

Balancing or Lobbying? On Access to Medicines, Border Measures and the European Parliament's Amendments to the Proposed EU Trademark Rules

Daniel Opoku Acquah†

Faculty of Law, University of Turku, Finland

Received 16 August 2014, revised 9 October 2014

Enhanced intellectual property rules are noted as among the forces limiting the global access to medicines. In the European Union (EU), it is the Border Measures Regulation that has caused major disruptions for generic medicines in transit at its borders in the past. However, the Commission's recent proposal for changes to the EU trademark rules promises another layer of restraint on access. In adopting the proposal, the European Parliament has moved to correct this syndrome by suggesting amendments that balance intellectual property and public health interest. But, can that pass the influence of corporate lobbyist? This essay argues that for the sake of certainty, the European Parliament's amendments are good law and should be maintained.

Keywords: Intellectual property rights, access to medicines, EU trademark rules, border measures, European Parliament

Since the incorporation of intellectual property into the World Trade Organisation (WTO) Agreements,¹ the issue of balancing the protection and enforcement of intellectual property rights on the one hand, and access to medicines (generic medicines)² on the other, has gained currency. Two incidents spawned this awareness: the first was the South African case³ in 1998, when about 39 multinational pharmaceutical companies took the South African government to court over the introduction of the South African Medicines and Related Substances Control Act (MRSCA),⁴ which contained a new Section 15C explicitly permitting parallel import of patented pharmaceuticals.⁵ The second, which is central to this paper, was the continuous seizure of generic medicines in transit at various European Union (EU) ports between 2008 and 2010 en route from India to destinations in Latin America and Africa.⁶ The legal basis of such seizures had been Regulation No (EC) 1383/2003⁷—the Border Measures Regulation (BMR), which sets out the conditions for action by the customs authorities when goods suspected of infringing an intellectual property right come under their supervision. Consequently, it has been the BMRs that have caused major disruptions for generic medicines in transit through the EU. For trademarks, the Court of Justice of the European Union (CJEU)

has long ruled that goods in transit did not constitute an infringement under the EU trademark rules.⁸ So where do trademarks come in? Against the background of a WTO dispute consultation for the seizure of generic medicines in transit at its borders,⁹ the EU agreed in principle to amend its BMR.¹⁰ It was anticipated that the new BMR¹¹ would balance these two conflicting, but related, policy objectives: intellectual property rights and access to medicines. However, with regard to its content the new BMR fell short of expectations. Whilst commentators decry the content of the new BMR as limiting access;¹² anti-counterfeiting stakeholders complain that the new regulation did not do enough to correct the *Philips* and *Nokia* impact¹³ (explained later), despite the fact that it has been the subject of heavy lobbying.¹⁴ The European Commission since proposed changes to EU trademark rules.¹⁵ Based on its content, it is argued that the proposed revisions are an attempt by the Commission to correct the *Philips* and *Nokia* impact with implications for global access to medicines.¹⁶

The European Parliament (EP) has moved to correct this “imbalance” by effectuating important amendments to the proposal package that balance intellectual property rights and public health. However, whether these amendments can withstand the influence of corporate lobbyists is uncertain based on previous and present developments. This paper posits that for the sake of certainty (erasing all

†Email: danacq@utu.fi

ambiguities), the amendments suggested by the EP are good law and should be maintained. In what follows, it will be instructive to first discuss how the BMR(s) led to the seizure of generic medicines in transit in the EU, and in what ways the new BMR falls short of addressing the *Philips* and *Nokia* impact. This will be followed by a detailed analysis of the contents of the proposed EU trademark rules and how they could affect the transit of generic medicines, the amendments suggested by the EP and the role of corporate lobbyists in the outcome of amendments.

BMR and the Seizure of Generic Medicines

It is important to clarify from the outset that the detention or seizure of generic medicines in transit at EU ports has been a major concern and a threat to public health for two reasons: Europe's geographic position and its transportation strength automatically makes it a transit hub for a significant percentage of the international medicines trade, and even South-South trade.¹⁷ In addition, many health-related NGOs have their headquarters in Europe, and the products they send into the field go through European customs territory.¹⁷ If pharmaceutical products are going to be regularly intercepted in transit through EU ports on grounds of alleged intellectual property infringement, the international generics trade may be seriously hampered, thereby putting public health at risk.

More than a decade ago, the third generation of the EU's BMR: Council Regulation 1383/2003 amended EU border control measures in such a way that supposedly implied permission to EU patent holders to demand seizure of infringing goods (including pharmaceutical products) in transit through EU ports as if they were counterfeits.¹⁸ Unlike its predecessors,¹⁹ Article 2(1)(c) of the Regulation defined goods infringing an intellectual property right to include patents and supplementary protection certificates (SPCs). SPCs in the EU generally extend the term of patent protection for five more years to compensate for delays in obtaining regulatory approval for medicinal products.²⁰ Including patents and SPCs within the scope of the BMR, effectively ensured that generic medicines in transit at EU borders could be legally intercepted because they infringed local patents or SPCs.

