WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

E

SCP/16/INF/2
ORIGINAL: ENGLISH
DATE: MARCH 18, 2011

Standing Committee on the Law of Patents

Sixteenth Session
Geneva, May 16 to 20, 2011

SUMMARY OF THE EXPERTS' STUDY ON EXCLUSIONS, EXCEPTIONS AND LIMITATIONS (DOCUMENT SCP/15/3)

prepared by the Secretariat

1. At its thirteenth session, held from March 23 to 27, 2009, the Standing Committee on the Law of Patents (SCP) decided that the Secretariat would "commission external experts a study on exclusions, exceptions and limitations focused on, but not limited to, issues suggested by members, such as public health, education, research and experimentation and patentability of life forms, including from a public policy, socio-economic development perspective, bearing in mind the level of economic development". Pursuant to that decision, the present study was commissioned to a group of academic experts who were responsible for the preparation of the following Sections of the study:

   I. Introduction by Professor Lionel Bently, Center for Intellectual Property and Information Law, Cambridge University, United Kingdom;
   II. Computer Programs by Professor Brad Sherman, University of Queensland, Australia;
   III. Biotechnology Protection: A Precarious Convergence? by Professor Denis Barbosa, Catholic University of Rio de Janeiro and Rio Grande do Sul, Brazil;
   IV. Patent Exclusions that Promote Public Health by Professor Shamnad Basheer, National University of Judicial Science, India;
   V. Patent Exceptions and Limitations in the Health Context by Professor Coenraad Visser, University of South Africa, South Africa;
   VI. The Patent System and Research Freedom: A Comparative Study by Professor Richard Gold, McGill University, Canada.

2. The study was coordinated by Professor Lionel Bently.

I. INTRODUCTION

3. A particular jurisdiction troubled by granting full patent rights over particular subject matter is faced with a choice: exclude that subject matter from patentability, or permit such subject matter as patentable, but address the concerns through exceptions to the rights granted to the patentee. Therefore, interesting questions arise as to which mechanism is optimal or whether there are advantages in using both. The answer may reflect not just the legal and bureaucratic structures, but also the socio-economic status of the country. This study provides comprehensive information about the state of the law over the world and sector specific analysis of exceptions and limitations. Further, it offers guidance to countries considering reforms and examines the relationship between exclusions, exceptions and socio-economic development.

4. The historical analysis of exclusions, exceptions and limitations suggests that the existence of exceptions is a more recent phenomenon, while exclusions from patentability have a lengthy history. The most obvious change between 1883 and 1987 is the proliferation of exclusions, such as methods of treatment, animal varieties, plant varieties, biological processes, nuclear technologies and computer programs. Then, the period between 1987 and 2010 is characterized by progressive restrictions on exclusions. Both technological development and the widespread acceptance of economic liberalism, among others, have made old distinction between patentable and non-patentable subject matter more arbitrary and difficult to justify.

5. As the expanded views of patentability in all fields of technology fed into the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and subsequently informed regional trading blocs, there has been a growth in international norms limiting and standardizing exclusions from patentability. However, the proliferation of exceptions has occurred in an environment of relatively limited international norms, although the experimental use exception or the private use exception has become widespread exceptions under national laws. Moreover, regional mechanisms did less to standardize exceptions than exclusions. The first significant limitation on exceptions at the international level was introduced by the TRIPS Agreement in Article 30 and indirectly through the principle of non-discrimination as to the field of technology.

6. In order to get to grips with the inter-relationship between exclusions and exceptions, it is important to understand the rationales for each. As regards exclusions, the following rationales have been identified by the study: (i) exclusions that clarify what is understood by the term “invention”; (ii) exclusions that reflect policy-decisions within other parts of the patent system;[1] (iii) exclusions that reflect the fact that protection is afforded elsewhere;[2] (iv) exclusions that reflect patent law’s cost-benefit analysis;[3] (v) exclusions in relation to inventions that are positively undesirable;[4] and (vi) exclusions that recognize countervailing policy considerations.[5] On the other hand, the rationales for exceptions to patentees’ rights tend to fall within three general categories: (i) those that reflect patent

---

1 For example, life forms, abstract principles, computer programs and business methods.

2 For example, literary, artistic works and plant varieties.

3 Some matters are excluded from patentability, because it is considered that the social costs of the legally enforceable rights outweigh the benefits.

