



SCHOOL OF LAW

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Submission by University of KwaZulu-Natal-Affiliated Academics* on The Draft Intellectual Property Policy of the Republic of South Africa Phase 1 2017

The authors of this submission congratulate the Inter-Ministerial Committee on Intellectual Property (IMCIP) on this Draft IP Policy. The sophistication and depth of its analysis is impressive as is the Policy's commitment to achieving a balanced, pro-development, and pro-health IP policy that uses legally-sanctioned policy space to propose a phased IP approach much more aligned with the socio-economic realities of South Africa and its constitutional and international obligations.¹ We agree with the vast majority of the policy proposals, but make several suggestions that we hope might improve the Policy even further. These are contained in Appendix A. We highlight below the main proposals in the draft IP Policy and provide our comments thereon.

Balance

"[T]here is a need for a comprehensive IP Policy that will promote a holistic, balanced and coordinated approach to IP that is mindful of the many obligations mandated under the South African Constitution." (p. 3.) "South Africa requires a coordinated and balanced approach to IP that provides effective protection of IPR and responds to South Africa's unique innovation and development dynamics." (p. 8.) We agree that the TRIPS Agreement allows an approach of balancing the interests of IP owners and users and that human rights, rights to development, and other constitutional obligations and international commitments require the Government of South Africa to recalibrate the existing imbalances between IP exclusive rights as incentives for innovation and ensuring equitable access to the benefits of scientific advancement.

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¹ Its international obligations are explicitly acknowledged in the Policy: "the state's duty to progressively realise the right to health is captured in international instruments which South Africa has ratified such as the International Covenant on Economic, Social and Cultural Rights (ICESCR), the Convention on the Rights of the Child (CRC), Convention on the Elimination of all Forms of Discrimination against Women and Girls (CEDAW), the Convention on the Rights of Persons with Disability (CRPD), and regional treaties such as the African Charter on Human and Peoples' Rights." (p. 13)

Right to Health

“As both a constitutionally guaranteed right, as well as a key development goal, the issue of access to health care services – and the role of IP in delivering public health – has been at the forefront of human rights debates in the country.” (p. 6.) “[P]ublic interest includes the nation's commitment to bring about reforms that promote equitable access to services and products involving IP, such as in the sphere of health.” (p. 9.)

The Policy concedes that “the South African government has to date not made full use of the flexibilities available within international trade rules through the pursuit of appropriate national policy and legislation. This is despite a constitutional imperative to increase access to medicines as a component of the state’s obligation to take reasonable measures toward the realization of the right to healthcare services.” (p. 13.) We strongly agree that the right to health needs greater prominence in South Africa’s IP policy.

IP and Development

“Economic literature, for instance, reveals an inconclusive link between increased IP protection and economic development, which is why a comprehensive IP Policy that examines the issue in the context of the South African reality, and optimises its regulation is necessary.” (p. 8.)²

Quite recently Dean Baker, Argun Jayadev, and Joseph Stiglitz have written a detailed critique of the idea that IP is good for or essential to development.³

² Although we agree with this statement, they disagree with the first part of the preceding sentence: “*Though there is broad agreement that IP is an important policy instrument in promoting innovation, technology transfer, research and development (R&D), creative expression, consumer protection, industrial development and more broadly, economic growth, the precise contours of IP regulation are contested.*” See Brook K. Baker, *Debunking IP-for-Development: Africa Needs IP Space Not IP Shackles* in *AFRICAN LAW AND ECONOMIC DEVELOPMENT: INTERNATIONAL PERSPECTIVES* (L. Boule, E. Laryea & F. Sucker, eds. 2014); Commission on Intellectual Property Rights, *INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY*, p. 23 (2002) (CIPR, *INTEGRATING IP AND DEVELOPMENT*) (finding that the considerable literature linking IP and development that exists is largely speculative, tentative, and questionable given limitations on data and methodology and concluding that there is a lack of evidence finding that FDI is positively related to IP protection in developing countries); Keith E Maskus, *PRIVATE RIGHTS AND PUBLIC PROBLEMS: THE GLOBAL ECONOMY OF INTELLECTUAL PROPERTY IN THE 21ST CENTURY*, p. 63 (Peterson Institute for International Economics 2012) (noting “[s]pecifically, there is scarce evidence that stronger IPRs encourage more access by the poorest and smallest countries to global technologies’ and that ‘there is no clear universal relationship between policy reforms that strengthen IPRs and subsequent innovation or R&D investments’); see also Padmashree G Sampath and Pedro Roffe, *UNPACKING THE INTERNATIONAL TECHNOLOGY TRANSFER DEBATE: FIFTY YEARS AND BEYOND* (ICTSD 2012) (reporting no direct evidence of IPR protection on promotion of technology transfer in developing countries); Albert G.Z. Hu & I.P.L. Png, *PATENT RIGHTS AND ECONOMIC GROWTH: EVIDENCE FROM CROSS-COUNTRY PANELS OF MANUFACTURING INDUSTRIES*, 1 (WIPO 2010) (“[T]here is scant empirical evidence to validate the basic premise that IP rights have fostered or do foster invention and creative work, still less economic growth.’).

³ *INNOVATION, INTELLECTUAL PROPERTY, AND DEVELOPMENT: A BETTER SET OF APPROACHES FOR THE 21ST CENTURY* (July 2017).

Intellectual Property rights are a social contrivance. Like other property rights, they are subject to a certain set of limitations and restrictions. We have argued here that it is increasingly clear that the main reason to support this contrivance, at least in its current form - the idea that it will increase welfare and innovation - is questionable both theoretically and empirically. Intellectual Property rights are becoming increasingly badly configured in the developed world, leading to a stifling of innovation, distortions in the direction of innovation, and a reduction in the benefits which accrue from any innovation that occurs. Many of these failures arise because there is, especially under currently prevalent IPR regimes, no clear relationship between the social returns to innovation and the private returns. The proliferation of me-too drugs, the increase in patent hold-ups and similar excesses buttress the argument that the IPR system in the developed world is poorly configured.

Moreover, whatever the weaknesses and socially malignant outcomes that arise out of poorly designed IPRs in developed countries, the enormity of the problem their adoption causes in developing countries is much higher. The sine qua non of development is widespread and rapid learning and the current IPR system works expressly to limit the capacity of developing countries to adopt such a path. We have provided both general examples and specific case studies to make this case. But it is not enough to simply criticize the system; there is a need for clear alternatives.⁴

We agree with the analysis of Baker et al that the argument that IP is essential to development in a country like South Africa is weak.

Phased Approach

“The comprehensive IP Policy will be implemented in a phased approach. ... Phase I covers IP and public health, coordination in international forums, and the implementation of commitments undertaken in international agreements.” (p. 4.) “The intention is to identify a range of strategic sectors for full SSE, including and beyond the health sphere, based on capacity within government, as well as development and public interest considerations. As government’s capacity expands, the fields which are subjected to full substantive patent examination will be expanded concomitantly and with ongoing consultation.” (p. 16.)

In their concluding comments, Baker et al argue for a comprehensive overhaul of the IP system:

A substantial recalibration of the international approach to Intellectual Property Rights is required to ensure the advancement of the standards of living and well-being of the entire world—and to ensure consistency with development

⁴ *Ibid.* at 70.

objectives and obligations and to support those innovations that have the highest value in terms of their contribution to addressing the challenges facing our global society.⁵

We agree that there is a need for substantial reassessment of both global and national IP regimes, and that in South Africa's instance a phased approach is both desirable and, as we discuss under the section analysing Article 27(1) below, legally permissible under the TRIPS Agreement.

Regional and Global Engagement

“Beyond compliance with international obligations, South Africa must play its part in shaping the global order at various forums where IP is discussed such as in World Intellectual Property Organization WIPO, the World Trade Organisation (WTO), the World Health Organisation (WHO), the Group of Twenty (G20), political formations such as the Brazil, Russia, India, China & South Africa form (sic) (BRICS) and in African regional organisations. ... International cooperation must aim to make IP a tool to achieve sustainable development within the country.” (pp. 8-9.)

We agree that South Africa can play a constructive role in regional and global dialogue on IP, arguing for a more balanced, pro-development approach and for considerations of promising alternatives to an IP-only innovation incentive system.

Maximise Use of TRIPS Flexibilities

“The leveraging of flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to ensure that South Africa protects IP rights while simultaneously promoting public health, local manufacture, research and development, innovation, food security, environmental considerations, transfer of technology and broad socio-economic development.” (p. 5.)

Sub-issues addressed by the Policy include:

- Local manufacture and export in line with industrial policy
- Patent–substantive search and examination
- Patent opposition
- Patentability criteria
- Disclosure requirements
- Parallel importation
- Exceptions
- Voluntary licensing
- Compulsory licences
- IP & competition law

⁵ *Ibid.* at 71.

We agree that South Africa is wholly justified in seeking to maximise adoption, use, and protection of all available TRIPS-compliant flexibilities.

Local Production

A key component of South Africa's development policy as reflected in the IP Policy is to promote local production of pharmaceuticals: "Increasing the local production of pharmaceuticals to meet domestic needs, as well as creating export opportunities within the continent and beyond, is an overarching goal of the IP Policy, and in line with the National Development Plan (NDP), as well as the National Industrial Policy Framework (NIPF), implemented through the Industrial Policy Action Plan (IPAP)." (p. 13.) In addition to this emphasis on industrial development policy, the Policy also recognises the contribution of local production to public health: "Growth of the domestic pharmaceutical industry will contribute to the sustainability of supply and allow the country to fulfil key health objectives as outlined in the National Drug Policy, in particular, to ensure the availability and accessibility of essential drugs." (p. 14.) We agree that promoting local production is a legitimate policy objective under the TRIPS Agreement as long as foreign IP applicants and rights holders are not unfairly discriminated against in the process. In particular, there is precedent in the patent laws of Brazil, India, and South Africa, among others, recognising a lack of local production as grounds for compulsory and government use licenses.

