



INTERPOL Global Conference: Ten Years of Combating Pharmaceutical Crime: Review and Prospects

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THE COUNTERFEITING OF MEDICINES:
PHARMACEUTICAL CRIME AND TRADEMARK INFRINGEMENT

*Document prepared by the Secretariat of the World Intellectual Property Organization (WIPO)**

* The views in this contribution do not necessarily reflect the views of the Member States of the World Intellectual Property Organization (WIPO).

1) INTELLECTUAL PROPERTY, PUBLIC HEALTH, AND PHARMACEUTICAL CRIME

1. The World Intellectual Property Organization (WIPO) is the global forum for intellectual property (IP) policy, services, information and cooperation. As a specialized agency of the United Nations, it raises awareness on IP issues, assists its 188 Member States in developing a balanced international intellectual property legal framework to meet society's evolving needs, and delivers capacity-building programs to help transition and developing countries benefit from using IP. WIPO also offers services for obtaining IP rights in multiple countries and resolving disputes and provides free access to unique knowledge banks of IP information.
2. The present paper examines the links between IP and pharmaceutical crimes, focusing specifically on the area of trademarks and counterfeit medicines.¹ It looks at the specific legal meaning of counterfeiting, delineates it from related concepts, analyzes the ways in which balanced IP enforcement mechanisms can mitigate the risks posed by counterfeit medicines, and describes WIPO's activities in this particular area at the intersection of IP and public health.
3. Other WIPO initiatives in the context of IP and public health relate to patent law and aim to help establish an environment that stimulates health innovation while ensuring widespread access to new, more effective and affordable products to address global health needs. On the one hand, WIPO Re:Search, a multi-stakeholder platform for sharing innovation in the fight against neglected tropical diseases, tuberculosis and malaria, was launched in October 2011. It provides access to IP for pharmaceutical compounds, technologies, and – most importantly – know-how and data available for research and development in these areas.² On the other hand, WIPO also maintains an active trilateral cooperation on public health, IP and trade with the World Health Organization (WHO) and the World Trade Organization (WTO). Intended to contribute to enhancing the empirical and factual information basis for policy makers and supporting them in addressing public health in relation to IP and trade, this cooperation has resulted in a set of joint activities, such as technical symposia, and the publication, in January 2013, of a comprehensive study on “Promoting Access to Medical Technologies and Innovation”.³

A) THE COUNTERFEITING OF MEDICINES AS A PHARMACEUTICAL CRIME

4. Pharmaceutical crime is an umbrella term for various illegal activities in relation to pharmaceutical products. Within this area, the illegal manufacture, trade, transport and distribution of counterfeit medicines are activities that infringe trademark rights and are thus of global concern.

i) The Meaning of Counterfeit Medicines

5. In the area of IP, the term counterfeiting has a specific technical meaning. In the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) it describes a particular type of trademark infringement. Footnote 14 to Article 51 of the TRIPS Agreement defines counterfeit trademark goods as “any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect

¹ While the following comments apply to the counterfeiting of all medical products, notably both medicines and medical devices, the term “counterfeit medicines” will be used for the sake of clarity.

² With a consortium of more than 80 members, the WIPO Re:Search platform has been able to facilitate 44 collaborative research agreements as well as technology transfer in the form of research sabbaticals for biomedical scientists from developing countries in overseas research institutions. More information about WIPO Re:Search may be found at <http://www.wipo.int/research/en/>.

³ The study and more detailed information on the joint activities is available at http://www.who.int/phi/implementation/trilateral_cooperation/en/, http://www.wipo.int/policy/en/global_health/trilateral_cooperation.html, and http://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm.

of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation".⁴ In the remainder of this paper, the term counterfeiting is always used in this trademark-specific sense.

6. Trademarks are signs that a producer uses in order to distinguish his goods⁵ from the goods of the same category offered by his competitors.⁶ They serve as a badge of origin, indicating the source of goods. As such, they allow consumers to make a choice between competing goods whose differences may otherwise not be apparent and to buy exactly the product which best suits their needs. Trademark owners, in turn, are encouraged to maintain and improve the quality of their products in order to meet consumer expectations.

7. However, in order to enable trademarks to fulfil these functions, the law has to ensure that only the producer of a given good may use, or authorize others to use, his trademark in relation to that good. National laws therefore grant those who fulfil the necessary conditions for registering a trademark in relation to their goods exclusive rights to that mark.⁷ This finds its rationale in the public interest of protecting consumers from both confusion and the deception of buying the wrong and perhaps even harmful products. Counterfeit medicines are an illustrative case in point. Through the unauthorized use of a validly registered trademark, their producers create the false impression that their goods were produced by the trademark owner. This may deceive consumers, who may believe that they are buying genuine medicine whereas in reality there is no connection between the trademark owner and the product in question.

