

**A FULL DESCRIPTION OF WTO TRIPS FLEXIBILITIES AVAILABLE TO ARIPO MEMBER STATES  
AND A CRITIQUE OF ARIPO'S COMPARATIVE STUDY ANALYZING AND MAKING  
RECOMMENDATIONS CONCERNING THOSE FLEXIBILITIES**

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Civil society advocates seek to constructively engage with the ARIPO Secretariat and ARIPO Member States on proposed reforms to the Harare Protocol and national legislation to take advantage of public health flexibilities allowed under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights<sup>1</sup> (TRIPS) to promote access to affordable medicines. We submit this paper for two purposes: (1) to clarify what the TRIPS Agreement does and does not require of ARIPO Member States and in particular to outline in detail TRIPS-compliant public health flexibilities that they might choose to enact at the national level and (2) to critique Chapter Two of A COMPARATIVE STUDY OF THE INDUSTRIAL PROPERTY LAWS OF ARIPO MEMBER STATES (COMPARATIVE STUDY) commissioned by the ARIPO Secretariat through WIPO that we believe inaccurately describes such flexibilities and thus inadequately analyzes Member State national legislation and inaccurately describes best practices for Member States' legal frameworks. This paper does not reexamine existing national legislation, but such a reexamination should be undertaken in light of the complete list of allowable TRIPS flexibilities identified in this paper rather than the partial list reviewed in the COMPARATIVE STUDY.

**1. ARIPO Member States' obligations, non-obligations, and flexibilities under the WTO TRIPS Agreement<sup>2</sup>**

The TRIPS Agreement is the key treaty affecting ARIPO Member States'<sup>3</sup> access to affordable medicines. TRIPS is fully or partially binding on seventeen of nineteen ARIPO members, so this section will start by outlining TRIPS obligations, common TRIPS-plus measures that can and should be avoided, and TRIPS-compliant public health flexibilities that can lawfully be incorporated into ARIPO Member States' national legislation. Thereafter, and in even greater detail, this section describes in full flexibilities that exist under the TRIPS Agreement, as clarified by the 2001 Doha Declaration on the TRIPS Agreement and Public Health,<sup>4</sup> and the 30 August 2003, Decision on Paragraph 6 of the Doha Declaration, now codified as TRIPS Article 31bis.<sup>5</sup>

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<sup>1</sup> World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Art. 8(1), 33 I.L.M. 81 (1994), [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_01\\_e.htm](https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm).

<sup>2</sup> This section of the analysis relies substantially on a previous analysis of TRIPS flexibilities co-authored by Brook Baker and Yousuf Vawda, SUBMISSION BY UNIVERSITY OF KWAZULU-NATAL-AFFILIATED ACADEMICS ON THE DRAFT INTELLECTUAL PROPERTY POLICY OF THE REPUBLIC OF SOUTH AFRICA PHASE 1 2017, <http://www.fixthepatentlaws.org/?p=1173>.

<sup>3</sup> There are currently 19 ARIPO Member States, all of whom are also signatories to the Harare Protocol. These are: Botswana, Eswatini (Swaziland), The Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, Sierra Leone, Sudan, Tanzania, Uganda, Zambia, Zimbabwe, and the Democratic Republic of São Tomé and Príncipe.

<sup>4</sup> World Trade Organization, Declaration on the TRIPS Agreement and Public Health (Doha Declaration), WT/MIN(01)/DEC/2, Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, paragraph 5(b), (c), [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

<sup>5</sup> Decision of the General Council of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr.1, [http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm); Article 31 bis added as of January 23, 2017, [https://www.wto.org/english/docs\\_e/legal\\_e/31bis\\_trips\\_e.pdf](https://www.wto.org/english/docs_e/legal_e/31bis_trips_e.pdf).

## 1.1 Obligations, TRIPS-plus measures, and flexibilities under the WTO TRIPS Agreement

The three charts below outline (1) the basic patent, data protection, and patent-related enforcement protections in the TRIPS Agreement affecting affordable access to medicines, (2) common TRIPS-plus measures, and (3) TRIPS compliant public health flexibilities.

**TRIPS minimum requirements.** The TRIPS Agreement established harmonized, minimum standards of intellectual property protection for copyright and related rights, trademarks, geographic indications, patents, protection of new varieties of plants, layout designs of integrated circuits, and undisclosed information including some trade secrets and test data. TRIPS also provided for minimum enforcement provisions and state-to-state dispute settlement. The provisions that are most relevant with respect to pharmaceuticals are patents, test data protection, and enforcement, which are summarized below.

**Chart 1: Minimum patent, data protection, and enforcement requirements in TRIPS**

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|-----------------------------------|---|
| <b>Standards of patentability</b> | Art. 27.1 <ul style="list-style-type: none"> <li>Patents shall be available for both products and processes</li> <li>Patents shall be available for any inventions ... provided they are new, involve an inventive step and are industrially applicable</li> </ul>  |
| <b>Exclusive rights</b>           | Art. 28 <ul style="list-style-type: none"> <li>Patents grant exclusive right to prevent third parties not having consent from “making, using, offering for sale, selling, or importing” the product or using the process</li> </ul>   |
| <b>Disclosure</b>                 | Art. 29 <ul style="list-style-type: none"> <li>Applicant shall disclose the invention in a sufficiently clear and complete manner</li> </ul>  |
| <b>Patent term</b>                | Art. 33 <ul style="list-style-type: none"> <li>Twenty years from filing date</li> </ul>   |
| <b>Non-discrimination</b>         | Art. 27.1 <ul style="list-style-type: none"> <li>Patents shall be available for all fields of technology without discrimination</li> <li>Patents shall be available and patent rights enjoyable without discrimination based on place of invention and whether products are imported or locally produced</li> </ul>   |
| <b>Enforcement</b>                | Arts. 41–47 <ul style="list-style-type: none"> <li>There must be fair, equitable and appealable judicial enforcement procedures allowing effective action against infringement</li> <li>Judicial authorities shall have the authority to order a party to desist from infringement and to prevent entry of infringing imported goods into channels of commerce immediately after customs clearance</li> <li>Judicial authorities shall have the authority to order an infringer to pay adequate compensation for the injury suffered when the infringer has knowingly, or with reasonable grounds to know, engaged in infringing activity</li> <li>Judicial authorities shall have the authority to order that infringing goods be disposed of outside the channels of commerce or destroyed</li> </ul> |

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|  | <ul style="list-style-type: none"> <li>• Judicial authorities shall have the authority to order the infringer to identify third persons involved in the production and distribution of infringing goods and their channels of distribution</li> <li>• Judicial authorities shall have the authority to order prompt and effective provisional measures to prevent an IP infringement and to preserve evidence thereof</li> <li>• Members shall provide for criminal procedures and penalties in cases of willful trademark counterfeiting or copyright piracy on a commercial scale</li> </ul> |
| <b>State-to-state dispute settlement</b>       | Art. 64 <ul style="list-style-type: none"> <li>• General Agreement on Tariffs and Trade (GATT) state-to-state dispute resolution applies to alleged Member violations of the TRIPS Agreement</li> </ul>  |
| <b>Data protection – unfair commercial use</b> | Art. 39.3 <ul style="list-style-type: none"> <li>• Applies when submission of data is required for marketing approval of pharmaceuticals containing new chemical entities only</li> <li>• Applies to undisclosed information only, and only where its origination involved considerable effort</li> <li>• Applies to unfair commercial use, not all uses, e.g. it would not apply to use by drug regulatory authority to approve generic equivalents</li> </ul>  |
| <b>Data protection – disclosure</b>            | <ul style="list-style-type: none"> <li>• Non-disclosure except where necessary to protect the public or</li> </ul> Non-disclosure unless data are protected against unfair commercial use  |

**TRIPS-plus measures.** The US and EU in particular are well known for trying to convince countries to enact even more patent, data, and enforcement rights than are required by the TRIPS Agreement.<sup>6</sup> Such measures, if adopted, are most commonly referred to as TRIPS-plus. Individually and collectively, TRIPS-plus measures reduce the policy space that ARIPO Member States would have to increase access to affordable medicines. Therefore, national legislation should be examined to identify any existing TRIPS-plus measures after which reform efforts should seek to eliminate such non-required protections.

**Chart 2: Key TRIPS-plus provisions negatively affecting access to medicines**

|   |   |
|---|---|
| <b>Eased standards of patentability</b> | <ul style="list-style-type: none"> <li>• Required patents on new uses or methods of use of known medicines</li> <li>• Required patents on new forms of known substances (e.g. active pharmaceutical ingredient regardless of improved therapeutic efficacy)</li> <li>• Lowering standards on novelty, on inventive step down to obviousness, and on industrial applicability to usefulness, allowing original and secondary patents on a broader range of ‘inventions’ and, in particular, allowing evergreening of patents on new formulations, dosages and standard optimization efforts</li> <li>• Adopting utility patent models that have absent or lower standards for inventive step and allow evergreening for the utility patent term, typically 10 years</li> </ul> |
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<sup>6</sup> See UNITAID, TRANS-PACIFIC PARTNERSHIP AGREEMENT: IMPLICATIONS FOR ACCESS TO MEDICINES AND PUBLIC HEALTH (2014).

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| <b>Elimination of patent exemptions</b>  | <ul style="list-style-type: none"> <li>• Required patents on diagnostic, therapeutic and surgical methods for treatment of humans</li> </ul>   |
| <b>Disclosure</b>                        | <ul style="list-style-type: none"> <li>• Lower disclosure requirements or prevention of allowable disclosure requirements</li> </ul>   |
| <b>Patent term extensions</b>            | <ul style="list-style-type: none"> <li>• Extensions for delays in processing patent applications</li> <li>• Extensions for delays in medicines registration process</li> </ul>   |
| <b>Patent oppositions and revocation</b> | <ul style="list-style-type: none"> <li>• No allowance of pre- and/or post-grant opposition procedures</li> <li>• Restrictions on grounds of patent opposition/revocation</li> </ul>  |
| <b>Weakened limited exceptions</b>       | <ul style="list-style-type: none"> <li>• Restrictions on use of early working/Bolar provision with respect to exporting patented subject matter for the purpose of obtaining foreign registration</li> <li>• No exception or weak exception for non-commercial and commercial research and educational use</li> <li>• No allowance of an exception for prior use</li> </ul>  |
| <b>No parallel importation</b>           | <ul style="list-style-type: none"> <li>• Disallowance of international exhaustion regime</li> </ul>  |
| <b>Data exclusivity</b>                  | <ul style="list-style-type: none"> <li>• Exclusive rights with respect to regulatory data prohibiting regulator's reliance on or reference to innovator's Art. 39.3 data or the fact of prior registration for a minimum period of years — prevents registration of follow-on generic products without new clinical trial data even in the absence of a patent</li> <li>• Possibility of extending data exclusivity upon submission of additional clinical data (evergreening data exclusivity)</li> </ul> |
| <b>Patent–registration linkage</b>       | <ul style="list-style-type: none"> <li>• Restricting the drug regulatory authority's ability to register a generic medicine whenever an originator claims that a patent would be infringed</li> </ul>  |
| <b>Mandatory injunctions</b>             | <ul style="list-style-type: none"> <li>• Outlawing of judicially mandated royalties remedy under Art. 44.2</li> </ul>  |
| <b>Enhanced civil remedies</b>           | <ul style="list-style-type: none"> <li>• Deterrent remedies, such as damages based on average retail price</li> </ul>  |
| <b>Broadened criminal remedies</b>       | <ul style="list-style-type: none"> <li>• Criminal sanctions for patent violations (beyond TRIPS requirement for criminal trademark counterfeiting and copyright piracy only)</li> </ul>  |
| <b>Enhanced border measures</b>          | <ul style="list-style-type: none"> <li>• Seizures of goods in transit</li> <li>• Mandatory destruction of goods</li> <li>• Third-party enforcement</li> <li>• Enhanced provisional measures</li> </ul>   |
| <b>Investment clause enforcement</b>     | <ul style="list-style-type: none"> <li>• Inclusion of IP as covered investments</li> <li>• Allowance of investment claims based on patent decisions (denial, revocation, invalidation, opposition, compulsory licences, registration of generics)</li> <li>• Investor–state dispute settlement allowing private arbitration of investment claims</li> </ul>  |

**TRIPS flexibilities.** In addition to imposing minimum IP-related obligations, the TRIPS Agreement contains multiple explicit public health flexibilities, and in addition there is interpretative freedom

to adopt and use implied ones as well. Article 1.1 of the Agreement clarifies that “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.” This provision recognizes that there is pluralism globally in intellectual property regimes and that there are minimal requirements but significant flexibility in interpreting and applying those requirements. Moreover, Article 7 of the TRIPS Agreement directly recognizes that there is a balance of rights and obligations in TRIPS and that its protections and enforcement should lead to the mutual advance of producers and users, should be conducive to social and economic welfare, and should contribute to the promotion of technological innovation and the transfer and dissemination of technology. Likewise, Article 8 permits Members to adopt measures necessary to protect public health and of vital important to socio-economic and technological development so long as such measure comply with TRIPS minimums. Members are also free to take measures to prevent abuse of IPRs by right holders.

In addition to these framing provisions, the TRIPS Agreement has flexibilities charted below with reference to the TRIPS provision providing for such flexibility. Of particular importance historically are parallel importation and compulsory licences, the right to which was further clarified in the Doha Declaration in the wake of developed country pressure against their adoption and use. The Doha Declaration in paragraphs 4 and 5 clarified that Member States

agree that the TRIPS Agreement does not and should not prevent measures to protect public health. ... [W]e affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Member’s right to protect public health and, in particular, to promote access to medicines for all. ... [W]e reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Thereafter the Declaration clarified countries’ rights to grant compulsory licences, including the freedom to determine the grounds upon which such licences might be granted; the right to determine what constitutes a national emergency or matter of extreme urgency; and the right to choose an exhaustion regime, including one that would permit parallel importation.<sup>7</sup> Paragraph 7 of the Doha Declaration also recommended the passage of a new extended transition period for LDC Members allowing them to deny patents and data protections for pharmaceuticals and Paragraph 6 further recommended the creation of a mechanism that would allow countries with insufficient manufacturing capacity to access imported medicines produced under a special compulsory licence.

Close analysis of the TRIPS Agreement, the Doha Declaration, the Paragraph 6 System and emerging state practice reveal the following TRIPS-compliant public health flexibilities. These flexibilities will be discussed in greater detail in the text following Chart 3.

**Chart 3: Key TRIPS public health flexibilities**

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| <b>LDC Transition Period and Pharmaceutical Extension</b> | <p>Art. 66.1</p> <ul style="list-style-type: none"> <li>• 2013-2021 general TRIPS transition period would allow avoidance of all IPR obligations</li> <li>• 2015-2033 pharmaceutical transition period would allow avoidance of pharmaceutical patents, data protection, mailbox obligations, and market exclusivity</li> </ul> |
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<sup>7</sup> Doha Declaration, *supra* note 4, Paragraph 5(b)-(d).

