

**SUBMISSION TO THE DEPARTMENT OF TRADE AND  
INDUSTRY ON THE INTELLECTUAL PROPERTY  
CONSULTATIVE FRAMEWORK**

by

Global Health Justice Center  
Solomon Center for Health Law and Policy  
Program On Regulation, Therapeutics, And Law

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## **I. Introduction**

The release of the draft Intellectual Property (IP) Consultative Framework is an important step for developing a national IP policy consistent with South African's human rights obligations. As scholars in the fields of law and medicine, based at Yale Law School and Brigham and Women's Hospital, we welcome the opportunity to provide comments on this vital process.<sup>1</sup>

The draft framework makes several advances. Though it does not address all of the issues that we believe are required for a health-protective patent policy, it candidly acknowledges aspects of South Africa's IP policies that need reform and makes many valuable recommendations regarding potential remedies. It also identifies key implementation considerations. In response to the request for comments, we urge the Department of Trade and Industry to move rapidly to begin implementation of the new framework, once it has incorporated reform proposals from this and other submissions. We also provide specific recommendations regarding the procedural and substantive aspects of patent law that will best protect health while complying with international obligations, drawing on our legal expertise in IP, international IP law, and the interaction between IP laws and the right to health.

Drawing on that expertise, we make three key recommendations.

**First, South Africa should explicitly acknowledge that the right to health supersedes IP protections.** Because human rights are fundamental and binding, whereas intellectual property protections are not, the right to health should be prioritized over intellectual property considerations. This obligation means, among other things, that South Africa should incorporate all available TRIPS flexibilities into domestic law and use these flexibilities to promote access to medicines.

**Second, South Africa should adopt a substantive search and examination (SSE) system.** The current 'depository' system results in poor quality patents that block access to technologies and impede innovation. To reduce the administrative burden posed by an SSE system, South Africa should introduce a patent opposition and/or priority examination system in the short term, and full search and examination over the medium term. Patent oppositions by third parties have been an important tool to lower the cost and increase the quality of patent examination across many countries. South Africa should also consider prioritizing substantive examination in critical sectors.

**Third, South Africa should maximize its use of TRIPS flexibilities.** It would be important for South Africa to adopt all TRIPS flexibilities considered critical by development

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<sup>1</sup> We provide the submission on behalf of the Yale Global Health Justice Partnership (GHJP), the Program On Regulation, Therapeutics, And Law (PORTAL) at Brigham and Women's Hospital, and Yale's Solomon Center for Health Law and Policy. GHJP is a joint program of Yale Law School and Yale School of Public Health that tackles contemporary problems at the interface of global health, human rights, and social justice. PORTAL has conducted extensive research on how laws and regulations influence the development, utilization and affordability of medicines. The Solomon Center for Health Law and Policy focuses on the intersection of law and the governance, practices, and business of health care, bringing together leading experts and practitioners to address cutting-edge questions of health law and policy.

experts;<sup>2</sup> below, we analyze three understudied options. In particular, we recommend that South Africa:

1. **Impose more stringent patentability criteria to ensure fewer and higher-quality patents.** For example, South Africa should prohibit patents on the new uses and forms of known substances, and impose a more stringent inventive step requirement.
2. **Streamline the procedures for government use and compulsory licensing.** A clear and powerful government use provision is vital. In contrast to the cumbersome South African procedure for government use, U.S. law provides that the government can use a patent at any time without prior negotiation, as long as reasonable and entire compensation is provided. Indeed, the U.S. government historically used such provisions to purchase generic versions of patented medicines and assure fair prices. South Africa may have an even greater need for such flexibilities given current health challenges.
3. **Raise the standard for receiving interdicts as interim or final relief.** Interdicts should be awarded only after consideration of the impact on the public good, including on access to medicines. Generic companies should not be barred from the market if it will keep medicines substantially out of reach of individuals, unless companies can prove that R&D costs specific to South Africa support the price.

Over the past several decades, South Africa has made great strides in increasing access to medicines, and led the global dialogue on pressing issues at the intersection of IP and health. It must now enshrine its commitment to health and human rights in its IP policy.

### **I. Intellectual Property Law and Human Rights**

The draft framework affirms that South Africa has a constitutional obligation to “take reasonable measures toward the realization of the right to healthcare services.”<sup>3</sup> Citing *PMA v. the President of the Republic of South Africa*, the draft framework rightly acknowledges South Africa’s “proud history of robustly engaging with issues that concern the intersection between IP and public health.”<sup>4</sup> It notes that the government has not made “full use” of the IP flexibility permitted within international law.<sup>5</sup> The final framework should go further by acknowledging that, as explained below, the right to health and IP protections are in tension with one another, and that when they conflict, the right to health must prevail.<sup>6</sup> As such, South Africa has an obligation both to include robust flexibilities in its framework, and also to use them.

The right to health is a fundamental right deeply rooted in South Africa’s domestic legal tradition and in the pre-democracy discourse of the Freedom Charter,<sup>7</sup> as well as in the international and regional legal systems. In international law, the right to health is established in

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<sup>2</sup> See UNDP, Chan Park, Achal Prabhala, Jonathan Berger, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* (2013) (recommending implementation of a range of flexibilities).

<sup>3</sup> Intellectual Property (IP) Consultative Framework, 4.1(iii).

<sup>4</sup> *Id.*, 4.1(i).

<sup>5</sup> *Id.*, 4.1(iii).

<sup>6</sup> See Global Health Justice Partnership, *Realizing the Right to Health in the Context of Intellectual Property: Submission for the United Nations Secretary General’s High Level Panel on Access to Medicines*, Feb. 27, 2016. [http://media.wix.com/ugd/148599\\_6146649b9100470e93ff1b2cfcff5003.pdf](http://media.wix.com/ugd/148599_6146649b9100470e93ff1b2cfcff5003.pdf) [Hereinafter: GHJP Submission to HLP]. The arguments in this section regarding the importance of the right to health relative to IP protections have been adapted from this submission.

<sup>7</sup> Freedom Charter, 1955 (“A preventative health scheme shall be run by the state; Free medical care and hospitalisation shall be provided for all”).

the International Covenant on Economic, Social and Cultural Rights (ICESCR), the Convention on the Rights of the Child (CRC), and the Convention on the Rights of Persons with Disability (CRPD).<sup>8</sup> South Africa has ratified all of these foundational treaties.<sup>9</sup> Article 12 of the ICESCR recognizes a binding right to the “highest attainable standard of physical and mental health”<sup>10</sup> and the Committee on Economic Social and Cultural Rights, responsible for ensuring compliance with this treaty, has further clarified that access to medicines is a core minimum obligation of this right to health.<sup>11</sup> The right to health is further affirmed in Article 16 of the African [Banjul] Charter on Human and Peoples’ Rights.<sup>12</sup> Additionally, the right to health is a progressively realizable right enshrined within the South African Constitution’s Section 27.<sup>13</sup>

By contrast, intellectual property protections are not afforded the same status as the right to health. The ICESCR protects the “the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author.”<sup>14</sup> However, intellectual property protections are just one way to ensure that this benefit is provided.<sup>15</sup> Furthermore, intellectual property protections are “generally of a temporary nature, and can be revoked, licensed or assigned to someone else.”<sup>16</sup> This is in contrast to human rights, like the right to health, which are considered “fundamental, inalienable and universal.”<sup>17</sup>

Binding right to health protections thus supersede intellectual property protections.<sup>18</sup> As the Special Rapporteur in the field of cultural rights recently stated, “where patents and human

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<sup>8</sup> G.A. Res. 2200A (XXI), International Covenant on Economic, Social and Cultural Rights (Dec. 16, 1966) Art. 12. <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx> [hereinafter ICESCR]; G.A. Res. 44/25, Convention on the Rights of the Child (Nov. 20, 1989), Art. 24; G.A. Res. 61/106, Convention on the Rights of People with Disability (Jan. 24, 2007), Art. 25.