8. It should be added that generic drugs may also be counterfeited. While "branded" and "generic" medicines are sometimes presented as opposites, they refer to different concepts. Generic medicines are typically understood as medicines which can be produced without a need for a licensing agreement, either because national law does not grant patent protection to the medicine in question, the patent protection of the medicine has expired⁸, or a compulsory license has been granted. The protection of patents, however, is distinct from that of trademarks. Medicines can bear trademarks irrespective of whether they also enjoy patent protection. In fact, when producers of generic medicines market their goods, they often not only use the international nonproprietary name of the pharmaceutical substance it contains but, in addition, their own trademark.

ii) Counterfeit Medicines and Public Health

9. The counterfeiting of medicines is often discussed in the context of medicines that pose a risk to public health. The seriousness of the latter issue has been recognized unanimously by the international community as unsafe medicines may be harmful or even lethal for unaware

⁴ National definitions of counterfeiting and counterfeit goods, however, vary and may be broader than the definition used by the TRIPS Agreement; see also below at 1.) B) iii).

⁵ It should be noted that trademarks may be registered in relation to both goods and services; see Articles 15.1 and 16.1 of the TRIPS Agreement. Given, however, that the problem of counterfeit medicines concerns goods only, this contribution only addresses trademarks in this context.

⁶ According to Article 15.1 of the TRIPS Agreement, "any sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark". The provision also contains a non-exhaustive list of eligible signs, notably "words including personal names, letters, numerals, figurative elements and combinations of colours as well as any combination of such signs".

⁷ According to Article 16.1 of the TRIPS Agreement, "the owner of a registered trademark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion".

⁸ See, for example, the definition of "generic drug" on the website of the WHO at <http://www.who.int/trade/glossary/story034/en/>.

patients.⁹ However, the public health debate uses a number of different terms, which bears a risk of confusion and makes it difficult to distinguish them from the legal notion of counterfeiting. This section seeks to delineate the various concepts from each other and explores whether counterfeit medicines may, in addition to the risk of consumer deception, also pose a risk to public health.

10. In the forum of the World Health Organization (WHO), the term “counterfeit medicine” had long been used since 1992 to describe a medicine “which is deliberately and fraudulently mislabelled with respect to identity and/or source”.¹⁰ In 2012, the World Health Assembly established a Member State Mechanism on Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit (SSFFC) Medical Products with a view to promoting the prevention and control of such products from a public health perspective, with trade and intellectual property considerations being expressly excluded.¹¹

11. When further exploring the SSFFC concept, a distinction must be made between substandard and the other categories of medical products. In 2010 the WHO Expert Committee on Specifications for Pharmaceutical Preparations adopted a definition, according to which “substandard medicines are pharmaceutical products that fail to meet either their quality standards or their specification, or both (...)”.¹² No such uniform definition has been adopted by WHO bodies for spurious/falsely-labelled/falsified/counterfeit medicines.¹³ Nevertheless, there seems to be a common perception that these continue to denote medicines that are “deliberately and fraudulently mislabelled with respect to identity and/or source”.¹⁴

12. Looking more closely at the relationship between the notion of counterfeit medicines (in its specific IP sense) and that of medicines mislabeled with respect to identify and/or source, it is clear that the two concepts overlap even though they are not entirely congruent.¹⁵ Most importantly, every medicine that is counterfeit is also mislabeled as to its source as the counterfeiter, through using another person’s trademark, creates the deceptive impression that the medicine was manufactured by the trademark owner. In addition, where counterfeit medicines do not contain the same pharmaceutical substance as the genuine product, they are also mislabeled as to the identity of the medicine. Finally, the notion of medicines that are mislabeled as to their identity and/or source is broader than that of counterfeit medicines and also covers medicines that make false statements as to their manufacturer or ingredients in ways other than the unauthorized use of a third party trademark.

⁹ On February 18, 2006, for example, the participants of the WHO International Conference *Combating Counterfeit Drugs: Building Effective International Collaboration* declared that “counterfeiting medicines ... is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems”.

¹⁰ WHO document WHO/EDM/QSM 99.1, Guidelines to Develop Measures to Combat Counterfeit Drugs (1999), available at http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf?ua=1.

