6-2020

Kenya's Intellectual Property Bill, 2020, and Its Shortcomings in Adopting all Lawful TRIPS Public Health Flexibilities

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KENYA'S INTELLECTUAL PROPERTY BILL, 2020, AND ITS SHORTCOMINGS IN ADOPTING ALL LAWFUL TRIPS PUBLIC HEALTH FLEXIBILITIES

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INTRODUCTION

Given the importance of access to medicines to human rights and well-being in Kenya, it is appropriate to analyze whether Kenya has currently incorporated the allowed public health flexibilities to the greatest extent possible in its draft Intellectual Property Bill, 2020.[2] This analysis will focus on the patent, utility model, and enforcement measures only as they are the ones directly relevant to access to medicines and other health technologies. The analysis starts with the premise that Kenya wishes to avoid granting unwarranted patents on unworthy inventions, especially with respect to medicines and other health technologies. In particular, the assumption is that Kenya wishes to avoid granting secondary patents or minor variations to known medicines and medical technologies which have the sole effect of extending patent monopolies and preventing local generic production or importation. It is assumed that Kenya wants to have a patent regime that prevents granting patents on new medical uses of medicines and on new formulation and dosages. In a word, the analysis assumes that Kenya wants to avoid evergreening. It assumes instead that Kenya wants to maximize TRIPS-compliant policy space to minimize unneeded patent barriers and

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[2] The Kenyan Parliament revised its Industrial Property Act in 2001 and it came into force in May 2002. The Act has subsequently been amended in 2002 (Act No. 2 of 2002) and 2007 (Act No. 7 of 2007). The Act is available at: http://www.kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=CAP.%20509. Kenya has now proposed to recodify its intellectual property law in a single bill, the Intellectual Property Bill, 2020, https://www.kipi.go.ke/images/docs/IPOK%20Bill%202020.pdf.

further to bypass patents to advance its public health and public interest needs. Finally it assumes that Kenya further desires to expand policy space that would allow growth of domestic and regional pharmaceutical capacity.

In crafting these recommendations, the author has relied extensively on EAC[3] and COMESA[4] recommendations that adoption and use of TRIPS-flexibilities be maximized, on academic and think-tank commentary, and on best practices from countries that have adopted and successfully used TRIPS flexibilities.[5] The paper also draws on the positive example of India, which has adopted the vast majority of recommended TRIPS-compliant public health flexibilities.

In sum, there are many positives in the proposed Kenyan Intellectual Property Bill, 2020, that have at least partially incorporated desired flexibilities but there are important gaps and omissions as well. On the plus side, the Bill incorporates several important TRIPS public-health flexibilities, including parallel importation and the right to issue government use and compulsory licenses. The Bill also incorporates a research exception and promotes close regulation of anti-competitive provisions in voluntary licenses. Also on the plus side, the Bill has updated the 2001 Act to adopt

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[3] East African Community, REGIONAL INTELLECTUAL PROPERTY POLICY ON THE UTILIZATION OF PUBLIC HEALTH-RELATED WTO-TRIPS FLEXIBILITIES AND THE APPROXIMATION OF INTELLECTUAL PROPERTY LEGISLATION (2013) [EAC REGIONAL IP POLICY].

[4] COMESA, Recommendations of the Workshop on Public Health and Access to Life-saving medicine in COMESA held on 1-5 March 2011 at Imperial Royale Hotel, Kampala, Uganda http://www.comesabusinesscouncil.org/attachments/article/27/Annex%20XVII-%20Recommendations%20of%20the%20TRIPS%20workshop,%201-4%20March,%202011.pdf:

TRIPS Flexibilities

1. COMESA Secretariat in collaboration with other relevant organizations to assist Member States to implement the COMESA IPR Policy by developing/updating national IPR policies, laws and regulations by taking into account the use of flexibilities provided for in the TRIPS Agreement.
2. COMESA LDCs and WTO Members to use the flexibilities in the TRIPS Agreement by ensuring investment promotion and protection for local production of pharmaceuticals.
3. COMESA Member States that are negotiating accession to the WTO to ensure that they benefit from the TRIPS flexibilities on Public Health and access to life-saving medicines available to existing Members of the WTO in their category. COMESA Member States that are already Members of the WTO to support those applying for accession.
4. Member States to support the extension of the period of TRIPS flexibilities as long as production in the region remains at low levels and does not meet the demand of the majority of the population.

[5] This analysis is informed by UNDP, GOOD PRACTICE GUIDE: IMPROVING ACCESS TO TREATMENT BY UTILIZING PUBLIC HEALTH FLEXIBILITIES IN THE WTO TRIPS AGREEMENT (2010) (UNDP GOOD PRACTICE GUIDE); UNDP, USING LAW TO ACCELERATE TREATMENT ACCESS IN SOUTH AFRICA: AN ANALYSIS OF PATENT, COMPETITION, AND MEDICINES LAW (2013) [UNDP SA REVIEW]; Carlos Correa, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES (2000) (Correa, INTEGRATING PUBLIC HEALTH); Carlos Correa, GUIDELINES FOR THE EXAMINATION OF PHARMACEUTICAL PATENTS: DEVELOPING A PUBLIC HEALTH PERSPECTIVE, WHO-ICTSC-UNCTAD (2007) (Correa, GUIDELINES FOR EXAMINATION); Carlos Correa, INTELLECTUAL PROPERTY AND COMPETITION LAW: EXPLORING SOME ISSUES OF RELEVANCE TO DEVELOPING Countries (2007) (Correa, IP AND COMPETITION LAW; Carlos M. Correa, PHARMACEUTICAL INNOVATION, INCREMENTAL PATENTING AND COMPULSORY LICENSING, SOUTH CENTRE RESEARCH PAPER 41 (2011) (Correa, PHARMACEUTICAL INNOVATION); and on legislation and regulations from India, the Philippines, Argentina, and Zanzibar.

