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WORLD INTELLECTUAL PROPERTY ORGANIZATION  
GENEVA

## STANDING COMMITTEE ON THE LAW OF PATENTS

Fourteenth Session  
Geneva, January 25 to 29, 2010

### PROPOSAL FROM BRAZIL\*

*Document prepared by the Secretariat*

1. The Annex to this document contains a proposal from Brazil in respect of exceptions and limitations to patent rights.

2. *The Members of the Standing Committee on the Law of Patents (SCP) are invited to consider the contents of the Annex.*

[Annex follows]

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\* Comments received from Members and Observers of the SCP on this document are available at:  
[http://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=154099](http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=154099)



*Permanent Mission of Brazil to the World Trade Organization and other  
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Note n<sup>o</sup>.03/40

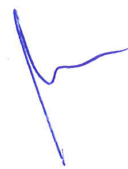
The Permanent Mission of Brazil to the WTO and other economic organizations in Geneva presents its compliments to the International Bureau and has the honor to present the attached proposal to be discussed during the upcoming fourteenth session of the Standing Committee on the Law of Patents (SCP), under item 7(b) of the Agenda (“Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights”).

2. At its twelfth session, in June 2008, the Standing Committee on the Law of Patents (SCP) “asked the WIPO Secretariat to establish, for the next session of the SCP, preliminary studies on four issues”. One of the studies was to address “exceptions from patentable subject matter and limitations to the rights, inter alia research exemption and compulsory licenses” (SCP/12/4/Rev; par.8(c)).

3. The attached document aims at contributing to the discussion of exceptions and limitations to patent rights under the correspondent agenda item. While not purporting to cover all interfaces of the matter with developmental concerns, it emphasizes the importance of promoting a wide and sustained debate on the issue in the SCP.

4. The Permanent Mission of Brazil avails itself of this opportunity to renew to the International Bureau the assurances of its highest consideration.

Geneva, January 15, 2010



**WORLD INTELLECTUAL PROPERTY ORGANIZATION**

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## EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

*submitted by the Delegation of Brazil*

### INTRODUCTION

1. At its twelfth session, in June 2008, the Standing Committee on the Law of Patents (SCP) “asked the WIPO Secretariat to establish, for the next session of the SCP, preliminary studies on four issues”. One of the studies was to address “exceptions from patentable subject matter and limitations to the rights, *inter alia* research exemption and compulsory licenses”.<sup>1</sup>

2. This submission will then focus on the discussion of exceptions and limitations to patent rights. While not purporting to cover all interfaces of the matter with developmental concerns, it emphasizes the importance of promoting a wide and sustained debate on the issue in the SCP.

3. The issue of exceptions and limitations is of utmost importance in the future work of the SCP, as it touches upon fundamental development concerns. A number of recommendations of the Development Agenda addresses directly or indirectly this issue, be it in connection with norm setting, public policy, technology transfer, access to knowledge or impact studies. For instance, recommendations 17 and 22 state that WIPO should take into account, in their activities, the flexibilities in international IP agreements<sup>2</sup> as well as address in its working documents for norm-setting activities, as appropriate and as directed by Member States, issues such as potential flexibilities, exceptions and limitations for Member States.<sup>3</sup>

### THE ROLE OF EXCEPTIONS AND LIMITATIONS IN PATENT LAW

4. Exceptions and limitations are intrinsic elements of every law. They serve a number of purposes by conferring the necessary flexibility to guarantee national security and to shape public policies to meet *inter alia* development, competition, and health surveillance goals. To build roads, prevent crimes, promote elections or avoid pandemics, for example, governments seek to ensure the compliance with rules that protect private goods and rights, as well as to make use of exceptions and limitations.

5. In order to fulfill the purposes above, patents may thus be subject to a special treatment. The patent system must strive for the equilibrium of rights among its users, which should, accordingly, not only comprise IP title holders, but also the society as a whole, so that the welfare of the society as a whole prevails. They all constitute legitimate “clients” of the system.

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<sup>1</sup> Document SCP/12/4/Rev. par.8(c).

<sup>2</sup> Document A/43/13/Rev. Recommendation 17.

<sup>3</sup> *Idem*. Recommendation 22.

