

# Enforcing Patent Rights against Goods in Transit: A New Threat to Transborder Trade in Generic Medicines

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'IP rights – especially patents – are tools for economic advancement that should contribute to the enrichment of society through (i) the widest possible availability of new and useful goods, services and technical information that derive from inventive activity, and (ii) the highest possible level of economic activity based on the production, circulation and further development of such goods, services and information.'<sup>1</sup>

## 1 Introduction

Intellectual property (IP) protection has critical consequences for transnational trade in generic medicines, one of South Africa's most important imports. The free transit of generic medicines, unhindered by patent claims, is essential for their importation into South Africa where they will be deployed to prolong or save lives. This article will discuss the import of using Council Regulation (EC) No 1383/2003<sup>2</sup> to halt the transit of generic medicines en route to developing countries. Dutch customs authorities have done this on several occasions, eg, in February 2009. Such action forces importing and exporting states to find alternative routes that may be more expensive and take longer than a route that traverses Dutch ports. Such a situation would obviously be contrary to the freedom of transit provided for by art 5 of the General Agreement on Tariffs and Trade (GATT).<sup>3</sup> Secondly, when consignments of medication do not reach their destinations, lives may be lost. This reverses the gains of the major battles won in South Africa and other developing countries to improve access to generic medicines. Thirdly, using patents to block, or delay, the provision of generic medication to ill people is unacceptable, because it violates the very foundations of, or justifications for, patent law. As shown by the quotation above, patents are intended to secure the public good, by enabling the production of, and trade in, useful goods.

This article is in seven sections, this introduction being the first. The second

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<sup>1</sup> Graham Dutfield *Intellectual Property Rights and the Life Science Industries* (2003) at 27.

<sup>2</sup> 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, (2003) OJ L 196/7.

<sup>3</sup> General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, The legal texts: the results of the Uruguay round of multilateral trade negotiations 17 (1999), 1867 UNTS 187, 33 ILM 1153 (1994).

section will define generic medicines and discuss patent infringement issues and counterfeit medication. It will also comment briefly on the manufacture and importation of generic medicines. The third section will then outline the provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights, including trade in Counterfeit Goods (TRIPS)<sup>4</sup> that enable the production of, and transborder trade in, generic medicines. The fourth section will briefly explain parallel importation and its significance to the provision of low-cost medicines. Both the third and fourth sections will outline the South African position. Section five will recount two recent seizures. Section six will discuss the legality of the seizures under TRIPS, the EU Regulations and art 5 of GATT. This part will also describe how the affected states are trying to resolve the impasse raised by the seizures. The seventh and final section will conclude the paper by reiterating the unlawfulness of the Dutch customs authorities' action and commenting on the significance of the seizures.

## 2 Generic Medicines

The definition of generic medicines is imprecise because it is both a commercial and a legal concept.<sup>5</sup> Further, TRIPS does not provide a definition. The European Generic Medicines Associations defines generics as follows:<sup>6</sup>

'A generic medicine contains the same active medicinal substance as an originator pharmaceutical product. Because it acts in the same way in the human body, it is interchangeable with the originator product'.

South Africa has a legislative definition in s 1 of the Medicines and Related Substances Act 101 of 1965, which refers to generic medicines as an 'interchangeable multi-source medicine'. It provides:

“‘interchangeable multi-source medicine’ means medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed’.

Regulations promulgated under this Act amplify this definition by providing:<sup>7</sup>

'2 (1) A medicine is considered therapeutically equivalent to another medicine if both medicines –

- (a) are pharmaceutically equivalent, i.e., contain the same amount of active substances in the same dosage form, meet the same or comparable standards and are intended to be administered by the same route; and
- (b) after administration in the same molar dose, their effects with respect to both efficacy and safety are essentially the same.

<sup>4</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights including Trade in Counterfeit Goods, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, 33 ILM 1125, 1197 ('the TRIPS Agreement').

<sup>5</sup> Livio Garattini & Fabrizio Tediosi 'A Comparative Analysis of Generics Markets in Five European Countries' (2000) 53 *Health Policy* 149 at 150.

<sup>6</sup> European Generic Medicines Association 'What Exactly Is a Generic Medicine?', available at <http://www.egagenerics.com/FAQ-generics.htm> (visited on 18 August 2009).

<sup>7</sup> Regulation 2 of the General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act Number 101 of 1965), GNR510 of 10 April 2003.

(2) Therapeutic equivalence is determined from comparative bioavailability, pharmacodynamic, clinical or *in vitro* studies which meet the requirements and accepted criteria for bioequivalence as determined by the Council.’

The concept of generic medicines raises two important issues: patent infringement and the production of harmful counterfeit medicines. I will briefly discuss these two issues in turn.

## 2.1 Patent Infringement

Generic medication can be produced in three distinct circumstances. First, generic medicine can be ‘manufactured without a licence from the innovating company and marketed after expiry of [the] patent’<sup>8</sup> over the original medicine. The manufacture of generics in this case would not infringe any patent rights because the relevant patent over the original medicine would have expired.

Secondly, generic medicines may be produced, marketed and distributed in a country where a patent was not obtained over the original brand name medication in the first place. This is distinct from the first scenario where there would have originally been a patent that had expired. In either case, there would be no patent infringement issues because there would be no patent rights over the original medicine in that jurisdiction at the time that generics would be manufactured.

