

## Standing Committee on the Law of Patents

**Twenty-Seventh Session**  
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CONSTRAINTS FACED BY DEVELOPING COUNTRIES AND LEAST DEVELOPED COUNTRIES (LDCs) IN MAKING FULL USE OF PATENT FLEXIBILITIES AND THEIR IMPACTS ON ACCESS TO AFFORDABLE ESPECIALLY ESSENTIAL MEDICINES FOR PUBLIC HEALTH PURPOSES IN THOSE COUNTRIES: SUPPLEMENT TO DOCUMENT SCP/26/5

*Document prepared by the Secretariat*

### INTRODUCTION

1. At its twenty-sixth session, held in Geneva from July 3 to 6, 2017, the Standing Committee on the Law of Patents (SCP) agreed that the Secretariat would supplement the study (document SCP/26/5) with inputs from members and observers of the SCP with respect to the constraints faced by developing countries and least developed countries (LDCs) in making full use of patent flexibilities and their impacts on the access to affordable especially essential medicines for public health purposes in developing countries and LDCs.
2. Pursuant to the decision, above, members and observers of the SCP were invited, through Notes C. 8687, C. 8688, C. 8690 and C. 8691 dated August 21, 2017, to provide the Secretariat with the said inputs. Taking into account those inputs and the comments made by the members and observers during the twenty-sixth session of the SCP, this document provides the information that supplements document SCP/26/5. It maintains the structure of document SCP/26/5 as much as possible. Due to the language policy of WIPO, it is not possible to fully reproduce the inputs received from the members and observers of the SCP. However, the original submissions are available on the SCP electronic forum website at: [http://www.wipo.int/scp/en/meetings/session\\_27/comments\\_received.html](http://www.wipo.int/scp/en/meetings/session_27/comments_received.html).

## CONSTRAINTS TO THE FULL USE OF PATENT FLEXIBILITIES BY DEVELOPING COUNTRIES AND LDCs

### Constraints encountered by governments at the stage of national implementation of flexibilities

#### *Constructive ambiguity of international treaties*

3. The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is of the view that when interpreting the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), including for the purpose of identifying flexibilities, it is important that the interpretation remains faithful to the Agreement<sup>1</sup> and that the tools recognized by international law be used for such interpretation<sup>2</sup>.

#### *Extrinsic influences*

4. In its submission to the SCP, the Ministry of Health of Colombia described the difficulties and pressures it had experienced in taking administrative steps to issue a declaration of public interest in order to issue a compulsory license.<sup>3</sup> In 2014, the IFARMA Foundation petitioned the Ministry of Health to issue a declaration of public interest as a step toward granting a compulsory license for imatinib. According to the national regulations, the first step for the issuance of a compulsory license on the ground of public interest in the patented technology is a “declaration of public interest”. Once this first step has been taken and the declaration has been published in the Official Gazette, the second step is taken by the Superintendency of Industry and Commerce (SIC) to review the issuance of a compulsory license.

5. After studying the petition by the IFARMA Foundation and verifying the requirements established by law, the Ministry of Health initiated the administrative procedure through Decision No. 354 of 2015, and published on its website all the information pertaining to the administrative procedure for the declaration of public interest. The patent holder, was informed of the initiation of the administrative procedure. The Ministry of Health received comments from various stakeholders on the petition.

6. Upon expiry of the deadline for comments on the petition, the Technical Committee for the Declaration of Public Interest, a body composed of high-level technical officials of the Ministry, initiated its action in order to issue a recommendation on the viability of the declaration of public interest. The first meeting of the Committee was held on April 30, 2015. After analyzing the available information and assessing the results of the relevant technical tests, the Committee recommended that the Minister of Health issue a declaration of public interest for the purposes of granting a compulsory license for imatinib, but that it first encourage a negotiation of the price with the patent holder. As part of the regulated procedure, the Committee’s recommendation report, together with other documentation, was published on the website of the Ministry of Health, inviting comments from interested parties.