Substantive Search and Examination

The Draft IP Policy recognises the critical importance of adopting a substantive search and examination system, most especially in initial stages with respect to pharmaceutical patents, arguing for: "The introduction of substantive search and examination (SSE) for patents, which is a key step towards ensuring that the patent regime fulfils its purpose of stimulating genuine innovation. This will benefit patent holders by granting them rigorously assessed rights, and benefit the public at large by ensuring that market exclusivity is only granted when appropriate. Importantly, substantive search and examination will not only apply in the health sphere; it will eventually have much broader application." (p. 5.) In the absence of a rigorous substantive examination system, "[u]sers of IP are prejudiced ... because subject matter that should be in the public domain can be unfairly monopolised by exclusive rights." (p. 5)

We agree that the legality of a phased approach cannot be seriously questioned as set forth in the Policy: "Fundamentally, adopting a SSE approach which takes into consideration a nation's capacity constraints and legitimate public interest by prioritising certain sectors would not conflict with [Article 27.1 of] the TRIPS Agreement." (p. 15.) Although Section 34 on its face would allow substantive search and examination, current regulations 40 and 41 of Patent Regulations, 1978, do not so provide and would need to be substantially reformed.

Opposition Procedures

To further ensure the quality of patent decisions, the Draft IP Policy also recommends the eventual adoption of pre- and post-grant opposition procedures: “It is recommended that, eventually, opposition proceedings are enacted in the law both prior to and after the grant of a patent. In the interim, owing to capacity constraints, it is recommended that patent law recognises a third-party submission system or “observation” to stand in for the pre-grant opposition process and for existing provisions in administrative law to be used in lieu of post-grant oppositions.” (p. 16.)

We agree that it is necessary to immediately proceed with a pre-grant third-party observation system and to promulgate regulations that allow existing administrative law provisions to be used to review granted patents. However, we also believe that South Africa should move expeditiously to enact legislation and promulgate implementing regulations for a full pre-grant and post-grant opposition system. Detailed legislative proposals in this regard are contained in Section 1 of Appendix A, *infra*.

Patentability Criteria

The Draft IP Policy acknowledges the appropriateness of addressing patentability criteria in South Africa: “In line with emerging international best practice, patentability criteria will be developed in order to promote genuine innovation through the patent system in South Africa. Such criteria will be implemented in the process of examination of patent applications and will aim to strike the optimal level of IP protection, promote innovation, and balance the rights of IP holders and users alike. It is recommended that patentability criteria form a part of the Patents Act, as well as any subsequent regulations and guidelines for the examination of applications.” (p. 18.) However, the Policy fails to specify sufficiently what those revisions should entail nor does it adequately address allowable patent exclusions. For that reason, we offer proposals on exclusions and patentability criteria that could and should be addressed in legislative and regulatory reform, as appropriate, in Sections 2 and 3 of Appendix A.

Disclosure Requirements

In addition to intending to address patentability criteria, the Draft IP Policy also addresses some, but not all TRIPS-compliant disclosure requirements: “In order to gain a full and fair understanding of a patent application, applicants are required to adequately disclose the nature of the invention therein. In order to assist in the process of examination of such applications, in addition to the existing disclosure requirements in the Patents Act, it is recommended that applicants be asked to provide information regarding the status of similar and related applications filed in other international jurisdictions.” (p. 19.) We certainly agree that disclosure of international applications is appropriate, but we also offer recommended legislative and regulatory reforms addressing additional required disclosures in Section 4 of Appendix A.

Parallel Importation

South Africa has had a totally ineffectual parallel importation regime, based in part on Section 15C of the Medicines and Related Substances Act of 1965, as amended in 1997. Recognising its failure of effective implementation, the Draft IP Policy proposes a reinvigorated parallel importation mechanism: “South Africa’s unique developmental needs, particularly in public health, require the exploration of every legal opportunity to support the viability and expansion of the public health system, including, in the case of patented products such as medicines, the ability to purchase said medicines from any external territory that is necessary. The implementation of parallel importation will be undertaken in a controlled manner pursuant to consultations with respective stakeholders.” Our recommendations concerning aspects of a new parallel importation scheme are set forth in Section 5 of Appendix A.

Exceptions

The Draft IP Policy recognises the need to expand South Africa’s limited exceptions as allowed by Article 30 of the TRIPS Agreement: “An environment of scientific inquiry and growth can be fostered by allowing researchers in all sectors of the economy to explore and experiment with products protected by patents. With particular patented products, such as medicines, it is furthermore essential to facilitate research, development and testing of IP products in the commercial and industrial sectors prior to the expiry of the patent term, in order that said products might reach the market as soon after the expiration date of the patented period as possible, in order to provide maximum benefit to society.” (p. 21.) Although the outlined proposals for expanding limited exceptions in the Draft IP Policy contain several important elements, we recommend an even more vigorous approach, discussed further in Section 6 of Appendix A.

Voluntary Licences

As acknowledged in the Draft IP Policy, South Africa has benefitted hugely from voluntary licences particularly those involving antiretroviral medicines: “Voluntary efforts by IP-holders to create fair and beneficial licences in the country are encouraged to the fullest extent, building on South Africa’s history of having taken advantage of many such national and international opportunities.” Although the Draft IP Policy proposes to facilitate voluntary licenses, particularly those that might benefit South Africa’s domestic enterprises, there is also scope under Article 40 of the TRIPS Agreement for South Africa to closely regulate the terms and conditions of voluntary licenses and to require disclosure of the same to encourage robust and fair competition.⁶ Suggestions

⁶ Article 40(2), in particular, states that “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

concerning possible legislative reforms governing regulation of voluntary licenses are discussed further in Section 7 of Appendix A.

Compulsory and Government Use Licences

In view of the fact that these flexibilities have not once been used in South Africa in respect of pharmaceutical products, the Draft IP Policy recognises the need to improve South Africa's compulsory and government use licensing scheme: "South Africa's unique challenges, including especially vulnerable populations and urgent development concerns, will require the scope of compulsory licences to be strengthened and clarified in a manner that is fair and compliant in relation to both international obligations and national law. **Following due process, guidelines will be introduced, including legal process for government use, and a renewed effort to facilitate the process of exporting IP goods, such as medicines, to the African continent. ... In order to promote the sustainability of supply, it is important to ensure that a workable compulsory licensing system is in place to achieve affordability of essential goods, and restrain anti-competitive practices, as the need arises.**" (p. 23.) (Emphasis added). Suggestions concerning legislative and regulatory reforms with respect to compulsory and government use licenses are addressed in Section 8 of Appendix A.

Utility model patents

The Draft IP Policy makes brief reference to adoption of utility model patents: "The promotion of economic empowerment through, among other means, the implementation of the "utility model" to support the registration of patents by resident small, medium and micro-enterprises (SMMEs), historically disadvantaged individuals, and companies who are operating in the informal sector. This entails enacting exclusivity similar to a patent right, granted by a state, to an inventor or the inventor's assignee, for a fixed period of time. However, the terms and conditions for granting a utility model are slightly different from those for ordinary patent, including a shorter term of protection and less stringent patentability requirements. The term "utility model" is sometimes addressed differently in other countries, with the terms "petty patents", "short-term patents" or "innovation patents"." (p. 5.) We remain skeptical about the appropriateness of utility model legislation in South Africa, most especially in the pharmaceutical context where use and abuse by patent holders to extend periods of exclusivities for innovations lacking an inventive step would be deeply regressive with respect to the goal of securing greater competition and affordable access to medicines in South Africa. Another possible form of abuse, in its recent South African incarnation, is that of "fronting", as the experience of Broad-Based Black Economic Empowerment has revealed.⁷ In summary, of

grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member."

⁷ See Department of Trade and Industry RSA *Economic Empowerment*, https://www.thedti.gov.za/economic_empowerment/fronting.jsp (accessed 2 October 2017); also, brief

all the possible options to support SMMEs and the informal economy, the utility model is the weakest.

Competition Law

The Draft IP Policy briefly addresses the intersection between competition law and intellectual property rights: “Competition law and policy have, in the recent past, been applied to cases involving IP and the public interest. Building on this recent history, a joint effort is recommended, along with the Competition Commission, to clarify the remit and scope of the intersection between competition law and IP.” (p. 25.) There are multiple abuses common to the assertion of patent rights, many of which have been prosecuted on competition grounds in other jurisdictions, for example: false assertion of patent rights, patent ‘evergreening’ and abusive litigation based on frivolous patents aimed at preventing legitimate competition, patent settlements and ‘pay-for-delay’ agreements between originator and generic companies, excessive, unconscionable pricing, refusals to licence especially in the context of dependent patents, and undue market concentration as a result of acquisitions and mergers. In general, developing countries like South Africa should be willing to apply robust competition law policies to tame abuses of intellectual property rights.⁸

UNDP has completed a major study of competition law and IP and has several model recommendations for measures to prevent abuses of IPRs.

Abuses of IP rights would ordinarily be subject to competition laws. However, IP laws may contain provisions dealing with different types of misconduct, such as restrictive practices in licensing agreements, fraud in the prosecution of patent applications, legally baseless requests for interlocutory injunctions and other abuses of enforcement measures. Some examples of provisions to deal with IP abuses are the following:

- The clauses in licensing agreements that adversely affect the technological development of the licensee, impose exclusive grant-back conditions, prevent any challenge to validity or impose mandatory joint licences will be deemed null and void.
- The omission or misrepresentation by the patent applicant of information known to him that would render one or more claims invalid will be deemed fraud and cause the patentee to lose the right to enforce the patent.

Fronting – Beware the BBBEE Commission <https://www.bbrief.co.za/2017/07/03/fronting-beware-bbbee-commission/> (accessed 2 October 2017).

⁸ See, UNDP, *USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES: A GUIDEBOOK FOR LOW- AND MIDDLE-INCOME COUNTRIES* (2014); Carlos Correa, *INTELLECTUAL PROPERTY AND COMPETITION LAW: EXPLORING SOME ISSUES OF RELEVANCE TO DEVELOPING COUNTRIES* (2007) (Correa, *IP AND COMPETITION LAW*; Sean Flynn, *Using Competition Policy Law to Promote Access to Knowledge*, in *ACCESS TO KNOWLEDGE IN THE AGE OF INTELLECTUAL PROPERTY*, 451-475 (Gaëlle Krikorian & Amy Kapczynski eds. 2010).

