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**EXCLUSIONS FROM PATENTABLE SUBJECT MATTER AND
EXCEPTIONS AND LIMITATIONS TO THE RIGHTS***

Document prepared by the Secretariat

* Comments made by Members and Observers of the SCP on this document are available at:
http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=153917

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EXECUTIVE SUMMARY

1. Pursuant to the decision of the Standing Committee on the Law of Patents (SCP) at its twelfth session held from June 23 to 27, 2008, in Geneva, the present document prepared by the Secretariat is submitted as a preliminary study on the issue of exclusions from patentable subject matter and exceptions and limitations to the rights. The document is divided into two distinct issues, namely, exclusions from patentable subject matter and exceptions and limitations to the rights, each of which are addressed from the following perspectives: (i) policy objectives and role; (ii) the international legal framework; and (iii) provisions contained in national and regional laws.

Exclusions from patentable subject matter

2. The patent system intends to promote innovation and to improve the social benefits resulting from that innovation. In order to meet that goal, patent laws provide various requirements to obtain a patent. Firstly, a patent is granted for “inventions”, but not for works of literatures and music, for example. Although the definition of “invention” is different from one country to the other, many national laws consider that, in particular, discoveries, abstract ideas and non-technical creations are not “inventions” within the meaning of patent law. Secondly, only those inventions that meet the three patentability criteria, i.e., novelty, inventive-step (non-obviousness) and industrial applicability (utility) are entitled to patent protection, so that only inventions that contribute to technical progress are rewarded. Even those latter inventions, however, do not necessarily support the ultimate goal of the patent system, that is, to enhance public welfare. In this case, from a public policy perspective, they may be excluded from patentability, even if they represent a significant scientific or technological advancement.

3. Although many countries share general public policy objectives, the concrete means as to how to reach those objectives often vary from one country to the other. Public policy consideration may be influenced by the socio-economic conditions and the country’s priorities, and *vice versa*. Historical, cultural and religious conditions may be important factors for shaping ethical and moral considerations. Therefore, public policy considerations are hardly ever static: they change over time, reflecting the needs and realities of the various countries.

4. Excluding certain categories of subject matter from patentability can neither stop inventors from inventing in the area of such subject matter, nor can it prohibit the commercial exploitation of such inventions. Indeed, where no patent exists, nobody is required to obtain the consent from the inventor to use the invention. It is sometimes argued that the control of commercial activities based on, for example, ethical, health and environmental grounds should rather be regulated by other laws than the patent law. On the other hand, some argue that the patent system does not exist in a vacuum, and that the State should not grant exclusive rights to inventions that obviously harm public interests and consequently do not deserve to generate any economic return thanks to patent protection.

5. As regards the international legal framework, the Paris Convention and the Patent Cooperation Treaty (PCT) do not address exclusions from patentable subject matter, although Article 4*quater* of the Paris Convention and Rules 39 and 67 of the Regulations under the PCT touch upon some related issues. The TRIPS Agreement, in Article 27.2 and 27.3, provides specific categories of subject matter that the WTO Members are entitled to exclude

from patentability. Further, Article 73 recognizes a freedom of the Members to take certain actions which they consider necessary for the protection of their essential security interests.

6. At the national/regional level, the exclusions from patentable subject matter provided for in national/regional legislation vary significantly. Nevertheless, certain categories of subject matter are considered to be excluded from patentability in many countries (see Annex II of document SCP/12/3 Rev.2). They include:

- inventions the exploitation of which is against *ordre public* or morality;
- diagnostic, therapeutic and surgical methods for the treatment of humans and animals;
- plant and animal varieties;
- plants and animals other than micro-organisms;
- essentially biological processes for the production of plants and animals;
- inventions affecting national security.

7. The present document summarizes the scope of each exclusion under national/regional laws and outlines some issues being discussed in relation to each type of subject matter.

8. The exact scope of those exclusions under the national/regional laws, however, needs careful analysis, since the interpretation of the legislative provisions vary. Further, the exclusions under national/regional laws alone do not provide the entire picture of what can, and what cannot, be patented at the national/regional level. For example, even if there is no explicit provision excluding certain categories of subject matter from patentability, a patent may not be granted on such invention because it may be considered lacking novelty, inventive step or industrial application.

Exceptions and Limitations to the Rights

9. In principle, the granting of exclusive patent rights is considered as an incentive for investment in innovative activities and the production of knowledge. To correct the potential inefficiencies of the market power created by such exclusive rights, a number of mechanisms are provided in the patent system, such as the patentability or the disclosure requirements. Nevertheless, granting full exclusive rights in all circumstances may not always meet the goal of promoting innovation and enhancing the public welfare. Consequently, in many, if not all, patent laws, the scope of the enforceable exclusive rights is carefully balanced with the interests of other parties, who may be prevented from using the patented invention for a limited period of time.

10. Generally speaking, there are two types of exceptions and limitations that allow States to fine-tune the different interests among stakeholders. First, there are provisions that exclude, or allow for the exclusion of, certain uses of a patented invention from being addressed in infringement proceedings in national laws as well as under international treaties. The second type of exceptions and limitations is characterized by the fact that a patentee cannot stop third parties from using his patented invention, but is entitled to remuneration against such use. In other words, although the injunctive relief is significantly limited, a right to remuneration against the use of the invention is maintained. So-called compulsory licenses (or non-voluntary licenses) are often used to put this type of limitation in place.

11. Similarly to the case of the exclusions from patentable subject matter, at first sight, the consequence of limiting the scope of the enforceable rights may seem to consist in less incentive for inventors to invest in innovative activities. It is, of course, a matter of public policy to determine whether, under certain circumstances, it may be more appropriate to allow other parties to use the patented technology than to allow the patentee alone to exercise the exclusive right with a view to better promote innovations and increase social welfare. However, the legal assurance of non-infringement through uses by others than the patentee does not necessarily mean that these other parties can immediately exploit the patented invention, since secret know-how may be involved for the optimal exploitation of the invention, particularly at the commercially profitable scale.

12. As regards the international treaties, Article 5.A of the Paris Convention provides certain rules regarding compulsory licenses. Further, certain limitations to the exclusive rights in view of the safeguard of the public interest to maintain the freedom of transport is regulated in Article 5*ter* of that Convention. Similarly, Article 27 of the Chicago Convention extends the exceptions to the patent rights with respect to international air navigation.

13. Articles 30 and 31 of the TRIPS Agreement provide the exceptions and limitations to the rights which may be provided by the WTO Members. According to Article 30, a Member may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. The *Canada-Patent Protection of Pharmaceutical Product* case (DS114) offers some guidance in interpreting Article 30. Article 31 provides that a Member may allow, under the stipulated conditions, other use by third parties or by the Government than that allowed under Article 30 without authorization of the right holder. The Declaration on the TRIPS Agreement and Public Health, adopted by the Fourth Session of the WTO Ministerial Conference at Doha on November 14, 2001, provides some guidance to the application of Article 31. Further, the Decision of the General Council of August 30, 2003, on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health allows WTO Members to “waive” the limitation on exports under compulsory licenses to least-developed country Members and other Members that have insufficient or no manufacturing capacities in the pharmaceutical sector for the patented product in question. Following the Decision of the General Council of December 6, 2005, on the Amendment of the TRIPS Agreement, an amendment to the TRIPS Agreement will replace the Decision of the General Council of August 30, 2003, when it is accepted by two thirds of the membership. Further, TRIPS Article 73 recognizing the freedom of the Members to protect essential security interests may be also relevant.

14. At the national/regional level, the exceptions and limitations to the rights provided for vary significantly. However, some convergence can be found. There are certain exceptions and limitations which are found in the legislations of many countries (see Annex II of document SCP/12/3 Rev.2). They include:

- private acts for non-commercial purposes;
- acts for the purpose of teaching;
- acts for experimental purposes or scientific research;
- preparation of medicines prescribed by doctors;
- continued use by a prior user;
- certain uses on foreign vessels, aircraft and land vehicles which temporarily or accidentally entered the national territory;

- acts for obtaining regulatory approval for pharmaceuticals;
- acts performed for a farmer's own use and for the development of new varieties.

15. Further, many national/regional laws provide for various situations under which compulsory licenses and government's use of patented inventions without the authorization of the patent owner may be allowed. The present document summarizes the scope of each of those exceptions under national/regional laws and outlines a number of issues being discussed in relation to each type of subject matter.

16. As regards the exhaustion of rights, some laws contain an explicit provision, while under some others, no provision is found in the legislation, and the case law determines under which circumstances the patent right is exhausted. The exhaustion of rights may not qualify specifically for being an exception or limitation to the rights in the narrow sense because, while exceptions and limitations impose limited "restrictions" to the enforcement of rights for certain kinds of uses of the patented invention, the exhaustion of rights addresses the specific question of the "non-existence" of the patent rights (or, in other words, of the scope of the rights) associated with the product which has been legitimately put on the market. On the other hand, the exhaustion of rights can be considered as forming part of the exceptions and limitations in the broad sense, as it also defines the permissive actions which can be taken by third parties without risking to infringe the rights. Article 6 of the TRIPS Agreement states that, for the purposes of dispute settlement under that Agreement, nothing in the TRIPS Agreement shall be used to address the issue of exhaustion of rights, subject to the provisions of Articles 3 and 4.

I. INTRODUCTION

17. At its twelfth session, held from June 23 to 27, 2008, in Geneva, the Standing Committee on the Law of Patents (SCP) asked the WIPO Secretariat to establish, for its next session, preliminary studies on four issues. These four issues are:

- Dissemination of patent information (*inter alia* the issue of a database on search and examination reports);
- Exceptions from patentable subject matter and limitations to the rights, *inter alia* research exemption and compulsory licenses;
- Patents and standards;
- Client-attorney privilege.

18. These four issues are not to be considered prioritized over other issues contained in the list which was established during the twelfth session of the SCP and was contained in the Annex to document SCP/12/4 Rev. (see paragraph 8(c) of document SCP/12/4 Rev.).

19. Accordingly, this document prepared by the Secretariat is a preliminary study on the issue of exclusions from patentable subject matter and exceptions and limitations to the rights¹ for the thirteenth session of the SCP, to be held from March 23 to 27, 2009.

20. The preliminary study addresses two distinct issues: exclusions from patentable subject matter and exceptions and limitations to patent rights. On each issue, the preliminary study contains (i) policy objectives and the role of exceptions and limitations, (ii) provisions under the international legal framework, and (iii) provisions contained in national/regional laws. As regards the provisions contained in national/regional laws, reference is made to Annex II of document SCP/12/3 Rev.2, which contains a summary of the exclusions from patentable subject matter and of the exceptions and limitations to the patent rights provided by the various national/regional laws.

21. At the twelfth session of the SCP, it was made clear that the *modus operandi* of the Committee, namely, to move forward along a number of tracks, including the preparation of preliminary studies, was agreed upon for the purpose of developing a work program for the SCP (see paragraph 123 of document SCP/12/5 Prov.). Against this background, the preliminary study aims to contextualize the current legal framework and to contain no conclusions.

II. EXCLUSIONS FROM PATENTABLE SUBJECT MATTER

(a) Exclusions from Patentable Subject Matter and Subject Matter Not Considered to be Inventions

22. As regards the exclusions from patentable subject matter, in view of the different approaches in the national/regional patent laws, the scope of this preliminary study may

¹ The terms “exclusions from patentable subject matter” and “exceptions and limitations to the rights” are used in this document, as they are commonly used at the international level (see, for example, SCP/12/3 Rev.2 and Articles 27 and 30 of the TRIPS Agreement).

require some further clarification. Generally speaking, there are two ways used in the national/regional laws in respect of this question.

23. The first method is to first define the term “invention”, i.e., subject matter than can be covered by patent protection, and to then specify the categories of subject matter that cannot be patented. In some legal systems, the law provides positive and explicit guidance on the definition of the term “invention”. For example, Article 2(1) of the Patent Law of Japan defines “invention” as a highly advanced creation of technical ideas by which a law of nature is utilized. In some other system, the law implicitly defines “invention” by providing a non-exhaustive list of subject matter that is not regarded as inventions. For example, the European Patent Convention does not provide an explicit definition of the term “invention”, but its Article 52(2) lists the following types of subject matter which, in particular, shall not be regarded as patentable inventions:

- discoveries, scientific theories and mathematical methods;
- aesthetic creations;
- schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- presentation of information.