4 For example, inventions which are contrary to public policy or accepted principles of morality, such as cloning human beings.

5 Examples include health and food security, free speech and privacy.

law's cost-benefit analysis (private use and the Bolar exemption); (ii) those necessary to the patent system;[6] and (iii) those that reconcile conflicts between the patent monopoly and other social goals or values.[7]

7. The review of the rationales suggests that exclusions and exceptions do different jobs in many cases, but have similar roles in some areas. The chief advantage of exclusions over exceptions is their potential for clarity and certainty. The disadvantage, however, is their bluntness. One consequence of the bluntness of exceptions is that they become prone to obsolescence, i.e., it removes all the incentive and may drive innovators to using alternative forms of protection or encourage secrecy. On the other hand, the chief advantage of exceptions is that they can be carefully tailored and subjected to finely tuned conditions. In addition, exceptions make standardization easier and less costly, offer considerable residual flexibility, and are administered primarily by the courts. On the contrary, the main disadvantage of exceptions is that they may prompt judicial expansion of patentee's rights, and does not leave users with much certainty.

8. In the areas where exclusions and exceptions are genuine alternatives, the author considers that the use of exceptions has not been fully explored. Establishing exceptions in developing countries where *ex ante* examination may be ineffective will give the public a more accurate idea of what it can and cannot do. Further, in an era of overlapping intellectual property rights, there might be significant benefits in attempting to carve out freedoms applicable to a number of relevant rights. Therefore, exceptions are likely to offer greater flexibility and nuances.

9. The author, however, suggests that careful thought be given to a broader use of exceptions, and that efforts be made so as to ensure that international norms do not stifle the important avenue for calibrating national patent policies. Obviously, not all the reasons for excluding certain subject matter from patent protection can be adequately reflected in the provisions of exceptions to the rights.

II. COMPUTER PROGRAMS

10. There has been a growing consensus in jurisdictions that computer programs as such are not patentable subject matter. This consensus is a product of a range of factors, such as continued expansion of the Member States of the European Patent Convention (EPC), the growth in bilateral free trade agreements that necessitate change, and the willingness of courts and patent offices to limit the scope of the subject matter limitations. Simultaneously, however, the overall trend has been towards more protection for computer programs and computer-implemented inventions. Despite such dynamic situations, the reality is that the laws dealing with the patentability of computer programs are ambiguous and lacking certainty in most countries.

11. Some of the earlier arguments used to justify the exclusion of computer programs from patentable subject matter are that they are protected by copyright law, and are effectively abstract "mathematical methods", "algorithms" or " abstract ideas". The nature of the debates and the arguments, however, has changed over the past ten years. The way technology is viewed has become more nuanced, and policy-based arguments have

---

6 For example, experimental use of a patented invention in order to ascertain whether the invention in fact works.

7 The most obvious examples are compulsory licenses relating to national security and emergencies.

become more important. In general, there are three different approaches that are used to exclude computer programs from patentable subject matter. They are: (i) direct legislative exclusion; (ii) indirect legislative exclusion; and (iii) non-legislative exclusion.

12. As computer programs are often seen as multifaceted products and processes, how to differentiate unpatentable subject matter (e.g., a computer program as such) from potentially patentable subject matter (such as a computer-implemented invention that embodies computer programs) has become an issue for discussions. The task of determining whether an invention falls under computer programs as such or computer-implemented inventions involves the following three questions:

(a) How to construe an invention that includes a computer program? Between two alternative interpretations, the "whole-contents approach" has wide support.

(b) How to characterize the invention? There is less consensus of opinions on this question. The "contribution approach" focuses on the contribution that the invention as a whole makes to the prior art, or the contribution effect that the invention has upon knowledge in the area in question. It, however, has aroused criticism, such that it fails to keep the subject matter inquiry separate and distinct from the questions as to novelty and inventive step. Therefore, the Board of Appeal at the European Patent Office (EPO) rejected the contribution approach on the grounds that no basis was found in the EPC.

Under the "any hardware" approach, an invention will be patentable subject matter if it embodies or is implemented by some technical means (such as a computer). Notable features of this approach are that questions about excluded subject matter are separable from other patentability requirements, and that the focus is on the character of the invention. Consequently, it becomes much easier for an invention to satisfy the subject matter requirement, although it does not mean that it necessarily lowers the standards of patentability.

