

# Special Section 301: US Interference with the Design and Implementation of National Patent Laws

Carlos M. Correa





# **RESEARCH PAPER**

**115**

## **SPECIAL SECTION 301: US INTERFERENCE WITH THE DESIGN AND IMPLEMENTATION OF NATIONAL PATENT LAWS**

**Carlos M. Correa\***

**SOUTH CENTRE**

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\* Carlos M. Correa is the Executive Director of the South Centre.





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South Centre  
Ch. du Champ d'Anier 17  
POB 228, 1211 Geneva 19  
Switzerland  
Tel. (41) 022 791 80 50  
[south@southcentre.int](mailto:south@southcentre.int)  
[www.southcentre.int](http://www.southcentre.int)

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## ABSTRACT

The continuous application of Special Section 301 by the Office of the United States Trade Representative (USTR) undermines the rule of law as a fundamental principle of a multilateral system based on the sovereign equality of states and the respect for international law. Interference with foreign countries' national intellectual property (IP) policies—which have significant socio-economic effects—negates their right to determine independently the level and modalities of protection of such property within the framework and policy space allowed by the international law. This paper examines the patent-related claims made by the USTR in relation to the developing countries on the USTR Priority Watch List. It argues that the regulations and practices identified by the USTR show a legitimate use of the flexibilities provided for by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and that the ignorance of the public interests of the countries concerned (for instance, with regard to access to affordable medicines) has contributed to the discredit (and ineffectiveness) of the Special Section 301.

*La poursuite de l'application par le Bureau du Représentant des États-Unis au commerce (USTR) de l'article 301 [de la Loi de 1974 sur le commerce extérieur] constitue une atteinte à l'État de droit en tant que principe fondamental d'un système multilatéral fondé sur l'égalité souveraine des États et le respect du droit international. L'ingérence qui en découle dans les politiques nationales en matière de protection de la propriété intellectuelle des pays étrangers, qui ont des effets socio-économiques importants, les prive du droit qui leur est reconnu de déterminer en toute indépendance le niveau et les modalités de cette protection dans le cadre et l'espace politique autorisé par le droit international. Le présent document examine les affirmations faites par l'USTR concernant la protection des brevets dans les pays en développement figurant sur sa liste de surveillance prioritaire. Il conclut que les réglementations et pratiques recensées par l'USTR montrent un usage légitime des flexibilités prévues par l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC), et que l'absence de prise en compte de l'intérêt général des pays concernés (par exemple, en ce qui concerne l'accès à des médicaments abordables) contribue à discréditer les dispositions de l'article 301 et nuit à leur efficacité.*

*La aplicación continua del Informe Especial 301 de la Oficina del Representante de Comercio de los Estados Unidos (USTR, por sus siglas en inglés) socava el estado de derecho como principio fundamental de un sistema multilateral basado en la igualdad soberana de los Estados y el respeto del derecho internacional. Las interferencias en las políticas nacionales en materia de propiedad intelectual (PI) de los países extranjeros —que tienen importantes efectos socioeconómicos— los privan de su derecho a determinar independientemente el nivel y las modalidades de protección de dicha propiedad en el marco y el espacio de políticas que permite el derecho internacional. En este documento se examinan las reivindicaciones relacionadas con las patentes presentadas por la USTR relativas a los países en desarrollo que figuran en la lista de vigilancia prioritaria de la USTR. Se sostiene que los reglamentos y las prácticas identificados por la USTR demuestran un uso legítimo de las flexibilidades previstas en el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC), y que la ignorancia de los intereses públicos de los países afectados (por ejemplo, con respecto al acceso a medicamentos asequibles) ha contribuido al descrédito (y la ineficacia) del Informe Especial 301.*



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## INTRODUCTION

The US Trade Representative (USTR) released on 29 March 2020 the *2020 Special 301 Report*<sup>1</sup> (hereinafter “the Report”), a rite the USTR has practised since 1989, when the first report based on Special Section 301 of the US Trade Act was issued. The Report aims at identifying “countries that deny adequate and effective protection” of intellectual property (IP) rights or “deny fair and equitable market access to US persons” who rely on IP protection. Based on this identification, the USTR determines which, if any, of these countries will be deemed “Priority Foreign Countries”.<sup>2</sup> The countries so identified are vulnerable to unilateral trade retaliation by the US government.<sup>3</sup>

Special Section 301 was introduced in 1988 into the US Trade Act by the Omnibus Trade and Competitiveness Act,<sup>4</sup> signed by President Ronald Reagan. This section was an elaboration—specifically for intellectual property— upon Section 301, which was incorporated into the US Trade Act of 1974 granting the USTR a range of responsibilities and authorities “to investigate and take action to enforce U.S. rights under trade agreements and respond to certain foreign trade practices”.<sup>5</sup>

Under Section 301, the USTR is authorized to adopt, at its discretion, various measures to remedy foreign trade practices that affect US exports. Section 301 authorized the USTR to (1) impose duties or other import restrictions, (2) withdraw or suspend trade agreement concessions or (3) enter into a binding agreement with the foreign government to either eliminate the conduct in question (or the burden to US commerce) or compensate the United States with satisfactory trade benefits. The USTR must give preference to duties (i.e. tariffs) if action is taken in the form of import restrictions.<sup>6</sup>

The key objective of Section 301 was to allow the US administration to exert pressure on other countries by threatening (and eventually implementing) those trade retaliatory measures. As noted by one commentator, it “was shaped quite deliberately to give the Executive the tools to use diplomatic and economic pressure to achieve a more ‘equitable’ world trading system, to the benefit of U.S. commerce”.<sup>7</sup> As noted by a commentator, “...the United States used Section 301 extensively to pressure other countries to eliminate trade barriers and open their markets to U.S. exports”.<sup>8</sup>

The incorporation of a “special” Section 301 in relation to intellectual property reflected the US government’s growing belief that the country’s long-term competitive advantages relied on its technological strength rather than on manufacturing, which many companies were shifting to foreign countries to benefit from lower production (notably labour) costs.<sup>9</sup>

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<sup>1</sup> Available from [https://ustr.gov/sites/default/files/2020\\_Special\\_301\\_Report.pdf](https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf).

<sup>2</sup> See <https://www.internationaltradeupdate.com/2019/12/23/ustr-seeks-comments-for-2020-special-301-review/>.

<sup>3</sup> They may include, for instance, removal of the targeted country from eligibility for receipt of trade preferences for developing countries under the Generalized System of Preferences (GSP).

<sup>4</sup> Available from <https://www.govtrack.us/congress/bills/100/hr4848/text>.

<sup>5</sup> See Andres B. Schwarzenberg, “Section 301 of the Trade Act of 1974”, version 5, updated 20 April 2020. Congressional Research Service. Available from <https://crsreports.congress.gov/product/pdf/IF/IF11346>.

<sup>6</sup> Id.

<sup>7</sup> Shirley A. Coffield, “Using Section 301 of the Trade Act of 1974 as a Response to Foreign Government Trade Actions: When, Why, and How”, *North Carolina Journal of International Law and Commercial Regulation*, vol. 6, No. 3 (1981), p. 381.

<sup>8</sup> Andres B. Schwarzenberg, op. cit.

<sup>9</sup> See e.g. Charles Kelley, Mark Wang, Gordon Bitko, Michael Chase, Aaron Kofner, Julia Lowell, James Mulvenon, David Ortiz and Kevin Pollpeter, *High-Technology Manufacturing and U.S. Competitiveness* (Rand Corporation, 2004). Available from [https://www.rand.org/content/dam/rand/pubs/technical\\_reports/2004/RAND\\_TR136.pdf](https://www.rand.org/content/dam/rand/pubs/technical_reports/2004/RAND_TR136.pdf).



Special Section 301 was “designed to use the credible threat of unilateral retaliation by the United States to ‘persuade’ trading partners to reform currently deficient intellectual property practices”.<sup>10</sup> Importantly, at the time that this Section was approved, the US was actively proposing—in the context of the Uruguay Round of GATT—the negotiation of an ambitious agreement on IP, which was finally adopted as the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement), one of the multilateral agreements in the World Trade Organization.<sup>11</sup> Thus, while the US government was seeking multilateral rules on IP, it was threatening countries that did not meet certain standards of IP protection with trade retaliation. At the GATT negotiations, India “expressed serious reservations about the progress of multilateral negotiations as long as the threat of bilateral action exists. The European Economic Community agreed with Brazil and India, contending that negotiations on the prevention of piracy and the protection of intellectual property rights will be viable only if the participants feel they are negotiating without coercion”.<sup>12</sup>

Special Section 301 has been used since its adoption, whether by Republican or Democratic US administrations, to pressure both developed and developing countries to adopt standards of IP rights that suit the interests of US companies. It explicitly aims to ensure “fair and equitable market access” in foreign countries “in order to protect the economic interests of the United States”.<sup>13</sup>

While the claims made in the Report—as in previous ones—cover several fields of IP and many countries, this paper focuses on the patent-related claims made in relation to developing countries on the “Priority Watch List”. The paper aims, in particular, to examine the extent to which the demands for changes made in the report undermine the flexibilities recognized by the TRIPS Agreement in the area of patent law. First, the paper discusses the legality of the US unilateral retaliatory system under WTO rules. Second, it considers the standards under which the IP regimes of foreign countries are judged by the USTR. Third, it briefly describes the major mismatch between the USTR’s dogmatic view about the effects of IP and the mainstream economic thinking in the US. Fourth, the paper examines the scope and content of the patent-related claims made in relation to developing countries that have been placed on the Priority Watch list: China, Indonesia, India, Algeria, Argentina, Chile and Venezuela.<sup>14</sup>

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<sup>10</sup> Bello and Holmer, op. cit., p. 259.

<sup>11</sup> See e.g. Carlos Correa, *Trade Related Aspects of Intellectual Property Rights. A Commentary on the TRIPS Agreement*, 2<sup>nd</sup> ed. (Oxford University Press, forthcoming).

<sup>12</sup> Trade. “TRIPRS” Negotiations On Collision Course, Warns India”, *Inter Press Service*, 13 July 13 1989. LexisNexis library, Intrad file, cited in Bello and Holmer, p. 273.

<sup>13</sup> Bello and Holmer, op. cit., p. 261. President Reagan, in signing the 1988 Trade Act, stated that the Special 301 would “strengthen the ability of U.S. firms to protect their patented, copyrighted, or trademarked goods and ideas from international thievery” (quoted in Bello and Holmer, loc. cit.).

<sup>14</sup> In the case of other “Priority Watch List” countries, no claims are made in relation to patent protection. With respect to Saudi Arabia, the main USTR claims relate to “satellite and online piracy” and the alleged lack of adequate protection of test data for pharmaceuticals (despite the country’s compliance with the TRIPS Agreement standard under Article 39.3 thereof). See Report, p. 57.