24. Article 52(3) clarifies that the subject matter or activities listed above are excluded from patentability only to the extent to which a European patent application or European patent relates to such subject matter or activities as such.

25. Whichever way has been chosen to define the term “invention” in the national/regional law, the notion of “invention”, i.e., patentable subject matter, is specified in the law, together with exceptions from such patentable subject matter.

26. The second technique is to list all types of subject matter which are not patentable. In other words, both (i) subject matter which is not considered to be an invention (for example, literary or artistic works, scientific theories and abstract ideas) and (ii) subject matter which is considered to be an invention, but is excluded from patentability (for example, an invention the exploitation of which is against morality) is referred to in the applicable law as “non-patentable subject matter” without distinguishing (i) and (ii) above.²

27. Since the mandate given to the International Bureau by the SCP was to prepare a preliminary study on the exclusions from patentable subject matter, in principle, this preliminary study focuses on subject matter which can be generally categorized as patentable subject matter (or inventions) but which is excluded from patent protection.

28. It should also be noted that a provision in the applicable patent law providing exclusions from patentable subject matter alone does not offer the entire picture of what can, or cannot, be patented and whether or not the granted patents are enforceable. For example, even if there is no explicit provision excluding certain inventions from patentability, a patent may not be granted for such an invention because it may be considered lacking novelty, inventive step

² Under some national laws, in addition to the subject matter referred to in (i) and (ii), certain types of subject matter that may not be novel or involve inventive step (for example, juxtaposition of known inventions, or aggregation or duplication of known properties of known components) are also included in the list of non-patentable subject matter.

or industrial application. Further, even if a patent is granted, the patentee may not be able in practice to enforce the patent, since the national law may provide that certain acts by third parties are not considered to be infringing.

(b) Policy Objectives of Exclusions

29. The patent system intends to promote innovation and to improve the social benefits resulting from that innovation. In order to meet that goal, patent laws do not allow the grant of patents for all new creations of our mind, but impose various requirements to obtain a patent. Firstly, a patent is granted for “inventions”, but not to, for example, works in the field of literature and music, which are covered by copyright protection. As described earlier, although the definition of the term “invention” is different from one country to the other, many national laws consider that, in particular, discoveries, abstract ideas and non-technical creations are not “inventions” within the meaning of patent law. Secondly, among those inventions, only those that meet the three patentability criteria, i.e., novelty, inventive-step (non-obviousness) and industrial applicability (utility) are entitled to patent protection so that only the inventions that contribute to technical progresses are rewarded.

30. Even those inventions that contribute to technical progress, however, do not always support the ultimate goal of the patent system, namely to enhance the public welfare. In such circumstances, from a public policy point of view, they may be excluded from patentable subject matter even if they represent a significant scientific or technological advancement.

31. Generally speaking, the choice of exclusions from patentable subject matter is carefully determined taking into account two aspects which are closely related: one aspect is whether a given invention should be excluded from protection with a view to discourage innovation. The second aspect relates to the question of whether a given invention should be excluded with the view to a risk of excluding access to the patented technology by third parties. The two aspects are closely related because, on the one hand, there will be no question of access to innovation, if innovation does not exist in the first place. Secondly, if the access to the patented technology is unreasonably hampered, innovation may not be encouraged in an efficient and effective manner.

32. While the improvement of social welfare and enhancement of industrial and economic development are common public policy objectives shared by all countries, the concrete ways to reach those goals and to shape the legal framework to achieve them vary from one country to the other. Public policy considerations are influenced by differences at the level of the socio-economic conditions and the countries’ priorities. Moreover, historical, cultural and religious considerations are often important factors influencing ethical and moral considerations. As a consequence, public policy considerations are never static, but change over time, reflecting the needs and realities of countries.

33. By definition, the patent system evolves with the technical advancements that ceaselessly bring new technical creations into our lives. The patent system, therefore, constantly faces the question as to whether and how it can adapt itself to new technologies. Certain questions are a matter of interpretation of existing laws, for example, whether a new technological creation falls under the definition of “invention” under the applicable patent law. However, one of the fundamental questions is, from a public policy perspective, and with a view to improving public welfare, whether such new subject matter should be covered by patent protection or not. Or should it be addressed through another protection mechanism? Is a new legal mechanism necessary? Should patent law be adapted and revised to

accommodate the new technology? It is, of course, inherent to the question that there is no one single straight-forward answer to the question.

(c) Role of Exclusions

34. A common view in respect of the patent system is that it is intended to promote innovation by encouraging investment in innovative activities with the prospect of economic returns through the grant of a limited exclusive right. According to such a model, the consequence of excluding certain types of subject matter from obtaining patent protection could be that there may be less incentive for inventors to invest in excluded subject matter.³

35. Since the right conferred by a patent is a negative exclusive right, that is, a right to prevent others from using the patented invention without the patent holder's consent, as opposed to a positive right utilization, the patent system can neither stop inventors from inventing in respect of subject matter excluded from patent protection, nor prohibit the commercial exploitation and use of such inventions. Indeed, where no patent exists, everybody can make and sell inventions which fall under the exceptions from patentable subject matter, without being required to obtain any consent from anyone. Another possible scenario is that, if no patent protection is possible, inventors may be encouraged to keep their inventions secret.

36. While the patent system intends to enhance public benefits by promoting innovation, there are other branches of the law that control commercial activities of goods and services on ethical, health, safety and environmental grounds, such as regulatory mechanisms concerning the marketing of pharmaceuticals, or safety standards for electronic apparatus, cars and planes. Accordingly, one argument put forward is that the patent system shall focus on the generation and promotion of innovations, and shall provide only minimal exceptions from patentability. According to that position, questions regarding the control of commercial activities due to, for example, ethical, health and environmental concerns should be left to other bodies of law. It is further argued that the patent office is not the appropriate body to raise and respond to ethical questions, and should rather concentrate on technical aspects of inventions, i.e., the contribution to the existing science and technology.

37. Others, however, argue that the patent system does not exist in the vacuum, and that the patent rights granted by (or on behalf of) the State, even if they are negative exclusive rights, are regarded as incentives for technological innovation, coupled with the expectation of future economic returns from the investment made. Therefore, the argument is that the State (the patent office) should not be tolerant in respect of inventions that obviously harm public interests, and should not grant exclusive rights, in the first place, to inventions that do not deserve any economic returns.

(d) Existing International Rules

38. Since patents are territorial rights, patents granted and enforced in each country (or region) are regulated by the national (or regional) patent law. Consequently, what shall be entitled to patent protection and what not is largely viewed from a national public policy

³ It should be noted that the patent system is just one incentive mechanisms to spur innovation. There are also other mechanisms such as, for example, subsidies and tax incentives.

perspective, taking into account the economic, social and cultural circumstances of the country at a certain point in time.

39. At the international level, some treaties address, either directly or indirectly, issues relating to exclusions from patentable subject matter. In general, the international rules increase legal certainty and transparency at the international level. Whether it is a minimum or a maximum standard, or whether it contains mandatory or optional rules, an international treaty provides guidance to the readers as to the national legal framework of the Member States to which the treaty is applicable.

(i) Paris Convention for the Protection of Industrial Property (Paris Convention)

40. The Paris Convention does not address issues regarding the exclusions from patentable subject matter. However, in connection with subject matter coverage and exclusions, Article 4^{quarter} of the Paris Convention provides that the Contracting States shall not refuse the grant of a patent or invalidate a patent on the ground that the sale of the patented product or of a product obtained by means of the patented process is subject to restrictions or limitations resulting from the domestic law.

41. It may happen that an invention leads to the manufacture of a product that does not conform to security, safety or quality requirements under the applicable laws. In other cases, the manufacture or sale of inventions may be restricted, because the State has granted an exclusive concession to a specific organization (for example, a State-owned organization). One commentary suggests that it would be, however, unfair to refuse or invalidate patents concerning those inventions, since in the first category of cases, the laws prescribing security, safety or quality requirements may be modified over time, and in the second case, a contractual or compulsory license could be obtained from the patentee.⁴

42. Article 4^{quarter} covers the cases where the sale of a product is subject to restrictions and limitations resulting from the national law, and the cases where the sale of a product is prohibited are left open. While refusal or invalidation of a patent may be possible under the applicable law if the invention concerned is contrary to *ordre public* or morality, this may not be accepted merely because the exploitation of the invention is prohibited or restricted by law or regulation.⁵

(ii) Patent Cooperation Treaty (PCT)

43. The PCT does not regulate substantive conditions of patentability, including the question as to what shall be patentable subject matter in the national phase or what should be the exceptions from such patentable subject matter. However, in the context of international search and international preliminary examination under the PCT, an International Searching Authority or an International Preliminary Examining Authority may decide not to search, nor to carry out an international preliminary examination in respect of certain categories of subject matter. No International Searching Authority is required to search an international application, and no International Preliminary Examining Authority is required to carry out an

⁴ G.H.C. Bodenhausen, "Guide to the Application of the Paris Convention for the Protection of Industrial Property", WIPO Publication No.611.

⁵ Id.

international preliminary examination in respect of an international application, if, and to the extent to which, its subject matter constitutes any of the following:

- scientific and mathematical theories;
- plant or animal varieties or essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes;
- schemes, rules or methods of doing business, performing purely mental acts or playing games;
- methods for the treatment of the human or animal body by surgery or therapy, as well as diagnostic methods;
- the mere presentation of information;
- computer programs to the extent that the International Searching Authority (or International Preliminary Examining Authority) is not equipped to search prior art (or to carry out an international preliminary examination) concerning such programs.⁶

44. While the aim of the International Searching and Preliminary Examining Authorities should be to issue international search reports and international preliminary reports on patentability that are as comprehensive as possible, in view of the different laws applied by the International Authorities regarding patentable subject matter, not all International Authorities are equally well equipped to handle all types of subject matter. Consequently, the PCT allows the International Authorities not to carry out any international search or international preliminary examination with respect to certain categories of subject matter.

(iii) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)

45. Article 27.2 and 3 of the TRIPS Agreement provides that WTO Members may exclude certain inventions from patentability. Those inventions are:

- inventions the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law (TRIPS Agreement, Article 27.2);
- diagnostic, therapeutic and surgical methods for the treatment of human or animals (TRIPS Agreement, Article 27.3(a));
- plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof (TRIPS Agreement, Article 27.3(b)).

⁶ Rules 39 and 67 of the Regulations under the PCT.

46. As provided in Article 27.3(b) of the TRIPS Agreement, this provision has been under review at the Council for TRIPS since December 1998. The Doha Ministerial Declaration of November 2001⁷ addressed the review of Article 27.3(b) together with the review of the implementation of the TRIPS Agreement under Article 71.1 and with the invitation for negotiations on outstanding implementing issues. The Doha Ministerial Declaration mandated the Council for TRIPS to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.

47. In addition, the TRIPS Agreement, in Article 73, recognizes the freedom of WTO Members to take certain actions which they consider necessary for the protection of essential security interests. Further, in accordance with Article 2.1 of the TRIPS Agreement, the WTO Members shall comply with Article 4*quater* of the Paris Convention concerning patentability of inventions in case of restriction of sale by a national law.

(e) National and Regional Laws

48. As a consequence of the different public policy considerations regarding patentable subject matter, the national and regional laws vary. However, at least at the legislation level, some convergence can be found. There are certain categories of subject matter that are excluded from patentable subject matter in many countries.⁸ They include:

- *ordre public* and morality;
- diagnostic, therapeutic and surgical methods for the treatment of humans and animals;
- plant varieties and animal varieties;
- plants and animals other than micro-organisms;
- essentially biological processes for the production of plants or animals;
- inventions affecting national security.

The exact scope of those exclusions at the national and regional levels, however, requires careful analysis. The respective jurisprudence diverges, and the requirements in respect of related issues, such as the definition of “invention” under the applicable patent law affects the way those exclusions are interpreted under the different laws.

(i) *Ordre public* and morality

49. A number of countries exclude from patentability inventions the commercial exploitation of which would encourage offensive and immoral behavior and harm the social order. As stated above, although excluding those inventions from patentability does not directly result in the prohibition of their manufacture and use, many countries exclude those inventions from patentability so that their exploitation, if against the general public interest, would not be encouraged by the patent system. It appears that some national laws use the

⁷ http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

⁸ See Annex II of document SCP/12/3 Rev.2.

term “*ordre public*” and some other laws use the term “public order”. In this paper, both terms are considered to have the same meaning.