¹¹ World Health Assembly Resolution 65.19 (May 26, 2012), available at <http://apps.who.int/medicinedocs/documents/s19994en/s19994en.pdf>.

¹² Forty-fifth Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (Geneva 2011), available at http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1, page 49.

¹³ In light of to the ongoing debate, the WHO Expert Committee on Specifications for Pharmaceutical Preparations did not agree on a definition; *ibid*, page 51. Moreover, the goals, objectives and terms of reference of the Member State Mechanism on SSFFC medical products note that the mechanism shall use the term SSFFC until a definition has been endorsed by the governing bodies of WHO and specify as one of the nine objective of the mechanism “to further develop definitions of ‘substandard/spurious/falsely-labelled/falsified/counterfeit medical products’ that focus on the protection of public health; see Annex to World Health Assembly Resolution 65.19.

¹⁴ See WHO Fact Sheet N°275, Medicines: spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines (May 2012), available at <http://who.int/mediacentre/factsheets/fs275/en/>. The Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health takes a similar approach defining counterfeit as “a false representation as regards identity and/or source” (Article 4(j)).

¹⁵ It should be noted that, based on Article 10 of the Paris Convention for the Protection of Industrial Property, many national laws also provide for remedies against false trade descriptions. Where this is the case, these mechanisms would also apply to medicines that are mislabeled as to identity and/or source.

13. In the fora of the World Customs Organization (WCO) and the International Criminal Police Organization (INTERPOL), the term “illicit medicines” is often used.¹⁶ It appears to cover all medicines in relation to which customs and police action is warranted. As this would not only include trademark counterfeiting but all other cases in which the manufacture or trade of a medicine does not comply with national laws and regulations, the concept is much broader than that of counterfeit medicines.

14. That counterfeit medicines may pose a risk to public health is a conclusion that suggests itself if one takes into account that the sole motivation for a counterfeiter to use another person’s trademark without authorization is the prospect of financial gains. Procuring the active ingredient of the genuine medicine and making sure that the counterfeit medicine contains it in the right dose and in an also otherwise safe manner, however, are costly processes that would minimize the counterfeiter’s financial profit and that he is therefore unlikely to undertake.

B) COMBATting COUNTERFEIT MEDICINES THROUGH IP ENFORCEMENT MEASURES

15. International IP law provides for a number of enforcement mechanisms aimed at remedying trademark counterfeiting. These mechanisms are implemented by individual States into their national laws, which creates an approximated, robust and readily available legal framework to mitigate the risks of counterfeit medicines.

i) The International Framework of Remedies Against Counterfeiting

16. Already since 1883, Article 9 of the Paris Convention for the Protection of Industrial Property foresees that States party to the Convention put in place legislation allowing for seizing goods unlawfully bearing a trademark on importation into their country, prohibiting such importation, or seizing such goods inside their country. Article 10 extends this to instances in which false indications of the source of goods or the identity of the producer, manufacturer, or merchant are used.¹⁷

17. The TRIPS Agreement obliges WTO members provide for effective action against IP infringements. Their judicial authorities shall have the authority to issue injunctions ordering the infringer to desist from the infringement (Article 44), to order the infringer to pay the right holder adequate damages (Article 45), and to order that infringing goods¹⁸ be disposed of outside the channels of commerce or destroyed (Article 46).

18. In addition, the TRIPS Agreement provides for the establishment of border measures. More specifically, Article 51 requires WTO members “to adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark (...) goods may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods”.

19. For cases of willful trademark counterfeiting on a commercial scale, States must also provide for criminal procedures and penalties (Article 61 of the TRIPS Agreement). Remedies

¹⁶ This is the case, for example, with the results of the international customs operation *Biyela 2* (conducted from May 26 to June 4, 2014) and the international police operation *Pangea VII* (conducted from May 13 to 20, 2014); see the press releases available at <http://www.wcoomd.org/en/media/newsroom/2014/september/biyela.aspx> and <http://www.interpol.int/News-and-media/News/2014/N2014-089>.

¹⁷ Articles 1 through 12 and Article 19 of the Paris Convention have been expressly incorporated into the TRIPS Agreement and must be observed by WTO members irrespective of whether or not they are party to the Paris Convention; see Article 2(1) of the TRIPS Agreement. To date, 176 States have adhered to the Paris Convention.

¹⁸ Likewise, judicial authorities shall have the authority to order the disposal of “materials and implements the predominant use of which has been in the creation of the infringing goods” (Article 46 of the TRIPS Agreement).

shall include imprisonment, monetary fines, and, in appropriate cases, the seizure, forfeiture and destruction of the infringing goods.¹⁹

ii) National Implementation of the TRIPS Enforcement Standards

20. Until today, 160 members have acceded to the WTO and, with the exception of least developed country members, are thus called upon to implement the IP enforcement mechanisms foreseen by the TRIPS Agreement.²⁰ As a practical consequence, the majority of States have established national legislation providing enforcement agencies with the necessary powers to effectively combat counterfeit medicines.

21. It is clear that IP enforcement mechanisms do not replace the need for standard setting or legislation in the area of medicines safety. At the same time, national systems may lack public health specific regulation while in the international arena discussions on appropriate remedies against unsafe medicines are still ongoing. Under these circumstances readily available national IP enforcement laws in many WIPO Member States do play a supportive role by removing those unsafe medicines from the markets that are also counterfeit and offering a deterrent to their production.

iii) The Necessity of a Balanced Approach

22. In implementing the TRIPS Agreement, WTO members may design their national enforcement mechanisms in such a way that they go beyond what is required by the Agreement, as the latter only sets minimum standards.²¹ The decision whether it would be appropriate for a State to create a more robust system of IP enforcement, however, requires careful balancing with other, potentially conflicting, socio-economic considerations.

23. This balance of interests has its source in the TRIPS Agreement itself, whose Articles 7 and 8 place IP into a broader context. Notably, Article 7 provides that the protection and enforcement of IP rights should promote social and economic welfare and achieve a balance of rights and obligations to the mutual advantage of both producers and users of technological knowledge. Article 8 allows for the adoption of measures “necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development”.

24. The relationship between IP enforcement and public health was, for example, under scrutiny when, on April 20, 2012, the High Court of Kenya found that Section 2 of the Kenyan Anti-Counterfeiting Act 2008, which at the time had not yet entered into force, was unconstitutional. It held that the definition of counterfeiting proposed by the Act was unduly broad and “likely to be read as including generic medicines”.²² In the Court’s view, this created

¹⁹ In appropriate cases, seizure, forfeiture and destruction of “any materials and implements the predominant use of which has been in the commission of the offence”, that is, in the present context, the wilful trademark counterfeiting on a commercial scale, shall also be available (Article 61 of the TRIPS Agreement).

²⁰ On June 12, 2013, the WTO Council for Trade-Related Aspects of Intellectual Property Rights decided to extend the transition period under Article 66.1 so that least developed country members of the WTO are not required to apply the provisions of the TRIPS Agreement, other than Articles 3, 4, and 5, until July 1, 2021, or until such a date on which they cease to be a least developed country member, whichever date is earlier; see WTO document IP/C/64.

²¹ Article 1.1 of the TRIPS Agreement.

²² High Court of Kenya, Petition No. 409 of 2008, available at <http://www.ip-watch.org/weblog/wp-content/uploads/2012/04/Kenya-Judgment-Petition-No-409-of-2009.pdf>. Section 2 of the draft Kenyan Anti-Counterfeiting Act – in its for the case relevant parts – defined counterfeiting as “taking the following actions without the authority of the owner of intellectual property rights subsisting in Kenya or elsewhere in respect of protected goods – (...) (d) in relation to medicine, the deliberate and fraudulent mislabeling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging”. See also Promoting Access to Medical Technologies and Innovation (n 3), box 4.17.

a danger of counterfeiting enforcement measures being used against generic medicines, which, in turn, would have adversely affected the right of access to affordable and essential medicines of those dependent on such drugs and thus infringed their right to life, human dignity and health.

25. Already in 2008 and 2009, several shipments of generic medicines had been detained in transit by the customs authorities of several European Union member States in application of EU Customs Regulation. These border measures were based on an alleged patent infringement in the transit country although the medicines, manufactured in India and destined to South American and African States, were not under patent protection in the countries of origin and destination. As a consequence, both India as well as Brazil (being one of the destination countries) brought complaints against the EU and the Netherlands under the WTO Dispute Settlement Understanding.²³ While no mutually agreed solution has yet been notified to the TRIPS Council, India reported that it had reached an understanding with the EU.²⁴

26. Against this background, the need for a balanced approach towards the implementation of the TRIPS enforcement framework into national or regional law becomes apparent. More specifically, it seems of utmost importance to establish unambiguous definitions of the term “counterfeiting” so that national and regional enforcement authorities clearly understand the difference between counterfeit and legitimate generic medicines. These caveats do not, however, call into question the usefulness of appropriately designed IP enforcement mechanisms to combat counterfeit medicines in the interest of consumer protection and public health.

2) WIPO ACTION AND MAIN ACHIEVEMENTS

27. WIPO’s activities in relation to counterfeit medicines fall under the Organization’s Strategic Goal VI: International Cooperation on Building Respect for IP.²⁵ In the spirit of Development Agenda Recommendation 45, this objective calls for an inclusive and balanced approach that places IP enforcement in the context of broader societal interests and especially development-oriented concerns.²⁶ To implement this goal, WIPO helps its Member States to establish awareness-raising strategies to encourage consumers to participate in the creation of an IP culture, on request offers assistance in the development of tailored and balanced national legislative frameworks for IP enforcement²⁷ and in the strengthening of its Member States’ capacities for an effective use of IP protection for development. In addition, the Organization provides a forum for international policy dialogue within which Member States explore, inter alia, the social and economic impact of counterfeiting and piracy and the importance of non-punitive measures to complement ongoing enforcement measures.²⁸ WIPO also closely engages with

²³ Disputes DS408 and DS409; see http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm as well as http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm.

²⁴ Ministry of Commerce and Industry of the Government of India, India EU Reach and Understanding on Issue of Seizure of Indian Generic Drugs in Transit (press release), July 28, 2011, available at <http://pib.nic.in/newsite/erelease.aspx?relid=73554>.

²⁵ WIPO’s revised framework of nine strategic goals was adopted during the Forty-Sixth Series of Meetings of the Assemblies of the Member States of WIPO on December 12, 2008; see paragraphs 35-39 of document A/46/12.

²⁶ The WIPO Development Agenda ensures that development considerations form an integral part of the Organization’s work. It was adopted during the Forty-Third Series of Meetings of the Assemblies of the Member States of WIPO from September 24 to October 3, 2007; see paragraphs 276-334 of document A/43/16. Recommendation 45 reads: “(...) to approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns, with a view that 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”, in accordance with Article 7 of the TRIPS Agreement”.

²⁷ Within its legislative assistance WIPO stresses the importance of a balanced approach towards the of the TRIPS enforcement mechanisms that takes due account of the flexibilities incorporated in the Agreement.

²⁸ More detailed information on the activities of the WIPO Advisory Committee on Enforcement may be found at <http://www.wipo.int/enforcement/en/ace/>.

partner organizations to facilitate systematic, effective, and transparent international cooperation on building respect for IP.

A) NATIONAL AND REGIONAL CAPACITY-BUILDING ACTIVITIES

28. Every year, WIPO provides technical assistance in the area of building respect for IP in form of numerous capacity-building activities for national law enforcement agencies in response to requests from its Member States.²⁹ Allowing for direct exchange with competent national authorities, these activities regularly reflect concerns over counterfeit medicines and the associated risks to public health. In the experience of these national experts, IP legislation can be used as an effective tool to address this very real problem, in particular where appropriately framed penalties serve as effective deterrents.

29. Moreover, a number of WIPO's national and regional capacity-building and awareness-raising activities included health-related aspects of consumer protection.³⁰ These activities explored the scope and prevalence of counterfeit medicines in the respective countries, reviewed, from an IP law enforcement perspective, the applicable legislative framework, and discussed avenues for forging strategic alliances at the national or regional level. The target audience reflected the cross-cutting nature of the problem and included officials from law enforcement, health or consumer protection agencies as well as industry representatives and legal practitioners. These activities raised awareness on the need to build cross-sectoral collaborations for effective results.

B) STEERING THE INTERNATIONAL DEBATE

30. In light of the regular requests from WIPO Member States for technical assistance in this area, WIPO initiated, in 2011, a *Multi-Stakeholder Roundtable on Technical Assistance Against Counterfeit Medicines*. Bringing together both intergovernmental as well as non-governmental international organizations active in providing technical assistance in the area of counterfeit medicines, the Roundtable serves as a forum for exchanging information and perspectives and exploring areas of synergy and cooperation between the participating organizations. The third and most recent meeting of the Roundtable took place in Brussels, Belgium, on September 8, 2014, and was chaired by WCO.³¹ The discussions at the Roundtable demonstrate that counterfeit medicines are a multi-faceted problem that, in order to be addressed in all its complexities, requires practical cooperation between all stakeholders. In that sense, the Roundtable has contributed to the quality, effectiveness and balance of the technical assistance that participating organizations provide in this area.