Furthermore, the language of Recital 8 and Article 10 of the Regulation turned out to be problematic. Recital 8 read: "Proceedings initiated to

determine whether an intellectual property right has been infringed under national law will be conducted with reference to the criteria used to establish whether goods produced in that Member State infringe intellectual property rights [...]". Interpretation of the ambiguous language of this Recital and Article would generate legal challenges both at the national and Union level.²¹ Two of such cases from Belgium and the UK which eventually ended up at the CJEU are discussed in this article. Although none of these cases actually concerned generic medicines, the outcome of the rulings would determine whether generic medicines in external transit²² could be seized at EU ports or not. These cases involve similar situations as those of generic medicines where the goods at issue had been seized at EU ports (whilst in transit) because they infringed local intellectual property rights. It is to be borne in mind that the seizure of generic medicines and other intellectual property related infringing goods at EU borders were conducted on the basis of the BMR and other EU secondary norms such as the EU Trademark Regulation.

In the Netherlands, for instance, where most of the seizures had taken place, the courts interpreted the text of Article 6(2) of Regulation 3295/94 (the second generation of the EU's BMR), and Recital 8 of Regulation 1383/2003 simply to mean that all goods falling under the scope of these regulations could be regarded by way of a "legal fiction", as goods produced in the Member State of the customs action – "the manufacturing fiction"²³—thus circumventing the burden of proving that the goods concerned would be traded in the Union, a condition which is, in principle, obligatory for the purposes of obtaining protection for all forms of intellectual property.²⁴ Hence, generic medicines making transit in the Netherlands that infringed local patents were seized under the pretext that they were illegally manufactured in the Netherlands and thereby infringed patent rights.

Furthermore, the CJEU somehow gave credence to this "fictional theory" in its early case law when it declared that the Regulation 3295/94 was applicable to non-Community goods in transit to a non-member country without particular reference to any need to prove that they were destined for the internal market.²⁵ Hence, EU Member States had to prohibit and punish the mere placing in external transit of counterfeit goods through their territories.²⁶ However, varying rulings by the CJEU over time led to a background of rather confused case law²⁷ until *Philips* and *Nokia*.

Impact of the *Philips* and *Nokia* decision

The CJEU's decision in *Philips* and *Nokia* seems to have finally resolved the controversy over whether counterfeit and pirated goods in transit could be seized or not. *Philips* concerned the suspension of release by customs authorities (in the port of Antwerp) of goods suspected of infringing Philips design shavers protected in the Benelux countries through an international design registration. The cargo of electric shavers was from China and bound for an unknown destination. It was not disputed that the detained shavers could classify as "pirated goods" within the meaning of the BMR if they were put on sale in Belgium or in another EU Member State where Philips held a copyright and enjoyed design right protection.²⁸ Upon notification from customs officers, Philips brought an action against Lucheng, Far East Sourcing, and Röhlig before the Court of First Instance of Antwerp, seeking a ruling confirming infringement and an order to pay damages.²⁹

Nokia involved the inspection at Heathrow Airport by the UK Customs of a consignment of mobile phones and accessories from Hong Kong en route to Colombia. The items carried a sign identical to the Community trademark registered by Nokia. Suspecting that the goods were counterfeits, the UK Customs informed Nokia about the goods but when Nokia requested seizure of the goods, the UK Customs refused Nokia's application for seizure arguing that their destination was Colombia and there was no evidence that they were going to be diverted to the EU market. As Nokia could not provide evidence that the goods would be diverted to the EU market, the UK customs decided to release the goods. Nokia brought an action against the UK Customs before the High Court of Justice of England and Wales. When the Court reasoned along similar lines as the UK customs, Nokia appealed to the Court of Appeal for England and Wales. Both the Antwerp Court and the Court of Appeal for England and Wales referred these questions to the CJEU.

The referring courts in both cases essentially asked the CJEU to determine whether or not the customs regulations had an effect on the substantive rules governing intellectual property in the context of goods in transit and also on the action which customs authorities could take in relation to goods in transit. The CJEU replied that goods coming from a non-Member State which are imitations of goods protected by a trademark, or copies of goods protected

by a copyright, cannot be classified as counterfeit goods or pirated goods within the meaning of the Customs Regulation merely on the basis of the fact that they are brought into the Union under a suspensive procedure. Those goods may only infringe intellectual property rights where, during their placement under a suspensive procedure in the customs territory of the EU, or even before their arrival in that territory, goods coming from non-Member States are the subject of a commercial act directed at EU consumers, such as sale, offer for sale, or advertising.³⁰ This ruling of the CJEU made the EU borders transit-friendly, thereby granting generic medicines a safe passage.