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|---|---|
| <b>Exclusions from patentability</b>                    | <p>Art. 27.3</p> <ul style="list-style-type: none"> <li>• No patents on mere discoveries</li> <li>• Surgical, diagnostic and therapeutic methods</li> <li>• No patents on plants or animals, except sui generis system for plant varieties</li> <li>• No patents on genes or extractions from naturally occurring matter</li> <li>• No patents on abstract ideas, discoveries, theories of nature, computer software or business methods</li> <li>• No patents for new uses and methods of use of known substances</li> <li>• No patents on admixtures, combinations or rearrangements of known substances or components</li> <li>• No patents on minor variations of known substances</li> </ul> |
| <b>Standards of patentability</b>                       | <p>Art. 27</p> <ul style="list-style-type: none"> <li>• High/strict standards of patentability, especially concerning combinations of prior art, novelty, inventive step and industrial applicability</li> </ul>  |
| <b>Disclosure</b>                                       | <p>Art. 29</p> <ul style="list-style-type: none"> <li>• Applicant must disclose all known practical methods of carrying out the invention, and the best known mode</li> <li>• Patent holder must disclose status of corresponding applications and patents in other jurisdictions</li> <li>• Patent holder must disclose INN on pharmaceuticals</li> </ul>  |
| <b>Opposition procedures and grounds for revocation</b> | <p>Arts. 62.4 and 32</p> <ul style="list-style-type: none"> <li>• Pre- and post-grant opposition procedures allowed with broad standing rights and easy-to-use administrative procedures</li> <li>• Broad grounds for revoking patents including inequitable conduct, fraud, non-payment of patent maintenance fees, failure to make required disclosures and failure to satisfy requirements/standards of patentability</li> </ul>   |
| <b>Patent term</b>                                      | <ul style="list-style-type: none"> <li>• No extensions for regulatory delays or for delays in granting patents</li> </ul>   |
| <b>Limited exceptions</b>                               | <p>Art. 30</p> <ul style="list-style-type: none"> <li>• Commercial and non-commercial research rights and educational use rights</li> <li>• Prior use and private, non-commercial use</li> <li>• Early working/Bolar exception allowed both domestically and for export for the purpose of obtaining regulatory approval</li> <li>• Formulation at pharmacies for individual use</li> <li>• Other limited exceptions as needed, including exception from Art. 31(f) with respect to production for export</li> </ul>  |
| <b>Parallel importation</b>                             | <p>Art. 6 and Doha Declaration</p> <ul style="list-style-type: none"> <li>• Adoption of international exhaustion rule and easy procedures for parallel importation</li> <li>• Possible restrictions on contractual limitations on export in support of parallel importation</li> </ul>  |

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| <p><b>Compulsory licences and government use</b></p> | <p>Art. 31, Art. 31bis, Art. 44.2, and Doha Declaration</p> <ul style="list-style-type: none"> <li>• Broad grounds for issuing a compulsory licence, including but not limited to excessive pricing, refusal to license/denial of access to an essential facility, failure to supply in sufficient quantities on reasonable terms, failure to work, including local working, to have redundant sources of supply, to allow combination products, and for any other matter of public interest or public health <ul style="list-style-type: none"> <li>○ Reasonable time limits on required prior negotiations</li> <li>○ Easy-to-use administrative procedures</li> <li>○ Continued validity of licence pending appeal</li> </ul> </li> <li>• Licences based on emergencies or matters of extreme urgency, including national security and public health crises, without prior negotiation</li> <li>• Public, non-commercial-use or government-use licences without prior negotiation</li> <li>• Licences to enable working of important dependent or interdependent patents or other significant innovations</li> <li>• Competition-based licences without prior negotiations and without restrictions on quantities exported</li> <li>• Production for export licences either pursuant to Art. 31bis or an Art. 30 limited exception</li> <li>• Judicial licences allowed pursuant to Art. 44.2</li> <li>• Clear, easy-to-use remuneration guidelines established</li> <li>• Efficient and easy-to-use administrative procedures</li> </ul> |
| <p><b>Enforcement Flexibilities</b></p>              | <p>Art. 51</p> <ul style="list-style-type: none"> <li>• No border measures required for suspected patent infringement of goods in transit</li> </ul> <p>Art. 61</p> <ul style="list-style-type: none"> <li>• No requirement of criminal penalties for patent violations</li> </ul> <p>Art. 44</p> <ul style="list-style-type: none"> <li>• Although injunctions must be an available remedy, it is also permissible to limit remedies to adequate remuneration like that provided for compulsory and government use licences</li> </ul> <p>Art. 50</p> <ul style="list-style-type: none"> <li>• Although provisional measures must be possible, their use is not mandatory</li> </ul> <p>Art. 45</p> <ul style="list-style-type: none"> <li>• Although compensatory damages must be an available remedy for infringement, alternative measures damages based on market value, selling price, or deterrence are not required.</li> </ul>  |
| <p><b>Competition policies</b></p>                   | <p>Art. 8.2 and Art. 40</p> <ul style="list-style-type: none"> <li>• Prevent abuse of IP rights by right holders or the resort to practices that unreasonably restrain trade or adversely affect international transfer of technology</li> <li>• Prevent licensing practices or IP rights conditions that restrain competition or adversely affect trade and may impede transfer of technology</li> </ul>  |

## 1.2 LDC Extension Periods

**Initial TRIPS-compliance LDC Extension:** The WTO TRIPS Agreement contains special provisions relevant to Least Developed Country (LDC) Members,<sup>8</sup> including ARIPO's LDC Members, The Gambia, Lesotho, Liberia, Malawi, Mozambique, Rwanda, Sierra Leone, Tanzania, Uganda, and Zambia.<sup>9</sup> Article 66.1 of the 1994 TRIPS Agreement reads as follows:

In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

The general requirement to become TRIPS compliant with respect to IPRs and their enforcement was extended from its original date of 2006 twice, first to 2013 (with some conditions) and later to 2021 (with fewer conditions).

**First TRIPS-compliance extension 2005-2013:** The 10-year exemption from implementing TRIPS obligations granted to LDCs in Article 66.1 of the TRIPS Agreement was scheduled to expire on 1 January 2006. Following a duly motivated request submitted by LDCs as a group in October 2005, the TRIPS Council adopted a decision (IP/C/40) which gave LDCs an extension of 7.5 years that exempted LDCs from having to apply any TRIPS provisions, other than Articles 3, 4 and 5 until 1 July 2013 (2005-2013 LDC Extension). Regrettably and without legal justification under the language of Article 66.1, that extension contained a stay-put or no-roll-back provision that prohibited LDCs from overturning existing levels of TRIPS-compliant IP protection.<sup>10</sup> On the plus side, the extension directly acknowledged LDC Members' right to seek a further extension of the pharmaceutical extension and of the general compliance extension.<sup>11</sup>

**Second TRIPS-compliance extension 2013-2021:** Pursuant to express allowance for countries to seek a further extension of 2005 LDC Extension, on June 11, 2013, the TRIPS Council further extended the general TRIPS-compliance transition period until 2021.<sup>12</sup> As an

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<sup>8</sup> The WTO only recognizes countries as having LDC status only when those countries have been designated as such by the United Nations. LDC status is based on three criteria relating to structural impediments to sustainable development: gross national income per capita, Human Assets index, and Economic Vulnerability index. There are currently 47 LDC countries.

<sup>9</sup> Three ARIPO Member States, Somalia, Sudan and the Democratic Republic of São Tomé and Príncipe, are not Member of the World Trade Organization, but they do have observer status. São Tomé and Príncipe is scheduled to graduate from LDC status on 13 December 2024.

<sup>10</sup> Extension of the Transition Period Under Article 66.1 for Least Developed Country Members (IP/C/40, 30 November 2005), Paragraph 5: "Least-developed country Members will ensure that any changes in their laws, regulations and practice made during the additional transitional period do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement." [http://www.wto.org/english/tratop\\_e/trips\\_e/ta\\_docs\\_e/7\\_1\\_ipc40\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_1_ipc40_e.pdf).

<sup>11</sup> Ibid. Paragraph 6: "This Decision is without prejudice to the Decision of the Council for TRIPS of 27 June 2002 on "Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products" (IP/C/25), and to the right of least-developed country Members to seek further extensions of the period provided for in paragraph 1 of Article 66 of the Agreement."

<sup>12</sup> Extension of the Transition Period Under Article 66.1 for Least Developed Country Members (IP/C/64, June 12, 2013), Paragraph 1.



improvement over the 2005-2013 LDC Extension, the 2013 decision did not affect LDCs' right to fully use flexibilities in the TRIPS Agreement.

2. Recognizing the progress that least developed country Members have already made towards implementing the TRIPS Agreement, including in accordance with paragraph 5 of IP/C/40, least developed country Members express their determination to preserve and continue the progress towards implementation of the TRIPS Agreement. Nothing in this decision shall prevent least developed country Members from making full use of the flexibilities provided by the Agreement to address their needs, including to create a sound and viable technological base and to overcome their capacity constraints supported by, among other steps, implementation of Article 66.2 by developed country Members.

Like the previous 2005 Extension, this extension was also without prejudice to the pharmaceutical extension or further extensions of the general TRIPS-compliance transition period.<sup>13</sup>

**Pharmaceutical transition period.** There is an additional LDC transition period with respect to patent requirements for pharmaceutical products, data protection, and exclusive marketing rights first via a transition period from 2002 until 2016 and second via an extension from 2016-2033.

***First pharmaceutical transition period 2002-2016:*** Paragraph 7 of the Doha Declaration directly addressed LDC Members need for an extended transition period with respect to pharmaceutical products:

We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Actualizing Paragraph 7's command, the TRIPS Council Decision adopted on 27 June 2002 states: "Least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016."<sup>14</sup> In response to a TRIPS Council recommendation, the General Council also granted a waiver (WT/L/478), by which LDCs' obligation under Article 70.9 to provide exclusive marketing rights for pharmaceutical products was waived until 1 January 2016.<sup>15</sup>

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[http://www.ipi.gov.mz/IMG/pdf/Decisao do Conselho do TRIPS da OMC sobre a extensao do prazo de transicao para os PMA.pdf](http://www.ipi.gov.mz/IMG/pdf/Decisao_do_Conselho_do_TRIPS_da_OMC_sobre_a_extensao_do_prazo_de_transicao_para_os_PMA.pdf).

<sup>13</sup> Ibid. Paragraph 3: "This Decision is without prejudice to the Decision of the Council for TRIPS of 27 June 2002 on "Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with respect to Pharmaceutical Products" (IP/C/25), and to the right of least developed country Members to seek further extensions of the period provided for in paragraph 1 of Article 66 of the Agreement."

<sup>14</sup> Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, [http://www.wto.org/english/tratop\\_e/trips\\_e/art66\\_1\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm).

<sup>15</sup> Least-Developed Country Members — Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, [http://www.wto.org/english/tratop\\_e/trips\\_e/art70\\_9\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art70_9_e.htm).

**Pharmaceutical transition period extension 2016-2033.** In February 2015, the LDC group at the WTO requested an extension of the 2016 deadline for as long as they remained LDCs.<sup>16</sup> On 6 November 2015, the TRIPS Council extended the pharmaceutical transition period to 2033 or until a country was no longer an LDC.<sup>17</sup> On 30 November 2015 a further decision was taken waiving mailbox and exclusive marketing rights requirements.<sup>18</sup> Both of these decisions were without prejudice to future requests for extensions.

It is clearly a best practice for ARIPO LDC Member States to Adopt the pharmaceutical extended transition period as recommended by the author of the COMPARATIVE STUDY and as already done by Liberia, Rwanda, Zanzibar, and Uganda. Of course, LDC Member States are also free not to comply with any TRIPS flexibilities until at least 2021 (or any further extension thereof) so long as they remain an LDC. The only exception to this substantial freedom is the obligation to provide national treatment and least favoured nation protections for any IPRs they do recognize.

### **1.3 Patentable subject matter, exclusions from patentability, stringent patentability, and differentiation by field of technology**

Article 27 of the TRIPS Agreement expressly allows exclusions from patentability for inventions that violate the *ordre public*; diagnostic, therapeutic and surgical methods for the treatment of humans or animal; and plants and animals other than micro-organisms and non-biological and microbiological processes.<sup>19</sup> However, the TRIPS Agreement does not directly restrict WTO and ARIPO Member States' right to define what constitutes patentable and patent-excludable subject matter, though there are prohibitions in Article 27.1 with respect to discrimination against particular fields of technology. However, "fields of technology," as a term of art, is not further defined, nor is the word "invention," meaning that Member States have considerable flexibility in defining patentable subject matter and exclusions from patentability beyond those listed in Article 27.2 and 27.3.<sup>20</sup> For example, many countries distinguish between "discoveries" and "inventions" and, unlike the United States, only provide patent protection for the latter. Other countries, including India, have chosen to allow patents on some discoveries but not others, most famously no patents on mere discoveries of new forms of existing substances unless they show significantly enhanced efficacy.<sup>21</sup> A large number of countries, including many ARIPO Member States, exclude patents on computer programs, business methods, abstract ideas, and laws of

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<sup>16</sup> Request For An Extension Of The Transitional Period Under Article 66.1 Of The Trips Agreement For Least Developed Country Members With Respect To Pharmaceutical Products And For Waivers From The Obligation Of Articles 70.8 And 70.9 Of The Trips Agreement, IP/C/W/605 (Feb. 23, 2015), [https://docs.wto.org/dol2fe/Pages/FE\\_Search/FE\\_S\\_S009-DP.aspx?language=E&CatalogueIdList=130506&CurrentCatalogueIdIndex=0&FullTextHash=371857150](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=130506&CurrentCatalogueIdIndex=0&FullTextHash=371857150).

<sup>17</sup> WTO Council for Trade-Related Aspects of Intellectual Property Rights, Extension of the Transition period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, D of the Council for DTRIPS of 6 November 2015, IP/C/73 (Nov. 6, 2015).

<sup>18</sup> WTO General Council, Least Developed Country Members – Obligation under Article 70.8 and Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, Decision of 30 November 2015, WT/L/97 (Dec. 2, 2016).

<sup>19</sup> See Shamnad Basheer, Shashwat Purohit & Prashant Reddy, PATENT EXCLUSIONS THAT PROMOTE PUBLIC HEALTH OBJECTIVES (WIPO SCP/15/3 Annex IV), [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_15/scp\\_15\\_3-annex4.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex4.pdf); Denis Borges Barbosa & Karin Grau-Kuntz, PATENTABLE SUBJECT MATTER AND EXCEPTIONS AND LIMITATIONS TO THE RIGHTS: BIOTECHNOLOGY (WIPO SCP/15/3 Annex III), [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_15/scp\\_15\\_3-annex3.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex3.pdf).

<sup>20</sup> WIPO has collected information on patent exclusions, which shows wide variation. CERTAIN ASPECTS OF NATIONAL/REGIONAL PATENT LAWS: EXCLUSIONS FROM PATENTABLE SUBJECT MATTER (status as of October 2018), [https://www.wipo.int/export/sites/www/scp/en/national\\_laws/exclusions.pdf](https://www.wipo.int/export/sites/www/scp/en/national_laws/exclusions.pdf).

<sup>21</sup> India Patents Act, section 3 (d).

nature. In addition to allowing clear exclusion, the TRIPS Agreement also allows countries to adopt stringent tests for the standards of patentability: novelty, inventive step, and industrial applicability. Such stringent standards might be particularly useful for patent offices with limited patent examination capacity to help expedite the patent examination process.<sup>22</sup>

In addition to being able to define patentable subject matter, broad class exclusions from patentability, and bright-line tests with respect to particular patentability criteria, WTO and ARIPO Member States are also permitted to differentiate their patent rules for particular areas of technology, adopting higher standards in one technology area and weaker ones in another.<sup>23</sup> As a WTO Dispute Resolution Panel has observed, “Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas”.<sup>24</sup> Although Member States cannot “discriminate” against a field of technology, Article 27.1, they can and do frequently “differentiate,” creating specialized rules and standards for the examination of patents in a particular field of technology. The Max Planck Institute Declaration on Patent Protection emphasizes that each field of technology is unique and avers that “Differentiation may relate to the requirements of patentability, patent eligibility and disclosure ... , to the exclusion of subject matter from patentability, as well as to the scope of protection ... .”<sup>25</sup>

Given the strategic importance of pharmaceutical patents in regard to the right to health, there are strong policy reasons for adopting differential rules for pharmaceutical patents.<sup>26</sup> A prime example of this is Argentina’s adoption of guidelines for the examination of patent applications related to chemical-pharmaceutical substances.<sup>27</sup> Another example is found in the India Patents Act, which has enacted multiple pharmaceutical-oriented exclusions from patentability for (1) naturally occurring substances; (2) new forms of known substances in the absence of evidence of significantly enhanced therapeutic efficacy; (3) new uses of known substances; (4) mere admixtures or what might be called combinations; and (5) methods of treatment.<sup>28</sup> These TRIPS-compliant options will be discussed further in the discussion below.

