

## **THE LEGALITY OF LOCAL PATENT WORKING REQUIREMENTS UNDER THE TRIPS AGREEMENT**

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### **ABSTRACT**

The balance between the individual's intellectual property rights and the public interest has been an area of dispute. This paper focuses on the legality of the local working requirements under TRIPS and the Paris Convention. Part II describes the controversy over the use of the local working requirements through *United States v. Brazil*. Part III clarifies the interpretations of TRIPS and the Paris Conventions as they relate to the local working requirements. It further analyzes the legality of the local working requirements under TRIPS, considering whether Article 30 and 31 of TRIPS would make legitimate the compulsory license based on local working requirements. Part IV concludes that local working requirements and the compulsory licenses they guarantee are permitted under the TRIPS. "Domestic legislation providing for local working requirements does not unjustifiably discriminate against other WTO members in violation of Article 27 of the TRIPS."

Keywords: Local working requirements, compulsory license, TRIPS, patent holder, WTO

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## I. Introduction

The intention of patent law is that a government grants a patentee certain exclusive rights in exchange for the patentees' disclosure of his invention. This exclusive right is essential for conferring economic privileges on individuals promote technological development, but this right is not absolute. It is qualified by limitations for various reasons, including public interests. The balance between the individual's intellectual property rights and the public interest has been an area of dispute. In the earliest period, because patent laws were national in scope, enforcing the patent system was within a country's own regime.<sup>1</sup> With globalization and the increasing use of international business transactions, sometimes this dispute results in a conflict between developed countries and developing countries. The case of *United States vs. Brazil* in 2001 presented the dilemma of how to draw the line.<sup>2</sup>

In *United States vs. Brazil*, the Brazilian government attempted to use local working requirements, which were contained in Article 68 of the Brazilian Industrial Property Law, which permitted the grant of a compulsory license "when a patent is not 'worked' in Brazil,"<sup>3</sup> as a means to force United States pharmaceutical companies to reduce the price of certain medicine. In May, 2000, the United States filed a complaint with the World Trade Organization ("WTO") against Brazil for enforcing local working requirements as part of its national laws, which the United States asserted to be prohibited by the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS").<sup>4</sup> In July of 2001, the United States and Brazil reached a mutually agreeable solution to the dispute, but the question of the legality of local working requirements has remained unanswered. Because "local working requirements came about as a balancing mechanism between a monopoly right and its impact on the public interest,"<sup>5</sup> the legal status of the local working requirements is critical. Only if the local working requirements are legal for the governments to use will this balancing mechanism be available.

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<sup>1</sup> See David R. Syrowik, *International Software Protection*, 70 MICH. B.J. 656, 657 (1991).

<sup>2</sup> See Paul Champ & Amir Attaran, *Patent Right and Local Working under the WTO TRIPS Agreement: an Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 382 (2002) (describing the United States claimed that Brazil's local working requirement violates Article 27(1) of the TRIPS).

<sup>3</sup> See Bryan Mercurio & Mitali Tyagi, *Treaty Interpretation in WTO Dispute Settlement: the Outstanding Question of the Legality of Local Working Requirements*, 19 MINN. J. INT'L L. 275, 275 (2010).

<sup>4</sup> See *id.* at 284.

<sup>5</sup> See *id.* at 281.

Therefore, this paper focuses on the legality of the local working requirements under TRIPS and the Paris Convention. Part II describes the controversy over the use of the local working requirements through *United States v. Brazil*. Part III clarifies the interpretations of TRIPS and the Paris Conventions as they relate to the local working requirements. It further analyzes the legality of the local working requirements under TRIPS, considering whether Article 30 and 31 of TRIPS would make legitimate the compulsory license based on local working requirements. Part IV concludes that local working requirements and the compulsory licenses they guarantee are permitted under the TRIPS. “Domestic legislation providing for local working requirements does not unjustifiably discriminate against other WTO members in violation of Article 27 of TRIPS.”<sup>6</sup>