## UNILATERAL TRADE RETALIATIONS UNDER WTO LAW

In 1998, the European Communities submitted a formal complaint against the US under the WTO Dispute Settlement Understanding (DSU), arguing the WTO incompatibility of Sections 301–310 of the US Trade Act. The European Communities contended that:

- Title III, chapter 1 (sections 301–310) of the Trade Act, as amended, and in particular sections 306 and 305 of the Act, are inconsistent with Articles 3, 21, 22 and 23 of the DSU; Article XVI:4 of the WTO Agreement; and Articles I, II, III, VIII and XI of GATT 1994;
- the Trade Act nullifies and impairs benefits accruing, directly or indirectly, to it under GATT 1994, and impedes the objectives of GATT 1994 and the WTO.<sup>15</sup>

Failing the parties' reaching an agreement during the consultations prescribed under the DSU, a panel was set up that ruled that "Article 23.2 [of the DSU] clearly, thus, prohibits specific instances of unilateral conduct by WTO Members when they seek redress for WTO inconsistencies in any given dispute".<sup>16</sup> The panel also noted that "[a]s a general proposition, GATT *acquis*, confirmed in Article XVI:4 of the WTO Agreement and recent WTO panel reports, makes abundantly clear that legislation as such, independently from its application in specific cases, may breach GATT/WTO obligations".<sup>17</sup> It further held that the DSU's

Article 23.1 is not concerned only with specific instances of violation. It prescribes a general duty of a dual nature. First, it imposes on all Members to "have recourse to" the multilateral process set out in the DSU when they seek the redress of a WTO inconsistency. In these circumstances, Members have to have recourse to the DSU dispute settlement system to the exclusion of any other system, in particular a system of unilateral enforcement of WTO rights and obligations. This, what one could call an "exclusive dispute resolution clause", is an important new element of Members' rights and obligations under the DSU. Second, Article 23.1 also prescribes that Members, when they have recourse to the dispute settlement system in the DSU, have to "abide by" the rules and procedures set out in the DSU. This second obligation under Article 23.1 is of a confirmatory nature: when having recourse to the DSU Members must abide by all DSU rules and procedures.<sup>18</sup>

The panel rejected the US argument that the fact that the US had the *discretion* to apply trade retaliatory measures immunized its legislation against being a violation of WTO rules. It argued that Article 23 of the DSU prohibits "legislation with certain discretionary elements and therefore the very fact of having in the legislation such discretion could, in effect, preclude WTO consistency".<sup>19</sup> The panel elaborated on this argument by providing an example regarding customs inspection:

Imagine, for example, legislation providing that all imports, including those from WTO Members, would be subjected to a customs inspection and that the

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<sup>15</sup> See [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds152\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds152_e.htm).

<sup>16</sup> World Trade Organization, "United States - Sections 301-310 of the Trade Act of 1974 - Report of the Panel", document WT/DS152/R. Available from [https://docs.wto.org/dol2fe/Pages/FE\\_Search/FE\\_S\\_S006.aspx?Query=\(@Symbol=%20wt/ds152/\\*\)&Language=ENGLISH&Context=FomerScriptedSearch&languageUICChanged=true#.%20para.%207.39](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20wt/ds152/*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUICChanged=true#.%20para.%207.39).

<sup>17</sup> Id., para. 7.41.

<sup>18</sup> Id., para. 7.43.

<sup>19</sup> Id., para. 7.54.

administration would enjoy the right, at its discretion, to impose on all such goods tariffs in excess of those allowed under the schedule of tariff concessions of the Member concerned. Would the fact that under such legislation the national administration would not be mandated to impose tariffs in excess of the WTO obligation, in and of itself exonerate the legislation in question? Would such a conclusion not depend on a careful examination of the obligations contained in specific WTO provisions, say, Article II of GATT and specific schedule of concessions?<sup>20</sup>

Thus, the panel concluded that the unilateral measures under Section 301 were inconsistent with the WTO multilateral rules on dispute settlement. The US was able, however, to neutralize this conclusion on the basis of the “US undertakings articulated in the Statement of Administrative Action approved by the US Congress at the time it implemented the Uruguay Round agreements and confirmed and amplified in the statements by the US to the panel”.<sup>21</sup> The Statement of Administrative Action (SAA) states that “the USTR will invoke the dispute settlement procedures of the WTO Dispute Settlement Understanding (DSU) for investigations that involve an alleged violation of (or the impairment of US benefits under) WTO Agreements. At the same time, the SAA makes clear that “[n]either Section 301, nor the DSU will require the” USTR to do so if it “does not consider that a matter involves” WTO Agreements”.<sup>22</sup>

The panel considered the SAA to have “remedied” the discretionary element in the US law<sup>23</sup> but noted:

Should the undertakings articulated in the SAA and confirmed and amplified by the US to this Panel be repudiated or in any other way removed by the US Administration or another branch of the US Government, this finding of conformity would no longer be warranted.<sup>24</sup>

The Dispute Settlement Body (DSB) adopted the panel report at its 27 January 2000 meeting.<sup>25</sup> The ambiguous conclusion in this ruling allowed the US to maintain its unilateral retaliatory machinery under the Trade Act to exert pressure on foreign countries. Hence, the “United States retains the flexibility to determine whether to seek recourse for foreign unfair trade practices in the WTO and/or act unilaterally”.<sup>26</sup>

Using that “flexibility”, the USTR has initiated 32 cases under Section 301 since the WTO’s establishment in 1995.<sup>27</sup> The use of that section has been activated under the Trump administration and applied recently against China,<sup>28</sup> the European Union and France.<sup>29</sup>

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<sup>20</sup> Id., footnote 568.

<sup>21</sup> Id., para. 8.1.

<sup>22</sup> Andres B. Schwarzenberg, op. cit.

<sup>23</sup> United States – Sections 301-310 of the Trade Act 1974 (DS 152), para. 7.134

<sup>24</sup> Id., para. 7.136.

<sup>25</sup> See United States – Sections 301-310 of the Trade Act 1974 (DS 152). Available from [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds152\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds152_e.htm).

<sup>26</sup> Andres B. Schwarzenberg, op. cit.

<sup>27</sup> Ibid.

<sup>28</sup> Aileen Kwa and Peter Lunenborg, “US’ Section 301 Actions: Why They are Illegitimate and Misguided”, Research Paper No. 86 (South Centre, September 2018). Available from [https://www.southcentre.int/wp-content/uploads/2018/09/RP86\\_US-Section-301-Actions-Why-They-are-Illegitimate-and-Misguided\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2018/09/RP86_US-Section-301-Actions-Why-They-are-Illegitimate-and-Misguided_EN.pdf).

<sup>29</sup> Andres B. Schwarzenberg, op. cit.

## WHAT STANDARDS DOES THE USTR APPLY?

Despite the WTO panel's warning about the illegality, under WTO rules, of the US unilateral measures grounded on the US Trade Act, the USTR has continued to use the authority conferred under said Act to force foreign sovereign countries to align their legislation and practices on IP with US businesses' interests. An important question is: what standards are applied by USTR to judge—and unilaterally condemn—the laws, regulations and practices of a foreign country?

In accordance with Special Section 301, the USTR is required to identify foreign countries that deny the "adequate and effective protection of intellectual property rights," or deny "fair and equitable market access to United States persons who rely upon intellectual property protection". This section further requires "the USTR to name as 'priority foreign countries' those countries: (i) whose acts, practices, or policies are the most onerous or egregious, and have the greatest adverse economic impact on the United States; and (ii) that are not entering into good faith negotiations or making significant progress in bilateral or multilateral negotiations to provide adequate and effective protection of intellectual property rights".<sup>30</sup>

The vagueness of the concept of "adequate and effective protection of intellectual property rights" is apparent. Under which circumstances and for whom is it "adequate"? "Effectiveness" relates to the capacity to produce a result,<sup>31</sup> but such a result may be reached to different degrees and in different ways. IP protection that could be "adequate" for the US may not, clearly, be so for another country at a different level of economic and technological development, as the effect of such protection depends strongly on the context in which it applies. In fact, the history of IP conclusively shows that the level of protection in the US and other developed countries evolved as they reached different levels of development. As noted by one US agency, "[w]hen the United States was still a relatively young and developing country..., it refused to respect international intellectual property rights on the grounds that it was freely entitled to foreign works to further its social and economic development".<sup>32</sup> It has been noted, moreover, that "[t]he United States emerged as the world's industrial leader by illicitly appropriating mechanical and scientific innovations from Europe" and that this was "a policy explicitly supported by the US leaders at that time to promote the economic strength and political independence of the new nation".<sup>33</sup>

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<sup>30</sup> Bello & Homer, op. cit., p. 261. The same authors note that "[r]ather than identifying countries as 'priority foreign countries' under Special 301, the USTR created a 'priority watch list' and a 'watch list', naming countries that are particularly lax in their protection of intellectual property rights or that have imposed barriers to market access" (Id. p. 267).

<sup>31</sup> See <https://www.merriam-webster.com/dictionary/effective>.

<sup>32</sup> US Congress, Office of Technology Assessment, *Intellectual Property Rights in an Age of Electronics and Information*, OTA-CIT-302 (Washington, D.C., US Government Printing Office, April 1986).

<sup>33</sup> See Doron Ben-Atar, *Trade Secrets. Intellectual Piracy and the Origins of American Industrial Power* (2004), quoted in James Surowiecki, "Spy v. spy" (*The New Yorker*, 2 June 2014). Available from [http://www.newyorker.com/talk/financial/2014/06/09/140609ta\\_talk\\_surowiecki](http://www.newyorker.com/talk/financial/2014/06/09/140609ta_talk_surowiecki). In accordance with this commentator, Alexander Hamilton, in his 1791 "Report on Manufactures", called on the country to reward those who brought us "improvements and secrets of extraordinary value from elsewhere. ...in practice, Americans were receiving patents for technology pirated from abroad" (ibidem). It has also been noted that "[i]ndeed, the U.S. continues to this day to resist some forms of IP expansion. For example, Congress has repeatedly refused to extend copyright law to cover fashion designs, leaving them unprotected by copyright in the U.S, in contrast to Europe, where they have broad protections. The result? A vibrant, innovative, fast-growing U.S. fashion industry that performs just as well, if not better, than its European competition". See also Roy Germano and Christopher Jon Sprigman, "The U.S. Chamber of Commerce's IP Myth", 21 June 2016. Available from [http://www.slate.com/articles/technology/future\\_tense/2016/06/the\\_u\\_s\\_chamber\\_of\\_commerce\\_s\\_ip\\_index\\_is\\_misleading\\_here\\_s\\_why.html](http://www.slate.com/articles/technology/future_tense/2016/06/the_u_s_chamber_of_commerce_s_ip_index_is_misleading_here_s_why.html).

Beyond the vague concepts of “adequate” and “effective” protection, the standards applied by the USTR to threaten trade sanctions are not defined in any regulation, nor in the Reports themselves. Their definition completely depends on the discretion of the USTR and is determined on an *ad hoc* basis every year, essentially based on the opinion of US businesses,<sup>34</sup> which, as is common in the pharmaceutical and entertainment industries, regularly make submissions detailing the alleged shortcomings of foreign countries’ legal systems in accordance with their own perceptions and interests.<sup>35</sup> There is no room for the consideration of the public interests of the countries concerned, notably in terms of the socio-economic impact that the implementation of the USTR demands could have, particularly in developing countries. The targeted countries are not given an opportunity to rebut the claims made regarding the unfairness or trade-restrictive effects of the measures in question. No evidence is provided in the USTR’s Special 301 Reports in respect of such effects. In fact, governments could not agree to participate in procedures under which their national laws and practices would be unilaterally judged by a foreign government, as this would mean a serious erosion of their sovereignty. The flawed methodology used by the USTR to produce its Special 301 Reports contributes to discrediting them as a legitimate basis on which to claim any removal of or change in IP measures in force in the targeted countries.<sup>36</sup>

The TRIPS Agreement mentioned above has set out the minimum standards of protection that the GATT parties considered satisfactory during the Uruguay Round’s negotiations to protect IP internationally. WTO members adhering to such standards comply fully with international law and should be free from any interference by a foreign State. Moreover, while WTO members are bound to comply with such standards, they are not obliged to grant “TRIPS-plus” protection in any area: that is, to provide broader, longer or additional IP rights.<sup>37</sup> Rather, they have the right to implement what have been termed “TRIPS flexibilities”: provisions allowed under the TRIPS Agreement—such as exceptions to exclusive rights, parallel importation or compulsory licenses—that help mitigate the effects of the exclusive rights conferred by TRIPS.<sup>38</sup>

US Special Section 301, however, is based on a different premise: the US can unilaterally apply trade sanctions *even if a country complies with the TRIPS Agreement*. The US law defines “unreasonable” acts, policies and practices as follows:

- (d)(3)(B) Acts, policies, and practices that are unreasonable include, but are not limited to, any act, policy, or practice, or any combination of acts, policies, or practices, which—
  - (i) denies fair and equitable—
  - (I) opportunities for the establishment of an enterprise,

<sup>34</sup> Each year, the USTR conducts a Special 301 review to identify the targeted countries. The USTR requests written comments that identify “acts, policies, or practices that may form the basis of a country’s identification as a Priority Foreign Country or placement on the Priority Watch List or Watch List. USTR also organizes a public hearing”. See

<https://www.internationaltradeupdate.com/2019/12/23/ustr-seeks-comments-for-2020-special-301-review/>.

