

No. 10-1150

IN THE

Supreme Court of the United States

MAYO COLLABORATIVE SERVICES (d/b/a MAYO MEDICAL
LABORATORIES) and MAYO CLINIC ROCHESTER,

Petitioners,

—v.—

PROMETHEUS LABORATORIES, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE FEDERAL CIRCUIT

**BRIEF OF *AMICI CURIAE* ASSOCIATION
INTERNATIONALE POUR LA PROTECTION DE LA
PROPRIÉTÉ INTELLECTUELLE AND INTERNATIONAL
ASSOCIATION FOR THE PROTECTION OF INTELLECTUAL
PROPERTY (U.S.) IN SUPPORT OF NEITHER PARTY**

RICHARD P. BEEM

President

INTERNATIONAL ASSOCIATION
FOR THE PROTECTION OF
INTELLECTUAL PROPERTY (U.S.)
Beem Patent Law Firm
The Monadnock Building
53 W. Jackson Boulevard,
Suite 1352
Chicago, Illinois 60604-3787
(312) 201-0011

PETER C. SCHECHTER

Counsel of Record

EDWARDS ANGELL PALMER
& DODGE LLP
750 Lexington Avenue
New York, New York 10022
(212) 912-2934
pschechter@eapdlaw.com

*Counsel for Amici Curiae Association Internationale pour
la Protection de la Propriété Intellectuelle and International
Association for the Protection of Intellectual Property (U.S.)*

TABLE OF CONTENTS

	PAGE
TABLE OF CONTENTS.....	i
TABLE OF AUTHORITIES.....	ii
INTEREST OF <i>AMICI CURIAE</i>	1
INTRODUCTION.....	3
SUMMARY OF THE ARGUMENT.....	5
ARGUMENT.....	6
CONCLUSION.....	13
APPENDIX.....	A1

TABLE OF AUTHORITIES

Cases	PAGE
<i>Henderson v. Shinseki</i> , 562 U.S. ___, 131 S. Ct. 1197 (2011).....	12
<i>Laboratory Corp. of America Holdings</i> <i>v. Metabolite Labs., Inc.</i> , 548 U.S. 124 (2006)	7, 8
 U.S. Constitution	
U.S. Const. art. I, § 8, cl. 8	3
 Statutes	
Patent Act of 1790, ch. 7, § 1, 1 Stat. 109 (April 10, 1790)	3
Patent Act of 1793, ch. 11, § 1, 1 Stat. 318 (February 21, 1793)	3
35 U.S.C. § 101.....	3, 6
35 U.S.C. § 102.....	3
35 U.S.C. § 103.....	3
35 U.S.C. § 112.....	3
35 U.S.C. § 281.....	9
35 U.S.C. § 283.....	9
35 U.S.C. § 284.....	9
35 U.S.C. § 285.....	9
35 U.S.C. § 287(c).....	4, 6
35 U.S.C. § 287(c)(1)	<i>passim</i>

	PAGE
35 U.S.C. § 287(c)(2)(A)	9
35 U.S.C. § 287(c)(2)(A)(i).....	9
35 U.S.C. § 287(c)(2)(A)(ii).....	9-10
35 U.S.C. § 287(c)(2)(A)(iii)	9
35 U.S.C. § 287(c)(2)(C)	11-12
35 U.S.C. § 287(c)(2)(D)	11-12

I. INTEREST OF AMICI CURIAE¹

This brief is submitted on behalf of *amici curiae* Association Internationale Pour La Protection De La Propriété Intellectuelle (“AIPPI”) and International Association For The Protection Of Intellectual Property (U.S.) (“AIPPI-US”) (hereinafter referred to collectively as “AIPPI”).

AIPPI is an international organization, founded in 1897, dedicated to the development, improvement, and legal protection of intellectual property. AIPPI is a politically neutral, non-profit organization headquartered in Switzerland having over 9000 members representing over 100 countries and operating mainly through National and Regional Groups, such as the AIPPI-US.

The members of AIPPI include intellectual property lawyers, patent and trademark attorneys, and patent agents in corporate and private practice throughout the world, as well as academics and other persons interested in intellectual property, and including members from North America, South America, Europe, Asia, Australia, and Africa.

The primary goals of AIPPI, in accord with its implementing statutes and regulations, are to promote the protection of intellectual property on a national and international basis and to study and

¹ The parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the Amici has made a monetary contribution to the preparation or submission of this brief.

compare existing law and proposed laws to propose improvements thereto. AIPPI pursues these objectives, in part, by working for the development, expansion and improvement of international and regional treaties and agreements and also of national laws relating to intellectual property. In its long history, AIPPI has adopted more than 700 Resolutions and Reports. An AIPPI “Resolution” is a Statement of Policy regarding a specific Intellectual Property issue, approved by the collective National and Regional Group members of AIPPI. Such a Resolution is issued only after lengthy study and discussion and subsequent vote by a majority of delegates present at an Annual Meeting of the Executive Committee of AIPPI. The presentation of these Resolutions and Reports to international Governmental Organizations, in particular the World Intellectual Property Organization (“WIPO”), has contributed considerably to the development, improvement and harmonization of the international protection of intellectual property. AIPPI has adopted a Resolution on an issue touching that before this Court: Resolution Q202 (“The impact of public health issues on exclusive patent rights”), discussed below and attached hereto (Appendix at A1-A5).

For at least the above-noted reasons, and on behalf of both resident and non-resident AIPPI members who seek, on behalf of the clients they represent, clarity in the applicability of patent rights in the United States to methods of medical treatment of patients, AIPPI submits this brief to this Court.

II. INTRODUCTION

The framers of the United States Constitution recognized the need to encourage innovation, and dissemination of the same, by rewarding inventors and granted the United States Congress the authority “[t]o promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.” U.S. Const. art. I, § 8, cl. 8. Congress enacted the first United States Patent Act in 1790 requiring, *inter alia*, the applicant to “have invented or discovered any useful art, manufacture, engine, machine, or device, or any improvement therein.” Patent Act of 1790, ch. 7, § 1, 1 Stat. 109 (April 10, 1790). Congress amended this Act in 1793 to require that the applicant “have invented any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement.” Patent Act of 1793, ch. 11, § 1, 1 Stat. 318 (February 21, 1793). In the revisions to the Patent Act of 1952, Congress amended the language of 35 U.S.C. § 101 to use the term “process” in lieu of “art,” stating: “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” The Patent Act of 1952 further required the subject matter of the invention to be novel (*see* 35 U.S.C. § 102), to be non-obvious (*see* 35 U.S.C. § 103), and to satisfy certain disclosure requirements (*see* 35 U.S.C. § 112).

The United States has been historically, and remains currently, a leader in innovation. Manufacturing, chemistry, electronics, biotechnology,

and computer software are just a few of the technological fields that have seen tremendous commercial development within the United States. The Patent Laws of the United States have accommodated and fostered innovation in and development of all of these technologies, and have helped the United States to achieve and maintain its position in the global economy.

Nearly all developed and developing nations worldwide have patent laws that likewise seek to foster innovation in and development of important technologies and advancements for their own societies and for the global society at large. In one important respect, however, the patent laws of the United States differ from those of virtually all other nations (the sole exception being Australia): only in the United States (and Australia) are methods of medical treatment of patients considered patent-eligible subject matter. Because this important distinction sets U.S. patent law apart from the patent laws of nearly every other country around the globe, the applicability of exclusive patent rights to methods of medical treatment of patients raises unique concerns for all people who seek medical treatment in the United States.

In 1996, Congress addressed these concerns at least partially by enacting 35 U.S.C. § 287(c), which eliminates a patentee's remedy by civil action, and the right to injunction, damages, and attorney fees against medical practitioners and related health care entities for the performance of certain patented medical procedures.