Does the New BMR Fail to Address the *Philips/Nokia* Impact?

Following the CJEU's decision in *Philips* and *Nokia*, anti-counterfeiting stakeholders expressed concerns that the Court had, by its ruling, seemingly made transit a safe harbour for the global trade in counterfeiting,³¹ by placing an inappropriately high burden of proof on right holders. Thus, it was highly anticipated that, the new BMR would seek to correct this "unsatisfactory solution"³² by making transit actionable under the law of the country of detention. In this direction, De Meyer and Gommers had proposed the inclusion of a 'rebuttable presumption' in the Regulation that would indicate that: "the goods detained will be put on the EU market in violation of the intellectual property right in question"³²

"Once this rebuttable presumption was raised, the declarant, the consignor or any other party interested in the trans-shipment shall be allowed to rebut that presumption by providing conclusive evidence that the goods are legitimate and have a destination where the intellectual property right in question shall not be violated."³² In as much as such an idea is convincing, making transit automatically actionable in the form recommended here would bring the EU norm into conflict with international law – the GATT Article V on freedom of transit. Specifically, the Article V(2) of the latter states that "there shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties. No distinction shall be made which is based on the flag of vessels, the place of origin, departure, entry, exit or destination, or on any circumstances relating to the ownership of goods, of

vessels or of other means of transport.” According to Abbott, until the EU Member States started seizing generic medicines in transit at their borders, “this fundamental principle of ‘freedom of transit’ had been so widely and consistently implemented that there had been virtually no controversy about it in the history of the WTO/GATT, despite the fact that goods were constantly moving in transit through its members.”³³

As the CJEU rightly pointed out in *Philips* and *Nokia*, it appears from Recital 2 of the Regulation that the objective of the EU legislature is restricted to preventing goods infringing intellectual property rights from being “placed on the internal market” and to adopting measures for that purpose “without impeding the freedom of legitimate trade.”³⁴

In its bid to address the matter, the EP suggested amendments (but not in the form of a rebuttable presumption) when it proposed in its legislative resolution of 3 July 2012 that Article 16(3) of the proposed BMR should be amended to include: “Where goods suspected of infringing intellectual property rights are not counterfeit or pirated goods, customs authorities shall communicate their intention to the declarant or, in cases where goods are to be detained, the holder of the goods before suspending the release or detaining the goods. The declarant or the holder of the goods shall be given the opportunity to express his/her views within three working days of receipt of that communication.”³⁵ This would have given the declarant or holder of infringing goods the opportunity to provide adequate evidence that the final destination of the goods is beyond the territory of the EU. However, for some unknown reasons, this clause was omitted from the final Regulation which is in force.

The EU Commission has since opted for transit to be actionable in its proposal for a revision of the Regulation on the EU trademark and for a recast of the Directive approximating the laws of the Member States relating to trademarks.³⁶ That, such a move is motivated by the *Philips* and *Nokia* decision reflects clearly in Recital 5.3(6) of the Explanatory Memorandum to the proposal which underscores the implications of *Philips* and *Nokia*, and then continues by adding: “[...] It is therefore proposed to fill the *existing gap* by entitling right holders to prevent third parties from bringing goods, from third countries, bearing without authorisation a trademark which is essentially identical to the trademark registered in respect of those goods, into the customs territory of the Union, regardless of whether they are released for

free circulation.” For anti-counterfeiting stakeholders, this may be a validation of the fact that there was something inherently wrong with the *Philips* and *Nokia* decision or the BMR. For advocates for access to medicines on the other hand, this would mean taking the law too far with regard to prevailing international norms.

Proposed Amendments to EU Trademark Rules and Implications for Access

The original proposal for amendments to the EU trademark rules as sent by the Commission to the EP came with provisions that threatened to stifle access. First, Recital 18 of the proposed Regulation entitled EU trademark right holders to stop counterfeit goods at the borders even if they are destined for a country outside the EU. Thus, the customs status of the counterfeit product did not matter anymore, contrary to what the CJEU had arrived at in *Philips* and *Nokia*. Generic medicines not only infringe patents and SPCs, but also, in certain situations, could infringe trademarks. By relying on the same or similar words identifying the active ingredient, the labels used to identify generics or the packaging often may be to some extent similar or close to the trademarks of the original manufacturer.³⁷ A trademark holder could hence rely on the BMR to detain such medicines at the EU borders on allegations of “ordinary” trademark infringements.