- An interlocutory injunction for the alleged violation of a patent related to pharmaceuticals shall not be granted unless the patentee has first notified the Attorney-General in writing of the application. The Attorney-General shall be deemed to be a party to the proceedings unless he gives written notice to the court that he does not desire to be a party.

If an interlocutory injunction is granted and:

- (a) the patentee subsequently discontinues the principal proceedings without the consent of the other parties thereto; or
 - (b) the principal proceedings are dismissed; and in either case the court declares that: (i) the patentee did not have reasonable grounds, in all the circumstances known to the patentee or which ought reasonably have been known to the patentee to believe that it would be granted final relief, or that each of the claims, in respect of which infringement is alleged, would have a reasonable prospect of being held to be valid if challenged by the defendant; or (ii) that the application for the interlocutory injunction was otherwise vexatious or not reasonably made or pursued, the court may, in addition to any other relief which it believes should be granted to any person, award a compensation to the defendant, to other affected parties and to the State for any damages sustained, or costs incurred, as a result of the grant of the interlocutory injunction.⁵ (Regarding this type of relief, see also Model 6 regarding potential remedies for wrongly invoked patents.)
- A party at whose request measures were taken and who has abused enforcement procedures shall provide to the party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse, including defendant expenses and appropriate attorneys' fees.⁹ (pp 151-152)

While we agree with the recommendations in the UNDP report and on the content of the Draft IP Policy on competition policy, we do not have additional recommendations at this time concerning proposed legislative and regulatory reforms.

Similarly, we have no comments on subsections 7 and 8 of the Draft IP Policy.

⁹ UNDP, USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES, *supra* note 8, at 151-152.

Appendix A

1. Patent Opposition

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 be able to appear at a hearing in support of their opposition if such hearings are provided for; and
- 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;
- 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 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 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 South Africa is not immediately at the stage of drafting proposed legislation, we offer the following legislative model as to how the Patents Act 57 of 1978 (Patents Act, 1978) might be adapted or amended as appropriate.

**Proposed Legislative Approach for Pre-Grant and Post-Grant Opposition
Procedures¹⁰**

New Section 34A

(1) Where an application for a patent has been published but a patent has not been

¹⁰ This proposed revision relies substantially on the Article 25 of the India Patents (Amendment) Act, 2005 with some amendments (India Patents Act).

granted, any person may, in writing, make representations to the Patent Office against the grant of the patent on the ground—

- (a) that the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims;
- (b) that the invention so far as claimed in any claim of the complete specification is not novel because the state of the art has been published, made available or disclosed before the priority date of the claim in South Africa or elsewhere subject to the exceptions in the relevant section;
- (c) that the invention so far as claimed is preceded by a claim with an earlier priority date than that of the applicant's claim;
- (d) that the invention so far as claimed in any claim was publicly known or publicly used in South Africa before the priority date of that claim. **Explanation.**—For the purposes of this clause, an invention relating to a process for which a patent is claimed shall be deemed to have been publicly known or publicly used in South Africa before the priority date of the claim if a product made by that process had already been imported into South Africa before that date except where such importation has been for the purpose of reasonable trial or experiment only;
- (e) that the invention so far as claimed is obvious and clearly does not involve any inventive step as defined in the relevant section, having regard to the matter published as mentioned in clause (b) or having regard to what was used in South Africa before the priority date of the applicant's claim or that the invention so far as claimed is not industrially applicable as defined in the relevant section;
- (f) that the subject of any claim of the complete specification is not an invention within the meaning of this Act as specified in the relevant section, or is otherwise not patentable under this Act;
- (g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;
- (h) that the applicant has failed to disclose to the Patent Office the information required by law or has furnished information which in any material respect was false and known to be false or incomplete;
- (i) that in the case of a Patent Cooperation Treaty application, the application was not made within twelve months from the date of the first application for protection for the invention made in a PCT country by the applicant or a person from whom he derives title.

(2) At any time after the grant of patent but before the expiry of a period of three years from the date of publication of grant of a patent, any person may give notice of opposition to the Patent Office in the prescribed manner on any of the following grounds set forth in subsection 1(a)-(i) above, but on no other ground.

(3) (a) Where any such notice of opposition is duly given under sub-section (2), the Patent Office shall notify the patentee.

(b) On receipt of such notice of opposition, the Patent Office shall, by order in writing, constitute a Board to be known as the Opposition Board consisting of such officers as he or she may determine and refer such notice of opposition along with

the documents to that Board for examination and submission of its recommendations to the Patent Office.

(c) Every Opposition Board constituted under clause (b) shall conduct the examination in accordance with such procedure as may be prescribed.

(4) On receipt of the recommendation of the Opposition Board and after giving the patentee and the opponent an opportunity of being heard, the Patent Office shall order either to maintain or to amend or to revoke the patent, shall render a decision in writing, and that decision shall be communicated promptly to both the opponent and the patent holder.

(5) In the event that the Patent Office issues an order under sub-section (4) that the patent shall be maintained subject to amendment of the specification or any other document, the patent shall stand amended accordingly.

2. Patentable subject matter, exclusions from patentability, *per se* rules on patentability, and differentiation

The TRIPS Agreement does not directly restrict Member States' right to define what constitutes patentable 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 defined, nor is the word "invention," meaning that Member States do have considerable flexibility in defining patentable subject matter and articulating exclusions from patentability beyond those listed in Article 27.2 and 27.3. 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.¹¹ Other countries classify excludable subject matter more as bright-line tests of what fails one of the three traditional standards of patentability: novelty, inventive step, and industrial applicability. Such *per se* rules might be particularly useful for patent offices with limited patent examination capacity to help expedite the patent examination process.¹²

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, 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

¹¹ India Patents Act, section 3 (d).

¹² 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].

another.¹³ 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”.¹⁴ 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 With specific regard to limitations of protection as set out in Articles 30 and 31 of the TRIPS Agreement ... , the non-discrimination principle does not apply at all. Contrary to what a WTO’s DSB panel mistakenly assumed (cf. WT/DS114/R of 17 March 2000), the Agreement does not subject these provisions to Article 27(1) of the Agreement. The principle of *in dubio mitius* precludes an interpretation to that effect. When designing exceptions and compulsory licenses, states thus remain free to discriminate with regard to the field of technology, provided that such action is reasonable in the light of other public policy goals.¹⁵

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.¹⁶ A prime example of this is Argentina’s adoption of guidelines for the examination of patent applications related to chemical-pharmaceutical substances.¹⁷ 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 know 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.¹⁸ These issues will be discussed further in the discussion below.

¹³ 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).

¹⁴ WTO, Canada – Patent Protection for Pharmaceutical Products, WT/DS 114/R, para 7.92.

¹⁵ Max Planck Institute, DECLARATION ON PATENT PROTECTION, *supra* note 13, at 4.

¹⁶ See RESOURCE BOOK ON TRIPS AND DEVELOPMENT: AN AUTHORITATIVE AND PRACTICAL GUIDE TO THE TRIPS AGREEMENT, UNCTAD-ICTSD, (2005), pp. 368–374 for a full discussion on the justifications for differential treatment of pharmaceutical patents (UNCTAD-ICTSD Resource Handbook).

¹⁷ 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>.

¹⁸ India Patents Act, *supra* note 10, section 3.

2.1 Substances found in nature

In addition to excluding 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” in Section 25(4)(b) of the Patents Act, 1978, domestic patent laws are free to exclude other natural substances from being considered inventions due to lack of a technical contribution to the art. 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,¹⁹ cells, cell lines and cell cultures, and seeds can also be excluded from patentability since they are essentially naturally occurring.

Recommended Legislative Approach

25(4)

- (c) for natural living beings and biological materials found in nature, even if extracted or isolated from it or purified, including the genome or germplasm of any natural living being, unless some change or process has altered the living creature causing it to exhibit significantly different properties;
- (d) for DNA (including complementary DNA sequences), cells, cell lines and cell cultures, and seeds.

Recommended Regulatory Approach

This provision probably does not need a great deal of regulatory specification, though the requirement for significantly different properties should be explicated.

2.2 No patents on new forms of known substances or existing chemical entities

In the context of pharmaceuticals and chemicals, one of the most important decisions that South Africa faces is whether it is 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

¹⁹ 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).

and optimization process.²⁰ 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 verified by the Max Planck Institute²¹ and already copied into the laws of the Philippines and into recommendations for patent law reforms in Brazil and East Africa.²² 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.²³

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 discovery of any new property or new use for a known substance or of 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

²⁰ WIPO, PATENT LANDSCAPE REPORT ON RITONAVIR (2011), available at 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).

²¹ Max Planck Institute, DECLARATION ON PATENT PROTECTION, *supra* note 13, at 5.

²² 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; 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).

²³ 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).

it does not include such factors as beneficial flow properties, better thermodynamic stability, or lower hygroscopicity.²⁴ 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.²⁵

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 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.²⁶

²⁴ *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).

²⁵ *Ibid.* at para. 188.

²⁶ ARGENTINE PATENT GUIDELINES, *supra* note 17; 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).

Recommended Legislative Approach

[India approach]

25(2)

(h) 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 discovery of any new property or new use for a known substance or of 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, (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),

[Argentina approach]

25(2)

(h) The discovery of a new form of a known substance, as defined further in Regulations developed by the relevant authority,

Recommended Regulatory Approach

This submission recommends that South Africa adopts either the India approach – an exemption from patentability on new forms of known substances with an exception for those that show a significantly enhanced therapeutic effect – or the Argentina approach – a basic exception for patents on new forms of known substances, but specified pursuant to regulatory guidelines rather than being detailed in full in the text of the Act. The Argentine Patent Guidelines are attached in full as a sub-appendix to this submission.

2.3 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.²⁷ 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

²⁷ UNDP SA REVIEW, *supra* note 12 at p. 44.

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, South Africa should also disallow patenting of mere admixtures and arrangements or rearrangements of known devices.

Recommended Legislative Approach

25(2)

(i) A substance or substances obtained by a mere admixture resulting only in the aggregation of the property of the components thereof or a process for producing such a substance or substances, or the mere arrangement or re-arrangement or duplication of known devices each functioning independently of the other in a known way,

Recommended Regulatory Approach

The relevant authority could promulgate regulations on this provision clarifying that it applies to pharmaceutical formulations of active ingredients and inert/expedient.

