sometimes suggest settlements.

Proceedings before OHIM are mainly written. Oral hearings are uncommon (other than the informal meetings held during the application process as mentioned above). Oral hearings may occur if OHIM feels one is necessary or if a party requests a hearing and OHIM deems it expedient. If a hearing is held, the hearing officers are the same officials who are working on the underlying application or opposition proceeding. The hearing is an informal conference; it provides an opportunity for a party to convey its arguments or highlight the evidence it has submitted to OHIM. The OHIM officials can ask questions of the parties or witnesses. An agenda will set forth the points to be discussed.

If OHIM decides that an oral hearing is needed, it selects the witnesses and frames the issues and issues a summons for the attendance of the witnesses. If a party requested the hearing, it selects the witnesses and frames the issues and OHIM will issue a summons to those witnesses. The officials working on a trademark case or an appeal may not have any personal interest in the matter and may be disqualified for partiality. Ex parte contacts are not allowed.

Trademark proceedings contain a form of separation of functions: officials working on an opposition cannot have also worked on the application; members of the cancellation division cannot have participated in application or opposition proceedings; and members of the Boards of Appeal cannot have participated in any prior proceedings. The primary record is contained in minutes that must be approved by the witnesses (but a recording of the hearing is also made). There is no specific time limit on making a trademark decision; it depends on the complexity of the case and the workload of the responsible officials.

Parties may appeal decisions of the Office to a Board of Appeals within two months after notification of the decision complained of. The Board will invite the parties to file observations and is empowered to take any action OHIM could have taken originally or it can remit the matter to OHIM. Board of Appeal decisions can be further appealed to CFI and ECJ. After an appeal is filed, the OHIM division that took the original decision can "revise" it.

The decision of the Office or the Board of Appeals must provide the legal interpretations and reasoning on which the decision is based. The statement of reasons must be detailed and respond to all arguments submitted by the parties (though if one or more of these arguments are sufficient to justify the decision the opinion need not consider all other arguments). The decision

is first notified to the parties and then published in the Community Trademarks Bulletin. A CTM is recorded in the Register of Community trademarks.

There is no duty of care imposed on OHIM since discovery of relevant facts and their presentation is up to the parties rather than to OHIM. Principles of res judicata apply so that invalidity or opposition cannot be invoked a second time. As in all other cases, complaints of maladministration can be filed with the Ombudsman.

D. *Food safety*

Food safety decisionmaking is triggered by an individual application for approval of a new food product.[101] The outcome is the promulgation of a regulation that allows any manufacturer that meets the standards to import the food item into the Community.[102] The exceptions are novel foods and genetically modified foods,[103] which result in an individualized decision covering only the particular applicant. Regardless of whether the process results in a rule or an individualized decision, the process used seems more appropriate to rulemaking than adjudication.

Depending on the particular type of product, an application to introduce food products is filed with a Member State (in the case of novel foods) or with the European Food Safety Agency (EFSA) (in case of other food products). This application triggers an extensive scientific assessment process by EFSA. In the case of novel foods, Member State officials conduct an initial assessment which is forwarded to Member States for comment; further investigation is carried out by EFSA. The assessment process can take between one and five years.

There is no opportunity for an adjudicatory hearing or other procedural protections in cases involving applications to introduce foods into the Community, even if the ultimate decision will be individualized or have an individualized impact.[104] A recent ECJ case (which involved procedures whereby a food supplement could be approved for sale in the Community) contains dictum that might, in the future, be the basis for a judicial decision (or for procedural regulations) that provide such protections. The Court suggested that EFSA procedures must meet the requirements of good administration. There must be provision for an applicant to make its views known and for a reasoned decision provided within a reasonable time.[105]

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[101] See generally Reg. 178/2002.

[102] It is unclear whether decisions of individual impact that are stated in regulations are judicially reviewable by the undertaking affected. See Boehringer Ingelheim Vetmedica GmbH v. Council, Case T-125/96, [1999] II-3427, ¶¶ 161-73 (indicating that the applicant for permission to market a veterinary medical product that is prohibited in a regulation has standing to challenge that regulation).

[103] See Reg. 258/97 (novel foods) and Reg. 1829/2003 (genetically modified food).

[104] 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 Regulations 1935/2004, Art. 14.

[105] *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).

The procedure used to approve an application to introduce a new food product begins with adoption of general legislation. For example, the responsible Commission service (DG SANCO) might initiate a legislative text dealing with a broad subject such as "obesity." After ad hoc consultations, consultations with advisory groups from Member States, and inter-service consultations, the draft text is submitted to the College of Commissioners for approval.

The second stage is the adoption of rules through the comitology process that include the approval of new food products. Once the products are approved, other manufacturers can then introduce identical products without securing approval. The Commission submits its decision to approve the product to SCFCAH (Standing Committee on Food Chain and Animal Health), which consists of food safety officials from Member States. The process of approval is politicized and ex parte contacts and political pressures are common. Generally the Commission submits draft proposals to SCFCAH to see whether there will be problems and it attempts to work out the problems in advance. If a proposal receives a qualified majority in SCFCAH, it must be adopted by the Commission; if it fails to achieve a qualified majority, the decision is made by the Council. There are relatively limited opportunities for input by the applicant or by other interested parties. The process of food safety regulation is described in greater detail in the report on rulemaking.

E. *State aids* [106]

Under Articles 87 to 89 of the Treaty, Member States may not grant subsidies or other advantage to entities unless first authorized to do so by the Commission.[107] Such subsidies have the potential to distort competition in the internal market and thus should be viewed as complementary to the regulation of private competition and monopoly discussed above.

Thus States must notify the Commission of schemes of new aid. If a State has granted state aid without prior authorization, it must recover the aid from the beneficiaries. The Commission may authorize various forms of aid if compatible with the common market (such as aid to make good the damage caused by natural disasters or aid to promote economic development of underdeveloped areas).[108]

State aid proceedings are bilateral, meaning that the proceedings are between the Commission and the Member State that grants the aid. Neither beneficiaries of the aid nor competitors of the beneficiary are parties to the proceedings. The Commission initiates a Phase I investigation when it receives a notification or receives information from a complainant that state aid will be or has been granted. Phase I lasts a maximum of two months following receipt of a complete notification. If the measure raises doubts about whether the aid is compatible with the common market, the Commission initiates a Phase II investigation. It notifies the concerned Member State of the decision to go to Phase II and publishes it in the Official Journal. The decision must summarize the relevant issues of fact and law and contain a preliminary assessment

[106] For a brief treatment of procedural rights in state aids cases, see Craig 2006 at 392-93.

[107] "Save as otherwise provided in this Treaty, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favoring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the common market." Treaty Art. 87(1). The details of state-aid regulation are set forth in Reg. 659/1999.

[108] Art. 87(2).

of the measures and set out the Commission's doubts about compatibility with the common market.

Phase II investigations generally take at least a year and often more than 18 months. The Commission's investigation runs to Member States, not to private enterprises. If the State does not reply to a request for information, its notification is deemed withdrawn. In practice, the Member State usually consents to the Commission's questioning the beneficiary of the aid, though the Member State controls the process. The one area in which the Commission takes investigative action directly against private parties involves compliance monitoring. The Commission does not give Member States access to its file, but it does inform the States of relevant information in its file. Private parties have no access to the file though the Commission usually discusses issues with the beneficiary of the aid.

During Phase II, the Member State concerned and any other interested parties can submit comments. The Member State can respond to any third-party comments. There is no oral hearing but there are informal meetings between Commission staff, Member State representatives, and other interested parties.

The proceeding closes with a Commission decision stating one of three possible outcomes: the measure does not constitute state aid, the measure is authorized, or the measure is not authorized. A final decision is taken by a majority of the Commissioners. The decision states the reasons for the Commission's conclusions. The Commission need not enter into a dialogue by addressing every issue of fact or law raised by any party, but it is required to consider all submissions. Decisions closing a Phase 2 investigation are published in full in the Official Journal. The Council may, by unanimous vote, authorize state aid in exceptional circumstances.

F. *Pharmaceutical licensing.*

A manufacturer wishing to introduce a pharmaceutical product into EU markets must obtain a marketing authorization to do so. Licensing of new medicines requires a delicate balance between the benefits of the medicine and its risks. The regulatory scheme extends not only to the decision about whether a new medicine can be introduced but also considers such specifics as the composition, therapeutic indications, prescription status, persons involved in the manufacturing process, method of packaging and package sizes, the wording of the package leaflet, labeling on the containers, and prescribing information for physicians.

The pharmaceutical licensing systems distinguish between centrally and decentrally approved products. The centralized procedure is administered at the Commission level and applies to biotechnology medicines and other innovative products. The decentralized procedure is administered at the Member State level and applies to other medicinal products. In the decentralized procedure, the decision on marketing authorization is prepared by the Reference Member State and the Concerned Member States as a rule follow the decision. A Coordination Group mediates disagreements between Member States under the decentralized procedure. In the event of further disagreement, the Committee for Medical Products for Human Use (CHMP) renders an arbitral opinion, which is the basis of a Commission decision that is binding on the involved Member States.

In the centralized procedure, the Commission makes decisions with the assistance of the European Medical Agency (EMEA) and the CHMP which is a division of the EMEA.The CHMP brings together scientific and regulatory expertise from the Member States and provides scientific assessment of medicines for human use on which Commission decisions are based. The Commission can vary, suspend or withdraw a marketing authorization if new scientific evidence

alters the risk-benefit assessment. In the future, it will be able to impose a range of financial sanctions in cases of infringement of certain legal obligations related to centrally approved products. EMEA and Member States engage in pharmacovigilance with respect to approved medicines. In general, proceedings in pharmaceutical cases are inquisitorial in nature rather than adversarial. The Standing Committee on Medicinal Products for Human Use represents Member States and is consulted by the Commission as part of the comitology process.

Applications for approval under the centralized procedure contain a great deal of data, particularly concerning clinical trials of the medicine. Applications are filed with EMEA in London. EMEA requests a six-month pre-filing announcement and applicants generally engage in a pre-submission meeting with EMEA to obtain procedural and regulatory advice. A project manager is appointed during the pre-filing period.

In general, the process within the CHMP should be completed within 210 days after an application is validated, but there are various clock-stops that extend the process. After validation, the CHMP appoints a rapporteur and a co-rapporteur to evaluate safety, efficacy, and quality and provide a preliminary assessment to the CHMP. Scientific advisory committees are often employed during this process. The CHMP ordinarily sends a list of questions and a positive or negative recommendation to the applicant who has up to six months to answer the questions and provide additional information.

Based on the applicant's response, the rapporteurs provide their joint assessment to the CHMP (a copy is provided to the applicant). The CHMP may request further oral responses. If CHMP's the report is negative (in part or in total), the applicant may request reassessment. The CHMP then drafts a final opinion, which is provided to the applicant and the Commission.

Applicants for marketing authorization and targets of regulatory review action have an opportunity to furnish written or oral explanations to the CHMP. These hearings are part of the investigation process and are conducted together with scientific evaluation of a medicine or the investigation of alleged infringements of marketing authorization obligations. The applicant can bring in experts or other witnesses to further explain its position. Third parties (such as scientists who oppose licensing a medicine) have no right to participate in these hearings, or more generally, in the licensing procedures, but their views should be taken into account.[109] No hearing officer is appointed. The CHMP then provides its detailed and reasoned opinion to the Commission along with extensive documentation. The Commission makes the final decision, which must contain a detailed statement of reasons. It involves the Standing Committee in the decision-making process. In the event the Commission disagrees with the Standing Committee, the Council makes the final decision. In cases of such disagreement, the Commission often refers the case back to the CHMP. All such decisions are posted on the Commission's web site. Similar procedural rights are provided in the draft Penalties Regulation.

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[109] See Olivieri v. Commission, Case T-326/99, [2003] II-6053. This case concerns a scientist who opposed an application for marketing authorization on the basis of her own research. CFI held that she had a right to have her opinion considered by CHMP but not to participate further in the proceedings which are bilateral between the applicant and the Commission. As a consequence, she also lacked standing to seek annulment of the Commission's decision approving the application.

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