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<sup>1</sup> “The object and purpose is that which is found in the wording of the treaty. The WTO has confirmed that it need not apply other rules of international law if applying 31(1) provides the answer. In particular, supplementary material, such as “*travaux préparatoires*”, is not the first port of call to illuminate the context.” See: Susy Frankel, ‘The WTO’s Application of “The Customary Rules of Interpretation of Public International Law” to Intellectual Property’, Victoria University of Wellington Legal Research Papers 46, no. 1 (2014).

<sup>2</sup> Understanding on the Rules and Procedures Governing the Settlement of Disputes, Article 3.2; Eric M. Solovy and Deepak Raju, ‘A Manufacturing-for-Export Exception to Patent Protection: A Proposal for Exporting Violations of the TRIPS Agreement and Beyond’, SSRN Scholarly Paper (Social Science Research Network, 18 July 2017), <https://papers.ssrn.com/abstract=3004845>.

<sup>3</sup> The comments prepared by Misión Salud and IFARMA Foundation and submission by the Civil Society Coalition also refer to the process regarding the declaration of public interest for imatinib in Colombia.

7. Following the recommendation of the Committee, the Ministry initiated a process to negotiate the price with the patent holder. Subsequent meetings, however, were held in vain to reach an agreement.

8. After analyzing all the information pertaining to the procedure, the Ministry of Health issued Decision No. 2475 of June 14, 2016, declaring the existence of reasons of public interest for imatinib, and requesting, in the alternative, that the National Commission for Pricing of Medicines and Medical Devices (CNPMDM) consider including the product into the direct price control scheme, using a general methodology that reflects the benefits of competition for the specific market. Decision No. 2475 was appealed by both the petitioners and the patent holder, and by Decisions Nos. 4008 and 4148 of 2016, the Decision No. 2475 was upheld on appeal. Consequently, the CNPMDM, presented its general methodology applicable to medicines that are declared to be of public interest in exceptional cases (Circular No. 03 of 2016). This Circular is the object of a request for nullity and restoration of rights before the Council of State which is still pending consideration.

9. The submission of the Ministry of Health of Colombia refers to the speech made by the Minister of Health at the World Health Assembly that “[...] the procedure was accompanied by a broad-based international debate and, I would like to say this clearly, some pressure. From our experience, it is clear that flexibilities exist in the theory of the multilateral treaties and declarations. In practice, however, they are difficult to apply”. The said submission states that the following communications and documents were found during the procedure:

- Communication of May 26, 2015 of the State Secretariat for Economic Affairs of the Swiss Confederation;
- Communication of April 27, 2016 of the Colombian Embassy in Washington, D.C., through which the Embassy transmits the concerns expressed by the United States Trade Representative (USTR) and the Finance Committee of the US Senate on the granting of a compulsory license for imatinib;
- Public Eye (former Declaration of Berne) and El Espectador published articles on the possibility that Novartis could sue Colombia on the grounds of the Bilateral Investment Agreement signed between Colombia and Switzerland;
- Through communication No. 20166630109142, AFIDRO “[...] considering the risk that a dangerous and unjustified precedent could be [set][...]” requested the Technical Secretariat of the Intersectoral Committee on Intellectual Property (CIPI) to hold an extraordinary session to try and reverse the decision taken on imatinib. During a session of the Subcommittee on Industrial Property, the Deputy Superintendent for Industrial Property at SIC introduced the memorandum of March 30, 2016, opposing the declaration of public interest<sup>4</sup>;
- Communication of February 2017 sent by the President of AFIDRO to the Secretary General of the Presidency of the Republic, in which its members reiterated the negative impact that the declaration of public interest would have on Colombia as it aspires to join the OECD;
- Request of the Pharmaceutical Research and Manufacturers of America (PhRMA) to the USTR to include Colombia on the “Priority Watch List”, citing, among other reasons, issuance of the declaration of public interest for imatinib and the allegation that Colombia does not comply with intellectual property protection standards;
- AFIDRO comments submitted to the USTR during consultations for the 301 Special Report; and
- Communication of June 23, 2015 from the Swiss Colombian Chamber of Commerce.