## II. Controversy over the Local Working Requirements

At the outset, the definition of local working requirements should be understood. ‘Local working’ refers to “the condition some countries impose on patentees that their patented product or process must be used or produced in the patent granting country.”<sup>7</sup> Hence, “local working requirements are domestic provisions which allow for the grant of a compulsory license when a patent is not ‘worked’ in that country.”<sup>8</sup> Failure to work the patent locally is regarded as an abuse by the patentee of his rights, so a compulsory license may be granted by the government, compelling the patentee to allow other parties to exploit his patented products and processes.<sup>9</sup> Considered from another angle, local working requirements require the patentee to actually make use of his patented ideas within the country that granted him the patent rights if he wishes to maintain his exclusive exploitive rights.<sup>10</sup> In the case of foreign patentees, the requirements pressure them to situate their production facilities within the country granting the patent.<sup>11</sup> The effect may be a technology transfer, as it would encourage patentees operating in countries with more advanced economies to transfer their technology to the country imposing the requirement.<sup>12</sup> These transfers serve a number of the policy goals of less developed economies: “employment creation, industrial

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<sup>6</sup> See *id.* at 326.

<sup>7</sup> Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law*, 35 OSGOODE HALL L.J. 243, 245 (1997).

<sup>8</sup> Mercurio & Tyagi, *supra* note 3, at 275.

<sup>9</sup> See Halewood, *supra* note 7, at 243.

<sup>10</sup> See Mercurio & Tyagi, *supra* note 3, at 281.

<sup>11</sup> See Halewood, *supra* note 7, at 245.

<sup>12</sup> See Marco Ricolfi, *the First Ten Years of the TRIPS Agreement: Is there an Antitrust Antidote Against IP Overprotection within TRIPS?*, 10 MARQ. INTELL. PROP. L. REV. 305, 343 (2006).

and technological capacity building, national balance of payments, and economic independence.”<sup>13</sup> In addition, as law professor Marco Ricolfi observes, “such a rule would accordingly not only be perceived as making a significant contribution towards the technological development of the Member of the grant but also as providing a formidable means of coercion over patentees.”<sup>14</sup>

*United States v. Brazil* is the leading WTO appellate case concerning local working requirements.<sup>15</sup> Therefore, introducing this case provides a useful way to understand the controversy over local working requirements.

The Brazilian government had long been working on controlling the HIV/AIDS epidemic in Brazil. Each year, it made enormous expenditures on buying antiretroviral medicine from the United States patent-holding pharmaceutical companies. Faced with intolerably high-priced medicine, the Brazilian government wanted to exercise Article 68 of the Brazilian Industrial Property Law which promulgated in 1996.<sup>16</sup> Article 68 of the Brazilian Industrial Property Law requires holders of Brazilian patents to make the product associated with the patent in Brazil.<sup>17</sup> If they fail to do this within three years, the government may impose a compulsory license (though the patent holder can defend against this by showing that production in Brazil was not a reasonable option).<sup>18</sup> The reasoning behind this law is that “failure to work a patent as a mode of exercise of the right that may be deemed abusive and, thus, subject to the remedy of compulsory licensing.”<sup>19</sup> If the government cannot compel the patent holder to produce the medicine in Brazil, it can grant the compulsory license and ask local pharmaceutical manufacturers to produce generic medicine. This will decrease the expenditures on anti-AIDS medicine and meet the demands of Brazilian AIDS patients. Brazil believed such a domestic provision would help public health, because more people could have access to necessary medicine.<sup>20</sup>

The United States challenged the local working aspects of the Brazilian Industrial Property Law by claiming it violated Article 27(1) of TRIPS, which prohibits discrimination as to “whether products are imported or

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<sup>13</sup> Halewood, *supra* note 7, at 245.

<sup>14</sup> Ricolfi, *supra* note 12, at 343.

<sup>15</sup> See Champ & Attaran, *supra* note 2, at 382.

<sup>16</sup> See Mercurio & Tyagi, *supra* note 3, at 295.

<sup>17</sup> See *id.*

<sup>18</sup> See *id.*

<sup>19</sup> See Ricolfi, *supra* note 12, at 344.