**No patents on naturally occurring substances.** In addition being expressly allowed under Art. 27 to exclude patents on “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes,” domestic patent laws are free to exclude other natural substances from being

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<sup>22</sup> Mohammed El Said & Amy Kapczynski, *Access to Medicines: The Role of Intellectual Property Law and Policy* (2011), p. 3, Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law, 7-9 July 2011; UNDP, USING LAW TO ACCELERATE TREATMENT ACCESS IN SOUTH AFRICA: AN ANALYSIS OF PATENT, COMPETITION, AND MEDICINES LAW 39 (2013) [UNDP SA REVIEW].

<sup>23</sup> Max Planck Institute, DECLARATION ON PATENT PROTECTION: REGULATORY SOVEREIGNTY UNDER TRIPS 4 (2014), available at <http://www.mpg.de/8133454/Patent-Declaration1.pdf> (accessed 2 October 2017).

<sup>24</sup> WTO, Canada – Patent Protection for Pharmaceutical Products, WT/DS 114/R, para 7.92.

<sup>25</sup> Max Planck Institute, DECLARATION ON PATENT PROTECTION, *supra* note 23, at 4.

<sup>26</sup> See RESOURCE BOOK ON TRIPS AND DEVELOPMENT: AN AUTHORITATIVE AND PRACTICAL GUIDE TO THE TRIPS AGREEMENT, UNCTAD-ICTSD, 368-374 (2005), (discussing in full the justifications for differential treatment of pharmaceutical patents) (UNCTAD-ICTSD Resource Handbook).

<sup>27</sup> Joint Resolution No. 118/20012, 546/2012 and 107/2012 of May 2, 2012, of the Ministry of Industry, Ministry of Health and the National Industrial Property Institute, approving the Guidelines for the Examination of Patent Applications of Pharmaceutical and Chemical Inventions, Date of Entry into Force: 16 May 2012 [ARGENTINE PATENT GUIDELINES], available at <http://www.wipo.int/wipolex/en/details.jsp?id=13007>.

<sup>28</sup> India Patents Act, *supra* note 21, section 3.

considered inventions due to lack of a technical contribution to the art.<sup>29</sup> Patent laws can also clarify that natural substances are excluded from patentability even if they were extracted, isolated, or purified, unless there is a change or alteration in the extract or isolate that causes it to exhibit different properties. DNA, complementary DNA,<sup>30</sup> cells, cell lines and cell cultures, and seeds can also be excluded from patentability since they are essentially naturally occurring.

**No patents on new forms of known substances or existing chemical entities.** Once patenting of pharmaceutical products is mandatory, one of the most important decisions that ARIPO Member States might face is whether they are going to make it easy or hard to obtain patents on variations of known chemical entities and known medicines. In order to achieve minor improvements in physicochemical properties like solubility, flow properties, or stability, pharmaceutical companies frequently file secondary patent applications on easily discovered, fairly routine variations in the form of a chemical entity, e.g., a new salt, ester, ether, polymorph, metabolite, pure form, isomer, or other derivative. There is a rich literature describing pharmaceuticals companies' efforts to extend the duration of their exclusive rights by seeking secondary patents at various steps of the drug-development and optimization process.<sup>31</sup> However, because these kinds of changes in "form" of the substance are well known and/or routinely discovered, they need not be patented at all. Alternatively, as in India, countries may choose to patent some new forms but only if they show significant therapeutic effects, an option recently affirmed by the Max Planck Institute<sup>32</sup> and already copied into the laws of the Philippines and into recommendations for patent law reforms in Brazil and East Africa.<sup>33</sup> In other words, India has chosen to create an exception to an allowable exclusion because of the potential benefits of the incremental discovery in terms of a significant enhancement of therapeutic effect. This choice has sharply – but not perfectly – restricted the patenting of unworthy secondary patent applications in India that "evergreen" or extend the length of monopolies on medicines.<sup>34</sup>

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<sup>29</sup> Denis Borges Barbosa & Karin Grau-Kunz, EXCLUSIONS FROM PATENTABLE SUBJECT MATTER AND EXCEPTIONS AND LIMITATIONS OF RIGHTS: BIOTECHNOLOGY (WIPO SPC/15/3), [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_15/scp\\_15\\_3-annex3.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex3.pdf).

<sup>30</sup> The United States, even with its robust biotech industry, recently found genes and other biological isolates non-patentable, though it did allow patents on complementary DNA. *Ass'n for Molecular Pathology v. Myriad Genetics*, 569 U.S. 12 (2013).

<sup>31</sup> WIPO, PATENT LANDSCAPE REPORT ON RITONAVIR (2011), available at [http://www.wipo.int/export/sites/www/freepublications/en/patents/946/wipo\\_pub\\_946.pdf](http://www.wipo.int/export/sites/www/freepublications/en/patents/946/wipo_pub_946.pdf); Carlos Correa, GUIDELINES FOR THE EXAMINATION OF PHARMACEUTICAL PATENTS: DEVELOPING A PUBLIC HEALTH PERSPECTIVE, WHO-ICTSC-UNCTAD, 21 (2007) (Correa, GUIDELINES FOR EXAMINATION); Nathalie Vernaz et al., *Patented Drug Extension Strategies on Healthcare Spending: A Cost-Evaluation Analysis*, 10:6 PLoS MEDICINES (2013); Andrew Hitchings, Emma Baker & Teck Khong, *Making medicines evergreen*, 345 BOSTON MED. J. e7941 (2012); Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh MY!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7:12 PLoS ONE e49470 (2012); Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents On Two HIV Drugs Could be Extended for Decades*, 31:10 HEALTH AFFAIRS 2286-2294 (2012).

<sup>32</sup> Max Planck Institute, DECLARATION ON PATENT PROTECTION, *supra* note 23, at 5.

<sup>33</sup> See Section 22.1 of the Intellectual Property Code of the Philippines; Center for Strategic Studies and Debates, BRAZIL'S PATENT REFORM: INNOVATION TOWARDS NATIONAL COMPETITIVENESS (2013) available at [http://infojustice.org/wp-content/uploads/2013/09/Brazilian\\_Patent\\_Reform.pdf](http://infojustice.org/wp-content/uploads/2013/09/Brazilian_Patent_Reform.pdf); the East African Community has also directly recommended that its Partners States "are to exclude from patentability ... Derivative of medical products that do not show significantly enhanced therapeutic efficacy/significant superior properties." REGIONAL INTELLECTUAL PROPERTY POLICY ON THE UTILIZATION OF PUBLIC HEALTH-RELATED WTO-TRIPS FLEXIBILITIES AND THE APPROXIMATION OF INTELLECTUAL PROPERTY LEGISLATION, Policy Statement No. 3(a)(iii), at 14 (2013) (EAC Regional IP Policy).

<sup>34</sup> Sudip Chaudhuri, Chan Park & K. M. Gopakumar, FIVE YEARS INTO THE PRODUCT PATENT REGIME: INDIA'S RESPONSE (2010); Bhaven N. Sampat & Tahir Amin, *How Do Public Health Safeguards in Indian Patent Law Affect Pharmaceutical Patenting in Practice*, 38 J. POLITICS, POLICY & LAW 735-755 (2013); Sadhana Srivastava and Kanikaram Satyanarayana, *The Impact of Amended Indian Patent Act on Access to Medicines in India*, EQUILIBRI (4 March 2014); Feroz Ali et al., PHARMACEUTICAL PATENT GRANTS IN INDIA: HOW OUR SAFEGUARDS AGAINST EVERGREENING HAVE FAILED, AND WHY THE SYSTEM MUST BE

The relevant provision of the India Patents Act is section 3(d) which states that “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance ... or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant” is not an invention. This exemption is further clarified by the following explanation: “salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy”. The Supreme Court of India has interpreted the enhanced efficacy standard to refer to therapeutic efficacy and has further clarified that it does not include such factors as beneficial flow properties, better thermodynamic stability, or lower hygroscopicity.<sup>35</sup> Similarly, enhanced efficacy does not include “increased bioavailability alone,” but only increased bioavailability that results in significantly enhanced therapeutic efficacy though a final decision on that issue is left to another day.<sup>36</sup>

The Argentine Patent Guidelines incorporate an even higher “discovery” standard than India, preventing patents on any new form of a known substances, regardless of increases in efficacy. These Guidelines state:

(3) Consideration of chemically related elements

(vi) Salts, esters and other derivatives of known substances. New salts of known active ingredients, esters of known alcohols, and other derivatives of known substances (such as amides and complexes) are deemed to be the same known substance and are not patentable.

(vii) Active metabolites. In some cases, pharmaceutical compounds generate, when administered to a patient, an active metabolite, which is the product of the metabolism of the compound in the organism. Metabolites are products derived from the active ingredients used. They cannot be considered to have been “created” or “invented”. Metabolites are not patentable independently from the active ingredient from which they derived, even though they may have safety and efficacy profiles differing from those of the parent molecule.

(viii) Prodrugs. There are inactive compounds referred to as prodrugs, which when hydrolyzed or metabolized in an organism, can give rise to a therapeutically active ingredient. In some cases, patent claims protect a drug and the prodrug(s) thereof. A prodrug may produce benefits if it can be administered more easily than an active compound. Patents on prodrugs, if granted, should exclude from the claim the active ingredient as such, if the latter has already been disclosed or if it is not patentable. As any subject matter claimed in a patent, a prodrug must be sufficiently supported by the information provided in the specification. It must comply with the requirements of novelty, inventive step and industrial application and include a description of the best method of obtaining it with an adequate characterization of the product obtained. In

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REFORMED (2018), <https://www.accessibsa.org/media/2018/04/Pharmaceutical-Patent-Grants-in-India.pdf>; Feroz Ali et AL., REJECTED IN INDIA: WHAT THE INDIAN PATENT OFFICE GOT RIGHT ON PHARMACEUTICALS PATENT APPLICATIONS (2009-2016) (2018), <https://www.accessibsa.org/media/2017/12/Rejected-in-India.pdf>.

<sup>35</sup> *Novartis AG v. Union of India and Ors*, paras. 180, 187, CIVIL APPEAL Nos. 2706–2716 OF 2013, Supreme Court of India, Date of Judgment: 1 April 2013, available at <http://supremecourtindia.nic.in/outtoday/patent.pdf> (accessed 2 October 2017).

<sup>36</sup> *Ibid.* at para. 188.

addition, the application should contain evidence that the prodrug is inactive or less active than the claimed compound, that the generation of the active compound (in the organism) ensures an effective level thereof, while minimizing the direct metabolism of the prodrug.<sup>37</sup>

Pursuant to these precedents, ARIPO Member States are free to exclude patents on new forms of known substances or to grant such patents only where there is evidence of significantly enhanced therapeutic efficacy.

**No patents on combinations, admixtures, and arrangements or rearrangements.** Just as they seek patents on new forms of known substances, pharmaceutical companies often seek secondary patents on combinations of previous known substances, including fixed-dose combination medicines, on admixtures of active ingredients with inactive expedients and binders, and on changes in dosage or altered methods of delivery. Combining known active ingredients is presumptively not inventive because combining prior art is routine for persons highly skilled in the relevant art(s). (See discussion of inventive step, *infra*.) Similarly formulating active pharmaceutical ingredients with known expedients is routine and obvious in pharmacological practice unless there are unexpected synergistic effects between the ingredients.<sup>38</sup> Thus, the section 3(e) of the India Patents Act excludes patents on a “substance obtained by a mere admixture resulting only in the aggregation of the property of the components thereof or a process for producing such substance.” Similarly, device manufacturers sometimes seek patents on the arrangement and re-arrangement of known devices. Section 3(f) of the India Patents Act excludes patents on “the mere arrangement or re-arrangement or duplication of known devices each functioning independently of the other in a known way.” Based on this precedent, ARIPO Member states could also disallow patenting of mere admixtures and arrangements or rearrangements of known devices.

**No patents on new uses or indications of known substances and exclusion of patents on diagnostic, therapeutic, and surgical methods:** Many countries, including several ARIPO Member States, limit patents on new or additional uses of known substances (in the pharmaceutical context new indications<sup>39</sup>), and many experts and expert reports have recommended that low- and middle-income countries adopt *per se* exclusions for patents on new uses or methods of use.<sup>40</sup> Exclusion of new use or method of use patents is expressly permitted by Article 27.3(a) of the TRIPS Agreement, which permits exclusions of patents on “diagnostic, therapeutic and surgical methods.” Under this approach, “there is no real difference between patent claims relating to the use of a substance and those relating to a therapeutic method: in both cases a new medical activity is claimed, i.e. *a new way of using* one or more known products.”<sup>41</sup> Andean Community patent law explicitly stipulates that both products and processes already patented and included

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<sup>37</sup> ARGENTINE PATENT GUIDELINES, *supra* note 27; see also Section 3(1)(v) of Zanzibar Industrial Property Act No. 4 of 2008 (excluding patents on new uses or form of known product or process).

<sup>38</sup> UNDP SA REVIEW, *supra* note 22 at p. 44.

<sup>39</sup> Carolyn Deere, THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES (2008); Correa, GUIDELINES FOR EXAMINATION, *supra* note 31.

<sup>40</sup> Carlos Correa, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES, 21 (2000) (Correa, INTEGRATING PUBLIC HEALTH); Commission on Intellectual Property Rights, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY, 45 (2002) [http://www.iprcommission.org/papers/pdfs/final\\_report/CIPRfullfinal.pdf](http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf); UNDP, GOOD PRACTICE GUIDE: IMPROVING ACCESS TO TREATMENT BY UTILIZING PUBLIC HEALTH FLEXIBILITIES IN THE WTO TRIPS AGREEMENT, 20-21 (2010) (UNDP GOOD PRACTICE GUIDE).

<sup>41</sup> See UNCTAD-ICTSD RESOURCE BOOK, *supra* note 26, at 387 (italics supplied).



in the state of the art may not be the subject of a new patent on the sole ground of having been put to a use different from the originally contemplated by the initial patent. Similarly, the East Africa Community has directly encouraged its Partner States to exclude patents on “new medical uses of known substances including micro-organisms ... .”<sup>42</sup> India explicitly prohibits patenting of all new uses and methods of use under its Amended (2005) Patents Act.<sup>43</sup> The author of the COMPARATIVE STUDY is clearly correct to recommend that ARIPO Member States should deny patents on new uses or methods of use.

**Adopting stringent standards of patentability.** Article 27.1 of the TRIPS Agreement provides that “patents shall be made available for any inventions, whether products or processes, provided that they are new, involve an inventive step and are capable of industrial application.” These three key terms are not defined in the TRIPS Agreement and historically there have been pluralistic interpretations of these standards by WTO Member States even after the passage of the TRIPS Agreement. This pluralism, along with the directive of Article 1.1 that “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice,” makes it clear that ARIPO Member States would have substantial interpretative freedom to adopt high or stringent standards of patentability. By setting the patent bar higher to prevent poor-quality patents, countries would grant fewer, but better quality patents and thereby incentivise researchers to seek breakthrough innovations rather than tinker with and around existing inventions merely to extend existing monopolies or wrest market share from a competitor. Granting fewer patents will also result in earlier competition, including from domestic manufacturers, and will lead to lower prices on essential public goods. Finally, having multiple and local sources of supply will also reduce the risk of supply disruptions.

Even in advanced economies such as the United States, with some of the least stringent patentability standards in the world, there is a growing recognition that overbroad patent protection can actually harm innovation. In a 2007 landmark decision, the US Supreme Court established a significantly more stringent test for ‘inventive step’. The court observed, “Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress, and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.”<sup>44</sup> The Court also noted, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.”<sup>45</sup>

Developing countries have also embraced the need to adopt strict standards. For example, the East Africa Community recommends that its member countries apply “a strict application of the three patentability criteria in their patent laws and patent examination guidelines enables EAC Partner States to maintain a broad policy domain in order to benefit public health purposes.”<sup>46</sup> More particularly, Policy Statement No. 2 says:

EAC Partner States are to strictly define in the patent laws and/or patent examination guidelines the patentability criteria, and apply them strictly, in order to keep a broad

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<sup>42</sup> EAC REGIONAL IP POLICY, *supra* note 33, Policy Statement No. 3(a)(ii), at 14.