Thirdly, generics can be manufactured, marketed and sold during the subsistence of the patent on the original pharmaceutical product under compulsory licences granted by the state.<sup>9</sup> There would be no patent infringement in this scenario because the generics would be lawfully produced, marketed and distributed under compulsory licence during the subsistence of the patent. Subsequent sections will outline the conditions under which compulsory licences can be granted.

## 2.2 Counterfeit Medication

It is important to stress that generic medication is not harmful or counterfeit. Counterfeit medication is ‘a medicine in respect of which a false representation has been made with regard to its contents, identity or source by any means including its labelling and packaging’.<sup>10</sup> Generic medication is produced under strictly controlled scientific conditions according to the same specifications as the brand name medication to which it is therapeutically equivalent. It is then often marketed and sold under the name of the active ingredient. In some cases, the World Health Organisation prequalifies generic medication. This is essentially a confirmation of the medication’s status as

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<sup>8</sup> Garattini & Tediosi op cit note 6 at 150.

<sup>9</sup> See WTO News Press/350/Rev.1 ‘Decision Removes Final Patent Obstacle to Cheap Drug Imports’, available at [http://www.wto.int/english/news\\_e/pres03\\_e/pr350\\_e.htm](http://www.wto.int/english/news_e/pres03_e/pr350_e.htm) (visited on 10 April 2010).

<sup>10</sup> Regulation 1 sv ‘counterfeit medicine’ of the General Regulations made in terms of the Medicines and Related Substances Act, 1965.

proper and safe off-patent medication. However, some unscrupulous people and companies do manufacture and sell counterfeit medication that does not meet proper pharmaceutical specifications. Therefore, care has to be taken, and most countries require the registration of generic medication to ensure that counterfeits are rooted out.

## 2.3 Manufacture and Importation

Generics are an important tool in developing countries' fight against diseases such as hypertension and HIV/AIDS, because they are significantly cheaper than patented pharmaceuticals.<sup>11</sup> For example, generics produced in India are reported to have reduced the cost of first line anti-retroviral (ARV) medication by 98 per cent.<sup>12</sup>

Unfortunately, only a few developing countries have the capacity to manufacture their own generics.<sup>13</sup> Of these, Brazil, India and Thailand have the largest generic manufacturing capacity.<sup>14</sup> Other developing countries such as South Africa have to rely on imports from India, Brazil and Thailand to meet their citizens' needs for generics. Most of this demand is met by India, the 'world's leading supplier of generic medicines'.<sup>15</sup> Trade and transit laws are thus of crucial importance, for they regulate the importation, exportation and transit of generics. I will first outline the provision for the manufacture of generics under TRIPS. Then I will discuss art 5 of GATT, which regulates the transit of goods between member states of the World Trade Organisation (WTO), and also the EU Regulations.

## 3 Intellectual Property Rights and Generic Medicine

The TRIPS Agreement is an annexure to the Agreement Establishing the WTO. Therefore it binds all member states of the WTO.<sup>16</sup> Articles 9 to 40 of the TRIPS Agreement provide for minimum standards of IP protection. Of these, arts 27 to 34 provide for patent protection. Pharmaceuticals are eligible for patent protection under art 27(1).<sup>17</sup> However, member states are permitted

<sup>11</sup> Frederick M Abbot 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 *Journal of International Economic Law* 469 at 472.

<sup>12</sup> Di McIntyre & Gavin Mooney (eds) *The Economics of Health Equity* (2007) at 259.

<sup>13</sup> Alexander Irwin, Joyce Millen & Dorothy Fallows *Global AIDS: Myths and Facts: Tools for Fighting the AIDS Pandemic* (2003) at 117.

<sup>14</sup> Nana K Poku, Alan Whiteside & Bjorg Sandkjaer *AIDS and Governance* (2007) at 206-7; Benjamin Coriat (ed) *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (2008) at 33-4.

<sup>15</sup> McIntyre & Mooney op cit note 12 at 259.

<sup>16</sup> WR Cornish & David Llewelyn *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* 6 ed (2007) at 29. As at 23 July 2008, the WTO had 153 members (see the World Trade Organisation *Understanding the WTO*, available at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/tif\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/tif_e.htm) (visited on 8 July 2009) at 112).

<sup>17</sup> Article 27(1) provides:

'Subject to the provisions of paragraphs 2 and 3, patents shall be available for *any inventions, whether products or processes, in all fields of technology*, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent

to provide for exclusions to patentability on the grounds of, among other things, protection of ordre public or morality and protecting human life.<sup>18</sup> These grounds could possibly be used to exclude the patentability of some pharmaceutical products. Further, there are flexibilities in TRIPS with regard to when developing and least-developed states would be obliged to provide patent protection for pharmaceuticals.<sup>19</sup> However, these exclusions and flexibilities are not relevant to South Africa because patent protection for pharmaceuticals was already provided for in South Africa when we acceded to TRIPS and it entered into force.

Patent rights for pharmaceuticals, and any other patented processes or products, are not absolute and are subject to three limitations.<sup>20</sup> These are:

- exceptions under art 30;
- compulsory licences under art 31; and
- action against anti-competitive practices under art 40.

Each of these limitations is outlined below with an explanation of how they enhance access to medication.