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<sup>4</sup> It opposed the declaration of public interest on the ground that the price factor alone was not sufficient to justify such declaration.

10. The submission of the Ministry of Health, however, indicates that it also received communications from other stakeholders who provided other views on the issue. For example:

- Letter sent by Dr. Marie-Paule Kieny, Assistant Director-General of WHO for Health Systems and Innovation;
- Communication sent by 121 world experts in public health and intellectual property;
- Letter addressed to USTR by 15 members of Congress;
- Letter from Senators Brown and Sanders to the USTR;
- Letter from the three civil society organizations in Colombia that requested for the declaration of public interest for imatinib to the co-Chairs of the United Nations Secretary General's High-level Panel on Access to Medicines;
- Letter from 28 international NGOs addressed to the President of the United States of America;
- Open Letter to the Government of Switzerland, signed by 17 NGOs and a former President of the Union for International Cancer Control (UICC); and
- Response of the Government of Switzerland to the open letter, in which it specifically declares that "Switzerland fully recognizes that WHO members have all the freedom to use the public health safeguards in the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health".

11. The comment prepared by IFARMA Foundation and submitted by the Civil Society Coalition also includes its report on the situations that surrounded the issuance of a compulsory license in Ecuador, in 2010 and four compulsory licenses for the treatment of arthritis, kidney transplants and cancers issued in 2014.

#### *National governance and internal coordination*

12. The input from the Russian Federation stated that challenges faced by producers of medicines in its country had been addressed at different authorities, such as the Federal Anti-Monopoly Service, Ministry of Health and Rospatent.

#### Constraints faced by various stakeholders in using a national legal framework that has implemented policy options

#### *Ambiguity and uncertainty of national law*

13. The comment drafted by the IFARMA Foundation and submitted by the Civil Society Coalition notes that in Colombia, the first obstacle for the use of compulsory license was multiple amendments to the national regulations governing the procedures for the issuance of compulsory licenses.<sup>5</sup> It states that an application for the declaration of public interest concerning access to direct-acting antivirals for the treatment of hepatitis C containing certain active ingredients was submitted to the Minister on October 28, 2015. Since then, the applicant has received no substantive response. As a result, IFARMA Foundation has filed a remedy for

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<sup>5</sup> The submission mentioned the following changes in the national regulations:

- Decrees 4302 of 2008 and 4966 of 2009, (both incorporated in Decree 1074 of 2015) regulate the competence and procedure for issuing the declaration of public interest, pursuant to Article 65 of the Decision 486 of the Commission of the Andean Community. The Decree was applied retroactively;
- Decision No. 0012 of January 2010, laying down the procedure for the granting of compulsory licenses;
- Decree 670 of 2017 amends Article 2.2.2.24.6, Chapter 24, *Procedure for issuing a declaration of public interest set out in Article 65 of the Decision 486 of the Andean Community*, Single Decree 1074 of 2015.

*amparo* (protective action) before the court. According to the comment prepared by the IFARMA Foundation, the delay in taking administrative action has generated debate as to which legislation governs such action, as the Ministry intends to apply a government decree adopted in 2017 retroactively.

*Legal, technical and technological requirements*

14. A request and grant of a compulsory license are legal acts, which shall strictly comply with the legal requirements prescribed in the applicable national law. In addition to the technical and technological knowledge of the medicine concerned, practical legal expertise is indispensable in order to steer the process. Particularly, where a compulsory license is sought for importation of the medicine, not only the laws pertaining to health and intellectual property but also trade law would be involved. The comment prepared by the International Treatment and Preparedness Coalition Latin-America and the Caribbean (ITPC-LATC) and submitted by the Civil Society Coalition addresses the challenges it faced in Guatemala in relation to the application for a compulsory license for lopinavir200mg/ritonavir50mg tablets.