<sup>43</sup> India Patents Act, *supra* note 21, section 3(d).

<sup>44</sup> *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 419 (2007).

<sup>45</sup> *Ibid* at 421.

<sup>46</sup> EAC REGIONAL IP POLICY, *supra* note 33, at 12.

public domain. In particular, they shall:

- a. Strictly apply the novelty standard through considering a wide concept of prior art consisting of everything disclosed to the public whether by use, in written or oral form, including patent applications, information implied in any publication or derivable from a combination of publications, which are published anywhere in the world and which can be actually or theoretically accessed by the general public;
- b. Clearly define the inventive step standard by referring to a 'highly' skilled person;
- c. Strictly apply the industrial application requirement and limit the patentability of research tools to only those for which a specific use has been identified.<sup>47</sup>

**Novelty.** The novelty requirement in patent law is designed to protect full and free access to and use of information already in the public domain and to thus avoid granting a statutory monopoly for inventions that are not truly new. Novelty can be interpreted narrowly, to apply only to prior art disclosed in the country issuing patents (called "relative novelty"), or it can be interpreted broadly to cover disclosures of the state of the art by whatever means anywhere in the world (called "absolute novelty"). Legislation could be clarified that disclosure of the state of the art covers all products and processes, or information about either, that has been made available to the public in the ARIPO Member State or elsewhere by written or oral description, by prior use even if secret, by exhibition, by disclosure in an earlier patent application, or in any other way.

**Markush claims and disallowance of selection patents.** Pharmaceutical companies frequently file "Markush" patent applications covering a broad range of possible compounds, indeed sometimes millions of compounds. As the company continues to engage in research and development to identify and optimize the key ingredient, the company applies for a subsequent patent that "selects" a smaller subset of compounds or eventually even one compound, usually on the basis that the selected compounds or compound shows a distinct advantage in technical application or avoids a distinct disadvantage. These subsequent patents, when allowed, are generally called "selection patents."<sup>48</sup>

The acceptance of overbroad Markush claims itself raises questions of whether they satisfy patentability and disclosure requirements. As Carlos Correa notes, "(g)iven that a search of prior art for millions of compounds is virtually impossible, the search of the patent office and the corresponding patent grant should be limited to what has been actually assessed and supported by the examples provided in the specification."<sup>49</sup> He proceeds to recommend that "(c)laims covering a large range of compounds should not be allowed. Patent offices should require patent applicants to provide sufficient information..."<sup>50</sup> Given that Markush claims account for a large proportion of all patents issued on pharmaceutical,<sup>51</sup> disclosure requirements should be tightened so that patents based on such claims do "not become a constraint for research on new

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<sup>47</sup> *Ibid* at 13.

<sup>48</sup> Selection patents are distinct from divisional patents. Divisional patent applications divide a previous patent to create distinct claims when an original patent application does not demonstrate sufficient "unity."

<sup>49</sup> Correa, GUIDELINES FOR EXAMINATION, *supra* note 31 at 12.

<sup>50</sup> *Ibid*.

<sup>51</sup> Carlos Correa, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* Research Paper 41, South Centre, September 2011 at 13.



compounds or an undue restriction to competition.”<sup>52</sup>

The TRIPS Agreement does not require Member States to grant selection patents. Moreover, there is a risk in allowing selection patents, because the applicant receives a full 20 years of patent protection on the selection patent even though it was included in the broader genus claim(s) of the original patent application. A strong novelty standard would result in the rejection of selection patents because they are not new (they were instead hidden in the haystack of the broad range of compounds claimed in the original patent application). Alternatively, Germany has refused selection inventions by holding that disclosure of even a large group of elements is fully equivalent, for the purposes of inventive step, to the disclosure of each compound within the group.

In May 2012, Argentina’s Ministry of Industry, Ministry of Health, and National Institute for Intellectual Property issued a joint resolution approving new guidelines for the examination of patent applications related to chemical-pharmaceutical substances.<sup>53</sup> The new guidelines specifically reject selection patents, stating:

(v) Selection Patent Applications

Selection patent applications are those where a single element or small group of elements is selected from a larger group, and they are claimed independently, based on a characteristic or characteristics not previously attributed to the larger group. Selections can be made from products (chemical compounds, their salts, isomers, esters, compositions, etc.) and/or processes (obtention of compounds or pharmaceutical compositions and others).

1. The disclosure of a group of chemical compounds (Markush formula) or groups of pharmaceutical compositions, even generically, discloses all the components of that group, which in this way become part of the state of the art.
2. There is no novelty in the selection of one or more elements already disclosed by the prior art, even though they may have different or improved properties, not previously demonstrated.
3. The discovery of a different or improved characteristic or property for a particular element or group of elements already known in the prior art does not mean that the product or process is novel.
4. Pharmaceutical compositions, their methods of preparation and medicaments containing them are not patentable if they are specifically related to an element or elements selected from a larger group of elements, since the product or process are not considered new.

***Inventive step.*** Like novelty, the inventive step requirement affords countries a wide degree of interpretive flexibility to set a high bar for inventiveness. The requirement of inventive step fundamentally tries to create a distinction between what can be “discovered” through regular scientific research and what is inventive because was non-obvious to a person or persons skilled or highly skilled in the relevant art and represents a technical advance over relevant prior art. Carlos Correa has observed that “[t]he best policy from the perspective of public health would seem to be the application of a strict standard of inventiveness so as to promote genuine

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<sup>52</sup> Ibid. at 23.

<sup>53</sup> ARGENTINE PATENT GUIDELINES, *supra* note 27.

innovations and prevent unwarranted limitations to competition and access to existing drugs”<sup>54</sup>. Setting the bar high for inventive step would prevent secondary patents on minor (and oftentimes trivial) changes to existing medicines, including new formulations, dosages, and delivery mechanisms, which can be used unfairly to prevent the entry of more affordable generic medicines.

One way to codify a high standard for inventive step is to define the hypothetical person who knows the prior art as one who is *highly skilled* because more alleged inventions would be obvious to him or her. Zanzibar has adopted this definition in Sec. 4.3 of its 2008 Industrial Property Act (Note: novelty is also defined in reference to a person highly skilled in the art, Sec. 4.2.a.) Another way to set a high standard for inventive step is to clarify that combining various pieces and forms of prior art is not inventive because undertaking such combinations is obvious to a highly skilled person. A third way of setting a high standard is to acknowledge that innovation is rarely a singular activity and thus that the standard should be “persons” highly skilled in the art so that alleged inventions by research teams are judged appropriately. Finally, a fourth way to define a high standard is to directly recognise that the prior art can “teach” or inform directly and indirectly. In other words, the ordinary processes of synthesising pre-existing information and making plausible inferences from different sources should not be considered inventive. Correa has suggested a description of such a person highly skilled in the art as having:

some specialized knowledge and not simply somebody with very general or ordinary knowledge in the relevant technical field. A person skilled in the art is not just an expert in his technical field but a person who should have some degree of imagination and intuition.<sup>55</sup>

Some countries and commentators resort to supplemental, secondary considerations in their inventive step analysis, including analysing whether the alleged invention addresses a “long felt need” or even whether the alleged invention achieved “commercial success.” However, these are essentially ad hoc judgements based on the commercial success of the patent holder who is seeking to preserve valuable exclusive rights. These factors, which favour patent applicants, are essentially irrelevant to the question of inventiveness at the time of the alleged invention.<sup>56</sup>

India’s Patents Law section 2(ja) offers a possible model, defining inventive step as “a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.”

***Industrial applicability.*** As with novelty and inventive step, the requirement of industrial applicability can be weak or strong. In general, a utility standard is weaker and more permissive than an industrial applicability standard. A weak utility standard, for example, allows patents on innovations that have no immediate or known practical benefit or use, but even in the United States patents are not granted if there is only “unverified or speculative utility.” One reason to adopt high standards of industrial applicability is to ensure that patents are not granted on abstract ideas that have not been concretised in actual technological activity. This is one basis upon which patents need not be granted founded on use or method of use claims alone, where

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<sup>54</sup> Correa, GUIDELINES FOR EXAMINATION, *supra* note 31 at 4.

<sup>55</sup> *Ibid.*

<sup>56</sup> UNDP SA REVIEW, *supra* note 22, at p. 34.

such uses are essentially abstract ideas.<sup>57</sup> Another reason to avoid patents on inventions with only ephemeral utility is that such patents can block follow-on research by inventors who might actually find a practical use for a claimed invention.

***Scope of protection limited to uses that have been claimed.*** In most jurisdictions, the scope of protection of a claimed invention is determined by the claims and uses disclosed in the patent application. Rather than affording “absolute product protection” for all possible uses, purposes or functions of the invention, whether known and claimed or not, Articles 27 and 28 of the TRIPS Agreement allow Member States to limit the scope of protection to those uses, purposes or functions that have been disclosed and expressly claimed in the patent, “purpose bound protection.”<sup>58</sup> Such a limitation is particularly important with respect to certain upstream, research, or even diagnostic technologies where there are strong public policies in favor of encouraging further innovation in the use of the platform technology.

#### **1.4 Disclosure requirements.**

Article 29 of TRIPS allows countries to require that the patent applicant disclose certain information in its patent application. It provides:

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
2. Members may require an applicant for a patent to provide information concerning the applicant’s corresponding foreign applications and grants.

In addition to the disclosures required or allowed by Article 29, ARIPO Member States are free to require other disclosure as described further below.

**Disclosure of all methods and identification of the best method for carrying out the invention.** Although the TRIPS Article 29.1 only requires disclosure in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art, it implicitly allows requirements that applicants disclose all methods of implementing the invention known to the inventor at the time of filing and explicitly allows identification of the best known method of implementation. Such disclosure is particularly important for researchers and inventors in the ARIPO region who can thereby both learn the best method of implementing the invention, but also be in a position to exercise research rights with respect to that invention. In many ways, disclosure of the best method acts as a form of technology transfer. In addition, disclosure of the best method of use will enable competitors to quickly come to the market when the patent expires and to do so on a competitive basis rather than being disabled by implementing the invention inefficiently.

Some countries, including the United States, have historically required disclosure of the best method for carrying out the innovation, though this requirement has recently been weakened in the United States by amendments to the U.S. Patent Act, which disallow invalidation actions

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<sup>57</sup> This is one justification for Article 27.3 of the TRIPS Agreement, which allows exclusions from patentability for “diagnostic, therapeutic and surgical methods for the treatment of humans or animals.”

<sup>58</sup> See, Max Planck Institute, DECLARATION ON PATENT PROTECTION, supra note 23, at 6-7.

based on failure to disclose the best method of working the invention.<sup>59</sup> The East Africa Community Policy goes further than the U.S. law and recommends disclosure of all know methods and identification of the best method for carrying out the invention.<sup>60</sup> In order to make the required disclosures even more useful and implementable, it is also possible to require that the disclosure enables working the invention by a person skilled at the level of art in the patenting country, as Zanzibar has done.<sup>61</sup>

**Disclosure of the status of foreign applications:** TRIPS Article 29.2 specifically permits Member States to require disclosure of the status of foreign patent applications for the same invention. Such disclosure can be very useful to ARIPO Member States, where patent examination capacity will be limited in the short term. With an initial disclosure requirement and an explicit duty to supplement such information regularly, patent examiners in ARIPO can be informed of grants, denials, suspensions, and even invalidations. India has taken partial advantage of this flexibility in section 8 of the India Patents Act by requiring information on the status of a foreign patent application until the domestic patent has been granted. Although India has chosen not to require additional information after the grant of a patent, a country is free to do so as invalidations or revocations in other jurisdictions may be taken into account – but may not be decisive – with respect to similar actions in another Patent Cooperation Treaty country.<sup>62</sup> Zanzibar appears to have created such an obligation in Article 9(b) of its Industrial Property Act. Rather than making it merely permissible for the patent office to ask for such information, relevant legislation should make such ongoing disclosures mandatory by the applicant/patent holder.

**Disclosure of all material prior art.** The patent applicant is often in the best position to ascertain existing art at the time of filing, ordinarily having done due diligence on freedom to patent prior to filing the patent application. Capacity-strapped patent examination offices, on the other hand, often find it onerous, bordering on impossible, to identify all relevant prior art, disclosed by any means, everywhere in the world. Thus, it makes sense for patent legislation to impose a duty on patent applicants to disclose all relevant prior art. In an effort to ensure that all relevant prior art is available to its patent examiners, the U.S. Patents and Trademark Office imposes upon the patent applicant a “duty of candour and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability.” An intentional failure to disclose all known material prior art is a fraud upon the Patents and Trademark Office and can result in an invalidation of the patent, and even triple damages under U.S. antitrust laws.<sup>63</sup>

**Disclosure of origin and evidence of fair and equitable benefit sharing.** According to Correa and Sarnoff: “Article 29.1 of the TRIPS Agreement specifies mandatory and facultative patent application disclosure requirements. But that Article does not preclude countries from imposing additional disclosure requirements for national applications, particularly when effectuating substantive conditions of entitlement.”<sup>64</sup> South Africa amended its Patents Act in 2005 to impose a duty to disclose whether an invention has been derived from an “indigenous biological resource,

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<sup>59</sup> Leahy-Smith America Invents Act, sec. 15.

<sup>60</sup> EAC REGIONAL IP POLICY, *supra* note 33, Policy Statement No. 7(a), at 17.

<sup>61</sup> Zanzibar Industrial Property Act, Article 6(4)(d) & (e).

<sup>62</sup> *See*, Paris Convention for the Protection of Industrial Property (1883 as amended through 1979), Article 4bis(2).

<sup>63</sup> *See*, e.g., *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1377 (Fed. Cir. 2007).

<sup>64</sup> Carlos Correa & Joshua D. Sarnoff, ANALYSIS OF OPTIONS FOR IMPLEMENTING DISCLOSURE OF ORIGIN REQUIREMENTS IN INTELLECTUAL PROPERTY APPLICATIONS, 24 (UNCTAD, 2006) (Correa/Sarnoff OPTIONS).

genetic resource, or traditional knowledge or use.” Failure to comply with this disclosure obligation is an express ground for revocation of the patent.<sup>65</sup> The duty of fair and equitable benefit sharing has been established in the Nagoya Protocol.<sup>66</sup> Pursuant to these precedents, UNCTAD recommended that Indonesia not only require disclosure of origin but also “evidence of PIC [prior informed consent] from the competent authority of the country of origin and evidence of fair and equitable benefit sharing.”<sup>67</sup> The author of the Comparative Study has recommended disclosure of origin, but that recommendation could be strengthened by requiring disclosure of evidence of prior informed consent and fair and equitable benefit sharing as well.

**Disclosure of international non-proprietary names and disease priorities for pharmaceutical-related applications.** It is often extremely difficult to identify the subject matter of a patent application given its technical nature and often obscure or meaningless titles. As described previously, there can also be multiple patents filed with respect to a particular final pharmaceutical product and it may be extremely difficult to discover all these related patents. Interested parties in India have previously proposed a requirement that the Indian government require applicants filing patent applications pertaining to pharmaceuticals to disclose the international non-proprietary name (INN) of the medicines to which the patent application applies. Where an INN has not yet been assigned, the proposal would require the patent holder to submit the relevant INN within 30 days of it being assigned. The East African Community has also recommended that its Partner States require disclosure of INNs.<sup>68</sup> The same proposal was made with respect to Uganda’s Industrial Property bill.<sup>69</sup> Although the version ultimately adopted by Uganda did not incorporate this requirement, there is still the possibility of reaching that outcome via implementing regulations. In addition to requiring disclosure of non-proprietary names, it would also be desirable for public health purposes to require disclosure of whether the patent application relates to priority diseases as identified by public health authorities.<sup>70</sup>

**Consequence for misrepresentation and non-disclosure – revocation of the patent.** In order for disclosure requirements to be meaningful and enforceable, there have to be consequences for misrepresentation or non-disclosure. Article 32 of the TRIPS Agreement recognizes Member States’ rights to revoke patents. It does not regulate the permissible grounds for revocation, but it does require a right of judicial review. This submission recommends that the right of suspension of consideration, revocation, or cancellation apply to misrepresentation or non-disclosure of all

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<sup>65</sup> South Africa Patents Act, sections 3A and 61(g). Other countries requiring such disclosure include Andean Community countries, Belgium, Bolivia, Brazil, China, Colombia, Costa Rica, Denmark, Ecuador, Egypt, the European Community (EC), Germany, India, the Kyrgyz Republic, New Zealand, Norway, Panama, Peru, the Philippines, Portugal, Romania, Sweden, Switzerland, Thailand, Venezuela, and perhaps others.