<sup>9</sup> United Nations Office of the High Commissioner, Ratification of 18 International Human Rights Treaties (Sept. 14, 2016), <http://indicators.ohchr.org>.

<sup>10</sup> ICESCR, Art. 12.

<sup>11</sup> Comm. on Econ, Soc., & Cultural Rights. E/C.12/2000/4. General Comment 14: The right to the highest attainable standard of health. (Aug. 11 2000) para 43(d) (“core obligations include at least the following obligations . . . to provide essential drugs”)

<sup>12</sup> African [Banjul] Charter on Human and Peoples’ Rights, Art. 16 (“1. Every individual shall have the right to enjoy the best attainable state of physical and mental health. 2. States Parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.”); *See also* African Commission on Human and Peoples’ Rights, Res. 141 on Access to Health and Needed Medicines (“recognizing that access to needed medicines is a fundamental component of the right to health and that States parties to the African Charter have an obligation to provide where appropriate needed medicines, or facilitate access to them”).

<sup>13</sup> SOUTH AFRICAN CONST. Sec. 27.

<sup>14</sup> ICESCR Art 15(1)(c).

<sup>15</sup> General Comment No. 17: The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author, para 2 (Jan. 12, 2006) [http://tbinternet.ohchr.org/\\_layouts/treatybodyexternal/Download.aspx?symbolno=E%2FC.12%2FGC%2F17&Lang=en](http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=E%2FC.12%2FGC%2F17&Lang=en) [hereinafter General Comment 17] (“the scope of protection of the moral and material interests of the author provided for by article 15, paragraph 1 (c), does not necessarily coincide with what is referred to as intellectual property rights under national legislation or international agreements.”)

<sup>16</sup> General Comment 17, para 2.

<sup>17</sup> *Id.*, para 1.

<sup>18</sup> *See supra* note 6

rights are in conflict, human rights must prevail.”<sup>19</sup> The Human Rights Council,<sup>20</sup> the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (the “Special Rapporteur on Health”),<sup>21</sup> as well as the recent report of the United Nations Secretary General’s High Level Panel on Access to Medicines<sup>22</sup> have all affirmed that the right to health supersedes IP protections.

The framework should similarly acknowledge that the right to health supersedes IP protections. In practice, protection of human rights at the national level means not only including TRIPS flexibilities in the framework but also ensuring they are used. The Special Rapporteur in the field of cultural rights,<sup>23</sup> the Human Rights Commission,<sup>24</sup> the Special Rapporteur on Health,<sup>25</sup>

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<sup>19</sup> U.N. GAOR, 70th Sess., 3rd Comm., Item 69 (b and c). Statement by Ms. Farida Shaheed, Special Rapporteur in the Field of Cultural Rights at the 70th session of the General Assembly. (26 Oct. 2015).

<http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=16918&LangID=E>.

<sup>20</sup> See Human Rights Commission. A/HRC/RES/12/27 (Oct. 22, 2009).

<http://www2.ohchr.org/english/issues/hiv/docs/A-HRC-RES-12-27.pdf>

(“The Agreement [i.e. TRIPS] can and should be interpreted and implemented in a manner supportive of the right to protect public health and, in particular, to promote access to medicines for all including the production of generic antiretroviral drugs and other essential drugs for AIDS-related infections”); See also; Human Rights Commission. A/HRC/RES/12/24 (Oct. 12, 2009). <http://daccess-dds-ny.un.org/doc/RESOLUTION/GEN/G09/167/45/PDF/G0916745.pdf?OpenElement> (“Encourages all States to apply measures and procedures for enforcing intellectual property rights in such a manner as to avoid creating barriers to the legitimate trade of medicines, and to provide for safeguards against the abuse of such measures and procedures”).

<sup>21</sup> See e.g. Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including the Right to Development, UN Doc. A/HRC/11/12. (Mar. 31, 2009). (recommending that in order to protect the right to health, developing countries use IP flexibilities to prevent IP law from being a barrier to access to medicines).

<sup>22</sup> See e.g. Report of the United Nations Secretary General’s High Level Panel on Access to Medicines, Sept. 2016, 9 <http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf> (“World Trade Organization (WTO) Members should commit themselves, at the highest political levels, to respect the letter and the spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies.”)

<sup>23</sup> U.N. GAOR, 70<sup>th</sup> Sess., 3<sup>rd</sup> Comm., Item 69(b and c), Statement by Ms. Farida Shaheed, Special Rapporteur in the Field of Cultural Rights as the 70<sup>th</sup> session of the General Assembly (Oct. 26 2015)

<http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=16918&LangID=E#sthash.fIB7xQpE.dpuf> (“States have a positive obligation to provide for a robust and flexible system of patent exclusions, exceptions and flexibilities based on domestic circumstances, including through the establishment of compulsory and government use licences when needed.”)

<sup>24</sup> Human Rights Council, Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights, A/HRC/RES/12/24 (Oct. 12, 2009), para 6 <https://documents-dds-ny.un.org/doc/RESOLUTION/GEN/G09/167/45/PDF/G0916745.pdf> (“Encourages all States to apply measures and procedures for enforcing intellectual property rights in such a manner as to avoid creating barriers to the legitimate trade of medicines, and to provide for safeguards against the abuse of such measures and procedures”).

<sup>25</sup> Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including the Right to Development, UN Doc. A/HRC/11/12, para. 94, 102 (Mar. 31, 2009) (“The framework of the right to health makes it clear that medicines must be available, accessible, acceptable, and of good quality to reach ailing populations without discrimination throughout the world. As has been evident, TRIPS and FTAs have had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfill the right to health....Developing countries and LDCs need to incorporate in their national patent laws all possible grounds upon which compulsory licenses, including government use, may be issued.”)

and the United Nations Secretary General's High Level Panel on Access to Medicines<sup>26</sup> have all suggested that to fulfill their human rights obligations, states must include TRIPS flexibilities in their national law. South Africa's constitutional guarantee of the right to health as a progressively realizable right similarly requires the adoption and use of TRIPS flexibilities for health purposes. The right to health is subject to progressive realization, meaning that resource constraints are relevant to what is required of the state. Critically, however, the use of TRIPS flexibilities saves, rather than requires the expenditure of state resources. As a result, where they will advance health, their use should be considered immediately required.<sup>27</sup>

In exercising flexibilities, South Africa should approach with skepticism claims that exercising flexibilities will negatively affect innovation. As the World Health Organization has noted, intellectual property protections will do little to incentivize innovation if the market for the innovation is not substantial.<sup>28</sup> South Africa's own experience in altering IP protections for essential HIV/AIDS medications shows how using flexibilities can expand access. For instance, the government's victory in *PMA v. the President of the Republic of South Africa* helped lower the cost of essential HIV/AIDS medication.<sup>29</sup> In light of this experience, the government should require any parties asserting that the use of flexibilities will harm innovation in any particular instance to prove their claim with detailed, concrete evidence.