*Other aspects that might affect the use of compulsory licenses*

15. Document SCP/26/5, paragraph 40, notes that the low number of compulsory license grants may not necessarily relate to constraints on its use as such in some cases, but may be due to the fact that no patent exists in the country concerned. In addition to the studies referred to in that paragraph, IFPMA states that, in reality, most pharmaceutical companies either do not patent in developing countries and least developed countries (LDCs) or do not enforce their rights in those jurisdictions.<sup>6</sup>

16. As regards patent protection of medicines listed on the WHO Model List of Essential Medicines (MLEM), a study conducted with respect to the 18<sup>th</sup> edition of the Model List of Essential Medicine (2013 MELM)<sup>7</sup> found that 20 of the 375 items on the List (5%) may be considered patented. Among those 20 patented items, 13 items relate to HIV/AIDS and the other seven items relate to antibiotics, other antiviral or non-communicable diseases (NCDs). The study found that there was great variability amongst the patent estates in the number of countries where patents were filed. The percentage of developing countries covered by a given patent estate ranged from less than one per cent to 44 per cent, and had a median of 15 per cent. In this limited sample, patents appear more frequently in China, the Philippines, and Indonesia for the East and the Pacific region; Brazil and Mexico for Latin America and the Caribbean; India for South Asia; South Africa for Sub-Saharan Africa; and Bulgaria, Romania, and Turkey for Europe and Central Asia. For those 20 MLEM products, 44 countries had no patent filings, 11 countries had a single filing, and 16 countries had two filings - these represent over half of the 137 countries covered by this study.

17. The authors of the above study noted that in the long-term, the protection of patented products on the MLEM would likely increase, due to the global demographic transition toward a higher prevalence of NCDs. In the 2015 MLEM, four medicines for treating cancers, covered by patents, were added.<sup>8</sup>

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<sup>6</sup> See: 'Novartis Position on Access to Healthcare' (Novartis Public Affairs, 2016), <https://www.novartis.com/sites/www.novartis.com/files/access-to-healthcare-perspective.pdf>; 'GSK Expands Graduated Approach to Patents and Intellectual Property to Widen Access to Medicines in the World's Poorest Countries', GSK, 31 March 2016.

<sup>7</sup> Reed F. Beall and Amir Attaran, *Global Challenges Report: Patent-based Analysis of the World Health Organization's 2013 Model List of Essential Medicines*, WIPO, available at: [http://www.wipo.int/policy/en/global\\_health/documents.html](http://www.wipo.int/policy/en/global_health/documents.html).

<sup>8</sup> *Ibid.*

18. In paragraphs 43 and 44, document SCP/26/5 describes some cases where actions taken by the government or a patentee, which might be supportive to availability of medicines, may have affected the eventual grant of a compulsory license. In addition to those cases, the comment prepared by the IFARMA Foundation and submitted by the Civil Society Coalition presented other situations. In another case in Colombia, the Ministry of Health adopted a different set of actions compared to the case documented in paragraphs 4 to 10 of this document. Despite the fact that the declaration of public interest was not issued by the Ministry of Health, the government enforced price-control mechanisms and investigated the company concerned.<sup>9</sup> In Peru, according to the IFARMA Foundation, the government has preferred to resort to other mechanisms such as donations. In the case of a patent granted on bisulfate atazanavir, the IFARMA Foundation reported that the patentee had offered to cut the price of the medicine. In the opinion of the IFARMA Foundation, however, that would not be commensurate with the potential savings from the introduction of generic competition.

*Other challenges where use of flexibilities has not led to intended policy outcomes*

19. As described in paragraph 45 of document SCP/26/5, reliance on flexibilities implemented in national systems does not necessarily lead to the intended outcome of improving access to medicines. In this connection, IFPMA refers to a study indicating that compulsory license prices exceed the median international procurement prices in 19 of the 30 case studies, often with a price gap of more than 25 per cent.<sup>10</sup>

IMPACT OF THE CONSTRAINTS ON THE ACCESS TO AFFORDABLE ESPECIALLY ESSENTIAL MEDICINES FOR PUBLIC HEALTH PUEPOSES IN DEVELOPING COUNTRIES AND LDCs