<sup>66</sup> 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 is an international agreement which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way. It entered into force on 12 October 2014, 90 days after the date of deposit of the fiftieth instrument of ratification.

<https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>

<sup>67</sup> Correa/Sarnoff OPTIONS, *supra* note 64.

<sup>68</sup> EAC REGIONAL IP POLICY, *supra* note 33, Policy Statement No. 7(b), at 17. The advantages and disadvantages of required disclosure of INN is the subject of ongoing investigation at WIPO. Updated Feasibility Study on the Disclosure of International Nonproprietary Names (Inn) in Patent Applications and/or Patents (SCP/28/5), [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_28/scp\\_28\\_5.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_28/scp_28_5.pdf).

<sup>69</sup> The Centre for Health, Human Rights and Development, MODEL PROVISIONS TO PROMOTE ACCESS TO AFFORDABLE MEDICINES IN THE INDUSTRIAL PROPERTY BILL 2009 (September 2012), <http://www.cehurd.org/wp-content/uploads/downloads/2012/09/IP-Bill-model-provisions.pdf>.

<sup>70</sup> UNDP SA REVIEW, *supra* note 22, at 52.

required information. A more progressive version of this requirement would allow administrative cancellation, but that might require a due process hearing.

### 1.5 Pre- and Post-Grant Opposition Procedures

ARIPO Member States frequently face critical capacity constraints when examining patent applications, especially in highly technical fields of technology. If patent examiners are undertrained or overburdened or if they lack access to prior art databases and other labor saving information technologies, then the predictable outcome is patents of poor quality – unwarranted patents that nonetheless grant exclusive rights and prevent competition. To help alleviate the problem of over-stretched patent offices and to ensure consideration of all relevant prior art and the correct application of patent eligibility and disclosure standards, multiple countries, developed and developing, have allowed TRIPS-compliant pre-grant opposition procedures that allow presentation of both evidence and legal arguments.<sup>71</sup> The TRIPS Agreement directly references the legality of administrative opposition procedures in Art. 62.3 requiring only that they be governed by general principles set out in paragraphs 2 and 3 of Art. 41. Art. 62.5 further states that final administrative decisions, including *inter partes* opposition procedures, shall be subject to review by a judicial or quasi-judicial authority. The EAC has recommended that its Partner States provide “for effective pre- and post-grant administrative patent application procedures” and that they should further, as ARIPO Members, discuss an amendment to the Harare Protocol “to take account of third party oppositions” and to allow a longer time within which to file written approval of ARIPO granted patents.<sup>72</sup> Even the U.S. has recently adopted a short post-grant opposition mechanism in section 6 of the new America Invents Act.

An effective pre-grant opposition procedure would:

- Require publication of pending patent applications prior to examination and make such applications available online on a fully searchable database;
- Allow for any natural or juristic person, even if acting solely in the public interest, to file a pre-grant opposition at any time after publication of the patent application but prior to the grant of a patent, with ample time for opponents to submit relevant evidence;
- Establish broad grounds for opposition including a failure to meet patentable subject matter, exclusion, or patentability criteria, failure to make required disclosures, and fraudulent commissions or omissions;
- Opponents should be given full legal standing and they should be able to appear at a hearing in support of their opposition if such hearings are provided for;
- The pre-grant opposition procedure should allow simple and expedited administrative procedures.

An effective post-grant opposition procedure would:

- Require immediate publication of granted patent applications and make such grants available online on a fully searchable database;

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<sup>71</sup> See WIPO, Opposition Systems, [https://www.wipo.int/scp/en/revocation\\_mechanisms/opposition/index.html](https://www.wipo.int/scp/en/revocation_mechanisms/opposition/index.html) (accessed 15 February 2019). Countries with pre-grant opposition systems include: Argentina, Colombia, Costa Rica, Egypt, Honduras, India, Mongolia, Pakistan, Portugal, Spain, and Zambia. Countries and regional bodies with post-grant oppositions include: Brazil, Denmark, Finland, Germany, India, Japan, Norway, Pakistan, Moldova, Korea, Sweden, Turkey, U.S.A., EAPO and EPO.

<sup>72</sup> EAC REGIONAL IP POLICY, *supra* note 33, Policy Statement No. 8.

- Allow for any natural or juristic person, even if acting solely in the public interest, to file a post-grant opposition within three years after the grant of a patent, or a further extension thereof upon showing of good cause;
- Establish broad grounds for post-grant invalidation including a failure to meet patentable subject matter, exclusion, or patentability criteria, failure to make required disclosures, and fraudulent commissions and omissions;
- Opponents should be given full legal standing and they should be able to appear at a hearing in support of their opposition;
- The post-grant opposition procedure should allow simple and expedited administrative procedures.

Although the author of the Comparative Study appears to recommend use of post-grant opposition procedures only, ARIPO Member States, should consider adoption of both pre- and post-grant opposition systems.

### 1.6 Parallel Importation

Article 6 of the TRIPS Agreement preserves Member States' right to choose the patent right exhaustion regime they prefer without the threat of WTO sanctions: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." As a practical matter, this means that countries are free to adopt national, regional, or international exhaustion.<sup>73</sup> If they choose international exhaustion, they will have the right of what is called parallel importation. Because the patent holder exhausts all of its IP-related rights to prevent further sale and distribution of its patented protected product once it receives its invention "reward" upon an initial sale, domiciliaries of the country applying international exhaustion are free to purchase and import that product into their country from another country where the product has been lawfully placed on the market. If the patented product has been sold more cheaply abroad by the patent owner or its licensee, then it will be cost-saving to parallel import. Protecting parallel importation has been recommended by the UK Commission on Intellectual Property Rights<sup>74</sup> and the World Health Organization<sup>75</sup>.

Although it is possible to limit the right of parallel importation (international exhaustion) to articles put on the market with the consent of the patent holder, it is perhaps preferable to allow parallel importation with respect to products put lawfully on the market anywhere in the world, which would cover originator products, voluntarily licensed products, and products produced pursuant to a lawful compulsory licence.<sup>76</sup> Kenya has adopted such a provision. Section 58(1) of the Kenyan Industrial Property Act specifically provides that the right of a patentee to preclude any person from importing patented products does not extend to "acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya." Clause

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<sup>73</sup> See Frederick M. Abbott, *First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation*, J. INT'L ECON. L. 607-636 (1998); EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: EXHAUSTION OF PATENT RIGHTS (WIPO SCP/21/7), [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_21/scp\\_21\\_7.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_7.pdf).

<sup>74</sup> CIPR, INTEGRATION OF IPRS AND DEVELOPMENT POLICY, *supra* note 40, at 42.

<sup>75</sup> WHO, REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, PUBLIC HEALTH AND INNOVATION, 124, paragraph 4.19 (2006).

<sup>76</sup> See Correa, INTEGRATING PUBLIC HEALTH, *supra* note 40, at 79-80 (admitting that such a rule might be subject to WTO challenge).

37 of the Industrial Property Regulations (2002) further clarifies that the limitation on the rights under a patent in section 58(1) of the Act extends to acts in respect of articles that are imported from a country where the articles were legitimately put on the market.<sup>77</sup> The East African Community more broadly also appears to support very liberal parallel importation rights, including with respect to medicines produced pursuant to a compulsory licence.<sup>78</sup> Similarly, India has adopted a framework that allows parallel importation of products legitimately put on the market: “Certain acts not to be considered as infringement. For the purposes of this Act – importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights.”<sup>79</sup> Likewise, Article 36.c of the Argentine Patent Law No. 24.481 of 1995 provides that the rights conferred by a patent shall have no effect against “any person who acquires, uses, imports, or commercializes in any way the product patented or obtained by the patented process once that said product has been legally placed on the market in any country. ...”<sup>80</sup> Accordingly, ARIPO Member States might choose to allow parallel importation of products that have been “legally placed in any market” not being limited to the ‘patented product’.

## 1.6 Limited Exceptions

Article 30 of the TRIPS Agreement allows limited exceptions to patent rights on the following terms: “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” There is much controversy whether this is a cumulative three-part test or a comprehensive overall assessment balancing the three listed factors.<sup>81</sup> And, of course, the exact contours of what is permitted are left very much undefined in the text. Nonetheless, there are several generally accepted limited exceptions, and liberal interpretations of the same, that ARIPO Member States should be free to adopt.<sup>82</sup>

**Research and education exception.** Patent regimes should avoid measures that have the impact of shutting down on-going innovation or the education of researchers. Developing a strong research capacity and adopting legal rules that facilitate the development of such capacity is fundamental to the economic and technological development of ARIPO Member States. Moreover, Article 30 of the TRIPS Agreement has been interpreted to allow a robust research exception that permits the use of patented inventions for research purposes, both commercial and non-commercial and further to allow use of the patented invention for educational purposes. Exceptions to patent rights for research, experimental, and educational purposes are widely

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<sup>77</sup> The continued viability of parallel importation in Kenya has been thrown into doubt by a tortured court decision in *Pfizer Inc. v. Cosmos Limited* (Case No. 49 of 2006, Judgment of the Industrial Property Tribunal at Nairobi, April 25, 2008).

<sup>78</sup> EAC REGIONAL IP POLICY, *supra* note 33, at 18.

<sup>79</sup> India Patents Act, *supra* note 21, section 107A.

<sup>80</sup> This provision was mentioned in the Mutually Agreed Solution to WTO complaints filed by the U.S.: Request for Consultations by the United State, Argentina – Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemical, WT/DS171/1 and Request for Consultations by the United States. The Mutually Agreed Settlement confirmed that patent holders would have the right to prevent third parties not having the owner’s consent from making, using, offering for sale, selling or importing the patented product in Argentina.

<sup>81</sup> Max Planck Institute, DECLARATION ON PATENT PROTECTION, *supra* note 23, at 8.

<sup>82</sup> See Christopher Garrison, EXCEPTIONS TO PATENT RIGHTS IN DEVELOPING COUNTRIES (Aug. 2006).



recognized worldwide as an important means to incentivise ongoing innovation.<sup>83</sup> Although some countries only allow a research exception for non-commercial purposes, it is generally preferable to specify that the research exception applies to both commercial and non-commercial research and experimental use. One reason for expanding the exception to cover commercial experimentation is because the distinction between non-commercial and commercial research is blurring with the advent of more interest and opportunity for academic researchers to file patents on their innovations. Several countries already allow for a broad research exception including Brazil, as well as regional blocs such as the OAPI.<sup>84</sup> A broad research exception should allow research “on” and research “with” the patented technology.

**Early working (and stockpiling) exception.** The early working or Bolar exception as it is known in the U.S. is a provision that allows research activities and product development that is reasonably related to the purpose of obtaining required marketing approvals for pharmaceutical and other products. For example, the early working exception allows a generic producer of medicines to reverse engineer the medicine, to conduct stability, bioequivalence and other required tests, to develop proof of manufacturing according to Good Manufacturing Practices, and thereafter to submit the compiled data to national drug regulatory authorities for the purpose of obtaining marketing approval. All these activities can occur before the patent expires so that the generic entrant is in a position to quickly enter the market upon patent expiry, instead of having to wait two or more years to complete the required research and product development and then additional years to obtain regulatory approval.

Early working rules can allow the use of the patent product or process with respect to both domestic and foreign registration. The East African Community has recommended that

In order to allow early market entry for generic producers, EAC Partner States shall amend their national patent law provisions on marketing approval/‘Bolar’ exception to:

- a. Authorise the use of patented substances by interested parties for marketing approvals by national and foreign medicines regulatory authorities.<sup>85</sup>

**Prior use, private or non-commercial use, and extemporaneous production of medicines.** The law in 69 countries allows for a prior use exception to patent rights typically to provide for a balance between the rights of patent holders and prior users.<sup>86</sup> A prior use exception typically allows a prior user to continue using or working the invention as had been done in the past, but not to expand or extend that use. Patent exclusivity is granted primarily to reward the inventor with commercial opportunities to recoup innovation costs and to incentivise on-going innovation. However, private and/or non-commercial use do not infringe the economic interests of the patent holder and thus such use is commonly recognized as a valid limited exception to patent rights.<sup>87</sup> Similarly, limited exceptions are recognized concerning the individual preparation of a medicine

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<sup>83</sup> See Evans Misati & Kyoshi Adachi, THE RESEARCH AND EXPERIMENTATION EXCEPTIONS IN PATENT LAW: JURISDICTIONAL VARIATIONS AND THE WIPO DEVELOPMENT AGENDA (2010); EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: EXPERIMENTAL USE AND/OR SCIENTIFIC RESEARCH (WIPO SCP/20/4), [https://www.wipo.int/edocs/mdocs/patent\\_policy/en/scp\\_20/scp\\_20\\_4.pdf](https://www.wipo.int/edocs/mdocs/patent_policy/en/scp_20/scp_20_4.pdf).

<sup>84</sup> Article 43(II) of Brazil’s Law No. 9279/96, as amended; Article 8(1)(c), Annex I of the Agreement Revising the Bangui Agreement of 2 March 1977, on the Creation of an African Intellectual Property Organization (1999).

<sup>85</sup> EAC REGIONAL IP POLICY, *supra* note 33, Policy Statement No. 5, p. 15-16.

<sup>86</sup> EXCEPTIONS AND LIMITATION TO PATENT RIGHTS: PRIOR USE (WIPO SCP/20/6), [https://www.wipo.int/edocs/mdocs/patent\\_policy/en/scp\\_20/scp\\_20\\_6.pdf](https://www.wipo.int/edocs/mdocs/patent_policy/en/scp_20/scp_20_6.pdf).

<sup>87</sup> EXCEPTIONS AND LIMITATION TO PATENT RIGHTS: PRIVATE AND/OR NON-COMMERCIAL USE (WIPO SCP/20/3), [https://www.wipo.int/edocs/mdocs/patent\\_policy/en/scp\\_20/scp\\_20\\_3.pdf](https://www.wipo.int/edocs/mdocs/patent_policy/en/scp_20/scp_20_3.pdf).

pursuant to a prescription<sup>88</sup> and the temporary or accidental presence of ships, vessels, aircraft, or land vehicles.<sup>89</sup> Accordingly, we recommend that ARIPO Member States adopt these additional limited exceptions.

### 1.7 Compulsory and government use licences

The TRIPS agreement allows involuntary use of patents as long as certain procedures are followed. It does not specify or otherwise limit the grounds upon which licences can be granted. More specifically, Article 31 of TRIPS allows for the use of an invention covered by a patent without the patent holder's authorisation subject to the following conditions:

- Each case must be considered on its individual merits (Art. 31(a));
- The proposed user has made a prior unsuccessful attempt to obtain a voluntary licence from the right holder on commercially reasonable terms and such efforts have not been successful with a reasonable period of time (Art. 31(b));
  - Such requirement is waived in circumstances of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, though the right holder must be notified (Art. 31(b));
  - Such requirement is also waived where compulsory licences have been granted to remedy anticompetitive practices (Art. 31(k));
- The scope and duration of use is limited to the purpose for which the use was authorised (Art. 31(c)) and the authorisation for use shall be terminated if and when the circumstances which led to the use cease to exist and are unlikely to recur, subject to the legitimate interests of the licensee being protected (Art. 31(g));
- The use is non-exclusive (Art. 31(c)) and non-assignable, except with that part of the enterprise or goodwill which enjoys such use (Art. 31(e));
- The use is “predominantly for the supply of the domestic market” except when issued to remedy anticompetitive practices (Art. 31(f) & (k)) and now with an additional exception under Article 31bis;
- The patent holder is paid adequate remuneration for such use taking into account the economic value of the authorisation (Art. 31(h)), though compensation may be adjusted downward if a compulsory licence is issued to remedy anticompetitive practices (Art. 31(k));
- The legal validity of any decision relating to the authorisation of the use, as well as the amount of remuneration, is subject to judicial or other independent review by a “distinct higher authority” in that jurisdiction (Art. 31(g) & (j)); and
- The right holder of a second patent that cannot be exploited without infringing the first patent may receive a licence if the second invention involves an important technical advance of considerable economic significance in relation to the first invention, the owner of the first patent receives a cross-licence to the second invention on reasonable terms, and the use authorised in the licence on the first invention shall not be assigned without assignment of the second patent (Art. 31(l)).