## **II. The Case for Substantive Search and Examination in South Africa**

The draft framework notes that South Africa's procedural system for registering patents is most akin to a depository system.<sup>30</sup> This is because the Companies and Intellectual Property Commission governed by the Patents Act and associated regulations "only conducts examination in relation to the formalities of the application."<sup>31</sup> The draft framework notes that despite the

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<sup>26</sup> Report of the United Nations Secretary General's High Level Panel on Access to Medicines, Sept. 2016, 9 ("World Trade Organization (WTO) Members must make full use of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities as confirmed by the Doha Declaration to promote access to health technologies when necessary.")

<sup>27</sup> For more on the doctrine of progressive realization within the international legal context, see ICESCR Art. 2(1) ("Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures").

<sup>28</sup> Comm. on Intellectual Property Rights, Innovation and Public Health. Public Health Innovation and Intellectual Property Rights. World Health Organization. (2006) 2.

<http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> ("[Intellectual property protections] can do little to stimulate innovation in the absence of a profitable market for the products of innovation."); Report of the United Nations Secretary General's High Level Panel on Access to Medicines, Sept. 2016, 8 <http://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf> ("new technologies are rarely developed for health conditions which cannot deliver high returns").

<sup>29</sup> See BBC, SA Victory in AIDS Drugs Case, Apr. 19, 2001 <http://news.bbc.co.uk/2/hi/africa/1285097.stm> (noting that the South African government's victory "gives the government powers to import or manufacture cheap versions of brand-name drugs").

<sup>30</sup> 4.1.12(i); See also Yu-Fang Wen and Thapi Matsaneng, Patents, Pharmaceuticals and Competition: Benefiting from an examination system, <http://webcache.googleusercontent.com/search?q=cache:TdDHIS037mIJ:www.compcom.co.za/wp-content/uploads/2014/09/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf>.

<sup>31</sup> IP Consultative Framework, 4.1.2 (i).

benefits of such a policy, “there are major drawbacks for both the producers and users of IP resulting from the depository system that render it crucial to work towards the adoption of SSE.”<sup>32</sup>

This submission elaborates further on these costs so as to add further weight to this important recommendation in the draft policy. Accepting the framework’s invitation to compare South Africa’s experience to that of BRICS countries,<sup>33</sup> this submission notes that South Africa’s ‘depository’ system results in it granting a significantly higher share of patents than almost any other BRICS country. As reflected in Table 1.1, in 2014, the most recent year on record, South Africa granted two-thirds of the patent applications it received.<sup>34</sup> This grant rate is seven times that of Brazil, almost five times that of India, and nearly triple that of China during the same period.<sup>35</sup> South Africa’s grant rate is exceeded only by that of Russia, which granted 84% of the patents it received in 2014.<sup>36</sup>

Table 1.1 BRICS Grant Rates, 2014 (Direct and PCT Patents)<sup>37</sup>

	Total Patent Applications <sup>38</sup>	Total Patent Grants <sup>39</sup>	Grant Rate <sup>40</sup>
Brazil	30,342	2,749	9%
China	928,177	233,228	25%
India	42,854	6,153	14%
Russia	40,308	33,950	84%
South Africa	7,552	5,065	67%

South Africa’s permissive approach to granting patents is particularly pronounced in the pharmaceutical sector. South Africa granted 2,442 pharmaceutical patents in 2008 alone, whereas Brazil granted only 278 such patents from 2003 to 2008.<sup>41</sup> At the same time that South Africa is granting patents at a higher rate than other BRICS countries, it is also granting most of these patents to non-residents. For example, in 2014 South Africa granted 4,620 patents to non-residents while granting 445 patents to residents.<sup>42</sup>

Examination is critical to an IP framework that protects the right to health, because there is documented evidence that pharmaceutical companies frequently use the patent system to extend their drug monopolies. They do this by creating a thicket of patents around medicines, making it nearly impossible for others to invent around the product to create bioequivalent generic

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*, 4.1.2 (i). 4.2(i)

<sup>34</sup> World Intellectual Property Organization. <http://ipstats.wipo.int/ipstatv2/index.htm?tab=patent>

<sup>35</sup> *Id.*

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

<sup>37</sup> *Id.*

<sup>38</sup> This metric defined as total patent applications (direct and PCT national phase entries) per filing office in 2014. World Intellectual Property Organization. <http://ipstats.wipo.int/ipstatv2/index.htm?tab=patent>

<sup>39</sup> This metric defined as total patent grants (direct and PCT national phase entries) per filing office in 2014. World Intellectual Property Organization. <http://ipstats.wipo.int/ipstatv2/index.htm?tab=patent>

<sup>40</sup> Defined as total patent grants divided by total patent applications. *See supra* notes 38, 39.

<sup>41</sup> Carlos M. Correa, Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing, South Centre, Sept. 2011 <http://apps.who.int/medicinedocs/documents/s21395en/s21395en.pdf>. Editorial. Reforming South Africa’s Procedures for Granting Patents to Improve Medicine Access. South African Medical Journal (2015). [http://www.scielo.org.za/scielo.php?script=sci\\_arttext&pid=S0256-95742015000900018](http://www.scielo.org.za/scielo.php?script=sci_arttext&pid=S0256-95742015000900018)

<sup>42</sup> Measured by total patent grants (direct and PCT national phase entries) per resident and non-resident by filing office. World Intellectual Property Organization. <http://ipstats.wipo.int/ipstatv2/index.htm?tab=patent>

alternatives without risking infringement. This delays generic competition and enables the patent holder to exact costs on competitors through litigation. Similarly, “evergreening,” a process where companies seek to extend the duration of their market exclusivity by applying for patents related to a product that only reflect minor changes to the initial patent covering the product, is common throughout the pharmaceutical industry.<sup>43</sup> For example, pharmaceutical companies have successfully sought to maintain IP protection for two key anti-retroviral drugs, ritonavir (Norvir) and lopinavir/ritonavir (Kaletra), by receiving “108 patents, which together could delay generic competition [in the U.S.] until at least 2028 - twelve years after the expiration of the patents on the drugs' base compounds and thirty-nine years after the first patents on ritonavir were filed.”<sup>44</sup>

The costs of patent thickets and evergreening can be substantial. According to the National Institute for Health Care Management in the United States, only 15% of the new pharmaceutical products between 1989 and 2000 were found to have provided a significant medical improvement.<sup>45</sup> A European Commission report found that between 2000 and 2007, 87% of pharmaceutical patent applications were for secondary patents, suggesting that they were a form of evergreening.<sup>46</sup> These strategies have been linked to the decline in inventiveness in the industry.<sup>47</sup> If industry is permitted patents for trivial innovations, it is cheaper to invest in minor modifications and evergreening than in developing transformative new medicines. Overly permissive patent standards can therefore undermine, rather than support, optimally useful innovation.