<sup>35</sup> See e.g. the submission of the American Chamber of Commerce in Argentina, available from <https://www.regulations.gov/document?D=USTR-2019-0023-0022>. The claims in this submission are reflected in the Report (see below).

<sup>36</sup> See e.g. Fabiana Jorge, “United States: An Obsolete Trade Practice Undermines Access to the Most Expensive Drugs at More Affordable Prices”, *SouthNews* (South Centre, forthcoming).

<sup>37</sup> See: Article 1.1 of the TRIPS Agreement.

<sup>38</sup> United Nations Development Programme, “Good Practice Guide: Improving Access to Treatment with Flexibilities in TRIPS”. Available from <https://www.undp.org/content/undp/en/home/librarypage/poverty-reduction/good-practice-guide-improving-access-to-treatment-by-utilizing-public-health-flexibilities-in-the-wto-trips-agreement/>.

(II) provision of adequate and effective protection of intellectual property rights notwithstanding the fact that the foreign\_country may be in compliance with the specific obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in section 3511(d)(15) of this title.<sup>39</sup>

While there have recently been several manifestations of the US government's contempt for multilateral rules—as exemplified by its obstruction of the appointment of members of the WTO Appellate Body.<sup>40</sup> The survival and enforcement of Special Section 301 is an early and clear manifestation of such contempt. The interference by the US government with the right of foreign countries to design and apply their own legislation and practices constitutes a major denial of basic principles of international law, which requires all States to refrain from promulgating and applying laws and measures that ignore the principles of the sovereign equality of States, non-intervention and non-interference in their internal affairs and freedom of international trade and navigation.<sup>41</sup> The lack of transparency, consistency and legal basis of the standards applied by the USTR in implementing Special Section 301 adds to the arbitrariness of the mechanism instituted by the US Trade Act.

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<sup>39</sup> United States, 19 US Code § 2411. Actions by United States Trade Representative. Available from <https://www.law.cornell.edu/uscode/text/19/2411>.

<sup>40</sup> See e.g., Danish and Aileen Kwa, "Crisis at the WTO's Appellate Body (AB): Why the AB is Important for Developing Members", Policy Brief No. 69 (South Centre, December 2019). Available from [https://www.southcentre.int/wp-content/uploads/2019/12/PB69\\_Crisis-at-the-WTO%E2%80%99s-Appellate-Body-AB-Why-the-AB-is-Important-for-Developing-Members\\_EN-1.pdf](https://www.southcentre.int/wp-content/uploads/2019/12/PB69_Crisis-at-the-WTO%E2%80%99s-Appellate-Body-AB-Why-the-AB-is-Important-for-Developing-Members_EN-1.pdf).

<sup>41</sup> See UN Charter. Available from <https://www.un.org/en/sections/un-charter/chapter-i/index.html>.



## USTR AND US ACADEMY DISAGREE

Special Section 301, as noted, pursues the strengthening or expansion of IP protection in foreign countries to further the interests of US businesses. The basic idea that seems to underpin the US government's policy on IP is that such protection is crucial to promote innovation in all sectors alike and everywhere. The USTR's Carla Hills observed in 1989 that the inadequate protection of IP rights not only harms the US economy but also "undermines the creativity, invention and investment that are essential to economic and technological growth in all countries".<sup>42</sup>

However, the great majority of US scholars would disagree. They are essentially sceptical about the relationship among IP protection (notably patents), the innovative strength of a country and its economic growth.

Scepticism about the role of patents in promoting innovation is not new. In 1958, Fritz Machlup famously said, in relation to the US patent system: "If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one".<sup>43</sup> Half a century later, two US scholars wrote:

In general, public policy should aim to decrease patent monopolies gradually but surely, and the ultimate goal should be the abolition of patents. After six decades of further study since Machlup's testimony in 1958 has failed to find evidence that patents promote the common good, it is surely time to reassess his conclusion that it would be irresponsible to abolish the patent system.<sup>44</sup>

While not advocating the abolishment of the patent system, many other scholars have expressed doubt about its claimed positive effects and propose reducing rather than expanding the rights it confers. For instance, the Nobel Laureate in economics, Joseph Stiglitz, asked whether "the incentives provided by the patent system [are] appropriate...? Sadly, the answer is a resounding 'no.'"<sup>45</sup> Another Nobel Laureate, Gary Becker, noted that

The current patent length of 20 years (longer for drug companies) from the date of filing for a patent can be cut in half without greatly discouraging innovation. One obvious advantage of cutting patent length in half is that the economic cost from the temporary monopoly power given to patent holders would be made much more temporary. In addition, a shorter patent length gives patent holders less of an effective head start in developing follow-on patents that can greatly extend the effective length of an original patent.<sup>46</sup>

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<sup>42</sup> Office of the United States Trade Representative, *Fact Sheet "Special 301" on Intellectual Property* (May 25, 1989) reprinted in 6 Int'l Trade Rep. (BNA) No. 22, at 718 (May 31, 1989, reprinted in 6 Int'l Trade Rep. (BNA) No. 22, at 719 (May 31, 1989). p. 2 (quoted in Bello and Holmer, op. cit., p. 265).

<sup>43</sup> Fritz Machlup, *An Economic Review of the Patent System* (Study of the Subcommittee on Patents, Trademarks and Copyrights, Committee on the Judiciary, US Senate, 85th Congress, 2nd Session Washington, D.C., USGPO, 1958).

<sup>44</sup> Michele Boldrin and David K. Levine, "The Case Against Patents", *Journal of Economic Perspectives*, vol. 27, No.1 (Winter 2013), pp. 3–22.

<sup>45</sup> Joseph E. Stiglitz, "Prizes, not patents", 6 March 2007. Available from <https://www.project-syndicate.org/commentary/prizes--not-patents?barrier=accesspaylog>

<sup>46</sup> See Gary Becker, "On Reforming the Patent System", 21 July 2013. Available from <http://www.becker-posner-blog.com/2013/07/on-reforming-the-patent-system-becker.html>.



Richard Posner (the University of Chicago) further explained that other factors may be more important than patents in promoting innovation. He stated:

In most [industries], the cost of invention is low; or just being first confers a durable competitive advantage because consumers associate the inventing company's brand name with the product itself; or just being first gives the first company in the market a head start in reducing its costs as it becomes more experienced at producing and marketing the product; or the product will be superseded soon anyway, so there's no point to a patent monopoly that will last 20 years; or some or all of these factors are present. Most industries could get along fine without patent protection.<sup>47</sup>

Frederic M. Scherer (Harvard University) observed: "...as economic studies have shown repeatedly, patents do not play a particularly important role in most fields of industrial innovation."<sup>48</sup> Representative of what has become the mainstream view among US economists is Jaffe and Lerner's book *Innovation and Its Discontents* on the failure of the patent system to promote innovation in the US.<sup>49</sup>

These are only some examples of the critical views held by most US scholars on the role of the patent system, in stark contrast with the aggressive pro-patent stance of the USTR in exercising its authority under the Trade Act. Such a stance can be explained only by the decisive influence of a number of industrial sectors—notably the pharmaceutical industry—in shaping US policy on intellectual property rights (IPRs).<sup>50</sup>

The economic evidence on the effect of patents in a sophisticated economy like the US suggests that the USTR promotes abroad a policy that has not been proven to be the best option even domestically. Similarly, there is no evidence suggesting that a stronger IP system leads to economic growth. For instance, based on a variety expansion model of endogenous growth, Furukawa<sup>51</sup> found that conferring stronger monopolization rights in some sectors will produce a negative effect on economic growth because, as a result of monopoly, the scale of production will fall and the experience gained through technological accumulation will decline. As a result, he concludes, "stronger IPR decreases the productivity of the final sector, the associated demand for innovation, and economic growth",<sup>52</sup> hence, IPR protection would not enhance growth.

Moreover, increasing patent protection in foreign countries does not seem to enhance innovation in the US. An empirical study on how policy reforms in the US and in 21 countries that increased patent protection affected innovation found that "the TRIPS Agreement has had significant impacts on innovation in the US", while "the effects of strengthening patent protection by individual countries are not statistically significant", thereby showing that the US market is already sufficiently profitable to provide innovation

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<sup>47</sup> Richard Posner, "Why There Are Too Many Patents in America", 12 July 2012. Available from <https://www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725/>.

<sup>48</sup> F.M. Scherer, "The political economy of patent policy reform in the United States", *Journal on Telecommunications and High Technology Law*, vol. 7, No. 2 (2009), pp.167–216.

<sup>49</sup> See Adam B. Jaffe and Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It* (Princeton, New Jersey, Princeton University Press, 2004). The situation has not changed since the publication of this book.

<sup>50</sup> See e.g. Susan K. Sell, "Industry strategies for intellectual property and trade: the quest for TRIPS, and post-TRIPS strategies", *Cardozo Journal of International and Comparative Law*, vol.10 (2002), p. 79.

<sup>51</sup> Yuichi Furukawa (2007), "The Protection of Intellectual Property Rights and Endogenous Growth: Is Stronger Always Better?", *Journal of Economic Dynamics and Control*, vol. 31, No. 11 (November 2007), pp. 3644–70. Available from [https://econpapers.repec.org/article/eedyncon/v\\_3a31\\_3ay\\_3a2007\\_3ai\\_3a11\\_3ap\\_3a3644-3670.htm](https://econpapers.repec.org/article/eedyncon/v_3a31_3ay_3a2007_3ai_3a11_3ap_3a3644-3670.htm).

<sup>52</sup> *Id.*

incentives and that further strengthening of foreign patent protection “simply increases the US innovators’ rent, but not their innovation”.<sup>53</sup> This study shows that USTR policy allows companies that hold patent rights in foreign countries to increase their profits through the control of foreign markets, without any relevant effect on innovation in the US. Such patent-based market control does not lead to more innovation in the foreign countries<sup>54</sup> but to the displacement of local production and higher prices for consumers. The literature, particularly on the effects of foreign-owned patents in developing countries,<sup>55</sup> is abundant, notably in relation to the barriers they may pose to access to affordable pharmaceuticals.<sup>56</sup> In summary, the USTR policy based on Special Section 301 supports a rentistic model without any positive effect on innovation in the US nor in the countries subject to retaliatory threats.