2.4 No patents on new uses (indications) of known substances and exclusion of patents on diagnostic, therapeutic, and surgical methods:

Many countries limit patents on new or additional uses of known substances (in the pharmaceutical context new indications²⁸), 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.²⁹ 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.”³⁰ Andean Community patent law explicitly stipulates that both products and processes already patented and included 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”³¹

²⁸ 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 20.

²⁹ Carlos Correa, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES, 21 (2000) (Correa, INTEGRATING PUBLIC HEALTH); CIPR, INTEGRATING IPRS AND DEVELOPMENT, *supra* note 2, at 45; 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).

³⁰ See UNCTAD-ICTSD RESOURCE BOOK, *supra* note 16, at 387 (italics supplied).

³¹ EAC REGIONAL IP POLICY, *supra* note 22, Policy Statement No. 3(a)(ii), at 14.

India explicitly prohibits patenting of all new uses and methods of use under its Amended (2005) Patents Act.³²

South Africa appears to allow patents on new surgical, diagnostic, or therapeutic uses of known substances or compositions in Section 25(9). This provision should be repealed. In its place, South Africa could and should explicitly exclude patents on new uses or methods of use of known substances or compositions.

Recommended Legislative Approach

25(2)

(j) New uses or methods of use of a known substance, composition, product or process, including health-related uses or methods of use of any pharmaceutical substance such as the second or subsequent indicated use of a medicine, unless there is a significant change in the underlying chemical structure;

25(9) [repealed]

Recommended Regulatory Approach

Regulatory provisions in this subsection should cross-reference the new form variations that are not patentable.

3. 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 by 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 South Africa has substantial interpretative freedom to adopt high standards of patentability. By setting the patent bar higher to prevent poor-quality patents, South Africa will 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 competition sooner, 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.

³² India Patents Act, *supra* note 10, section 3(d).

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.”³³ 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.”³⁴

Developing countries have also embraced the need to adopt strict standards. For example, the East Africa Community recommendation 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.”³⁵ 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 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.³⁶

3.1 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”),

³³ *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 419 (2007).

³⁴ *Ibid* at 421.

³⁵ EAC REGIONAL IP POLICY, *supra* note 22, at 12.

³⁶ *Ibid* at 13.

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”). At present, Section 25 (6) of the Patents Act, 1978 covers state-of-the-art disclosures made in South Africa and elsewhere, though this interpretation could be made more clearly in Section 25(7) addressing patent application disclosures. Section 25(8) is also somewhat problematic in that it considers prior secret use on a commercial scale within South Africa to be part of the prior art, but does not so consider secret prior use elsewhere nor non-commercial use. 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 South Africa 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.

Recommended Legislative Approach

25(6) The state of the art shall comprise all matter (whether a product, a process, information about either, or anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description, by **prior use even if secret, by exhibition**, or in any other way. [added text in bold]

25(7) The state of the art shall also comprise matter contained in an application, open to public inspection, for a patent, notwithstanding that that application was lodged at the patent office and became open to public inspection on or after the priority date of the relevant invention, if—

- (a) that matter was contained in that application both as lodged and as open to public inspection; and
- (b) the priority date of that matter is earlier than that of the invention.

25(8) Deleted

Recommended Regulatory Approach

Regulatory provisions in this subsection should cross-reference the new form variations that are not patentable.

3.2 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.”³⁷

The acceptance of overbroad Markush claims itself raises questions of whether they satisfy patentability and disclosure requirements. As 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.”³⁸ 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...”³⁹ Given that Markush claims account for the largest proportion of all patents issued in South Africa over a three-year period,⁴⁰ disclosure requirements should be tightened so that patents based on such claims do “not become a constraint for research on new compounds or an undue restriction to competition.”⁴¹ See recommended legislative approach under paragraph 4.1.

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.⁴² 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

³⁷ Selection patents are distinct from divisional patents, which are addressed in Articles 37 and 40 of the Draft Amended Patents Act. Divisional patent applications divide a previous patent to create distinct claims when an original patent application does not demonstrate sufficient “unity.”

³⁸ Correa, GUIDELINES FOR EXAMINATION, *supra* note 20 at 12.

³⁹ *Ibid.*

⁴⁰ Carlos Correa, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* Research Paper 41, South Centre, September 2011 at 13.

⁴¹ *Ibid.* at 23.

⁴² ARGENTINE PATENT GUIDELINES, *supra* note 17.

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.

Although South African Patent Law does not presently directly address selection patents, we recommend that the law be clarified to preclude selection patents.

Recommended Statutory Approach

Section 25(9) (new) There is no novelty in the selection of one or more elements already disclosed in prior art, including granted or disclosed patent applications, even though they may have different or improved properties or advantages or avoid previous disadvantages.

Recommended Regulatory Approach

The Regulations could incorporate the Argentine Guidelines in their entirety or the discussion of selection patents quoted above.

3.3 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. 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 innovations and prevent unwarranted limitations to competition and access to existing drugs”⁴³. Setting the bar high for inventive step

⁴³ Correa, GUIDELINES FOR EXAMINATION, *supra* note 20 at 4.

would prevent secondary patents on minor (and oftentimes trivial) changes to existing medicines, 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. 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 or 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.⁴⁴

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.⁴⁵

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.”

Recommended Legislative Approach

Section 25(10) [replace and insert new] Subject to the provisions of section 39 (6), an invention shall be deemed to involve an inventive step only if the Invention would not have been obvious to a person or persons highly skilled in the relevant art.

⁴⁴ Ibid..

⁴⁵ UNDP SA REVIEW, *supra* note 12, at p. 34.

- a. A person highly skilled in the art is not just an expert in his technical field but a person who can learn directly and indirectly from the art and who has a significant degree of imagination and intuition.
- b. Where an invention entails combinations or prior art from different technical fields, the requirement of inventiveness should be evaluated from the perspective of persons highly skilled in the relevant art.
- c. A feature of inventiveness is that the product or process involves a technical advance as compared to the existing knowledge or having prospective economic significance or both and that makes the invention not obvious to a person or persons highly skilled in the relevant art.

Recommended Regulatory Approach

The regulations could further specify the strictness of the inventive step requirement and possibly give some examples thereof. Relevant examples could address, among other matters: (1) combining prior art; (2) combining art from different technical fields or areas of expertise; (3) learning indirectly and drawing inferences from existing art using normal imagination and creativity; (4) combining the expertise of a group of experts working on a particular technical problem in order to create a unitary invention; (5) the degree of technical advance or economic significance that might be taken into account.

3.4 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 such uses are essentially abstract ideas.⁴⁶ 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. Because South Africa has already adopted a standard of industrial applicability, further clarifications might best be addressed by regulations confirming that the standard is more rigorous than mere utility.

⁴⁶ 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.”

3.5 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.”⁴⁷ 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.

Recommended Legislative Approach

Section 25(13) The scope of protection of the patent is limited to those uses, purposes or functions that have been disclosed and expressly claimed in the patent.

Recommended Regulatory Approach

The regulations could make clear examples of how this might apply in the case of “upstream” or platform technology including research tools and diagnostic technologies.

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, countries are free to require other disclosure as described further below.

⁴⁷ See, Max Planck Institute, DECLARATION ON PATENT PROTECTION, supra note 13, at 6-7.

4.1 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 South Africa 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, already require 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 based on failure to disclose the best method of working the invention.⁴⁸ 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.⁴⁹

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.⁵⁰

Recommended Legislative Approach

Section 32(3) [delete existing and substitute] A complete specification shall

- a. have an abstract;
- b. sufficiently describe, ascertain and, where necessary, illustrate or exemplify the invention in a clear, concise and complete manner so as to allow each embodiment of the invention to be evaluated, carried out, performed, worked, or implemented by a person having ordinary skill in the relevant art in South Africa;
- c. describe each and every method by which the Invention can be worked or implemented and which is known by the Applicant at the time of filing the

⁴⁸ Leahy-Smith America Invents Act, sec. 15.

⁴⁹ EAC REGIONAL IP POLICY, *supra* note 22, Policy Statement No. 7(a), at 17.

⁵⁰ Zanzibar Industrial Property Act, Article 6(4)(d) & (e).

- Application or the date of priority, including identification of the best known method;
- d. end with a claim or claims defining the invention for which protection is claimed.
 - e. where it is based on a Markush-type of claim, specify that the coverage of the patent should be limited to what is actually enabled by the disclosure in the specification.

Recommended Regulatory Approach

Regulations with respect to Markush claims could further specify:

“An application including a Markush claim should contain sufficient information to allow a person skilled in the art to perform the invention over the whole area claimed, using his common general knowledge, without undue burden and experimentation, and without needing inventive skill.

Claims of limited scope could be granted if evidence is provided that the same claimed function will be obtained through the substitution of any member within the same family class. Such evidence should include fusion point, infrared absorption spectrum (IR) or nuclear magnetic resonance (NMR) obtained through testing and experimentation, and other information needed to enable the reproduction by the disclosed method of each embodiment of the invention. Applicants may also be requested to submit electronic files to facilitate the prior art search.”⁵¹

4.2 Disclosure of the status of foreign applications

As the Draft IP Policy states, 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 countries such as South Africa, 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 South Africa 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

⁵¹ Correa, GUIDELINES FOR EXAMINATION, *supra* note 20 at 23.

country.⁵² Zanzibar appears to have created such an obligation in Article 9(b) of its Industrial Property Act.

Recommended Legislative Approach

New Section 32(7)

(a) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside South Africa in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file, along with his application or within the prescribed period,

(i) a statement setting out the detailed particulars of such foreign application; and

(ii) an undertaking that, up to the date of denial or expiration of the patent, he would keep the Patent Office informed in writing, from time to time, of detailed particulars as required under clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside South Africa subsequent to the filing of the statement referred to in the aforesaid clause, within the prescribed time.

(b) At any time after an application for a patent is filed in South Africa, unless the application is denied, the Minister may require the applicant to furnish details, as may be prescribed, relating to the status of the application in countries outside South Africa, and in that event the applicant shall furnish to the Minister information available to him within such period as may be prescribed.