This brief attempts to serve the Court by providing both a global perspective on the issue of patent eligibility for methods of medical treatment

of patients, and a commentary on the effectiveness and impact of the current U.S. statutory scheme affecting this issue. Finally, AIPPI urges that federal subject matter jurisdiction is lacking here, in light of that U.S. statutory scheme.

III. SUMMARY OF THE ARGUMENT

AIPPI's mandate is to study the way patent systems around the world protect intellectual property and make recommendations for improvement. To this end, AIPPI has studied the particular limitations of exclusive patent rights in a wide variety of countries to determine the extent such limitations may play a role in providing access to patented medicines, other medical or biological products, and methods of medical treatment of patients, so as to facilitate health care, notably in the context of public health crises. AIPPI, through its Resolution Q202 (*see* Appendix at A5, Resolution Para. 5), encourages all member countries to allow medical personnel the freedom to provide medical treatment of patients without the authorization of any patentee, at least under certain circumstances discussed further below.

In the overwhelming super-majority of countries (indeed, in all 33 countries studied by AIPPI other than the United States and Australia), the societal objective of allowing medical treatment of patients to be unfettered by exclusive patent rights is achieved by excluding methods of medical treatment of patients from patent eligibility altogether. In the United States, this objective is supposed to be achieved by a statutory scheme eliminating, more or less, the availability of cer-

tain provisions of the Patent Laws with respect to certain types of potential actions against certain defined sets of individuals and entities. *See generally* 35 U.S.C. § 287(c).

Thus, while the question presented asks whether such claims fall within the ambit of patentable subject matter under 35 U.S.C. § 101, any such inquiry may be unnecessary and, as a matter of law, is prohibited if the district court lacked subject matter jurisdiction over the action. *See* Rule 12(h)(3), Fed. R. Civ. P.

For reasons that are not clear, Congress' legislative effort to achieve a globally-desired limitation of exclusive patent rights, at least under certain circumstances, appears to have been unapplied, misapplied, or simply overlooked by the district court and the Court of Appeals for the Federal Circuit in this case. AIPPI urges this Court to apply the statutory scheme eliminating entirely this patent dispute (and the attendant costs to society, the medical profession, and patients themselves) involving medical treatment of patients.

IV. ARGUMENT

AIPPI's Resolution Q202 ("The impact of public health issues on exclusive patent rights"), adopted at the Boston Congress, September 6-11, 2008, states (Appendix at A5, Resolution Paragraph 5):

To the extent that the patent law permits patentability of methods of medical treatment, the law should provide for an exception to the rights of a patentee, allowing medical personnel to use

patented methods of medical treatment, without the authorisation of the patentee, in circumstances where it is not practicable to negotiate a licence before treatment.

AIPPI did not study the issue of patent eligibility of methods of medical treatment of patients, *per se*. However, such study was not necessary, as only two of the countries' laws studied allowed for such patent eligibility at all (those two countries being Australia and the United States).² In the realm of public health issues, notably in the context of public health crises, it was resolved that a nation's patent laws should not impede or impair access to medical treatment, at least under certain circumstances. Given the state of the laws around the world, it should be understood that Resolution Q202 confirms the current situation in most countries, even including the United States, at least in theory.³

In *Laboratory Corp. of America Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006), a prior case presenting essentially the same question as is presented in this case, and in which certiorari had been granted but then dismissed as having

² See AIPPI Summary Report, Question Q202 attached hereto (Appendix at A6-A42), Sec. (I)(5), at A16.

³ At the time AIPPI Resolution Q202 was adopted, Australia was the only studied country in which methods of medical treatment were eligible for patenting and in which there was no defense, exclusion or exemption of any kind from liability for patent infringement resulting from the practice of such methods. See AIPPI Summary Report, Question Q202, Sec. (I)(5), Appendix at A16, and discussion of "Medical treatment defence," Appendix at A34.

been improvidently granted, Justices Breyer, Stevens, and Souter wrote that “special public interest considerations” are implicated by the question of patent eligibility for methods of medical treatment of patients because allowing such patents would “inhibit doctors from using their best medical judgment,” would “force doctors to spend unnecessary time and energy to enter into license agreements,” and would “divert resources” from healthcare tasks to “the legal task of searching patent files,” among other deleterious effects. *Id.* at 135. These are the very same concerns addressed in AIPPI Resolution Q202. At minimum, there is a recognized danger, or at least special undesirability, of requiring doctors to negotiate and obtain patent licenses in order to treat patients, at least when “not practicable” to do so before treatment.

It is difficult to imagine many circumstances in which it would be “practicable” for a physician to identify the need for, seek and then successfully obtain a patent license before ordering optimization of a course of drug administration to a patient. In this case, a method of dosage optimization for a specific patient, by that patient’s physician, is precisely what is claimed in the patent-in-suit. Respondent has previously argued that the “entire purpose of these inventions is to improve a process of patient treatment. *There are, in fact, no uses of the claimed processes other than in connection with patient treatment.*” (See *Prometheus Labs., Inc. v. Mayo Collaborative Servs. (dba Mayo Medical Labs)*, Appeal No. 2008-1403, Appellant’s Reply Brief dated April 24, 2009, at 14 (Fed. Cir.) (emphasis added). Thus,

the “special public interest considerations” previously recognized by this Court are precisely implicated here.

Under current U.S. law, the provisions of 35 U.S.C. § 287(c)(1) of the Patent Act eliminate the availability of 35 U.S.C. § 281 (remedy by civil action), § 283 (injunction), § 284 (damages), and § 285 (attorney fees) against both the “medical practitioner” and “related health care entity” (defined as including but not limited to nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic), at least as to a “medical activity,” defined as “the performance of a medical or surgical procedure on a body.” Thus, when Section 287(c)(1) applies, the courts lack subject matter jurisdiction to hear a specified class of claims of patent infringement against specified classes of potential infringers.

By enacting Section 287(c)(1), Congress has pronounced that at least some medical activities should be outside of, and free from interference by, the patent system. AIPPI respectfully suggests that both the infringement claims at issue and the named defendants in this case fall within those specified classes.

The definition of “medical activity” to which the exemption of § 287(c)(1) applies contains three exceptions codified in Section 287(c)(2)(A), but none of them applies here. It is indisputable that neither Section 287(c)(2)(A)(i) (“use of a patented machine, manufacture, or composition of matter”) nor Section 287(c)(2)(A)(iii) (practice of process in violation of a biotechnology patent) applies. Similarly, while Section 287(c)(2)(A)(ii) removes “the

practice of a patented use of a composition of matter” from the exemption, the claims at issue in this case do not fall within this exemption.

U.S. Patent No. 6,355,623, “Method of treating IBD/Crohn’s disease and related conditions wherein drug metabolite levels in host blood cells determine subsequent dosage” (hereinafter “the ’623 patent”), describes a method of improving the treatment of autoimmune diseases by providing physicians a way to “individually calibrate a patient’s dosage [of a particular medication] without having to take a wait-and-see approach.” Brief for the Respondent in Opposition (to the petition for writ of certiorari), at 4. First, at least one asserted claim, i.e., claim 46, of the ’623 patent recites only “determining” a patient’s metabolite levels. (It is apparent that such “determining” requires withdrawal of a certain amount of the patient’s blood, without question a “medical activity.”) Second, as Respondent argues, the asserted patent claims are not drawn to the use of a composition of matter but instead are “processes to generate useful treatment information for physicians.” Brief for the Respondent in Opposition (to the petition for writ of certiorari), at 12. Instead of requiring that the drug dosage be increased or decreased based on metabolite levels found in the patient’s blood, the claims simply “indicate a need” to adjust the dosage. *See* Petition for a Writ of Certiorari, at 6-7 (“Importantly, Prometheus’s claims do *not* recite what is to be done once the physician mentally recognizes the correlation.”).