<sup>20</sup> See GRAEME B. DINWOODIE & ROCHELLE C. DREYFUSS, A NEOFEDERALIST VERSION OF TRIPS: THE RESILIENCE OF THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME 45 (U.S.A., Oxford University Press 2012).

locally produced.”<sup>21</sup> In response, Brazil claimed that Article 5(A)(2) of the Paris Convention explicitly grants a right to make use of local working requirements.<sup>22</sup> Additionally, it claimed the validity of Article 5(A)(2) was reaffirmed by its incorporation into Article 2(2) of TRIPS, which requires that the Paris Convention’s obligation should not be derogated.<sup>23</sup> These relevant treaty provisions are as follows:

Article 27(1) of the TRIPS:

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>24</sup>

Article 5(A)(2) of the Paris Convention:

Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.<sup>25</sup>

Article 2(2) of the TRIPS:

Nothing in Parts I to IV shall derogate from existing obligations that members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.<sup>26</sup>

As the controversy came to global notice, a debate over a potential conflict between the obligation under Article 27(1) of TRIPS and the right granted by Article 5(A)(2) of the Paris Convention has emerged. The issue of whether the local working requirements are legal under the international trade regime began to be considered.<sup>27</sup> However, in July, 2001, the U.S./Brazil case was settled before a final decision could be issued.<sup>28</sup> The settlement required that Brazil provide the United States officials with advance notice prior to invoking Article 68 of the Brazilian Industrial

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<sup>21</sup> See Mercurio & Tyagi, *supra* note 3, at 275.

<sup>22</sup> See *id.* at 285.

<sup>23</sup> See *id.* at 286.

<sup>24</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 1869 U.N.T.S. 299 [hereinafter “TRIPS”].

<sup>25</sup> Paris Convention for the Protection of Industrial Property art. 5(A)(2), Mar. 20, 1883, amended Oct. 2, 1979, 21 U.S.T. 1538, 828 U.N.T.S. 305 [hereinafter “Paris Convention”].

<sup>26</sup> TRIPS art. 2(2).

<sup>27</sup> See Mercurio & Tyagi, *supra* note 3, at 275.

<sup>28</sup> See Champ & Attaran, *supra* note 2, at 380-1.

Property Law. The question of the legality of local working requirements has remained unanswered.<sup>29</sup>

### III. Legal Analysis of Local Working Requirements under the TRIPS

May WTO members legally regulate local working requirements on their national laws? May they grant a compulsory license to a local producer when the patentee has failed to ‘work’ locally? Would a compulsory license violate the TRIPS? Although some believe that the TRIPS totally prohibits local working requirements,<sup>30</sup> I argue that local working requirements continue to be generally permissible. This means that when the patentee has failed to work the patent locally, the government of the patent granting country may issue a compulsory license for the patent to a local producer pursuant to their national laws.

Even though there are various perspectives to examine this situation, such as ascertainment of the objectives and principles of the TRIPS,<sup>31</sup> I will apply the simplest form of legal analysis, contextual treaty interpretation.

When there is a potential conflict between different provisions within one treaty or within different treaties, it is urgent, when a dispute arises, to find a means to interpret the provisions which elucidates their meaning.<sup>32</sup> In the WTO, the Dispute Settlement Body (“DSB”) plays this role and attempts to clarify the current conflicting provisions of these agreements, in accordance with “customary rules of interpretation of public international law.”<sup>33</sup> More specifically, it prefers to take guidance from the context of the whole agreement to settle on an acceptable explanation,<sup>34</sup> because the text of a treaty must be read as a whole in order to grasp the point of a single

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<sup>29</sup> See Mercurio & Tyagi, *supra* note 3, at 296.

<sup>30</sup> See Halewood, *supra* note 7, at 249.

<sup>31</sup> See Vienna Convention on the Law of Treaties, opened for signature May 23, 1969, art. 31, 1155 U.N.T.S. 331, 340, entered into force Jan. 27, 1980, reprinted in 8 I.L.M.679, 691-92 [hereinafter the “Vienna Convention”]. It is useful to look to the principles of treaty interpretation of the Vienna Convention, which applies with respect to TRIPS in disputes before the WTO. Following the general rule of treaty interpretation at Article 31 of the Vienna Convention, Article 27(1) of TRIPS must be interpreted “in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.” See also Champ & Attaran, *supra* note 2, at 390.

<sup>32</sup> See Mercurio & Tyagi, *supra* note 3, at 278.

<sup>33</sup> See Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 3(2), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments- Results of the Uruguay Round, 33 I.L.M. 1125 (1994); see also Mercurio & Tyagi, *supra* note 3, at 297.