31. Since 2004, WIPO has also regularly organized, in a public-private partnership with INTERPOL, (WCO) as well as the International Chamber of Commerce Business Action to Stop Counterfeiting and Piracy (ICC/BASCAP) and the International Trademark Association (INTA),

²⁹ In the twelve-month period between September 2013 and August 2014, for example, WIPO conducted or participated in some twenty-five training programs worldwide; a comprehensive overview of all activities in the area of building respect for IP may be found at <http://www.wipo.int/enforcement/en/activities/current.html>.

³⁰ WIPO National Seminar on Counterfeit Medicines and Public Health, Kuala Lumpur, Malaysia, December 22 and 23, 2008; WIPO National Workshop on Combating Counterfeit Medicines, Pretoria, South Africa, November 19, 2009; USPTO/WIPO Workshop on Combating Health and Safety Counterfeit Products in the East African Community, Dar es Salaam, United Republic of Tanzania, March 10 to 12, 2010; WIPO Regional Workshops on the Dangers of Counterfeit Goods to Public Health in Manila, Philippines, October 24 and 25, 2011, in Mombasa, Kenya, November 1 to 3, 2011, and Casablanca, Morocco, December 5 and 6, 2011. During the WIPO Regional Workshop on the Enforcement of IP Rights for the Judiciary and Law Enforcement Officials, Lusaka, Zambia, July 26 and 27, 2012, a roundtable discussion was organized on "A Balanced Application of Border Measures and the Legitimate Trade in Generics".

³¹ The first and second meetings of the Roundtable took place on January 21, 2011, and November 26, 2012 and were both chaired by WIPO.

the *Global Congress on Combatting Counterfeiting and Piracy*.³² At each of the seven Congresses to date, panels dedicated to counterfeit medicines have highlighted the pressing need to address the problem and have sought for practical solutions.

32. In addition, WIPO participated in a *Conference on Fraudulent Medicines*, organized by the United Nations Office on Drugs and Crime (UNODC) in Vienna, Austria, on February 14 and 15, 2013, and a *Conference on Falsified Medicines: A Complex Problem*, organized by the United Nations Interregional Crime and Justice Research Institute (UNICRI) in Geneva, Switzerland, on March 31, 2014.

3) LESSONS LEARNED AND PROSPECTS FOR THE FUTURE

33. WIPO's past activities aimed at analyzing the social and economic impact of counterfeiting in order to better understand the problem and tackle it more effectively. It has become apparent how important it is to provide factual and unbiased information about the risks of counterfeit medicines and the mechanisms available to mitigate these risks. This includes explanations of and awareness raising on the basic functioning of trademark law, the public interest objectives it serves, the remedies available to counter trademark infringements, and the balanced approach required for the implementation of international standards into national law.

34. What is more, counterfeit medicines and trademark enforcement cannot be looked at in isolation as, in the practical experience of many WIPO Member States, they are part of the bigger problems of pharmaceutical crimes and unsafe medicines in general. Although these are public health issues, WIPO can play a supporting role by highlighting the positive results that enforcement mechanisms, including deterring penalties, have had in some of its Member States in remedying and preventing trademark infringements. In this regard, appropriately balanced IP enforcement legislation may supplement public health regulation.

35. In light of the cross-cutting nature of pharmaceutical crime, any forceful national response requires close collaboration between health authorities, customs agency, police, prosecutors and other relevant stakeholders. In order to facilitate a holistic approach that tackles pharmaceutical crimes in all its aspects, enhanced cooperation between all relevant international organizations would be desirable. Pooling the expertise of each of them in the realm of their specific mandate would render the technical assistance provided to individual Member States more effective. In addition, it would be helpful if internationally coordinated operations against pharmaceutical crime more clearly distinguished between trademark counterfeit medicines and medicines that are illicit for other reasons, such as health regulation. This would generate empirical data that would help understand the size of the problem of counterfeit medicines and devising appropriately targeted responses.

36. The INTERPOL Conference *Ten Years of Combating Pharmaceutical Crime: Review and Prospects* is an important initiative as it not only allows for dialogue amongst the various international organizations but it also includes relevant private stakeholders. The World Intellectual Property Organization very much welcomes the opportunity to contribute to this discussion and remains available for further collaboration in the quest for appropriate solutions to the problems posed by counterfeit medicines.

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³² More information on the Global Congress on Combatting Counterfeiting and Piracy may be found at <http://www.ccapcongress.net>.