### 3.1 National Exceptions under Art 30

Article 30 provides that member states may provide for limitations under their national laws as long as such exceptions ‘do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties’. In *Canada – Patent Protection of Pharmaceutical Products*, the WTO Panel found that this exception enabled member states to allow third parties to use patented pharmaceutical products without licence from the owner during the subsistence of the relevant patent to gain health regulatory approval for their generic versions of that product.<sup>21</sup> In some jurisdictions, such ‘Bolar’ provisions are accompanied by the extension of patent terms for the original medicines.<sup>22</sup> However, such an extension of patent terms is not mandatory.<sup>23</sup> Secondly, the panel found that the ‘stockpiling’ of patented pharmaceuticals before the relevant patents expired was unacceptable. Obviously, if allowed, this would have been an important

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rights enjoyable *without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced*’ (emphasis supplied).

<sup>18</sup> Article 27(2).

<sup>19</sup> Initially, developing countries were given until 1 January 2000 to provide patent protection for pharmaceuticals, which was extended to 1 January 2005, and least developed countries were initially given until 1 January 2006, which was extended to 1 January 2016 (Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-developed Country Members for Certain Obligations with Respect to Pharmaceutical Products 27 June 2002).

<sup>20</sup> WTO ‘Pharmaceutical Patents and the TRIPS Agreement’ (TRIPS: Drug patents, technical note) (21 September 2006), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/pharma\\_ato186\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm) (visited on 8 July 2009).

<sup>21</sup> *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel adopted on April 7, 2000 (WT/DS114/R, of March 17, 2000).

<sup>22</sup> David Vaver (ed) *Intellectual Property Rights: Critical Concepts in Law* (2006) at 406.

<sup>23</sup> *Idem* at 407.

tool for those countries seeking to build reserves of medicines for distribution after the expiry of relevant patents. This ruling has therefore been criticised for not being progressive enough and failing to achieve a fair balance between the users of medicines and patent holders.<sup>24</sup>

Bolar provisions were incorporated into South Africa's domestic law through an amendment of the Patents Act 57 of 1978 in 2002. This amendment inserted s 69A on acts of non-infringement into the Act, which states:

- (1) It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a **non-commercial scale** and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.
- (2) It shall not be permitted to possess the patented invention made, used, imported or acquired in terms of subsection (1) for any purpose other than for the obtaining, development or submission of information as contemplated in that subsection.'

Clearly, this section complies with TRIPS because it enacts provisions that the WTO dispute settlement panel found acceptable.

### 3.2 Compulsory Licences under Art 31

Compulsory licensing is currently provided for by art 31 and the 2003 Doha Decision on the implementation of par 6 of the Doha Declaration ('the Waiver Decision').<sup>25</sup> Article 31 was amended in 2005 by the introduction of art 31bis,<sup>26</sup> which effectively incorporates the Waiver Decision into TRIPS. However, this amendment has not yet come into force, and the Waiver Decision will be effective until it comes into force. The amendment will come into force after acceptance by two-thirds of the WTO member states. The initial deadline for such acceptance was 1 December 2007, but the Council Decision of 18 December 2007 extended it to 31 December 2009.<sup>27</sup> On 17 December 2009, the deadline was again extended to 31 December 2011.<sup>28</sup>

Article 31 allows member states to provide for compulsory licences in their domestic legislation. The grounds on which compulsory licences are to be granted are left to the member states to decide. However, art 31 stipulates that twelve provisions have to be 'respected' before compulsory licences can be validly granted. For example, art 31(h) provides that satisfactory remuneration must be paid to the patent-holder paying consideration to the 'economic value of the license'. Article 31(f) provides that use of the medicines manufactured

<sup>24</sup> Robert Howse *The WTO System: Law, Politics & Legitimacy* (2007) at 295; Justin Malbon & Charles Lawson *Interpreting and Implementing the TRIPS Agreement: Is It Fair?* (2008) at 14.

<sup>25</sup> Doc. WT/L/540 and Corr.1 (1 September 2003).

<sup>26</sup> Amendment of the TRIPS Agreement, General Council Decision (6 December 2005), Doc. WT/L/641 (8 December 2005).

<sup>27</sup> Amendment of the TRIPS Agreement – extension of the period for the acceptance by members of the protocol amending the TRIPS Agreement, Decision of 18 December 2007, Doc. WT/L/711 (21 December 2007).

<sup>28</sup> Amendment of the TRIPS Agreement – second extension of the period for the acceptance by members of the protocol amending the TRIPS Agreement, Decision of 17 December 2009, WT/L/785 (18 December 2009).

under compulsory licence shall be ‘predominantly for the supply of the domestic market’. Article 31(f) prevents countries with the capacity to make generics under compulsory licences from exporting a significant amount of those generics to other countries. This is obviously to the detriment of countries with little or no pharmaceutical manufacturing capacity, because it places limits on the amounts of generics that they can import from countries with manufacturing capacity. Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health directed the Council for TRIPS to resolve this problematic position speedily.<sup>29</sup> The Council’s solution to this problem was the 2003 Waiver Decision, the ‘paragraph 6 solution’ which in essence was a rule-based waiver of the art 31(f) requirement.<sup>30</sup> It removed the limits on exports under compulsory licence to member states with limited pharmaceutical products manufacturing capacity, provided that member states met certain conditions. For example, both the exporting and importing countries have to issue compulsory licences and advise the TRIPS Council of the import and export.<sup>31</sup>

I will not engage in a full-scale analysis of the Waiver Decision and art 31 but will simply make a few comments about their substantive provisions and some practical issues.<sup>32</sup> The WTO hails the Waiver Decision and its incorporation into TRIPS as art 31bis by the 2005 amendment as laudable and has reaffirmed its commitment to them.<sup>33</sup> However, there has been a much more sceptical response to these developments by scholars and non-governmental organisations. In particular, the rule-based waiver provided for by the Waiver Decision and art 31bis has been criticised for being too complex and thus unworkable.<sup>34</sup> History shows that it is in fact unworkable because to date only one WTO member state, Rwanda, has used it and notified its intention to import generics.<sup>35</sup> The main impediment to using the

<sup>29</sup> Declaration on the TRIPS Agreement and Public Health (14 November 2001), Doc. WT/MIN(01)/DEC/2 (20 November 2001).