Second, Article 9(5) of the Regulation enables action to be taken against goods in transit when the packaging or labels infringe local trademarks, even if the packaging or labels are imported with the intention of subsequently attaching them to the goods.³⁸ The Article reads: “The proprietor of a European trademark shall also be entitled to prevent all third parties from bringing goods, in the context of commercial activity, into the customs territory of the Union without being released for free circulation there, where such goods, including packaging, come from third countries and bear without authorisation a trademark which is identical to the European trademark registered in respect of such goods, or which cannot be distinguished in its essential aspects from that trademark”. For trade in generic medicines, granting such a broad trademark right to cover all forms of trademark infringements including packaging could be particularly problematic; more so, when it is included as a substantive part of the Regulation.

It is a known fact that traffickers intentionally ship trademark symbols and packaging materials separately from counterfeit goods, so that the goods are “branded” afterwards, once they are within the EU. Such a tactic allows infringers to limit their losses if the goods are intercepted.³⁹ Thus, although the clause as mentioned above may be defended on the basis that it is aimed at traffickers of counterfeit products; it is not axiomatic that only traffickers engage in such activity. It may be possible that genuine products (such as generic medicines) are shipped under similar circumstances where the labels or packaging are separate from the product. It is important to clarify that, although generally speaking, “counterfeiting” is defined these days as covering infringements of an intellectual property right,⁴⁰ generic medicines are not counterfeits.⁴¹ Generic medicines are marketed in compliance with international patent law. They are identified either by their internationally approved non-proprietary scientific name (INN) or by their own brand name⁴² which is important for clear identification, safe prescription and dispensing of medicines to patients, and for communication and exchange of information among health professionals and scientists worldwide.⁴³ Hence, generic medicines have become essential contributors for governments of developing countries in their efforts to contain public health care budgets, as prices of generic medicines tend to be 20%–80 % lower than those of originator medicines.⁴⁴ It is in this direction that the EP’s amendments to the Commission’s proposal package that aims at balancing protecting trademark rights and at the same time, access to medicines is commendable and should be maintained.

EP’s Amendments and the Role of Corporate Lobbyist

As one among the EU legislative institutions, the EP moved to curtail the possible effects of the Commission’s proposal for changes to the EU trademark rules on transit of generic medicines as enumerated above. Before the EP adopted the report, its Committee on Legal Affairs made substantial amendments to Recital 18 and Article 9(5) of the proposed package by introducing clear and specific additions to the said provisions seeking to erase all ambiguities. Recital 18 has now been amended to include this: “With the aim of strengthening trademark protection and combatting counterfeiting more effectively, and without prejudice to WTO rules,

in particular Article V of the GATT on freedom of transit; the proprietor of a European Union trademark should be entitled to prevent third parties from bringing goods into the customs territory of the Union without being released for free circulation there, where such goods come from third countries and bear without authorisation a trademark which is essentially identical to the European Union trademark registered in respect of such goods. This should be without prejudice to the smooth transit of generic medicines, in compliance with the international obligations of the European Union, in particular as reflected in the ‘Declaration on the TRIPS Agreement and Public Health’⁴⁵ adopted by the Doha WTO Ministerial Conference on 14 November 2001.”⁴⁶

The specific reference in this recital to the GATT Article V and the Doha Declaration underpins the EP’s efforts at fairness and transparency and further portrays the EP as an institution that is genuinely working to ensure that the EU complies with its international obligations (e.g., freedom of transit) in its intellectual property rule-making. The Doha Declaration affirmed the right of WTO Member States to implement TRIPS in such a way as to protect public health and to promote access to medicines for all. The subsequent waiver of Article 31(f) of TRIPS permitted Member States lacking sufficient manufacturing capacity to import necessary medicines from any other Member State. In 2005, the WTO Member States adopted the waiver as an amendment to TRIPS (Article 31bis). Such an addition therefore corroborated the fact that the European legislature did not want the EU’s internal system to hinder global access to medicines.

On the other hand, due to its increased powers, the EP has also become the target of corporate lobbyists.⁴⁷ This has led to the possibility that laws are watered down by the time they go through parliamentary vote. A typical example of this is Article 9(5) of the proposed Regulation. The Committee on Legal Affairs of the EP had intended to fill the gap (which it failed to accomplish with regard to the BMR) when it introduced the “right to be heard” clause for transiting trademark infringing goods in its amendments to the Commission’s proposal by adding that:

“Without prejudice to the obligations of customs authorities to carry out adequate customs controls in accordance with Article 1 of Regulation (EU) No 608/2013, this provision

shall not apply if the third party proves that the final destination of the goods is a country outside the Union and if the proprietor of the European Union trademark is not able to prove that his trademark is also validly registered in that country of final destination. In cases where the country of final destination has not yet been determined, the proprietor of the European Union trademark shall have the right to prevent all third parties from bringing the goods out of the Union again unless the third party proves that the final destination of the goods is a country outside the Union and the proprietor of the European Union trademark is not able to prove that his trademark is also validly registered in that country of final destination.”⁴⁸