The mismatch between USTR and economic thinking and evidence shows how IP policies may be determined by some industries’ interests rather than by academic thinking<sup>57</sup> or consumers’ concerns.<sup>58</sup> This is true not only with respect to the countries targeted by the USTR but with respect to the US as well. As noted by one commentator:

Indeed, while President Trump, the Department of Health and Human Services and the FDA [Food and Drug Administration] have made deliberate efforts to increase competition in the US pharmaceutical market, some of the agreements negotiated by the USTR and the Special 301 Reports focus on provisions that would do exactly the opposite: broaden and lengthen the monopolies granted to pharmaceutical companies thus delaying or deterring the launch of generic and biosimilar drugs and with that, the chances of lowering drug prices.<sup>59</sup>

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<sup>53</sup> Larry D. Qiu and Huayang Yu, “Does the Protection of Foreign Intellectual Property Rights Stimulate Innovation in the US?”, *Review of International Economics*, vol. 18, No. 5 (November 2010), pp. 882–95. Available from <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1467-9396.2010.00914.x>.

<sup>54</sup> A study, for instance, examined the effect of a more rigorous IP system through an index of economic complexity of 94 developing countries from 1965 to 2005. The paper presents evidence that developing countries have not enjoyed the benefits of global IPR standardization. See: Cassandra Mehlig Sweet and Dalibor Sacha Eterovic Maggio, “Do Stronger Intellectual Property Rights Increase Innovation?”, *World Development*, vol. 66 (February 2015), pp. 665–77. Available from <https://www.sciencedirect.com/science/article/abs/pii/S0305750X14002630>.

<sup>55</sup> See e.g. Carlos Correa, ed, *Intellectual Property and Economic Development* (London, Edward Elgar, forthcoming).

<sup>56</sup> See e.g., Germán Velásquez, Carlos M. Correa and Vitor Ido, *Intellectual Property, Human Rights and Access To Medicines: A Selected and Annotated Bibliography*, 3rd ed. (South Centre, 2020). Available from <https://www.southcentre.int/book-by-the-south-centre-2020/#more-14014>.

<sup>57</sup> See, however, Jean-Frédéric Morin, “Paradigm Shift in the Global IP Regime: The Agency of Academics”, *Review of International Political Economy*, vol. 21, No. 2 (2014). Available from [https://www.researchgate.net/publication/259202700\\_Paradigm\\_Shift\\_in\\_the\\_Global\\_IP\\_Regime\\_The\\_Agency\\_of\\_Academics](https://www.researchgate.net/publication/259202700_Paradigm_Shift_in_the_Global_IP_Regime_The_Agency_of_Academics).

<sup>58</sup> See e.g. Mark Halle, “The exhaustion of intellectual property rights: should countries favour consumers or private interests?” *IISD Commentary* (June 2007). Available from [https://www.iisd.org/site/default/files/publications/com\\_exhaustion.pdf](https://www.iisd.org/site/default/files/publications/com_exhaustion.pdf).

<sup>59</sup> Fabiana Jorge, op. cit.

## DEVELOPING COUNTRIES ON THE PRIORITY WATCH LIST

The USTR placed 10 countries, including some US major trading partners like India and China, on the “Priority Watch List” in its 2020 Report, alleging that their enforcement of IP has deteriorated or remained at inadequate levels that deny US companies fair and equitable market access. The USTR claims relate to patent policies in seven developing countries, as examined below.

### China

Not surprisingly, the Report devotes a long section to articulating its recurrent claims<sup>60</sup> in relation to China’s protection of IP, including patents.<sup>61</sup> China’s alleged lack of respect for IP is a persistent argument of the US government that underpins the trade war launched by the US<sup>62</sup> against its major competitor in trade as well as in leadership in key technologically advanced sectors.<sup>63</sup>

While noting that China has issued a number of regulations but “not enacted new Patent Law reforms, despite releasing a new draft of amendments to the Patent Law in January 2019”,<sup>64</sup> the Report expresses “strong concerns” about the presence of “competition law concepts in the patent law and measures, an undue emphasis on administrative enforcement, and the absence of critical reforms...”.<sup>65</sup> These vague observations suggest that the USTR has the right to determine the balance between competition and monopoly that a foreign patent law should incorporate and that the room for competition should be narrowed. It is worth recalling in this respect the statement by the US Federal Trade Commission in its report entitled “To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy”:

Competition can stimulate innovation. Competition among firms can spur the invention of new or better products or more efficient processes. Firms may race to be the first to market an innovative technology. Companies may invent lower-cost manufacturing processes, thereby increasing their profits and enhancing their ability to compete. Competition can prompt firms to identify consumers’ unmet needs and develop new products or services to satisfy them.<sup>66</sup>

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<sup>60</sup> See e.g. Nirmalya Syam and Carlos Correa, “US Claims under Special Section 301 against China, Undermine the Credibility of the WTO”, Policy Brief No. 51 (South Centre, 2018). Available from [https://www.southcentre.int/wp-content/uploads/2018/09/PB51\\_US-Claims-under-Special-Section-301-against-China-Undermine-the-Credibility-of-the-WTO\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2018/09/PB51_US-Claims-under-Special-Section-301-against-China-Undermine-the-Credibility-of-the-WTO_EN.pdf).

<sup>61</sup> As noted, this paper addresses only patent-related claims in the Report, which, however, covers many other areas, such as the protection of test data for pharmaceuticals: “China continues to impose unfair and discriminatory conditions on the effective protection against unfair commercial use, as well as unauthorized disclosure, of test or other data generated to obtain marketing approval for pharmaceutical products” (Report, p. 44). Some such claims are unrelated to IP rights, for instance: “China should also address delays, a lack of transparency, and inadequate engagement with pharmaceutical suppliers in government pricing and reimbursement processes” (Report, p. 54).

<sup>62</sup> See: e.g. The People’s Republic of China, the State Council Information Office, *China’s Position on the China-U.S. Economic and Trade Consultations* (June 2019). Available from [http://english.www.gov.cn/archive/white\\_paper/2019/06/02/content\\_281476694892692.htm](http://english.www.gov.cn/archive/white_paper/2019/06/02/content_281476694892692.htm).

<sup>63</sup> See e.g. Anthea Roberts, Henrique Choer Moraes and Victor Ferguson, “The U.S.-China trade war is a competition for technological leadership”, 21 May 2019. Available from <https://www.lawfareblog.com/us-china-trade-war-competition-technological-leadership>.

<sup>64</sup> Report, p. 44.

<sup>65</sup> Ibid.

<sup>66</sup> United States, Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (October 2003), p. 2. Available from <https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf>.

In addition, the “emphasis on administrative enforcement” may simply reflect the options of right-holders for a fast and cost-effective system that does not substitute for judicial enforcement. Chinese administrative bodies are reported to “offer a relatively fast and cost-effective way to deal with trademark and copyright infringements and to gather evidence for patent infringements”.<sup>67</sup> Local IP offices in China are administrative enforcement authorities responsible for “handling and mediating patent infringement dispute, ordering the ceasing of infringement, and punishing acts of passing off in the area of patents”. Importantly, “[i]f the parties and respondents are dissatisfied with the order of Local IP Offices, they may file a lawsuit with the court”.<sup>68</sup> Many other countries provide for administrative enforcement.<sup>69</sup>

The Report also argues that “the August 2019 issuance of a new Drug Administration Law and the October 2019 draft revisions to the Drug Registration Regulation represent missed opportunities to establish an effective mechanism for early resolution of potential patent disputes and data protection”. This statement seems to refer to what is generally known as “patent linkage”, a TRIPS-plus mechanism actively promoted by the US in order to link the drug regulatory authorities’ granting of marketing approval with a drug’s patent status. “Patent linkage” is not an international standard of protection; the European Union (EU), for instance, does not apply it, nor does it require its partners to do so under the free-trade agreements entered into by the EU. One reason for this is that, in essence, “patent linkage changes the nature of patent law from a private right, where enforcement depends on the rights-holder’s diligence, to a public right, where enforcement is undertaken by national authorities, financed by taxpayers”.<sup>70</sup>

In 2017 the CFDA published draft legislation of a proposed patent linkage procedure for public review.<sup>71</sup> Importantly, the “Economic And Trade Agreement Between the Government of the United States of America and the Government of the People’s Republic of China” of 15 January 2020<sup>72</sup> included a specific provision on the subject (see Box 1) under which China committed to introducing some form of “patent linkage”, although limited to the supply of information to rights-holders and the availability of “preliminary injunctions or equivalent effective provisional measures”. Despite this commitment, the Report considered China as not providing the “adequate” and “effective” protection the US seeks.

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<sup>67</sup> European Union, China IPR SME Help Desk, *Enforcement of Intellectual Property Rights in China* (2013). Available from [https://www.china-iprhelpdesk.eu/sites/all/docs/publications/EN\\_Enforcement\\_Aug-2013.pdf](https://www.china-iprhelpdesk.eu/sites/all/docs/publications/EN_Enforcement_Aug-2013.pdf).

<sup>68</sup> ZHAO Meisheng, “The Intellectual Property Protection and Enforcement in China” (2016). Available from [https://www.wipo.int/edocs/mdocs/enforcement/en/wipo\\_ace\\_11/wipo\\_ace\\_11\\_6\\_ppt.pdf](https://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_11/wipo_ace_11_6_ppt.pdf).

<sup>69</sup> See e.g. Jinzo Fujino and Hideaki Yoshida, *The Enforcement of the Intellectual Property Rights in Japan* (Japan Patent Office, Asia - Pacific Industrial Property Center, Japan Institute for Promoting Invention and Innovation, 2018). Available from [https://www.jpo.go.jp/e/news/kokusai/developing/training/textbook/document/index/66\\_enforcement.pdf](https://www.jpo.go.jp/e/news/kokusai/developing/training/textbook/document/index/66_enforcement.pdf).

<sup>70</sup> Kyung-Bok Son, Ruth Lopert, Deborah Gleeson and Tae-Jin Lee, “Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States”, *Globalization and Health* vol. 14, No. 101 (2018). Available from <https://doi.org/10.1186/s12992-018-0423-0>.

<sup>71</sup> See e.g. Adam Rimmer, “What does the US-China trade deal mean for pharmaceutical patent holders?” Available from <https://www.reddie.co.uk/2020/01/23/what-does-the-us-china-trade-deal-mean-for-pharmaceutical-patent-holders/>.

<sup>72</sup> Available from [https://ustr.gov/sites/default/files/files/agreements/phase%20one%20agreement/Economic\\_And\\_Trade\\_Agreement\\_Between\\_The\\_United\\_States\\_And\\_China\\_Text.pdf](https://ustr.gov/sites/default/files/files/agreements/phase%20one%20agreement/Economic_And_Trade_Agreement_Between_The_United_States_And_China_Text.pdf).

### Box 1. US–China Economic and Trade Agreement: patent linkage

#### Article 1.11: Effective Mechanism for Early Resolution of Patent Disputes

1. If China permits, as a condition of approving the marketing of a pharmaceutical product, including a biologic, persons, other than the person originally submitting the safety and efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval by China or in another territory, China shall provide:

- . (a) a system to provide notice to a patent holder, licensee, or holder of marketing approval, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use;
- . (b) adequate time and opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies in subparagraph (c); and
- . (c) procedures for judicial or administrative proceedings and expeditious remedies, such as preliminary injunctions or equivalent effective provisional measures, for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use.

2. China shall establish a nationwide system for pharmaceutical products consistent with paragraph 1, including by providing a cause of action to allow the patent holder, licensee, or holder of marketing approval to seek, prior to the marketing approval of an allegedly infringing product, civil judicial proceedings and expeditious remedies for the resolution of disputes concerning the validity or infringement of an applicable patent. China may also provide for administrative proceedings for the resolution of such disputes.

