Counterfeiting and Public Health

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1. INTRODUCTION

In the debate about counterfeiting and public health there is a tendency to conflate three distinct issues: first, counterfeit goods that infringe trademarks; second, medicines suspected of infringing patents; and, third, falsified medicines which contain the wrong or insufficient active ingredients.[1]

2. COUNTERFEITING

Counterfeiting is a term with a very specific meaning in intellectual property law. It describes the theft of brand owners' intellectual property, namely a trademark violation.[2] This very specific meaning of the term is set out in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which defines counterfeiting as use of a trademark or mark similar to a trademark without the permission of the rights holder.

Specifically, the TRIPS Agreement defines 'counterfeit goods' in footnote 14 of Article 51 as:

> any goods, including packaging, bearing without authorisation a trademark which is identical to the trademark validly registered in respect 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.[3]

[1] See also South Centre/Center for International Environmental Law (CIEL) (2008), 'The International Medical Products Anti-Counterfeiting Taskforce (IMPACT): Is the WHO on the Right Track?', *Intellectual Property Quarterly Update*, Third Quarter, 1.

[2] See also Clift, C. (2010), 'Counterfeit Medicines: Health and Harm', *The World Today*, **66** (12): http://www.chathamhouse.org/publications/twt/archive/view/169913 (accessed 12 March 2012).

[3] Article 51, footnote 14, of the TRIPS Agreement: http://www.wto.org/english/tratop_e/trips_e/t_agm4_e.htm#Footnote14 (accessed on 13 March 2012).

In the context of pharmaceutical products, the World Health Organization (WHO) uses a similar definition to describe a counterfeit medicine as one that is 'deliberately and fraudulently mislabelled with respect to identity and/or source.'[4] Particular countries also define in different ways what is to be understood by counterfeiting. In the United States, it is directly related to trademark violations.[5] Other countries focus instead on the active pharmaceutical ingredients (APIs) contained in medicinal products.[6]

In the EU, Directorate General Taxation and Customs Union (TAXUD) of the European Commission has reported that '[c]ounterfeiting is a growing and increasingly dangerous phenomenon' and that '[c]ounterfeited . . . articles threaten the health and safety of EU citizens, their jobs, Community competitiveness, trade, and investment in research and innovation'.[7] In 2010, EU Customs seized more than 103 million counterfeit and pirated goods and handled more anti-counterfeiting cases than ever before. A total of more than 79 000 cases were dealt with in 2010, up nearly 84 per cent from 2009.[8] For TAXUD, the increasing use of the Internet to sell medicines classified as counterfeit and the fact that the high

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[4] WHO (1992), *Counterfeit Drugs: Report of a Joint WHO/IFPMA Workshop*, WHO/DMP/CFD/92 1–3 April, Geneva. This definition was incorporated into the 1999 WHO Guidelines for the Development of Measures to Combat Counterfeit Medicines, WHO/EDM/QSM/99, and is also included in the WHO Quality Assurance of Medicines Terminology Database of 8 December 2011: http://www.who.int/medicines/services/expertcommittees/pharmprep/20111208_QASterminologyDB.pdf (accessed 13 March 2012).

[5] United States Federal Food Drug and Cosmetic Act, SEC. 201, Title 21 United States Code 321, G(2):

> The term 'counterfeit drug' means a drug which, or the container or labelling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer or distributor.

[6] South Centre/CIEL, supra n. 1, 7.

[7] Directorate General for Taxation and Customs Union of the European Commission (2010), *Customs Controls – A serious problem for everyone*: http://ec.europa.eu/taxation_customs/customs/customs_controls/counterfeit_piracy/combating/index_en.htm.

[8] European Commission, Taxation and Customs Union, Report on EU customs enforcement of intellectual property rights: Results at the EU border – 2010, p. 11: http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/statistics_2010.pdf (accessed 13 March 2012).

quality of such goods often makes identification impossible without technical expertise increases the challenge customs face.