(c) How to determine whether the invention as characterized is excluded? In most countries, patent laws outline the type of subject matter that is excluded (negative rule). While there is widespread acceptance on the negative rule, there has also been a push to develop a positive rule about the subject matter that may be patented. A range of different tests, therefore, has been used to decide on the patent eligibility of an invention. Even if the approaches vary between countries, and there are often variations within specific jurisdictions, the author outlined some approaches used to determine patentable subject matter. They include: (i) technical character test; (ii) physical change test; (iii) tests that encompass the non-physical; and (iv) the any hardware approach. An increasing number of patent offices offer specific guidance about the types of inventions that will or will not be regarded as patentable subject matter.

13. Further, the author reviews general questions that arise when considering the status of computer programs as patentable subject matter. Those questions are: (i) whether the test used to determine patentable subject matter matters; (ii) when the questions about subject matter should be addressed; and (iii) who should determine the subject matter exception. The first question gives rise to interesting questions about the roles of excluded subject matter and other criteria for patentability (in particular, inventive step), in regulating the patentability of computer programs and computer-implemented inventions.

14. This Section also contains a summary of national, regional and international laws and practices with respect to exclusions of computer programs from patentable subject matter.

III. BIOTECHNOLOGY PROTECTION: A PRECARIOUS CONVERGENCE?

15. Even if there is relative convergence of the standards of exclusions in the area of biotechnological inventions on the basis of Article 27 of the TRIPS Agreement, two discerned trends still stand; a liberal pattern epitomized by the American view, and a more contained view found in Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (EU Biotechnology Directive) and the practice of the EPO.

16. At the international level, Article 27 of the TRIPS Agreement sets limited exclusions from patentable subject matter regarding biotechnological inventions. One of the notable effects of Article 27 is that protection of plant varieties – either by patents or by an effective *sui generis* system – is obliged. A number of Free Trade Agreements include provisions that oblige the introduction of, or require the best efforts to introduce, plant and animal patents. With respect to exceptions and limitations to the rights, there are no explicit rules in multilateral treaties that specifically address biotechnological patents, although Articles 30 and 31 of the TRIPS Agreement provide the general standards. One of the important questions concerning exceptions and limitations in the field of biotechnology is the exhaustion doctrine applicable to biological inventions that involve self-replicating material.

17. As regards the exclusions related to specific categories of biotechnological inventions, the following issues are highlighted:

    Humans. Inventions, the scope of which directly covers human beings, are generally excluded from patentable subject matter based on the morality or *ordre public* exclusions. More specifically, such inventions may include a human being as a whole, parts of the human body (including human embryonic stem cells), intracellular elements, processes for cloning humans, gene therapy, processes for generating organs and use of embryos.

    Animals. Non-biological and microbiological processes for obtaining animals are not excludable under Article 27.3 of the TRIPS Agreement. However, their patentability may be objected on the grounds of morality or *ordre public*.

    Plants. When it comes to patent protection on plants, two specific problems need to be considered: (i) the effects of conflicting or overlapping protection with plant variety protection; and (ii) the extent of the farmers' privilege.

18. The interaction between patent protection on plants and plant variety protection is a complex issue. The patent system must not defeat the plant variety system, and the latter's exceptions and limitations must not be frustrated by double protection. The EU Biotechnology Directive provides some guidance as to the relationship between the two systems. For example, it clarifies: (i) distinct fields of protection under patents and under plant variety rights; (ii) the breeder's and farmer's exceptions in respect of patents; and (iii) the possibility of a compulsory license in cases where a patentee cannot exploit his invention that represents a significant technical progress without infringing the existing plant variety right, and *vice versa*.

19. In order to examine the developmental effect of exclusions, exceptions and limitations regarding biotechnological inventions, the applicable development model (i.e., the freedom model or the growth model) and the relative role of the patent system in attaining development need to be clarified. Some studies suggest that non-IP considerations are

much more relevant to encourage biotechnology and to promote development. Other studies, however, indicate that proper balancing of the patent appropriation model and public access to biotechnological knowledge could serve the interests of developing countries. Along that line, the author was of the opinion that exclusions, exceptions and limitations relating to biotechnological inventions must be considered cautiously. Empirical studies would be certainly required before reaching any conclusions on the developmental dimensions of patent and plant variety protection and exclusions, exceptions and limitations therefrom in relation to biotechnological inventions.