50. Some national laws expressly provide that inventions that cause a serious prejudice to the health or life of humans or animals, or are harmful to the preservation of plants or the protection of the environment, be excluded from patentability. In a broader sense, such inventions may be also considered to contravene public order and morality under jurisdictions that do not provide a specific provision.

51. Technological developments sometimes raise new concerns about public order and morality. Applications of biotechnological innovations in the areas of, for example, health and agriculture have provided new perspectives and created hope for new solutions. On the other hand, the advancement of genetic technologies has spurred ethical considerations in various areas, for example, manipulations of the genetic identity, use of human embryos and human cloning. Consequently, the “bioethics” discipline may influence the interpretation of the *ordre public* and morality clause in certain countries. In some countries, the law explicitly provides that the human body at any stage of development is excluded from patentable subject matter, and that processes for cloning humans, modifying the germ line genetic identity of humans, uses of human embryos for industrial or commercial purposes and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit, and animals resulting from that process, are not patentable because the commercial exploitation of those inventions is against *ordre public* and morality. While some or all of those inventions are presumably considered unethical in most countries, some other countries would apply the general provision concerning *ordre public* and morality to accommodate such specific concerns.

52. What constitutes a contravention against public order and morality depends on the time and the place. In certain cases, the question of public order and morality will be answered differently even by individuals in the same country, depending on age, background, personal convictions etc. Thus, the term “public order or morality” is interpreted on a case-by-case basis, reflecting the fundamental values of society in a given context.

- (ii) Diagnostic, therapeutic and surgical methods for the treatment of humans or animals

53. Many countries exclude inventions concerning diagnostic, surgical or therapeutic methods for the treatment of humans or animals from patentability. This exclusion is based on humanitarian and public health considerations: new techniques in the area of diagnostic, therapeutic and surgical methods should be disseminated as widely as possible among the medical and veterinary practitioners without them having to fear a possible infringement of patents. Thus, a doctor may apply the method of treatment that he believes the best suited for a patient, and the patient can benefit from the evolution of those methods. Some laws expressly clarify that this exclusion does not apply to any apparatus or product (such as medical devices, medical products and medicinal substances) that may be used for the purpose of diagnosis, surgery or therapy.

54. It should be noted that, in some countries, inventions concerning diagnostic, surgical or therapeutic methods for the treatment of humans or animals are not patentable because they are not regarded as inventions that meet the requirement of industrial applicability.

55. The term “diagnostic methods” allows for some room for interpretation. According to one jurisprudence, the diagnosis consist of (i) examining the patient and collecting data; (ii) comparison of the data with standard value; (iii) finding of any significant deviation from the standard; and (iv) attribution of the deviation to a particular clinical picture. In order to fall under the exclusion from patentable subject matter, the claim must include method steps relating to all of those phases.⁹ However, in another jurisdiction, (i) methods of measuring the conditions of the human body for medical purposes to detect diseases or to examine the health conditions or (ii) preparatory methods for diagnosis (for example, a method for arranging electrodes for taking an electro-cardiogram) are considered to be diagnostic methods that fall under the exclusion.¹⁰

56. Some laws state that inventions concerning diagnostic, surgical or therapeutic methods for the treatment of humans or animals are excluded from patentability when such methods are practiced on the human or animal body. The EPO’s Board of Appeal held that, except for the last phase of the diagnosis which is a mental decision process performed by the medical practitioner, all the phases that constitute the diagnosis must be performed on the human or animal body.¹¹

57. In the United States of America, while medical or surgical processes are patentable subject matter, no remedy is available if such patents are infringed by a medical practitioner performing a medical activity.

(iii) Inventions Relating to Plants and Animals

58. Since the TRIPS Agreement provides a certain flexibility, the exclusions from patentable subject matter concerning inventions relating to plants and animals vary significantly among the different laws. In some countries, no provision exists that excludes this category of inventions from patentability. Other countries exclude some or all of the inventions relating to plants and animals, such as plant and animal varieties, plants and animals in general (other than microorganisms) and essentially biological processes for the production of plants or animals (other than non-biological or microbiological processes), but not all of those inventions are always excluded in all countries. In 2001, WIPO prepared an extensive questionnaire regarding practices related to the protection of biotechnological inventions under the patent and plant variety protection systems by WIPO Member States, containing many questions concerning exclusions of biotechnological inventions from patentability. Information received from the Member States in connection with that questionnaire can be found in document WIPO/GRTKF/IC/1/6.

Plant and animal varieties

59. As regards plant varieties, many countries have been protecting them under a *sui generis* system that intends to promote the breeding of new plant varieties.¹² As a consequence, a number of those countries exclude plant varieties from patent protection. The

⁹ EPO Enlarged Board of Appeal, G 1/04, OJ 5/2006.

¹⁰ JPO Examination Guidelines, Section II, Chapter 1, 2.1.

¹¹ EPO Enlarged Board of Appeal, G 1/04, OJ 5/2006.

¹² In accordance with Article 27.3(b) of the TRIPS Agreement, Members of the WTO shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system.

reason for such exclusion is (and surely was at the time the *sui generis* system was established) that plant varieties are adequately and sufficiently protected by the *sui generis* system, which provides specific criteria, rights and limitations that are different from the patent system. It is generally considered that such a *sui generis* system provides a proper incentive for breeders to develop new varieties, taking into account the interests of third parties. On the other hand, there are a number of countries that protect plant varieties under both the patent system and the *sui generis* system. They consider that, as long as the new plant variety complies with the requirements of patent law, which has increasingly been the case with the advent of genetic engineering techniques, there is no reason not to preclude breeders from the possibility of protecting their new plant varieties through the patent system.

60. The development of biotechnology, in particular, genetic engineering, has made it possible to engineer and subsequently create a new plant variety instead of using traditional techniques, such as crossing and selections. While the well-known crossing or selection techniques may not qualify for patent protection, new plant varieties created using genetic engineering may increase the likelihood of new plant varieties being in compliance with novelty and inventive step requirements (and, in some systems, technical character). It is thus argued that, in such cases, the options for reward offered by the patent system should be available to the breeders as well.

61. As regards animal varieties, while no *sui generis* protection mechanism has been established, some countries exclude them from patentable subject matter. Traditionally, animal breeding is conducted through the selection of desired characteristics, and the techniques used are either known or protected through trade secrets. However, the development of transgenic and cloning technologies may have an impact on the “engineering” of animal breeding. As regards inventions relating to breeding technologies, patent protection may be sought, for example, on a method of genotyping animals to enhance the creation of animals with selected characteristics, including gene marker tools for such selection, a process of producing such animals using the above method or the animal *per se*. While not many examples of patents granted on breeds or on animals intended for food production have been found, it was reported that animal patenting was an emerging controversial issue in the livestock sector.¹³ At the same time, some hold the view that patenting in this area facilitates scientific development by providing incentives for R&D and investments.¹⁴

62. Some countries exclude plant and animal varieties, but not the plants and animals *per se*. In those countries, there is a need to distinguish unpatentable “plant and animal varieties” on the one hand and patentable “plants and animals” on the other. In Europe, the distinction was determined in such a way that if the technical feasibility of the plant invention is not confined to a particular plant variety, it is not excluded from patentable subject matter.¹⁵ A plant grouping which is characterized by a particular gene (and not its whole genome) is not

¹³ The State of the World’s Animal Genetic Resources for Food and Agriculture, p.287-289
Commission on Genetic Resources for Food and Agriculture, FAO, 2007.

¹⁴ Id.

¹⁵ Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Article 4.2; Implementing Regulations to the Convention on the Granting of European Patents, Rule 27.

covered by plant variety protection, and is therefore eligible for a patent even if it comprises new varieties of plants.¹⁶

Plants and animals other than micro-organisms

63. Some countries exclude not only plant and animal varieties, but also plants and animals (other than microorganisms) as a whole from patentable subject matter. The wording of the provisions under national laws in this respect, however, reflects various considerations and shows a different scope of the exclusion. For example, the relevant provisions in some of the national laws include the following terminology: “plants and animals except microorganisms”; “plants and animals in whole or any part thereof other than microorganisms, but including seeds, varieties and species”; “living materials and substances already existing in nature”; “biological and genetic material occurring in nature or derived therefrom by reproduction”; “natural biological materials”; “living beings, in whole or in part, other than transgenic microorganisms”; “natural living beings, in whole or in part, and biological material, including the genome or germ plasm of any natural living being, when found in nature or isolated therefrom”.

64. While a full analysis of the interpretation of those various national provisions would go beyond the scope of this preliminary study, it should be noted that the exact scope of the exclusions relating to plants and animal under a given national law may require thorough understanding of other provisions of the relevant national law. For example, even if there is no explicit provision excluding plants and animals or biological material that exists in nature from patentability, patents may not be granted to such plants and animals or biological material because they may be considered to be discoveries or to lack novelty. In other cases, such living organisms may be considered non-patentable on ethical or moral grounds.

65. Similarly, with respect to parts of plants and animals, such as cells, cell lines, genes and genomes, in some countries, they are explicitly excluded from patentable subject matter, while in some other countries, they are considered as a particular type of chemical substance, if isolated and purified from their natural environment. In the latter case, whether such an invention would obtain patent protection or not depends on other conditions of patentability, such as novelty, inventive step (non-obviousness), industrial applicability (utility) and the disclosure requirement. This shows that the precise scope of protection of plant and animal related inventions is determined by the different patentability criteria, and that the mere exclusions from patentability does not provide the full picture as regards patent protection for such inventions.

66. Some further believe that the patenting of life forms should be unconditionally prohibited because it is unethical in itself. Some others consider that such patenting is harmful in respect of public health, restrictions on research materials, limitations on competition as in the case of gene use restriction technologies (GURTs), human rights, agricultural security, bio-piracy, traditional knowledge and farmers’ rights.¹⁷ However, some others consider that there is no need to categorically exclude inventions from patentability in order to prevent their exploitation, since the exploitation of those inventions can be regulated through national laws

¹⁶ Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Recital 31.

¹⁷ WTO document IP/C/W/369.

other than the patent law, for example, laws on the protection of the environment, public health or animal welfare.¹⁸

67. With respect to patents on genetic material, concerns have been expressed with respect to the compliance with the Convention on Biological Diversity (CBD). It is argued that patenting genetic material limits access to such genetic material and can conflict with the sovereign rights of countries over their genetic resources.¹⁹ In the Council for TRIPS, concerns have been expressed about the granting of patents covering genetic material in its natural state or genetic material that has been merely isolated from nature and not otherwise modified in connection with the criteria for patentability.²⁰ It was said that the granting of overly broad patents could impede access to and use of genetic resources in a way which gave rise to questions of compatibility with the CBD, and restricted research by third parties.²¹ However, there are also other views according to which the granting of patents on inventions which use genetic resources does not stand in the way of fulfilling the provisions of the CBD relating to the sovereign rights of countries over access to genetic resources in their territories and prior informed consent as a condition of such access. It is said that holding a patent on isolated or modified genetic materials does not amount to ownership of the genetic material itself, nor does it provide property rights with regard to the source from which the original material is obtained, since a patent on an isolated, identified and modified gene provides the patentee only with the right to prevent others from producing, marketing and using the modified gene without his consent.²²

68. With respect to the use, development, conservation and management of animal genetic resources, it is generally recognized that an improved coherence among various policy objectives, such as economic development, environmental protection, animal health, food safety, consumer protection, intellectual property rights, innovation incentives, genetic resources conservation, and access to and equitable sharing of benefits arising from the use of animal genetic resources, is needed, taking into account the distinctive features of animal genetic resources that need distinctive solutions.²³

69. As regards the implications of patent protection in respect of life forms for transfer and dissemination of technology, some hold the view that such patent protection could raise the cost of technology in this area by virtue of the exclusive rights given to right holders to prevent others from using the protected technology. On the other hand, there is another view that patent protection builds confidence among investors and stimulates investments in this field, and that technology in the hands of the private sector can be transferred most effectively through market mechanisms, such as licensing, supported by adequate intellectual property protection.

¹⁸

Id.

¹⁹ WTO document IP/C/W/368/Rev.1

²⁰ Id.

²¹ Id.

²² Id.

²³ Global Action Plan for Animal Genetic Resources, adopted by the International Technical Conference on Animal Genetic Resources for Food and Agriculture, FAO, September 3 to 7, 2007 [<http://www.fao.org/docrep/010/a1404e/a1404e00.htm>].