3. The United States affirms that existing US measures afford treatment equivalent to that provided for in this Article.

A similar situation arises in relation to the Report's claim about "restrictive patentability criteria, which do not permit innovators to rely on supplemental data on a consistent basis".<sup>73</sup> It should be noted, first, that the issue of "supplemental data" is not a matter of "patentability criteria". Second, the determination of the patentability criteria is one of the important flexibilities granted under the TRIPS Agreement.<sup>74</sup> Many scholars, UN organizations and the European Parliament<sup>75</sup> have advocated for the application of rigorous standards to avoid the grant of "low-quality" patents that may distort legitimate competition, such as "evergreening" and "patent thickets".<sup>76</sup> Third, many jurisdictions do not admit the use of post-filing data to support patentability, as the patent applicant is

<sup>73</sup> Report, op. cit., p. 44.

<sup>74</sup> See e.g. Carlos Correa, *Trade Related Aspects of Intellectual Property Rights. A Commentary on the TRIPS Agreement*, op. cit. chapter 9.

<sup>75</sup> European Parliament Resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI)): "...emphasises that the European Patent Office (EPO) and the Member States should only grant patents on medicinal products that strictly fulfil the patentability requirements of novelty, inventive step and industrial applicability, as enshrined in the European Patent Convention" (para. 48).

<sup>76</sup> Bronwyn H. Hall, Christian Helmers, Georg von Graevenitz and Chiara Rosazza Bondibene, "A study of patent thickets: final report prepared for the UK Intellectual Property Office, 29 October 2012. Available from [https://eml.berkeley.edu/~bhall/papers/HHvGR\\_Patent\\_Thickets\\_FIN\\_29Oct12.pdf](https://eml.berkeley.edu/~bhall/papers/HHvGR_Patent_Thickets_FIN_29Oct12.pdf).

presumed to have all the information about his or her invention at the time of filing in order to avoid speculative patent applications. Fourth, the TRIPS Agreement does not impose any obligation on member States with regard to such use. Finally, the US–China “Economic and Trade Agreement” referred to does provide for a commitment to permitting pharmaceutical patent applicants to rely on supplemental data, even during judicial proceedings (see Box 2).

**Box 2. US–China Economic and Trade Agreement: supplemental data**

Article 1.10: Consideration of Supplemental Data

1. China shall permit pharmaceutical patent applicants to rely on supplemental data to satisfy relevant requirements for patentability, including sufficiency of disclosure and inventive step, during patent examination proceedings, patent review proceedings, and judicial proceedings.

The USTR’s claim about “the lack of patent term extensions to compensate for unreasonable delays that occur in granting a patent or in relation to marketing approvals”, similarly, refers to a TRIPS-plus protection that is, however, included in the 2020 US–China Economic and Trade Agreement (see Box 3).

**Box 3. US–China Economic and Trade Agreement: extension of the patent term**

Article 1.12: Effective Patent Term Extension

1. The Parties shall provide patent term extensions to compensate for unreasonable delays that occur in granting the patent or during pharmaceutical product marketing approvals.

. China shall provide that:

- (a) China, at the request of the patent owner, shall extend the term of a patent to compensate for unreasonable delays, not attributable to the applicant, that occur in granting the patent. For purposes of this provision, an unreasonable delay shall at least include a delay in the issuance of the patent of more than four years from the date of filing of the application in China, or three years after a request for examination of the application, whichever is later.
- (b) With respect to patents covering a new pharmaceutical product that is approved for marketing in China and methods of making or using a new pharmaceutical product that is approved for marketing in China, China, at the request of the patent owner, shall make available an adjustment of the patent term or the term of the patent rights of a patent covering a new product, its approved method of use, or a method of making the product to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial use of that product in China. Any such adjustment shall confer all of the exclusive rights, subject to the same limitations and exceptions, of the patent claims of the product, its method of use, or its method of manufacture in the originally issued patent as applicable to the approved product and the approved method of use of the product. China may limit such adjustments to no more than five years and may limit the resulting effective patent term to no more



than 14 years from the date of marketing approval in China.

3. The United States affirms that existing US measures afford treatment equivalent to that provided for in this Article.

With the above provision China will be bound to extend the patent term for pharmaceutical products. Patent term extension provisions are typical in free-trade agreements entered into by the US and EU;<sup>77</sup> they provide the so-called “originator” industry the possibility of charging high prices beyond the 20-year terms of protection that have become the norm since the adoption of the TRIPS Agreement. The ensuing delay in the market entry of pharmaceutical products can entail significant costs for patients and health providers. A study in Chile, for instance, on 12 medicines marketed by nine companies that requested such an extension, found that a significant volume of sales would be affected.<sup>78</sup> The same study noted that “as of November 2015 there were 475 patent applications pending which, if accepted for registration, could also request supplementary protection, aggravating the effects of the problem detected by the FNE (National Economic Prosecutor’s Office)”.<sup>79</sup> This extension significantly delays the entry of generic competition, such as with respect to medicines for cancer, diabetes and glaucoma. On average, the patents have lasted for 25.5 years.<sup>80</sup>

The Report, published three months after the signing of the US–China Economic and Trade Agreement, does recognize the commitments made by China in the Agreement with regard to “patent linkage”, supplemental data and patent term extension but declares the intent of the United States to “work closely with U.S. industry to monitor developments and to ensure that China’s new system [on patent linkage] works as contemplated”.<sup>81</sup>

Finally, the Report complains that

The Human Genetic Resources Administrative Regulation, which went into effect in July 2019, mandated collaboration with a Chinese partner for any research, sharing of all records and data, and joint ownership of any patent rights resulting from the collaboration. These and other requirements, such as the requirement to sign an undertaking letter to certify compliance with China’s regulations, create significant hurdles for pharmaceutical innovators seeking to bring products to market in China, including by conducting research and clinical trials in China.<sup>82</sup>

This complaint shows the broad and variable scope of USTR demands in the context of Special Section 301, as it is completely unrelated to the protection of patents but refers rather to the science and technology policy in China. It is standard for partners in research to share data and output (including ownership of patents), and there is no international standard that would prohibit this practice. The argument about the hurdles created by “the requirement to sign an undertaking letter to certify compliance with China’s regulations” is quite surprising, as it seems to imply that US companies should be freed from compliance with the laws of the country where they operate.

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<sup>77</sup> See e.g. Jean-Frédéric Morin and Jenny Surbeck, “Mapping the new frontier of international IP law: introducing a TRIPS-plus dataset”, *World Trade Review*, vol. 19, No. 1 (2020).

<sup>78</sup> Chile, Fiscalía Nacional Económica, *Estudio sobre el sistema de protección suplementaria de patentes en Chile y sus efectos en materia de libre competencia* (January 2016). Available from <http://www.fne.gob.cl/wp-content/uploads/2016/02/FNE-Proteccion-suplementaria.pdf>.

<sup>79</sup> Ibid. See also <http://www.fne.gob.cl/fne-detecta-extension-errada-de-patentes-en-al-menos-12-medicamentos/>.

<sup>80</sup> Ibid.

<sup>81</sup> Report, p. 45.

<sup>82</sup> Id., pp. 44–45.



The USTR's claims regarding how the patent system works in China do not end here but extend to a number of alleged, actual or potential, discriminatory or unfair practices and interpretations (see Box 4).

**Box 4. Further claims of the USTR against China on patent issues<sup>83</sup>**

China should address the continuing problems with the difficulty of obtaining evidence of infringement, disclosure obligations in standards-setting processes, the failure to clarify that a patentee's right to exclude extends to manufacturing for export and the need to harmonize China's patent grace period and statute of limitations with international practices.

After various ministries issued a November 2018 memorandum of understanding (MOU) imposing "social credit system" penalties for certain categories of patent-related conduct, CNIPA issued in October 2019 the Trial Measures for Administering the List of Targets for Joint Punishment Due to Serious Dishonesty in the Patent Field. These measures lack critical procedural safeguards, such as notice to the targeted entity, clear factors for determinations, or opportunities for appeal. The United States objects to any attempt to expand the "social credit system" in the field of IP.

Implementation of the Standardization Law has failed to establish that standards-setting processes are open to domestic and foreign participants on a non-discriminatory basis or to provide sufficient protection for standards-related copyright and patent rights and protections from public disclosure for enterprise standards.

In January 2020 China published for public comment a revised draft of the Anti-Monopoly Law (AML). This draft's provisions contain clarifications about the fair competition review system but raise concerns that China's competition authorities may continue to target foreign patent-holders for AML enforcement and use the threat of enforcement to pressure US patent-holders to license to Chinese parties at lower rates, despite the United States' having repeatedly expressing strong concerns regarding this practice. It is critical that China's AML enforcement be fair, transparent and non-discriminatory, afford due process to parties, focus only on the legitimate goals of competition law, and not be used to achieve industrial policy goals.

All the claims in Box 4 are beyond any international standards, notably the TRIPS Agreement, and show the USTR's degree of interference with national policies in using the Special Section 301. The USTR seems to believe that national patent policies must be framed and applied in accordance with US companies' wishes so as to operate in an ideal framework in which none of their conduct can be subject to scrutiny or orientation under the public policies of the foreign country concerned.

**Indonesia**

As in the case of China, the USTR charges against Indonesia that led it to being considered a "Priority Watch List" country show the broadness of the USTR's allegations in relation to patent laws and its contempt for the standards defined under the TRIPS Agreement. Such charges include:

*Patentability standards*

In accordance with the Report, "Indonesia's 2016 Patent Law continues to raise

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<sup>83</sup> Id., p. 45.

concerns, including with respect to the patentability criteria for incremental innovations...”<sup>84</sup>

Indonesia introduced in 2016 a welcome amendment to its patent law, inspired by section 3(d) of the Indian Patent Act,<sup>85</sup> that prevents the “evergreening” of pharmaceutical patents.<sup>86</sup> In accordance with such amendment, patents are banned with respect to “discoveries of (i) the new use for any existing and/or known products and (ii) the new form of an existing compound that shows no increase of efficacy and changes of chemical structure of the existing compound”.<sup>87</sup> This amendment is fully compatible with the TRIPS Agreement, which, as noted above, does not define the standards of patentability and leaves WTO members the (important) flexibility to determine how such standards will be applied.<sup>88</sup> In fact, neither India, Indonesia nor the Philippines (which incorporated a similar provision into its patent law in 2008)<sup>89</sup> have been subject to complaints under WTO rules on the grounds of violating the TRIPS Agreement.

### *Grounds and procedures for issuing compulsory licenses*

In accordance with the Report,

In December 2019, the Ministry of Law and Human Rights (MLHR) issued Regulation 30/2019, which establishes procedures for compulsory licenses and addresses a number of concerns included in the previous compulsory licensing regulation, Regulation 39/2018.<sup>90</sup>

The United States welcomes Indonesia’s efforts to eliminate the 2016 Patent Law’s local working requirement, including by introducing an amendment to the law through the Job Creation omnibus bill.<sup>91</sup>

The grant of compulsory licenses is one of the recognized rights under the TRIPS Agreement, along with the determination of the grounds for such a grant in accordance with national public policies.<sup>92</sup> Indonesia is one of the WTO countries that has issued compulsory licenses, which it did in 2004 and 2012 to enhance access to medicines.<sup>93</sup> Lack of local working is one of the legitimate grounds for compulsory licenses, as expressly recognized under Article 5A of the Paris Convention for the Protection of Industrial Property (hereinafter “the Paris Convention”).<sup>94</sup> Regulation 39/2018<sup>95</sup> and

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<sup>84</sup> Id., p. 48.

<sup>85</sup> See below.

<sup>86</sup> See e.g. Carlos Correa, “Tackling the proliferation of patents: how to avoid undue limitations to competition and the public domain”, Research Paper No. 52 (South Centre, 2014). Available from [https://www.southcentre.int/wp-content/uploads/2014/09/RP52\\_Tackling-the-Proliferation-of-Patents-rev\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2014/09/RP52_Tackling-the-Proliferation-of-Patents-rev_EN.pdf).

<sup>87</sup> See <https://wipo.lex.wipo.int/en/text/421121>.

<sup>88</sup> See e.g. Carlos Correa, 2014, op. cit.

<sup>89</sup> “Section 22. Non-Patentable Inventions - The mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant”.

<sup>90</sup> Report, op. cit., p. 48.

<sup>91</sup> Report, op. cit., p. 49.

<sup>92</sup> See e.g. Carlos Correa, “Guide for the granting of compulsory licenses and government use of pharmaceutical patents”, Research Paper No. 107 (South Centre, 2020). Available from <https://www.southcentre.int/wp-content/uploads/2020/04/RP-107.pdf>.

<sup>93</sup> See <https://ipaccessmeds.southcentre.int/wp-content/uploads/2020/04/Covid-19-CL-Table-FINAL.pdf>.

<sup>94</sup> Article 2.1 of the TRIPS Agreement provides that “In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967)”.

<sup>95</sup> This Regulation established in Article 20 the following: “1. A Patent Holder shall be obligated to make a product or implement a process in Indonesia. 2. The production or the application of a process as referred

Regulation 30/2019 clarified some of the aspects relating to the conditions and procedures for the request and grant of such licenses in case of failure to locally work a patent, in line with the national law and the Paris Convention. As noted in the Report, however, the Job Creation Omnibus Bill submitted by the government in February 2020 would derogate, if approved, Article 20 of the Patent Law No. 13 of 2016, which obligates patent holders to manufacture the product or use the process in Indonesia within 3 years of the grant date, failing which a compulsory license can be granted.<sup>96</sup> Not surprisingly, “[t]he United States welcomes Indonesia’s efforts to eliminate the 2016 Patent Law’s local working requirement, including by introducing an amendment to the law through the Job Creation omnibus bill. The United States urges the passage of this amendment...”<sup>97</sup>

#### *Disclosure of origin in patent claims related to traditional knowledge and genetic resources*

Indonesia has been particularly active with other developing countries in promoting an amendment to the TRIPS Agreement in order to prevent the misappropriation of genetic resources and traditional knowledge through an obligation (to be spelled out in a new article 29bis) of the patent applicant to disclose their origin or source in patent applications. Developing countries have also made efforts—so far unsuccessful—to introduce a provision for that purpose in the texts under negotiation at the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) of the World Intellectual Property Organization (WIPO).<sup>98</sup> Article 26 of Indonesian Law No. 13 of 28 July 2016 on Patents contains an elaborated provision on the matter (see Box 5).

#### **Box 5. Indonesia: obligation to disclose the origin of genetic resources and traditional knowledge**

Article 26 (1) If an invention as being associated with and/or derived from a genetic resource and/ or traditional knowledge, it is mandatory to disclose the origin of the genetic resource and/or traditional knowledge in question in a clear and true manner in its patent description. (2) Information about a genetic resource and/ or traditional knowledge mentioned in sub Article 26 (1) If an invention as being associated with and/or derived from a genetic resource and/ or traditional knowledge, it is mandatory to disclose the origin of the genetic resource and/or traditional knowledge in question in a clear and true manner in its patent description. (2) Information about a genetic resource and/ or traditional knowledge mentioned in sub article (1) is endorsed by a competent authority authorized by the government. (3) Benefit sharing and/or access for the utilization of a genetic resource and/or traditional knowledge substantiated in sub article (1) is conducted based on national laws and international laws in the realm of genetic resources and traditional knowledge.

While strongly opposed by the US, the referenced disclosure obligation, as adopted by the Indonesian and a large number of other countries,<sup>99</sup> is fully compatible with the

to in paragraph (1) must support the transfer of technology, absorption of investment, and/or provision of employment”. See <https://zico.group/blog/new-provisions-on-patent-regulations-in-indonesia/>.

<sup>96</sup> “Indonesia proposes to revoke controversial patent working requirements via Omnibus Law”, *Rouse: The Magazine* (19 February 2020). Available from <https://www.rouse.com/magazine/news/indonesia-proposes-to-revoke-controversial-patent-working-requirements-via-omnibus-law/>.

<sup>97</sup> Report, op. cit., p. 49.

<sup>98</sup> See e.g. Nirmalya Syam and Thamara Romero, “Intellectual property and misappropriation of genetic resources and traditional knowledge: a global problem in search of a multilateral solution” (South Centre, forthcoming).

<sup>99</sup> See WIPO, *Disclosure Requirements Table* (2019). Available from <https://www.wipo.int/>

TRIPS Agreement and does not represent a challenge to nor a diminution of the patentees' rights. It simply aims to increase transparency so as to avoid the misappropriation of traditional knowledge and genetic resources and ensure compliance with the benefit-sharing obligations under the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.<sup>100</sup>

The USTR's claim about maintenance fees is another notable example of the USTR's unbound approach in judging foreign countries' laws and policies. It claims that Indonesia "has imposed excessive and inappropriate penalties upon patent holders as an incentive to collect patent maintenance fees". This claim relates to the action taken by the Indonesian patent office to recover the unpaid annual fees along with interest (reportedly amounting to around US\$12,000,000) that had caused a significant financial loss to the government.<sup>101</sup> The Directorate General of Intellectual Property Rights (DGIP) decided not to accept "any new patent filing applications from the defaulter patent owners who have not cleared the pending debt of their previously filed Patents".<sup>102</sup> The USTR notes that "although DGIP has extended its deadline to collect the fees, the United States continues to monitor the issue".<sup>103</sup> This suggests that the USTR is protecting the interests of US companies even when they are found to have failed to comply with the law of the country where they seek patent protection.

## India

India's patent policy has evolved in line with the TRIPS Agreement, having in view the protection of rights owners as well as the public interest, notably in relation to access to pharmaceuticals. The patent reform of 2005, in particular, introduced an innovative approach to deal with "evergreening" of pharmaceutical patents through the introduction of section 3(d) in the Patent Act.<sup>104</sup>

The alleged "narrow patentability criteria under the India Patents Act" is one of the "longstanding concerns of the innovative industries" in accordance with the USTR.<sup>105</sup> The Report notes that,

In the pharmaceutical sector, Section 3(d) of the India Patents Act also remains problematic. One implication of its restriction on patent-eligible subject matter is the failure to incentivize innovation that would lead to the development of improvements with benefits for Indian patients.<sup>106</sup>

Interestingly, however, neither the US nor other WTO members has brought a case under the DSU rules arguing that section 3(d) is in violation of the TRIPS Agreement. As noted above, the Indian approach has been followed by other countries; it is a legitimate option for ensuring that patents relating to pharmaceuticals are granted when an

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[export/sites/www/tk/en/documents/pdf/genetic\\_resources\\_disclosure.pdf](https://www.export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf).

<sup>100</sup> Gurdial Singh Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries*, Research Paper No. 36 (South Centre, March 2011).

<sup>101</sup> See Deepika Sharma, "Indonesia: unpaid patent annual fee causes huge losses to patent office of Indonesia", 12 November 2018. Available from <https://www.mondaq.com/patent/753344/unpaid-patent-annual-fee-causes-huge-losses-to-patent-office-of-indonesia>.

<sup>102</sup> Ibid.

<sup>103</sup> Report, p. 49.

<sup>104</sup> See Bhaven N. Sampat and Kenneth C. Shadlen, "Indian pharmaceutical patent prosecution: the changing role of Section 3(d)", *PLoS One* (2018). Available from <https://pubmed.ncbi.nlm.nih.gov/29608604/>.

<sup>105</sup> Report, op. cit., p. 50.

<sup>106</sup> Ibidem.

invention genuinely makes a contribution to the pre-existing technological pool. Moreover, a study has shown that the Indian grant rate of pharmaceutical patent applications is about 12 percentage points higher than the Japanese rate, only 10 percentage points lower than the EPO, and much higher than the grant rate in Argentina or Brazil.<sup>107</sup> Furthermore, this study found that the fact that “nearly all rejections citing Section 3(d) also gave other grounds for denying the patent—also suggests that the actual scope for independent 3(d) rejections may be quite limited”.<sup>108</sup> Another study found that the application of section 3(d) has not been as strict as often claimed, as in some cases patents on pharmaceutical inventions that were granted in India were deemed “to lack novelty or inventive step in jurisdictions that have much more liberal patentability criteria than India”.<sup>109</sup>

The Report also ambiguously claim as a “particular concern” “the potential threat of compulsory licenses and patent revocations”.<sup>110</sup> This claim, though not surprising, is quite paradoxical not only because India has granted only one compulsory license since the adoption of the patent regime in the country,<sup>111</sup> but also because the US has granted the largest number of compulsory licenses of any nation,<sup>112</sup> including through court decisions in accordance with the precedent set by the US Supreme Court in *eBay vs. MercExchange*.<sup>113</sup> According to a study by US scholars, this case marked “a sea change in U.S. patent policy. The *eBay* decision removed the presumption of injunctive relief. Subsequent legal and policy changes reduced the costs of challenging patent validity and narrowed the scope of patentable subject matter”.<sup>114</sup>

On the other hand, patent revocation in India can be declared only on the specific grounds provided for by the law<sup>115</sup> and is subject to judicial review as required under the TRIPS Agreement.<sup>116</sup> The risk of a patent’s revocation in India is not higher than in the US or other jurisdictions. On the contrary: given the lax standards of patentability applied in the US, the risk of revocation may be higher there. It has been noted in this regard

<sup>107</sup> Bhaven N. Sampat and Ken Shadlen, “The effects of restrictions on secondary pharmaceutical patents: Brazil and India in comparative perspective”. Available from [https://economics.harvard.edu/files/economics/files/sampat-bhaven\\_effects\\_of\\_restrictions\\_on\\_secondary\\_pharma\\_patents\\_brazil\\_and\\_india\\_3-4-16.pdf](https://economics.harvard.edu/files/economics/files/sampat-bhaven_effects_of_restrictions_on_secondary_pharma_patents_brazil_and_india_3-4-16.pdf), pp. 17–18.

<sup>108</sup> *Id.*, p. 30.

<sup>109</sup> Chan Park, “Implementation of India’s patent law: a review of patents granted by the Indian Patent Office”, in UNDP, *Five Years into the Product Patent Regime: India’s Response*, p. 101. Available from [https://www.undp.org/content/dam/india/docs/five\\_years\\_into\\_the\\_product\\_patent\\_regime\\_india%e2%80%99s\\_response.pdf](https://www.undp.org/content/dam/india/docs/five_years_into_the_product_patent_regime_india%e2%80%99s_response.pdf).

<sup>110</sup> Report, *op. cit.*, p. 50.

<sup>111</sup> “India’s first-ever compulsory license was granted by the Patent Office on March 9, 2012, to Natco Pharma for the generic production of Bayer Corporation’s Nexavar, a life saving medicine used for treating Liver and Kidney Cancer. Bayers sold this drug at exorbitant rates, with one month’s worth of dosage costing around Rs 2.8 Lakh. Natco Pharma offered to sell it around for Rs 9000, making it affordable for people belonging to every stratum. All the 3 conditions of section 84 were fulfilled and the decision was taken for the benefit of general public” (Nayanikaa Shukla, “India: compulsory licensing In India”, 18 January 2019. Available from <https://www.mondaq.com/india/patent/772644/compulsory-licensing-in-india>.)

<sup>112</sup> Scherer has noted that “[l]iterally tens of thousands of patents” have been compulsorily licensed in the United States. See F. M. Scherer’s (1998) comments, in *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy*, Robert Anderson and Nancy Gallini. Eds. (Alberta, University of Calgary Press). See also Carlos Correa, “Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries”, T.R.A.D.E. Working Papers No. 5 (South Centre, October 1999). Available from [https://www.southcentre.int/wp-content/uploads/2020/04/Intellectual\\_Property\\_Rights\\_and\\_the\\_Use\\_of\\_Co.pdf](https://www.southcentre.int/wp-content/uploads/2020/04/Intellectual_Property_Rights_and_the_Use_of_Co.pdf).

<sup>113</sup> Available from <https://www.supremecourt.gov/opinions/05pdf/05-130.pdf>.

<sup>114</sup> Filippo Mezzanotti and Timothy S. Simcoe, “Patent policy and American innovation after eBay: an empirical examination” (22 May 2018). Available from <https://ssrn.com/abstract=3183402>.

<sup>115</sup> See e.g. Rohit Hebbale, “Patent revocation in India”, 29 June 2018. Available from <https://www.intepat.com/blog/patent/patent-revocation-india/>.

<sup>116</sup> See Article 32 of the TRIPS Agreement (“An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available”).

that “[a] comparison between PTAB [Patent Trial and Appeal Board] proceedings and their equivalents in other major jurisdictions reveals that the high invalidation rate is unique to the U.S. In 2015, 75 percent of patents in the U.S. were invalidated...”.<sup>117</sup> In accordance with a report by the US’s Government Accountability Office, “[W]hen the courts do rule on validity, they generally invalidate almost half of the patents that are challenged...”.<sup>118</sup>

The Report also argues that “patent applicants continue to confront costly and time-consuming pre- and post-grant oppositions, long waiting periods to receive patent approval, and excessive reporting requirements”.<sup>119</sup> Pre- and post-grant oppositions, however, are fully legitimate and routinely applied in many countries.<sup>120</sup> Furthermore, such procedures are not regulated by the TRIPS Agreement (except in relation to general procedural principles). As noted by WIPO:

No international treaty expressly regulates the substantive requirements with respect to various administrative revocation mechanisms, such as opposition systems, re-examination procedures or other administrative revocation procedures available under the national/regional laws as such. Countries are free to provide, or not to provide, such mechanisms in their national laws.<sup>121</sup>

It is also worth noting that the US strengthened the post-grant examination procedures in 2011,<sup>122</sup> reportedly leading to a duplication of administrative proceedings and patent infringement litigation.<sup>123</sup> In accordance with a statistical analysis, only 4% of the 1,556 petitions submitted to the Patent Trial and Appeal Board (PTAB) ended with a decision that upheld all claims as patentable; in 69% of cases, all claims were deemed unpatentable.<sup>124</sup> Currently, the PTAB decides about 12,000 appeals and 1,500 trial proceedings per year; in addition, the PTAB’s decisions can be appealed to the US Court of Appeals for the Federal Circuit.<sup>125</sup>

## Algeria

The USTR Report’s claims regarding Algeria are particularly overbroad, even going beyond the area of IP, and vague. Thus, in accordance with the Report:

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<sup>117</sup> Douglas R. Nemec, “After period of high invalidation rates, new US patent challenge procedures may slow down to moderate pace”, 26 April 2016. Available from <https://www.skadden.com/insights/publications/2016/04/after-period-of-high-invalidations-rates-new-us-pat>.

<sup>118</sup> Government Accountability Office, *Intellectual Property: Patent Office Should Define Quality, Reassess Incentives, and Improve Clarity*. GAO-16-490 (30 June 2016). Available from <https://www.gao.gov/products/GAO-16-490>, p. 11.

<sup>119</sup> Report, op. cit., p. 50.

<sup>120</sup> See e.g. WIPO, *Opposition Systems*. Available from [https://www.wipo.int/scp/en/revocation\\_mechanisms/opposition/index.html](https://www.wipo.int/scp/en/revocation_mechanisms/opposition/index.html).

<sup>121</sup> Ibid.

<sup>122</sup> See e.g. Patricia Carson and Ashley Cade, “Implications of *inter partes* review proceedings on biotech/pharma litigation”, *Future Science Pharmaceutical Patent Analyst*, vol. 8, No. 3 (10 June 2019). Available from <https://www.future-science.com/doi/10.4155/ppa-2019-0010>.

<sup>123</sup> See Anne S. Layne-Farrar, “The cost of doubling up: an economic assessment of duplication in PTAB proceedings and patent infringement litigation”, *Landslide*, vol. 10, No. 5 (May–June 2018). Available from [https://www.crai.com/sites/default/files/publications/The\\_Cost\\_of\\_Doubling\\_Up\\_An\\_Economic\\_Assessment\\_of\\_Duplication\\_in\\_PTAB\\_proceedings\\_Landslide\\_May\\_2018\\_Layne\\_Farrar.pdf](https://www.crai.com/sites/default/files/publications/The_Cost_of_Doubling_Up_An_Economic_Assessment_of_Duplication_in_PTAB_proceedings_Landslide_May_2018_Layne_Farrar.pdf).

<sup>124</sup> Steve Brachmann and Gene Quinn, “Are more than 90 percent of patents challenged at the PTAB defective?”, 14 June 2017. Available from <https://www.ipwatchdog.com/2017/06/14/90-percent-patents-challenged-ptab-defective/id=84343/>.

<sup>125</sup> Janet Gongola, “The Patent Trial and Appeal Board: who are they and what do they do?”. Available from <https://www.uspto.gov/learning-and-resources/newsletter/inventors-eye/patent-trial-and-appeal-board-who-are-they-and-what>.



Significant challenges continue with respect to fair and equitable market access for U.S. intellectual property (IP) right holders in Algeria, notably for pharmaceutical and medical device manufacturers. The ban on the importation of 368 pharmaceutical products and medical devices originally imposed in 2009 remains in place.

Quite obviously, a ban on the importation of pharmaceuticals or other products is strictly a trade issue, not a matter of IP protection. Notably, Algeria is bound by neither the WTO rules on tariffs nor the TRIPS Agreement.<sup>126</sup>

In addition to claiming the lack of protection for “undisclosed test or other data generated to obtain marketing approval for pharmaceutical products”, the USTR generically claims that “Algeria needs to make more progress to provide adequate and effective IP protection and enforcement, including providing adequate judicial remedies in cases of patent infringement”.

Notably, the European Commission Staff Working Document on the protection and enforcement of IP rights in third countries did not identify Algeria as a country where inadequacies of intellectual property enforcement exist,<sup>127</sup> while the Algerian patent law provides for patent infringement remedies that are standard in most national laws.<sup>128</sup>

## Argentina

The USTR’s claims against Argentina are substantially based on patent law issues,<sup>129</sup> which are characterized as “long-standing and well-known challenges to intellectual property (IP)-intensive industries, including those from the United States”.<sup>130</sup>

In accordance with the Report,

a key deficiency in the legal framework for patents is the unduly broad limitations on patent-eligible subject matter. Pursuant to a highly problematic 2012 Joint Resolution establishing guidelines for the examination of patents, Argentina rejects patent applications for categories of pharmaceutical inventions that are eligible for patentability in other jurisdictions, including in the United States. Additionally, to be patentable, Argentina requires that processes for the manufacture of active compounds disclosed in a specification be reproducible and applicable on an industrial scale.

The Report makes reference to Joint Resolutions 118/2012, 546/2012 and 107/2012,<sup>131</sup> under which the government approved detailed guidelines for examining pharmaceutical

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<sup>126</sup> Algeria is not a WTO member. A Working Party to consider Algeria’s accession to the WTO was established on 17 June 1987 and met for the last time in 2014. See [https://www.wto.org/english/thewto\\_e/acc\\_e/a1\\_algerie\\_e.htm](https://www.wto.org/english/thewto_e/acc_e/a1_algerie_e.htm).

<sup>127</sup> Commission Staff Working Document, *Report on the Protection and Enforcement of Intellectual Property Rights in Third Countries* (2020). Available from [https://trade.ec.europa.eu/doclib/docs/2020/january/tradoc\\_158561.pdf](https://trade.ec.europa.eu/doclib/docs/2020/january/tradoc_158561.pdf).

<sup>128</sup> See e.g. Adams & Adams, *Adams & Adams Practical Guide to Intellectual Property in Africa* (Pretoria, Pretoria University Law Press, 2012) p. 27.

<sup>129</sup> The lack of “data exclusivity” is another longstanding US claim, despite the US’s having already failed to impose it on Argentina through a formal WTO complaint. The complaint ended in 2002 with a mutually agreed solution under which Argentina maintained data protection in accordance with the standard of Article 39.3 of the TRIPS Agreement, which does not require such exclusivity, merely protection against unfair competition. See [https://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds171\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds171_e.htm).

<sup>130</sup> Report, op. cit., p. 60.

<sup>131</sup> Ministerio de Industria, Ministerio de Salud e Instituto Nacional de la Propiedad Industrial, Resolución Conjunta 118/2012, 546/2012 y 107/2012, “Apruébanse las pautas para el examen de Patentabilidad de



patent claims relating to formulations, salts, polymorphs, enantiomers and other matters, which are often the basis on which the pharmaceutical industry “evergreens” its basic patents. Such patents allow rights-holders to extend their control of the market and prevent or delay generic competition.<sup>132</sup> The referenced guidelines were designed and are applied in the context of the freedom to regulate this matter granted by the TRIPS Agreement. They aim at a rigorous, scientifically-based, examination of patent applications<sup>133</sup> and have never been the subject of a complaint by the US or any other WTO member under the WTO rules. The guidelines have led to a reduction in the rate of approval of such applications, which nonetheless remains higher than that of Brazil,<sup>134</sup> where no similar claim has been raised by the USTR.<sup>135</sup>

The argument that Argentina applies an overly narrow standard of industrial applicability likewise negates the room left under the TRIPS Agreement to define how such a standard is applied. Any WTO member has the right to avoid patenting developments deprived of a technical character or which can only be performed at the laboratory level (e.g. a method to produce a biotechnological product without the required purity or ability to be scaled up for industrial production). The US instead applies the broad standard of “utility”, which allows for the patenting of business methods and other subjects of a non-technical nature, but nothing obliges other countries to follow the same approach.<sup>136</sup>

Another USTR complaint relates to the guidelines adopted by the Argentine patent office to examine patents on biotechnological inventions:

Stakeholders assert that Resolution 283/2015, introduced in September 2015, also limits the ability to patent biotechnological innovations based on living matter and natural substances. These measures have interfered with the ability of companies investing in Argentina to protect their IP and may be inconsistent with international norms.<sup>137</sup>

This paragraph clearly reflects the nature of the USTR’s Special Section 301 reports: they are an instrument for US businesses to influence foreign countries’ legislation and practices that rely on the political and economic power of the US. If the Argentine standards for the granting of biotechnological inventions were “inconsistent with international norms”, the US could have recourse to the WTO dispute settlement system (which the US has put in existential crisis).<sup>138</sup> But it has not done so. Resolution 283/2015 does not prevent the granting of patents on biotechnological inventions; rather, it clarifies the application of the patent law, in particular, by spelling out the sufficiency-of-disclosure requirement in order to disallow broad claims based on homologous sequences. Patent applicants often deliberately draft vague descriptions in an attempt to extend the scope

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las solicitudes de Patentes sobre Invenciones Químico-Farmacéuticas”. Available from <https://www.wipo.int/edocs/lexdocs/laws/es/ar/ar109es.pdf>.

<sup>132</sup> See e.g. Carlos Correa, 2014, op. cit.

<sup>133</sup> See e.g. Mauricio Aragno and Mercedes Salamano, “Posicionamiento de las Pautas de Patentabilidad a través del análisis de Oposiciones a patentes de medicamentos”, April 2018. Available from [https://www.researchgate.net/publication/327045257\\_Posicionamiento\\_de\\_las\\_Pautas\\_de\\_Patentabilidad\\_a\\_traves\\_del\\_analisis\\_de\\_Oposiciones\\_a\\_patentes\\_de\\_medicamentos](https://www.researchgate.net/publication/327045257_Posicionamiento_de_las_Pautas_de_Patentabilidad_a_traves_del_analisis_de_Oposiciones_a_patentes_de_medicamentos).

<sup>134</sup> Bhaven N. Sampat and Ken Shadlen, loc. cit.

<sup>135</sup> See Report, op. cit., p. 78.

<sup>136</sup> For an analysis of the implications of the transplantation of the utility standards, see Sivaramjani Thambisetty, Legal Transplants in Patent Law: Why Utility is the New Industrial Applicability. LSE Law, Society and Economy Working Papers 6/2008. London: London School of Economics and Political Science Law Department. Available from <http://www.lse.ac.uk/law/working-paper-series/2007-08/WPS2008-06-Thambisetty.pdf>.

<sup>137</sup> Report, op. cit., p. 60.

<sup>138</sup> See Danish and Qwa, 2019, op. cit.

of their rights<sup>139</sup> or submit overly broad claims with the argument of an (unproven) equivalence among the elements included in the claim.<sup>140</sup> The Resolution also aims to ensure that plant and animals as such do not get indirectly patented through the protection of their parts and components. These are not additional limitations to patentability but measures required to properly implement the patent law and regulations adopted consistently with the TRIPS Agreement.

Finally, the Report points to the backlog at the Argentine patent office,<sup>141</sup> a matter that does not imply a denial of protection. This problem is shared by a large number of patent offices in the world, many of which have faced “massive backlogs of applications”.<sup>142</sup>

While Argentina’s National Institute of Industrial Property had agreed to participate in the Patent Prosecution Highway (PPH) with the US Patent and Trademark Office, the agreement reportedly expired in March 2020. The participation of developing countries’ patent offices in a PPH raises justified concerns, as it may influence the examination of patent applications on the basis of standards that are unsuitable or inconsistent with the applicable national law.<sup>143</sup>

## Chile

While the US–Chile free trade agreement—which entered into force in 2004—introduced provisions on “patent linkage”,<sup>144</sup> the US has never been satisfied with how Chile has implemented such provisions (the same applies to test data protection) and has complained about this over the years. The USTR urges Chile once again in the Report

to make effective its system for resolving patent issues expeditiously in connection with applications to market pharmaceutical products and to provide adequate protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products.<sup>145</sup>

The relentless repetition of this claim shows the ineffectiveness of the USTR’s Special Section 301 reports and its irrelevance when a country exercises the choice to prioritize the public interest and otherwise complies with its international obligations. Despite those reiterative complaints and the availability of a dispute-resolution mechanism under Chapter 22 of the US–Chile free trade agreement, the US has never formally initiated a complaint against Chile on the subject. The USTR’s frustration with this matter seems evident in the Report:

It is critical that Chile address the long-standing Chile FTA [free trade agreement] implementation issues and other IP issues. It has now been over fifteen years

<sup>139</sup> See e.g., Alexandra Karin Zaby and Gaétan de Rassenfosse, “The economics of patent backlog”, Annual Conference 2016 (Augsburg): Demographic Change 145673, Verein für Socialpolitik / German Economic Association. Available from <https://ideas.repec.org/p/zbw/vfsc16/145673.html>, p. 30.

<sup>140</sup> A typical example are the so-called “Markush claims”, under which millions of compounds can be protected under a single patent. See: Edward H. Balance, “Understanding the Markush Claim in Chemical Patents”. Available from <https://pubs.acs.org/doi/pdf/10.1021/c160002a022>.

<sup>141</sup> Report, op. cit., p. 60.

<sup>142</sup> Zaby, Alexandra Karin & de Rassenfosse, op. cit.

<sup>143</sup> Nirmalya Syam, *Robust Patent Examination or Deep Harmonization? Cooperation and Work Sharing between Patent Offices* (South Centre, forthcoming).

<sup>144</sup> Wael Armouti and Mohammad Nsour, “Data exclusivity for pharmaceuticals in free trade agreements: models in selected United States free trade agreements”. *Houston Journal of International Law*, vol. 40, No. 1 (2017–2018). Available from <http://www.hjil.org/wp-content/uploads/Nsour-FINAL.pdf>.

<sup>145</sup> Report, op. cit., p. 62.

since the Chile FTA entered into force, and the United States urges the need for tangible progress in these areas in 2020.<sup>146</sup>

The Report makes a quite questionable remark regarding compulsory licenses:

Chile's Ministry of Health has maintained Resolution 399 since 2018, which declared that there are public health reasons that justify issuing compulsory licenses on certain patent-protected drugs used to treat hepatitis C. While Chile has not issued a compulsory license, the resolution satisfies an initial legal requirement after which a third party may then make the request. The United States urges Chile to ensure transparency and due process in any actions related to compulsory licenses. To maintain the integrity and predictability of IP systems, Chile should use compulsory licenses only in extremely limited circumstances and after making every effort to obtain authorization from the patent owner on reasonable commercial terms and conditions.<sup>147</sup>

This remark ignores Chile's right, under international law, to determine the grounds on which it will grant compulsory licenses. Such a right is not limited under the US–Chile free trade agreement. The demand for Chile to use compulsory licenses only in “extremely limited circumstances” is unjustified. The practice in the US—a major user of the compulsory licenses system, as noted above—shows instead the US's granting of such licenses (and government use) on a variety of grounds, including considerations of “equity”, as judged by the courts in line with the above-mentioned Supreme Court decision in *eBay vs. MercExchange*. In addition, a government is not bound in all circumstances to make “every effort to obtain authorization from the patent owner on reasonable commercial terms and conditions”, as the Supreme Court decision and its saga demonstrates.<sup>148</sup> It is also worth noting that the high prices charged by Gilead, the owner of the patent over sofosbuvir—a medicine to treat hepatitis C—has provoked a strong reaction by many governments<sup>149</sup> and civil society.<sup>150</sup>

## Venezuela

The Report is very brief regarding Venezuela, another “Priority Watch country”. In addition to general observations about the country's low ranking in competitiveness and IP protection according to standards developed by private institutions, the Report notes:

Venezuela's reinstatement several years ago of its 1955 Industrial Property Law, which falls below international standards and raises concerns about trade agreements and treaties that Venezuela subsequently ratified, has created significant uncertainty and deterred investments related to innovation and IP protection in recent years. Additionally, Venezuela's Autonomous Intellectual Property Service has not issued a new patent since 2007.<sup>151</sup>

This critical claim relates to the lack of issuance of patents. As Venezuela is a WTO member, any other member (including the US) would have had the opportunity to

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<sup>146</sup> Id., p. 63.

<sup>147</sup> Id., p. 62.

<sup>148</sup> Christopher B. Seaman and Ryan T. Holte, “Patent injunctions on appeal: an empirical study of the federal circuit's application of *eBay*”, *Washington Law Review*, vol. 92 (March 2017). Available from <https://scholarlycommons.law.wlu.edu/cgi/viewcontent.cgi?article=1514&context=wluofac>.

<sup>149</sup> Malaysia, for instance, implemented the government use of the patent on sofosbuvir to improve access to this hepatitis C treatment. See <https://ipaccessmeds.southcentre.int/wp-content/uploads/2020/04/Covid-19-CL-Table-FINAL.pdf>.

<sup>150</sup> Germán Velasquez, “Access to hepatitis C treatment: a global problem”, Research Paper No. 77 (South Centre, May 2017). Available from <https://www.southcentre.int/research-paper-77-may-2017/>.

<sup>151</sup> Report, op. cit., p. 64.

challenge the alleged contravention under the DSU as a TRIPS Agreement violation, but no complaint has been articulated in that regard. In any case, it is worth recalling that WTO rulings cannot oblige a sovereign country to change its legislation or practices; they only allow the complaining party to suspend concessions or seek compensation.<sup>152</sup> It should also be noted that Venezuela is already subject to unilateral economic sanctions that “are extremely broad and fail to contain sufficient measures to mitigate their impact on the most vulnerable sectors of the population”.<sup>153</sup> Such measures can “have far-reaching implications on the rights to health and to food in particular, in a country where there are already serious shortages of essential goods”.<sup>154</sup> Further retaliations under the WTO rules, if allowed, would only add to the socio-economic problems Venezuela faces.

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<sup>152</sup> See Article 22 of the DSU.

<sup>153</sup> Michelle Bachelet, High Commissioner for Human Rights, “UN rights chief bemoans unilateral sanctions on Venezuela, fearing ‘far-reaching implications’”, *UN News*, 8 August 2019. Available at <https://news.un.org/en/story/2019/08/1043981>.

<sup>154</sup> *Ibid.*

## CONCLUSIONS

The continuous application of Special Section 301 by the USTR undermines the rule of law as a fundamental principle of a multilateral system based on the sovereign equality of states and respect for international law. Interference with foreign countries' national IP policies—which have significant socio-economic effects—negates their right to determine independently the level and modalities of protection of such property within the framework and policy space provided by the international treaties to which those countries have adhered. That section is incompatible with the principles of the UN Charter, which calls on all States to refrain from promulgating and applying laws and measures that are against international law and the principles of the sovereign equality of States, non-intervention and non-interference in their internal affairs, and freedom of international trade and navigation.

The preservation of Special Section 301 after the entry into force of the Agreement establishing the WTO and the US law provision allowing the USTR to initiate an “investigation” puts pressure on, and eventually, retaliates against, a WTO member even if the member complies with the TRIPS Agreement, and is an expression of disdain for a system of rules that the US decisively contributed to building. Moreover, this section is broadly applied on the basis of undefined, *ad hoc* standards essentially framed by US businesses, with complete ignorance of the legitimate public interests of the countries concerned (for instance, with regard to access to affordable medicines). This has contributed to discrediting the USTR's actions under Special Section 301, as well as to its ineffectiveness, as targeted countries continue to preserve their regulations and policies despite the USTR's claims.<sup>155</sup>

As examined above, the patent-related claims made by the USTR in relation to the developing countries on the Priority Watch List primarily aim to address the demands by pharmaceutical (and biotech) US companies for increased levels of protection beyond the agreed-upon standards under the TRIPS Agreement. Such demands aim to erode the policy space that governments enjoy for defining the patentability requirements mandated by said Agreement, notably so as to frame them in a way that ensures that patents are granted on genuine inventions and that “evergreening” and other practices—which limit legitimate competition—are prevented.

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<sup>155</sup> Research on the extent to which Special Section 301 has effectively led to the regulatory amendments sought by the USTR is likely to show that the targeted countries have kept their regulations unchanged. Examples of resilience are provided e.g. by Argentina, China and India, which have repeatedly been on the USTR's lists.

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Chemin du Champ-d'Anier 17  
PO Box 228, 1211 Geneva 19  
Switzerland

Telephone: (41) 022 791 8050  
E-mail: [south@southcentre.int](mailto:south@southcentre.int)

Website:  
<http://www.southcentre.int>

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