20. In addition to several studies and countries' experiences regarding the impact of the use of certain patent law provisions on access to medicines, reported in paragraph 49 of document SCP/26/5, IFPMA notes that intellectual property rights may increase the availability of new treatments to populations in developing countries by creating increased incentives for marketing efforts by originators.<sup>11</sup> It further refers to another study that analyzed data on launches of 642 new molecules in 76 countries, which shows that longer duration and stronger patent rights accelerate diffusion.<sup>12</sup>

21. At the same time, some scholars pointed out that there was no single effect of patent protection on availability of medicines in developing countries and LDCs. Some studies have found that the effects of patent protection on the launch of pharmaceuticals differ based on the distribution of income within a country<sup>13</sup> or the country income level<sup>14</sup>. For example, Borrell

<sup>9</sup> Through the judicial procedures, the Ministry of Health was ordered to initiate penalty proceedings for maintaining internal price of the medicine in question above international reference pricing and to include the medicine in the list of "parallel imports". Furthermore, another judgement ordered the Ministry of Health to bring the price in order and directed the SIC to investigate whether Abbot Laboratories had respected fixed reference pricing. Based on the investigation, SIC fined Abbott Laboratories of Colombia 3.8 billion pesos for selling Kaletra® 53 to 66 per cent above the price set by the Government.

<sup>10</sup> Reed F. Beall, Randall Kuhn, and Amir Attaran, 'Compulsory Licensing Often Did Not Produce Lower Prices For Antiretrovirals Compared To International Procurement', Health Affairs 34, no. 3 (1 March 2015): 493–501.

<sup>11</sup> Margaret Kyle and Yi Qian, 'Intellectual Property Rights and Access to Innovation: Evidence from TRIPS', Working Paper (National Bureau of Economic Research, December 2014), doi:10.3386/w20799.

<sup>12</sup> Iain M. Cockburn, Jean O. Lanjouw, and Mark Schankerman, 'Patents and the Global Diffusion of New Drugs', American Economic Review 106, no. 1 (January 2016): 136–64.

<sup>13</sup> Joan-Ramon Borrell, Patents and the faster introduction of new drugs in developing countries (Applied Economics Letters, Vol. 12, No. 6, pp. 379-382, 2006).

<sup>14</sup> Jean O. Lanjouw, Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry (U.C. Berkeley, 2005).

found that while the patent regime has had a strong positive influence on the availability of HIV/AIDS therapies in developing countries with relatively equally distributed incomes, that has not been the case in developing countries with relatively large income inequalities. In a study evaluating multilateral and bilateral trade on, *inter alia*, biopharmaceutical products subsequent to the implementation of the TRIPS Agreement, Delgado et al. found mixed results for developing countries, and concluded that the TRIPS Agreement had not yet to spur significant changes in the level of biopharmaceutical trade to developing countries and LDCs.<sup>15</sup>

22. The submission by SIC of Colombia stressed the importance of the relationship between competition law, innovation and patents. Where the entry of new economic agents into the market is encouraged, a successful agent would try to generate products and services that are more innovative than other agents. This is an economy that does not compete “in” the market but “for” the market, as new creations seek to surpass and replace each other, rather than competing simultaneously in the market. Therefore, competition and innovation are closely linked. With regard to the industrial property, particularly patents, through the grant of the exclusive rights, the State seeks to repay the high costs and important risks that accompany the innovation process, protect inventions from imitations and encourage the continuity of innovation process. At the same time, the possibility of patenting fosters a kind of innovation race among different companies, in which all of them will seek to reach a truly novel innovation. This applies to all markets, regardless of whether a fundamental right is at stake or not. SIC therefore states that both competition law and intellectual property have coinciding aims, even though the latter confers exclusive rights to its owner. Both branches promote fair market practices and seek the development of society in general.

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<sup>15</sup> Mercedes Delgado, Margaret Kyle, Anita M. McGahan, The Influence of TRIPS on Global Trade in Pharmaceuticals, 1995-2006 (NBER Conference on Location of Biopharmaceuticals, 2010).