Essentially biological processes for the production of plants or animals other than microbiological processes

70. Some countries exclude from patentability essentially biological processes for the production of plants and animals other than microbiological processes. While the exact scope of the expressions “essentially biological processes” and “microbiological processes” should be referred to the applicable national law, in general, it is understood that the provision excludes naturally-occurring biological processes from patentable subject matter, while providing the possibility of patenting, for example, gene manipulation processes. The European Patent Convention (EPC), in its Rule 26(5), defines an essential biological process as a process that consists entirely of natural phenomena, such as crossing or selection. However, a case is pending before the EPO’s Enlarged Board of Appeal in relation to the interpretation of the term “essentially biological process” (G2/07).²⁴ The questions referred to are:

“1. Does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?

“2. If question 1 is answered in the negative, does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?

“3. If question 2 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?”

(iv) Inventions affecting national security

71. In some countries inventions affecting national security or, more specifically, inventions concerning nuclear processes and products are excluded from patentable subject matter.

III. EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

(a) Policy Objectives of Exceptions and Limitations

72. In principle, patents confer exclusive rights during a limited period to prevent others from making, using, offering for sale, selling or importing a patented invention without the patentee’s consent. The grant of such rights is considered to be an incentive for investment in innovative activities and production of knowledge. To correct the potential inefficiencies of the market power created by such exclusive rights, a number of mechanisms are provided in

²⁴ <http://www.epo.org/patents/appeals/eba-decisions/referrals/pending.html>.

the patent system. For example, not all new creations may obtain a patent: to be patentable, an invention has to form part of patentable subject matter, must be new and involve an inventive step (be non-obvious) and must be capable of industrial application (be useful). Further, the invention shall be described in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and, in certain jurisdictions, be described by indicating the best mode for carrying out the invention. Such information about patented inventions (in many countries, information about inventions described in patent applications as well) is publicly available through the publication of patents (and, in many cases, patent applications). The patent rights need to be carefully balanced with the interests of other parties, including competitors and the general public.

73. Many States believe that granting full exclusive rights in all circumstances does not meet the ultimate goal of promoting innovation and enhancing public welfare in all circumstances. Therefore, the scope of the enforceable exclusive rights is carefully designed under national patent laws in order to strike the right balance between the legitimate interests of the right holders and the legitimate interests of third parties.

74. Generally speaking, there are two types of exceptions and limitations that allow States to fine-tune the different interests among the stakeholders: first, provisions that exclude, or allow for the exclusion of, certain types of uses of patented inventions from being addressed in infringement proceedings are found in national laws as well as in international treaties. Patentees cannot enforce their rights against certain acts done by third parties, although they would normally be considered as infringement. In other words, third parties are free to perform those limited acts without having to expect infringement procedures against them. The underlying consideration is that the public interest justifies, under certain circumstances, denying the enforcement of the exclusive rights granted to patentees.

75. The second type of exceptions and limitations relate to situations where patentees cannot stop third parties from using the patented invention, but are entitled to remuneration against such use. In other words, although the possibility of obtaining injunctive relief may be significantly limited, a right to remuneration is maintained. Compulsory licenses (or non-voluntary licenses) are one type of mechanisms used to put this type of limitations in place.

(b) Role of Exceptions and Limitations

76. In an analogous manner to the exclusions from patentable subject matter, at first sight, the consequence of limiting the scope of the enforceable rights may lead to reducing the incentives for inventors to invest in innovative activities. It is a public policy choice whether, under certain circumstances, it is considered more adequate to allow anybody to use the patented technology, or to allow the patentee to exercise the exclusive rights with a view to better promote innovation and increase social welfare. However, the legal assurance of non-infringement through uses by others than the patentee does not necessarily mean that these others can immediately exploit the patented invention. While the patent system requires the disclosure of patented inventions in a manner clear and complete so that a person skilled in the art can carry out the claimed invention, often, a significant amount of know-how is involved in order to achieve an optimal exploitation of the invention.

(c) Existing International Rules

77. Again, exceptions and limitations to the exclusive rights are regulated in national (and sometimes regional) laws applying a national/regional public policy perspective, and taking into account the legitimate rights of the patentees and of third parties. At the international level, some international treaties address issues relating to exceptions and limitations to the rights.

(i) Paris Convention

78. Article 5.A of the Paris Convention provides certain rules concerning compulsory licenses in respect of patents and utility models. Article 5.A(2) recognizes the right of each member States to take legislative measures providing for the grant of compulsory licenses to prevent abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work. Member States are free to define the expressions “abuses which might result from the exercise of the exclusive rights conferred by the patent” or “failure to work”.²⁵ Other examples of such abuses may be the refusal of granting a license on reasonable terms and conditions, or the failure to supply the national market with sufficient quantities of the patented product or demanding excessive prices for such product.²⁶

79. Article 5.A(4) provides the procedure applicable to obtain compulsory licenses. As regards compulsory licenses on the grounds of failure to work or insufficient working, such licenses shall not be granted before the expiration of a period of four years from the filing date or three years from the date of the grant of the patent, whichever period expires last. Such period takes into account the time necessary for a patentee to organize the exploitation of the invention, either by himself or by a licensee. The competent authority of the country concerned shall refuse the compulsory license, if the patentee justifies his inactivity with legitimate reasons. The compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of sub-licenses, except with that part of the enterprise or goodwill which exploits the license. This requirement is intended to prevent the grantee of the compulsory license from obtaining a stronger position than it was warranted by the purpose of the compulsory license, namely, to provide a sufficient working of the patented invention.²⁷

80. It should be noted that Article 5.A does not deal with compulsory licenses other than those whose purpose it is to prevent abuses of a patentee. Member States are free to provide analogous or different measures under the applicable law.

81. Article 5ter of the Paris Convention also provides certain limitations on the exclusive rights in the public interest, namely to maintain the freedom of transport. Its effect is, in principle, that if ships, aircrafts or land vehicles temporarily visit foreign countries, their owners are not required to obtain licenses on patents in force in these countries in order to avoid infringing such patents in each country.²⁸ The provision requires Member States not to consider the following as infringements of the rights of a patentee:

²⁵ Actes de la conférence réunie à Londres, 1934, p.174.

²⁶ Actes de la conférence réunie à La Haye, 1925, p.434.

²⁷ G.H.C. Bodenhausen, “Guide to the Application of the Paris Convention for the Protection of Industrial Property”, WIPO Publication No.611.

²⁸ Id.

- the use on board vessels of other countries of the Union of devices forming the subject of his patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter the waters of the said country, provided that such devices are used there exclusively for the needs of the vessel;
- the use of devices forming the subject of the patent in the construction or operation of aircraft or land vehicles of other countries of the Union, or of accessories of such aircraft or land vehicles, when those aircraft or land vehicles temporarily or accidentally enter the said country.

(ii) Convention on International Civil Aviation (Chicago Convention)

82. The Convention on International Civil Aviation (Chicago Convention) was concluded in 1944 with the objectives of developing the international civil aviation in a safe and orderly manner and of establishing international air transport services on the basis of equality of opportunity, and sound and economical operation. 190 States are party to this Convention.

83. Article 27 of the Chicago Convention extends the exceptions to the patent rights with respect to international air navigation so that the authorized entry of an aircraft in the territory shall not entail any seizure of the aircraft on the grounds of a patent infringement. The provision provides that, while engaged in international air navigation, any authorized entry of an aircraft of a contracting State into the territory of another contracting State or authorized transit across the territory of such State with or without landings shall not entail any seizure or detention of the aircraft or any claim against the owner or operator thereof or any other interference therewith by or on behalf of such State or any person therein, on the ground that the construction, mechanism, parts, accessories or operation of the aircraft is an infringement of any patent, design, or model duly granted or registered in the State whose territory is entered by the aircraft. Further, a similar exception to the patent rights applies to the storage of spare parts and spare equipment for the aircraft and the right to use and install the same in the repair of an aircraft of a contracting State in the territory of any other contracting State, provided that any patented part or equipment so stored shall not be sold or distributed internally in or exported commercially from the contracting State entered by the aircraft.

(iii) TRIPS Agreement

84. While Article 28 of the TRIPS Agreement provides the exclusive rights conferred by a patent to its owner, Articles 30 and 31 provide certain exceptions and limitations to the exclusive rights that WTO Members may provide in their national laws. Since Articles 30 and 31 are permissive (“may”) provisions, Members are permitted, but not obliged, to provide those exceptions and limitations.

85. Article 30 allows Members to provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. In a similar manner as it is the case with the three-step-test under Article 9(2) of the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention), Article 30 establishes three conditions, namely, (i) that the exceptions to the exclusive rights must be “limited”; (ii) that the exceptions do not unreasonably conflict with a normal exploitation of the patent; and

(iii) that the exceptions do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. In conjunction with the *Canada-Patent Protection of Pharmaceutical Product* case (DS114),²⁹ the Dispute Settlement Panel provided some guidance with respect to the above three conditions in Article 30.

86. First, the Panel found that the three conditions apply cumulatively, and “the exact scope of Article 30’s authority will depend on the specific meaning given to its limiting conditions”. When examining the words of those conditions, “both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind, as well as other provisions of the TRIPS Agreement which indicate its objective and purposes”.

87. Second, the Panel held that the “limited” character of an exception should be “measured by the extent to which the exclusive rights of the patent owner have been curtailed”.

88. With respect to the expression “normal exploitation of the patent”, the Panel considered that it referred to the “commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent”. The term “normal” was interpreted by the Panel as the combination of “an empirical conclusion about what is common within a relevant community” and “a normative standard of entitlement”. Further, the Panel’s decision stated that, while the specific forms of patent exploitation by the patent owner are not static, “protection of all normal exploitation practices is a key element reflected in all patent laws”. In the specific circumstances of the case, the Panel concluded that the “additional period of *de facto* market exclusivity created by using patent rights to preclude submissions for regulatory authorization should not be considered “normal”. It was not a “natural or normal consequences of enforcing patents rights”, but rather an “unintended consequences of the conjunction of the patent laws with product regulatory laws” that resulted in such additional period of *de facto* market exclusivity.

89. As regards the third criteria, the Panel concluded that the term “legitimate interest” must be “defined in the way that it is often used in legal discourse – as a normative claim calling for protection of interests that are ‘justifiable’ in the sense that they are supported by relevant public policies or other social norms”. In the specific circumstances of the case, the Panel considered that the “interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized that it could be regarded as a ‘legitimate interest’ within the meaning of Article 30”.

90. Article 31 of the TRIPS Agreement provides that a Member may allow, under the stipulated conditions, other use than that allowed under Article 30 without authorization of the rights holder. Those other uses are typically compulsory licenses and government use without the authorization of the right holder. The conditions laid down in Article 31 are:

²⁹ The dispute concerned the regulatory review provision and the stock piling provision under the Patent Act of Canada, which allowed generic pharmaceutical manufacturers to override the patent rights in certain situations. As regards compliance with Article 30, the Panel found that, while the stock piling provision did violate Article 30 because it was not a “limited” exception to the rights, the regulatory review provision was justified under Article 30 by meeting all criteria in that Article. [http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm].

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstance of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (j) decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (k) are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent (“the second patent”) which cannot be exploited without infringing another patent (“the first patent”), the following additional conditions shall apply:

(i) invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

(iii) use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

91. With respect to the grant of compulsory licenses and what constitutes a “national emergency or other circumstances of extreme urgency”, the Declaration on the TRIPS Agreement and Public Health,³⁰ adopted by the Fourth Session of the WTO Ministerial Conference at Doha on November 14, 2001, provides some guidance for the interpretation and application of Article 31. The Declaration states that, in paragraph 4, the Members agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating the commitment to the TRIPS Agreement, the Members affirmed that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all. In this connection, the Members reaffirmed the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibilities for this purpose. Paragraph 5 of the Declaration states that, in the light of paragraph 4 above, while maintaining the commitments under the TRIPS Agreement, Members recognize that these flexibilities include: (a) in applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles; (b) each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted; and (c) each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

92. Furthermore, in order to solve the problem of Members with insufficient or no manufacturing capacities in the pharmaceutical sector facing difficulties in making effective use of compulsory licensing, following up on paragraph 6 of the Declaration, WTO Members decided, in 2003, on a “waiver” that removed limitations on exports under compulsory licenses to least-developed country Members and other Members that have insufficient or no manufacturing capacities in the pharmaceutical sector for the patented product in question.³¹ Following the Decision of the General Council of December 6, 2005, on the Amendment of

³⁰ http://www.wto.org/english/thewto_3/minist_e/min01_e/mindecl_trips_e.htm.