<sup>30</sup> Peter Drahos ‘Four Lessons for Developing Countries from the Trade Negotiations Over Access to Medicines’ (2007) 28 *Liverpool LR* 11 at 12-3.

<sup>31</sup> Gabriel L Slater ‘The Suspension of Intellectual Property Obligations Under TRIPS: A Proposal for Retaliating Against Technology-Exporting Countries in the World Trade Organization’ (2009) 97 *Georgetown LJ* 1365 at 1394.

<sup>32</sup> For a comprehensive analysis of art 31bis, see Senai W Andemariam ‘The Cleft-stick Between Anti Retroviral Drug Patents and HIV/AIDS Victims: An In-Depth Analysis of the WTO’s TRIPS Article 31 bis Amendment Proposal of 6 December 2005’ (2007) 4 *Intellectual Property Quarterly* 414; Frederick M Abbott & Jerome H Reichman ‘The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS provisions’ (2007) 10 *Journal of International Economic Law* 921; Kevin Outterson ‘Disease-Based Limitations on Compulsory Licenses Under Articles 31 and 31bis’ Boston University School of Law Working Paper No. 09-26 (May 20, 2009), available at <http://ssrn.com/abstract=1407522> (visited on 18 July 2009) (to appear in Carlos Correa (ed) *Research Handbook on Intellectual Property Law and the WTO* pending June 2010).

<sup>33</sup> Paragraph 40, Ministerial Declaration, Sixth Session Hong Kong (18 December 2005) Doc. WT/MIN(05)/DEC (22 December 2005).

<sup>34</sup> Drahos op cit note 25 at 20-2; Solomon Frank Sacco ‘A Comparative Study of the Implementation in Zimbabwe and South Africa of the International Law Rules That Allow Compulsory Licensing and Parallel Importation for HIV/AIDS Drugs’ (2005) 5 *African Human Rights LJ* 105 at 114.

<sup>35</sup> The World Trade Organisation reports that only one notification to use the system has been made to date. See WTO ‘TRIPS and Public Health: Dedicated Webpage for Notifications’, available at

paragraph 6 solution is the administrative procedures to be followed by the importing and exporting states. However, it has been argued that ‘article 31*bis* can be made functional, even if imperfectly, through a combination of political will, good lawyering, financial support for appropriate implementation efforts and collective action’.<sup>36</sup> Another criticism is that there was a better, simpler and therefore more suitable solution that could have been crafted under art 30.<sup>37</sup>

### 3.2.1 Compulsory Licensing of Pharmaceuticals in South Africa

Although the Patents Act provides for compulsory licences, South Africa has so far not issued any compulsory licences to permit the production of patented pharmaceuticals.<sup>38</sup> Section 56(1) of the Patents Act provides that ‘any interested person who can show that the rights in a patent are being abused may apply to the commissioner in the prescribed manner for a compulsory licence under the patent’. The Patents Act provides that the rights in a patent shall be deemed to be abused if:

- ‘the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the commissioner no satisfactory reason for such non-working’;<sup>39</sup>
- ‘the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms’;<sup>40</sup>
- ‘by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being

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[http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm) (visited on 9 July 2009); Council for Trade-Related Aspects of Intellectual Property Rights – Notification under paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – Rwanda Doc. IP/N/9/RWA/1.

<sup>36</sup> Frederick M Abbott & Jerome H Reichman ‘Strategies for the Protection and Promotion of Public Health Arising Out of the WTO TRIPS Agreement Amendment Process’ Contributions to the WHO Second Public Hearing – Section 1, Draft Global Strategy and Plan of Action, available at [http://www.who.int/phi/public\\_hearings/second/contributions\\_section1/Section1\\_Abbott&Reichman.pdf](http://www.who.int/phi/public_hearings/second/contributions_section1/Section1_Abbott&Reichman.pdf) (visited on 18 August 2009).

<sup>37</sup> Drahos op cit note 25 at 21; Frederick M Abbott ‘The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health’ (2005) 99 *American Journal of International Law* 317 at 338; Duncan Matthews ‘WTO Decision On Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?’ (2004) 7 *Journal of International Economic Law* 73 at 88-92.

<sup>38</sup> Sacco op cit note 29 at 117.

<sup>39</sup> Section 56(2)(a).