Granting so many low-quality patents comes with significant costs to access as well. They add years to exclusivity, raising medicine costs.<sup>48</sup> For example, one U.S. government insurance programs could have saved \$1 billion between 2000-2004 by preventing market exclusivity

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<sup>43</sup> See e.g. United Nations Development Program, Guidelines for the examination of patent applications relating to pharmaceuticals (“There is a proliferation of patent applications in the field of pharmaceuticals claiming polymorphs, salts, formulations and so on, which are often made to prevent generic competition rather than to protect genuine inventions. So-called evergreening patents do not contribute to the technological pool and they limit the market entry of generic products.”); Amy Kapczynski, Chen Park, Bhaven Sampat, “Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of Secondary Pharmaceutical Patents,” Dec. 5, 2012, PLOS One (providing an empirical analysis demonstrating that secondary patents are particularly prevalent for best-selling pharmaceutical drugs, providing evidence of evergreening as an industry strategy).

<sup>44</sup>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, *Health Affairs*, v. 31, n. 10, 2286–2294, 2012.

<sup>45</sup> See Carlos Correa, Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective, International Centre for Trade and Sustainable Development (Jan. 2007), viii [http://www.ictsd.org/sites/default/files/research/2008/06/correa\\_patentability20guidelines.pdf](http://www.ictsd.org/sites/default/files/research/2008/06/correa_patentability20guidelines.pdf)

<sup>46</sup> European Commission (EC). *Pharmaceutical Sector Inquiry Preliminary Report*. DG Competition Staff Working Paper, 2008, <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.htm>; see further UNDP Good Practices Report, 20, <http://apps.who.int/medicinedocs/documents/s17762en/s17762en.pdf>.

<sup>47</sup> United National Development Programme, Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement, (2010), 19 <http://apps.who.int/medicinedocs/documents/s17762en/s17762en.pdf> (“As fewer new molecules are being discovered, originator pharmaceutical companies are increasingly trying to extend the patent terms of existing medicines by seeking patent protection on various new use and secondary features of medicines.”)

<sup>48</sup> See Amy Kapczynski, Chen Park, Bhaven Sampat, “Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of Secondary Pharmaceutical Patents,” Dec. 5, 2012, PLOS One (“If the future looks like the past (and the patent landscape in other countries like that in the U.S.) a conservative estimate is that eliminating secondary patents could free up 36% of new medicines for generic production, since only 64% of drugs in our sample had patents with chemical compound claims.”)

extensions on just three drugs.<sup>49</sup> A system that accepts these low-quality patents at face value furthers a neocolonial system that permits the North to extract resources from the South, undermining health and human rights along the way. As we discuss below, South Africa can address this by adopting a Substantive Search and Examination system, as well as comprehensively implementing and using TRIPS flexibilities to protect health.

### **III. Alternative Models and Elements of Substantive Search and Examination**

Given the negative impact of the existing system on innovation, economic growth, and health, the need for a substantive search and examination system is clear. Though every examination system involves some administrative burden, the draft framework recommends studying other models, particularly from BRICS countries, to determine how one could be implemented in South Africa.<sup>50</sup> This submission draws on lessons from the Indian examination system<sup>51</sup> as well as those of other countries to propose possible ways that South Africa could implement an effective but administratively feasible substantive search and examination system. Two options may be introduced to minimize the administrative burdens posed by such a system.

#### **A. Patent Opposition System**

Patent oppositions by third parties, both pre- and post-grant, are a key tool to lower the cost and increase the quality of patent examination.<sup>52</sup> As described above, questionable patents are a growing problem globally, and poor quality patents are understood to be blocking access to technologies and impeding innovation in countries around the world. A study by the U.S. Federal Trade Commission, for example, found that patents were deemed invalid in 30% of the fully litigated infringement cases between a generic manufacturer and an originator company.<sup>53</sup> Although patents can be invalidated through litigation, proceedings “entail the prohibitive costs and risks of litigation” and are extremely lengthy.<sup>54</sup> In response, the U.S. and E.U. have developed low cost post-grant administrative proceedings.<sup>55</sup> No such option exists in South Africa, despite the fact that, on average, it may take up to three years to litigate the validity of a single patent in local courts.<sup>56</sup> Indeed, one study found that only 7 infringement and revocation cases were litigated between 2003 and 2008.<sup>57</sup>

As the IP framework acknowledges, permitting third parties to challenge patents through simplified administrative proceedings would “augment the capacity of CPIC to conduct SSE.”<sup>58</sup>

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<sup>49</sup> See Aaron S. Kesselheim, Michael A. Fischer, Jerry Avorn, “Extensions of intellectual property rights and delayed adoption of generic drugs: effects on Medicaid spending,” *Health Affairs*, 25, 1637-1647, 2006.

<sup>50</sup> IP Consultative Framework 4.1.2(iii), 4.2(i).

<sup>51</sup> For a detailed discussion of the Indian examination system and its use of TRIPS flexibilities, see Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector*, 97 Calif. L. R. 1571 (2009).

<sup>52</sup> Tahir Amin, Rahul Rajkumar, Priti Radhakrishnan & Aaron S. Kesselheim, *Expert Review Of Drug Patent Applications: Improving Health In The Developing World*, *Health Affairs* w948 (2009).

<sup>53</sup> US FEDERAL TRADE COMMISSION, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (2002).

<sup>54</sup> IP Consultative Framework, 4.1.3(ii).

<sup>55</sup> 35 U.S.C § 311 (2015) (Inter partes review); 35 U.S.C § 321 (2015) (Post-grant review); The European Patent Convention art. 99, 1973.

<sup>56</sup> UNDP, Chan Park, Achal Prabhala, Jonathan Berger, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* 54 (2013).

<sup>57</sup> Yousuf Vawda, *Patent Law in Emerging Economies: South Africa*, in *Emerging Markets and the World Patent Order* (Fredrick Abbott, Carlos Correa & Peter Drahos eds., 2013).

<sup>58</sup> IP Consultative Framework, 4.1.3(i).

Third parties can provide important information, analysis, and context. Together with helping focus attention on the most important patents from a public perspective, third parties allow examiners to better evaluate (and re-evaluate) patent applications. Third parties have increasingly filed oppositions against patents on medicines across low- and middle-income countries, including Brazil, China, India and Thailand.<sup>59</sup>

The Indian opposition system has been particularly successful. India's examination system affords three opportunities to challenge a patent grant: either pre-grant or post grant before the Intellectual Property Appeal Board or through a counterclaim in an infringement suit.<sup>60</sup> The ability to challenge a patent pre-grant is particularly significant because it occurs before the patent office has solidified its view, and before the patent has emerged and prevented competition.<sup>61</sup> Because in India "any person" can file a pre-grant opposition on rather broad substantive grounds, many organizations have been able to use this provision to challenge patents.<sup>62</sup> Between 2005 and 2010, Indian pharmaceutical companies alone filed around 150 pre-grant oppositions.<sup>63</sup> Civil society groups have also played an important role in filing patent oppositions. As a result, insufficiently supported patent applications for key HIV/AIDS drugs—including lopinavir/ritonavir and tenofovir—have appropriately been rejected.<sup>64</sup> Because it will not always be obvious which patents are important, or problematic, prior to their grant, it is also critical that the law permits low-cost administrative post-grant and invalidation proceedings as well.<sup>65</sup>

The design of the patent opposition regime would be critical to its success. If introduced, five features should be implemented to strengthen the effectiveness of the patent examination and opposition regime:

- First, following the Indian system, South Africa should introduce both a pre- and post-grant patent opposition mechanism. In India, pre-grant oppositions can be filed any time after the patent application is published and before the patent is granted; post-grant oppositions can be filed until one year after the patent grant was published. Both the European Union and United States also have a post-grant opposition system;
- Second, the government should adopt broad standing requirements, allowing any person to file oppositions, even if acting only in the public interest (e.g., civil society groups);<sup>66</sup>
- Third, the government should ensure that pre-grant proceedings are not prejudicial to post-grant challenges. Moreover, to implement effective post-grant and invalidity

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<sup>59</sup> UNDP, Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement 23 (2010).