³¹ Decision of the General Council of August 30, 2003, on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health [http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm].

the TRIPS Agreement,³² an amendment to the TRIPS Agreement will replace the Decision of the General Council of August 30, 2003 once it is accepted by two thirds of the WTO membership.

93. As regards exhaustion of rights, Article 6 of the TRIPS Agreement states that, for the purposes of dispute settlement under that Agreement, subject to the provisions of Articles 3 and 4, nothing in the TRIPS Agreement shall be used to address the issue of exhaustion of intellectual property rights. The Doha Ministerial Declaration on the TRIPS Agreement and Public Health clarified that the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights was to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the most-favored-nation treatment and national treatment provisions contained in Articles 3 and 4.

94. In addition, the TRIPS Agreement, in Article 73, recognizes the freedom of Members to take certain actions which they consider necessary for the protection of essential security interests. Further, in accordance with Article 2.1 of the TRIPS Agreement, the WTO Members shall comply with Articles 5.A and 5ter of the Paris Convention concerning limitations to the patent rights.

(d) National and Regional Laws

95. It could be said that the exclusive rights conferred by a patent and the exceptions and limitations to such rights are two sides of the same coin seeking to balance the legitimate interests of the patent owner and the legitimate interests of third parties with a view to promote innovation, disseminate technical knowledge and encourage transfer of technology. Since the socio-economic conditions in a country and its priorities do influence the public policy considerations that underpin the adjustment of the different interests at stake, it may not come as a surprise that the different laws contain a variety of provisions addressing exceptions and limitations. Nevertheless, some convergence can be found in the different laws and, for example, the legislation of many countries provide that a patentee cannot enforce his rights in respect of the following acts performed by third parties:³³

- private acts for non-commercial purposes;
- acts for the purpose of teaching;
- acts for experimental purposes or scientific research;
- preparation of medicines prescribed by doctors;
- continued use by a prior user;
- certain uses on foreign vessels, aircrafts and land vehicles which temporarily or accidentally entered the national territory;
- acts for obtaining regulatory approval for pharmaceuticals;
- acts performed for a farmer's own use and for the development of new varieties.

96. Further, a significant number of national/regional laws provide for various situations under which compulsory licenses and government use of the patented invention without the authorization of the patent owner may be allowed.

³² Decision of the General Council of December 6, 2005, on the Amendment of the TRIPS Agreement [http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm].

³³ See Annex II of document SCP/12/3 Rev.2.

97. As regards the exhaustion of rights, some laws contain an explicit provision, while under some others, no provision is found in the legislation, and the case law determines under which circumstances the patent right is exhausted. The exhaustion of rights may not qualify specifically for being an exception or limitation to the rights in the narrow sense because, while exceptions and limitations impose limited “restrictions” to the enforcement of rights for certain kinds of uses of the patented invention, the exhaustion of rights addresses the specific question of the “non-existence” of the patent rights (or, in other words, of the scope of the rights) associated with the product which has been legitimately put on the market. On the other hand, the exhaustion of rights can be considered as forming part of the exceptions and limitations in the broad sense, as it also defines the permissive actions which can be taken by third parties without risking to infringe the rights.

98. Other exceptions and limitations although less frequently, are found in national laws. They include:

- limited exceptions to the rights conferred by a patent, which shall not unjustifiably prejudice the exploitation of the patent or do unjustified harm to the legitimate interests of the owner thereof, due account being taken of the legitimate interests of third parties;
- use or sale of products obtained from a legitimate source, but made and sold without the authorization of the patent owner;
- non-repeated use of biological material, other than plants, to obtain viable new material;
- biological material obtained by reproduction, multiplication or propagation of the material put on the market by the patent owner for that purpose, other than for multiplication or propagation purposes;
- use of an essential element of the invention by a person who was unaware that it was for carrying out the invention;
- acts performed by any person who proves that he was unaware that the patent existed;
- products existing in the country before the filing date (priority date);
- use of patented medical or surgical procedures by a medical practitioner performing a medical activity.

99. The following paragraphs describe further details on some of the exceptions and limitations frequently found in national/regional laws:

- (i) Private acts, non-commercial use and acts for teaching

100. It is common not to extend the exclusive patent rights to third parties’ activities that are performed in the private sphere or for non-commercial purposes only. In some countries, the right conferred by a patent is limited to prevent the use of the patented invention by authorized third parties for commercial or industrial activities. In some other countries, the right conferred by a patent encompasses all kinds of activities by unauthorized third parties, but an explicit exception is provided so that the patent right does not extend to personal or non-commercial activities.

101. Similarly, some countries exclude acts for teaching from the ambit of the patent right so that teachers can use patented inventions for education purposes without having to fear infringing the patent.

(ii) Experimental use and scientific research

102. A number of countries provide a so-called research exemption either in their law or through case law in the common law countries. In general, the research exemption enables researchers to examine the stated effects of patented inventions and improve such patented inventions without having to fear infringing the patent. Such a contribution to a positive environment for research activities is expected to add to the development of technologies, which is precisely one of the objectives of the patent system. Proponents of the research exemption argue that, since much research is cumulative in nature, negotiating and concluding multiple patent licenses before any actual research takes place could involve significant transaction costs. Further, it is alleged that, since it cannot be known at the outset which research line will be successful, the greater the possibility of using the reservoir of existing knowledge is, the greater the possibility is to achieve a breakthrough.³⁴

103. In the *Canada-Patent Protection of Pharmaceutical Product* case (DS114),³⁵ the WTO Dispute Settlement Panel referred to the research exemption in conjunction with its ruling on Article 30 of the TRIPS Agreement:

“We may take as an illustration one of the most widely adopted Article 30-type exceptions in national patent laws - the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement. It is often argued that this exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a “legitimate interest” in using the patent disclosure to support the advance of science and technology. While the Panel draws no conclusion about the correctness of any such national exceptions in terms of Article 30 of the TRIPS Agreement, it does adopt the general meaning of the term “legitimate interests” contained in legal analysis of this type.”

104. In certain cases, a patentee may have better opportunities to license his patented invention if third parties can examine the effect of the patented invention before commercialization or can work on improvements of the patented invention the commercial exploitation of which would require the consent of the patentee.

105. Although the general policy objectives of the experimental use/research exemption under national laws are more or less in line with the description above, the text of those provisions is not always exactly the same, and, in addition, the interpretation of those texts may vary from one country to the other. In particular, formulations such as “acts *for the purposes of* experimental use or scientific research” or “acts done for experimental purposes *relating to* the subject matter of the invention” (*emphasis added*) gives some room for interpretation of the exact scope of the provision. Consequently, the scope of the exemption may be different in various jurisdictions.

³⁴ “Research use of patented knowledge: a review”, STI working paper 2006/2, OECD.

³⁵ http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm.

106. In some countries, the text of the experimental use exemption explicitly states that the exemption is applicable when the experiment was made without commercial or gainful intent. In some other countries, the provision explicitly states that the experimental use exemption is applicable also for acts anticipating a future commercial exploitation. In some other countries, the statutory law is silent on this point, and the courts had to decide on the scope of the exemption.

107. Another issue is the scope of the term “experiment”. Experiments may be conducted for a wide range of different purposes, for example, checking how the patented invention works, determining the validity of the patented claims, investigating unknown effects or new uses of the patented invention or exploring possibilities of further development. The next paragraphs give some examples of the term “experiment” is interpreted.

108. In the United Kingdom, only experiments which generate genuinely new information are covered by the exemption, for example, 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 under specific conditions will work under different conditions as well. The exemption does not extend to experiments which are designed to verify existing knowledge (for example, to demonstrate to a third party that a product works as claimed), and consequently, clinical trials to obtain regulatory approval are not acts done for experimental purposes.³⁶ In the countries that provide such an interpretation, a separate provision may have to be enacted in order to exclude acts for obtaining regulatory approval from patent infringement (see item (vi) below).

109. In Germany, two cases, *Clinical Trial I*³⁷ and *Clinical Trial II*,³⁸ clarified the situation in respect of the experimental use exemption in that country. In *Clinical Trial I*, the Court concluded that the scope of the experimental use defense include “checking of the utilisability of the subject-matter of the patented invention and checking possibilities of further development”. It does not matter “whether the experiments are used only to check the statements made in the patent or else to obtain further research results, and whether they are employed for wider purposes, such as commercial interests.” The experimental use may be conducted in order to “discover the effects of a substance or possible new uses hitherto unknown.” The Supreme Court stated that, in principle, the experimental use exemption excludes all experimental acts as long as they serve to gain information, and thus the acts to support an application to a regulatory authority can be covered by the experimental use defense. In *Clinical Trial II*, the Court took a similar view by stating that an activity “oriented towards clearing up uncertainties with regard to the object of the patented invention or bringing out new discoveries about said object” qualifies as experimental use under the exception, provided that these activities with research purposes relate to the object of the patented invention, and that clinical trials conducted for the same indication as that of the patented invention can be covered under the experimental use exemption. The Court also provided examples of activities not considered as an “experiments” under the exception, which include: research having no relation whatsoever to the technological theory; clarification of commercial facts; experiments undertaken at a scale that cannot be justified

³⁶ “The Patent Research Exception: a Consultation”, UK Intellectual Property Office; *Monsanto v Stauffer and Micro-Chemicals Ltd v Smith Kline and French Inter-America Ltd*.

³⁷ R.P.C.623 [1997].

³⁸ R.P.C.423 [1998].

by research purposes; and research not for the purpose of technological progress, but rather for competition purposes.

110. Looking at the issue from a slightly different angle, questions have been raised as to the role of the patented invention in connection with the experiment. It appears that, in general, the research exemption applies to research *on* or *into* a patented invention, for example, working *on* the patented invention in order to explore unknown effects or further develop the invention. However, there are also cases where research is conducted *with* or *using* the patented invention. For instance, a patented invention may be used on another invention for research purposes in order to, for example, explore more about such other invention.

111. The question as to whether the experimental use exemption covers this latter case was somehow addressed through the concerns raised in the context of research involving the use of genetic information where patents have been granted on DNA sequences.³⁹ It was observed that, in the area of genetic research, in particular, patents granted on up-stream research results such as PCRs and ESTs (so-called “research tools”) could impede the down-stream innovation, since the use of the research tools could be crucial for the development of down stream innovation (such as pharmaceutical applications) and as, in many cases, there was no way to invent around the patented research tools. In this case, the down stream researchers are not conducting research *on* the research tool patents, but rather conducting research *with* the research tool patents. From a policy perspective, first, an appropriate balance should be found between the incentives for innovators to further develop innovative research tools and the interests of other researchers to use those research tools, and second, a balance between the legitimate rights of up-stream researchers (including the exclusive patent rights holders) and access to the results of up-stream research with a view to promote the follow-on research. It seems that many countries do not apply the research exemption to research made *with* the patented invention, although Belgium recently amended its Patent Act to extend the coverage of the exemption to “acts accomplished for scientific purposes *on* and/or *with* the subject matter of the patented invention”.⁴⁰

112. In the context of pharmaceutical and biomedical research, another question has been raised, namely to what extent clinical tests can be regarded as experimental, since treatment activities and the continuing search for further genetic knowledge often enough go hand in hand.⁴¹

113. In the United States of America, there is no statutory research exemption provision, but a “truly narrow”⁴² exception exists with respect to experimental activities developed by case law. In 1813, the Supreme Court stated that it could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.⁴³ In another case in 1813, the Supreme Court distinguished between the making with an intent to use for profit and for the mere purpose of philosophical experiment

³⁹ Nuffield Council on Bioethics, “The ethics of Patenting DNA”, July 2002.

⁴⁰ Article 28.1(b) of the Belgian Patent Act of 1984, as amended by the Law of April 28, 2005.

⁴¹ Patenting and the Research Exemption [http://www.ipr-helpdesk.org/documents/BP-Patenting-and-the-Research-Exemptio_0000003268_00.xml.html].

⁴² Roche Prods., Inc v. Bolar Pharm. Co., 773 F.2d 858, 863 (Fed. Cir.1984).