20. This Section also provides information regarding exclusions, exceptions and limitations with respect to biotechnological inventions in diverse countries and regions.

IV. PATENT EXCLUSIONS THAT PROMOTE PUBLIC HEALTH

21. This Section seeks to evaluate the patent and public health interface from the viewpoint of *ex-ante* mechanisms, i.e., ways in which countries have sought to limit the grant of patents to certain categories of subject matter in order to promote access to public health goods. Among patent eligibility exclusions, two kinds of exclusions, namely, methods of medical treatment and inventions, the exploitation of which is against *ordre public*/morality, are covered in this Section.

22. Methods of medical treatment are excluded from patent eligible subject matter in most countries with the justification that such patents would fetter the freedom of physicians and prevent them from helping patients with the latest medical advances, which would cause a tension between patent law and concerns of public health. While some countries had initially interpreted other patentability criteria, such as the industrial applicability, to oust new medical methods, the methods of medical treatment began to be seen as a non-patent eligible subject matter stemming from public policy concerns. Europe is a good example in this respect. The patent law of the United States of America permits granting patents on methods of medical treatment, but prevents the enforcement of such patents against doctors and related healthcare professionals.

23. While the patenting of medical methods is seen as conflicting with ethical concerns in developed countries, the attention of developing countries is more in terms of affordable medicines and accessible healthcare. In the latter countries, the conflict between the standard patent rationale of incentivizing innovation and fostering an optimal public health outcome is stark. Therefore, the emergence of technologically proficient developing countries might balance out the competing innovation and public health policies in ways that are different from other countries. This Section also contains a summary of national, regional and international laws (including the TRIPS Agreement) with respect to exclusions of medical methods.

24. In many countries, the interpretations of terms such as “surgery”, “therapy”, “diagnostic methods” and “medical treatment” have been developed through case law. In Europe, for example, an invention which only led to the acquisition of diagnostic data is not a diagnostic method excluded from patentable subject matter. In addition, to what extent the proximity between the human or animal body and the medical treatment is required is a complicated issue. For example, the patent eligibility of *in vitro* methods of diagnosis was widely debated in India.

25. As regards *“ordre public”* and “morality” exclusions, both terms are filled with inherent ambiguity, since the scope of their application largely depends on the local cultures and practices of Member States. There has been enduring controversy between the positivist

school[8] and the school of natural law,[9] which caused a debate on the inclusion of the morality dimension in Article 27 of the TRIPS Agreement even amongst the developed countries (for example, the European countries and the United States of America). One of the problems with considering the morality dimension is that several inventions have multiple uses of which only one may be immoral. Therefore, the author emphasized that denying patents on certain inventions on the grounds of morality was a double-edged sword and needed to be exercised carefully. A survey on national and regional laws with respect to the scope of morality exclusion is also included in this Section.

V. PATENT EXCEPTIONS AND LIMITATIONS IN THE HEALTH CONTEXT

26. This Section surveys and reflects upon exceptions and limitations relating to health contexts, particularly on the following four topics: (a) compulsory licenses; (b) medicines prepared for an individual case in a pharmacy or by a medical professional; (c) parallel imports; and (d) the regulatory exception. A large part of this Section addresses the issue of compulsory licenses, and analyzes international limitations (in particular, Article 31 of the TRIPS Agreement and the Doha Declaration) and different approaches in national laws, and presents selected case-studies where national authorities have granted compulsory licenses in relation to pharmaceuticals. Moreover, this Section contains a summary of various national laws with respect to compulsory licenses.

27. Before examining exceptions and limitations to patents relating to health, the author emphasized the significance of the human right framework in the context of such exceptions and limitations. In his view, the human right framework provides an organizational matrix for the diverse pro-health provisions in patent laws, and sheds light on the competing claims of patentees and consumers.

28. At the international level, provisions concerning compulsory licenses were first introduced in Article 5 of the Paris Convention. Further, Article 31 of the TRIPS Agreement provides detailed rules with respect to the use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government. Compulsory licenses fall broadly into three main categories: licenses to correct abuse of rights, licenses to address national emergency or a situation of extreme urgency, and dependant patents, amongst which the first two categories are particularly significant in the context of public health. The main controversy between developing and developed countries was how to interpret the provisions concerning compulsory licenses and how to protect patentees' rights. The author investigates such controversy, and examined the Doha Declaration and the subsequent amendment to the TRIPS Agreement.