<sup>34</sup> See Mercurio & Tyagi, *supra* note 3, at 307.

provision.<sup>35</sup> “One cannot simply concentrate on a paragraph, an article, a section, a chapter or a part.”<sup>36</sup>

As already stated, Article 27 of the TRIPS does not allow discrimination between products which are imported and those locally produced. Therefore, on its face, TRIPS seems to prohibit local working requirements which only protect patents that are manufactured within the nation and deny protection to patented products which are only imported into the nation. However, this Article must not be read alone. Article 30 and Article 31 are relevant to Article 27(1). They read as follows:

Article 30-Exception to Rights Conferred:

Members may provide limited exceptions to the exclusive right conferred by a patent, provided that 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 account of the legitimate interests of third parties.<sup>37</sup>

Article 31-Other Use without Authorization of the Right Holder:

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

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

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial

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<sup>35</sup> See Champ & Attaran, *supra* note 2, at 38.

<sup>36</sup> *Id.*

<sup>37</sup> TRIPS art. 30.

use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(I) where such use is authorized to permit the exploitation of a patent (“the second patent”) which cannot be exploited without infringing another patent (“the first patent”), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and



(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.<sup>38</sup>

In essence, Article 30 permits limited exceptions to the exclusive rights conferred by the grant of a patent. Article 31 allows for “other use without authorization of the right holder.” “Other use,” which is defined in a footnote to TRIPS, refers to “use other than the use permitted under Article 30.”<sup>39</sup> Taken together, “Article 30 sets out a first tier of eponymous exceptions to the patent rights referred to in Article 27(1), while Article 31 sets out a second tier of exceptions more liberally called other use.”<sup>40</sup>

Another customary rule of interpretation of public international law that the WTO favors is *lex specialis derogate legi generali*, which establishes that where a general legal provision runs afoul of a specific provision, the specific provision prevails.<sup>41</sup> Article 27 of the TRIPS articulates general protections, but Article 30 and 31 provide specific exceptions. Under *lex specialis derogate legi generali*, the Article 30 and 31 exceptions are superior to the Article 27 rights.<sup>42</sup>

Thus, if local working laws can be justified under Article 30 or 31, they supersede the general provision of Article 27(1).<sup>43</sup> They cannot be justified under Article 30, because it only permits exceptions to patent rights as long as they are limited, do not conflict with normal exploitation, and do not unreasonably prejudice the legitimate interests of the owner.<sup>44</sup> “It does not appear to contemplate compulsory licensing, at least for commercial use.”<sup>45</sup> However, Article 31 does justify the local working laws. It pertains directly to compulsory licensing, and sets out the procedures and conditions of issuing a compulsory license without the authorization of the patent holder.<sup>46</sup> There are two sets of conditions for getting a compulsory license, one with more demanding than the other. For non-emergency circumstances, a compulsory license may be obtained if the “proposed user” attempts to get permission from the patent holder on “reasonable commercial terms and conditions” in a “reasonable period of time.” For emergency circumstances,

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<sup>38</sup> TRIPS art. 31.

<sup>39</sup> *Id.*

<sup>40</sup> See Champ & Attaran, *supra* note 2, at 386.

<sup>41</sup> See *id.* at 387.

<sup>42</sup> See *id.* at 386.

<sup>43</sup> See *id.* at 387.

<sup>44</sup> TRIPS art. 30.

<sup>45</sup> See Champ & Attaran, *supra* note 2, at 383.

<sup>46</sup> See Levon Barsoumian, *India's Use It or Lose It: Time to Revisit TRIPS?*, 11 J.

this requirement is waived. All that is required is notification of the patent holder.

Further, since Article 31 supersedes Article 27(1), there is no potential conflict between Article 27(1) and Article 2(2), which incorporates the Paris Convention's obligation and explicitly grants a right to make use of local working requirements. Therefore, the compulsory licenses of local working requirements are permitted under TRIPS. "Domestic legislation providing for local working requirements does not unjustifiably discriminate against other WTO members in violation of Article 27 of the TRIPS."<sup>47</sup>

#### **IV. Conclusion**

The balance between the individual's intellectual property rights and the public interest has always been difficult. In regard to local working requirements, the universal consensus at present seems to require that the patentee's exclusive rights should yield to the public interest to some degree, especially when it comes to public health. The compulsory licenses of local working requirements are permitted under the TRIPS. WTO members may incorporate local working environments into their national laws. Once the patentee fails to work the patent locally, a government, most likely the government of a developing country, can grant compulsory licenses to other manufacturers. This will help developing countries obtain new technology and give them greater leverage in their international transactions.

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<sup>47</sup> Mercurio & Tyagi, *supra* note 3, at 326.