⁴³ Whittemore v. Cutter, 29 Fed Cas. 1120 (C.C.D. Mass. 1813).

or to ascertain the verity and exactness of the specification.⁴⁴ Consequently, acts with an intent to use the invention for profit or for commercial purposes are considered not to be covered by the case law exception. In *Madey v. Duke*, the issue was whether research activities in non-State universities fall under the exception.⁴⁵ The Court concluded that, as long as the act was in furtherance of the alleged infringer's legitimate business and was not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act did not qualify for the very narrow and strictly limited experimental use defense.⁴⁶ The Court did not apply the experimental use exception to the Duke University's activities, since those research activities unmistakably furthered the institution's legitimate business objectives, including educating and enlightening students and the faculty participating in these projects.

114. A Conference was organized by the OECD in 2006 on the effect of national policies relating to exemptions for research use of patented invention.⁴⁷ The summary report concluded that

- at present, there was no empirical evidence of a widespread problem in accessing patented invention for research, and concerns were confined mostly to specific fields of research (such as life science) and countries (such as the United States of America);
- nevertheless, concerns over research use could expand to other areas of research (such as nanotechnology) and to other countries considering the ongoing trend towards more multidisciplinary research;
- a balanced patent system should facilitate inventions that build on earlier findings, but the line may be difficult to draw, especially for patented research tools;
- alternative mechanisms to facilitate access to inventions for research purposes were also available; and
- further studies were needed to better understand emerging issues relating to research access to patented inventions and identify good practices for promoting it across different sectors and countries.

(iii) Preparation of prescribed medicines

115. In a number of countries, the preparation of medicines for an individual in accordance with a prescription given by a doctor or a dentist and such medicines prepared are regarded as not infringing patent rights. Such an exception is aiming at preventing patents being an obstacle for patients to access medicines which were prescribed by a medical practitioner. In some countries, the provision explicitly provides that the exception is limited to extemporaneous preparations in a pharmacy, while in some other countries, issues such as who may prepare a prescribed medicine or where such medicine shall be prepared are not addressed in the law.

⁴⁴ *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813).

⁴⁵ State universities and its employees acting in their official capacity have immunity from patent infringement on the ground of the Eleventh Amendment. See a presentation by Prof. Sean O'Conner at the "WIPO Colloquia on Selected Patent Issues: Research Exemption" [http://www.wipo.int/meetings/en/2006/patent_colloquia/10/].

⁴⁶ *Madey v. Duke University*, 307 F.3d. 1351 (Fed. Cir. 2002).

⁴⁷ OECD Conference on Research Use of Patented Inventions, Madrid, May 18-19, 2006 [http://www.oecd.org/document/39/0,3343,en_2649_34797_36807591_1_1_1_1,00.html].

(iv) Continued prior use

116. Many countries allow a third party to continue using a patented invention if he had used the invention for the purpose of his business in good faith before the filing date (or the priority date) or had made effective or serious preparations for that purpose. There are cases where a patent may be granted even if the patented invention had been used by a third party before the patent application was filed. For example, if the third party was using the invention in his business prior to the filing date (priority date) in secret, such use would not be regarded as prior art, and consequently, a patent would be issued. In another case, even if the prior user was using the invention in his business publicly, a patent examiner might overlook the existence of the prior art, and a patent may be issued. In this case, theoretically, it is possible to revoke the patent, but in practice, the prior user may have financial constraints or other reasons that makes it difficult to invalidate the patent. In both cases, the patentee (who is the later inventor but the first filer of the patent) can enforce his patent only by allowing the prior user to continue his business using the patented invention. If the prior user has to renounce the continued use of his invention simply because he did not file a patent application, this may be too harsh, as he may have made important investment to use the invention.

117. In many countries, continued prior use complying with the conditions laid down in the applicable law is excluded from infringement actions. In other countries, such as Japan and the Republic of Korea, for instance, the law provides prior users the possibility to continue the use of the patented invention for the purpose of his business through the grant of a statutory non-exclusive license.

118. In order to balance the legitimate interests of the patentee and of the prior user, provisions in the national laws contain a number of conditions under which the prior use exception can be applied. The first question is: who are the prior users entitled to benefit from the exception? In many national laws, the prior user must be using the invention for the purpose of his business, or be making serious preparations to use the invention for that purpose, in good faith. A German court held that a person who has obtained an invention from the true inventor for a single and defined purpose has no right to benefit from the exception, since it is provided by law in a spirit of equity.⁴⁸ The Japanese Law explicitly states that the prior user must be a person who has made the invention by himself without knowledge of the contents of the invention claimed in a patent application, or a person who, without knowledge of the contents of the invention claimed in a patent application, has learned the invention from another person who had made the invention. Therefore, it appears that the Japanese law takes into account how the prior user obtained the knowledge of the invention concerned when considering the entitlement of the prior user to the exception.

119. A second question relates to the issue of how to define the term “use” covered by the exception? The Patent Act of the United Kingdom, for example, clarifies that the prior use exception applies to acts which would constitute an infringement of the patent if it could be enforced. The extent of the use required on the filing date (or priority date) has been considered by a number of national courts. For example, a third party used a particular process one single time only for the manufacture of a small quantity of the product and no follow-up to that experience had occurred. The third party was not entitled to the prior use

⁴⁸ German Reichsgericht, December 15, 1928 (Prop. Ind., 1931, p.146), quoted in Ladas “Patents, Trademarks and Related Rights: National and International Protection”.

exception.⁴⁹ The fact that one had placed an order for the product, exhibited it at an international exhibition, and shown specimens to clients, gives no entitlement to enjoy the prior use exception.⁵⁰ In another case, it was held that the prior user was required to have acknowledged, at the time of beginning the utilization, that he was achieving a specific technical effect through a specific technical means.⁵¹ It was also held that the prior use exception was not recognized because of the abandonment of the manufacture of the product,⁵² but that prolonged non-utilization alone did not cause the loss of the prior user defense.⁵³

120. In the context of the “use” of the invention, it should be noted that the French Industrial Property Code states that “any person who, within the territory in which this Book applies, at the filing date or priority date of a patent was, in good faith, in possession of the invention which is the subject matter of the patent shall enjoy a personal right to work that invention despite the existence of the patent.” On the face of it, the provision does not require “using” or “making serious preparations for such use” of the invention, but the “possession” of the invention to enjoy the exception. The choice of the word “possession” rather than the word “use” seems to be derived from balancing the interests of the patentee and the interest of prior inventor(s) who chose not to file patent applications, but rather to keep the invention secret. The underlying consideration seems to be that the grant of a patent to a later inventor shall not take away all the rights of the earlier inventors who already possessed the invention secretly at the filing date (priority date). It is explained that the exception is: to preserve the acquired rights of third parties, more specifically, it protects the use of the invention before the filing date; to protect the earlier inventor(s); and to limit the patent rights where the prior exploitation owed nothing to the patentee.⁵⁴ As regards the interpretation of the term “possession”, the full knowledge of the patented technology is required.⁵⁵

121. Third, the scope of the prior user exception is limited to the “continued” use of the invention concerned for the purposes of the prior user’s business or his enterprise. Therefore, it is generally understood that the scope of the exception covers only acts which were conducted, or which were under preparation to be conducted, by the prior user at the filing date (or priority date). The Japanese Patent Law explicitly provides that the prior users’ exception is applicable only to the extent to which the invention is used and for the purpose of such use.

122. Fourth, some national laws explicitly state that the entitlement to continue using the invention is a private entitlement accorded to the prior user. For example, the law of the United Kingdom and France provide that the prior user right may only be transferred together with the business, the enterprise or the part of the enterprise to which it belongs.

⁴⁹ Supreme Court of Austria, June 1, 1932 (pro. Ind., 1034, p.220), quoted in Ladas “Patents, Trademarks and Related Rights: National and International Protection”.

⁵⁰ Supreme Court of Denmark, March 26, 1923 (prop. Ind., 1937, p.114), quoted in Ladas “Patents, Trademarks and Related Rights: National and International Protection”.

⁵¹ German Supreme Court, April 30, 1964 (GRUR, 1964, p.446), quoted in Ladas “Patents, Trademarks and Related Rights: National and International Protection”.

⁵² Commercial Court of Vienna, Prop. Ind. (1938), p.234.

⁵³ German Supreme Court, January 7, 1965 (GRUR, 1965, p.411), quoted in Ladas “Patents, Trademarks and Related Rights: National and International Protection”.

⁵⁴ Marc Savatier “L’exploitation des brevets d’invention et l’intérêt général d’ordre économique”.

⁵⁵ Jean Foyer et Michel Vivant “Le droit des brevets”; Johanna Schmidt-Szalewski et Jean-Luc Pierre “Droit de la propriété industrielle”.

123. In the United States of America, the defense to infringement by earlier inventors is limited to the use of patents regarding methods of doing or conducting business. In order to enjoy this exception, the prior user must, in good faith, have reduced the subject matter to practice at least one year before the filing date (or priority date) and commercially used it before that date. Other conditions are similar to the prior use exceptions in other countries. A prior user may not assert the defense if the subject matter on which the defense is based was derived from the patentee or persons in privity with the patentee. The defense extends only to the specific subject matter claimed in the patent with respect to which the prior user can assert the defense, except that the defense shall also extend to variations in the quantity or volume of use of the claimed subject matter. A prior user who has abandoned the commercial use of the subject matter may not rely on activities performed before the date of such abandonment in establishing a defense with respect to actions taken after such abandonment. The defense granted to the prior user is of a personal nature, and therefore, it shall not be licensed or assigned or transferred to another person except as an ancillary and subordinate part of a good faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates.

124. In Japan, where the validity of an invalidated patent was restored through a court procedure or where a decision by the appeal board to refuse a patent application was overturned by a court, a similar safeguard for good faith prior users is provided so that a party who has been using the patented invention for the purpose of his business, or has made serious preparations to use the invention for that purpose, in good faith after the invalidation or refusal of a patent, but before the restoration or grant of the patent, can continue to use the patented invention, but only to the extent to which the invention was used and limited to the purpose of such use.

- (v) Certain uses on foreign vessels, aircraft and land vehicles which temporarily or accidentally enter national territory

125. According to the Paris Convention, its Member States shall not consider the use of devices of board vessels for the needs of the vessel, and of devices and accessories of aircrafts and land vehicles, which temporality or accidentally enter the water and territory of the country, as infringement of patent rights. Further, according to the Chicago Convention, the authorized entry of aircrafts on the territory for the purpose of international air navigation shall not entail to the seizure of the aircraft, and the patent rights shall not extend to the storage of spare parts and spare equipment for the aircraft nor to the right to use and install the same in the repair of an aircraft of a contracting State in the territory of any other contracting State. Since a great majority of countries are parties to those Conventions, such exceptions appear often in national patent laws. Those exceptions are considered to be facilitating the operation of international transport.

126. In addition to the devices of vessels, aircrafts and land vehicles temporarily or accidentally entering the territory, some countries also provide similar exceptions for spacecrafts and satellites, since these may need to temporarily cross foreign territories for the purpose of being launched to space or upon return from space.

- (vi) Acts for obtaining regulatory approval

127. Many countries provide an exception relating to the use of patented products (particularly pharmaceutical products) for the purpose of obtaining regulatory approval to

place the product on the market. Such exception is often called “Bolar exception” because of the case *Roche Products v Bolar Pharmaceuticals*⁵⁶ decided by the US Court of Appeals for the Federal Circuit (CAFC) in 1984. The CAFC ruled that the research exemption in the United States of America did not cover Bolar’s acts to carry out equivalent tests for the regulatory approval of the generic medicine before the expiration of the relevant patent owned by Roche. The US legislators considered that it was not appropriate to prevent generic pharmaceutical manufactures from starting to prepare and obtain regulatory approval for the generics, since it would delay the entrance of generic medicines on the market for a substantial period, extending the effective protection period beyond the patent term. Consequently, an explicit exception was introduced in the patent law, stating that acts solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products, other than those products primarily manufactured using certain genetic manipulation techniques, were not infringement acts.

128. As states above, in some countries, the experimental use exemption is construed broadly to encompass acts by third parties to obtain regulatory approval. In some countries, case law confirmed such an interpretation,⁵⁷ and in some other countries,⁵⁸ the experimental use provisions explicitly state that they include acts for obtaining regulatory approval.