<sup>60</sup> Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 Calif. L. R. 1571, 1598 (2009).

<sup>61</sup> *Id.* ("The posture of pre-grant oppositions tends to favor opponents, because the patent's grant may be avoided entirely or at least delayed for a period in which competitors may work the invention without threat of penalty.")

<sup>62</sup> *Id.*

<sup>63</sup> UNDP, Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement 23 (2010).

<sup>64</sup> *Id.*

<sup>65</sup> World Intellectual Property Organization, *Opposition Systems and Other Administrative Revocation and Invalidation Mechanisms*, SCP/18/4 (Apr. 3, 2012). [http://www.wipo.int/edocs/mdocs/scp/en/scp\\_18/scp\\_18\\_4.pdf](http://www.wipo.int/edocs/mdocs/scp/en/scp_18/scp_18_4.pdf) (collecting examples of countries that have opposition proceedings).

<sup>66</sup> See South African Const. Sec. 38 (permitting broad standing rules for any claims with respect to the Bill of Rights).

proceedings, it is also critical that granted patents do not enjoy a presumption of validity;

- Fourth, the government should impose stringent disclosure requirements.<sup>67</sup> One potential model is Section 8 of the Indian Patents Act.<sup>68</sup> The disclosure requirements of this Act mandate patent applicants to keep the Controller General apprised of any negative ruling or actions in foreign jurisdictions.<sup>69</sup> “The value of this information to the Indian Patent Office is substantial: it puts examiners on notice of potential problems with applications, which is particularly valuable in light of the office’s limited examining resources.”<sup>70</sup> Given the need to prioritize limited resources, a patent applicant should be required to provide information about the status of the applications in other countries and continually provide updates; disclose all relevant prior art; and specify whether the application relates to a disease or public health priority.<sup>71</sup> By imposing these duties on a patent applicant, examiners would have more time to devote to substantive evaluation. The government should also require patent holders to disclose, when a request is filed by third parties at the patent office, any patents that they hold that they believe cover particular medical technologies. In addition, the government should require disclosure of the international non-proprietary name at the point at which it is known.<sup>72</sup> These disclosures would ensure transparency and facilitate public engagement with patent quality and policy. To ensure compliance, the government should impose strict penalties for failure to meet the disclosure requirements, namely recognizing as it as potential ground for opposition and/or revocation of the patent; and
- Fifth, the government should publish information about patent applications in readily accessible digital databases. Transparency is fundamental to the patent opposition regime: it undergirds the participation of third parties, which, in turn, supports the effectiveness of the patent opposition system. Reducing transaction costs would give incentives to more parties to intervene, resulting in more information for examiners and higher quality examinations. This would require several changes to South African law, including amending the dated Patents Act to allow publication of information about an application before the grant of a patent.<sup>73</sup>

## B. Priority Examination System

South Africa could also limit administrative burdens associated with an SSE system by prioritizing substantive examination in certain sectors. By limiting the scope of fields examined, the government could reduce the initial cost of introducing an SSE system by reducing the number of patent examiners required. Such an approach would also allow the gradual development of capacity, as examiners, applicants, and third parties developed a tacit understanding of the requisite

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<sup>67</sup> Because of their vital importance to unopposed patent applications, these requirements should be introduced independently even if no patent opposition system is developed.

<sup>68</sup> Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector*, 97 Calif. L. R. 1571, 1601 (2009).

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at 1601-2.

<sup>71</sup> UNDP, Chan Park, Achal Prabhala, Jonathan Berger, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* 53 (2013).

<sup>72</sup> *Id.*, 51.

<sup>73</sup> *Id.*, 54.

procedures. The government could further supplement the priority system by requiring disclosure of the status of foreign patent applications,<sup>74</sup> and by exploring work-sharing arrangements with other patent offices known to impose robust patentability criteria (e.g., India). Ultimately, a priority system would allow the government to experiment with institutional arrangements, learn from best practices, and, if it later desired, to scale up innovations over time, minimizing the possibility of “teething problems.”<sup>75</sup>

Given South Africa’s capacity constraints and right to health obligations, adopting a prioritization approach is unlikely to be deemed a violation of the TRIPS agreement. Article 27.1 provides, in part, that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”<sup>76</sup> But the WTO’s Canada-Generics decision held that the article 27.1 nondiscrimination provision does “not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas.” The concept of a “bona fide exception” has not been defined, but should be informed by the regulatory flexibilities explicitly enshrined in TRIPS, including Article 8 and the Doha Declaration. As a leading treatise notes, the fact that “public health and, in particular pharmaceuticals . . . has been singled out as an issue requiring special attention in the implementation of TRIPS, suggests that public health-related patents may deserve to be treated differently from other patents.”<sup>77</sup> South Africa thus can persuasively argue, if it prioritizes the examination of pharmaceutical patents, that this differential treatment is justified under TRIPS.<sup>78</sup>

In practice, countries also routinely differentiate among patents for purposes of examination. The U.S. offers a salient example: U.S. law permits prioritization of patents as well as extended patent terms for certain products, and specialized review proceedings for certain fields of technology. For example, the U.S. government may prioritize patent applications that it deems important,<sup>79</sup> and may expedite applications for technologies that address humanitarian challenges, including medical technologies.<sup>80</sup> The U.S. also offers patent term extensions for pharmaceutical

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<sup>74</sup> See Section 8, Indian Patents Act (1970).

<sup>75</sup> IP Consultative Framework, 4.1.2(iv).

<sup>76</sup> TRIPS Art. 27.1.

<sup>77</sup> UNCTAD-ICTSD, Resource Book on TRIPS and Development 374 (2005); *see also*, Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (2012).

<sup>78</sup> South Africa could also prioritize “health inventions”, rather than pharmaceutical patents. Because patents implicating health would reach across different fields of technology as that term is usually understood in patent law, such a provision would not implicate the Article 27.1 at all. See UNDP, Chan Park, Achal Prabhala, Jonathan Berger, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* 40 (2013). But we do not believe this approach to be necessary, given the other arguments available to defend a focus on pharmaceutical patents.

<sup>79</sup> 37 C.F.R. § 1.102 provides that applications will be prioritized on the following basis:

“(b) Applications wherein the inventions are deemed of peculiar importance to some branch of the public service and the head of some department of the Government requests immediate action for that reason, may be advanced for examination.

(c) A petition to make an application special may be filed without a fee if the basis for the petition is:

(1) The applicant’s age or health; or

(2) That the invention will materially:

(i) Enhance the quality of the environment;

(ii) Contribute to the development or conservation of energy resources; or

(iii) Contribute to countering terrorism.