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<sup>88</sup> EXCEPTIONS AND LIMITATION TO PATENT RIGHTS: EXTEMPORANEOUS PREPARATION OF MEDICINES (WIPO SCP/20/5)  
[https://www.wipo.int/edocs/mdocs/patent\\_policy/en/scp\\_20/scp\\_20\\_5.pdf](https://www.wipo.int/edocs/mdocs/patent_policy/en/scp_20/scp_20_5.pdf).

<sup>89</sup> Garrison, *supra* note 82, at 2-3, 6-9, 9-11.

**Grounds for and conditions on compulsory licences.** As clarified by the Doha Declaration,<sup>90</sup> WTO Member States have complete freedom to determine the grounds upon which compulsory licences may be granted and to decide which concerns, including health concerns, are a national emergency or matter of extreme urgency. There are no disease restrictions, country-status restrictions, or field of technology restrictions. Although the Paris Convention<sup>91</sup> does place some limits on the timing of compulsory licences for non-working, in other instances it is permissible to do so after the patent has been granted. Compulsory and government use licences have been used much more extensively than previously acknowledged.<sup>92</sup>

**National emergencies or matters of extreme urgency:** Article 31 of the TRIPS Agreement allows countries to avoid prior negotiations for a voluntary licence when they have determined according to their own standard that there is a national emergency or matter of extreme urgency.

**Dependent patents and improvements:** Article 31(l) of the TRIPS Agreement defines conditions under which compulsory licences for dependent patents may be issued:

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

- (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
- (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
- (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

This provision encourages a process of continuing and incremental innovation, but on its face applies only to second patentable inventions. Nonetheless, ARIPO Member States also retain freedom to determine that improved medicines and other technologies might warrant the issuance of a compulsory licence on an underlying patented invention even in the absence of a granted second patent.

**Multiple, alternative, and broad grounds for compulsory licences:** As a general rule, countries are far better off articulating multiple, alternative, and broad grounds for compulsory licences instead of restricted grounds.<sup>93</sup> After all, a patent is a sovereign grant of exclusive rights and patentees take such rights with full knowledge of the possibility that the granting government

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<sup>90</sup> Doha Declaration, *supra* note 4, paragraph 5(b), (c).

<sup>91</sup> Paris Convention, *supra* note 62, Article 5A(4), “A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.” Available at [http://www.wipo.int/treaties/en/text.jsp?file\\_id=288514](http://www.wipo.int/treaties/en/text.jsp?file_id=288514).

<sup>92</sup> Ellen t’ Hoen, PRIVATE PATENTS AND PUBLIC HEALTH: CHANGING INTELLECTUAL PROPERTY RULES FOR ACCESS TO MEDICINES (2015).

<sup>93</sup> Brook K. Baker, PROCESSES AND ISSUES FOR IMPROVING ACCESS TO MEDICINES: WILLINGNESS AND ABILITY TO UTILIZE TRIPS FLEXIBILITIES IN NON-PRODUCING COUNTRIES, UK DFID, Health Systems Resource Centre (2004); Cecilia Oh, *Compulsory licences: recent experiences in developing countries*, 1 INT’L J. INTELLECTUAL PROP. 22-36 (2006); Jerome H. Reichman & Catherine Hasenzahl, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS: HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS, AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE USA (2003); Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9:1 PLOS MED e1001154 (2012).

might issue compulsory and government-use licences. Accordingly, this submission recommends that the grounds for compulsory licences should be expansive as allowed by the Doha Declaration.<sup>94</sup> Thus, it is highly desirable to list additional specific grounds, e.g., to redress a failure to meet demand to an adequate extent and upon reasonable terms, to remedy a refusal to grant a licence on reasonable terms to the detriment of a trade or industry or economy, to remedy an excessive price, to reduce the risk of stock-outs, to promote the development and marketing of rational fixed-dose combinations, and to protect public health and the public interest more broadly.<sup>95</sup>

**Competition-based licences:** Article 31(k) of the TRIPS Agreement authorises the issuance of competition-based compulsory licences and waives requirements of prior negotiation and limitations on exports with respect to such licences.<sup>96</sup> The East Africa Community has specifically recommended that its Partner States adopt compulsory licence remedies for abuse of patent rights<sup>97</sup> and the UNDP has also done so in its recent analysis of the intersection between IP and competition policy.<sup>98</sup> Because competition-based licences have several other advantages – the possibility of lower royalties and an obligation to protect the acquired interests of the licensee, such licences have advantages for domestic licensees, most especially with respect to access to external markets. To operationalize Article 31(k), countries should clarify what constitutes anti-competitive practices, including excessive pricing, refusals to license, refused access to essential facilities, and failure meet reasonable needs or reasonable terms.

It would be especially important to specify that the refusal of a requested licence would justify a competition-based CL. Refusals to deal have been recognized historically as grounds for compulsory licences in multiple jurisdictions, including China, Argentina, and Germany, and in other countries where those refusals cause specific adverse effects, e.g., United Kingdom, Canada, and South Africa.<sup>99</sup> An important variant of the refusal to deal line of authority is the refusal to license an essential facility. Several jurisdiction have recognized that intellectual property rights can constitute essential facilities, including influentially the European Union, at least “where the refusal to license prevents the introduction of a new product or allows the intellectual property holder to monopolise a secondary market.”<sup>100</sup> Thus, for example, the Italian Competition Authority granted a compulsory licence against Merck based on its refusal to grant a licence to a competitor to produce an antibiotic active ingredient, which was considered to be an essential resource for the production of a generic equivalent.<sup>101</sup> As a basic principle, there should be clear and easy-to-use procedures.<sup>102</sup>

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<sup>94</sup> Doha Declaration, *supra* note 4, para. 5(b), “Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”

<sup>95</sup> See UNDP SA REVIEW, *supra* note 22, at 71.

<sup>96</sup> See TRIPS, *supra* note 1, Article 31(k), (b) and (f).

<sup>97</sup> EAC REGIONAL IP POLICY, *supra* note 33, Policy Statement No. 11(b), at 21.

<sup>98</sup> UNDP, USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES: A GUIDEBOOK FOR LOW- AND MIDDLE-INCOME COUNTRIES, 141-142 (2014), <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-competition-law-to-promote-access-to-medicine.html>.

<sup>99</sup> Carlos M. Correa, INTELLECTUAL PROPERTY AND COMPETITION LAW: EXPLORING SOME ISSUES OF RELEVANCE TO DEVELOPING COUNTRIES, 5 (2007), [https://ipronline.org/resources/docs/corea\\_Oct07.pdf](https://ipronline.org/resources/docs/corea_Oct07.pdf).

<sup>100</sup> *Ibid.* at 12.

<sup>101</sup> Autorità Garante della Concorrenza e del Mercato (AGCM), *Press Release: Pharmaceuticals: Antitrust Authority Rules Merck Must Grant Free Licences for the Active Ingredient Finasteride* (2007), <http://www.agcm.it/en/newsroom/press-releases/1096-a364-merck-active-ingredients-conclusion-of-investigation.html>.

<sup>102</sup> Baker, PROCESSES AND ISSUES FOR IMPROVING ACCESS TO MEDICINES, *supra* note 93.

**Compulsory licences for domestic production and/or import:** ARIPO Member States' patent law should explicitly clarify that compulsory licences can be issued both to domestic and foreign licensees. Although countries may pursue industrial development objectives to increase their pharmaceutical production capacity, many ARIPO Member States have little or no such capacity at present, meaning that they should retain the option of sourcing more affordable generics from foreign sources.

**Failure of working and of local working as grounds for a compulsory licence:** The Paris Convention in Article 5A(2) authorises countries of the Union to provide for compulsory licences in case of failure by the patentee to work the patent locally. There are time limits affecting when such licences can be issued: the last of either four years from the filing of the patent application or three years after it grant. Likewise, although this proposition is not without some controversy,<sup>103</sup> local working requirements are fully permissible under TRIPS and not just with respect to the issuance of compulsory licences.<sup>104</sup> ARIPO Member States should retain the right to issue compulsory licences on the grounds that the patent is not worked locally even though it is economically feasible to do so, but a reasonable time period for working must be established, and the right holder must be afforded the opportunity to prove that local production within the specified time period is not economically or procedurally feasible.

**Provisional compulsory licences on pending patents:** In some instances, a patent application may not yet have been granted even though the related product has already entered the market. In such circumstances and when public interest concerns so dictate, it should be possible to issue a provisional compulsory licence to take effect if and when the relevant patent or patents are granted. A complication in such licences might arise concerning whether royalties are due retroactively if a patent is ultimately granted.<sup>105</sup> Better practice would be for countries not to allow for retroactive infringement claims and thus a retroactive royalty would not be due. Although provisional compulsory licences are a useful option for countries in some circumstances, they do not obviate the need for use of oppositions to weed out unworthy patents.

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<sup>103</sup> Those who argue against the legality of local working requirements often point to Article 27.1 of the TRIPS Agreement which prohibits discrimination against imports in the granting patents available or enjoyment of patent rights.

<sup>104</sup> Michael Halewood, *Regulating Patent Holders: Local Working Requirement and Compulsory Licences at International Law*, 35 OSGOODE HALL L.J. 243-287 (1997); Bryan Mercuriio & Mitali Tyagi, *Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements*, 19 MINN. J. INT'L L. 275-326 (2010); Chia-Ling Lee, *The Legality of Local Patent Working Requirements under the TRIPS Agreement*, 2 N.T.U.T. J. of Intell. Prop. L. & Mgmt. 39-48 (2013); Paul Champ and Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the Brazil Patent Dispute*, 27 YALE J. INT'L L. 365-293 (2002).

<sup>105</sup> In some jurisdictions, generics that have notice of pending patent applications and their potential infringement face retroactive patent infringement/damage claims under the "provisional rights doctrine. For example, in the U.S., a generic company would be subject to reasonable royalty claims for making, using, selling, offering to sell, or importing "infringing" products if the infringer received actual notice of the potential infringement for a use substantially identical to the claimed invention once the patent has been granted. 35 U.S.C. § 154(d) (2012); see Sharick Naqi, *Comment on Provisional Patent Rights*, 10 Nw. J. Tech. & Intell. Prop. 595 (2012); see Patent Act, R.S.C. 1985, c. P-4 s. 55(2) (2017) (Can.) (similar rule). Provisional remedies are reportedly available in Australia, Brazil, China, France, Germany, India (may be contested), Italy, Japan, Malaysia, Russia, South Korea, Spain, Sweden, Taiwan, the United Kingdom, and Vietnam. Carlos O. Mitelman, *Blog: Protection of Patent Applications Pre-grant*, Int'l L. Off. (Oct. 15, 2007), <http://www.internationallawoffice.com/newsletters/detail.aspx?g=85fa48e4-e3b1-4794-a3aa-e7dfccbb676d>; Matthew Cutler, *International Patent Litigation Survey: A Survey of Patent Characteristics in 17 International Jurisdictions* (2008).

**Government use licences.** In addition to stating broad grounds for government-use licences, ARIPO Member States should clarify who can issue government-use licences and the procedures for doing so. Article 31(b) of the TRIPS Agreement clearly allows for government-use (“public non-commercial use”), requiring only notice<sup>106</sup> and remuneration<sup>107</sup>. The United States has the simplest and easiest to use government use provision in the world. Pursuant to 28 U.S.C. section 1498(a), any U.S. official or government contractor receiving the authorisation or consent of the government<sup>108</sup> can make use and manufacture the invention of a patent subject only to the patent holders right to seek reasonable and entire compensation for the same. U.S. use of section 1498 has been quite extensive, with the primary user being the U.S. Dep’t of Defense, but licensed products have historically included medicines and other health technologies.<sup>109</sup>

The “public, non-commercial use” restriction in TRIPS Article 31 does not limit who the licensee may be but instead requires that the patent will be used “by or for the government (emphasis added).” Accordingly, when governments grant government-use licences to private entities for the purpose of supplying medicines in the public sector or for servicing people with government insurance, this is use “for” the government even though the pharmaceutical licensee may be making a normal profit in manufacturing and marketing the medicine to the government or its beneficiaries. In addition, it is permissible for ARIPO Member States to issue government-use licences for importation.

**Article 31bis and an Article 30 exception: compulsory licences allowing production for export.**

A fundamental flaw in the Article 31(f) of the TRIPS Agreement is that it limits exportation of goods produced pursuant to a compulsory licence to non-predominate quantities. This provision creates a serious disadvantage for countries that have insufficient capacity to manufacture medicines locally, or where it is inefficient to do so, and who must therefore rely on imports. In such instances, governments could issue an “ordinary” compulsory licence to a foreign company, but, if there were also an applicable patent in the country of production/export, then a compulsory licence might not allow export **of** sufficient quantities to fulfill foreign needs because of the “predominantly for the supply of the domestic market” rule.

The drafters of the Doha Declaration recognised this dilemma and, in paragraph 6, instructed the WTO to devise an expeditious solution. On 30 August 2003 the WTO General Council issued a decision declaring a waiver from Article 31(f).<sup>110</sup> The 30 August 2003 Decision imposed onerous procedural requirements on both importing and exporting countries issuing compulsory licences and further restricted the quantity of pharmaceutical products that might be exported. The

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<sup>106</sup> “[W]here the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.”

<sup>107</sup> TRIPS, *supra* note 1, Article 31(h).

<sup>108</sup> “For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.”

<sup>109</sup> Hannah Brennan, Amy Kapczynski, Christine Monahan, & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH. 275 (2016).

<sup>110</sup> Decision of the General Council of 30 August 2003, *supra* note 5. The “temporary waiver” of the Decision was made into a permanent proposed amendment to TRIPS in December 2005, under a new Article 31bis; the amendment has since been ratified, [http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm).



Decision has been called “labyrinthine”<sup>111</sup> and as being “neither expeditious, nor a solution.”<sup>112</sup> As evidence of its impracticality, the Decision was only used once by a Canadian company, Apotex, to export antiretrovirals to one country, Rwanda, and then only after a multi-year delay.<sup>113</sup> Nonetheless, the waiver provision has recently received sufficient ratifications to be codified in TRIPS Article 31bis. For a regional trade agreement block that includes a majority of LDCs, such as the EAC, Article 31bis allows intra-regional distribution of imported pharmaceutical products produced pursuant to Art. 31bis compulsory licences.<sup>114</sup> There have been several proposals to simplify domestic implementation of the 30 August 2003 Decision, including a so-called one-licence solution proposed in Canada.<sup>115</sup>

ARIPO Member States can and should adopt Article 31bis making its use as simple and expeditious as possible as either a producer/exporter or as a user/importer. Not only could they adopt the one-licence solution, they could also provide for strict time limits on the obligation to engage in negotiations for a voluntary licence, they can waive prior negotiations in response to compulsory licences issued on the grounds of emergency or for public, non-commercial use, and they could, like Canada, adopt remuneration guidelines with tiered royalties,<sup>116</sup> or fixed percentage royalties.

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<sup>111</sup> Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines, Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 *IND. INT’L & COMP. L. REV.* 613-715 (2004); Frederick M. Abbott & Jerome H. Reichman, *The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provision*, 10 *J. INT’L ECON. L.* 921-987 (2007); Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 *AM. J. INT’L L.* 317 (2005).

<sup>112</sup> Médecins Sans Frontières Canada, *Neither Expeditious, Nor a Solution: the WTO August 30 Decision is Unworkable*, 2 (2006).

<sup>113</sup> For a discussion of the timeline for the Apotex license and a summary of debate at the WTO on the effectiveness of the 30 August 2003 Decision, see ICTSD, *Canada Medicines Bill Under Threat*, 15:10 *BRIDGES* (23 March 2011), <http://www.ictsd.org/bridges-news/bridges/news/canadian-access-to-medicines-bill-under-threat>.

<sup>114</sup> Article 31bis:

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:
  - (i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

See Chikosa Banda, *Intellectual Property and Access to Essential Pharmaceuticals: Recent Law and Policy Reforms in the Southern Africa Development Community Region*, 31 *MARYLAND J. INT’L L.* 44 (2017), <https://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1645&context=mjil>.

<sup>115</sup> Richard Elliott, *Fixing Canada’s Access to Medicines Regime – Bill C-398*, IP-WATCH (18 Nov. 2012), available at <http://www.ip-watch.org/2012/11/18/fixing-canadas-access-to-medicines-regime-bill-c-398/>; Bill C-398 available at <http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=5391829&File=4>.

<sup>116</sup> See Canadian Access to Medicine Regime (CAMR), sections 21.01 to 21.19 of the Patent Act. “Under CAMR, the remuneration, or royalty fee, to be paid by the license holder to the patent holder is calculated according to a formula which multiplies the monetary value of the supply contract by an amount that fluctuates on the basis of the importing country’s rank on the UN Human Development Index. Under this formula, the lowest country on the index would pay a royalty of approximately 0.02 percent, and the highest 3.5 percent. Where a patent holder is of the view that the royalty resulting from the application of the formula is inadequate, it may apply to the Federal Court for an order setting a higher amount. In considering the merits of such an application, the Court must take into account the economic value of the use of the licensed product by the importing country and the humanitarian and non-commercial reasons underlying the issuance of the license.” REPORT ON THE STATUTORY REVIEW OF SECTION 21.01 TO 21.19 OF THE PATENT ACT (2007), available at [http://www.camr-rcam.gc.ca/doc/camr\\_rcam\\_report\\_rapport-eng.php#fnb74-ref](http://www.camr-rcam.gc.ca/doc/camr_rcam_report_rapport-eng.php#fnb74-ref).

In addition, like India, ARIPO Member States could make granting of humanitarian licences for export mandatory.

However, ARIPO Member States may have additional freedom under Article 30 of the TRIPS Agreement to adopt an even more expeditious system – essentially a limited exception to allow the importation or exportation of unlimited quantities of pharmaceutical products when needed to address an insufficiency of efficient pharmaceutical manufacturing capacity for the medicine in question in the importing country.<sup>117</sup> Although several countries, including Canada, China, India, the Netherlands, the European Commission, Korea, and Switzerland have adopted laws implementing Article 31bis,<sup>118</sup> only Uganda seems to have adopted both Article 31bis procedures and an Article 30 limited exception system.

**Judicial licences:** Right holders often seek provisional measures (temporary injunctions or interdicts) even before the alleged infringing party has had an opportunity to be heard in court. These provisional measures allow orders not only against continuing (alleged) infringement, but also seizures and Impounding of suspected infringing goods. Moreover, in some jurisdictions such as South Africa, they cannot be appealed because they are considered interlocutory. Broad forms of provisional relief pose a significant disincentive for generic producers, including local producers, to enter the market. Even where the generic producer believes the putative patent right to be weak or that its conduct is not infringing, the patent holder has an immediate upper-hand that stops the business of the generic producer in its tracks, even after it has invested considerable resources to enter the market.<sup>119</sup> If and when the case proceeds to trial, patent holders typically seek the entry of a permanent injunction against infringement, which completely halts the infringing competition no matter what its social value. These provisional measures and permanent injunctions/interdicts are highly prejudicial to alleged infringers, denying them their rights to fair administrative justice and, in our view, constitute bad law.

Articles 50.1<sup>120</sup> and 44.1<sup>121</sup> of the TRIPS Agreement require Member Countries to provide provisional measures and permanent injunctions to prevent infringement, including the entry of infringing, imported products into the market. Although these provisions require that provisional measures and injunctions should be *available* in some circumstances, these circumstances can be *strictly limited* by equitable principles, including the interest of the public in access to medicines. Thus, in the absence of exceptional grounds for provisional or injunctive relief, remuneration in the form of on-going royalties can be awarded instead of an injunction or interdict.

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<sup>117</sup> Baker, *supra* note 111.

<sup>118</sup> See, *Members' laws implementing the 'Paragraph 6' system*, World Trade Organization, available at [http://www.wto.org/english/tratop\\_e/trips\\_e/par6laws\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm).

<sup>119</sup> See, UNDP SA REVIEW, *supra* note 22, at 74.

<sup>120</sup> "The judicial authorities shall have the authority to order prompt and effective provisional measures: (a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance; (b) to preserve relevant evidence in regard to the alleged infringement."

<sup>121</sup> "The judicial authorities shall have the authority to order a party to desist from an infringement, *inter alia* to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right."



The legality of such a limitation on injunctive and provisional relief under TRIPS is clarified by Article 44.2 of the TRIPS Agreement, which allows for the judicial award of compensation as an alternative to injunctive relief:

Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply *or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available* (emphasis added).

There is now strong precedent for the granting of judicial, royalty-bearing licences both in the United States and in India. In the United States, in the leading case, *eBay Inc. v. MercExchange, L.L.C.*,<sup>122</sup> the U.S. Supreme Court overturned decades of practice whereby parties claiming patent infringements were routinely granted temporary and permanent injunctions. *eBay* reversed that trend and ruled that courts should award injunctions only after evaluating traditional equitable principles, in the U.S. the standard four-factor balancing test. Since the *eBay* decision, it has now become almost routine that U.S. courts order ongoing royalty-arrangements in lieu of issuing permanent injunctions, especially, but not only, when the patent holder is a non-practising entity.<sup>123</sup> Similarly, in India, courts have become willing to deny injunctions and instead grant royalty-bearing licences in infringement cases, especially where public health interests are at stake.<sup>124</sup> In *Roche v. Cipla* the court weighted harm to third parties and noted that it could not “be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted.”<sup>125</sup> In this context, it is noteworthy that the South African representative to the WTO TRIPS Council has endorsed US decisions refusing injunctive relief in cases of infringements of medical patents, opting instead to award damages in the form of royalty payments.<sup>126</sup>

Based on these precedents, ARIPO Member States can ensure that temporary and permanent court interdicts are not mandatory and that instead that courts have specific discretion to award compensatory damages in the form of on-going royalties, especially with respect to medicines required to meet public health needs.

**Compulsory licences on know-how.** Because patent applicants do not always disclose sufficient information to allow efficient production, even by persons skilled in the art, compulsory licences

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<sup>122</sup> 547 U.S. 388 (2006).

<sup>123</sup> See, Jaideep Venkatesan, *Compulsory Licensing of Nonpracticing Patentees after eBay v. MercExchange*, 14 VA. J. LAW & TECH. 26-47 (2009).

<sup>124</sup> See *Hoffman La Roche v. Cipla & Anr*, IA No. 642/2008 in CS (OS) No.89/2008. The refusal to grant a preliminary injunction was vindicated by an eventual trial on the merits in 2012 where it was found that Cipla had not in fact violated the patent at issue. Elsewhere, the Supreme Court of Appeal in South Africa has recently ruled that the impact on a temporary injunction on the public interest should be weighed before entering such an order, but on the merits of the case rejected awarding a royalty and instead awarded the temporary order. *Cipla Medpro (Pty) v Aventis Pharma SA, Aventis Pharma SA & others v Cipla Life Sciences (Pty) Ltd & others* 2013 (4) SA 579 (SCA).

<sup>125</sup> *Ibid* at para 85.

<sup>126</sup> Knowledge Ecology International *WTO TRIPS Council (October 2017): South Africa highlights examples of compulsory licensing in Germany, Malaysia, and the US* available at <https://www.keionline.org/node/2885> (accessed 21 October 2017).

on patents alone might be insufficient to achieve the desired purpose of allowing competing production and sale of patented goods, especially medicines. In some instances, it might actually be necessary to gain access to a right holder's "know how," even though such know how might be subject to trade secret protection.<sup>127</sup> Accordingly, it would be desirable for ARIPO Member States' patent law to clarify that if access to know how is needed to fully effectuate the purpose of a compulsory or government-use licence then a compulsory licence on such know how should be issued on reasonable terms and conditions. One of the terms would be separate compensation to the right holder beyond the royalty due on the patent right alone. Secondly, however, in order to protect the know-how owner's interest in preventing further dissemination of its trade secrets, there could be a confidentiality term prohibiting the know-how licensee disclosing the know-how to third parties without the consent of the right holder.

**Adequate remuneration.** Article 31(f) of the TRIPS Agreement requires adequate remuneration to the right holder based on the economic value of the licence in the country that issues it. Love has described multiple models for determining adequate remuneration.<sup>128</sup> For example, legislation in Canada provides tiered royalty rates set at 4 percent of the generic price and adjusts the rate downwards according to the importing country's rank on the UNDP Human Development Index. Similarly, the East African Community has recommended that Partner States shall "include in their patent laws a provision stating that the remuneration shall not exceed the UNDP recommended figure of 4%, and take anti-competitive behaviour into account when determining the amount of remuneration." There is additional precedent for remuneration guidelines in the legislation of the Philippines.<sup>129</sup>

It would be permissible for ARIPO Member States to adopt Remuneration Guidelines, which would greatly simplify the process of issuing compulsory and government-use licences. For example, Zanzibar has adopted a 4% ceiling in Article 14(1)(b) of its Industrial Property Act. The Remuneration Guidelines could make allowance for a modest upward adjustment based on disclosed, extraordinary research and development costs or therapeutic breakthrough in the case of pharmaceuticals. The Remuneration Guidelines could conversely allow downward adjustment based on the use of public funds to research and develop the patented invention or if the patent holder has already recovered significantly more than its research and development costs as adjusted for risk and opportunity costs. Finally, the Remuneration Guidelines should address compulsory licences issued to remedy anti-competitive behavior in which case royalties can be reduced even to 0%. Royalties on exports to countries with insufficient manufacturing capacity should be based on the economic value of the authorisation in the country of importation.

**Easy-to-use and efficient compulsory licensing procedures.** As discussed previously, compulsory-licensing procedures should be expeditious and easy-to-use. Some of the procedures concerning compulsory and government-use licences have been discussed above, including timelines for prior negotiations for voluntary licences and remuneration guidelines. Expedited administrative procedures, rather than judicial procedures, which cost substantially more, should be used. Moreover, independent administrative review by a distinct higher authority is permissible in lieu of judicial review with respect to the legal validity of a licence and the amount of remuneration.<sup>130</sup>

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<sup>127</sup> Max Planck Institute, DECLARATION ON PATENT PROTECTION, *supra* note 23, at 11.

<sup>128</sup> See James Love, REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES, 66-67 (UNDP and WHO 2005) for a comprehensive review of proposed remuneration guidelines.

<sup>129</sup> Section 35-B(3), the Philippine Republic Act no. 165 of 1947, as amended by Presidential Decree 1263 in 1977.

<sup>130</sup> Article 31(i) & (j) of the TRIPS Agreement.

Once a licensing decision has been made, even though the patent holder might have a right of appeal to a higher administrative body, there should be no possibility of obtaining a stay or provisional order to prevent the operationalisation of the licence.

This submission does not directly state an opinion on which public official[s] ARIPO Member States should empower to issue compulsory and government use licences. This issue should, of course, be addressed in any legislative reform process. However, government use licences in particular may properly be issued by multiple officials depending on the public need and the duties of the particular official.

## 1.8 Enforcement Flexibilities

There are important TRIPS-compliant flexibilities that might be adopted in the enforcement arena. It is widely recognized that IP rightholders and certain governments are pursuing a “new enforcement agenda” that seeks to expand both private and public enforcements rights and to espouse new, deterrent remedies and even criminal sanctions for IP violations.<sup>131</sup> Clearly, rightholders are entitled under TRIPS to pursue private enforcement of their putative rights when they feel their substantive patent rights to exclude others from using the patented product or process are being infringed so long as they do not abuse these private enforcement rights by filing frivolous or abusive claims. These private claims, often pursued by foreign rightholders with deep pockets, already act as a significant deterrent for many potential infringers. However, the TRIPS Agreement does not require a recalibration of national law to give rightholders greater enforcement rights than the TRIPS minimum. Nonetheless, rightholders and their rich country supporters are seeking deterrent rather than compensatory damages, they are seeking mandatory rights to provisional and injunctive relief, they are seeking enhanced, extra-judicial border measures, and they are seeking criminal law measures and ex parte forfeitures for alleged IP violations. In essence, they are seeking to impose ever-higher burdens – and costs – of enforcement on governments and potential competitors. The TRIPS Agreement does require countries to establish judicial mechanisms to redress patent violations and to secure borders. However, these limited provisions do not require the following, all of which can be lawfully excluded as remedies in ARIPO Member States:

- No border measures required for suspected patent infringement of goods in transit (Art. 51)<sup>132</sup>
- No requirement of criminal penalties for patent violations (Art. 61)<sup>133</sup>

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<sup>131</sup> Pedro Roffe & Saviert Seuba, *THE ACTA AND THE PLURILATERAL ENFORCEMENT AGENDA* (Cambridge 2015); ICTSD, *ISSUE PAPER 22: THE GLOBAL DEBATE ON THE ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS AND DEVELOPING COUNTRIES* (2009); Susan K. Sell, *THE GLOBAL IP UPWARD RATCHET, ANTI-COUNTERFEITING AND PIRACY ENFORCEMENT EFFORTS: THE STATE OF PLAY* (June 9, 2008); Xavier Seuba, *FREE TRADE OF PHARMACEUTICAL PRODUCTS: THE LIMITS OF INTELLECTUAL PROPERTY ENFORCEMENT AT THE BORDER*, Programme on IPRs and Sustainable Development Series • Issue Paper 27 (2010); UNDP, *DISCUSSION PAPER – ANTI-COUNTERFEITING LAWS AND PUBLIC HEALTH: WHAT TO LOOK OUT FOR* (2012); Ermias Tekeste Biadgleng, *IP RIGHTS UNDER INVESTMENT AGREEMENTS: THE TRIPS-PLUS IMPLICATIONS FOR ENFORCEMENT AND PROTECTION OF PUBLIC INTEREST* (Aug. 2006); Christopher Gibson, *A LOOK AT THE COMPULSORY LICENSE IN INVESTMENT ARBITRATION: THE CASE OF INDIRECT EXPROPRIATION* (2009).

<sup>132</sup> Brook K. Baker, *Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough*, PIJIP RESEARCH PAPER SERIES (2012)

<http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1026&context=research>

<sup>133</sup> In the face of inherent uncertainty about patent validity and enforceability and in light of the negative impact of criminal sanctions on innovation activity, it is simply inappropriate to impose criminal liability on a party for infringing a patent. See, Irina C. Manta, *The Puzzle of Criminal Sanctions for Intellectual Property Infringement*, 24 HARVARD J. LAW & TECH. 469-518 (2011); Christopher Buccafusco & Jonathan S. Masur, *Innovation and Incarceration: An Economic Analysis of Criminal Intellectual Property*, 87 S. CAL. L. REV. 275-334 (2014) (“According to our analysis, there is a

- Although injunctions must be an available remedy, it is also permissible to limit remedies to adequate remuneration like that provided for compulsory and government use licences (Art. 44)
- Although provisional measures must be possible, they are not mandatory (Art. 50)
- Although compensatory damages must be an available remedy for infringement, alternative measures damages based on market value, selling price, or deterrence are not required (Art. 45)

### 1.9 Competition Policy

Although the TRIPS Agreement is primarily oriented towards articulation of standards for protecting and enforcing intellectual property rights, it also recognizes that governments have rights under sovereign competition law to regulate and prevent anti-competitive abuses of patent, data, and voluntary licenses.

For example, Article 8.2 of the TRIPS Agreement provides that: “Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.” It should be noted that there are three kinds of separate harms addressed in this provision: abuse of IPRs, practices that unreasonably restrain trade, generally believed to entail anti-competitive and unfair trade practices, and practices that adversely affect international transfer of technology, which creates some scope for countries to take measures protecting and promoting industrial policy and local production. Although countries’ freedom to prevent IP abuses is not unlimited and although the mere exercise of exclusive rights granted by patents and other IPRs may not necessarily be considered abusive, even the non-abusive exercise of IPRs can result in restraints to trade, negative impacts on technology transfer, or violations of other important public policies.

Based on findings of other anti-competitive and collusive behaviors, including “product hopping” and “pay for delay” or “reverse payment” settlements between patent holders and generic companies, government should have the power to issue injunctions, impose fines, require rebates, and impose criminal sanctions.

- Product hopping or switching is an anti-competitive strategy adopted by patent holders that involves introduction of a new version of a patented drug that would otherwise shortly face expiration of patent protection. The old version can be withdrawn from the market effectively blocking generic substitution as prescribers cease to prescribe the old version in favor of the new, generally more expensive, patent protected version.<sup>134</sup> The U.S. Second Circuit Court of Appeal found that product hopping was an antitrust violation in *State of New York v. Activis PLC*<sup>135</sup> and there have been similar verdicts in Europe.<sup>136</sup>

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limited and tentative case for the use of criminal liability, including imprisonment and alternative sanctions, for only some types of copyright infringement—and none at all for patent infringement”); Max Planck Institute, DECLARATION ON PATENT PROTECTION, *supra* note 23, at 12.

<sup>134</sup> Dmitry Karshedit, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 Iowa L. Rev. (forthcoming 2019); James B. Musgrove et al., *Product Hopping: Can Patent Non-Use Be an Abuse of Dominant Market Position in Canada*, 6 J. EUR. COMP. L. & PRAC. 722 (2015).

<sup>135</sup> 787 f.3d 638 (2<sup>nd</sup> Cir. 2015).

<sup>136</sup> Case T-321/05—*AstraZeneca v Commission* (1 July 2010), [2010] ECR II- 2805.

- Pay-for-delay agreements typically involve monetary payments of non-monetary benefits from patent holders to potential generic competitors to settle patent infringement or invalidation proceedings resulting in the generic company delaying or abandoning market entry. Beginning in 2001, the U.S. Federal Trade Commission has filed a number of lawsuits to stop such agreements. A 2010 FTC study estimated such agreements has cost consumer \$3.5 billion annually.<sup>137</sup> In 2013, the U.S. Supreme Court affirmed that the FTC could and should investigate pay-for-delay agreements applying rule-of-reason analysis.<sup>138</sup>
- Although no competition authorities have yet granted competition relieve relating to exploitation of patent thickets or defensive, recent commentators suggest that developing countries might well bring claims based on “patent thickets” involving multiple overlapping patent application for new formulations, processes, chemical variations, and new uses/indications purposely designed to preclude generic market entry or based on defensive patenting designed to block the development of new competing products.<sup>139</sup> A case pursuing this theory is currently being litigated in the U.S.<sup>140</sup>

As previously discussed, under TRIPS Article 31(k) allows for compulsory licences to remedy anticompetitive practices. It should be noted that the term “anti-competitive” practices is not further defined in Article 31(k), but that Article 31(k) does not have the further qualification list in Article 40, below concerning “an adverse effect on competition *in the relevant market* [emphasis added].”

Article 40 of the TRIPS Agreement is most directly on point with respect to governmental authority to regulate the terms and conditions of voluntary licences. Under Article 40.1:

Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

There are plausible arguments that Art. 40.1 imposes “an obligation on Members to address certain forms of anticompetitive practices in licensing agreements.”<sup>141</sup> Although Art. 40.1 most obviously applies to anti-competitive terms in contractual licences, by referencing more broadly “licensing practices and conditions,” “refusals to license, discriminatory grant of licenses as well as discriminatory license terms, and restrictive clauses in general, all fall within the scope of the provision.”<sup>142</sup> According to authoritative interpretation, Art. 40 also applies can apply to cross-licences and patent pools.<sup>143</sup>

Under Article 40.2:

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<sup>137</sup> U.S. Federal Trade Commission. PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS. AN FTC STAFF STUDY (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

<sup>138</sup> *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237-38 (2013).

<sup>139</sup> Duncan Matthews & Olga Gurgula, *Patent Strategies and Competition Law in the Pharmaceutical Sector: Implication For Access to medicines*, Queen Mary U. of London, School of Law, Legal Studies Research paper No. 233/2016 (2016) [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2779014###](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2779014###).

<sup>140</sup>

<sup>141</sup> See, UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT, *supra* note 26, at 554-556.

<sup>142</sup> *Ibid.* at 556.

<sup>143</sup> *Ibid.*

Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.<sup>144</sup>

Article 40.2 recognizes Members sovereign judgment to define anti-competitive abuses in IP licences. Despite the clause requiring an adverse competitive effect in the relevant market, Members may define per se competition violations that have no redeeming features and are in all foreseeable contexts and applications anticompetitive. Of course, what might be considered anti-competitive in one country, context, or market, might not be considered so elsewhere. In addition, countries can list provisions that are subject to a rule-of-reason analysis whereby they might be presumed anti-competitive, but the licensor is allowed to rebut such a finding. Rule of reasoning analysis varies in different jurisdictions, but may, as in the U.S., be based primarily on the issue of whether anti-competitive impacts are offset by enhanced efficiency, though in the case of patents, analysis should focus on adverse innovation impacts. Article 40.2 also requires that measures to control or prevent the putative anti-competitive practices and conditions must be “consistent with TRIPS” and “appropriate,” meaning they must be proportionately tailored to remedy the anti-competitive harm. Appropriate response can vary all the way from criminal law enforcement, and fines to government initiated administrative or judicial enforcement, to rights of private enforcement by licensees for nullification, licence termination, and/or damages.

Although Art. 40 directly authorizes countries to address competition concerns in voluntary licences, “Members are not confined to apply a competition test in dealing with licensing agreements. They may take measures based on other criteria and with objectives difference from those of competition law – for instance to reduce royalty payments or to ensure licensees the possibility of exporting to various territories.”<sup>145</sup> The UNDP has published a list of per se abusive or anti-competitive provisions in voluntary licences:

- (i) exclusive grant-back provisions and/or zero-royalty grant-backs; grant-backs of know-how and unrelated improvements;
- (ii) non-challenges to validity of industrial property rights;
- (iii) ineligibility to become a compulsory licensee;
- (iv) exclusive dealing;
- (v) restrictions on research;
- (vi) restrictions on use of personnel;
- (vii) price-fixing;
- (viii) restrictions on adaptations;
- (ix) exclusive sales or representation agreements;
- (x) tying arrangements;
- (xi) export restrictions, particularly for the supply to countries without a blocking patent;
- (xii) restrictions on publicity of licensed products;

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<sup>144</sup> The list of potentially impermissible provisions or practices is non exhaustive and indeed not uniformly agreed upon. For example, whereas the U.S. outlaws no-challenge clauses, German law allows them.

<sup>145</sup> Carlos Correa, *Intellectual property and competition – room to legislate under international law*, in UNDP, USING COMPETITION LAW, supra note 98, at 53.

- (xiii) payments and other obligations after expiration of industrial property rights;
- (xiv) restrictions after expiration of the licensing agreement.<sup>146</sup>

## 2. Critique of the Comparative Study of the Industrial Property Laws of ARIPO Member States

The main purpose of this paper is to fully outline allowable TRIPS-compliant flexibilities that ARIPO Member States might incorporate in their national legislation to take full advantage of opportunities to maximize access more affordable medicines to combat HIV, TB, malaria and other infectious and non-infectious diseases. However, the previous study commissioned by the ARIPO Secretariat, A COMPARATIVE STUDY OF THE INDUSTRIAL PROPERTY LAWS OF ARIPO MEMBER STATES (COMPARATIVE STUDY), which purports in Chapter Two to analyze whether Member States have taken advantage of available TRIPS flexibilities and to recommend best practices for harmonization of Members' legal frameworks, failed woefully to comprehensively identify and analyze all relevant TRIPS flexibilities and best practices. Accordingly, in this section of the paper we briefly identify the main weaknesses, omissions, and incomplete or erroneous analyses in the COMPARATIVE STUDY in the hopes that ARIPO and its Member States will commission an even more detailed and accurate analysis of their existing industrial property legislation to identify areas for potential law reform. Even more importantly, we hope that ARIPO Member States will realize the importance of harmonizing their intellectual property rules to take maximum advantage of TRIPS flexibilities, not the narrow, "race to the bottom" harmonization recommended all too often in the COMPARATIVE STUDY.

The main weakness in the COMPARATIVE STUDY is its failure to address the vast majority of TRIPS flexibilities identified in Section 1. Without a proper analysis of TRIPS flexibilities, it is impossible to properly assess domestic legislation to identify law reform opportunities that might maximize ARIPO's Member States' policy space to enhance access to more affordable medicines of assured quality. The second major weakness in the COMPARATIVE STUDY is its apparent decision to base many of its weak and under-inclusive recommendations not on well-known TRIPS-compliant flexibilities but instead on what some ARIPO Members have incorporated in existing law. This would lead not only to the perpetuation of several TRIPS-plus measures but also to a huge lost opportunity to incorporate "best practice" flexibilities into Member States' industrial property laws.

Specific areas where the COMPARATIVE STUDY inadequately describes TRIPS flexibilities outlined in Section 1 of this paper include:

- pp. 16-17 – Although there is a brief discussion of Member States flexibility to define what constitutes an invention there is no substantive discussion of the flexibility to establish stringent standards of patentability and instead an erroneous statement that novelty, non-obviousness, and utility is equal to the novelty, inventive step and industrial applicability standard set forth in the TRIPS Agreement.
- pp. 17-19 – Similarly, the discussion of "non-inventions" is limited to those articulated in the Harare Protocol<sup>147</sup> and the discussion of other exclusions to patentability is limited to

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<sup>146</sup> UNDP, USING COMPETITION LAW, *supra* note 98, at 141-142.

<sup>147</sup> Paris Convention, *supra* note 62, Section 3(10)(h): The following in particular shall not be regarded as inventions within the meaning of paragraph 10(a): (i) Discoveries, scientific theories and mathematical methods; (ii) Aesthetic creations; (iii) Schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (iv) Presentation of information.

those set forth in Article 27 of the TRIPS Agreement, meaning that there is no discussion of other allowable non-inventions and exclusions such as: (1) mere variations to known substance substances that do no enhance therapeutic efficiency, (2) admixtures and combinations of previously known substances, and (3) naturally occurring substances, including genes, and their isolates.

- Throughout there is no discussion of limited exceptions under Article 30 including extremely important ones: (1) research and education, (2) private use, (3) prior use, (4) early working, and (5) extemporaneous production of medicines.
- pp. 22, 29 – Although the analysis does at one point recommend that ARIPO LDCs take advantage of the pharmaceutical extension period, the analysis inaptly suggests at another point that LDCs might shorten patents instead of eliminating them by full use of the LDC pharmaceutical transition period.
- pp. 21-22 – There is an inadequate discussion of the pharmaceutical waiver/extension with no discussion whatsoever of how it applies to data protection and the elimination mailbox and market exclusivity obligations; indeed, on p. 25 there is an incorrect statement that mailbox rules still apply.
- p. 22 – The analysis erroneously suggests that limitations on patents for new uses of known substances is only available or appropriate for LDCs whereas it is permissible and appropriate for middle-income members as well.
- pp. 25-28 – The analysis gets off on the wrong foot by seeming to suggest that countries can only adopt pre-grant or post-grant opposition procedures, whereas it is perfectly legal to adopt both. The analysis then underplays the significance of pre-grant oppositions by only referencing existing state practice in the ARIPO region to rely on related but less robust rights to submit observations and objections. The analysis should at least reference the advantages of formal pre-grant opposition procedures. Finally, the analysis fails to discuss the details and advantages of administrative post-grant opposition procedures versus judicial revocation and invalidation. Both can result in the revocation or invalidation of a previously granted patent, but administrative procedures are generally much quicker and less costly and thus more appropriate in the ARIPO region.
- P. 30 – The analysis fails to point out that granting patent holders the right to exploit or work their patented invention is actually TRIPS-plus, as Art. 28 of the TRIPS Agreement merely grants rights to prevention others from exploiting the patented invention – it does not require positive rights.
- pp. 31-22 – The analysis does not fully address the flexibilities that countries have to require disclosure and update on foreign applications suggesting only that such a requirement is option rather than that it is recommended, nor does it discuss recommendations concerning disclosure of INNs.
- pp. 33-37 – Unfortunately, the discussion of government use and compulsory licences totally inadequate, though it does discuss existing state practice in the region. It fails to clarify governments' untrammelled rights to define grounds for compulsory licences. In addition, it fails to adequately discuss licences for emergencies and urgent needs, competition-based licences, Art. 31bis licences, and judicial licences. Finally, it inaccurately opines that all compulsory licences, including those grounded on refusals to license, must be delayed to meeting the non-working timelines in Article 5(4)(A) of the Paris Convention; those guidelines apply only to non-working licences not licences issued on alternative grounds.
- p. 38 – The analysis suggests that parallel importation requires that products be placed



- on the market with the consent of the owner rather than legally placed on the market.
- pp. 38-39 – The analysis of enforcement measures fails to address the flexibilities that countries have to limit remedies for infringement.
  - There is no discussion of use of competition policy to prevent abuse of patents or to regulated voluntary licenses as allowed in TRIPS.

Because of these multiple gaps, inaccuracies, and inadequate analysis, the procedural, substantive, and general recommendations of the COMPARATIVE STUDY on pages 41-41 are woefully incomplete. There are no recommendations concerning country adoption of the vast majority of flexibilities discussed at length in Section 1 of this paper. Even in the few areas where the consultant does make recommendations, several of them seem misguided. For example, the Study inappropriately seems to suggest that since the majority ARIPO Members provide for judicial invalidation procedures, countries that have post-grant opposition procedures should drop them. Likewise, there is only a single recommendation on compulsory licences, namely that LDCs, and LDCs only, adopt Article 31bis options for non-producing countries to make use of compulsory licences even though non-LDC ARIPO Members might similarly have insufficient domestic manufacturing capacity to make appropriate use of compulsory licences for import.

### **3. Conclusion**

We regret to conclude that the COMPARATIVE STUDY does not provide a reliable basis for best practices industrial property law reform for ARIPO Member States. A proper and full set of recommendations for making use in the full of TRIPS public health flexibilities would address all of the topics discuss in Section 1 of this analysis. Unfortunately, the selective, incomplete, and in some instances inaccurate analysis in the COMPARATIVE STUDY leaves ARIPO Member States misinformed not only about possible reforms to their own domestic legislation, but also misinformed about reforms that should be consider to the Harare Protocol, which is discussed in a separate civil society submission.

The civil society organizations seeking to engage in the ARIPO law reform process so as to ensure maximum affordability and accessibility to life-saving medicines is fully prepared to engage further with the ARIPO Secretariat concerning proposed TRIPS-flexibility reforms both at the regional and national level. We therefore reiterate our requests to be involved in ARIPO meetings on these topics, to be able to present our analysis and recommendations, and to assist ARIPO and its Member States in their effort to take advantage of TRIPS flexibilities to help advance their commitment to secure the right to health for their populations.

SIGNED:

1. AIDS and Rights Alliance for Southern Africa (ARASA)
2. Health GAP (Global Access Project)
3. Kenya Legal and Ethical Network on HIV/AIDS (KELIN)
4. Pan-African Treatment Access Movement (PATAM)
5. Southern African Programme on Access to Medicines and Diagnostics (SAPAM)
6. Third World Network
7. Women's Coalition Against Cancer (WOCAC)
8. Zimbabwe National Network of PLHIV (ZNNP+)