29. A health-sensitive patent law may provide several grounds for compulsory licenses. They include: non-working or insufficient working of a patent, refusal to deal, anti-competitive practices, emergency, government use, and public interest. In relation to the first ground, whether domestic demand must be met through local working or whether meeting domestic demand through importation would be sufficient to meet the "working" requirement is still an area of contention.

---

[8] The positivist argues that a patent should be granted on an invention as long as it is novel, inventive and displays an industrial application, and that morality, unless well-defined in terms of the law, should have no role to play in the decision to grant or withhold a patent.

[9] The school of natural law supports an idea that a patent should not be granted on an invention which offends society's morals regardless of whether the invention fulfills the standard patentability criteria.

30. With respect to parallel imports, in the public health context, the importation of a patented medicine from a country where it is sold at a lower price can reduce the price of pharmaceuticals by introducing competition. It, however, can also affect the negotiation of tiered pricing regimes with pharmaceutical companies.

31. Lastly, the regulatory exception, also known as the Bolar exception, is primarily aimed at assisting the generic pharmaceutical industry to obtain, during the term of patent protection, regulatory approval for the eventual sale of patented medicine after the expiration of the patent. Generally, allowing a third party to undertake, without the patentee's authorization, acts necessary for the purpose of obtaining regulatory marketing approval could result in promoting the affordability of off-patent medicines.

VI. THE PATENT SYSTEM AND RESEARCH FREEDOM: A COMPARATIVE STUDY

32. This Section investigates exclusions and exceptions that affect research and development in science and technology. It is essential to understand both the effect of patent rights on providing an incentive to undertake research and on making subsequent research more difficult, time consuming or expensive. Against this backdrop, exclusions and exceptions do not exist in isolation. Instead, they work within the context of legal rules governing what can be patented, the scope of patent rights and the means to enforce those rights.

33. Concerning the impact of exclusions from patentable subject matter on research, both the international legal frameworks to which countries adhere (e.g., the TRIPS Agreement, the EU Biotechnology Directive, NAFTA, Mercosur, the Eurasian Patent Convention) and national regimes were examined. Based on the premise that virtually all exclusions from patentability could be conceived as creating a science commons that facilitates research, the commonalities and differences between national laws and policy underpinnings of various exclusions were discussed. These exclusions include, for example, fundamental knowledge, methods of medical/surgical treatment, biotechnology-related exclusions, and life forms. Further, the definition of the term "invention" and the description requirement were analyzed in respect of their impacts on research.

34. Regarding exceptions to patent rights, international instruments, including regional agreements, were reviewed. Further, national provisions from a representative sample of countries were examined and commonalities and trends in national patent laws pertaining to exceptions affecting research were identified. While national laws must comply with the requirement of the TRIPS Agreement, there remains considerable room to enact them. The following differences in national laws were analyzed:

(a) Prior users. While the prior user's exception may help trade secret holders, this exception is narrow in scope and its impact on research is limited.

(b) Experimental use. Since this exception varies in breadth from country to country, the emphasis must be laid on three characteristics that define different types of exceptions, namely, (i) whether it allows for experimentation *on* or *with* an invention, (ii) whether the exception applies to experiments with a *commercial* purpose or *not*, and (iii) whether it is *statutory* or *judicial exception*.

(c) Regulatory approval (Bolar/Safe harbor). The scope of provisions for regulatory review varies for each country, and some countries have no exceptions at all.

35. Focusing on the motivation behind major groups of exclusions and exceptions, the study concludes that, in short, certain exclusions and exceptions were introduced in order to prevent fundamental research results from being appropriated through property rights, and some other exclusions and exceptions were provided with a view to their particular impact on the biomedical researchers. Moreover, particular attention was given to the experimental use exception/Bolar exception and disclosure/secrecy dualisms. Further, the study emphasizes a common will in all jurisdictions to strike a balance between incentives for researchers to invent and third parties' rights in order to optimize innovation. The balance should be struck between: (a) secrecy and patents; (b) harmonization and diversification; and (c) patentees' rights and third parties' rights. In addition, striking a balance may depend on the level of economic development of different jurisdictions. The tradeoffs sometimes differ, but there is a common will between jurisdictions to ensure that researchers can avail themselves of the necessary freedom to progress in their research. This policy choice is in line with one of the main functions of the patent system which is to promote research that is beneficial to society.

[End of document]