New Section 32(8)

(1) Where substantive examination is conducted for an Application, the patent examiner may request the Applicant and/or Patent office in another country to provide any other documents necessary for completeness of the application as follows:

a. authenticated copy of documents pertaining to the results of substantive examination performed for the Patent application filed overseas;

b. authenticated copy of the issued Patent document in regard to a Patent application filed overseas;

c. authenticated copy of the decision for rejection of the Patent application filed ~~for~~ overseas, if the Patent application is rejected;

d. authenticated copy of the decision to cancel the Patent previously issued overseas, if the Patent has been previously cancelled; and/or

e. other documents as may be necessary.

(2) The documents referred to in paragraph (1) may constitute the basis for the consideration of the Minister in deciding to approve or reject an Application.

⁵² See, Paris Convention for the Protection of Industrial Property (1883 as amended through 1979), Article 4bis(2).

Recommended Regulatory Approach

It is recommended that the regulations can further specify the time-frames and forms for the required disclosures.

4.3 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 US 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 US antitrust laws.⁵³

Recommended Legislative Approach

Article 32 (8) The Applicant has a duty to disclose to the Patent Office, as required in the application or otherwise, all information known to the applicant at the time of application or the priority date to be material to patentability, including all relevant prior art; in addition the Applicant shall have an ongoing duty to promptly disclose newly acquired prior information or prior art up to the date of patent denial or patent expiry.

Recommended Regulatory Approach

It is recommended that it be specified by regulation whether such relevant known information and prior art be disclosed together with the application or separately, and it should further specify the requirement to disclose information acquired after the submission of the application, if material.

4.4 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

⁵³ See, e.g., *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1377 (Fed. Cir. 2007).

national applications, particularly when effectuating substantive conditions of entitlement.”⁵⁴ 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, genetic resource, or traditional knowledge or use.” Failure to comply with this disclosure obligation is an express ground for revocation of the patent.⁵⁵

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.”⁵⁶

Recommended Legislative Approach

Section 25(3C) In addition the applicant must provide evidence of prior informed consent from a competent authority of the country of origin, and further evidence of fair and equitable benefit sharing.

Recommended Regulatory Approach

It is recommended that the form of required informed consent and evidence of fair and equitable benefit sharing be specified in implementing regulations.

4.5 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.⁵⁷ The same proposal was made with respect to Uganda’s Industrial Property bill.⁵⁸ 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

⁵⁴ Carlos Correa & Joshua D. Sarnoff, ANALYSIS OF OPTIONS FOR IMPLEMENTING DISCLOSURE OF ORIGIN REQUIREMENTS IN INTELLECTUAL PROPERTY APPLICATIONS, 24 (UNCTAD, 2006) (Correa/Sarnoff OPTIONS).

⁵⁵ South Africa Patents Act, sections 3A and 61(g).

⁵⁶ Correa/Sarnoff OPTIONS, *supra* note 53.

⁵⁷ EAC REGIONAL IP POLICY, *supra* note 22, Policy Statement No. 7(b), at 17.

⁵⁸ The Centre for Health, Human Rights and Development, Model provisions to promote access to affordable medicines in the Industrial Property Bill 2009, September 2012, available at <http://www.cehurd.org/wp-content/uploads/downloads/2012/09/IP-Bill-model-provisions.pdf>

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.⁵⁹

Recommended Legislative Approach

Section 32(8) If the invention relates to a pharmaceutical product, the application shall disclose the international non-proprietary name of the product, wherever such name is available at the time of filing or the priority date; in the event that the international non-proprietary name is unavailable, the applicant shall have a duty to inform the Patent Office within 30 days when said name is known, unless the patent application has been denied or the patent has expired.

Recommended Regulatory Approach

It is recommended that the regulations specify the forms and time-frames for the required disclosure.

4.6 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 information required in the Act. A more progressive version of this requirement would allow administrative cancellation, but that would ordinarily require a due process hearing. The current forgiveness of fraud in Section 63 of the Patents Act should be rescinded.

Recommended Legislative Approach

Section 61(1)(j) that the patent application misrepresented information or did not make required disclosures.

Delete Section 63.

Recommended Regulatory Approach

If the Patent Office determines that it would be appropriate to have administrative due process hearing to determine cancellation based on misrepresentation or failure to make required disclosures, it is recommended that the regulations specify procedures for such hearings.

⁵⁹ UNDP SA REVIEW, *supra* note 12, at 52.

5. 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.⁶⁰ If they choose international exhaustion, as South Africa has done, they will have the right of what is called parallel importation. The relevant provision in the Patents Act reads as follows: "The disposal of a patented article by or on behalf of a patentee or his licensee shall, subject to other patent rights, give the purchaser the right to use, offer to dispose of and dispose of that article."⁶¹

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 Rights⁶² and the World Health Organization⁶³.

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.⁶⁴ 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 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

⁶⁰ 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)

⁶¹ Section 45(2) of the Patents Act, inserted by Patents Amendment Act 58 Of 2002.

⁶² CIPR, INTEGRATION OF IPRS AND DEVELOPMENT, *supra* note 2, p. 42.

⁶³ WHO, REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, PUBLIC HEALTH AND INNOVATION, 124, paragraph 4.19 (2006).

⁶⁴ See Correa, INTEGRATING PUBLIC HEALTH, *supra* note 29, at 79-80 (admitting that such a rule might be subject to WTO challenge).

imported from a country where the articles were legitimately put on the market.⁶⁵ 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.⁶⁶

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.”⁶⁷ Similarly, 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. ...”⁶⁸

Accordingly, this Review recommends allowing parallel importation of products that have been “legally placed in any market” not being limited to the ‘patented product’.

Recommended Legislative Approach

Section 45(2) The Prohibition as referred to in subsection (1) shall not apply to any person who acquires, uses, imports, or commercializes in any way any product, whether patented or produced pursuant to a voluntary or compulsory licence, which has been legally placed in the market anywhere in the world.

Recommended Regulatory Approach

The current regulatory scheme for parallel importation needs to be substantially redrafted and simplified, in both the Patents and Medicines Acts. New implementing regulations should clarify that the parallel imported product cannot be marketed in South Africa unless it has received the required regulatory approvals, and that formalised reliance procedures need to be put in place, as per the enabling provisions in section 2B(2)(a) and (b) of the Medicines Act, as amended.

⁶⁵ 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).

⁶⁶ EAC REGIONAL IP POLICY, *supra* note 22, at 18.

⁶⁷ India Patents Act, *supra* note 10, section 107A.

⁶⁸ 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.

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.⁶⁹ 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 South Africa should adopt.⁷⁰

6.1 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 countries like South Africa. 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.

Exceptions to patent rights for research, experimental, and educational purposes are widely recognized worldwide as an important means to incentivise ongoing innovation.⁷¹ 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.⁷² A broad research exception should allow research “on” and research “with” the patented technology.

⁶⁹ Max Planck Institute, DECLARATION ON PATENT PROTECTION, *supra* note 13, at 8.

⁷⁰ See, Christopher Garrison, EXCEPTIONS TO PATENT RIGHTS IN DEVELOPING COUNTRIES (Aug. 2006).

⁷¹ See Evans Misati & Kyoshi Adachi, THE RESEARCH AND EXPERIMENTATION EXCEPTIONS IN PATENT LAW: JURISDICTIONAL VARIATIONS AND THE WIPO DEVELOPMENT AGENDA (2010).

⁷² 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).

Recommended Legislative Approach

Section 69A(3) It shall not be an act of infringement to use a patent for the purposes of education or commercial or non-commercial research, trial, or analysis in connection with scientific or technological studies; and the said education, research, trial, or analysis can be both on and with the patented product or process.

Recommended Regulatory Approach

There is probably no need for further regulatory specification on these recommended changes.

6.2 Early working (and stockpiling) exception

The early working or Bolar exception is a provision that allows research activities and product development reasonably related to the purpose of registering or 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.

At present, South Africa allows early working only with respect to obtaining regulatory approval in the country. However, 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.⁷³

Recommended Legislative Approach

Section 69A (new text in bold)

(1) It shall not be an act of infringement to make, use, exercise, offer to dispose of, dispose of, **export** or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law **in South Africa or another country**

⁷³ EAC REGIONAL IP POLICY, *supra* note 22, Policy Statement No. 5, p. 15-16.

that regulates the manufacture, production, distribution, use or sale of any product.
(2) It shall not be permitted to possess the patented invention made, used, **exported**, imported or acquired in terms of subsection (1) for any purpose other than for the obtaining, development or submission of information as contemplated in that subsection.

Recommended Regulatory Approach

There is probably no need for further regulatory specification on these recommended amendments.

6.3 Private and other non-commercial purposes

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. Similarly, limited exceptions are recognized concerning the individual preparation of a medicine pursuant to a prescription and the temporary or accidental presence of ships, vessels, aircraft, or land vehicles.⁷⁴ Accordingly, we recommend that South Africa adopt these additional limited exceptions.

Recommended Legislative Approach

Section 69A

- (4) It shall not be an act of infringement to use a Patent before the termination of its term for purely private and/or non-commercial uses, including the individual preparation in a pharmacy or by a medical professional, of a medicine in accordance with a prescription;
- (5) It shall not be an act of infringement where an invention is used in any ship, vessel, aircraft, or land vehicle of any other country entering the territory of South Africa temporarily or accidentally provided that such invention is used exclusively for the needs of the ship, vessel, aircraft or land vehicle and not used for the manufacturing of anything to be sold within South Africa.

Recommended Regulatory Approach

There is probably no need for further regulatory specification on this recommended amendment.

7. Regulation of Voluntary Licences

WTO Member States are fully empowered under international law to closely regulate the terms of intellectual property licences to prevent anticompetitive terms. TRIPS Article

⁷⁴ Garrison, *supra* note 65, at 2-3, 6-9, 9-11.

8(2) clarifies that: "Appropriate measures, provided 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." More particularly, TRIPS Article 40.2 states that Members may specify in their domestic laws 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." It also specifies some presumptively anti-competitive practices.⁷⁵ The East Africa Community directs its Partner States to prevent anti-competitive behavior and to list licensing terms that may be considered unjustified restrictions on competition and authorise patent registrars to refuse to register such licensing contracts.⁷⁶ It is further generally agreed that countries can require publication of licensing agreements.