Again, for unknown reasons, the latest adopted report by the EP on the proposal package shows some modifications to this provision which only reverts to the original language in which the Article appeared when it came from the Commission. The only new change is that the Article now starts with: “Without prejudice to WTO rules, in particular Article V of the GATT on freedom of transit [...]”.⁴⁹ In as much as a reference to the GATT Article V is laudable, the form in which the present modification comes makes it particularly obscure (adding somewhat only an aesthetic touch or a feel-good dose to the provision) in that the latter part of the provision permitting trademark holders to block counterfeit goods in transit contradicts the GATT Article V.⁵⁰ Until this contradiction is clarified, this provision may well negate or weaken Recital 18 as it stands now for the obvious reason that the former is a substantive part of the Regulation. It can be inferred that if Article 9(5) as originally entered by the EU Commission were not problematic, the Committee on Legal Affairs would not have contemplated amending it in the first place.

It may be conjectured that such an outcome could no doubt be linked to heavy lobbying from corporate stakeholders in Brussels⁵¹ whose interests many a times shape intellectual property rules to suit their businesses and ambitions. The story of the 2011 battle around food labelling rules is a telling example of how a massive investment in industry lobbying could be rewarding. Members of the European Parliament (MEPs) opted for a labelling scheme that had been developed and promoted by industry, instead of the more consumer-friendly “traffic-light” option.⁵² Such developments often show the extent to which not just

the Commission, but also the EP, has become the target of high industrial influence.⁵² On the other hand, the EP’s rejection of the Anti-Counterfeiting Trade Agreement (ACTA) in summer 2012, which effectively precluded the Union and its Member States from acceding to the Agreement, speaks volumes about what the EP can do in its bid to consolidate democracy and societal interest. Thus, on the issue of finding a balance between access to medicines and intellectual property, it may be crucial for the EP to use its powers (in a similar way) to strike the proper balance without compromising in favour of corporate lobbying.

Conclusion

Increasingly, intellectual property laws being promulgated by the EU are becoming broader and more exclusive. Accordingly, whilst one regime of law could be criticised for stifling access to medicines, amendments to those (existing) laws, or the negotiation of new ones, more often than not, tend to create more ambiguities or even worsen the situation. This could be the case with regard to the Commission’s proposal for changes to the EU trademark rules. The form in which the proposal came from the Commission inherently suggests that the new rules do not seek to deviate from the enforcement regimes already in place. If anything, their purpose is to enhance the rules to meet modern trends; meaning, to improve the framework conditions for businesses to innovate and to boost economic growth, but not much to do with public health or welfare, despite the fact that these rules tend to have impact on the latter.

It is in this direction that the EP’s Committee on Legal Affairs’ amendments to the proposal package is to be commended. The Committee, acting in line with its powers, sought to align the new Regulation with international law by including explicit (and implicit) references to the WTO Agreements and the Doha Declaration in Recital 18 and Article 9(5). Such indications are significant for the global access to medicines and therefore, are good law and should be maintained. This is particularly crucial because the EP recently adopted the Regulation at its first reading after voting on the report from its Legal Committee. Interestingly, the adopted Regulation comes with some modifications to Article 9(5) which only reverts to the original language in which the Article appeared when it came from the Commission. For the sake of unambiguity concerning the transit of generic

medicines, the EP will have to reconsider those amendments proposed by its Legal Committee. The adopted Regulation is still subject to scrutiny and debate. Thus, it is likely that further compromises and amendments may follow as seen with Regulation 608/2013. However, how that will turn out, it remains to be seen.

References

- 1 See Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C to the Marrakesh Agreement Establishing the World Trade Organization (WTO), 15 April 1994, 33 I.L.M 1125, 869 U.N.T.S. 299.
- 2 The European Generic Medicines Association defines generic medicine as a medicine that is developed to be the same as a medicine that has already been authorised (the 'reference medicine'). A generic medicine contains the same active substance(s) as the reference medicine, and it is used at the same dose(s) to treat the same disease(s) as the reference medicine. However, the name of the medicine, its appearance (such as colour or shape) and its packaging can be different from those of the reference medicine, <http://www.egagenerics.com/index.php/generic-medicines/introduction>.
- 3 In 1996, a National Drug Policy Committee constituted by the Health Minister of South Africa released a revised National Drug Policy, setting forth a number of different objectives designed to address the issue of access to medicines, including lowering drug prices, supporting the development of a local pharmaceutical industry for the local production of essential drugs, and promoting the prescription of generic drugs in both the public and private sectors. Out of this came a controversial legislative proposal – the South African Medicines and Related Substances Control Act (MRSCA) which contained a new Section 15C which explicitly permitted parallel imports of patented pharmaceuticals. This was signed into law by President Nelson Mandela on 12 December 1997. Fearing a domino effect in the developing world, the US pharmaceutical industry, backed by the US Government, vigorously opposed the enactment of Section 15C. In an attempt to block the implementation of the amendments, the pharmaceutical companies took the matter to court and challenged the constitutionality of the amended MRSCA before the High Court of South Africa in February 1998. This controversy between the United States, the pharmaceutical companies and South Africa attracted a great deal of attention in the media, among NGOs and activists in 1999 which ultimately led to a shift in the US Administration's policy towards South Africa. At about the same time, the plaintiffs in the MRSCA case announced the suspension of their lawsuit against the South African government.
- 4 See Medicines and Related Substances Control Amendment Act No. 90 of 1997, South African Government Gazette No. 18,505 of 12 December 1997 (amending the Medicines and Related Substances Control Act No. 101 of 1965, as amended by Acts Nos. 65/1974, 17/1979, 20/1981 and 94/1991).
- 5 See Notice of Motion in the High Court of South Africa (Transvaal Provincial Division), Case No. 4183/98.
- 6 Cepuch C, Fighting counterfeits without endangering public health, *Bridges*, 14 (3) (2010) 13.
- 7 See Council Regulation (EC) No. 1383/2003, concerning customs actions against goods suspected of infringing certain intellectual property rights (2003, O.J. L 196/7), amending Council Regulation (EC) No. 3295/94 of 22 December 1994 laying down measures concerning the entry into the Community and the export and re-export from the Community of goods infringing certain intellectual property rights.
- 8 Case C-405/03, *Class International v Colgate-Palmolive*, 18 October 2005 [2005] ECR I-8735, para 61; Case C-281/05, *Montex Holdings Ltd v Diesel SpA*, [2006] ECR I-10881, paras 26-27. In both cases, the CJEU ruled that the transit of goods did not constitute an infringement under the Trademark Harmonisation Directive and Community Trademark Regulation. For trademarks rules, see Council Regulation (EC) No. 207/2009 of 26 February 2009 on the Community Trade Mark (2009, O.J. L 78/1); and Directive 2008/95/EC of the European Parliament and of the Council on 22 October 2008 to approximate the laws of the Member States relating to trademarks (2008, O.J. L 299/25).
- 9 See Request for Consultations by India, European Union and a Member State Seizure of Generic Drugs in Transit, WT/DS408/1, 19 May 2010; also, Request for Consultations by Brazil, European Union and a Member State Seizure of Generic Drugs in Transit, WT/DS409/1, 19 May 2010. The global significance of the matter is reflected by the fact that on 28 May 2010, Brazil, Canada and Ecuador requested to join the consultation and on 31 May 2010, China, Japan and Turkey requested to join the consultation.
- 10 See European Commission: Proposal for a Regulation of the European Parliament and of the Council Concerning Customs Enforcement of Intellectual Property Rights, COM (2011) 285 final, 25 May 2011. Also, see EU reach an understanding on issue of seizure of Indian generic drugs in transit, Press Release, Government of India Ministry of Commerce and Industry, 28 July 2011, <http://pib.nic.in/newsite/erelease.aspx?relid=73554> (accessed 12 August 2014).
- 11 See Council Regulation (EU) No. 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No. 1383/2003 (new BMR) in force since January 2014.
- 12 Baker B K, Settlement of India/EU WTO dispute re seizures of in-transit medicines: Why the proposed EU border regulation isn't good enough, Program on Information Justice and Intellectual Property Research Paper Series, 1 (1) (2012); Saez C, New EU customs regulation might allow wrongful seizures of generic drugs in transit, NGOs say, *Intellectual Property Watch*, 17 October 2013.
- 13 Joined cases C-446/09 and C-495/09, *Philips and Nokia*, judgment given 1 December 2011, not yet reported. By the CJEU's decision, European customs could check on counterfeit goods transiting through the EU borders but could only stop them if there was a risk of those goods being diverted onto the Single Market. This meant in practice that customs were powerless against counterfeit goods en route to a third country. Provisions of the proposed trademark regulation seek to correct this by allowing customs to stop counterfeit trademarks goods even if destined for a country outside the EU.