<sup>40</sup> Section 56(2)(c).



prejudiced, and it is in the public interest that a licence or licences should be granted’;<sup>41</sup> or

- ‘the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under licence from the patentee or his predecessor or successor in title’.<sup>42</sup>

Such an application may be opposed by the patentee or any other interested person.<sup>43</sup>

If the application is successful, a compulsory licence will be issued. Conditions<sup>44</sup> may be attached to the licence at the discretion of the commissioner, ‘including a condition precluding the licensee from importing into the Republic any patented articles’.<sup>45</sup>

Further, such licences must

- ‘include a provision that, subject to adequate protection of the legitimate interests of the licensee, the licence shall, on application by the patentee, be terminated if the circumstances which led to its grant cease to exist and, in the opinion of the commissioner, are unlikely to recur’;<sup>46</sup>
- ‘be non-exclusive and shall not be transferable except to a person to whom the business or part of the business in connection with which the rights under the licence were exercised has been transferred’.<sup>47</sup>

These licences are also subject to amendment or revocation.<sup>48</sup> These provisions were introduced into the Patents Act in 1997 to ensure compliance with art 31 of TRIPS.

### 3.3 Action against Anti-Competitive Practices under Art 40

The third limitation of patent rights is that members have leeway to take suitable action against anti-competitive practices under art 40. One way to correct the harm wrought by anti-competitive practices would be to grant compulsory licences, in which case the art 31 provisions are relaxed.<sup>49</sup> A

<sup>41</sup> Section 56(2)(d).

<sup>42</sup> Section 56(2)(e).

<sup>43</sup> Section 56(3).

<sup>44</sup> Section 56(7) provides:

‘In determining the conditions on which any licence is granted the commissioner shall have regard to any relevant facts, including the risks to be undertaken by the licensee, the research and development undertaken by the patentee and the terms and conditions usually stipulated in licence agreements in respect of the subject-matter of the invention, between persons who voluntarily enter into such agreements’.

<sup>45</sup> Section 56(4)(a).

<sup>46</sup> Section 56(4)(c).

<sup>47</sup> Section 56(5).

<sup>48</sup> Section 56(9).

<sup>49</sup> Article 31(k) provides that in such circumstances a member state does not have to respect the art 31(b) requirement that there should have been attempts to secure a voluntary licence on reasonable commercial terms and the art 31(f) requirement that use of the generics manufactured under compulsory licence should be predominantly for domestic needs.

second way to remedy such harm is to subject the perpetrators to the competition-law system. South Africa's competition-law regime is based on the Competition Act 89 of 1998, and its administrative and adjudicatory bodies are the Competition Commission, the Competition Tribunal and the Competition Appeal Court. Appeals from the Competition Appeal Court lie to the Supreme Court of Appeal. There has not been a ruling from the Competition Tribunal or the Competition Appeal Court on anti-competitive practices by pharmaceutical companies with respect to ARVs. However, in 2002 the Treatment Action Campaign (TAC) and others laid a complaint of 'unlawfully fixing excessive prices' for ARVs against GlaxoSmithKline and Boehringer-Ingelheim.<sup>50</sup> After an extensive investigation, the Competition Commission found that the pharmaceutical companies had contravened the competition legislation and that there were grounds for referral to the Competition Tribunal.<sup>51</sup> However, the complainants opted for a settlement with the pharmaceutical companies that included their issuance of voluntary licences to generic companies. This was because the complainants believed that this step would facilitate the provision of cheaper medicines more speedily than would continuing with proceedings before the Tribunal.<sup>52</sup> What this has shown is that the Competition Commission is both willing and able to investigate complaints against pharmaceutical manufacturers. As shown by the above facts, this encourages manufacturers to be more enthusiastic and sincere about issuing voluntary licences.

#### 4 Exhaustion of Rights and Parallel Importation

Parallel importation is another alternative to brand name medication. It is best explained by example. Suppose that there is a patent over brand name medication X in state A where it sells at \$100 per capsule, but that the same medication is available in state B at half price. State A would then buy medication X from state B and import it into its territory without getting permission or a licence from the patent holder in state A.<sup>53</sup>

Article 6 provides that a member state's exhaustion of IP rights regime is not contestable under the WTO Dispute settlement system.<sup>54</sup> Paragraph 5(d) of the Doha Declaration further provides: 'The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such

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<sup>50</sup> Edwin Cameron *Witness to AIDS* (2005) at 179-82; Brook K Baker 'Threat of Compulsory Licenses at the South African Competition Commission Results in Generic Licenses for AIDS Medicines' Health Global Access Project ('GAP') Briefing Paper (10 December 2003), available at [http://www.healthgap.org/press\\_releases/03/121003\\_HGAP\\_BP\\_RSA\\_Comp\\_Com.html](http://www.healthgap.org/press_releases/03/121003_HGAP_BP_RSA_Comp_Com.html) (visited on 9 July 2009).

<sup>51</sup> *Ibid.*

<sup>52</sup> *Ibid.*

<sup>53</sup> Nunn op cit note 34 at 119 note 1 defines parallel importation as follows: 'Parallel importation occurs when patented drugs are produced and sold in one market and then imported into a second market without authorisation of the patent holder in the second market.'

<sup>54</sup> For a commentary on the background to this article, see Vaver op cit note 22 at 110.

exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.’