UNDP has published a list of restrictive practices in licensing agreements that were suggested for adoption by Indonesia:

The following provisions in licensing agreements may be considered abusive or anti-competitive *per se*:

- (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;
- (xiii) payments and other obligations after expiration of industrial property

⁷⁵ TRIPS Article 40: *supra* note 6

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.

2.

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.

⁷⁶ EAC REGIONAL IP POLICY, *supra* note 22, Policy Statement No. 11(a), at 20-21.

rights;
(xiv) restrictions after expiration of the licensing agreement.⁷⁷

Recommended Legislative Approach

New Section 58A

(1) Licensors shall file notice of licensing agreements involving granted patents with the Patent Office and shall also file a certified copy of such licence, which copy shall be made available to the public on a website maintained by the Patent Office.

(2) Licensing agreements shall not contain provisions that are anti-competitive, abusive, or may disadvantage the South African economy, enterprises, or consumers nor contain limits that hinder South Africa's capabilities in undertaking the transfer, mastery, and development of technology.

(3) Failure to meet the requirements of subsection (1) and (2) may result in the licence being unenforceable against third parties, invalidation of offending licence provisions, and/or the granting of a competition-based compulsory licence allowing exportation of unlimited quantities, limiting the amount of remuneration payable, and eliminating any requirement of prior negotiation with the patent holder.

Recommended Regulatory Approach

This submission recommends that both the Patent Office and the Competition Commission adopt regulations specifying licensing terms that may be considered anti-competitive, including those referenced in UNDP, USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES.⁷⁸ In addition to listing specific per se anti-competitive licensing terms, there should also be a more general provision referencing terms with any other anticompetitive effect.

8. 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

⁷⁷ See, UNDP, COMPETITION LAW *supra* note 8, at 141-142.

⁷⁸ *Ibid* at 141-152

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));
- 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)).

The Doha Declaration on the TRIPS Agreement and Public Health clarified that “[e]ach Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted,” and that “[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”⁷⁹ Compulsory and government use licenses have been used much more extensively than previously acknowledged.⁸⁰

8.1 Grounds for and conditions on compulsory licences

As clarified by the Doha Declaration, WTO Member States have complete freedom to

⁷⁹ 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), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed 3 October 2017).

⁸⁰ Ellen t’ Hoen, PRIVATE PATENTS AND PUBLIC HEALTH: CHANGING INTELLECTUAL PROPERTY RULES FOR ACCESS TO MEDICINES (2015).

determine the grounds upon which compulsory licences may be granted. There are no disease restrictions, country-status restrictions, or field of technology restrictions. The Paris Convention⁸¹ does place some limits on the timing of compulsory licences for non-working, but these are fully accommodated in Section 56(2)(a) of South Africa's Patent Act.

As a general rule, countries are far better off articulating multiple and broad grounds for compulsory licences instead of restricted grounds.⁸² After all, a patent is a sovereign grant of exclusive, i.e., monopoly, rights and the patentee takes such rights with full knowledge of the possibility that the granting government might issue compulsory and government-use licences. Countries should retain maximum policy space for the exercise of government discretion about the myriad circumstances where involuntary use should be permitted to safeguard public interests.

The substantive grounds for the granting of a compulsory licence under South African law are currently quite limited: compulsory licenses for dependent patents under Section 55; abuse of patent under Section 56, including that the demand for the patented article is not being met to an adequate extent and on reasonable terms; prejudicial refusal to grant a licence on reasonable terms to the detriment of a trade or industry or economy and the public interest in issuing a compulsory licence; and the price of an imported patented product is excessive compared to its price where it is manufactured.

This submission recommends that the grounds for compulsory licences should be expanded much further than this incomplete list. As stated above, the Doha Declaration reaffirms that countries are free to determine the grounds upon which licences might be granted.⁸³ Thus, it is highly desirable to list additional specific grounds, e.g., to prevent 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.⁸⁴

⁸¹ Paris Convention, *supra* note 51, 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.

⁸² 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).

⁸³ Doha Declaration, *supra* note 75, para. 5(b), "Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."

⁸⁴ UNDP SA REVIEW, *supra* note 12, at 71.

Article 31(k) of the TRIPS Agreement specifically authorises the issuance of competition-based compulsory licences and waives requirements of prior negotiation and limitations on exports with respect to such licences.⁸⁵ The East Africa Community has specifically recommended that its Partner States adopt compulsory licence remedies for abuse of patent right⁸⁶ and the UNDP has also done so in its recent analysis of the intersection between IP and competition policy.⁸⁷ 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. Such licences should be easy to obtain and should not require recourse to specialised investigations and adjudications, if clear standards are provided as to what might constitute an anti-competitive practice. As a basic principle, there should be clear and easy-to-use procedures.⁸⁸

Additionally, as proposed by the Union for Affordable Cancer Treatment⁸⁹ mandatory licences should be granted automatically if the grounds, for example, of unaffordability are present, and further that the remedies available for infringement circumscribed to exclude injunctions (see proposed amendments in section 56(2)(iii) *infra*). If the Government of South Africa concludes that provision for mandatory compulsory licences is unsound, then alternatively it can provide for presumptive licences.

Recommended Legislative Approach

Section 56(1)

Any interested person who can show that the rights in a patent are being abused **or that any of the additional grounds listed under sub-section (2) are present**, may apply to the relevant authority or tribunal in the prescribed manner for a compulsory licence under the patent.

Section 56(1)A

- a. An application for compulsory licence on the grounds referred to in sub-Section 56(2) below may be filed at any time after issuance of the patent.
- b. An application for compulsory licence on the grounds referred to in sub-Section 56(2) below, other than **h** and **m**, shall not be granted unless the potential licensee has negotiated for a voluntary licence on commercially reasonable terms for a commercially reasonable time of no more than three months, and been unsuccessful.

⁸⁵ See TRIPS Article 31(k), (b) and (f).

⁸⁶ EAC REGIONAL IP POLICY, *supra* note 22, Policy Statement No. 11(b), at 21.

⁸⁷ UNDP, COMPETITION LAW *supra* note 8.

⁸⁸ Baker, PROCESSES AND ISSUES FOR IMPROVING ACCESS TO MEDICINES, *supra* note 77.

⁸⁹ Union for Affordable Cancer Treatment, *UACT and 22 Cancer Treatment NGOs Submit Comments on South Africa IP Policy* available at <https://cancerunion.org/2017/10/10/uact-and-22-cancer-treatment-ngos-submit-comments-on-south-africa-ip-policy/> (accessed 13 October 2017).

c. A compulsory license may be granted to one or more licensees taking into account that it is ordinarily desirable to have multiple licensees in order to encourage competition.

Section 56(2)

(i) The rights in a patent shall be deemed to be abused if—

(a) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the relevant authority or tribunal no satisfactory reason for such non-working;

New b. the patented invention has not been worked locally in South Africa other than by importation and the patent holder fails to demonstrate that it is not economically or technologically feasible at present to manufacture in whole or in part in South Africa;⁹⁰

. [Para. (b) deleted by s. 45 (b) of Act No. 38 of 1997.]

(c) the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms;

(d) by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a licence or licences should be granted; or

(e) the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under licence from the patentee or his predecessor or successor in title.

(ii) Additional Grounds:

f. the patent is not worked or not fully worked in South Africa by the patent holder, including--

(fi) that the patented invention is not available to the public at a reasonably affordable price;

(fii) that the patented invention has not been worked locally in South Africa other than by importation and the patent holder fails to demonstrate that it is not economically or technologically feasible to manufacture in whole or in part in South Africa;

g. the patent is worked by the patent holder or licensee in a form and by means harmful or abusive to the public interest;

⁹⁰ See Commentary in paragraph 8.3 *infra*,

- h. there is an emergency or other urgent matter of national interest, in which case prior negotiation for a licence on reasonable commercial terms is not required;
- i. the patent holder has refused to grant a licence on reasonable terms within a reasonable period of time of no more than three months, despite a request to do so, for the purpose of access to an essential facility, including to be able to produce and market rational fixed-dose combination medicines;
- j. there is a risk of supply interruptions of essential products such as medicines;
- k. there is a need to promote local production and technology transfer;
- l. there is any other public interest or public health need;
- m. the patent holder has been found to have engaged in an anti-competitive practice.

(iii) Mandatory [or Presumptive] Grounds

A compulsory licence on a patented invention in respect of a medicine, vaccine or other medical technology shall be granted [or presumed necessary], subject to the payment of a reasonable and affordable royalty, whenever a medicine or vaccine is not available at a price that is reasonable and/or affordable for the general population or any significant group of potential patients, and there is evidence that access is limited due to the price. A decision that the price for a product is not generally reasonable and/or affordable may be made by the relevant authority or tribunal, including the Ministers of Health, and Trade and Industries, the premiers of provinces, the South Africa Competition Commission, or by a Judge of the High Court.

Timeliness:

Delete existing Section 56(4)

New Section 56(4)

The relevant authority or tribunal shall, upon receipt of an application under this section:

- a. inform the patent holder of such application and afford it an opportunity to oppose the application;
- b. set the application down for hearing without undue delay;
- c. afford all parties the opportunity to attend, make representations, and be represented at the hearing;
- d. issue a decision to approve or reject the issuance of a compulsory licence no later than thirty (30) days after the hearing has been completed.
- e. An application for compulsory licence may be granted to a South African licensee if in the opinion of the relevant authority or tribunal, the patent can be worked in South Africa on a feasible economy of scale and may benefit the general

public; and such application may also be granted for importation where it is considered advantageous to do so.⁹¹

Recommended Regulatory Approach

The implementing regulations could specify commercially reasonable licensing terms or specify unreasonable terms, as well as the procedures and time-frames for the relevant aspects of the process.

8.2 Compulsory licences for domestic production and/or import

South Africa's patent law should explicitly clarify that compulsory licences can be issued both domestically and to foreign licensees as needed.

Recommended Legislative Approach

Section 56(4)

- e. An application for compulsory licence may be granted to a South African licensee if in the opinion of the relevant authority or tribunal, the patent can be worked in South Africa on a feasible economy of scale and may benefit the general public; and such application may also be granted for importation where it is considered advantageous to do so.