<sup>80</sup> 79 Fed. Reg. 18670.

products—and only pharmaceutical products—to compensate for delays in regulatory approval.<sup>81</sup> In the U.S., business method patents are also eligible for a specialized form of review proceeding that contains unique procedural requirements.<sup>82</sup> No one has argued, to our knowledge, that these provisions—though they select certain fields of technology for special examination proceedings—violate TRIPS, and no dispute so alleging has ever been initiated.

We note, finally, that the state could adopt one of these examples by prioritizing examination of patents at the suggestion of certain ministers. Insofar as several ministries were involved, this would help redress any concerns about discrimination by field of technology.<sup>83</sup>

Both the doctrinal interpretations of the TRIPS agreement, and subsequent State practice, thus suggest that prioritizing examination of patents due to public health concerns and capacity constraints would be consistent with the agreement. Ultimately, it is also important to note that the World Trade Organization dispute resolution system does not permit retroactive sanctions, thus enabling, if not giving incentives to states to fully utilize flexibilities they believe are consistent with the agreement.

#### **IV. TRIPS Flexibilities**

Despite a constitutional imperative to increase access to medicines, South Africa has to date to “not made full use of the flexibility within international law through the pursuit of appropriate policy and legislation.”<sup>84</sup> Acknowledging this limitation, the IP framework importantly highlights several gaps in South African legislation. Still, as much of the discussion proceeds at a high-level, no detail is given for many critical flexibilities. While South Africa should adopt all TRIPS flexibilities understood as important by development experts,<sup>85</sup> three options are analyzed below in greater depth.

##### **A. Patentability Criteria**

Article 27 of the TRIPS Agreement requires States to make available patents for inventions provided that they are new, involve an inventive step, and are capable of an industrial application.<sup>86</sup> However, TRIPS does not define the meaning of these criteria and, instead, leaves it to the discretion of States. Indeed, Article 1 notes that States are free to “to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.” Consequently, many states have interpreted the requirements of novelty, inventive step, and industrial applicability differently based on their public priorities. Relying on other exceptions within the TRIPS Agreement, some states have also limited the scope of patentability.

Applying stringent patentability criteria will result in fewer patents and raise the quality of patents. More stringent criteria will also give incentives for research and development, precluding inefficient rewards for evergreening and nominal innovation. Each of the four patentability criteria options are discussed below.

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<sup>81</sup> 35 U.S.C § 156.

<sup>82</sup> 77 Fed. Reg. 48680.

<sup>83</sup> See 37 C.F.R. § 1.102 (“Applications wherein the inventions are deemed of peculiar importance to some branch of the public service and the head of some department of the Government requests immediate action for that reason, may be advanced for examination.”)

<sup>84</sup> IP Consultative Framework, 4.1(iii).

<sup>85</sup> UNDP, Chan Park, Achal Prabhala, Jonathan Berger, Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law (2013).

<sup>86</sup> TRIPS Art 27.1.

### i. Novelty

Like most countries, South Africa statutorily defines novelty using an absolute standard, in which disclosure of an invention in any form *anywhere in the world* before the filing date will preclude the grant of patent. Yet, in practice, South African courts have construed the novelty requirement extremely narrowly: small differences between the prior art and the patent claims are considered novel. As the Supreme Court of Appeal notes, “if the description in the prior document differs, *even in a small respect*, provided it is a real difference. . . the anticipation fails.”<sup>87</sup> Such an expansive interpretation of the novelty standard has meant that experienced patent applicants can satisfy the standard through clever drafting, resulting in superfluous patents.<sup>88</sup>

In addition, rather than applying a more stringent criterion to inventions with vast public health consequences, the current South African system expressly grants an exception to the novelty requirement for pharmaceuticals. Section 25(9) of the Patents Act allows for the patenting of new uses of known substances—that is, even if a substance was already known, the novelty requirement can be satisfied if the therapeutic use had not been known.

Similarly, South Africa permits “selection patents,”<sup>89</sup> in which companies can obtain new patents for inventions “selected” from a set of compounds that were already patented. By allowing grants of multiple patents on the same technology, South Africa effectively extends the monopoly of a patent beyond 20 years. However, in similar cases, Argentina has recently rejected selection patents.<sup>90</sup>

To fulfill its constitutional obligations, South Africa should apply a more robust conception of novelty that objectively reflects whether the claimed invention is genuinely new, not simply if it was presented as new. It should also stop granting patents for new uses of known substances,<sup>91</sup> and selection patents.

### ii. Inventive Step

The Patents Act provides that an invention shall be deemed to involve an inventive step if “it is not obvious to a person skilled in the art, having regard to any matter which forms . . . part of the state of the art.”<sup>92</sup> To assist in this determination, South African courts have adopted a four-part test from the U.K.<sup>93</sup> Much of the analysis necessarily depends on the extent to which the

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<sup>87</sup> *Schlumberger Logelco Inc. v. Cofl exip SA*, 2003 (1) SA 16 (SCA), quoting *Netlon Ltd and Another v. Pacnet (Pty)*

Ltd. 1977 (3) SA 840 (A) (emphasis added)

<sup>88</sup> See e.g., UNDP, Chan Park, Achal Prabhala, Jonathan Berger, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* 28 (2013).

<sup>89</sup> See *B-M Group Ltd. v. Beecham Group Ltd.*, 1980 BP 343 (holding selection patents are valid insofar as “the selected members” have some substantial, special, peculiar advantage over the other, unselected members).

<sup>90</sup> UNDP, Chan Park, Achal Prabhala, Jonathan Berger, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* 30 (2013); 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 (2012), available at <http://www.wipo.int/wipolex/en/details.jsp?id=13007>.

<sup>91</sup> New uses of known substances could also be seen as a method of medical treatment, which may be excluded from patentability under TRIPS Art. 27.3(a).

<sup>92</sup> UNDP, Chan Park, Achal Prabhala, Jonathan Berger, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* 31 (2013).

<sup>93</sup> *Ensign-Bickford, Ltd. v. AECI Explosives & Chemicals Ltd*, 1999 (1) SA 70 (SCA) (“(1) What is the inventive step said to be involved in the patent in suit?; (2) What was, at the priority date, the state of the art (as statutorily defined) relevant to that step?; (3) In what respect does the step go beyond, or differ from, the state of the art?; (4) Having regard to such development or difference, would the taking of the step be obvious to the skilled man?”).

hypothetical person is “skilled in the art.” South African courts, following U.K. precedent, have set an exceedingly low standard, defining the person as someone who is familiar with the background literature but is “incapable of a scintilla of invention.”<sup>94</sup> In effect, this has all but negated the inventive step requirement, resulting in unwarranted patents except in the few cases where the prior literature contains an explicit suggestion to make the invention.<sup>95</sup> To comply with its constitutional obligations, South Africa should use the flexibility in defining the inventive step requirement to set a high bar for inventiveness. As Professor Carlos Correa notes, “[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 innovations and prevent unwarranted limitations to competition and access to existing drugs.”<sup>96</sup> In the U.S., for example, the Supreme Court has recently developed a more stringent standard, holding that “a person of ordinary skill is also a person of ordinary creativity, not an automaton.”<sup>97</sup> Indian law requires that the invention not be obvious to a person skilled in the art, *and* that it involves a technical advance or has economic significance.<sup>98</sup>