However, there are concerns that statements about levels of counterfeiting are based either on inaccurate use of the term 'counterfeit', or on customs seizures, with the actual quantities of infringing goods in free circulation in any particular market largely unknown, or on estimated losses derived from industry surveys. Industry estimates of levels of counterfeit are considered to exhibit an upward bias, with the difficulty in estimating levels of actual counterfeiting and piracy exacerbated by the failure to use the definition of the terms as set down in the TRIPS Agreement.[9]

The high levels reported in most industry-based surveys has been identified as a problematic aspect of the expert reports used as the basis of the 2007 Organization for Economic Co-operation and Development (OECD) report on counterfeiting.[10] The OECD report has also been criticized for framing the problem of intellectual property-related crime exclusively through the lens of 'counterfeiting' and lost corporate revenue, in doing so overlooking the social costs of intellectual property enforcement that restricts access, creates barriers to follow-on innovation, and encourages anti-competitive business practices.[11]

A key assumption in most estimates is that the sale of counterfeit goods displaces legitimate sales, regardless of how the price of goods may be affected by stronger intellectual property protection. An issue of concern for the OECD has been the extent to which assumptions can be made about the degree of substitutability between infringing and legitimate items.[12] Likewise, the methodology used in the surveys to calculate levels of intellectual property rights infringement in third countries has been criticized on grounds that it is largely based on the industry's subjective opinion.[13] For developing countries there is a risk that the promotion of increased emphasis on intellectual property rights enforcement, based on imperatives driven by industry figures, increases the need for the allocation

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[9] Tekeste Biadgleng, E. and Munoz Tellez, V. (2008), *The Changing Structure and Governance of Intellectual Property Enforcement*, Geneva: South Centre, p. 20.

[10] Organization for Economic Co-operation and Development (OECD) (2007), *The Economic Impact of Counterfeiting and Piracy*, DSTI/IND(2007)9/PART4/REV1.

[11] Shaw, A. (2008), 'The Problem with the Anti-Counterfeiting Trade Agreement (and what to do about it)', *KEStudies*, **2**, 1–9, at 5.

[12] Olsen, K. (2005), *Counterfeit and Piracy: Measurement Issues*, Background Report for the WIPO/OECD Expert Meeting on Measurement and Statistical Issues, Geneva, 17–18 October, OECD: http://www.oecd.org/dataoecd/42/44/35651123.pdf (accessed on 13 March 2012).

[13] Tekeste Biadgleng, and Munoz Tellez, *supra* n. 8, p. 20.

of additional human and financial resources and limits the scope for utilizing TRIPS flexibilities in favour of public health. There is also the problem that systematic research on the health and safety effects of counterfeit products is almost non-existent.[14]

Given the very specific meaning of counterfeiting adopted by the TRIPS Agreement and the WHO, there are concerns that use of this term to describe medicines that are generic drugs sold legitimately on the market will create confusion and risk prioritizing the enforcement of intellectual property rights over public health.[15] The counterfeiting of high-price medicines is a growing illegal business. Generic drugs that do not infringe trademarks are not counterfeit goods. Unauthorized uses of a product that are allowed by law, such as products made under legitimate limitations and exceptions to patents, or generic medicines that are off-patent or legitimately licensed under voluntary or non-voluntary licences, are not counterfeit products.[16] So, not all infringements of patents or other intellectual property rights can be described as counterfeits, and often the issue of what constitutes infringement is itself a matter of controversy, with issues of patent validity quite different from trademark law, where the relationship between rights and exceptions to rights is complex.[17]

Consequently, it is important to differentiate between counterfeiting and the importation of legitimate products at a lower price, as 'grey market' parallel traded goods that are acquired legitimately in one market, and resold legally under the exhaustion of rights doctrine in another market.[18] The tendency to conflate the two issues has the effect of stigmatizing the practice and ignoring the potential benefits of parallel trade if the view is taken that restrictions on parallel trade can lead to anti-competitive behaviour, and by facilitating market segmentation and price discrimination, resulting in higher prices for consumers in markets that have a lack of competition.

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[14] Olsen, *supra* n. 12.

[15] Mara, K. (2010), 'Counterfeit Medicines in WTO Dispute Process, Heating up at WTO', *Intellectual Property Watch*, 12 May 2010: http://www.ip-watch.org/weblog/2010/05/12/counterfeit-medicines-in-wto-dispute-process-heating-up-at-who/ (accessed on 13 March 2012).

[16] Love, J. (2008), *What is a Counterfeit?*, Knowledge Ecology International (KEI): http://keionline.org/node/81 (accessed on 13 March 2012).

[17] Love, ibid.

[18] Matthews, D. and V. Munoz-Tellez (2007), 'Parallel Trade: A User's Guide', in A. Krattiger, R.T. Mahoney, L. Nelson et al (eds) *Intellectual Property Management in Health and Agriculture Innovation: A Handbook of Best Practices*, Oxford, UK: MIHR and Davis, USA: PIPRA, pp. 1429–34.

3. PATENT INFRINGEMENT

Patent infringement is not included in the definitions of counterfeiting used by the TRIPS Agreement or the WHO. Recently, however, the term counterfeiting has been used misleadingly to describe patent infringement, particularly in relation to generic medicines. A recent example of confusion over this topic was the assertion that Switzerland was a major source of counterfeit medicines. According to Swiss officials, this actually referred to a case involving a dispute over alleged patent infringement, an area of much complexity and controversy, not usefully described as counterfeiting at all.[19]

In fact, patent infringement cases lie outside the scope of counterfeiting and are dealt with more appropriately by civil proceedings before national courts brought by the right holder.[20]

4. FALSIFIED MEDICINES

'Falsified medicines' is the term that can best distinguish sub-standard pharmaceutical products from counterfeits which contain the correct active ingredients but nonetheless violate trademark law. Falsified medicines are a major threat to public health and safety. They may not possess any medicinal properties, may have insufficient active ingredients or may contain the wrong medicine. Suppliers of falsified medicines try to bypass the regulatory oversight by medicine licensing and supervisory authorities. Such illegal trade often occurs through the Internet.[21] Moreover, these products are channelled increasingly through the legal supply chain.[22] These falsified medicines are part of the broader phenomenon of sub-standard pharmaceuticals that are manufactured below established standards of safety, quality and efficacy. They are usually deliberately and fraudulently mislabelled with respect to identity and/or source and

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[19] Love, *supra* n. 16.

[20] Matthews, D. (2008), *The Fight against Counterfeiting and Piracy in the Bilateral Agreements of the EU*, Brussels: Directorate General External Policies of the Union, European Parliament Briefing Paper.

[21] European Medicines Agency (EMA), *Falsified medicines:* http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000186.jsp&mid=WC0b01ac058002d4e8&jsenabled=true (accessed 13 March 2012).

[22] Directorate General Health and Consumers of the European Commission, *Citizen's Summary – Legal Proposal on Measures Preventing the Entry into the Legal Supply Chain of Medicinal Products which are Falsified in Relation to their Identity, History or Source*.

therefore also infringe trademarks and can additionally be considered counterfeit products because of this. These products may also include products with the correct ingredients but which are inserted in packaging which violates trademarks.[23]

Until recently, most of the falsified medicines circulating in developed countries were new, expensive lifestyle medicines, such as hormones, steroids and antihistamines. In developing countries the most common falsified medicines have been those used to treat life-threatening conditions such as HIV/AIDS, tuberculosis and malaria. As the phenomenon spreads, more and more falsified medicines are becoming available, including anti-cancer drugs.[24]

Unlike counterfeit medicines which may contain the same active ingredients as trademarked goods, however, falsified medicines contain the wrong or insufficient active ingredients. They can kill people and, as falsifications become more sophisticated, the risk that falsified medicines reach patients increases. These falsified medicines can be unsafe, inefficient, or of low quality thus posing a risk to human health. Yet political wrangling over language and confusion over how to deal with the public health implications of this phenomenon is hampering international action.[25] Although countries unanimously recognize the threat posed by falsified medicines, many also believe that intellectual property rights enforcement concerns should not dominate the search for solutions.[26]

5. THE WORLD HEALTH ORGANIZATION AND 'COUNTERFEIT MEDICINES'

Given that poor quality and sub-standard medicines can pose a major threat to public health, the WHO has endeavoured to promote the improvement of drug quality and safety. Historically, the WHO has focused its activities on strengthening the capacity of national drug regulatory authorities to identify and eradicate falsified medicines rather than promoting greater involvement of law enforcement agencies and the use of trademark or other intellectual property rights to address public health

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[23] Ibid.

[24] Ibid.

[25] See also Clift, *supra* n. 2.

[26] Saez, C. (2011), 'WHO Members to Work to Disentangle Problem of Fake Medicines', *Intellectual Property Watch*, 26 February: http://www.ip-watch.org/weblog/2011/02/26/who-members-to-work-to-disentangle-problem-of-fake-medicines-ip-issues/ (accessed on 13 March 2012).

concerns. The WHO has a clear mandate to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices and, in 2008, this mandate was reinforced by World Health Assembly (WHA) adoption of a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.[27]

In addition to its other initiatives, since 2006 the WHO has also been sponsoring and acting as Secretariat to a new body called the International Medicinal Products Anti-Counterfeiting Taskforce (IMPACT), which in the past has been criticized for developing its own definition of counterfeit medicines that is not widely accepted by member countries in their national law.[28] More recently, in 2010, IMPACT refined its terminology and refers to spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines, which IMPACT defines as medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source. This approach is more clearly in line with internationally-recognised definitions than the previous approach of IMPACT, which tended to speak exclusively of 'counterfeit' medicines.[29]

Until 2011, for instance, the IMPACT website itself noted that: 'counterfeit medical products are a major public health risk for all communities. The phenomenon has grown in recent years due to counterfeiting methods becoming more sophisticated and to the increasing amount of merchandise crossing borders'. This statement has now been removed from the IMPACt site.

Since 2011, by adopting a broader conception of SFFC medicines, IMPACT seeks to coordinate efforts in order to protect public health against substandard and SFFC medical products.[30] It works in partnership with major anti-counterfeiting organizations such as the World Customs Agency and INTERPOL.[31] In addition, through informal networks of enforcement officers, IMPACT facilitates communication between enforcement and health authorities, seeks to improve international collaboration and develop appropriate mechanisms that will enable import-

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[27] World Health Assembly (2008), *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, WHA61.21, 24 May: http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf (accessed on 13 March 2012).

[28] South Centre/CIEL, *supra* n. 1, p. 1.

[29] World Health Organisation (2010) *Medicines: spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines*, Fact Sheet No. 275: http://www.who.int/mediacentre/factsheets/fs275/en/index.html

[30] International Medical Products Anti-Counterfeiting Taskforce – IMPACT: http://www.who.int/impact/en/ (accessed 10 April 2012)

[31] Saez, *supra* n. 26.

ing countries, especially in the developing world, to trigger investigation and identification of the actual source of SFFC medicines plaguing their markets.[32]

According to IMPACT in 2006, using its pre-SFFC terminology, counterfeiting of medicines is greater in those regions where regulatory and legal oversight is weaker, and therefore:

- most developed countries with effective regulatory systems and market control (eg USA, EU, Australia, Canada, Japan, New Zealand) currently have a very low proportion, ie less than 1 per cent of market value;
- many developing countries in Africa, parts of Asia, and parts of Latin America have areas where more than 30 per cent of the medicines on sale can be counterfeit. Other developing countries, however, have less than 10 per cent overall, a reasonable estimate for all developing countries is therefore between 10 per cent and 30 per cent;
- many of the former Soviet republics have a proportion of counterfeit medicines which is above 20 per cent of market value – this falls into the developing country range. However other sources estimate that the real figure could be much higher;
- medicines purchased over the Internet from sites that conceal their actual physical address are counterfeit in over 50 per cent of cases.[33]

In relation to specific countries, IMPACT has reported that:[bl]

- the Russian Federal Service for Health Sphere Supervision (FSHSS) reported that 10 per cent of all drugs on the Russian market were counterfeit;
- China's research and development-based Pharmaceutical Association estimated that about 8 per cent of over-the-counter drugs sold in China were counterfeit.

Indian pharmaceutical companies have suggested that in India's major cities, one in five strips of medicines sold is falsified. They claim a loss

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[32] World Health Organization (2010), *Medicines: spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines*, Fact Sheet No. 275: http://www.who.int/mediacentre/factsheets/fs275/en/index.html (accessed 13 March 2012)

[33] IMPACT (2006), *Counterfeit Medicines: an update on estimates*: http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf (accessed 13 March 2012).

in revenue of between 4 and 5 per cent annually. The industry also estimates that spurious drugs have grown from 10 to 20 per cent of the total market.[34]

In order to provide guidance to WHO member countries on how best to draft national legislation to address concerns about counterfeit goods, on 12 December 2007 IMPACT adopted 'Principles and Elements for National Legislation against Counterfeit Medical Products'.[35] This document, prepared by the IMPACT Working Group on Legislative and Regulatory Infrastructure, raises a number of concerns, not least because the definition of counterfeit medicines contained in the document was incorporated without prior consultations with WHO member states, even though it amounted to a significant change of policy in that it redefined previous WHO guidelines on counterfeiting.

> The IMPACT's definition of counterfeit medicines states that:
> A medical product is counterfeit when there is a false representation in relation to its identity,[36] history or source.[37] This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components,[38] with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging. Quality defects or non-compliance with Good Manufacturing Practices/ Good Distribution Practices (GMP/GDP) in legitimate, authorized medical products should not be confused with counterfeiting.

The IMPACT definition significantly expanded the accepted WHO understanding of counterfeiting by replacing 'deliberately and fraudulently' with 'a false representation', the latter which can occur irrespective of whether there was deliberate intent of any person or producer of goods. The effect was that even where there is no consumer deception, a medicine could still be considered as a counterfeit, with the burden of proof shifted away from enforcement officers to the producer or distributor of the counterfeit medicine. By incorporating the term 'false representation' the IMPACT

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[34] Ibid.

[35] IMPACT (2007), 'Principles and Elements for National Legislation against Counterfeit Medical Products', p. 3. Text endorsed by the IMPACT General Meeting, 12 December: http://www.who.int/impact/events/FinalPrinciplesforLegislation.pdf (accessed 13 March 2012).

[36] IMPACT, ibid, p. 4: eg any misleading statement with respect to name, composition, strength, or other elements.

[37] IMPACT, ibid, p. 4: eg any misleading statement with respect to manufacturer, country of manufacturing, country of origin, market authorization holder.

[38] IMPACT, ibid, p. 4: This refers to ingredients or any other component of a medical product.

definition also broadened the possibility of intellectual property infringements to include not only trademark violations but also infringement of a patent. Finally, one positive step taken by the IMPACT definition was that it stated that quality defects or non-compliance with GMP/GDP in legitimate, authorized medicinal products should not be confused with counterfeiting. This was welcome as a means to help ensure that legitimate parallel trade in grey market goods or generic products are not to be considered infringements of intellectual property rights.[39]

The IMPACT definition of counterfeiting was debated in the context of the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) during discussions on proposals to develop and strengthen legislative and regulatory oversight mechanisms and other measures against the production, trafficking and use of counterfeit medicines. However, WHO member states did not reach a consensus on including the IMPACT definition in the outcomes of the IGWG process and it was not included in the resulting WHA Global Strategy and Plan of Action for Public Health, Innovation and Intellectual Property in May 2008.[40]

It is also unclear how the work of IMPACT relates to the other activities of the WHO. Concerns about the work of IMPACT were raised at the WHA in May 2008 when a draft resolution on counterfeiting, sponsored by Gambia, Ghana, Nigeria, Tunisia, and United Arab Emirates, and later co-sponsored by the European Union,[41] presented arguments that IMPACT initiatives were causing concern amongst WHO member states.[42]

On 11 May 2010, nearly 50 public health non-governmental organizations (NGOs) also voiced concerns by sending an open letter to the Director General of the WHO, Margaret Chan, urging the WHO to find terminologies in the fight against dangerous medicines that are more public-health than intellectual-property oriented.[43]

Subsequently, the 63rd World Health Assembly on 21 May 2010 established a new WHO working group on 'substandard/spurious/falsely-labelled/falsified/counterfeit' medical products. The working group looked

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[39] South Centre/CIEL, *supra* n. 1, p. 9.

[40] World Health Assembly, *supra* n. 27.

[41] A61/A/Conf. Paper No 1.

[42] Third World Network (2008), *IP: Counterfeit Issue Stirs Debate Among WHO Member States*, SUNS No. 6536 12 August: http://www.twnside.org.sg/title2/health.info/2008/twnhealthinfo20080802.htm (accessed 13 March 2012).

[43] Third World Network (2010), *NGO Open Letter Over WHO's Involvement in 'Counterfeit Medicinal Products' and in the IMPACT*: http://www.twnside.org.sg/title2/health.info/2010/health20100504.htm.

again at IMPACT's definition of counterfeit medicines in the context of its mandate to examine, from a public health perspective: the WHO's role in measures to ensure availability of quality, safe, efficacious and affordable medical products; the WHO's relationship with IMPACT; and the WHO's role in the prevention and control of medical products of compromised quality, safety and efficacy such as substandard/spurious/falsely-labelled/falsified/counterfeit medical products from a public health perspective, excluding trade and intellectual property considerations.[44] As a result of this initiative, IMPACT revised its terminology and replaced references to counterfeit medicines with SFFC medicines in all its documentation post-2011.

6. SEIZURES OF 'COUNTERFEIT' MEDICINES IN TRANSIT THROUGH THE EU

The international policy debate about the status of so-called 'counterfeit' medicines and the free trade in generic pharmaceutical products that are legitimately made available on the market came to even greater prominence on 19 May 2010 when Brazil and India initiated consultations under the WTO dispute settlement procedure relating to the seizure of generic medicines considered as counterfeit products in the EU. The situation arose because EU Border Measures Regulation (BMR) 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights extends beyond counterfeit goods that infringe trademarks and includes the possibility that infringing acts can relate to patents and other intellectual property rights including copyright works, supplementary protection certificates, plant protection rights or geographical indications.[45]

The BMR permits customs authorities to seize all goods intended for

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[44] O'Mara, K. (2010), 'New Resolution Gives Governments Control Of WHO Work On False Medicines', *Intellectual Property Watch*, 21 May 2010: http://www.ip-watch.org/weblog/2010/05/21/new-resolution-gives-governments-control-of-who-work-on-false-medicines/ (accessed 13 March 2012).

[45] Article 2, paragraph 1(c) of Council Regulation (EC) No. 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, OJ L 196, 2 August 2003: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R1383:en:NOT (accessed on 13 March 2012).

import, export and re-export that are suspected of infringing intellectual property rights, even when an application has not been lodged by the right holder. This includes goods suspected of infringing a patent, with the effect that medicines can be seized by customs and listed in customs statistics under the broad heading of counterfeit and pirated goods. However, the determination of whether or not the medicinal products in question actually infringe a patent will depend on the national law of the member state when the alleged violation occurred and requires proceedings to be initiated to this effect. This statistical reporting of medicinal products alleged to infringe a patent under the heading of counterfeit goods unhelpfully confuses disputes over patent infringement with counterfeit medicines that infringe trademarks, as defined by the TRIPS Agreement and the WHO.[46] This has heightened fears that the medicines suspected of infringing patents are being confused with counterfeit medicines.

The concerns of Brazil and India involved several shipments of medicines in transit from India to other developing countries that were detained en route through the EU on the grounds that they violated intellectual property rights, even though they were not destined for EU markets. At issue was the extent that the BMR can legitimately allow for goods suspected of patent infringement to be delayed and detained by customs authorities.

Acting under the terms of the BMR, since 2008 customs authorities in the Netherlands have seized, delayed and returned several shipments of generic medicines in transit through EU ports, en route to destinations in South America and Africa. They have done so on grounds of suspected patent infringement.[47] The shipments in question have originated in the main from India and the intended final destination has generally been developing countries including Brazil, Colombia, Nigeria, Peru and Venezuela. The medicines at issue have been protected by patents in the EU but have not been subject to patents in the country of origin or the intended final destination. Based on complaints of alleged infringement by the owners of patents, Dutch customs authorities have seized a substantial number of consignments of generic medicinal products in transit through the Netherlands. These consignments have then been destroyed, returned to the country of origin or, in a few cases, permitted to proceed

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[46] South Centre/CIEL, *supra* n. 1, p. 11.

[47] Grosse Ruse-Khan, H. (2010), *A Trade Agreement Creating Barriers to International Trade? Seizures of Generic Drugs in Transit and International IP Enforcement*, Society of International Economic Law Online Proceedings Working Paper No. 2010/18, p. 3.

to the country of destination. In all cases the Dutch authorities have acted pursuant to the BMR.[48]

While Brazil and India, together with other developing countries, have taken a strong stand against falsified medicines,[49] they have taken an equally strong position in their complaints that the BMR conflates counterfeiting of trademarked goods with broader issues of patent infringement disputes and goods that are legitimately in transit through the EU. On 12 May 2010 Brazil and India filed requests for consultations with the European Union and the Netherlands under the WTO dispute settlement process over the seizure of generic medicines in transit through the EU.[50]

According to Brazil and India's requests for consultations, the EU and Dutch border measures were inconsistent with Article 1(1) of the TRIPS Agreement,[51] together with various provisions of the border measures section (Articles 51–60) of the TRIPS Agreement. It has been argued that the alleged patent infringements by goods in transit do not result from a failure to meet the minimum standards of the TRIPS Agreement on intellectual property protection and enforcement and are therefore TRIPS-plus.[52]

The arguments presented by India were also instructive in that they made explicit the link between Article 28,[53] read together with Article 2

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[48] Ibid, p. 3.

[49] See, for example, Gleicher, D. (2010), *India, Brazil and South Africa Make a Stand on Falsified and Substandard Medicines*, Global Health Europe, 21 October: http://www.globalhealtheurope.org/index.php?option=com_content&view=article&id=352:india-brazil-and-south-africa-make-a-stand-on-falsified-and-substandard-medicines&catid=60:your-opinion&Itemid=108 (accessed on 13 March 2012).

[50] *Request for consultations by India: European Union and a Member State – Seizure of Generic Drugs (EU Seizure of Generics)*, WT/DS409/1, 19 May 2010; *Request for consultations by Brazil: EC – Seizure of Generics*, WT/DS409/1, 19 May 2010.

[51] Article 1.1 of the TRIPS Agreement (Nature and Scope of Obligations):

> Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

[52] Grosse Ruse-Khan, *supra* n. 47, p. 7.

[53] Article 28 of the TRIPS Agreement (Rights Conferred):

> 1. A patent shall confer on its owner the following exclusive rights:
> (a) where the subject matter of a patent is a product, to prevent third parties not

of the TRIPS Agreement,[54] Article 4*bis* of the Paris Convention,[55] and the last sentence of Article 6(i) of the WTO Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.[56] According to India, a cumulative

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having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

[54] Article 2 of the TRIPS Agreement (Intellectual Property Conventions): '1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).'

[55] Article 4bis of the Paris Convention (Patents: Independence of Patents Obtained for the Same Invention in Different Countries):

1. Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not.
2. The foregoing provision is to be understood in an unrestricted sense, in particular, in the sense that patents applied for during the period of priority are independent, both as regards the grounds for nullity and forfeiture, and as regards their normal duration.
3. The provision shall apply to all patents existing at the time when it comes into effect.
4. Similarly, it shall apply, in the case of the accession of new countries, to patents in existence on either side at the time of accession.
5. Patents obtained with the benefit of priority shall, in the various countries of the Union, have a duration equal to that which they would have, had they been applied for or granted without the benefit of priority.