more rigorous standards of patentability and disclosure, including additional exclusions from patentability for new methods of using and new uses of existing medicines and required disclosures to include the best method for practicing the invention. However, the proposed Bill could still include even higher standards of patentability, more exceptions to exclusive patent rights, and strong pre- and post-grant opposition procedures. It could also make it easier to issue government use and compulsory licenses and broaden even further the grounds for doing. Finally, it should also ensure that utility models do not cover medicines or other medical technologies.

ANALYSIS OF KEY PROVISIONS

I. Exclusions from patentability

Article 47 of the Bill describes the meaning of inventions and excludes certain subject matter as non-patentable. Although Article 47 does not exclude patents on plants and animals, Article 52(a) does: "The following shall not be patentable: (a) plant varieties as provided for in the Seeds and Plant Varieties Act (Cap. 326), but not parts thereof or products of biotechnological process… ." Unfortunately this exclusion is incomplete in terms of what is permitted by Article 27.1 of the TRIPS Agreement in that it allows patents on animals and parts of plants, including presumably seeds, and it fails to exclude patents on genes and other isolates of naturally occurring substances. This later omission could block access to some gene-based medical technologies, particularly certain forms of diagnostic testing; it could also block access to medicines extracted from or duplicating naturally occurring substances. The EAC recommends that there be an explicit exclusion for "Natural substances including micro-organisms, even if purified or otherwise isolated from nature."[6]

Proposed Article 47(3)(e) is a very aggressive provision excluding patent protection for "public health related methods of use or uses of any molecule or other substances whatsoever used for the prevention or treatment of any disease which the Cabinet Secretary responsibility for matters relating to Health may designate as a serious health hazard or as a life-threatening disease." This important provision allows the Minister of Health to exclude patents on methods of use or uses of certain medicines entirely from patent protection on compelling public health grounds. Some authors have strenuously defended the TRIPS-compatibility of this provision.[7]

In addition to this exclusion, Kenya could make use of other public health exclusions like the ones used in Section 3(d) of the India Patents Act, "the

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[6] EAC REGIONAL IP POLICY, Policy Statement No. 3(a)(i), at 13.

[7] Robert Lewis-Lettington & Peter Munyi, WILLINGNESS AND ABILITY TO USE TRIPS FLEXIBILITIES: KENYA CASE STUDY, DFID: Health Systems Resource Centre Issues Paper (2004), http://www.who.int/hiv/amds/countries/ken_UseTRIPsFlexibilitiesDFID.pdf.

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 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. With respect to the new-form exclusion, Indian Supreme Court has interpreted enhanced efficacy to require proof of significantly increased therapeutic efficacy not simply better physical property or even increased bioavailability alone.[8] The EAC has recommended adoption of this exclusion.[9] Kenya could also adopt India-style exclusions on combinations and admixtures of know substances (see section 3(e) of the India Patents Act).

II. Standards of patentability

Article 48 defines standards of patentability in TRIPS-standard terms "An invention is patentable if it is new, involves and inventive step, is industrially applicable" but fortunately drops ill-advised patents on "new uses", a provision in the 2001 Act as amended. Granting patents on new uses of medicines is highly undesirable and is not required by TRIPS. Indeed, a new use is more in the nature of an idea than an actual new industrial application. The EAC has directly encouraged its Partner States to exclude patents on "new medical uses of known substances including micro-organisms … ."[10] However, by existing regulation and KIPI Examination Guidelines, new use patents are considered to be process patents,[11] so these provisions should be amended if the Bill is adopted.

Novelty: Subsection 49(1) has a standard definition of novelty: "An invention is new if it is not anticipated by prior art." Kenya appropriately adopts a global standard of novelty and includes disclosure that is written, oral, or by use, exhibition of other non-written means (subsection 49(2)) though it also has a twelve-month "grace" period (subsection 29(5)). Kenya also includes prior disclosed patent applications in its definition of prior art (subsection 49(4)). This standard is discussed at length in paragraph 6.31 of the Examination Guidelines, which clarifies that novelty determinations should not be based on combining separate items of prior art together but that

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[8] *Novartis AG v. Union of India and Ors*, paras. 180, 187 (2013).

[9] 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." EAC REGIONAL IP POLICY, Policy Statement No. 3(a)(iii), at 14.

[10] EAC REGIONAL IP POLICY, Policy Statement No. 3(a)(ii), at 14. For EAC Partner States seeking to consider new medical uses principally patentable as processes under the patentability criteria (like Kenya), the EAC further recommends that they "shall strictly apply the patentability requirements on a case-by-case basis." This author thinks it is superior to reject new use patents altogether as India has done.

[11] Legal Notice 50, THE INDUSTRIAL PROPERTY REGULATIONS, 2002, Section 36, http://www.wipo.int/wipolex/en/text.jsp?file_id=128385. *See* also Kenya Industrial Property Institute, GUIDELINE FOR THE EXAMINATION OF PATENTS, UTILITY MODELS, AND INDUSTRIAL DESIGNS [EXAMINATION GUIDELINES], para 6.22 (2007), http://www.wipo.int/edocs/lexdocs/laws/en/ke/ke018en.pdf.

the disclosure of prior art can be either explicit or implicit. Limiting prior art to a single source goes against the recommendation of the EAC, which recommends that EAC Members "Strictly apply the novelty standard through considering a wide concept of prior art …, including … information … derivable from a combination of publications."[12] In addition, Kenya could reject selection claims on Markush patent applications that cover a broad range of possible compounds.[13] Because the "selected" compounds are in fact already disclosed in the Markush claim, they can be excluded from patentability. Alternatively, Kenya could exclude Markush claims as be overly broad.

Inventive step: Inventive step is often the most important patentability criteria with respect to medicines and other health technologies. Section 50 of the proposed Bill says: "An invention shall be considered as involving an inventive step if, having regard to the prior art relevant to the application claiming the invention, it would not have been obvious to a person skilled in the art to which the invention pertains on the date of the filing of the application, or, if priority is claimed, on the priority date validly claimed in respect thereto." It is highly desirable to codify high standards for inventive steps. The Kenyan Examination Guidelines do incorporate relatively high standards by (1) acknowledging that with respect to "a person skilled in the art," "There may be instances where it is more appropriate to think in terms of a group of persons, e.g., a research or production team, than a single person" for example, with advance technologies involving complex chemical substances (Paragraph 6.33.2); (2) simple juxtaposition or aggregation of known features is not inventive (Paragraph 66.33.5); and (3) it is permissible to combine the disclosure of one or more documents, parts of documents or other pieces of prior art, to assess inventive step (Paragraph 6.33.11).

On the negative side, Kenya could assess inventive step by means of a higher standard – "a person (or groups of persons) highly skilled in the relevant art(s), including persons with some degree of imagination and intuition."[14] The EAC specifically recommends that inventive step be defined by reference to a person "highly" skilled in the arts.[15] This definition would acknowledge the special skills of true experts, the distributed nature of expertise in modern research ventures, and the growing interdisciplinary of research. The inventive stop standard could also be strengthened by more directly acknowledging that prior art can teach indirectly. In addition, there are several undesirable elements in Kenya's Examination Guidelines, namely consideration of long-felt need and commercial success (apparently borrowed

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[12] EAC REGIONAL IP POLICY, Policy Statement No. 2(a), at 13.

[13] "Markush claims are broadly drafted claims covering a family of a large number (sometimes millions) of possible compounds through the definition of a chemical structure with multiple functionally equivalent chemical entities allowed in one or more parts of the compound." Carlos M. Correa, TACKLING THE PROLIFERATION OF PATENTS: HOW TO AVOID UNDUE LIMITATIONS TO COMPETITION AND THE PUBLIC DOMAIN, South Centre Research Paper No. 52, at 4 (2014).

[14] Correa, GUIDELINES FOR THE EXAMINATION OF PHARMACEUTICAL PATENTS, at 4.

[15] EAC REGIONAL IP POLICY, Policy Statement No. 2(b), at 13.

from U.S. law) and the granting of selection patents, which merely serve to extend patent life for previously disclosed substances.

Industrial applicability: Section 51 of the Bill states that "an invention shall be considered industrially applicable, if, according to its nature, it can be made or used in any kind of industry, including agriculture, medicines, fishery and other services." This definition is stronger that the concept of usefulness or utility adopted by some countries. One reason to adopt high standards of industrial applicability is to ensure that patents are not granted on abstract ideas that not concretized in actual technological activity. Another reason is 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 practice use for a claimed invention. Kenya's definition of industrial applicability is relatively strong, but it could be further strengthened by adopting the recommendation of the EAC that "the patentability of research tools [be limited] to only those for which a specific use has been identified."[16]

III. Disclosures

Best mode: The TRIPS Agreement allows countries a great deal of flexibility with respect to required disclosures. Article 29.1 states that the applicant may be required "to indicate the best mode for carrying out the invention known to the inventor." As an improvement to the 2001 Industrial Property Act, the proposed Bill, Section 34(5), requires that the description of the invention in an application for a patent shall "disclose the invention and the best mode for carrying out the invention in such full, clear, concise and exact terms as to enable a person skilled in the art to make use and to evaluated the invention … ." An even better requirement, would compel disclosure of all known modes for carrying out the invention, including identification of the best mode, as recommended by the EAC.[17] The failure to disclose "the best method for performing the invention known to the owner of the patent at the time when the specification was lodged at the Institute" is one of the listed grounds for revoking or invalidating a patent in Section 129(3)(g) of the Bill.

Material prior art: The proposed Bill does not currently require the patent applicant to disclose known 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 relevant prior art. In an effort to ensure that all relevant prior art is available

[16] EAC REGIONAL IP POLICY, Policy Statement No. 2(c), at 13.
[17] EAC REGIONAL IP POLICY, Policy Statement No. 7(a), at 17.

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.

Disclosure of origin: The proposed Bill does not require disclosure of the origin of inventions derived from indigenous biological resources, genetic resources, or traditional knowledge or use, nor does it require disclosure of means for benefit sharing with respect to the same. Such a disclosure requirement is permissible under TRIPS[18] and has been adopted for example in South Africa[19]. Such a provision reduces biopiracy and misappropriation of traditional knowledge.

Foreign applications: Article 29.2 of the TRIPS Agreement allows Member States to require disclosure of foreign patent applications for the same invention and to keep the Member State appraised of subsequent grants, denials, suspensions, and invalidations. Instead of requiring such disclosure, Section 64(1) of the proposed Bill merely allows the Managing Office to request such information. It would be preferable if these disclosures were mandatory.

International non-proprietary name: Finally, as recently had been proposed in India and as is recommended by the EAC, Kenya could require that the patent applicant include the international non-proprietary name for any pharmaceutical-related invention.[20] This would make it much easier to focus examinations of pharmaceutical patents, particularly with respect to weak secondary, evergreening patent applications.

Consequences of non-disclosure – revocation: At present, the consequences of not disclosing required content under Section 129 of the Bill is limited to inadequate description of the claim or failure to disclose the best known method of performing the invention, and misrepresentation (Section 129(3)(f), (g) and (h)). If the additional recommended disclosures discussed above are added, failure to provide these disclosures should also result in revocation.

IV. Limitations and Exceptions

Article 30 of the TRIPS Agreement allows for limited exceptions to patent rights so long as they "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

[18] Carlos Correa & Joshua D. Sarnoff, ANALYSIS OF OPTIONS FOR IMPLEMENTING DISCLOSURE OF ORIGIN REQUIREMENTS IN INTELLECTUAL PROPERTY APPLICATIONS, 24 (UNCTAD, 2006).
[19] South Africa Patents Act, sections 3A and 61(g).
[20] EAC REGIONAL IP POLICY, Policy Statement No. 7(b), at 17.

parties." Some of the most important limited exceptions affecting access to medicines and other health technologies that Kenya should adopt are discussed below.

Prior use: Section 82 of the Bill provides a limited exception to patent rights for "prior users" who in good faith had used the invention or was making effective and serious preparations for such use. This provision might rarely apply in the pharmaceutical context, but it might at least on occasion and thus it is a good provision to have in effect and is quite consistent with state practice elsewhere.

Research exception: Article 84(1) of the Bill creates a limited exception for non-commercial or non-industrial scientific research. This formulation does not make full use of the flexibility allows by Article 30 of the TRIPS Agreement. According to WIPO research, many countries have adopted a much broader research and education exception that allows both commercial and non-commercial research "on or with" the patented product or process and likewise allows for education use as well. The EAC directly recommends such an approach.[21] Allowing commercial research facilitates the process of incremental innovation that might lead to commercialization, including the commercialization of dependent technologies. Allowing research with as well as on the patented subject matter allows the researcher to use patented upstream research platforms without being bogged down in license negotiations. In this regard, the EAC recommends that EAC Partner States patent law "Provide a right to claim a non-exclusive licence for the use of patented research tools against the payment of compensation."[22] This right could be automatic.

Early working/Bolar exception: Kenya has an early working/Bolar exception in Section 80(2) of the Bill.[23] However, Kenya's Bolar provision is limited in two ways that could be improved. First, it would seem to allow working the patent for the purpose of registration only within Kenya. Second, the exception would seem to be valid only when the registrant confirms that it will not commercialize the registered product until after patent expiration. TRIPS Article 30 allows research activities and product development reasonably related to the purpose of registering or obtaining required marketing approvals for pharmaceuticals and other medical products. For example, the early working exception allows a producer of medicines to reverse engineer a medicine, to conduct stability, bioequivalence and other required tests, to develop proof of manufacturing according to Good Manufacturing Practice, and thereafter to submit the compiled data to national drug regulatory authorities for the purpose of obtaining marketing

[21] EAC REGIONAL IP POLICY, Policy Statement No. 4(a), at 15. The EAC notes that "The preponderant purpose of commercial research must be the generation of new knowledge of the patented subject."
[22] EAC REGIONAL IP POLICY, Policy Statement No. 4(b), at 15.
[23] "The rights conferred on the owner of the patent under this section shall not apply to acts by third parties necessary to obtain approval or registration of a product from the Institute, for the purpose of commercialising the product after expiry of the patent."

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. Similarly, if the generic entrant believes that a granted patent on the medicine is invalid, as a result of a TRIPS-compliant, but best-practice early working exception, the registrant can immediately enter the market even before patent expiration. It is important to note that early working rules can and should allow the use of the patent product or process with respect to both domestic and foreign registration. This would, for example, facilitate a local producer being able to expand into regional and foreign markets more quickly. The EAC firmly recommends the adoption of a broad Bolar exception.[24]

Parallel importation: Article 84(2) of the Bill states: "The rights under the patent shall 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 by the owner of the patent or with his express consent." This is a very significant amendment to the provisions of the 2001 Act, which not include the phrase "by the owner of the patent or with his express consent." The earlier provision has a very conflicted history whereby it was initially adopted, subsequently repealed surreptitiously and then later reinstated.[25] That provision had been further clarified by Clause 37 of the Industrial Property Regulations of 2002, which provides that: "The limitations of rights under a patent in section 58(2) of the Act extends to acts in respect of articles that are imported from a country where the articles were legitimately put on the market." The impact of this version of the international exhaustion rule, recommended by Professor Carlos Correa[26] and by the EAC[27], is quite profound. It meant that Kenya will not only be allowed to parallel import any medicines sold by the originator/patent holder in another country or with its consent, if it is cost advantageous to do so, it will also be allowed to import products sold by voluntary or compulsory licensees.

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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;
>
> b. Clarify the scope of the marketing approval/'Bolar' exception to the effect that generic producers may use patented substances for acts 'reasonably related' to the development and submission of information required for marketing approvals."

EAC REGIONAL IP POLICY, Policy Statement No. 5, p. 15-16.

[25] The amendment that was inexplicably incorporated into the law would have been the more common international exhaustion rule that would have added the phrase "by the owner of the patent or with his express consent." This would have resulted in a much less robust parallel importation rule that would have prevented, for example, importation of medicines produced pursuant to a properly issued compulsory license. For a brief history of this provision, *see* Lewis-Lettington & Munyi, at 17-20.

[26] *See* Correa, INTEGRATING PUBLIC HEALTH, at 79-80 (admitting that such a rule might be subject to WTO challenge).

[27] EAC REGIONAL IP POLICY, at 18.

For reasons that are unclear, the proposed Bill has adopted the more common, but less permissive international exhaustion/parallel importation rule, which will therefore require an amendment to the Industrial Property Regulations of 2002. Although this statutory and regulatory change would eliminate the risk of a TRIPS compliance challenge, it also means that Kenya will have fewer options to import generic equivalents lawfully produced abroad. Accordingly, it might need to increase its use of compulsory or government use licenses to overcome patent barriers to source medicines. Unfortunately, foreign compulsory licensees do not have untrammeled rights to export wherever they want. Article 31(f) of the TRIPS Agreement still places restrictions on the export of medicines produced pursuant to a compulsory license, limiting such exports to non-predominant quantities except with respect to competition-based licenses (see Article 31(k)). Similarly, parallel exportation/importation will not work automatically with respect to export licenses granted under the August 30 Decision waiver mechanism because of requirements about notification and the requirement of a compulsory license in the importing country if a local patent is in effect therein.

Other Exceptions: Section 84(3) of the proposed Bill confirms an exception for the use of patented articles in aircrafts, land vehicles or vessels of other countries temporarily in the airspace, territory or waters of Kenya. Section 84(5) clarifies that compulsory licenses for reasons of public interest or based on interdependence of patents and by the provisions on State exploitation of patented inventions are exceptions to patent protections. Finally, Section 84(6) states that patent rights "shall not extend to variants or mutants of living forms or replicable living matter that is distinctively different from the original for which patents were obtained where such mutual or variant are deserving of separate patents."

V. Required Patent Examinations

Section 70(3) of the proposed Bill would amend 44(1)(a) of the 2001 Act to require examination of patent applications.

VI. Pre- and Post-Grant Oppositions

Post-grant: Kenya's proposed Bill adopts a form of post-grant opposition in Section 129(1) of the Bill, which provides that "An interested person may institute proceedings against the owner of a patent or a registered utility model or industrial design request[ing] the Tribunal to revoke or invalidate the [same]." The Bill removes a nine-months limitation requirement in the 2001 Act. This recourse to administrative proceedings is far superior to more costly and time-consuming judicial resolution, especially where the Tribunal can develop IP expertise over time.

Pre-grant: Unfortunately, Kenya makes no similar provision for pre-grant opposition, though allowing such procedures is somewhat impractical under current ARIPO procedures, which require notification of non-

acceptance within six months of the grant of an ARIPO patent. Nonetheless, Kenya could adopt pre-grant opposition procedures and bypass ARIPO strictures and timelines by automatically denying pharmaceutical (or other) patents when a pre-grant opposition has been filed. This would provide the KIPI with plenty of time to carefully consider opposition evidence and arguments.

Low- and middle-income countries frequently face critical capacity constraints when examining patent applications, especially in highly technical fields of technology. If patent examiners are undertrained or overburdened or if they lack access to prior art databases and other labor saving information technologies, then the predictable outcome is patents of poor quality – unwarranted patents that nonetheless grant exclusive rights and prevent competition. To help alleviate the problem of over-stretched patent offices and to ensure consideration of all relevant prior art and the correct application of patent eligibility and disclosure standards, multiple countries, developed and developing, have allowed pre-grant opposition procedures that allow presentation of both evidence and legal arguments. The EAC has recommended that its Partner States provide "for effective pre- and post-grant administrative patent application procedures" and that they should further, as ARIPO Members, discuss an amendment to the Harare Protocol "to take account of third party oppositions" and to allow a longer time within which to file written approval of ARIPO granted patents.[28]

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 and failure to make required disclosures;
- Opponents should be given full legal standing and they should be able to appear at a hearing in support of their opposition if such hearings are provided for;
- The pre-grant opposition procedure should allow simple and expedited administrative procedures.

[28] EAC REGIONAL IP POLICY, *supra* note 5, Policy Statement No. 8.

VII. Compulsory licenses and government use

Compulsory licenses: As clarified by the Doha Declaration, WTO Members have complete freedom to determine the grounds upon which compulsory licenses may be granted. There are no disease restrictions, country-status restrictions, or field of technology restrictions. The Paris Convention[29] does place some limits on the timing of compulsory licenses for non-working, but otherwise countries have near total discretion to define permitted grounds for issuing compulsory licenses. As a general rule, countries are far better off articulating multiple and broad grounds for compulsory licenses instead of restricted grounds.[30] After all, a patent is a sovereign grant of exclusive, i.e., monopoly, rights and the patentee takes such rights with full notice of possibility that the granting government might issue compulsory and government-use licenses. 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.

Kenya's proposed IP Bill regulates the granting of compulsory licenses in sections 97-78 of the Bill. Sections 97 and 98 provide regrettably limited grounds for granting a patent, that must be improved. Section 97(1) provides for compulsory licenses when the patented invention "is not being supplied on reasonable terms to Kenya," but the applicant must wait four years from the date of application or three years from the grant of the patent, whichever is later, before seeking a compulsory license. This waiting period is enacted in part to comply with Article 5A(4) of the Paris Convention for the Protection of Industrial Property, which technically applies only in the case of failure to work or insufficient working. However, the Kenyan provision is broader by virtue of requiring supply on reasonable terms, but it also needlessly requires an over-long waiting period whenever the patented invention is not being supplied on reasonable terms even though it is being worked in Kenya, e.g., when prices are excessive, where there are refusals to license, etc. Section 98(1) of the Bill is also unnecessarily limited in that it applies only to the granting of dependent patents – patents needed to work a

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[29] Paris Convention for the Protection of Industrial Property (1883 as amended through 1979), 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.

[30] 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 licenses: 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).

new invention that constitutes an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent. This dependent-patent exception is directly authorized by TRIPS Article 31(l). However, there is nothing in TRIPS that prohibits a compulsory license for the working of a dependent technology even if that technology is not patented.

The permissible grounds for compulsory licensing in Kenya is capable of broad interpretation, but could still be improved. As stated above, the Doha Declaration reaffirms that countries are free to determine the grounds upon which licenses might be granted.[31] This freedom further emphasized by the EAC.[32] Common grounds include unreasonable pricing, emergencies and matters of extreme urgency, and refusals to license. However, it is highly desirable to list addition 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. Indeed, although this proposition is not without some controversy,[33] there is scope under Article 31 of the TRIPS Agreement to permit compulsory licenses for failure to work the patented invention locally within Kenya by manufacturing or using the process in Kenya,[34] much as both Brazil and India have done. The Paris Convention in Article 5A(2) directly authorizes countries of the Union to provide for compulsory licenses in case of failure by the patentee to work the patent locally (e.g. to produce locally, rather than merely import). Such a provision as this would certainly be a boon to local and regional production of medicines.

Similarly, Kenya should provide for competition-based compulsory licenses as recommended by the EAC.[35] It has done so with respect to government use licenses (Section 105(1)(b)), but it could also do so for revised Section 97 licenses. If it does so, it should take advantage of additional flexibilities removing the requirement of prior negotiation and limits of quantities exported (TRIPS Article 31(k)). In order to speed up its access to medicines even in the pre-grant stage where a pending patent can operated as a de facto patent in terms of deterring competition, Kenya should provide for tentative or provisional compulsory licenses on medicines with pending patents and when denied patents are under appeal. These licenses

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[31] Doha Declaration, 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."
[32] EAC REGIONAL IP POLICY, Policy Statement No. 10(a), at 20.
[33] 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.
[34] 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 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).
[35] EAC REGIONAL IP POLICY, Policy Statement No. 11(b), at 21.

could be royalty free with a catch-up payment if the patent is ultimately granted. Finally, Kenya could take the bold step of allowing compulsory licenses for know-how. In many instances, a patent can best be operationalized only via access to otherwise trade-secret know-how. Based on additional compensation a license could be imposed granting involuntary access to the same.[36]

Kenya has comprehensively incorporated the required procedures of the TRIPS compulsory licenses in the proposed Bill. Nonetheless, there are other elements of the compulsory licensing regime that could be improved. For example, Kenya should directly reference the right to supply a compulsory license via importation. With a wise amendment to the 2001 Act, Kenya has explicitly waived the requirement for prior negotiation in cases of national emergency or other circumstances of extreme urgency regardless of whether the license is premised initially on non-working under section 99(2) of the proposed Bill as recommended by the EAC.[37] To speed up the issuance of compulsory licenses it could specify the minimum time period for prior negotiation for a voluntary license on commercially reasonable terms, e.g., the 90-days only recommended by the EAC.[38] Kenya could also follow the best practice recommendation that it set remuneration guidelines to simplify the determination of adequate remuneration.[39] In this regard, the EAC has recommended that Partner States shall "include in their patent laws a provision statement 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."[40]

Article 31bis licenses: A fundamental flaw in the Article 31(f) of the TRIPS Agreement is that it limits exportation of goods produced pursuant to a compulsory licenses to non-predominate quantities. This provision creates a serious disadvantage for countries that have insufficient capacity to manufacturer 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 license to a foreign company, but, if there were also an applicable patent in the country of production/export, then a compulsory license 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 "predominately for domestic use" rule.

The drafters of the Doha Declaration recognized this dilemma and instructed the WTO to devise an expeditious decision in paragraph 6 of the

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[36] Max Planck Institute, DECLARATION ON PATENT PROTECTION: REGULATORY SOVEREIGNTY UNDER TRIPS, at 11 (2014), available at http://www.mpg.de/8133454/Patent-Declaration1.pdf.
[37] EAC REGIONAL IP POLICY, Policy Statement No. 10(g), at 20.
[38] EAC REGIONAL IP POLICY, Policy Statement No. 10(f), at 20.
[39] *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.
[40] EAC REGIONAL IP POLICY, Policy Statement No. 10(e), at 20.

Declaration. Belatedly, on 30 August 2003 the WTO General Council issued a decision declaring a waiver from Article 31(f), the so-called Paragraph 6 Decision.[41] After long delays, the TRIPS Agreement is now amended to add Article 31bis now codifying the earlier Decision. Unfortunately, Article 31bis imposes considerable procedural requirements on both importing and exporting countries issuing compulsory licenses and further restricts the quantity of pharmaceutical products that might be exported. These procedural requirements have been called "labyrinth"[42] and as being "neither expeditious, nor a solution."[43] Nonetheless, Kenya should amend its compulsory licensing regime to allow use of Article 31bis as both an importing and exporting country. The EAC has certainly recommended that Partner States do so.[44] In doing so, it should follow innovative suggestions for simplifying domestic implementation of the Article 31bis, including a so-called one-license solution that was proposed in Canada but allowed to lapse in Parliament.[45]

Government use: Kenya has adopted a much more progressive grounds allowing for government use. The grounds articulated in Section 105(1)(a) are quite broad, including the "public interest" generally and more particularly "national security, nutrition, health, environmental conservation, or the development of any other vital sector of the national economy." Section 105(1)(b) also allows government use licenses where the Director General determines that the manner of exploiting the patent is not competitive. The government use can be ordered "by the Cabinet Secretary" and shall allow exploitation of the protected invention by a Government Ministry, Department, agency or other person (Section 105(1)). The Procedures for issuing a government-use order are clarified in Regulation 43 of the Industrial Property Regulations, namely a request that the Minister act.

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[41] 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. At present, less than half of all WTO members had ratified the amendment. http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

[42] 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).

[43] Medecins Sans Frontieres Canada, NEITHER EXPEDITIOUS, NOR A SOLUTION: THE WTO AUGUST 30 DECISION IS UNWORKABLE, 2 (2006).

[44] EAC REGIONAL IP POLICY, *supra* note 5, Policy Statement No. 10(b)-(d), at 20.

[45] 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.

Government use explicitly allows for satisfaction by importation as well as by local production (Section 105(2)). There are conflicting provisions on adequate remuneration. Subsections 105(1) and (8) require adequate compensation whereas Subsections 105(3) and (4) do not require payment of compensation, which would run afoul of the adequate remuneration requirements of Article 31 of the TRIPS Agreement.

The Bill could be improved if it clarified that the Department could act *sua sponte* to allow use by or for the government. The United States has an extremely liberal government use provision requiring no formalities whatsoever. Section 105 of the Bill requires prior negotiation with the patent owner for a contractual license except in the case of national emergency or other extreme urgency. The requirement of prior negotiations for government use license is clearly TRIPS-plus and should be rejected. Governments are not required by TRIPS Article 31 to consult with patent owners for public, non-commercial use let alone try to negotiate a contractual license allowing government use. Likewise, the Bill fails to provide for remuneration guidelines, as discussed above, and it fails to exclude injunctive relief as a remedy with respect to government use licenses as recommended by the EAC.[46] Finally, it would be preferable if Section 105 more directly referenced that the government use were for "public, non-commercial use" as specified in Article 31 of the TRIPS Agreement.

VIII. Regulation of contractual licenses:

WTO Member States are fully empowered under international law to closely regulate the terms of intellectual property licenses to prevent anticompetitive terms. TRIPS Article 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.[47] The East Africa Community directs its Partner States

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[46] EAC REGIONAL IP POLICY, Policy Statement No. 10(h), at 20.

[47] TRIPS Article 40:

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

to prevent anti-competitive behavior and to list licensing terms that may be considered unjustified restrictions on competition and authorize patent registrars to refuse to register such licensing contracts.[48]

Kenya has adopted extensive rules regulating contractual licenses in Sections 90-96 of the Bill. Contractual terms prohibited are listed in Section 94 of the Bill. Section 94's general prohibition is against clauses that impose unjustified restriction on the licensee with the consequence that the contract, taken as a whole, is harmful to the economic interest of Kenya, if those clauses also require, among others: (i) importation of technologies obtainable on the same terms within Kenya, (ii) disproportion prices or royalties compared to the value of the technology, (iii) acquisition of materials from the licensor or other limited source other than to ensure quality, (iv) limits on eligible buyers, (v) grant back rights without consideration, (vi) volume limitation and exports prohibitions, (vii) prohibitions on use of other technologies, (viii) fixed prices, (ix) waivers of liability, (x) restricted use after the expiration of the contract, (xi) choice of non-Kenya law, (xii) unreasonably long periods, (xiii) non-adaptation to local conditions, (xiv) mandatory tie-ins or requirements to accept additional technologies and future improvements, and/or many other prohibited conditions including royalties on patents outside of Kenya (double royalties). At this point, it would be better for Kenya to actually enforce its supervision of contractual licenses rather than to seek amendment to its current comprehensive rules.

IX. Enforcement

Injunctions: In terms of enforcing patent rights, Section 81(1)(a) of the Bill allows patent holders to obtain injunctions to restrain patent infringement and Section 132(a) states that the Tribunal "shall grant … an injunction to prevent infringement where infringement is imminent or to prohibit the continuation of the infringement, once infringement has started," whereas Article 44 of the TRIPS Agreement allows countries freedom to allow compensation only – essentially a judicially issued license.[49] Such an allowance has been used in the United States[50] and in India[51].

Provisional Protection: Section 77 the Bill grants TRIPS plus rights to claim compensation for offending acts during the pendency of the application

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[48] EAC REGIONAL IP POLICY, Policy Statement No. 11(a), at 20-21.

[49] The legality of such a limitation on injunctive and provisional relief under TRIPS is clarified by Article 44.2 of the TRIPS Agreement, "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)."

[50] *eBay, Inc., v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

[51] *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 v. Aventis Pharma*; *Aventis Pharma SA v. Cipla Life Sciences* [2012] ZASCA 108 (26 July 2012).

for a patent, if the application has been published in English under the Patent Cooperation Treaty or if the offender received written notice in English about the published application. This provision requires compensation even with respect to a patent application that is subsequently denied with no subsequent recourse against the unsuccessful patent applicant. This provision is TRIPS-plus and should be rejected. Section 81 of the Bill also allows compensation for infringement following publication of an application, as if the patent had been granted where the alleged infringer had actual knowledge that the invention he was using was the subject matter of a published application or he had received written notice of the same.

Criminal enforcement: In addition to unnecessarily requiring injunctions, the Bill in Section 135 undesirably provides for criminal sanctions for intention violations of patents, utility models, or industrial designs, including up to five years of imprisonment. The TRIPS Agreement does not require criminal enforcement of IP rights, except in the narrow context of criminal trademark infringement and copyright piracy on a commercial scale.[52] Whether a patent right is violated by a particular act is often a question of refined judicial interpretation. Producers of alleged patent infringing products might well assume that their acts will not be infringing, they may be ignorant of the patent claim in issue, or they may sincerely believe that the asserted patent is invalid and that they would win any infringement case. In the face of inherent uncertainty about patent validity and enforceability and in light of the negative impact of criminal sanctions on innovation activity, it is simply inappropriate to impose criminal liability on a party for infringing a patent,[53] especially because other remedies are available including damages and in extraordinary cases injunctive relief. This provision should be rejected.

X. Utility Models

Utility models are essentially lesser patents on minor innovations that fall short of meeting patentability criteria, usually novelty or inventive step. In addition to having lesser standards, utility model systems, including Kenya's, typically do not require substantive examination of the merits of the application.[54] Under Article 107(1) of its Bill, Kenya legislates that "An invention qualifies for a utility model certificate if it is new and industrially applicable." This Review concludes that Kenya should deny utility models

[52] Article 61.

[53] *See*, Irina C. Manta, *The Puzzle of Criminal Sanctions for Intellectual Property Infringement*, 24 HARVARD J. LAW & TECH. 469-518 (2011); Christopher Buccafusco & Jonathan S. Masur, *Innovation and Incarceration: An Economic Analysis of Criminal Intellectual Property*, 87 S. CAL. L. REV. 275-334 (2014) ("According to our analysis, there is a limited and tentative case for the use of criminal liability, including imprisonment and alternative sanctions, for only some types of copyright infringement—and none at all for patent infringement"); Max Planck Institute, DECLARATION ON PATENT PROTECTION, at 12.

[54] Uma Suthersanen, UTILITY MODELS AND INNOVATION IN DEVELOPING COUNTRIES, UNCTAD-ICTSD (2006); Draft Amended Patents Act, Article 101.

on pharmaceuticals.[55] The vast majority of utility models on pharmaceuticals, including biodiversity-based and traditional-knowledge-based medicines, are likely be filed by foreign pharmaceutical companies. Accordingly, utility models based on minor variations in formulations, dosages, or chemical form, instead of aiding local pharmaceutical manufacture, would serve instead primarily to delay generic competition and to raise the cost of needed medicines. Because the TRIPS Agreement does not require utility models, it is possible to distinguish between fields of technologies therein. Although the EAC does not go so far as to recommend that there not be any protection for small-scale innovations, it suggests that the protection be in the form of a right to compensation rather than via exclusive rights.[56]

CONCLUSION

Although there are many positive elements in patent sections of the proposed Intellectual Property Bill, 2020, there are many additional TRIPS-compliant provisions that should be included. There is little point in recodifying existing law, only to fall short in adopting provisions that can go as far as legally permissible to ensure increased access to affordable health products in Kenya, especially as it faces the COVID-19 pandemic. The recommended additions and changes are neither radical nor controversial. They are common sense adjustments that will help conserve public and private resources while limiting or curtailing excessive monopoly control by multinational biopharmaceutical companies over life-saving medicines.

[55] "The utility model law should comprise a detailed list of excluded subject matter which must mirror the exclusions under the patent law. Moreover, it is worth considering excluding some types of invention as dictated by public policy such as chemicals or pharmaceuticals or biological material or substances or processes." Suthersanen, at 38. Japan, Korea, and Italy among others exclude utility models on chemical compositions and/or pharmaceuticals directly.

[56] EAC REGIONAL IP POLICY, Policy Statement No. 3(b), at 14.