6. We understand that the enforcement of IPRs demands ensuring rights, and imposing obligations to title holders, third parties and the society, while guaranteeing that the society as a whole will reap benefits from such protection. The focus of the current IP system, however, heavily lies on ensuring rights to the IP title holders. Their claims are, undoubtedly legitimate, but certainly incomplete from the perspective of the public policy.

7. Director-General Francis Gurry in his report to the 47<sup>th</sup> Series of Assemblies of the Members States of WIPO (September 22 to October 1, 2009), has asked “What does a Member State get out of being part of this Organization?”. The question remains unanswered unless changes occur. A judicious balance of rights and obligations would be a good start in that direction, so as to help society as a whole to understand, accept and thus fully support an improved IP system; and exceptions and limitations to patent rights are fundamental elements to reach this equilibrium.

8. The naïve assumption that providing IP title holders with stronger rights will, by itself, foster innovation or attract investments is no longer acceptable. The open and global economy has rejected this assumption and severely hit the very essence of the patent system, whereby a country would confer an artificial and temporary “monopoly” for the inventor in exchange of having the invention revealed allegedly benefiting the society. No such thing is currently taking place, with a few countries excepted. What, then, does a Member State get out of being part of WIPO? If contributing to the welfare of the society does not constitute a major aspect of what a country could get out of being part of a member-driven UN Organization such as WIPO, what could it possibly be?

9. One could of course question what “society” means in the current patent system. Or what “title holder” means for that matter, as the actual inventor hardly corresponds today to the owner of the patent, as it used to be in the recent past. One could, furthermore, argue that society will reap no benefits if inventions and knowledge generation are not fully protected, since investments would no longer be made. However, to anyone with a minimum understanding of the system, such simplistic conclusions and extreme situations are unimaginable, and the reason is quite simple: creativity and creative economy do not rely solely on an increasingly stronger IP systems.

10. It is neither a question of simply criticizing the system. The current patent system is well anchored to multilateral agreements on trade and will be supported by WIPO (and WTO) Members as long as the majority of Members States decides to do so. Therefore, the key issue is about revising old assumptions and starting to recover the essentials of the patent system.

11. Let us turn our efforts to understand how we can effectively derive benefits from the patent system as it stands today. Despite the complaints, the protection is, as we see it, well defined. However, it is not clear as to what extent such protection affects third parties or as to where exactly the boundaries of the protection are.

12. In that context, some questions arise. How are Members making use of exceptions and limitations provided in their legislation? Have they really been useful for the purposes of meeting public policy goals or society needs? Are compulsory licenses and other mechanisms established in their legislations indeed available for prompt use whenever deemed necessary, without authorization of the right holder? Are exceptions or limitations truly being explored? Why and, if not, why not?

13. Taking the example of the compulsory licensing mechanism, one must soon notice that it is not that simple to make effective use of them. The WTO Doha Ministerial Conference, which adopted the “Declaration on the TRIPS Agreement and Public Health”, stressed quite clearly “that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement”.<sup>4</sup> Although specifically related to address public health issues, the Declaration certainly reflected and continues to reflect the technology access difficulties of several other – if not all – technological fields in the majority of the countries.

14. A complex system was designed to try to tackle the problem and yet just one single case of compulsory license has been notified to the WTO so far, involving Rwanda and Canada.<sup>5</sup> Rwanda, however, is certainly not the only country in the world to face critical public health problems.

15. During the post WTO period, after a long period of negotiations, the government of Brazil decided in May 2007 to sanction the compulsory licensing of an antiretroviral drug in order to address urgent public health problems. Our country then suffered an intense discredit campaign led by some international actors, as if it was ignoring the rules agreed by all WTO Members, with which we fully complied. The defamatory process cast on Brazil an inconvenient image of a piracy-lenient country. Is this what we should expect from the supporters of the current system?

16. Our experience also illustrates how difficult it is to effectively make use of compulsory licenses. Our pharmaceutical industry took almost two years to develop and produce the licensed patent, because, unfortunately the patent, as granted in Brazil and in other countries, was not sufficiently revealed to allow its production as promptly as desired.

17. We reserve the right to come back to the discussion of this problem in other documents concerning to what extent the disclosure of patents is preserving (or not) the essentials of the patent system. The question we now pose ourselves is: considering the checks and balances of the patent system, what is the value of a patent if a third party cannot use it when it falls into the public domain or, exceptionally, when its compulsory licensing is deemed necessary?