Recommended Regulatory Approach

Implementing regulations could clarify when it would be advantageous to issue a licence for importation, including more affordable price, lack or insufficiency of local capacity, to secure alternate sources of supply, to obtain better quality products, etc.

8.3 Local working requirement and failure of local working as grounds for compulsory licences

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 (e.g. to produce locally, rather than merely import). Likewise, although this proposition is not without some controversy,⁹² local working requirements are fully permissible under TRIPS and not just with respect to the issuance of compulsory licences.⁹³ To ensure

⁹¹ See commentary in paragraph 8.2 *infra*.

⁹² 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.

⁹³ Michael Halewood, *Regulating Patent Holders: Local Working Requirement and Compulsory Licenses 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*

certainty, the definition of local working should also be clarified.

We agree that the local working requirement is lawful and that South Africa 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 that a reasonable time period must be established. We also propose that the right holder be afforded the opportunity to prove that local production within the specified time period is not economically feasible. However, we are of the view that a general failure to work the patent, even by import, need not be satisfied only via a licence to a local company. There may well be circumstances where local capacity is absent or insufficient or where the government can arrange a licence to a foreign entity that allows for some domestic inputs, including packaging and labeling.

Recommended Legislative Approach

Section 56(2)

- b. the patented invention has not been worked locally in South Africa other than by importation and the patent holder fails to demonstrate that it is not economically or technologically feasible at present to manufacture in whole or in part in South Africa;

Recommended Regulatory Approach

Implementing regulations should specify the kinds of forms of evidence required to take advantage of the exception to the local working requirement.

8.4 Government use licences

In addition to dramatically expanding the grounds for government-use licences beyond the current grounds set forth in Section 56, South Africa 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 or “public non-commercial use”, meaning use “by or for” the government and requiring only notice⁹⁴ and remuneration⁹⁵. The United States has the simplest and easiest to use government use provision. Pursuant to 28 U.S.C. section 1498(a), any U.S. official or government contractor receiving the authorisation or consent of the government⁹⁶ can make use and manufacture the

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).

⁹⁴ “[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.”

⁹⁵ Article 31(h).

⁹⁶ “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

invention of a patent subject only to the patent holders right to seek reasonable and entire compensation for the same. There are no special administrative hearings and in fact no explicit requirement of notice, despite the provisions of Article 31(b) of the TRIPS Agreement requiring the same. Government use of section 1498 has been quite extensive, with the primary user being the U.S. Department of Defense, but affected products cover many other products including medicines and other health technologies.⁹⁷

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 and a “public, non-commercial use” 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 would be permissible for South Africa to issue government-use licences for importation. Finally, the TRIPS Agreement requires certain conditions even with respect to public, non-commercial use licences, essentially the same conditions discussed in paragraph 8.1 above.

South Africa has made provision for government use licences in Sections 4 and 78 of the Patents Act, but unnecessarily requires prior negotiation, which can slow down the process of securing government use.⁹⁸ The current provisions also do not explicitly follow all of the prerequisites of TRIPS Article 31.

Recommended Legislative Approach

Repeal current Sections 4 and 78

Section 4

- (1) Any properly designated South Africa public official or any government contractor, domestic or foreign, receiving the authorisation or consent of the South Africa government can make public, non-commercial use of a patent pursuant to the provisions of [amended] Section 78 of this Act.
- (2) For the purposes of this provision, the use or manufacture of an invention described in and covered by a patent granted in South Africa by a contractor, a

Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.”

⁹⁷ 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).

⁹⁸ Section 4. State bound by patent. “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.”

Section 78. Acquisition of invention or patent by State. “The Minister may, on behalf of the State, acquire, on such terms and conditions as may be agreed upon, any invention or patent.”

subcontractor, or any person, firm, or corporation for the Government and with the authorisation or consent of the Government, shall be construed as use for South Africa.

Section 78

- (1) If the Government intends to authorise public, non-commercial use of a patent, the Government shall promptly notify the patent holder of this matter in writing, if and when the Government knows of the patent without being required to make a patent search; however in no event is the Government or its authorised contractor required to engage in any prior negotiations with the patent holder.
- (2) If the Government authorises public non-commercial use of a patent as referred to in paragraph (1), adequate remuneration shall be provided for the patent holder, pursuant to Remuneration Guidelines established by regulation.
- (3) If the Government authorises public, non-commercial use of a patent, such use shall be subject to the following conditions:
 - a. That the licensed use is non-exclusive;
 - b. That the grounds for licensing the use are stated;
 - c. That the scope and duration of licensed use is limited to the purpose for which the use was authorised, and the licence shall be terminated if and when the circumstances which led to its authorisation cease to exist and are unlikely to recur, subject to the legitimate interests of the licensee being protected;
 - d. That the exploitation of the invention under a compulsory licence shall be predominantly for the supply of the market in South Africa.
- (4) Further provisions concerning procedure for use of patents by or for the Government shall be stipulated in a Government Regulation.

Recommended Regulatory Approach

As stipulated, regulations concerning public, non-commercial use shall be further stipulated in a Government Regulation. In addition, as discussed further below, remuneration guidelines shall also be established by a Government regulation.

8.5 30 August 2003 Decision 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 would have to be issued in that country as well. The Article 31(f) paradox is that the licensed exporting company might not be able to export 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 instructed the WTO, in paragraph 6 of the Declaration, to devise an expeditious solution. Unfortunately, the decision-making was not expeditious, but finally on 30 August 2003 the WTO General Council issued a decision declaring a waiver from Article 31(f), the so-called 30 August 2003 Decision.⁹⁹ In addition to being delayed, the 30 August 2003 Decision imposes onerous procedural requirements on both importing and exporting countries issuing compulsory licences and further restricts the quantity of pharmaceutical products that might be exported. The Decision has been called “labyrinthine”¹⁰⁰ and as being “neither expeditious, nor a solution.”¹⁰¹ As evidence of its impracticality, the Decision has only been used once by a Canadian company, Apotex, to export antiretrovirals to one country, Rwanda, and then only after a multi-year delay.¹⁰² The waiver provision has now received sufficient ratifications to be codified in TRIPS Article 31bis.

There have been several proposals to simplify domestic implementation of the 30 August 2003 Decision, including a so-called one-licence solution that was proposed in Canada but allowed to lapse in Parliament.¹⁰³ South Africa can and should adopt all lawful flexibilities to make use of the 30 August 2003 Decision as simple and expeditious as possible. Not only could it adopt the one-licence solution, but it could also provide for strict time limits on the obligation to engage in negotiations for a voluntary licence on commercially reasonable terms, it could waive prior negotiations in response to compulsory licences

⁹⁹ 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, available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm. The “temporary waiver” of the Decision was made into a permanent proposed amendment to TRIPS in December 2005, under a new Article 31bis, available at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm. The amendment will become part of TRIPS only upon ratification by at least two-thirds of the WTO members. May 2014, less than half of all WTO members had ratified the amendment. See Members accepting amendments of the TRIPS Agreement, available at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

¹⁰⁰ 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).

¹⁰¹ Medecins Sans Frontieres Canada, “Neither Expeditious, Nor a Solution: the WTO August 30 Decision is Unworkable”, (2006) at p. 2.

¹⁰² 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), available at <http://www.ictsd.org/bridges-news/bridges/news/canadian-access-to-medicines-bill-under-threat>.

¹⁰³ 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>.

issued on the grounds of emergency or for public, non-commercial use, and it could, like Canada, adopt remuneration guidelines with tiered royalties,¹⁰⁴ or it could adopt fixed percentage royalties as discussed further below. In addition, like India, South Africa could make granting of humanitarian licences for export mandatory.

However, as referenced briefly above, South Africa also has 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.¹⁰⁵ Although several other countries, including Canada, China, India, the Netherlands, the European Commission, Korea, and Switzerland have adopted laws implementing the 30 August 2003 Decision,¹⁰⁶ only Uganda seems to have adopted both the 30 August 2003 Decision and an Article 30 limited exception system.

Recommended Legislative Approach

Section 56A

- (1) In the event it is not possible for a pharmaceutical product patented in South Africa to be produced in South Africa, the relevant authority or tribunal may issue a compulsory licence for the import of that pharmaceutical product.
- (2) In the event that any country requires a pharmaceutical product patented in South Africa for treatment of an endemic disease and it is economically feasible for the pharmaceutical product to be produced in South Africa, the relevant authority or tribunal shall issue a compulsory licence at the request of that country for production of the patented pharmaceutical product for export to the country requesting it, if the importing country or countries have insufficient capacity to manufacture the pharmaceutical product domestically.
- (3) As an alternative to the mechanism described in paragraphs (1) and (2), South Africa hereby adopts Article 31*bis* of the TRIPS Agreement and the Annex thereto.

¹⁰⁴ 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 licence 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 licenced product by the importing country and the humanitarian and non-commercial reasons underlying the issuance of the licence.” 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.

¹⁰⁵ Baker, *supra* note 99.

¹⁰⁶ 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.

(4) The procedures and requirements of the Article 31bis shall be further specified by a Government Regulation.

Section 56B

Alternatively and in lieu of using Section 56A, the relevant authority or tribunal shall issue a compulsory licence at the request of another country for production of the patented pharmaceutical product of reasonable quantities for export to the country requesting it, if the importing country or countries have insufficient capacity to manufacture the pharmaceutical product domestically.

Recommended Regulatory Approach

Pursuant to authority granted above, implementing regulations for the Article 31bis mechanism should be carefully drawn with respect to required conditions, notifications and procedures set forth in the Decision. It is important to adopt the single-licence approach and thus to allow licensees “to export to one or more eligible importing countries” as defined in Article 31bis, which includes least developed countries automatically and other countries that have provided required notifications to the WTO. There should be no limits on the pharmaceutical products that can be exported and pharmaceutical products should be defined expansively: “pharmaceutical product” means any patented product, product manufactured in pursuance of a voluntary or compulsory licence or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, and includes active ingredients necessary for its manufacture and diagnostic kits needed for its use.” If the licence is being issued to satisfy a public, non-commercial use in the importing country, there shall be no obligation for the prospective licensee to have engaged in prior negotiations with the patent holder. Finally, the time period for prior negotiations should be reduced to one month (30 days).

8.6 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 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.¹⁰⁷ If and when the

¹⁰⁷ See, UNDP SA REVIEW, *supra* note 12, at 74.