- 14 Vrins O, European Commission's proposal for a regulation concerning customs enforcement of IP rights, *Journal of Intellectual Property Law & Practice*, 6 (11) (2011) 774.
- 15 For the original proposals from the Commission, see European Commission COM (2013) 161 final: Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 207/2009 on the Community Trade Mark (Brussels, 27 March 2013), <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0161:FIN:EN:PDF>; Also, European Commission COM (2013) 162 final: Proposal for a Directive of the European Parliament and of the Council to approximate the Laws of the Member States relating to Trade Marks, <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0162:FIN:EN:PDF>.
- 16 This is explicitly stated in the Recital 5.3(6) of the explanatory memorandum to the proposed package.
- 17 Seuba X, Free trade of pharmaceutical products: The limits of intellectual property enforcement at the border, ICTSD Programme on IPRs and Sustainable Development, Working Paper No. 27 (ICTSD, Switzerland), 2010 p. 1.
- 18 Abbott F M, Seizure of generic pharmaceuticals in transit based on allegations of patent infringement: A threat to international trade, development and public welfare, *World Intellectual Property Organization Journal*, 1 (2009) 43.
- 19 See Council Regulation No. 3842/86 laying down measures to prohibit the release for free circulation of counterfeit goods (OJ L 357, 18 December 1987, 1); and Council Regulation (EC) No. 3295/94 of 22 December 1994.
- 20 See Regulation (EC) No. 469/2009 of The European Parliament and of The Council of 6 May 2009 concerning the Supplementary Protection Certificate for Medicinal Products, O.J. (L 152) 1 (2009). That means, for patented medicinal products that obtained an SPC in the EU, their generic equivalents cannot be placed on the EU market or permitted to "transit" at its borders without any form of licensing agreements for five years after the patent has expired. That is, five more years after patent expiry, generic medicines shall not be available in the markets of developing countries. For more on this, see Acquah D, Extending the limits of protection of pharmaceutical patents and data outside the EU – Is there a need to rebalance?, *IIC International Review of Intellectual Property and Competition Law*, 45 (3) (2014) 256-283.
- 21 Case C-383/98, *Polo Lauren* [2000] ECR I-2519; Case C-60/02, *Montres Rolex* [2004] ECR I-651; Case C-281/05, *Montex Holdings Ltd v Diesel SpA*, [2006] ECR I-10881; and *Philips and Nokia*, etc. In *Montex*, the goods were detained due to the application of BMR. However, the questions referred to the CJEU were limited to the Trademark Directive.
- 22 Article 91 of Council Regulation (EEC) No. 2913 /92 of 12 October 1992 establishing the Community Customs Code defines external transit as "allowing the movement from one point to another within the EU customs territory of (1) non-Community goods, without such goods being subject to import duties and other changes or to commercial policy measures [...]".
- 23 The "manufacturing fiction" appears to have been applied for the first time in a patent case by the Hoge Raad der Nederlanden in its judgment of 19 March 2004 (LJN AO 0903, *Philips v Postec and Princo*), and it was subsequently adopted by the president of the Rechtbank Den Haag in a decision of 18 July 2008 and by the Rechtbank van eerste aanleg te Antwerpen itself in a judgment of 9 October 2008.
- 24 Opinion of Advocate General Crux Villalón, in joined cases C-446/09 and C-495/09, *Philips and Nokia* at para 3.
- 25 Case C-383/98, *Polo Lauren* [2000] ECR I-2519; Case C-60/02, *Montres Rolex* [2004] ECR I-651.
- 26 See *Montres Rolex* [2004] ECR I-651 at para 58. The CJEU had reached that conclusion by making reference to Articles 2 and 11 of Regulation 3295/94).
- 27 See Opinion of Advocate General Crux Villalón, in joined cases C-446/09 and C-495/09, *Philips and Nokia* at para 5. Contrary to its decisions in *Polo Lauren* and *Rolex*, the CJEU ruled in *Class International*, *Montex* and in *Philips/Nokia* that intellectual property owners could no longer rely on Union trademark and customs laws to demand seizure of counterfeit and pirated goods in transit unless there was clear evidence of a substantial risk of diversion onto the EU market.
- 28 Schneider M & Vrins O, Regulation (EC) 1383/2003, in *Enforcement of Intellectual Property Rights Through Border Measures: Law and Practice in the EU*, edited by O Vrins & M Schneider, 2nd edition (Oxford University Press), 2012, p. 159.
- 29 Micara A G, Court of Justice balances IP rights and international trade, *Journal of Intellectual Property Law & Practice*, 7 (4) (2012) 239-241.
- 30 Joined cases C-446/09 and C-495/09, *Philips and Nokia* at para 57.
- 31 De Meyer C and Gommers C, Urgent memo to the EU: Don't let transit be a safe harbour, *Journal of Intellectual Property Law & Practice*, 7 (5) (2012) 346-349.
- 32 De Meyer C and Gommers C, Urgent memo to the EU: Don't let transit be a safe harbour, *Journal of Intellectual Property Law & Practice*, 7 (5) (2012) 349.
- 33 Abbott F M, Seizure of generic pharmaceuticals in transit based on allegations of patent infringement: A threat to international trade, development and public welfare, *World Intellectual Property Organization Journal*, 1 (2009) 45-6.
- 34 Joined cases C-446/09 and C-495/09, *Philips and Nokia* at para 64.
- 35 See European Parliament legislative resolution of 3 July 2012 on the proposal for a regulation of the European Parliament and of the Council concerning customs enforcement of intellectual property rights [COM (2011) 0285 – C7-0139/2011 – 2011/0137(COD)] (Amendment 52).
- 36 European Commission COM (2013) 161 final; European Commission COM (2013) 162 final.
- 37 Ruse-Khan H G, A trade agreement creating barriers to international trade?: ACTA border measures and goods in transit, *American University International Law Review* 26 (3) (2011) 674.
- 38 Recital 20 of the proposed EU Trademark Regulation.
- 39 See Schneider M & Vrins O, Regulation (EC) 1383/2003, in *Enforcement of Intellectual Property Rights Through Border Measures: Law and Practice in the EU*, edited by O Vrins & M Schneider, 2nd edition (Oxford University Press), 2012, p. 119.
- 40 The economic consequences of counterfeiting (OECD, France), 1998, p. 5-6, <http://www.oecd.org/sti/ind/2090589.pdf> (accessed 9 August 2014).
- 41 Acquah D, Extending the limits of protection of pharmaceutical patents and data outside the EU – Is there a