129. The scope of the Bolar-type exceptions, however, varies among national laws. First, in some countries, the exception covers regulatory approval of any products, while in some other countries, the coverage of the exception is limited to pharmaceuticals or medicinal products. In the United States of America, the exception covers drugs and veterinary biological products, but not products manufactured using primarily certain genetic manipulation techniques. The US Supreme Court ruled that the Bolar exception was also applicable to all categories of FDA regulated products, such as medical devices, food additives and color additives.⁵⁹

130. Second, with respect to pharmaceuticals, all types of marketing authorizations are covered in some countries, while in some other countries, only certain types of marketing authorizations, for example, the abbreviated procedure (marketing approval of generics, referring to the data submitted in respect of the marketing authorization of the earlier medicine that has been already registered) are covered by the exception.

131. Third, in some countries, the regulatory approval has to be requested in the country where the relevant acts occurred in order to enjoy the exception, while in some other countries, activities for regulatory approval in any country are covered by the exception.

132. Fourth, expressions such as “acts for regulatory approval”, “acts *solely for uses reasonably related to* regulatory approval” or “acts *exclusively aiming at* regulatory approval” appearing in national laws offer some room for interpretation. In *Merck v. Integra*,⁶⁰ the US Supreme Court confirmed that the Bolar exception applied to all uses of patented inventions that are reasonably related to the development and submission of any information under the

⁵⁶ Roche Products v. Bolar Pharmaceuticals, 733 F.2d. 858(Fed. Cir. 1984).

⁵⁷ Japan Supreme Court Decision, Case No. 1998 (ju) 153 (April 16, 1999).

⁵⁸ For example, Spain and Italy.

⁵⁹ Eli Lilly &Co. v. Medtronic, Inc., 496 U.S.661 (1990).

⁶⁰ Merck KGaA v. Integra Lifesciences I, Ltd.,125 S. Ct. 2372, No. 03-1237 (2005).

FDA, which includes preclinical studies of patented compounds that may be submitted to the FDA, studies that perform a risk-benefit analysis of a proposed clinical trial, safety-related tests that are not necessarily compliant with FDA regulations and studies to generate pharmacological, toxicological, pharmacokinetic and biological qualities of the drug in animals. The Supreme Court stated that the Bolar exception did not categorically exclude either experimentation on drugs that are not ultimately the subject of an FDA submission or use of patented compounds in experiments that are not ultimately submitted to the FDA.

(vii) Farmer's privilege and breeder's exception

133. As regards inventions relating to biological material, one characteristic of those inventions is that some of them are self-reproducible. Here, the question has arisen as to whether patent protection covers any subsequent material which is the result of propagation and reproduction. Some countries take the view that the patentee of such self-reproducible material should be able to enjoy the same degree of protection as the one enjoyed by the patentee of non-self-reproducible products.

134. For example, the European Directive 98/44 on the Legal Protection of Biotechnological Inventions, the provisions of which shall be complied with by the EU Member States, states that the protection conferred by a patent on a product containing or consisting of genetic information shall, in general, extend to all material in which the product is incorporated and in which the genetic information is contained and performs its function. As regards the scope of patent protection for propagated or multiplied material derived from a patented biological material, the Directive clarifies that the protection conferred by a patent on biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics. Similarly, where a patent is granted for a process that enables biological material to be produced possessing specific characteristics as a result of the invention, the scope of such process patent covers any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing the same characteristics.

135. The EU Directive, however, derogates from the rights of patentees, which extend to the propagated and multiplied materials, if the propagating material incorporating the patented invention is sold to a farmer for farming purposes by the patentee or with his consent. More specifically, the EU Directive stipulates that the sale or other form of commercialization of plant propagating material to a farmer by the patentee or with his consent for agricultural use implies the authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, to the extent and under the conditions provided for by the applicable plant variety protection law. Such an exception provides a mechanism under the national patent laws, which is analogous to the farmer's privilege contained in the plant variety protection system in Europe.

136. Further, with respect to reproducible animal material, a similar provision has been included in the EU Directive so that farmers may use patent-protected livestock for agricultural purposes. The sale or any other form of commercialization of the breeding stock or other reproducible animal material to a farmer by the patentee or with his consent implies the authorization for the farmer to use the protected livestock for agricultural purposes. This authorization includes making the animal (or the material) available for the purposes of pursuing agricultural activities, but not for sale within the framework or for the purpose of a commercial reproduction activity.

137. In addition, some countries provide an explicit provision in the patent law stating that the patent right does not extend to acts in view of creating or discovering and developing other plant varieties. Such a provision responds to particular concerns of plant breeders who wish to conduct activities for the purposes of experiment and of developing other varieties without having to fear infringing any patent. In the countries that apply a broad research exemption, activities in relation to the creation and development of a new variety may fall under the research exemption.

(viii) Compulsory licenses and government use

General

138. A large number of countries have, in their national legislation, provisions that allow the government and/or third parties, under certain circumstances and conditions, to use a patented invention without the authorization of the right holder. Such provisions differ from other exceptions, since, while the injunctive relief is significantly limited, the right to remuneration for that use is maintained. In general, those provisions are considered as an instrument to prevent abuses of the exclusivity inherent in the patent rights. They are also considered as tools to ensure that the patent system contributes to the promotion of innovation in a competitive environment and to the transfer and dissemination of technology, meeting the objectives of the system and responding to the public interest at large. They are also seen as safeguards for governments to ensure national security and to respond to national emergencies. In order to meet such objectives, national laws contain various conditions and grounds for granting compulsory licenses, taking into account the interests of various stakeholders including the right holder, third parties and the public at large.

139. For example, Article 83 of the Indian Patent Act articulates the general principles applicable to the grant of compulsory licenses and other actions under Chapter XVI of the Act. It states that, in exercising the powers conferred by Chapter XVI, the following general considerations shall be taken into account:

- (a) patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
- (b) patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
- (c) the protection and enforcement of patent rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;
- (d) patents granted shall not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;
- (e) patents granted shall not in any way prohibit the Central Government to take measures to protect public health;

(f) patent rights shall not be abused by the patentee or by persons deriving the title or interest on the patent from the patentee, and he shall not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

(g) patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

140. Some consider that the existence of a statutory provision on compulsory licenses *as such* is important to ensure a fair exercise of the patent rights, such as encouraging the conclusion of voluntary licenses or inducing competition.⁶¹ However, another author takes a more cautious approach in saying that it could be neither measured nor discounted to what extent the threat of applying a compulsory license enhances the bargaining position of would-be voluntary licensees.⁶² One author notes that, in cases where know-how not disclosed in the patents is required for the exploitation of the patented invention, the cooperation of the right holder has to be ensured, and this can be done only through the conclusion of voluntary licenses or through reverse engineering. Therefore, according to that author, compulsory licenses may be most effective when the technology is already known and only access to it is required.⁶³ The extent of the effectiveness of compulsory licenses may, therefore, depend on various factors such as the specificities of the technology, the technological capacity of would-be licensees, the specificities of the national market such as the size of the market, as well as geographical, commercial, legal and other conditions. One paper⁶⁴ states that, while one should not assume without further investigation that compulsory licenses will necessarily or automatically discourage any particular investment in R&D, presumably beneficial uses of compulsory licenses (such as selected uses of compulsory licenses to address emergencies or to remove specific technology supply bottlenecks) impose social costs of their own. The paper thus suggests that policy makers should view the compulsory licenses as but one item in an arsenal of tools that may be used to promote coherent and effective national systems of innovation.

141. The WTO Members have to comply with the conditions under Article 31 of the TRIPS Agreement, and are bound by the Decision of the General Council of August 30, 2003, on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Paragraph 6 Decision). Therefore, the national legislation often contains provisions which are imported from Article 31 of the TRIPS Agreement. Further, some national laws provide specific provisions in order to implement the Paragraph 6 Decision. Consequently, the conditions described in paragraphs 90 to 92 above are commonly found in many national laws.

⁶¹ Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries*, 2001, p.328.

⁶² W. R. Cornish, *Intellectual property: Patents, Copyright, Trade Marks and Allied Rights*, Fourth Edition, p.295-296.

⁶³ Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries*, 2001, p.328.

⁶⁴ Jerome Reichman, Catherine Hasenzahl "Non-voluntary licensing of patented inventions", UNCTAD-ICTSD Capacity Building Project on IPRs, Issue Paper No. 5.

142. As confirmed by the Doha Declaration on the TRIPS Agreement and Public Health, each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. Indeed, national legislation provides different grounds for the grant of compulsory licenses. Some of the grounds often contained in national legislations include, for example: non-working or insufficient working of the patented invention; anti-competitive practices and unfair competition; public interest, including public health, national security, national emergencies and other circumstances of extreme urgency; failure to obtain a voluntary license under reasonable terms within a reasonable period; and dependent patents and other titles that relate to the protection of inventions. The following paragraphs contain a brief description of each of those grounds for the grant of compulsory licenses with examples found in national legislation. Since the conditions for the grant of compulsory licenses under the national legislation have, to a large extent, been harmonized through the TRIPS Agreement, the following description focuses on the grounds on which compulsory licenses may be granted.

Grounds

[Non-working or insufficient working]

143. Many countries provide that, where a patentee fails to work a patent, or such work by the patentee is insufficient, a compulsory license may be granted, provided that all other requirements are met. In accordance with Article 5(4) of the Paris Convention, a compulsory license based on this ground may not be applied for before the expiration of a period of three years from the grant of the patent or four years from the filing date, whichever period expires last. Such a period may be necessary for a patentee to prepare the exploitation, by himself or by licensees, of the invention in the country concerned, since an immediate exploitation in all countries where the patent was granted is generally impossible.⁶⁵ A safeguard for the patentee is provided so that, in general, if he could justify his inactivity with legitimate reasons, a request for a compulsory license would be refused, as provided for in the TRIPS Agreement. Since the purpose of such a compulsory license is to rectify the situation of non-working or insufficient working, the applicant of the compulsory license should normally demonstrate his ability to produce the patented product and to supply the market.

144. Some national laws simply state that, if a patentee is not working or sufficiently working the invention without any legitimate justification, a third party may request a compulsory license. In some countries, their laws provide detailed provisions clarifying the circumstances that may be applicable. Those clarifications include the types of activities by the patentee that are considered as “working”, in particular, whether importation of the patented invention is considered as “working” in the country or not, and the situations under which working by the patentee is not considered “sufficient”. The following paragraphs provide examples of national provisions.

145. *Argentina*: If a patented invention is not or not sufficiently exploited, serious preparations for its exploitation have not been made, or if such exploitation has been discontinued for one year or longer, any person may request a compulsory license, except where the non-exploitation is due to *force majeure*.

⁶⁵ G. H. C. Bodenhausen, Guide to the Application of the Paris Convention, p.70.

146. Objective difficulties of a technical and legal character, such as delays in obtaining registration or marketing approval from the authorities, which are beyond the patentee's control and which make the exploitation of the patent impossible, shall be considered as *force majeure*. However, lack of economic resources and lack of economic feasibility shall not by themselves constitute justifiable exceptions.

147. The distribution and marketing to a sufficient degree so as to satisfy the needs of the domestic national market under reasonable commercial conditions is considered a sufficient exploitation.

148. *Brazil*: A compulsory license may be granted on the grounds of non-exploitation of the patented product in Brazil for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process, except in the case where this is not economically feasible, in which case importation shall be permitted. Further, a compulsory license may be granted if a patented invention is not commercialized in a way that meets the needs of the market.

149. *Costa Rica*: A patentee is obliged to exploit the patent in Costa Rica in a permanent and stable form, allowing the market to be appropriately and reasonably supplied. The form of exploitation may be, among others, local production and importation of legitimate products. Where such obligation has not been met, a compulsory license may be requested.

150. *France*: Any public or private legal person may be granted a compulsory license under the patent provided that, at the time of the application for such license and failing legitimate reasons, neither the owner of the patent nor his successor in title:

- (a) has begun to work or has made real and effective preparations for working the patented invention on the territory of a Member State of the European Community or another State party to the Agreement on the European Economic Area;
- (b) has marketed the product that is the subject matter of the patent in a quantity sufficient to satisfy the needs of the French market.

151. The same shall apply where working, as mentioned under (a) above, or marketing, as mentioned under (b) above, in France has been discontinued for more than three years. For the purposes of the application of the relevant provision, the importation of patented goods manufactured in a State party to the Agreement Establishing the World Trade Organization shall be considered working of the patent.