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 are highly prejudicial to alleged infringers, denying them their rights to fair administrative justice and, in our view, constitute bad law.

Article 50.1¹⁰⁸ and Article 44.1¹⁰⁹ 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 at least 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. This is particularly necessary because South African courts are typically reluctant to adopt the approach of awarding damages or royalties rather than injunctive relief in interlocutory applications, arguing that to do so would be tantamount to granting a compulsory licence.¹¹⁰ In this context, it is noteworthy that the South African representative to the WTO TRIPS Council last week came out in full support of the need to issue compulsory licences in the public interest, and in particular, the South African delegation's endorsement of US court decisions to refuse injunctive relief in cases of infringements of medical patents, opting instead to award monetary damages, usually in the form of royalty payments.¹¹¹ 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

¹⁰⁸ "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."

¹⁰⁹ "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."

¹¹⁰ See *Cipla Medpro (Pty) v Aventis Pharma SA, Aventis Pharma SA & others v Cipla Life Sciences (Pty) Ltd & others* 2013 (4) SA 579 (SCA).

¹¹¹ 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).

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, the leading case, *eBay Inc. v. MercExchange, L.L.C.*,¹¹² 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.¹¹³ 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.¹¹⁴ 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.”¹¹⁵

Based on these precedents, South Africa can amend its Patent Act, to ensure that temporary and permanent court interdicts issued pursuant to Section 65(6) of the Patent Act are not mandatory and that instead courts have specific discretion to award compensatory damages in the form of on-going royalties that provide adequate remuneration, especially with respect to medicines required to meet public health needs.

Recommended Legislative Approach

Section 65(3)d

- i. such interdict available under subsection (3)a need not be issued when there is another satisfactory remedy in the form of adequate on-going remuneration in the form of a percentage royalty payment;
- ii. the discretion of the court to order a percentage royalty payment shall be particularly appropriate with respect to pharmaceutical products required to meet a public health need;

¹¹² 547 U.S. 388 (2006).

¹¹³ See, Jaideep Venkatesan, *Compulsory Licensing of Nonpracticing Patentees after eBay v. MercExchange*, 14 VA. J. LAW & TECH. 26-47 (2009).

¹¹⁴ 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).

¹¹⁵ *Ibid* at para 85.

- iii. the amount of adequate remuneration in the form of an ongoing percentage royalty payment shall be guided by the Remuneration Guidelines promulgated pursuant to Section 78(2).

Recommended Regulatory Approach

This provision will not require implementing regulations.

8.7 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, in some cases compulsory licences 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.¹¹⁶ Accordingly, it would be desirable to amend South Africa's 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 shall 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 should be a confidentiality term prohibiting the know-how licensee disclosing the know-how to third parties without the consent of the right holder.

Recommended Legislative Approach

Section 56C

In addition to the government use or compulsory licence permissible under Sections 4 and 56, an additional involuntary licence may be issued on otherwise confidential manufacturing know-how when it is not commercially practicable to implement the patent pursuant to a compulsory or government use licence based on the patent disclosures alone, on the following terms and conditions:

1. In order to obtain such a licence on know-how, the prospective licensee must have first asked the know-how owner for a licence thereto on commercially reasonable terms for a period of not less than three months and have been unsuccessful in obtaining such a voluntary licence;
2. A licence on know-how shall be conditional on the payment of adequate remuneration, taking into account the economic value of the use, pursuant to Remuneration Guidelines promulgated by the relevant authority or tribunal, the said remuneration being in addition to any remuneration paid with respect to any patent related compulsory licence;
3. The said licence on know-how shall be non-exclusive and non-assignable;

¹¹⁶ Max Planck Institute, DECLARATION ON PATENT PROTECTION, *supra* note 13, at 11.

4. The know-how disclosed shall be considered confidential and the licensee shall be required to enter into a written agreement not to disclose the information to third parties and that if such disclosure is made the licence may be revoked and the licensee may be sued for damages.

Recommended Regulatory Approach

This provision should have implementing regulations addressing the circumstances under which the patent disclosures are considered insufficient to allow commercially practical implementation of the patent. The proposed Remuneration Guidelines should address compensation for know-how, which might ordinarily be a lump-sum payment. The regulations should also address the form and substance of the required confidentiality term.

8.8 Provisional Compulsory Licence Concerning a Pending Patent Application

In some instances, a patent application may not yet have been granted, even though a product based on the patent has already entered the market. This can be particularly so with respect to the use of certain pharmaceutical products during, for example, the outbreak of an epidemic. In such circumstances and when public health and 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.

Recommended Legislative Approach

Section 56D

In the event that the grant of a patent is pending, but the grounds for issuing a compulsory license listed in Section 56(2) as amended are present, the relevant authority or tribunal may issue a provisional compulsory licence to come into effect only if or when the relevant patent or patents are granted. In such event, adequate remuneration pursuant to Remuneration Guidelines shall only be due from the grant of the relevant patent.

8.9 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.¹¹⁷ 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

¹¹⁷ See James Love, REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES, UNDP and WHO (2005) at pp. 67–76 for a comprehensive review of proposed remuneration guidelines.

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.¹¹⁸

The existing Section 56(7) of the South African Patent Law stipulates that “In determining the conditions on which any licence is granted the commissioner shall have regard to any relevant facts, including the risks to be undertaken by the licensee, the research and development undertaken by the patentee and the terms and conditions usually stipulated in licence agreements in respect of the subject-matter of the invention, between persons who voluntarily enter into such agreements.” This is normally understood to provide for adequate remuneration. Similarly, Section 78 calls for agreed upon terms and conditions, which might also reasonably be interpreted to cover adequate remuneration. The proposed amendments of both sections previously discussed provide for TRIPS-compliant term “adequate remuneration” to be determined pursuant to remuneration guidelines promulgated by the Patent Office.

We further recommend that Remuneration Guidelines establish a normal royalty of 4% of wholesale cost, 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 an upward adjustment of no more than 2% based on disclosed, extraordinary research and development costs or therapeutic breakthrough in the case of pharmaceuticals. The Remuneration Guidelines could conversely allow downward adjustment of no more than 2% 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%, and provide further that royalties on exports to countries with insufficient manufacturing capacity should be based on the economic value of the authorisation in the country of importation and use.

Recommended Legislative Approach
<p>Section 56(7) repealed and in its place:</p> <p>(a) A compulsory licensee must pay adequate remuneration to the patent holder, taking into account the economic value of the authorisation.</p> <p>(b) The amount of remuneration to be paid and method of payment shall be determined by the relevant authority or tribunal.</p>

¹¹⁸ Section 35-B(3), the Philippine Republic Act no. 165 of 1947, as amended by Presidential Decree 1263 in 1977.

- (c) The relevant authority or tribunal shall determine the amount of remuneration and method of payment as referred to in (a) and (b) taking into account the economic value of the authorisation and pursuant to Remuneration Guidelines promulgated by the Patent Office, with a presumptive royalty rate 4% of the net wholesale selling price, and using the methods of payment customarily used in licensing agreements, but with further provision that the remuneration guidelines can be increased or decreased by no more than 2% based on conditions listed in the Remuneration Guidelines.
- (d) If the authorisation is issued to remedy anti-competitive conduct, the Remuneration Guidelines shall stipulate that the percentage payment can be reduced accordingly, including to zero.
- (e) If the authorisation is issued to export to countries with insufficient pharmaceutical manufacturing capacity pursuant to Section 56B, the economic value shall be based on the value in the country of importation and use, but if there are no patent rights on the imported pharmaceutical product in the country of importation and use, then the percentage payment should be zero.

Section 78(2) If the Government works a Patent as referred to in sub-section (1), adequate remuneration shall be provided for the patent holder pursuant to the Remuneration Guidelines described in Section 56(7).

Recommended Regulatory Approach

The proposed Remuneration Guidelines should be published, and any level of discretion that applies should be described along with factors that affect the exercise of that discretion. It is clear that it is preferable to set a presumptive royalty rate and to limit upward or downward adjustment to limited special circumstances as discussed in the text above.

8.10 Compulsory licencing 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.¹¹⁹ 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.

¹¹⁹ Article 31(i) & (j) of the TRIPS Agreement.

This submission does not directly state an opinion on which public official[s] should be empowered to issue compulsory and government use licences. This issue should, of course, be addressed in any legislative reform process, and we have therefore used the generic appellation “relevant authority or tribunal”. 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.

Recommended Legislative Approach

Section 56(8A)

- (a) Examination of an application for a compulsory licence shall be conducted by the relevant authority or tribunal.
- (b) In conducting examination as referred to in paragraph (1), the relevant authority or tribunal shall summon the Patent Holder and the applicant(s) to hear their evidence and opinions.
- (c) The Patent Holder shall put forward evidence and opinions in accordance with the stipulated period.
- (d) If the Patent Holder does not put forward his or her opinions within two months of notice of the application, the Patent Holder is presumed to consent to issuance of the compulsory licence.

Sections 75 and 76 repealed

New Section 75

- (1) An appeal may be filed before the relevant authority or tribunal or such other distinct higher authority designated by the Patent Office for hearing such appeals against a decision by the relevant authority or tribunal for the issuance of a compulsory licence only in regard to material pertaining to the legality of the licence and the amount of remuneration and method of payment.
- (2) A claim process before the relevant authority or tribunal or such other distinct higher authority designated by the Patent Office for hearing such appeals as referred to in sub-section (1) shall not stay the working of the compulsory licence.

New Section 76

- (1) A Government decision that a patent will be worked by or for the Government on its own behalf pursuant to Section 78 is final, subject only to the provision for appeal in subsection (2).
- (2) In the event that the Patent Holder disagrees with the legality of the government use and/or the amount of remuneration stipulated by the Government, he or she may lodge an appeal with the relevant authority or tribunal or such other distinct higher authority designated by the government for hearing such appeals.
- (3) A claim for appeal as referred to in sub-section (2) shall not stay the working of a Patent by the Government.

Recommended Regulatory Approach
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Implementing regulations should further specify requirements for applications for compulsory licences and the forms of evidence and presumptions in hearings on such applications. The regulations should seek to ensure expeditious and easy to use procedures.
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