In addition to immunizing the allegedly infringing activity from suit, Section 287(c) also frees certain classes of defendants in an infringement suit,

Petitioners here, from liability. The evidence of infringement presented by Respondent Prometheus centered on the patient treatment activities of Dr. Rokea A. el-Azhary, M.D., Ph.D., a clinical dermatologist working in the Dermatology Department at Mayo Clinic Rochester, who is unquestionably a “medical practitioner” entitled to the protection of 35 U.S.C. § 287(c)(1). That evidence concerned blood tests ordered by Dr. el-Azhary from the Biochemical Genetics Laboratory of Mayo Clinic Rochester.⁴ Mayo Clinic Rochester is unquestionably a “related health care entity” with respect to Dr. el-Azhary, and is also entitled to the immunity from suit provided by 35 U.S.C. § 287(c)(1). Prometheus argues in passing that while “individual doctors generally are immune from suit, . . . the commercial entities that enable and induce the infringement (such as Mayo’s for-profit laboratory) are not.” *See* Brief for the Respondent in Opposition (to the petition for writ of certiorari), at 34. However, 35 U.S.C. § 287(c) makes no distinction between “for-profit,” “not-for-profit,” and any other types of the defined “related health care entities” based upon financial motivation or any other criteria, for that matter; all are immune from suit unless one of the three § 287(c)(2)(A) exceptions applies. There does not appear to be any reason to conclude that Mayo Clinic Rochester and its related Mayo Collaborative Services are not “related health care entities” within the meaning of 35 U.S.C. § 287(c)(2)(C) and

⁴ It is understood that the Biochemical Genetics Laboratory at Mayo Clinic Rochester is actually part of Petitioner Mayo Collaborative Services, strictly as a matter of corporate organization.

(D), both entitled to be free from patent infringement suits of the instant type.

Thus, it appears that both named defendants are plainly “related health care entities” and that, accordingly, Congress has eliminated availability of a federal civil action for patent infringement of Prometheus’ patent against them. The immunity from suit provided by Congress in 35 U.S.C. § 287(c)(1) should be given effect, and the case should be dismissed for lack of federal subject matter jurisdiction. That this issue apparently was not raised before either the district court or the Federal Circuit is of no import, as it is hornbook law that “[o]bjections to subject-matter jurisdiction . . . may be raised at any time.” *Henderson v. Shinseki*, 562 U.S. ___, ___, 131 S. Ct. 1197, 1202 (2011).

Dismissal of this action for lack of federal subject matter jurisdiction comports with the letter and spirit of AIPPI Resolution Q202, which states that medical personnel should not be constrained by patent rights in circumstances where it “not practicable to negotiate a licence before treatment.” Given the nature of the patent claims in this case and the types of defendants against whom the assertions of infringement have been made, allowance of the infringement action would either: (a) require a hospital laboratory such as the Biochemical Genetics Laboratory at Mayo Clinic Rochester to identify, obtain, and maintain a complete library of patent licenses covering every test that any doctor at Mayo Clinic Rochester might ever order, or (b) require the hospital laboratory to itself order a patent infringement search and study each time a Mayo Clinic

doctor orders a diagnostic blood test, and then obtain a license when deemed necessary or advisable in the opinion of Mayo Clinic Rochester's qualified patent counsel. Because neither of these options is "practicable," application of Congress' legislative solution in 35 U.S.C. § 287(c)(1) is appropriate and would achieve the purpose of AIPPI Resolution Q202.

V. CONCLUSION

The U.S. Congress has chosen to implement a public policy nearly deemed universally desirable, namely, freedom of doctors and their related facilities from patent infringement concerns, by eliminating availability of federal civil actions in certain defined circumstances. AIPPI, through its Resolution Q202, supports this public policy for at least the "special public interest considerations" previously recognized by Justices Breyer, Stevens, and Souter. This case appears to fall squarely within the statutory immunity from patent suit under 35 U.S.C. Sec. 287(c)(1), yet this seemingly critical issue does not appear to have been briefed, or even seriously raised, at any stage of the proceedings below. AIPPI respectfully submits that in view of Congress' withdrawal of the remedy by civil action in cases such as this one, federal subject matter jurisdiction is lacking, and that the case should be dismissed on this basis.

Respectfully submitted,

PETER C. SCHECHTER
Counsel of Record
EDWARDS ANGELL PALMER
& DODGE LLP
750 Lexington Avenue
New York, New York 10022
(212) 912-2934
pschechter@eapdlaw.com

Attorneys for Amici Curiae
Association Internationale Pour
La Protection De La Propriété
Intellectuelle And International
Association For The Protection
Of Intellectual Property (U.S.)

APPENDIX

A1

[LETTERHEAD OF AIPPI]

Resolution

Question Q202

The impact of public health issues on exclusive patent rights

Yearbook 2008/I, pages 367-369
Congress Boston, 6-11 September 2008

AIPPI

Noting that:

- 1) The focus of this resolution is exceptions to exclusive patent rights applicable to medicines and other medical products.
- 2) Access to affordable medicines and other medical products is a pressing issue but exceptions to exclusive patent rights alone cannot resolve this issue.
- 3) AIPPI has studied exceptions to exclusive patent rights in previous questions, leading in particular to:
 - i) The resolution of the Executive Committee of Barcelona in 1990—Question Q101, Yearbook 1991/I, page 298 entitled ‘Parallel Import Of Patented Products’ (*Barcelona Parallel import Resolution*);
 - ii) The resolution of the Executive Committee of Tokyo in 1992—Question Q105, Yearbook 1992/III, pages 282-283

entitled ‘Experimental Use as a Defence to a Claim of Patent Infringement’ (*Tokyo Experimental Use Resolution*); and

- iii) The resolution of the 38th Congress of Melbourne in 2001—Question Q156, Yearbook 2001/I, pages 511-512 entitled ‘International Exhaustion of Industrial Property Rights’ (*Melbourne International Exhaustion Resolution*).
- 4) The Barcelona Parallel Import Resolution resolved that a patentee be able to invoke its patent against parallel import of a patented product, notwithstanding the circumstances under which such product has first been put on the market in a given country “B”, subject to exception by contractual agreement authorising import into another country “A”.
- 5) Paragraph 3 of the Tokyo Experimental Use Resolution resolved that each country should except acts done for experimental purposes from the rights of the patentee on the basis that experimental use:
 - i) Includes any use of the patented invention performed for academic purposes and having no commercial nature;
 - ii) Includes testing to evaluate the teaching of the patent and validity of the patent;
 - iii) Includes any use of the patented invention to an extent appropriate to experimentation (as opposed to commercial use) which is for the purpose of improv-

ing the invention or making an advance over the invention or finding an alternative to the invention, but not the commercial exploitation of the subject of any improvement or advance; and

- iv) Should be subject to the overriding principle that the use must involve work on the subject of the patent; use merely to obtain the advantage of the invention disclosed by the patent is not experimental use.
- 6) The Melbourne International Exhaustion Resolution affirmed the Barcelona Parallel Import Resolution and resolved that there should be no international exhaustion of industrial property rights (patents, trademarks, designs and plant breeder's rights) notwithstanding that regional exhaustion may be applied in order to foster regional integration of different national economies under a uniform regulatory and legal framework.
- 7) The patent law in some countries provides for an exception to exclusive patent rights for on "extemporaneous" preparation of a medicine in a pharmacy For individual cases in accordance with a medical prescription issued by a medical doctor (commonly referred to as the individual prescriptions exception).
- 8) A number of WTO Members have not yet ratified Article 31bis of the TRIPs.