[56] Article 6 of the Decision of the General Council of 30 August 2003 on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health:

With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:
(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product

reading of these provisions confirms, *inter alia*, that the rights conferred on the owner of a patent cannot be extended to interfere with the freedom of transit of generic goods lawfully manufactured within, and exported from, India.

India further argued that Articles 41 and 42 of the TRIPS Agreement were at issue because the BMR had created barriers to legitimate trade, permitted the abuse of rights conferred on the owner of a patent, were unfair and inequitable, unnecessarily burdensome and complicated, and created unwarranted delays.[57] Finally, India argued that Article 31 of the

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produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

[57] Article 41 of the TRIPS Agreement (Enforcement of intellectual property rights – General obligations):

1. Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.
2. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.
3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.
4. Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there shall be no obligation to provide an opportunity for review of acquittals in criminal cases.
5. It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

Article 42 of the TRIPS Agreement (Enforcement of Intellectual Property Rights – Fair and Equitable Procedures):

TRIPS Agreement,[58] read together with the WTO Decision of 30 August 2003, was at issue because the EU Regulation authorized the interference with the freedom of transit of medicines that may be produced in, and exported from, India to WTO members with insufficient or no capacity in the pharmaceutical sector that seek to obtain supplies of such products needed to address their public health problems by making effective use of compulsory licensing.

On 28 July 2011, India announced an "Understanding" with the EU that puts more conditions on EU customs authorities before they can stop shipments of generic pharmaceuticals passing through Europe.[59] The Understanding will ensure that the existence of a patent will not hinder

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Members shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice which is timely and contains sufficient detail, including the basis of the claims. Parties shall be allowed to be represented by independent legal counsel, and procedures shall not impose overly burdensome requirements concerning mandatory personal appearances. All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence. The procedure shall provide a means to identify and protect confidential information, unless this would be contrary to existing constitutional requirements.

[58] Article 31 (Other Use Without Authorization of the Right Holder):

Where the law of a Member allows for other 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, the following provisions shall be respected:
(a) authorization of such use shall be considered on its individual merits;
(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

[59] Press Release (28 July 2011), Information Bureau, Government of India, *Indian EU Reach an Understanding on Issue of Seizure of Indian Generic Drugs in Transit*, http://pib.nic.in/newsite/erelease.aspx?relid=73554 (accessed 10 April 2012)

on passing generic shipments through the EU.[60] A key element of the Understanding is the core principle that the mere fact that medicines are in transit through EU territory, and that there is a patent title applicable to such medicines in EU territory, does not in itself constitute enough grounds for customs authorities in any Member State to suspect that the medicines at stake infringe patent rights.[61]

7. CONCLUSION

By conflating issues of counterfeiting with patent infringement, the seizure of generic drugs by the Dutch customs authorities under the auspices of the BMR raises the prospect that public health imperatives are being jeopardized by a tendency to merge concerns about counterfeit goods that infringe trademarks, with the debate about how best to deal with medicines suspected of infringing patents. In fact, the most immediate concern for public health lies elsewhere with falsified medicines containing the wrong or insufficient active ingredients that may be a risk to human health. These are separate issues and should be treated as such.

Given the above discussion it is clear the diversity of meanings attributed to the term 'counterfeit medicines' highlights an urgent need for a universally-recognized definition that makes explicit the fact that only trademark violations can be considered acts of counterfeiting.[62] Public health is not necessarily at risk from such counterfeit medicines. It is falsified medicines that are the real concern.

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[60] Baker, B.K. (2012) *Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border. Regulation Isn't Good Enough*, PIJIP Research Paper No. 2012-02 American University Washington College of Law, Washington, D.C.

[61] Intellectual Property Watch (2011), *EU-India Agreement In WTO Dispute Raises Bar For EU Drug Seizures*: http://www.ip-watch.org/2011/07/30/eu-india-agreement-in-wto-dispute-raises-bar-for-eu-drug-seizures/ (accessed 10 April 2012)

[62] See also South Centre/CIEL, *supra* n. 1, p. 7.