152. *India*: Any person may make an application for a compulsory license on the following grounds: the reasonable requirements of the public with respect to the patented invention have not been satisfied; the patented invention is not available to the public at a reasonable affordable price; or the patented invention is not worked in India.

153. The reasonable requirements of the public shall be deemed not to have been satisfied:

- (a) if, by reason of the refusal of the patentee to grant a license on reasonable terms,
 - (i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or

- (ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or
- (iii) a market for export of the patented article manufactured in India is not being supplied or developed; or
- (iv) the establishment or development of commercial activities in India is prejudiced; or

(b) if, by reason of conditions imposed by the patentee upon the grant of licenses under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India is prejudiced; or

(c) if the patentee imposes a condition upon the grant of licenses under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive packaging licensing; or

(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable; or

(e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by:

- (i) the patentee or persons claiming under him;
- (ii) persons directly or indirectly purchasing from him; or
- (iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement.

154. *Switzerland*: Not exploiting the invention sufficiently in Switzerland is a ground for requesting a compulsory license. Importation is considered as exploitation of the patent in Switzerland.

155. *Thailand*: Any person may apply for a compulsory license if it appears, at the time when such application is filed, that the patentee unjustifiably failed to exercise his legitimate rights as follows:

- (a) that the patented product has not been produced or the patented process has not been applied in the country, without any legitimate reason; or
- (b) that no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high prices or does not meet the public demand, without any legitimate reason.

156. *United Kingdom*: With respect to patents which are granted to nationals or residents of the WTO Members, the following grounds apply:

- (a) a demand in the United Kingdom for the patented product is not met on reasonable terms;
- (b) by reason of the refusal to license, the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;

- (c) by reason of conditions imposed by the patentee on the grant of a voluntary license, the manufacture, use, or disposal of materials not protected by the patent or the establishment or development of any commercial or industrial activities within the United Kingdom is unfairly prejudiced.

157. With respect to patents which are granted to non-nationals and non-residents of the WTO Member, a compulsory license may be granted on the basis of more liberal grounds, for example, where a demand for the patented product in the United Kingdom is met to a substantial extent by importation from a non-WTO Member State.

[Other abuses]

158. Some national laws provide the possibility of granting a compulsory license to prevent abuses which might result from the exercise of the exclusive patent rights, other than non-working or insufficient working of the patent. Anti-competitive practices by patentees abusing the economic power derived from the exclusivity of the patent are one example. The law of Brazil, for instance, contains a provision that covers the abusive exercise of the patent rights in general.:

159. *Brazil*: A compulsory license may be granted if the patentee exercises his right in an abusive manner, or if the patentee engages in abuse of economic power by means of exploiting the patent, proven pursuant to law in administrative or judicial decision. Where a compulsory license is granted on the ground of the abuse of the economic power, the licensee of the compulsory license who proposed local manufacture may import the object of the compulsory license during the maximum of one year from the grant of the license, provided it has been put on the market directly by the patentee or with his consent. If such importation is made, a third party may also import such product, provided that it has been put on the market by the patentee or with his consent.

[Remedy anti-competitive practices]

160. Some countries provide specific provisions under the patent law that allow the grant of compulsory license in order to remedy an anti-competitive practice engaged by the patentee.

161. *Argentina*: The competent unfair competition authority may grant a compulsory license if it finds that the patentee has engaged in anti-competitive practices. For the purpose of the patent law, anti-competitive practices include, among others: the establishment of comparatively excessive prices for the patented products as compared to the average prices prevailing in the market, or prices being discriminatory for the patented product, in particular where other offers exist to supply the market against prices considerably lower than those charged by the patentee for the same product; the refusal to supply the local market under reasonable commercial conditions; the obstruction of commercial or production activities; and any other act being comprised in the practice considered punishable by the anti-competition law of Argentina.

162. *Chile*: A compulsory license may be granted in cases where the patentee has incurred in conducts or practices declared contrary to free competition, in direct relation with the use or exploitation of the patent, according to the final decision of the competition court.

163. In some countries, such a remedy is regulated in the competition law, under which compulsory licenses may be granted by a competition authority where it finds that it is an appropriate remedial action against an anti-competitive practice. For example, in *In re Rambus*, the US Federal Trade Commission (FTC) determined that Rambus had acquired monopoly power through deceptive, exclusionary conduct in connection with its participation in the standardization process, and ordered Rambus to license its patented technology by setting a maximum royalty rate.

[Failure to obtain a voluntary license]

164. In some countries, if a voluntary license could not be concluded between the parties on reasonable terms and conditions within a reasonable period of time, a compulsory license may be granted.

165. *Argentina*: Where a third party has made attempts to obtain a voluntary license on reasonable terms and conditions, after 150 days from the day on which the voluntary license was sought for, a compulsory license may be granted.

166. *China*: Where any entity which is qualified to exploit the invention or utility model has made requests for authorization from the patentee of an invention or utility model to exploit its or his patent on reasonable terms and conditions, and such efforts have not been successful within a reasonable period of time, the Patent Administration Department Under the State Council may, upon the request of that entity, grant a compulsory license to exploit the patent for invention or utility model.

[Public interest]

167. Many countries allow the grant of compulsory licenses on grounds of public interest. This notion includes, in particular, national emergencies and extreme urgencies, national security and public health. In some countries, situations that are more specific are envisaged in the law, such as a compulsory license on a patent relating to diagnostics or on a patent concerning a biotechnological research tool or accessory. The exact scope of the grounds relating to public interest considerations varies from one country to the other, reflecting different policy considerations among countries. The following paragraphs show examples of various grounds relating to public interest considerations:

168. *Argentina*: Health emergency or national security.

169. *Brazil*: In case of national emergency or public interest as declared in an act of the Federal Executive Power, a temporary and non-exclusive compulsory license may be granted *ex officio*, provided that the patentee or his licensee does not satisfy the needs. In the context of an *ex officio* compulsory license for non-commercial public use in cases of national emergency or public interest, the national emergency is understood to be a condition of impending danger to the public, even if existing only in a part of the national territory. Those facts relating to, among others, public health, nutrition, protection of the environment, as well as those of primordial importance to the technical or social and economic development of Brazil, are considered as being within the public interest.

170. *Chile*: A compulsory license may be granted in cases where such a license may be justified on grounds of public health, national security, non-commercial public use, national emergency or any other reasons of extreme urgency.

171. *China*: Where a national emergency or any extraordinary state of affairs occurs, or where the public interest so requires, the Patent Administration Department under the State Council may grant a compulsory license to exploit the patent for invention or utility model.

172. *France*: Where the interests of public health demand, the Minister responsible for industrial property, at the request of the Minister responsible for health, may subject patents granted for the following to *ex officio* licenses:

- (a) medicine, medical disposition, medical disposition for *in vitro* diagnostics, annexed therapeutic product;
- (b) processes for obtaining (i), products necessary for obtaining (i) or processes to manufacture such product;
- (c) methods for diagnostics *ex vivo*.

173. The patents on products, processes or methods of diagnostics may be subject to *ex officio* licenses only where (i) such products or products obtained from such processes or such methods being made available to the public in insufficient quantity or quality or at abnormally high prices, or (ii) the patent is exploited under conditions contrary to the public health interests, or the exploitation of the patent is declared anti-competitive following a definitive judicial or administrative decision. As from the date of publication of the order subjecting the patent to *ex officio* licenses, any qualified person may apply to the Minister responsible for industrial property for the grant of a license to work the patent. The license shall be granted by order of that Minister under fixed conditions, particularly in respect of its duration and field of application, but excluding the amount of the royalties to be paid in consideration thereof.

174. *India*: Circumstances of national emergencies and extreme urgency

175. *Japan*: Where the working of a patented invention is particularly necessary in the public interest, a compulsory license may be granted.

176. *Mexico*: National emergency or security, if the production, supply or distribution of basic commodities to the public would be prevented, hindered or made more expensive

177. *Switzerland*: Where the public interest requires, a person with whom the patentee refused to conclude a license without sufficient reason may apply to the Court for the grant of a license to use the patented invention.

178. In addition, any person who intends to use a patented biotechnological invention as an instrument or an accessory of research has a right to non-exclusive license.

179. Further, with respect to a product or process invention concerning diagnostics for humans, a compulsory license may be granted to remedy a practice determined after judicial or administrative process to be anti-competitive.

[Dependent patents]

180. Many countries provide the possibility of requesting a compulsory license where the exploitation of a patent (second patent) cannot be exploited without infringing another patent (first patent). The conditions that need to be fulfilled according to the TRIPs Agreement are: the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent; the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and the compulsory license granted shall be non-assignable except with the assignment of the second patent.

181. The justification for such a compulsory license is that the patent system should promote, rather than hamper, the exploitation of new technology, i.e., the invention claimed in the second patent, although the legitimate interest of the right holder of the first patent should be respected. In general, the public is expected to enjoy the benefits of the latest technology through the exploitation of the second patent.

182. In the countries that provide other IP titles that protect inventions, such as utility models, a conflict of exclusive rights between the patentee and the holder of another title may arise. Therefore, some countries provide that a compulsory license may be granted if the patent cannot be exploited without infringing another IP title or *vice versa*. Similar to the dependent patents, the owner of the other IP title shall be entitled to a cross-license on reasonable terms to use the invention claimed in the patent or *vice versa*.

183. Further, in respect of the development of genetic engineering, a patentee may not be able to exploit his invention without using a new plant variety protected by a plant variety protection certificate. In order to ensure access to such a plant, some countries provide the possibility of a compulsory license in cases where the patentee cannot exploit his invention, if it represents a significant technical progress of considerable economic interest, without infringing the prior plant variety right. Where such a compulsory license is granted, the holder of the plant variety right is entitled to a cross-license on reasonable terms to use the patented invention. Similarly, where a breeder cannot exploit his plant variety right without infringing a patent, a compulsory license may be granted to the breeder.

184. An explicit provision is found in at least one country according to which, where a compulsory license was granted, but the licensee could not work the patented invention without infringing another patent, the licensee may apply for a license under such other patent, provided that the invention of the applicant involves an important technical advance of considerable economic significance in relation to the invention for which the license is applied for.

Government use

185. In addition to the above, a number of countries lay down in their national laws an explicit provision that entitles the government, or a third party who is authorized by the government, to use the patented invention without authorization of the patentee under certain circumstances. In some countries, such government use is permitted if the public interest, such as national security, nutrition, health or the development of other vital sectors of the national economy so requires or if the government use adequately remedies the anti-competitive practice engaged by the patentee or his licensee. As in the case of the

grounds for the grant of compulsory licenses, the grounds for government use are stricter in some jurisdiction, and more liberal in others.

186. For example, in France, the State may at any time obtain *ex officio*, in order to meet its defense requirements, a license to work an invention that is the subject of a patent application or a patent, whether the working is to be done by the State itself or on its behalf.

187. In the United Kingdom, for the services of the Crown, a government may:

- make, use, import or keep the product, or sell or offer to sell it where to do so would be incidental or ancillary to making, using, importing or keeping it; or
- in any event sell or offer to sell it for foreign defense purposes or for the production or supply of specified drugs and medicines, or dispose or offer to dispose of it, in the United Kingdom in relation to the subject of a patent application or a patent, without any consent by the right holder.

188. The services of the Crown includes:

- the supply of anything for foreign defense purposes;
- the production or supply of specified drugs and medicines; and
- such purposes relating to the production or use of atomic energy or research into matters connected therewith as the secretary of State thinks necessary to expedient.

189. In the United States of America, a third party who uses a patented invention in the performance of a Government contract in effect obtains immunity to liability for patent infringement of the patent. This is based on 28 USC §1498(a) which states that:

“Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.”

190. This provision acts as a codification of a defense in litigation between private parties. Consequently, where an infringement action is found in the performance of a Government contract, the recourse for the patentee is limited to a recovery of reasonable compensation through litigation against the US Government at the US Court of Federal Claims.

License of Right

191. In many countries, a patentee may request a recordal of a license of right in the patent registry. Once the entry is made and that fact is officially published, any person may obtain a license, at any time, under the patent on terms to be agreed between the parties. In return, the patentee often enjoys a reduction of maintenance fees.

192. In the United Kingdom, for example, instead of applying for the grant of a compulsory license, a third party may apply for an entry to be made in the register to the effect that licenses under the patent are to be available as of right (license of right). If the Comptroller is satisfied that the requirements, which are the same as the conditions and grounds stipulated for the grant of a compulsory license, are met, he may register the license of right as requested.

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