### iii. Industrial Applicability

In most countries, the standard of industrial applicability is generally satisfied so long as the claimed invention has some commercial use. Following the example of Canada, and the E.U., South Africa should reject applications that have “unverified and speculative utility”<sup>99</sup> Granting speculative patents “may confer power to block off whole areas of scientific development, without compensating benefit to the public.”<sup>100</sup>

### iv. Scope of Patentability

Limits on the scope of patentability are also key to the effective design of a health-protective patent system. Patents should be expressly restricted to certain subject matter, so that they may not be granted on, for example, products of nature, abstract ideas, or laws of nature. The U.S. Supreme Court, for example, has rejected patents on diagnostic methods and genes, following the exceptions enumerated in TRIPS.<sup>101</sup> Countries also exercise flexibility in how they define an “invention” under TRIPS, and frequently exclude from patentability broad categories not explicitly mentioned in TRIPS. South Africa, the E.U. and the U.K., do not provide patents for business methods.<sup>102</sup> Similarly, India has targeted the practice of evergreening in pharmaceuticals: the Indian Patents Act provides that a “new form of a known substance which does not result in

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<sup>94</sup> *Technograph Printed Circuits Limited v. Mills and Rockley (Electronics) Limited* (1972) RPC 346.

<sup>95</sup> See also Yousuf Vawda, Patent Law in Emerging Economies: South Africa, in *Emerging Markets and the World Patent Order* (Fredrick Abbott, Carlos Correa & Peter Drahos eds., 2013) (describing how SA court all but ignored inventive step criterion in *Pfizer & Ano v Cipla Medpro & Ors* 2005 BIP 1).

<sup>96</sup> ICTSD, WHO, UNCTAD, UNDP, Carlos Correa, *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective* 4 (2007).

<sup>97</sup> *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007).

<sup>98</sup> Indian Patents Act (1970).

<sup>99</sup> UNDP, Chan Park, Achal Prabhala, Jonathan Berger, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* 35 (2013).

<sup>100</sup> *Brenner v. Manson*, 383 U.S. 519 (1966).

<sup>101</sup> *Mayo Collab. v. Prometheus Labs* 132 S.Ct. 1289 (2012); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); see also TRIPS Art. 27.1.

<sup>102</sup> Patents Act, Section 25(2) (South Africa); European Patent Convention, Art. 52(c), Patents Act, Section 2(c) (UK).

increased efficacy of that substance” does not constitute an invention.<sup>103</sup> The Indian Supreme Court has further held that “in the case of a medicine that claims to cure a disease, the test of efficacy can only be ‘therapeutic efficacy.’”<sup>104</sup> Argentina sets a more stringent threshold by prohibiting patents on all new forms of known substances, irrespective of efficacy.<sup>105</sup> India also excludes patents on naturally occurring substances, and “mere admixtures.”<sup>106</sup>

To prevent frivolous patents, South Africa should similarly limit the scope of patentability. Adopting broad exclusions *ex ante* could also considerably simplify the patent examination process. Most importantly, it could reduce the practice of evergreening, in which patent holders artificially extend the term of their market exclusivity. Amongst its other costs, evergreening burdens the search and examination processes.

## **B. Government Use and Compulsory Licensing**

The TRIPS agreement provides considerable flexibility in how States develop their “government use” and compulsory licensing procedures.<sup>107</sup> The U.S., for example, has a government use provision that reserves expansive powers to the government. U.S. law provides that the government can use a patent at any time without prior negotiation, as long as reasonable compensation is provided.<sup>108</sup> The patentee cannot request an injunction (or interdict) to stop the government from using its patent. Historically, the U.S. government used the provision to purchase generic versions of patented medicines.<sup>109</sup> In the 1950s, the Defense Department, for example, purchased an antibiotic from an Italian producer instead of the patent-holding company, Pfizer, because the Italian drugs were significantly cheaper.<sup>110</sup> The Comptroller General upheld the procurement, even though Pfizer was later willing to lower the price for the government. Several years later, the Comptroller General criticized attempts to amend the law by noting that an amendment would “forgo one of the valuable powers which the Government has to assure fair

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<sup>103</sup> Section 3(d) further states that “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.”

<sup>104</sup> *Novartis AG v. Union of India*, AIR 2013 SC, App. No. 2706-2716 of 2013.

<sup>105</sup> UNDP, Chan Park, Achal Prabhala, Jonathan Berger, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* 43 (2013); 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 (2012), available at <http://www.wipo.int/wipolex/en/details.jsp?id=13007>.

<sup>106</sup> Section 3(d), Indian Patents Act (1970).

<sup>107</sup> TRIPS Art. 31(b).

<sup>108</sup> 28 U.S.C. § 1498(a) (2012) (“Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . . 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> See 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.* 260 (2016) (“Federal agencies continued to procure generic drugs at steep discounts throughout the 1960s. According to one source, the Department of Defense’s Military Medical Supply Agency relied on § 1498 to procure approximately fifty drugs in one three-year period, producing savings of \$21 million.”).

<sup>110</sup> *Charles Pfizer & Co., Inc.*, B-141459, 119 U.S.P.Q. 187 (Comp. Gen.), at \*1 (1960).

prices.”<sup>111</sup> The attempts were unsuccessful, and the provision remains identical to that enacted in 1942. A range of U.S. government agencies continue to use the provision—from the National Institute of Health, to the General Services Administration.

In contrast to the U.S. provision, the South African government provision is neither expansive, nor specific. Instead, it needlessly imposes strenuous requirements of dubious value. Section 4 of the Patents Act provides,

A patent shall in all respects have the like effect against the State as it has against a person: Provided that a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee.

Three limitations are worth nothing. First, nowhere in the TRIPS agreement does it require that a patent have a “like effect” against the State as it has against a person. Such a conception artificially limits the regulatory and discretionary powers of the State, including the ability to provide no interdicts in cases involving government use (or injunctions, as will be described in greater detail below). Second, as the IP framework notes, the provision “goes beyond what is provided for in TRIPS by requiring Ministers of State to enter into . . . negotiations before an application to the Commissioner of Patents can be made.” Third, in situations where a voluntary agreement cannot be reached—likely the most frequent scenario—the commissioner determines the conditions for government use. Because use of the power thus effectively requires judicial authorization, the process necessarily entails risky, lengthy and expensive litigation. These costs would further deter use of the provision.

The South African compulsory license procedures are similarly flawed. As a UNDP report notes, unlike TRIPS requirements, “*any* application for a compulsory license must be heard by the Commissioner in what amounts to a full judicial proceeding.”<sup>112</sup> In short, the current procedure for obtaining a compulsory license is “risky, cumbersome and expensive.”<sup>113</sup>

To fulfill its right to health obligations, South Africa must eliminate bureaucratic hurdles associated with the government use and compulsory license procedures. The need to develop a more robust framework—particularly for government use—is only made more urgent in a country where most of the population depends on public healthcare services.

### **C. Relief for Infringement**

South African patent law provides for interdicts to be granted both as an interim measure and as final relief. Given the important public health consequences of both interim and final interdicts in pharmaceutical cases, the final framework should adopt stringent standards for granting these interdicts.

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<sup>111</sup> *Patent Infringement: Hearing on S. 1047 Before the Subcomm. on Patents, Trademarks, & Copyrights of the S. Comm. on the Judiciary*, 89th Cong. 70 (1965). See also 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.* 260 (2016) (describing historical use of the provision).