18. For instance, a study requested by the United States Federal Trade Commission shed light on the risks that poor patent quality and legal standards and procedures may bear to competition and how they jeopardize innovation by raising its costs.<sup>6</sup> In addition, the Pharmaceutical Sector Inquiry, conducted by the Pharma Task Force of the European Commission, has also proven that patents are increasingly misused to delay or avoid generic competition even after their expiration dates.<sup>7</sup>

19. Adopting such strategies may be considered normal in the corporate world. Companies may be subject to penalties for not abiding by the national or international rules of fair

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<sup>4</sup> Paragraph 6 of the WTO Declaration on the TRIPS Agreement and Public Health.

<sup>5</sup> See [http://www.wto.org/english/news\\_e/news07\\_e/trips\\_health\\_notif\\_oct07\\_e.htm](http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm) as well as [http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_notif\\_export\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm)

<sup>6</sup> USFTC – *To Promote Innovation: the Proper Balance of Competition and Patent Law and Policy*. October 2003. Available in <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>

<sup>7</sup> See <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>

competition. However, they absolutely cannot be deemed normal – or acceptable – within the patent system, as they ultimately destroy its essentials.

20. We are now facing a moral deadlock. Developed countries seem to be the only ones capable of reaping any advantage from the system, as very little guidance is provided in order to satisfy the objectives of the TRIPS Agreement, whereby “the protection and enforcement of intellectual property 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”.<sup>8</sup>

## PROPOSAL

21. The Paris Convention for the Protection of Industrial Property does not expressly prescribe specific rules on limitations and exceptions to patent rights, allowing the parties to adopt varied approaches to the matter. The TRIPS Agreement contains a more detailed provision, which foresees a three-step test to establish the acceptable limits to the exceptions on patent exclusive rights. According to TRIPS Article 30, exceptions: (a) must not unreasonably conflict with normal exploitation of the patent; (b) must not unreasonably prejudice the legitimate interests of the patent owner; and (c) must take account of the legitimate interests of third parties. In addition, Article 31 provides for “Other Use Without the Authorization of the Right Holder”.

22. On national or regional level, a cursory analysis shows that IP legislations frequently foresee a number of situations where patent exclusive rights may be exempted.<sup>9</sup> A non-exhaustive list of them includes: (a) private non-commercial use; (b) use in teaching; (c) research and experimentation; (d) preparation of individually prescribed medicines; (e) certain uses of foreign means of transportation, temporarily in national territory; (f) *bona fide* prior use; (g) submission of information for regulatory approval; (h) non-commercial use of propagating material; and (i) compulsory license.

23. Limitations and exceptions to patent rights are common parts of laws and legal doctrine. One can thus argue that there may be palpable convergence among Members as to the importance of those flexibilities to the patent system. Yet, the existence of different approaches to limitations and exceptions may cause uncertainties on policy spaces used by Members regarding why and how they are being used, if so, and how they are linked to innovation policies or addressing public health, nutrition, or environmental concerns. Moreover, it seems that a minority of countries makes effective use of them, especially when considering developing countries.

24. In light of the systemic importance of having well functioning provisions of limitations and exceptions in national or regional legislations and the concerns raised by the limited use of limitations and exceptions by developing countries, Brazil proposes that a working program be established in the SCP to carry out a wide and sustained debate on this issue, in three phases.

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<sup>8</sup> Objectives of the WTO TRIPS Agreement (article 7).

<sup>9</sup> Document SCP/12/3 – *Report on the International Patent System*.

25. The first phase shall promote the exchange of detailed information on all exceptions and limitations provisions in national or regional legislations, as well as on the experience of implementation of such provisions, including jurisprudence. The first phase shall also address why and how countries use – or how they understand the possibility of using – the limitations and exceptions provided in their legislations.

26. The second phase shall investigate what exceptions or limitations are effective to address development concerns and what are the conditions for their implementation. It is also important to evaluate how national capacities affect the use of exceptions and limitations.

27. The third phase shall consider the elaboration of an exceptions and limitations manual, in a non-exhaustive manner, to serve as a reference to WIPO Members.

28. The establishment of such working program would be an important step in the implementation of the Development Agenda.

[End of Annex and of document]