Considering that:

- 1) Patent law provides for a number of exceptions to exclusive patent rights which may play a role in providing access to patented medicines and other medical products.
- 2) Compulsory licensing is a more appropriate and proportionate means of providing access to patented medicines and other medical products than expropriation of patent rights.

Resolves that:

- 1.1) Patent law should provide for an exception to the rights of a patentee, allowing a party to undertake, without the authorisation of the patentee, experiments relating to the subject-matter of the invention, irrespective of whether the ultimate aim of the experiments may be commercial.
- 1.2) Paragraph 3 of the Tokyo Experimental Use Resolution is affirmed insofar as it is not in conflict with paragraph 1.1.
- 2) Patent law should provide for an exception to the rights of a patentee, allowing a party to undertake, without the authorisation of the patentee, acts necessary for the purpose of obtaining regulatory approval for medicines and other medical products such as medical devices, diagnostics, research tools and the like.
- 3) The Barcelona Parallel Import Resolution and the Melbourne International Exhaustion Resolution are each affirmed.

- 4) To the extent that the patent law provides for an individual prescriptions exception, the exception should be limited to preparation of medicines as and when required for an individual patient and should not extend to situations where medicines are prepared on a larger scale.
- 5) To the extent that the patent law permits patentability of methods of medical treatment, the law should provide for an exception to the rights of a patentee, allowing medical personnel to use patented methods of medical treatment, without the authorisation of the patentee, in circumstances where it is not practicable to negotiate a licence before treatment.
- 6) Concerning public health:
 - a) the patent law should provide that a compulsory license can only be granted in exceptional and strictly defined circumstances.
 - b) the law should not permit expropriation of patent rights.
- 7) Article 31bis of the TRIPS should be promptly ratified by WTO Members that have not yet done so.

[LETTERHEAD OF AIPPI]

Summary Report

Question Q202

The impact of public health issues on exclusive patent rights

This Question considers the limitations of exclusive patent rights in a wide variety of countries. Its particular focus is limitations which may play a role in providing access to patented medicines and other medical or biological products so as to facilitate health care, notably in the context of public health crises.

The Reporter General has received 33 Group Reports from the following countries (in alphabetical order): Argentina, Australia, Belgium, Brazil, Bulgaria, China, Columbia, Denmark, Ecuador, Egypt, Estonia, Finland, France, Germany, Ireland, Italy, Japan, Malaysia, Mexico, the Netherlands, Norway, Peru, Philippines, Portugal, Republic of Korea, South Africa, Spain, Sweden, Switzerland, Thailand, Turkey, United Kingdom and United States of America.

The Reports provide a comprehensive review of the limitations imposed on exclusive patent rights under national patent laws. This Summary Report cannot attempt to reproduce the detailed rules explained by each Group or carefully selected examples used to illustrate those rules in practice. It may also be the case that particular words and phrases which have a specific meaning in their

original language cannot be translated fully. If any doubt exists as to the exact position in a particular jurisdiction, reference should be made to the original Group Reports.

I) Analysis of current law and case law

- 1) *Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?*

The vast majority of the Groups reported that a research or experimental use exception was recognised in their jurisdiction (either through statutory measures or doctrine and jurisprudence). In these jurisdictions an otherwise infringing act will not infringe if it is done for experimental purposes relating to the subject matter of the invention.

The patent laws generally do not give a definition of “experimental” but it is recognised that an act is an experiment if it seeks to generate genuinely new information (and not if it seeks simply to verify existing knowledge). The UK Group Report quoted the Court of Appeal in *Monsanto v Stauffer* where it was observed that experiments are “trials carried out in order to discover something unknown, or to test a hypothesis, or even in order to find out whether something which is known to work in specific conditions . . . will work in different conditions”.

A number of Group Reports (Belgium, Denmark, Finland, Germany, Sweden, Switzerland, UK) note that this does not rule out an ultimate commercial aim, so long as the trials are experiments. In these jurisdictions experimental use is not only permitted for a purely scientific purpose, but also for mixed scientific and commercial purposes.

On the other hand, trials to demonstrate to a third party (e.g. a regulator) that a product works as its maker claims are not “experiments”, according to the UK Group Report.

The German Group Report emphasises that the experimental use exception is limited in that experiments will only be deemed permissible if they use the patented subject matter as the object of the test and not merely as a means of realisation. Moreover, experiments which are conducted to clarify economic factors, such as market demand, price acceptability or distribution possibilities are not permissible. The German and Dutch Group Reports point out that experiments may only be carried out to an extent justifying the experimental purpose; clinical trials that take place on a very large scale do not fall under the research exception.

In a number of countries (Argentina, Brazil, Ecuador, France, Italy, Malaysia, the Philippines), research and experimental use are only permitted for a purely scientific purpose, but not a commercial purpose. Similarly, in the United States, the research exception is limited to narrowly non-commercial uses such as “gratifying a philosophical taste, or

curiosity, or for mere amusement". The exception does not even extend to pure scientific research if research is the infringer's business.

Turkey and the Republic of Korea provide for a research or experimental use exception, but it is not clear whether experimental use is permitted for commercial purposes.

In Thailand experimental use for a commercial purpose is permitted provided that it does not unreasonably conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent holder. The Thai Group Report does not specify what this proviso means.

In Australia and South Africa, there is no express provision to provide for a research or experimental use exception from infringement. In the South African case of *Monsanto v Stauffer* the High Court stated that even experimental use will amount to infringement if the experiment uses the patented invention. The use of the patent to prepare for marketing registration of its own similar product was, therefore, found to constitute infringement. In Australia, researchers tend to act on the assumption that a research exception exists, but in the absence of Australian court authority, it is not clear what the conditions are in which the exception would operate or what the scope of the exception would be.

- 2) *Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?*

The European Union (EU) introduced a Community-wide Bolar exemption under Directive 2004/27/EC (with respect to medicinal products for human use) and Directive 2004/28/EC (with respect to veterinary medicinal products) which were implemented by all member states on October 30, 2005. Therefore, all of the reporting Groups which are member states of the European Union or the European Economic Area (EEA), respectively (Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, Portugal, Spain, Sweden, United Kingdom) recognise a Bolar-type exception. This Bolar exemption applies to experimental activities carried out by generic manufacturers with a view to obtaining a marketing authorisation for a generic drug. These are essentially bioequivalence studies and such further studies as may be required to cater for any differences between the basic approved product and the “generic” or “biosimilar” product.

The Bolar exception is limited to human and veterinary medicinal products. The Dutch Group Report states that research tools or medical devices would not be covered by this exception as these products will generally not meet the definition of medicinal product. Conversely, the Swedish Group reports that the Bolar exception would include biological products if these are to be considered as reference medicinal products, and the use of research tools would be covered by the exception if they are substantially related to the reference medicinal product.

The Irish Group report notes that the Bolar exemption does not entitle innovative companies to make experimental uses of patented medicines or research tools for the purpose of seeking a marketing authorisation for a **new** medicinal product. On the other hand, in Denmark, France and Germany the Bolar exception is not limited to acts directed at obtaining market approval of a generic, but rather encompasses market approval of innovative drugs as well.

A Bolar-type exception is also recognised in most other jurisdictions (Argentina, Australia, Brazil, Malaysia, South Africa, Switzerland, Thailand, Turkey, United States).

In the United States, the Bolar exception is broadly applied to pre-clinical testing of drugs or potential drugs “at least as long as there is a reasonable basis to believe that the compound tested could be the subject of . . . and the experiments will produce the types of

information relevant to” an application for approval for clinical trials or marketing (*Merck KGaA v Integra Lifesciences*). The Bolar exception is limited to drugs for human use; other biological products would only be covered to the extent that they are regulated as drugs. The exception does not apply if the drug is primarily manufactured using recombinant DNA or hybridoma technology or if the drug is a new animal drug or veterinary biological product.