<sup>112</sup> United Nations Development Programme, Chan Park, Achal Prabhala, Jonathan Berger, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* (2013) 61 [http://www.undp.org/content/dam/undp/library/hiv aids/English/using\\_law\\_to\\_accelerate\\_treatment\\_access\\_in\\_south\\_africa\\_undp\\_2013.pdf](http://www.undp.org/content/dam/undp/library/hiv aids/English/using_law_to_accelerate_treatment_access_in_south_africa_undp_2013.pdf)

<sup>113</sup> *Id.*

The standard for issuing an interim interdict is (a) a prima facie right; (b) a well-grounded apprehension of irreparable harm if the interim relief is not granted and the ultimate relief is eventually granted; (c) that the balance of convenience favors the granting of an interim interdict; and (d) that the applicant has no other satisfactory remedy.<sup>114</sup> It is possible to appeal when the request for an interim interdict is denied but not when it is granted.<sup>115</sup>

The final IP framework should require courts to consider a strict standard for granting interim interdicts in matters of public health. Former Deputy President of the Supreme Court of South Africa Judge Louis Harms has stated that “a court always has a wide discretion to refuse an interim interdict even if the requisites have been established.”<sup>116</sup> The U.S. Supreme Court has recently adopted a similar view, noting that courts should use their discretion when granting interim interdicts in intellectual property cases, and not issue interdicts unless it is in the public interest.<sup>117</sup> Allowing interdicted parties to challenge the grant of an interim interdict would be an additional safeguard to ensure that interdicts do not have harmful public health consequences.

Under the Patents Act, a plaintiff in proceedings for infringement is entitled to final relief through (1) interdict, (2) delivery of the infringing product, or (3) damages. The final IP framework should indicate that interdicts should only be awarded after consideration of the impact on the public good, including access to medicines. Generic companies should not be barred from the market if it will keep medicines substantially out of reach of individuals, unless companies can prove that R&D costs specific to South Africa support the price.

This approach is rooted in established practice. Judge Harms notes that in “pharmaceutical patent cases, where public health concerns or the constitutional rights to health care arises, a court may have to consider whether or not to leave the rights holder to a damages claim instead of a final interdict.”<sup>118</sup> He proceeds to note that English common law as well as TRIPs Art. 45 both afford flexibilities to award damage as opposed to an interdict.<sup>119</sup> In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, a case balancing a patent against public health concerns, the U.S. Court of Appeals for the Federal Circuit similarly noted that courts have discretion as to whether to award an interdict as final relief.<sup>120</sup> The Indian High Court held in *F. Hoffmann-LA Roche AG v. Cipla Ltd.* that the court must consider public health implications of granting an interdict, and in that case denied an injunction where the impact would be substantially higher prices, which the court concluded would undermine the constitutional right to life and health.<sup>121</sup> The United Nations

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<sup>114</sup> Judge Harms, WIPO/ACE/2/4/Rev., 20,

[http://www.wipo.int/edocs/mdocs/enforcement/en/wipo\\_ace\\_2/wipo\\_ace\\_2\\_4\\_rev.pdf](http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_2/wipo_ace_2_4_rev.pdf); see also *Cipla Medpro (Pty) Ltd v Aventis Pharma SA, Aventis Pharma SA and Others v Cipla Life Sciences (Pty) Ltd and Others* (139/2012, 138/2012) [2012] ZASCA 108; 2013 (4) SA 579 (SCA) para 52 (26 July 2012) (holding that a court must take into account “‘public interest’ factors,” including public health, when analyzing the “balance of conveniences”)

<sup>115</sup> Judge Harms, WIPO/ACE/2/4/Rev., 20,

[http://www.wipo.int/edocs/mdocs/enforcement/en/wipo\\_ace\\_2/wipo\\_ace\\_2\\_4\\_rev.pdf](http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_2/wipo_ace_2_4_rev.pdf)

<sup>116</sup> *Id.*

<sup>117</sup> See *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

<sup>118</sup> Judge Harms, WIPO/ACE/2/4/Rev., 20,

[http://www.wipo.int/edocs/mdocs/enforcement/en/wipo\\_ace\\_2/wipo\\_ace\\_2\\_4\\_rev.pdf](http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_2/wipo_ace_2_4_rev.pdf)

<sup>119</sup> *Id.* Elsewhere, Judge Harms cautions the South African judiciary that “judges with an anti-monopolistic mindset should beware that it does not contaminate their attitude towards rights holder.” *Id.*

<sup>120</sup> 733 F.2d 858, 866 (Fed. Circ. 1984) (“Counsel are equally mistaken in their apparent belief that once infringement is established and adjudicated, an injunction must follow.”)

<sup>121</sup> *F. Hoffmann-LA Roche AG v. Cipla Ltd.*, India, High Court of Delhi, Mar. 19, 2008 (“[T]his Court is of the opinion that as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a life saving drug, the balance has to be tilted in favour of the latter.”)

Development Program (UNDP) has argued that South Africa's constitutional obligations may place "a positive obligation on the State to *refuse* the grant of final interdicts in cases where public health concerns are intertwined."<sup>122</sup> The UNDP goes on to suggest that "the Patents Act can recognize this obligation expressly by providing that final interdicts shall not be granted where the payment of damages is sufficiently adequate to compensate the patent holder or where it would not be in the public interest to do so."<sup>123</sup> This recommendation would go a long way to ensuring that a final interdict does not stop the flow of essential medicines to patients.

The necessary changes in patent law may be easily integrated into current common law standards for interim and final interdicts. When a court is faced with an application for an interim interdict that could potentially reduce access to medicine there should be a presumption that the balance of conveniences is against the grant of an interdict. Patent law should state that the rights granted by a patent do not extend to a right to a final interdict when such an interdict is likely to reduce access to medicines.

## **V. Conclusion**

Three years have passed since the publication of the Draft National Policy on Intellectual Property.<sup>124</sup> In the intervening years, pharmaceutical companies have been able to apply for, and receive, patent grants that have a critical bearing on the public health. As noted above, the existing policy does little to adequately ensure that these patents are high quality and foster innovation.

The current draft framework represents an important step towards addressing the shortcomings in South Africa's existing IP laws. This framework can be strengthened by (1) acknowledging the primacy of the right to health when it conflicts with IP protections, (2) recommending the implementation of an SSE system through patent opposition and/or priority examination, and (3) adopting critical flexibilities including stricter patentability criteria, government use and compulsory licensing, as well as higher standards for granting interim or final interdicts. Given the grave public health implications, it will be critical for the South African government to publish the final framework and recommend the policy approaches, patent standards and procedures discussed in this submission as a matter of urgency.

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<sup>122</sup> United Nations Development Programme, Chan Park, Achal Prabhala, Jonathan Berger, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* (2013) 78 [http://www.undp.org/content/dam/undp/library/hiv aids/English/using\\_law\\_to\\_accelerate\\_treatment\\_access\\_in\\_south\\_africa\\_undp\\_2013.pdf](http://www.undp.org/content/dam/undp/library/hiv aids/English/using_law_to_accelerate_treatment_access_in_south_africa_undp_2013.pdf)

<sup>123</sup> *Id.*

<sup>124</sup> Notice 918, Draft National Policy on Intellectual Property, 2013 <http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf>