

## **EXPERT REPORT RW (B)**

### **THE WORLD TRADE ORGANISATION'S AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY**

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The World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property (WTO's TRIPS) establishes minimum patent, copyright, trademark, geographical design, industrial design and trade secret protections which must be guaranteed by all member countries, including South Africa. Countries are free to provide intellectual property protections that exceed those mandated by TRIPS, but not less.

The WTO provides for enforcement of its rules through a dispute settlement process in which countries may file complaints against other countries they allege are violating obligations contained in WTO agreements, including the TRIPS agreement. After a period of consultation, complaints are brought to a dispute settlement panel, which hears arguments from the disputants, and issues a written decision. That decision may be appealed. Countries whose laws are successfully challenged at the WTO must change their laws to be compliant, or pay fines or accept trade sanctions. Countries that change their laws to become compliant do not face penalty.

#### **TRIPS Obligations and the Right to Compulsory Licensing**

TRIPS requires countries to provide patents on all inventions that are "new, involve an inventive step and are capable of industrial application." This obligation covers both products and processes, and applies to all fields of technology, including pharmaceuticals.<sup>1</sup> A patent confers exclusive rights on its holder to make, use, sell or import the patented product or to use a patented process.<sup>2</sup> TRIPS requires that patents extend for a minimum of 20 years after the date of filing.<sup>3</sup>

TRIPS also provides for certain limitations to patent rights, among them the right for countries to undertake compulsory licensing.<sup>4</sup> Compulsory licensing involves the

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<sup>1</sup> TRIPS Article 27.1

<sup>2</sup> TRIPS Article 28

<sup>3</sup> TRIPS Article 33

<sup>4</sup> TRIPS Article 31.

authorisation by a government for a third party to make use of a patent, without the consent of the patent holder.

Countries maintain complete flexibility under TRIPS to determine the circumstances under which compulsory licenses shall be issued, and all patent holders know that a condition of the patent grant is that it might be subjected to compulsory licensing, subject to national law.

It has often been reported that TRIPS makes compulsory licensing available only in cases of emergency, but this is incorrect. TRIPS states only that, in situations of emergency, countries are permitted to bypass the obligation to undertake negotiations for a voluntary license in advance of issuing a compulsory license.<sup>5</sup> The fact that TRIPS treats emergency situations as a special circumstance in which it permits derogation from normal procedural requirements for compulsory licensing confirms that the Agreement does not limit compulsory licensing to emergency situations.

Countries' complete flexibility to determine the grounds for issuance of a compulsory license was reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health, issued at the 2001 Ministerial held in Doha, Qatar. "Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted," the Declaration reiterated.<sup>6</sup>

### **Requirements for Compulsory Licensing**

While TRIPS does not impose limitations on the grounds for compulsory licensing, it does mandate that certain procedures be followed in consideration of compulsory license requests.

The key procedural requirements are that:

- \* Compulsory licensing requests be considered on their individual merits;<sup>7</sup>
- \* Consideration of compulsory licenses be preceded by efforts to negotiate voluntary licenses on reasonable commercial terms, and that such efforts have not been successful within a reasonable period of time;<sup>8</sup>
- \* Authorised use must be predominantly for the domestic market;<sup>9</sup>
- \* The right holder must be paid adequate remuneration;<sup>10</sup> and

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<sup>5</sup> TRIPS Article 31(b).

<sup>6</sup> Doha Declaration on the TRIPS Agreement and Public Health, Paragraph 5.

<sup>7</sup> TRIPS Article 31(a)

<sup>8</sup> TRIPS Article 31(b)

<sup>9</sup> TRIPS Article 31(f)

<sup>10</sup> TRIPS Article 31(h)

\* Both the decision to issue a compulsory license and the level of remuneration must be subject to judicial or administrative review.<sup>11</sup>

### **Compensation Rules in Compulsory Licensing Cases**

TRIPS rules themselves do not give guidance as to what constitutes "adequate remuneration." The upper bound of what constitutes "adequate remuneration" would be the lost profits of the patent holder, and some have advocated such a standard.<sup>12</sup> But this high end approach is illogical, for it eliminates the benefits of compulsory licensing and effectively makes the authority to issue compulsory licensing meaningless.<sup>13</sup> International experience in establishing royalty rates varies, with rates below 1 percent (and zero or negative in certain circumstances)<sup>14</sup> to as 22 percent or higher.

The UN Development Programme has recommended countries establish royalty guidelines for compulsory licensing of pharmaceuticals that presumptively set royalties at 4 percent, and then adjust them up or down slightly depending on the investment by the patent holder, innovativeness of the product, and other factors.

### **Enhanced Flexibility for Compulsory Licensing to Remedy Anti-Competitive Practices**

The TRIPS rules on compulsory licensing provide for special treatment of compulsory licenses issued to remedy anti-competitive practices. For compulsory licenses issued to remedy anti-competitive practices, countries maintain the flexibilities available for compulsory licensing generally -- meaning, among things, that they may define anti-competitive practices for which compulsory licensing is a presumptive or possible remedy as they see fit -- and also are permitted to relax certain procedural requirements.

There are three enhanced flexibilities for compulsory licensing to remedy anti-competitive practices.

First, it is not necessary that there have been a prior effort to negotiate voluntary licenses.<sup>15</sup>

Second, countries do not need to require that compulsory licenses issued to remedy anti-competitive practices be used predominantly for the domestic market.<sup>16</sup> This is important to give competitors the economies of scale necessary to make efficient use of a compulsory license and enter into meaningful competition with the patent holder.

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<sup>11</sup> TRIPS Article 31(i); TRIPS Article 31(j).

<sup>12</sup> Marty Adelman at the Bank, June 2, 2003.

<sup>13</sup> F. M. Scherer at the Bank, June 2, 2003.

<sup>14</sup> See below (competition section of TRIPS)

<sup>15</sup> TRIPS Article 31(k)

<sup>16</sup> TRIPS Article 31(k)

Third, "the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases."<sup>17</sup> This includes the option of zero-royalty licensing.

### **The TRIPS Agreement's Non-Discrimination Provision**

One particular issue raised by the TRIPS agreement is whether special rules can be crafted for pharmaceuticals. Article 27.1 of the Agreement specifies that, subject to certain qualifications not relevant here, "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."<sup>18</sup> The Article 27.1 non-discrimination provision means that countries are not free, say, to deny patents to inventions related to cellular telephones.

A consistently aggressive interpretation of this provision in all circumstances might bar countries from taking common-sense measures to address problems in particular areas of the economy. If Article 27.1 denied countries the ability to tailor limited exceptions to patent rights to meet special needs arising in particular fields of technology, countries would be required to impose overbroad exceptions on patent rights.

Confronted exactly with this problem, however, a WTO panel ruled that such an interpretation would be misguided.<sup>19</sup> While TRIPS prohibits discriminatory treatment of patents in a particular field of technology, the panel ruled, it permits "differentiation" -- differential treatment to address bona fide problems particular to certain fields of technology.

The EC-Canada patent dispute dealt with Canadian regulations that enabled generic pharmaceutical makers to make or import small amounts of patented products to get regulatory approval prior to patent expiry, and to begin stockpiling supplies before patent expiry for immediate sale at expiry. The WTO dispute settlement panel upheld Canada's regulatory review exception (often known as early working or the Bolar exception), but ruled the stockpiling exception to be a TRIPS violation.

In so doing, the panel addressed the EC's argument that Canada's regulations were TRIPS-invalid because they contradicted the Agreement's prohibition on discrimination by field of technology. It rejected this claim, stating that it was TRIPS-compliant for countries to craft rules specific to pharmaceuticals (or, more generally, particular fields of technology), if there was a bona fide reason to do so.

The panel held: "Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27

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<sup>17</sup> TRIPS Article 31(k)

<sup>18</sup> TRIPS Article 27.1

<sup>19</sup> Canada -- Patent Protection of Pharmaceutical Products -- Complaint by the European Union and their Member States, Report of the Panel, WT/DS114/R, 17 March 2000.

does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas."<sup>20</sup>

The Doha Declaration on the TRIPS Agreement and Public Health contains provisions specifically targeted to pharmaceuticals, and so the distinction between discrimination and differentiation is essential for the Doha Declaration to be compatible with TRIPS. Paragraph Six of the Doha Declaration obligated WTO members to craft a pharmaceutical-specific solution to the compulsory licensing problems faced by countries with markets too small to achieve economies of scale.<sup>21</sup>

Paragraph Seven of the Doha Declaration also specifically authorises differential treatment of pharmaceuticals, permitting Least-Developed Countries not to enforce patents on pharmaceuticals until 2016.<sup>22</sup> The Paragraph Seven non-enforcement provision is unique to pharmaceuticals; LDCs must enforce patents in other fields of technology.

In addition to the "early working" provisions that were in dispute in the EC-Canada case, numerous laws in industrialised countries which would otherwise appear to violate TRIPS' non-discrimination provision must also be justified as TRIPS-compatible on the basis that they are legitimate manifestations of the "differentiation" principle.

The French patent law provides for a compulsory licensing regime that is unique to pharmaceuticals.<sup>23</sup>

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<sup>20</sup> Canada -- Patent Protection of Pharmaceutical Products -- Complaint by the European Union and their Member States, Report of the Panel, WT/DS114/R, 17 March 2000, at 7.92.

<sup>21</sup> Doha Declaration on the TRIPS Agreement and Public Health, Paragraph Six ("We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002." Although small market countries are able to issue compulsory licenses, including for importation, they may not be able to find any TRIPS-legal exporters, since the exporters are restrained by patents in their home countries. Even if compulsory licenses are issued in the exporting country, licensees must produce predominantly for the domestic market, according to Article 31(f). Note that there are solutions to this problem available without further action by the TRIPS Council (which failed to meet the 2002 deadline in the Declaration): If countries issue compulsory licenses pursuant to Article 31(k) to remedy anti-competitive practices, the licensees are not subjected to the Article 31(f) limitation. Further, countries may adopt legislation pursuant to Article 30 stipulating that it is not a patent violation to make and export a patented product, solely for the purpose of exporting to another country where patents are not in effect or where a compulsory license has been issued and adequate remuneration is to be paid to the patent holder.

<sup>22</sup> Doha Declaration on the TRIPS Agreement and Public Health, Paragraph Seven ("We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016 ...").

<sup>23</sup> "Where the interest of public health demand, patents granted for medicines or for processes for obtaining medicines, for products necessary in obtaining such medicines or for processes for manufacturing such products may be subject to ex officio licences in accordance with Article L. 613-16 in the event of such medicines being made available to the public in insufficient quantity or quality or at (abnormally high prices) by order of the Minister responsible for industrial property at the request of the

The United States maintains statutory compulsory licensing provisions that are unique to clean air technology and atomic energy patents.<sup>24</sup>

And the European Union recently adopted a mandatory compulsory licensing regime for agricultural biotechnology patents.<sup>25</sup> The EU has specifically defended this compulsory licensing system as justified on the differentiation principle articulated in the EC-Canada case.<sup>26</sup>

Finally, on the issue of discrimination, the particular scope of the TRIPS anti-discrimination provision must be noted. It bars discrimination based on field of technology. Rules that may apply unevenly to categories of patents not based on field of technology do not contradict Article 27.1.

Rules that apply specifically to patents related to public health or patents related to vital consumer goods do not run afoul of Article 27.1, because public health and vital consumer goods are not fields of technology.

Article 27.1's non-discrimination provision thus does not stand as a barrier to reasoned and legitimate efforts to craft patent-related rules specific to addressing public health problems. This conclusion is particularly clear after the Doha Declaration: "It is implicit within the Doha Declaration that differentiation in patent rules may be necessary to protect public health. The singling out of public health, and in particular pharmaceuticals (paragraphs 6 and 7), as an issue needing special attention in TRIPS implementation constitutes recognition that public health-related patents deserve to be treated differently from other patents."<sup>27</sup>

### **Interpreting the TRIPS Agreement after the Doha Declaration on the TRIPS Agreement and Public Health**

The Doha Declaration has clarified that the TRIPS Agreement should be understood from the vantage point of public health.

In addition to the noting the grave public health problems -- including, but not limited to HIV/AIDS, tuberculosis and malaria -- afflicting many developing countries, the

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Minister responsible for health." Art. L. 613-16, Law No. 92-597 of July 1, 1992 on the Intellectual Property Code (Legislative Part).

<sup>24</sup> Clean Air Act, 42 USC Sec 7608; Atomic Energy Act, 42 USC Sec 2183.

<sup>25</sup> Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, July 6, 1998.

<sup>26</sup> Paul Vandoren, Letter to Machiel van der Velde and James Love of the TransAtlantic Consumer Dialogue, October 23, 2002, accessible on the Internet at: <<http://lists.essential.org/pipermail/ip-health/2002-October/003612.html>>.

<sup>27</sup> Carlos Correa, Implications of the Doha Declaration on the TRIPS Agreement and Public Health, World Health Organization, June 2002, 40.

Declaration asserts that TRIPS must serve as "part of the wider national and international action to address these problems."<sup>28</sup>

It creates an interpretative rule for the TRIPS Agreement, establishing that its provisions are to be interpreted to promote public health: "[W]e affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."<sup>29</sup>

In the same phrase, it urges not just interpretation, but national implementation in a fashion so as to protect public health and promote access to medicines for all.

And the Declaration reaffirms the right of all Member states "to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose" of protecting public health.<sup>30</sup>

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<sup>28</sup> Doha Declaration on the TRIPS Agreement and Public Health, Paragraph Two.

<sup>29</sup> Doha Declaration on the TRIPS Agreement and Public Health, Paragraph Four.

<sup>30</sup> Doha Declaration on the TRIPS Agreement and Public Health, Paragraph Four.