The Australian and Thai Group Reports note that the Bolar exception is limited to drugs; other products such as biological products, medical devices, and research tools are excluded from the exception.

In Argentina, Brazil, Malaysia, and South Africa, the Bolar-type exception is not limited to pharmaceutical products; it applies to any other product requiring regulatory approval. This would for example not only cover pharmaceutical, but also agrochemical products which require marketing authorisations before such products may be put on the market. The Brazilian and Malaysian Group Reports state that biological tools and research tools would also be covered by this exception. The Swiss Group is of the opinion that biological products would also be covered to the extent they require regulatory approval; however, medical devices and research tools do not seem to be exempted.

In Ecuador, Japan and the Republic of Korea, no Bolar-type exception is recognised under the patent laws. However, in Ecuador and in

Japan, clinical trials and other acts seeking to obtain approval of a generic product are exempted under the research exception. Also in the Republic of Korea, researchers tend to act on the assumption that using an invention without the patentee's consent for the purpose of obtaining approval of a generic product will be covered by the research exception; there is, however, no court authority.

In China, Columbia, Peru and the Philippines, a Bolar-type exception is not recognised and using an invention without the patentee's consent for the purpose of obtaining approval of a generic product will not be covered by the research exception. However, in Peru a Bolar-type exception will soon be recognised under the patent law since the Trade Promotion Agreement Peru-USA includes a Bolar-type exception. Similarly, in China and the Philippines it is expected that the law will soon be amended to provide for a Bolar-type exception.

- 3) *Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?*

Within the EEA, regional exhaustion applies, i.e. a patented product, put on the market anywhere in the EEA by the patentee or with his consent, is free to move anywhere in the EEA. However, parallel imports of patented medicines, medical devices or similar from outside the EEA are not permitted.

In most other countries, only national exhaustion of rights applies and parallel imports of patented medicines, medical devices or similar from outside the country are generally not permitted (Brazil, China, the Philippines, South Africa, Switzerland, Turkey, United States).

In Argentina, Columbia, Ecuador, Egypt and Peru, international exhaustion of patent rights applies; as a result, parallel imports of patented medicines, medical devices or similar are permitted.

In Australia and Japan, parallel importation is only permissible to the extent the patentee has not made it a condition of sale that the purchaser may not import their goods into Australia and Japan.

In South Africa, even though national exhaustion applies, the parallel importation of patented medicines has specifically been provided for by an amendment of the South African Medicines and Related Substances Act. According to this amendment, the Minister may, based on Article 8 of TRIPS, prescribe conditions for the supply of more affordable medicines so as to protect the health of the public, and in particular may determine that the patent rights shall not extend to acts in respect of medicines which have been put on the market.

The principle of exhaustion does not apply if the products were put on the market under a compulsory license, the reason being that they were not made available “by the patentee

or with his consent". This is the general view in Europe, in accordance with ECJ 9 July 1985, C-19/84 *Pharmon v. Hoechst*. This is also the view in Egypt, Japan and Malaysia, but not in the Republic of Korea where the patent rights are exhausted even if the products were put on the market under a compulsory license.

- 4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

An individual prescriptions exception is recognised under the patent laws of Argentina, Belgium, Brazil, Bulgaria, Denmark, Finland, France, Germany, Italy, Japan, Philippines, Republic of Korea, Spain, Sweden, Thailand, Turkey, and UK.

The patent laws in these countries provide that no infringement arises where there is an extemporaneous preparation of a medicine in a pharmacy for individual cases where such is in accordance with a medical prescription issued by a registered medical practitioner. The German and Swedish Group Reports state that this exemption does not allow stockpiling of pharmaceuticals in a pharmacy. Rather, a doctor's prescription for one single patient is required on the basis of which the medicine is prepared in the pharmacy.

An individual prescriptions exception is not recognised under the patent laws of Australia, Peru, Ecuador, Egypt, Estonia, Malaysia, Mexico, Netherlands, Peru, South Africa, Switzerland, and United States.

- 5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?*

Methods of medical treatment are only patentable subject matter in Australia and in the United States. In all other reporting countries methods of medical treatment are not patentable.

Australian patent law does not provide for a medical treatment defence or similar exception to the patentee's rights. One Australian case (*Bristol-Myers Squibb & Co. v FH Faulding & Co. Ltd.*) suggested that medical practitioners who wish to use patented methods of medical treatment should seek a compulsory license.

In the United States where a medical practitioner performs a medical activity that infringes or actively induces infringement of a patent, the medical practitioner and related healthcare entity (hospital, clinic, medical school, etc.) are exempt from suit for infringement. The exemption extends to the performance of methods of medical treatment, but not to the use of a patented product.

- 6) *Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your*

country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.

Compulsory licenses are available under the patent laws of all reporting countries.

The general requirements of Art. 31 TRIPS are applicable in all reporting countries. For instance, as a general rule, a person may only apply for a compulsory licence under the patent provided he has made efforts to obtain a license from the proprietor on reasonable commercial terms and conditions and his efforts have not been successful within a reasonable period. In accordance with TRIPS, this requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, as pointed out by the Philippine Group. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.

Compulsory licenses are available on a number of grounds. Generally speaking, the following grounds are available:

- In most reporting countries (Argentina, Belgium, Brazil, Columbia, Denmark, Ecuador, Egypt, Estonia, Finland, France, Italy, Japan, Malaysia, Mexico, Netherlands, Peru, Portugal, Philippines, Republic of Korea, Spain, Sweden, Thailand, Turkey), a compulsory license may

be applied for on the ground of failure to work or insufficient working.

The Argentine, Mexican and Philippine Group Reports point out that importation of the product embodying the invention is deemed to be sufficient working of the patent.

Compulsory licenses are not granted if the patent owner is able to give valid reasons for their failure to work the invention, e.g. if the inactivity derived from a force majeure event, including objective difficulties in obtaining market approval before a regulatory authority. This is specifically stated in the Group Reports of Argentina, Brazil, Columbia, Ecuador, Japan, Malaysia, Mexico, Peru, Philippines, Thailand, and Turkey.

In accordance with Article 5 (A) (4) Paris Convention, a compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last. This is specifically stated in the Group Reports of Argentina, Australia, Belgium, Bulgaria, Denmark, Egypt, France, Japan, Sweden, Thailand, and UK.

The Belgian and Mexican Group Reports state that the applicant must have the

necessary means to undertake effective and continuous manufacturing in accordance with the patented invention.

The Danish, Italian and Spanish Group Reports note that working of the invention within the EEA or in a WTO country is considered working in the respective country.

- In the vast majority of the reporting countries (Argentina, Australia, Belgium, Brazil, Bulgaria, China, Columbia, Ecuador, Egypt, Estonia, Finland, France, Germany, Italy, Japan, Malaysia, Netherlands, Peru, Portugal, Republic of Korea, South Africa, Spain, Sweden, Switzerland, Thailand, Turkey, and UK) a compulsory license may be applied for in the case of dependency, i.e. if the holder of a second patent covering an improvement on an invention that has already been patented by a third party may not practice its invention without authorization by the holder of the prior (first) patent. In accordance with Art. 31 (I) TRIPS agreement, in case of dependency the additional condition applies that the invention claimed in the second patent has to involve an important technical advance of considerable economic significance in relation to the invention claimed in the prior (first) patent.
- In Estonia, the Netherlands, and Norway a compulsory license may also be

granted if it is necessary for using a granted plant breeder's right.

- In most reporting countries (Argentina, Brazil, Bulgaria, China, Columbia, Denmark, Ecuador, Egypt, Estonia, Finland, France, Netherlands, Peru, Portugal, Philippines, Republic of Korea, Spain, Sweden, Switzerland, Thailand, and Turkey) a compulsory license may be applied for in the case of a national emergency or national security and/or based on other public interest grounds.

United States patent law also provides for the compulsory licensing of patents considered especially important to public welfare, i.e. patents related to "nuclear material or atomic energy" and patents that are necessary to enable a person to comply with the restrictions of the Clean Air Act.

Public health is expressly recognised as a public interest within the meaning of compulsory licensing provisions. This is expressly mentioned by the German, Japanese, and Portuguese Groups. Specifically, in Belgium and France a compulsory license may be applied for in the interest of public health for a medicine, a medical device, a product or medical device used for performing a diagnosis, the process necessary for the manufacture thereof, or a diagnosis method applied outside of the human or animal body. Some Groups (France,

Egypt, South Africa) specify that compulsory licenses may be granted in case the quantity and/or quality of patent protected medicines do not meet the public demand, if such medicines are sold at excessive prices or in case of chronic, incurable or endemic diseases.

Malaysian law does not refer to the concept of compulsory licensing in relation to public interest, but allows the government to authorize a Government Agency or a third party designated by the government to use a patent without previous license. For instance, in October 2003, the Malaysian government authorised a Malaysian company to import anti-retroviral medicines used in the treatment of AIDS from Indian manufacturer CIPLA.

- In some reporting countries (Argentina, Australia, Brazil, Columbia, Ecuador, Egypt, Germany, Italy, Philippines, Republic of Korea, Switzerland, UK, and United States) a compulsory license may be applied for to remedy a practice determined after judicial or administrative process to be anti-competitive. A similar concept applies in Malaysia although it is not referred to as compulsory licensing. The German Group emphasises that compulsory licenses on the basis of anti-trust law have a greater practical significance than compulsory licences on the basis of patent law. Notably, compulsory licenses under

anti-trust law are generally available in cases where the compliance with a general industry standard requires the use of a patent.

- In Switzerland compulsory licences are also available for research tools and diagnostic products.

In the United States, the broadest legal authority for the compulsory licensing of patents exists when patents are used by the federal government, limited only by a constitutional requirement of just compensation. In addition, some commentators in the United States have suggested that the Supreme Court's recent rejection of a general policy of granting permanent injunctions against patent infringers in *eBay Inc. v. MercExchange* creates a de facto compulsory license in favour of patent infringers who are willing to let the courts decide the appropriate licensing fee.

In Bulgaria, a granted compulsory licence will be revoked if the licensee does not start preparations for the use of the invention within one year after the grant of the compulsory licence. In Columbia, Ecuador, and Mexico the same rule applies, but two years after the grant of the compulsory license.

In the vast majority of the reporting countries no compulsory licenses have been granted.

In Brazil two compulsory licenses have been granted to the Brazilian Ministry of Health based on public interest grounds for the

importation of the anti-retroviral drug Efavirenz of Merck & Co. In addition, three compulsory licenses were granted for a Brazilian patent covering a process for manufacture of a vaccine against aftosa and one compulsory license was granted for a Brazilian patent of Monsanto Company.

In Denmark, in 1969 the Supreme Court granted a compulsory license to a Danish pharmaceutical company for a patent of Swiss Geigy AG regarding a process for manufacture of phenylbutazone on the ground of failure to work.

In Italy, the Competition Authority granted generic manufacturers compulsory licences to remedy an abuse of dominant position by Merck & Co.

In Portugal, a compulsory licence was granted to SAPEC AGRO for Portuguese patent no. 76,136 of Syngenta regarding a plant protection product.

In the Philippines, a total number of 6 compulsory licences have been granted, and in Thailand a total of 7 compulsory licenses have been granted. For more detailed information, including the name of the licensor, the licensee and the product covered, please refer to the respective Group Reports.

In the Republic of Korea, a total number of 6 compulsory licences have been applied for, but none granted so far.

- 7) *Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other leg-*

islative amendment in your country with a view to implementing the WTO decision of August 30, 2003? Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.

The majority of reporting countries have ratified and implemented Article 31bis TRIPS either directly (Australia, China, Japan, Mexico, Norway, Switzerland, UK, USA) or through the adoption of European Regulation 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, UK).

Argentina, Columbia, Ecuador, Egypt, Estonia, Malaysia, the Philippines, Thailand and Turkey have not yet ratified Article 31bis TRIPS or enacted any other legislative amendment with a view to implementing the WTO decision of August 30, 2003. Brazil has not ratified Article 31bis TRIPS, but enacted another legislative amendment with a view to implementing the WTO decision of August 30, 2003. Peru has not ratified Article 31bis TRIPS, but the Trade Promotion Agreement Peru-USA recognises the necessity of access to medicines in accordance with the WTO decision of August 30, 2003.

France, Switzerland, Sweden, and UK, among others, declared that they will not use the system as importing member for the purposes of Article 31bis TRIPS and its Annex.

In the vast majority of the reporting countries no compulsory licenses have been granted for the importation or exportation of pharmaceutical products.

In Brazil two compulsory licenses have been granted to the Brazilian Ministry of Health for the importation of Efavirenz patented by Merck & Co.

- 8) *Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?*

In most reporting countries the government is allowed to make use of a patented invention without previous license based on public interest grounds. For instance, in Brazil and in Thailand the government is allowed to make use of a patented invention without previous license in the case of a national emergency or national security. Similarly, in Finland, the Netherlands, and Norway the government is only allowed to make use of a patented invention without previous license in the case of war or national defence, respectively. In China, Germany, Ireland, Malaysia, the Netherlands, and the Philippines the government is required to compensate the patentee. The French Group notes that the government may rely on the Public Health Act to make use of a patented

invention in case of an emergency, notably an epidemic.

The United States government is allowed to make any use of patents without previous licenses, limited only by a constitutional requirement of just compensation. Similarly, in the UK any government department may make use of a patented invention without previous licence, limited only by the statutory requirement of reasonable compensation. Even the National Health Service's use of an invention has been deemed to be Crown use. Analogous rules regarding Crown use apply in Australia.

The South African and UK Groups point out that the State use and Crown use, of a patented invention in essence amount to compulsory licenses, although they are not "licenses" in law because State use and Crown use are deemed not to be an act of patent infringement.

The Swedish Group Report notes that the government may also apply for a compulsory licence.

The Argentine, Columbian, Ecuadorian, Estonian, Italian, Japanese, Mexican, Peruvian, Portuguese, Spanish, Swiss and Turkish Groups state that their governments are not allowed to make use of patents without previous licenses.

The Belgian and Danish Groups state that no such provision exists under their laws.

- 9) *Is the government allowed to expropriate a patent and, if so, under which conditions?*

In most reporting countries (Argentina, Brazil, Denmark, Egypt, Italy, Portugal, Spain, Switzerland, Sweden, USA) the governments are allowed to expropriate a patent, if the public interest requires so and the patentee is fully compensated. Similarly, in Finland, France, Norway, Sweden the government is only allowed to expropriate a patent in the case of war.

There have been no reported instances of the government expropriating a patent. The Swedish Group points out that in case of expropriation of a patent regarding national security, such expropriation would likely be kept confidential. The Danish Group stresses that expropriation is not necessary as compulsory licensing provides sufficient remedy.

The Bulgarian, Columbian, Chinese, Estonian, Japanese, Malaysian, Mexican and Turkish Groups state that their governments are not allowed to expropriate a patent.

The Belgian, Ecuadorian, Peruvian, Philippine, and South African Groups state that no such provision exists under their laws.

- 10) *If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals),*

which have not been discussed above, please explain.

The Brazilian Group notes that patent applications for pharmaceutical products undergo a double examination in Brazil, one performed by the Brazilian Patent Office and one performed by the regulatory authority ANVISA for the purpose of taking into account public health policy grounds. For instance, ANVISA has rejected second medical use claims and patent applications relating to anti-HIV drugs to assure access to essential medicines.

The Bulgarian and Spanish Groups state that regulatory law rather than patent law facilitates access to medicines by waiving the requirement of marketing authorizations for pharmaceutical products in the case of epidemics, spreading of chemical agents or nuclear radiation. In addition, the Spanish Group Report notes that allowing the importation and use of medicines which are not approved in Spain, but necessary for the medical treatment, in essence amounts to facilitating access to medicines.

The Danish and French Groups point out that access to medicines is facilitated by the fact that the regulatory authorities may grant marketing authorizations for generics prior to expiry of the patent protection. The Danish, French, and Norwegian Groups note that their laws specifically facilitate access to generic drugs to the extent that they provide incentives for doctors to prescribe generic drugs (for instance, by providing for reim-

bursement by the health insurance for the cost of the generic only unless the doctor sets out medical grounds for prescribing the original product).

In this regard, United States Group refers to the Orange Book mentioned in the question which provides up to date information on generic drug approvals and is made available by the Food and Drug Administration in electronic form at <http://www.fda.gov/cder/ob/default.htm>. Similarly, in Norway, generic drug approvals are also accessible on the website of the Medicines Agency.

II) Proposals for adoption of uniform rules

1) Should patent law provide for

- *research and experimental use exception;*
- *Bolar exception;*
- *parallel import of patented medicines;*
- *individual prescriptions exception;*
- *medical treatment defence;*
- *compulsory licensing;*
- *expropriation;*
- *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*

If so, under what circumstances? If not, why not?

Research and experimental use exception

The majority of Groups (Argentina, Australia, Belgium, Brazil, Bulgaria, China, Columbia, Denmark, Ecuador, Finland, Ireland, Italy, Mexico, Netherlands, Norway, Peru, Portugal, Republic of Korea, Spain, Sweden, Switzerland, Thailand, Turkey, UK) are in favour of a research and experimental use exception.

The Australian and Dutch Groups stress that legal clarification of the exception is required.

Some Groups (Argentina, Peru, Turkey) think that the experimental use exception should be strictly limited to cases involving non-commercial purposes. On the other hand, the Thai Group specifically states that the exception should not be limited to non-commercial purposes.

The Norwegian and UK Groups are of the opinion that this exception should be limited to experiments on the subject matter of the invention. The Swiss Group notes that the exception should not cover the use of a patented invention as a tool in research on other objects.

The Japanese Group does not think that the experimental use exception is required. In case the patent laws provide for such exception, the Japanese Group believes that resolution Q105 adopted in Tokyo in 1992 should be followed (with the exception of point 4). According to this resolution the experimental

use exception is supported by AIPPI and should essentially be limited to non-commercial purposes (the resolution mentions use of the patented invention for academic purposes having no commercial nature, testing to evaluate the leaching of the patent and validity of the patent, improving the invention or making an advance over the invention or finding an alternative to the invention, but not the commercial exploitation of the subject of any improvement or advance). The resolution further stresses that the use must involve work on the subject of the patent; use merely to obtain the advantage of the invention disclosed by the patent is not experimental use. AIPPI further resolved that the experimental use exception should be narrowly interpreted and the burden of proof should lie on the third party relying on the experimental use exception. Point 4 of the resolution Q105 (which, according to the Japanese Group, should not be followed) states that use by a party during patent life for the purpose of any regulatory approval to sell after patent expiry is not experimental use.

Bolar exception

The majority of Groups (Argentina, Australia, Belgium, Brazil, Bulgaria, China, Denmark, Ecuador, Finland, Germany, Ireland, Italy, Mexico, Netherlands, Peru, Portugal, Republic of Korea, Spain, Sweden, Switzerland, Thailand, Turkey, UK) is in favour of a Bolar exception. Some Groups (Denmark, Germany, UK) are of the opinion

that the Bolar exception should cover both generic and non-generic (innovative) drugs (e.g. selection inventions), but should only encompass such measures which are necessary to obtain market approval.

The Dutch Group thinks that the Bolar exception should apply to all products that require regulatory approval. The Thai Group thinks it should also cover biological products and research tools.

The Swedish Group thinks a Bolar exception is acceptable if it is balanced with a system of patent term extension. Similarly, the Ecuadorian Group stresses that the Bolar exception is only acceptable as long as generic manufacturers may not market the product prior to expiry of the patent. In this regard, the French group thinks that there should be an efficient legal remedy for patentees to prevent the marketing of generics prior to expiry of the patents.

The Japanese Group again does not think that this exception is required, but in case it is deemed to be required, it should be covered by the experimental use exception. Conversely, the Swiss Group takes the view that the Bolar exception should go beyond the general research exception and allow the use of patented inventions in bioequivalence studies, batch validation and the like. It should, however, not allow stock-piling and preparation for large-scale manufacturing.

The Columbian Group is against a Bolar exception.

Parallel import of patented medicines

The majority of Groups (Argentina, Denmark, Finland, Germany, Ireland, Italy, Norway, Japan, Netherlands, Sweden, Switzerland, Turkey, UK) is against international exhaustion and parallel import of patented medicines. The Japanese and UK Groups think that AIPPI should reconfirm resolution Q101 (adopted in Melbourne in 2001) which rejected international exhaustion.

Most European Groups (Denmark, Finland, Germany, Ireland, Italy, Norway, Sweden, as well as Turkey) think that regional exhaustion in homogenous economic areas such as the EEA is acceptable.

Some Groups (Brazil, Bulgaria, China, Columbia, Ecuador, Mexico, Peru, Thailand) are in favour of parallel import. The Ecuadorian Group stresses that any developing country should be entitled to have access to medicines at the best possible price.

The Australian Group thinks that parallel imports could increase access to patented medicines and does not unreasonably dilute the rights of the patentee.

Individuals prescriptions exception

Most Groups (Argentina, Belgium, Brazil, Bulgaria, China, Finland, Ireland, Italy, Japan, Mexico, Norway, Portugal, Republic of Korea, Sweden, Thailand, Turkey) are in favour of an individual prescriptions exception. Some Groups (Australia, Ecuador) think that the exception may be appropriate for

one-off, non-commercial prescriptions in cases of patient need, but agree that situations should be avoided where medicines are prepared on a large scale basis.

The Dutch, German, Swiss and UK Groups think that this exception has no relevance in practice and, therefore, do not see the need for it.

Medical treatment defence

Some Groups (Argentina, Belgium, Brazil, China, Columbia, Japan, Mexico, Norway) are in favour of a medical treatment defence, insofar as there is a need for such exception.

The Australian Group (which is the only reporting country where—besides the United States—methods for medical treatment are patentable) is of the view that in a commercial context it is unlikely that a medical practitioner would be sued and that, therefore, an explicit defence is unnecessary.

Some Groups (Bulgaria, Ecuador, Ireland, Sweden, Turkey) think that methods for medical treatment should remain non patentable.

Compulsory licensing

Most Groups (Argentina, Belgium, Brazil, Bulgaria, China, Columbia, Denmark, Ecuador, Finland, Ireland, Italy, Japan, Mexico, Netherlands, Norway, Portugal, Republic of Korea, Sweden, Switzerland, Thailand, Turkey, UK) are in favour of compulsory licensing under the current regime.

Some Groups (Australia, Germany) are critical because of the long lead times for the production of medicines. In the context of a pandemic, it may be that more than one licensee is required to provide sufficient product.