This flexibility is important because a member state’s exhaustion rules will determine whether it can legally engage in parallel importation of patented medicines where these are available in other countries (where they are also patented) at a cheaper price. A member state may adopt national, regional or international exhaustion.<sup>55</sup> The principle of exhaustion means that once the patented goods are sold, they may then be traded elsewhere, because the patent holder’s rights would have been exhausted by the first sale.<sup>56</sup> However, it is important to note that the patent holder does not lose the right to object to the unauthorised production of the medicine.<sup>57</sup> Under a national exhaustion regime, that first sale needs to be within that country. Under a regional exhaustion regime, it needs to be within that region and under an international exhaustion regime it can occur in any part of the world. An international exhaustion regime is most conducive to parallel importation.

#### 4.1 Parallel Importation of Pharmaceuticals in South Africa

Parallel importation is permitted by s 15C of the Medicines and Related Substances Act, which provides:

**‘15C. Measures to ensure supply of more affordable medicines**

‘The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-

- (a) notwithstanding anything to the contrary contained in the Patents Act 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
- (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;
- (c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).’

The introduction of this section in 1997 was hotly contested and there was intense lobbying and action by civil society.<sup>58</sup> The Pharmaceutical Manufacturers Association of South Africa (PMASA) opposed this amendment by launching litigation in 1998. Further, the United States of America and the European Union threatened trade sanctions against South Africa.<sup>59</sup> Further

<sup>55</sup> Peter K Yu *Intellectual Property and Information Wealth: Issues and Practices in the Digital Age* (2007) at 120; Nuno Pires de Carvalho *The TRIPS Regime of Patent Rights* (2005) 108 at 112.

<sup>56</sup> Ben Kiromba Twinomugisha ‘Implications of the TRIPS Agreement for the Protection of the Right to Access to Medicines in Uganda’ (2008) 2 *Malawi LJ* 253 at 264-5.

<sup>57</sup> Nuno Pires de Carvalho op cit note 55 at 108.

<sup>58</sup> Nunn op cit note 34 at 119-20; Ellen ’t Hoen ‘TRIPS, Pharmaceuticals Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha’ in: Sofia Gruskin, Michael A Grodin, Stephen P Marks, George J Annas *Perspectives on Health and Human Rights* (2005) at 206; Irwin, Millen & Fallows op cit note 13 at 126-7; Kavaljit Singh ‘Patents vs. Patients: AIDS, TNCs and Drug Price Wars’ Third World Network (TWN), available at <http://www.twinside.org.sg/title/twr131c.htm> (visited on 8 July 2009).

<sup>59</sup> Hoen op cit note 58 at 205-6.

details pertaining to the litigation and trade sanction threats will not be provided here, because they are adequately canvassed elsewhere.<sup>60</sup> Suffice to note that the litigation was withdrawn after a settlement agreement was reached between the parties.<sup>61</sup> The United States changed its stance after it signed an understanding with South Africa in terms of which South Africa stated that it would honour its TRIPS obligations.<sup>62</sup>

Section 15C finally entered into force on 2 May 2003. In the same year, regulations were issued to provide for parallel importation under the section.<sup>63</sup> These regulations define parallel importation as ‘the importation into the Republic of a medicine protected under patent and/or registered in the Republic that has been put onto the market outside the Republic by or with the consent of such patent holder’. A parallel importer must obtain a permit from the Minister of Health and the medicine to be imported must be registered.<sup>64</sup> Further, the medicine must be imported from a person licensed by a recognised regulatory authority.<sup>65</sup> In addition, since 2004 South Africa has issued pharmaceutical price regulations.<sup>66</sup>

## 5 The Seizures

There have been many seizures of consignments of generic medicines.<sup>67</sup> However, this section recounts two incidents. On 12 December 2008 Dutch customs authorities seized a consignment of Losartan-API, a generic medicine used to treat hypertension manufactured by Dr Reddy’s laboratories, which was on the way from India to Brazil. On its release the consignment was returned to India.<sup>68</sup> And in February 2009, Dutch customs authorities

<sup>60</sup> Sacco op cit note 29 at 118; Susan Cleary & Don Ross ‘The 1998-2001 Legal Struggle Between the South African Government and the International Pharmaceutical Industry: A Game-Theoretic Analysis’ (2002) 27 *Journal of Social, Political and Economic Studies* 445, also available at <http://www.uab.edu/philosophy/faculty/ross/AIDS%20paper.htm> (visited on 20 August 2009).

<sup>61</sup> Department of Health 2001 *Joint Statement of Understanding between the Republic of South Africa and the Applicants in the Matter between the Pharmaceutical Manufacturers’ Association of South Africa and Others and the President of the Republic of South Africa and Others*, available at <http://www.info.gov.za/speeches/2001/010426345p1003.htm> (visited on 21 August 2009).

<sup>62</sup> Department of Trade and Industry, 17 September 1999 *Joint Understanding between the Governments of South Africa and the United States of America*, available at <http://www.info.gov.za/speeches/1999/9909201219p1007.htm> (visited on 21 August 2009).

<sup>63</sup> Regulation 7 of the General Regulations made in terms of the Medicines and Related Substances Act op cit note 7.

<sup>64</sup> Regulation 7(1)(c)-(d).

<sup>65</sup> Regulation 7(1)(b).

<sup>66</sup> For a discussion of these regulations, see Kerry Williams ‘Pharmaceutical Price Regulation’ (2007) 23 *South African Journal on Human Rights* 1.

<sup>67</sup> Statement by Brazil at TRIPS Council: Public Health Dimension of TRIPS Agreement (3 March 2009), available at <http://keionline.org/blogs/2009/03/04/brazilian-intervention-at-trips-council> (visited on 23 June 2009).