- need to rebalance?, *IIC International Review of Intellectual Property and Competition Law*, 45 (3) (2014) 256-283. (Noting that the TRIPS Article 51 (footnote 14), and WHO all define counterfeits to cover trademark infringements. It should however be noted that Article 2 of the EU Border Measures Regulation extend the definition of goods infringing an intellectual property rights to cover a broad range of intellectual property including patents, supplementary protection certificates etc., and those protected in the Member State of action.
- 42 International Nonproprietary Names (INN), also known as a generic name, identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognised and is public property. As unique names, INN have to be distinctive in sound and spelling, and should not be liable to confusion with other names in common use. To make INN universally available they are formally placed by WHO in the public domain, hence their designation as “nonproprietary”. They can be used without any restriction whatsoever to identify pharmaceutical substances.
- 43 See <http://www.who.int/medicines/services/inn/innquidance/en/> (accessed 9 August 2014).
- 44 Simoons S & De Coster S, Sustaining generic medicines markets in Europe, *Journal of Generic Medicines*, 3 (4) (2006) 262.
- 45 The Doha Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference Declaration of 14 November 2001, WT/MIN(01)/DEC/2 World Trade Organization.
- 46 See European Parliament legislative resolution of 25 February 2014 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 207/2009 on the Community trade mark (COM(2013)0161 – C7-0087/2013 – 2013/0088(COD)) (Ordinary legislative procedure: first reading), (Amendment 115, Recital 18).
- 47 Who’s driving the agenda at the DG Enterprise and Industry? The dominance of corporate lobbyist in DG Enterprises Expert Group, Alliance for Lobbying Transparency and Ethics Regulation (ALTER-EU), July 2012, http://www.alter-eu.org/sites/default/files/documents/DGENTR-driving_0.pdf. Further corroborating this claim is the more recent report, A year of broken promises: Big business still put in charge of EU expert groups, despite commitment to reform, ALTER-EU, November 2013. Also see Europe Inc. in crisis – The EU’s alliance with big business is dead-end, Corporate Europe Observatory, 16 April 2014, <http://corporateeurope.org/lobbycracy/2012/04/europe-inc-crisis-eus-alliance-big-business-dead-end> (accessed 8 August 2014).
- 48 See Committee on Legal Affairs: Report on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 207/2009 on the Community trademark [COM (2013)0161 – C7-0087/2013 – 2013/0088 (COD)], 12 February 2014 (Amendment 28, Article 9).
- 49 COM (2013)0161 – C7-0087/2013 – 2013/0088 (COD) (Amendment 28 and 116).
- 50 The WTO system essentially binds governments to keep their trade policies within agreed limits to everybody’s benefit. It is therefore telling that the EU as a signatory to the WTO Agreements would possibly come up with a law that would seemingly contradict the freedom of transit. Indeed, the GATT Article XX(d) permits exception for rules on customs enforcement, the protection of patents, trademarks and copyrights, and the prevention of deceptive practices but only when such rules “are not inconsistent with the provisions of this Agreement”. Equally, the TRIPS Article 51 requires WTO Members to adopt procedures permitting intellectual property owners to prevent counterfeit trademark and pirated copyright goods from entering national markets through detention at the border and notification by customs authorities but does not extend to goods in transit.
- 51 Vrins O, European Commission’s proposal for a regulation concerning customs enforcement of IP rights, *Journal of Intellectual Property Law & Practice*, 6 (11) (2011) 774.
- 52 Europe Inc. in crisis – The EU’s alliance with big business is dead-end, Corporate Europe Observatory, 16 April 2014, <http://corporateeurope.org/lobbycracy/2012/04/europe-inc-crisis-eus-alliance-big-business-dead-end>, p.1-2 (accessed 8 August 2014).