Some Groups (Argentina, Bulgaria, Sweden, UK) emphasize that compulsory licensing should be narrowly construed. The Swedish Group notes that extensive interpretation of Article 31(1) TRIPS “national emergency or other circumstances of extreme urgency” would erode the patent system to an extent where incentives for R&D might be weakened.

The Japanese Group thinks that AIPPI should reconfirm resolution Q187 (Limitations on exclusive IP Rights by competition law) adopted in Berlin in 2005. This resolution does not specifically mention compulsory licensing, but makes it clear that if the exercise of IP rights contravenes competition law, then the law should allow for the necessary remedies.

Expropriation

Only few Groups (Argentina, Australia, Brazil, China, Thailand) are in favour of expropriation.

Some Groups (Finland, Mexico, Philippines, Sweden, Turkey) take the view that expropriation should only be allowed in very exceptional circumstances.

Many Groups (Belgium, Columbia, Ecuador, Germany, Norway, Switzerland) think that compulsory licensing is adequate to address public health concerns and that expropriation is disproportionate and unnecessary. Additional Groups (Bulgaria, Japan, Netherlands, UK) are also against expropriation.

The Argentinean Group stresses that the limitation should be narrowly construed. The Australian Group states that the government needs to justify any expropriation decision it makes.

Other limitations

No Group has suggested other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, and medical devices. The French Group stresses that there should not be additional limitations beyond those provided by TRIPS.

- 2) *Do you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

The South-African and Swiss Groups note that access to affordable medicine is not the only critical factor for ensuring effective treatment to poor people suffering from pandemic and endemic illnesses. Effective and accessible health care systems, improved living (sanitary and dietary) conditions and better education all play an important part. The Swiss and UK Groups further mention that most of the drugs classified by WHO as

essential drugs are either available off-patent or not patent protected, yet over a third of the world's population still has no access to these drugs.

The Argentinean and Ecuadorian Groups stress that governments and laws may facilitate access in other ways by limitation of patent rights, for instance by controlling (subsidizing) the prices of patented medicines.

The Korean Group stresses the importance of adopting information tools such as the Orange Book to facilitate access to medicines.

As to patent law, the Swiss Group is of the opinion that patents are not an obstacle to the access to medicines, but to the contrary stimulate research and ensure that new medicines are found and brought to the market. Similarly, the South African Group points out that unduly limiting the protection afforded by patent rights on its own will not necessarily provide a solution. The Norwegian Group is also of the opinion that a well-functioning patent system will in itself have the effect of facilitating access. The Dutch Group is also of the view that a better safeguarding of the patentee's rights will facilitate access. The Dutch Group even recommends the use of non-violation complaints against countries which, when applying compulsory licenses in the context of public health, strictly act in accordance with the rules, but de facto against the spirit of TRIPS. Furthermore, the Dutch Group proposes that additional measures (such as extension of

patent term, additional recognition of inventors) be introduced into patent law in order to compensate the disadvantageous consequences of the grant of compulsory licenses.

In the context of patent law, the South African Group further proposes that the following initiatives be considered: providing for incentives to encourage relevant R&D (e.g. innovation prize models), supporting relevant innovative activities (e.g. research on the basis of traditional remedies) and promoting effective and sustainable technology transfer. Similarly, the Swedish Group thinks that incentives for development of new products, based on market exclusivity for a limited time should be considered. The Swedish Group makes reference to the orphan drug provisions adopted in the EU in this context. These provisions grant 10 years of market exclusivity in the EU in return for the development of orphan medical products, meaning that for 10 years no other company could obtain permission to market a similar drug. Orphan drugs are defined as drugs intended to alleviate rare diseases. Another example would be the pediatric exclusivity provisions adopted in the EU. In order to enhance the development of pediatric medicines these provisions offer a 6 months patent term extension to makers of pediatric medicines. Similar provisions exist in the US.

The German Group points out that exclusions from patentability (as in the case of methods for medical treatment) also serve to facilitate access to medicines and the like.

The Mexican Group notes that more stringent examination of patentability also facilitates access to the extent that unjustified patents are avoided.

- 3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?*

Most Groups (Argentina, Australia, Bulgaria, Columbia, Denmark, Finland, Italy, Mexico, Norway, the Philippines, Republic of Korea, South Africa, Spain, Sweden, UK) are in favour of harmonizing limitations of patent rights.

Some Groups (Argentina, Philippines, Spain) think that harmonization should be achieved through WTO. The Spanish Group also mentions the SPLT as possible means of harmonization. The Australian Group suggests that AIPPI takes the lead in promoting harmonization efforts.

Some Groups (Belgium, Ecuador, Ireland, Switzerland) are specifically in favour of harmonizing the major exceptions, notably the research and experimental use exception and Bolar exception.

The German Group thinks it is more important to harmonize the effects of a patent rather than the exceptions.

The Irish Group is against harmonizing the rules governing parallel import as this involves complex economic issues. Further-

more, the Irish group thinks that harmonization of compulsory licensing at TRIPS level is sufficient.

Some Groups (Brazil, Portugal, Thailand) are against harmonizing limitations of patent rights. The Thai Group states that each country should have the freedom to stipulate the limitations of patent rights taking into account the public interests of the country. The Turkish Group does not think that harmonizing the limitations of patent law will be possible.

Conclusion

It appears from the Reports that patent law provides for a number of limitations which may play a role in providing access to patented medicines, diagnostics, medical devices and the like. Most of these limitations, including the research and experimental use exception, individual prescriptions exception, medical treatment defence, compulsory licensing provisions, and expropriation, facilitate access to new medical products *per se*, either on a short term or long term basis. Some limitations specifically seek to provide access to affordable medicines and the like, i.e. the parallel import of patented medicines as well as the Bolar exemption—to the extent that it only covers generic drugs. Finally, access to medical products may also be affected by the availability of sufficient supplies. Some of the limitations will also ensure access to adequate supplies, notably in the context of public health crises. These include above all the compulsory licensing provisions, and expropriation. Most Groups focussed on medicines

in their Reports, but depending on the circumstances diagnostics, medical devices, biological products and the like may be just as important.

It follows from the Group Reports that there is large consensus as to the necessity of a research and experimental use exception, but it needs to be debated in the Working Committee whether the Groups are in favour of a research and experimental use exception which does not rule out an ultimate commercial aim, so long as the trials are experiments. If so, Q105 (Experimental use as a defence to a claim of patent infringement) which was adopted in Tokyo in 1992 will have to be revisited. Similarly, the Groups generally support a Bolar exception, but it will have to be discussed in the Working Committee whether the Bolar exception should also cover non-generic (innovative) products and extend to all products that require regulatory approval. It may be that this is another area where harmonisation could be achieved. The parallel import of patented medicines does not seem to have support and resolution Q101 (rejecting international exhaustion) could, therefore, be reconfirmed. The individual prescriptions exception—to the extent it has any relevance in practice—appears to be generally accepted, provided medicines are not to be prepared on a large scale basis. It is not entirely clear whether there is sufficient support in the Group Reports for a statement saying that medical methods should remain non-patentable, but it appears from the Group Reports that to the extent medical methods are patentable, the law should provide for a medical treatment defence. It also follows from the Group Reports that not only the neces-

sity of compulsory licensing provisions is recognised, the Groups also seem to agree that they should generally be narrowly construed. Only few Groups are in favour of expropriation, but due to the inherent linkage to notional public policy principles this is unlikely an area where harmonisation could be achieved, except perhaps a resolution providing that expropriation should only be allowed in exceptional circumstances as determined by governments, given that compulsory licensing is the more adequate and proportionate means of providing access. Finally, the Working Committee will have to consider whether AIPPI should support initiatives which provide for incentives, including patent term extension and market exclusivity, for development of new medical products.