<sup>68</sup> The Letter from 16 NGOs dated 18 February 2009 to Dr Margaret Chan, Director-General (DG) World Health Organisation, copied to Mr. Kunio Mikuriya, DG World Customs Organization, Mr. Francis Gurry, DG World Intellectual Property Organization and Mr. Pascal Lamy, DG World Trade Organization, available at [http://www.keionline.org/misc-docs/seizures/WHO\\_seizures\\_18feb.pdf](http://www.keionline.org/misc-docs/seizures/WHO_seizures_18feb.pdf) (hence ‘Letter to DG WHO’); CUTS Centre for International Trade, Economics and Environment (CITEE) Briefing Paper 4/2009; Sangeeta Shashikant ‘Developing Countries Attack Dutch Seizure of Generic Medicines’ Third World Network (TWN), available at [http://www.twinside.org.sg/title2/intellectual\\_property/info.service/2009/twn.ipr.info.090202.htm](http://www.twinside.org.sg/title2/intellectual_property/info.service/2009/twn.ipr.info.090202.htm) (all visited on 23 June 2009).

seized a consignment of abacavir sulphate tablets, a generic second-line antiretroviral (ARV) manufactured by Aurobindo that had obtained prequalification from the World Health Organisation (WHO), en route from India to Nigeria.<sup>69</sup> The consignment was bought by UNITAID for distribution in Nigeria by the Clinton Foundation. At the time of writing (May 2010) it is not clear what has become of the seized consignment, but it probably suffered the same fate as the Losartan-API consignment and was returned to India. No developments beyond the seizure have been reported. Whether the consignment eventually reaches Nigeria, the harm has been done. It is not difficult to imagine that some people may have died and others suffered unnecessarily while awaiting the arrival of the medication.

As was to be expected these seizures led to heated exchanges in various fora such as the European Parliament<sup>70</sup> and TRIPS council meetings.<sup>71</sup> The following section evaluates the legality of the seizures.

## 6 The Legality of the Seizures

Now I will examine the legality of the seizures under TRIPS, the EU Regulations and GATT. As is obvious from par 3 above, TRIPS enables the manufacture of, and trade in, generic medication. Further, art 51 note 13 provides that there is no obligation on member states to exercise border control measures against goods in transit. Border control measures (provided for in arts 51 to 61) enable member states to prevent the entry of counterfeit goods or infringing goods from entering their markets. These measures include the seizure, detention and even destruction of infringing goods. As the consignments seized by the Dutch customs authorities were not intended for the Dutch market, there was no justification for the seizures.

The EU regulations invoked by the Dutch customs authorities when they detained the consignments of generics en route to Brazil and Nigeria do not in fact allow their action. This is because the rules target ‘counterfeit goods’, ‘pirated goods’ and ‘goods which, in the member state in which the application for customs action is made, infringe a patent under that member state’s law’.<sup>72</sup> The medication in transit was none of these. Although it was reported that there is a patent over the medication in the Netherlands, the

<sup>69</sup> PlusNews ‘Nigeria: Seizure of Drug Shipment Threatens ARV Access’ (13 March 2009), available at <http://www.plusnews.org/report.aspx?ReportID=83459> (visited on 23 June 2009).

<sup>70</sup> EU Coherence ‘MEPs Ask Questions About Seizures of Generic Medicines on Their Way to Developing Countries’ (11 March 2009), available at [http://fairpolitics.nl/europa/cases/trips\\_and\\_medicines/2009\\_03\\_11\\_meps\\_ask\\_questions\\_about\\_seizures\\_of\\_generic\\_medicines\\_on\\_their\\_way\\_to\\_developing\\_countries](http://fairpolitics.nl/europa/cases/trips_and_medicines/2009_03_11_meps_ask_questions_about_seizures_of_generic_medicines_on_their_way_to_developing_countries).

<sup>71</sup> International Centre for Trade and Sustainable Development (ICTSD) ‘Fight over Generic Drug Seizure Takes Centre Stage at TRIPS Council Meeting’, available at <http://ictsd.net/i/news/bridgesweekly42823> (visited on 23 June 2009). The matter was again raised in council meetings held on 12 March 2010 (see WTO ‘Members Ask: Is the “Par.6” System on Intellectual Property and Health Working?’, available at [http://www.wto.org/english/news\\_e/news10\\_e/trip\\_02mar10\\_e.htm](http://www.wto.org/english/news_e/news10_e/trip_02mar10_e.htm) (visited on 14 May 2010)).

<sup>72</sup> Article 2(1).

medication in transit did not in fact infringe the rights of the Netherlands patent holder because they were not intended for the Netherlands market.<sup>73</sup>

Indeed, even the Dutch trade minister Frank Heemskerck has recently admitted that the effect of the EU regulations was less than ideal and said that the regulations would be reviewed.<sup>74</sup> This admission was probably prompted by the realisation that the effect of the customs authorities' action was counter to the position advanced by the WTO through the Doha Declaration and the other decisions outlined above. The admission also went against the grain of resolutions adopted by the European Parliament confirming the WTO position<sup>75</sup> and EC Regulations pertaining to the export of medicines manufactured under compulsory licences.<sup>76</sup>

Article 5 of GATT secures freedom of transit by, among other things, requiring member states to keep consignments in transit free from 'unnecessary delays or restrictions', customs and transit duties and to impose only reasonable charges for administrative costs and services.<sup>77</sup> In my view, the Dutch seizures of generics en route to Nigeria and Brazil fall foul of this provision because they were in fact merely unreasonable delays or restrictions. They were unreasonable because there was no legal justification for them. The goods had not entered Dutch territory, because they were in transit and there were no violations of IP laws in both the exporting and importing countries. The importing and exporting countries can therefore resort to the WTO dispute settlement system alleging violations of art 5.

It is difficult to assess the prospects of success of such action, as the dispute settlement panel has not addressed art 5 so far.<sup>78</sup> At the inception of this controversy it seemed unlikely that an art 5 dispute would be brought before the panel, because none other than the WTO's Director-General, Pascal Lamy, had pointed out that this remedy is not the most suitable. In a letter written in response to the letter sent to him by sixteen NGOs he wrote: 'I sense that at this stage Article 5 of the DSU concerning disputes is not of relevance in this case.'<sup>79</sup> Instead, he encouraged the affected member states to seek a resolution at the TRIPS Council and through bilateral negotiations. This amounted to confirmation of the appropriateness of civil society and developing states' attempts to bring intense political pressure to bear on the Dutch authorities. As

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<sup>73</sup> Shashikant op cit note 68 reports that DuPont holds the Dutch Patent over the brand name hypertension medication.

<sup>74</sup> Radhika Pandeya 'Dutch Minister Admits to Flaw in EC Rule' (10 February 2009), available at <http://www.nfia-india.com/nethnews.html?id=27> (visited on 13 July 2009).

<sup>75</sup> See, eg, the European Parliament resolution of 12 July 2007 on the TRIPS Agreement and access to medicines.

<sup>76</sup> Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. (2006) OJ L 157/1.

<sup>77</sup> For a commentary on this article, see Nora Neufeld 'Article V of the GATT 1994 – Scope and Application' WTO Secretariat Doc. G/C/W/408 (10 September 2002), available at <http://r0.unctad.org/tl/ppt-2004-11-24/wto.pdf> (visited on 9 July 2009).

<sup>78</sup> Idem at 7; WTO 'Index of Disputes Issues', available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_subjects\\_index\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm) (visited on 9 July 2009).

<sup>79</sup> Letter from Pascal Lamy dated 4 March 2009, available at <http://www.keionline.org/misc-docs/seizures/dglamyresponse.pdf> (visited on 14 May 2009).

mentioned already, civil society and the affected states have already raised the matter at the TRIPS Council and are harnessing the power of the media. Media reports on the matter have been scathing about the Dutch customs authorities' action.<sup>80</sup> This is a strategy that has worked effectively in South Africa in the past. Indeed, it has had some success with the admission by the Dutch Minister of Trade that the implementation of the regulations would be reconsidered. Despite these early indications that a formal dispute would not be instigated, on 12 May 2010 India and Brazil initiated the WTO dispute settlement process.<sup>81</sup> This was done by filing requests for consultations between India, Brazil, the EU and the Netherlands. These parties have 60 days, from the date of the requests, to meet and consult with one another. If the consultations do not render a solution acceptable to all the parties, a panel will be constituted to hear the dispute formally.<sup>82</sup> It could very well be that this request for consultations will spur on the negotiations between the parties and that resolution will be achieved before a panel is constituted.

## 7 Conclusion

In my view, the seizures are clearly unlawful, because they are in breach of TRIPS, the EU Regulations and art 5 of GATT. The disputes regarding the transit of generic medication show that there is some conflict between the implementation of the EU's regulations and the WTO's position with regard to the provision of generic medication to its member states. Fortunately, there has been some indication from the Dutch that the application of the regulations will be reconsidered and that they will be implemented in a manner consistent with the WTO-brokered system. Brazil and India have now demonstrated their intention to seek a legal solution by requesting consultations with the EU and the Netherlands. The full processes of the WTO's dispute settlement system will therefore be followed if a negotiated solution both bilaterally between the affected states and multilaterally at the TRIPS Council fails.

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<sup>80</sup> See, eg, PlusNews op cit note 69; David Cronin 'The Reek of Double Standards' *The Guardian*, UK (11 March 2009), available at <http://www.guardian.co.uk/commentisfree/2009/mar/10/drugs-trade-eu>; Andrew Jack, Frances Williams & Michael Steen 'Dutch Seizure of HIV Drugs Highlights Patent Friction' *Financial Times*, UK (5 March 2009), available at <http://www.ft.com/cms/s/0/0a0a0a9e-0928-11de-b8b0-0000779fd2ac.html> (visited on 14 May 2009).

<sup>81</sup> Jonathan Lynn 'India, Brazil Challenge EU at WTO Over Drugs' Alertnet, available at <http://www.alertnet.org/thenews/newsdesk/LDE64B1O6.htm>; *Wall Street Journal* 'Brazil Confirms WTO Consultations on EU Medication Seizures' (12 May 2010), available at [http://online.wsj.com/article/BT-CO-20100512-713129.html?mod=WSJ\\_World\\_MIDDLEHeadlinesAsia](http://online.wsj.com/article/BT-CO-20100512-713129.html?mod=WSJ_World_MIDDLEHeadlinesAsia) (visited on 14 May 2010).

<sup>82</sup> WTO 'Understanding the WTO: Settling Disputes: the Panel Process', available at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/disp2\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp2_e.htm) (visited on 14 May 2010).