Statement on Anti-evergreening Provisions in the Patent Laws of Asian Countries

Members of the VIPP (Visionary Intellectual Property Professors for the Betterment of IP Study and Regimes in Asia) Initiative,

Observing that although countries have various multilateral, regional and bilateral trade arrangements for the granting and enforcement of patents, there are no arrangements on anti-evergreening provisions in the patent laws of Asian countries,

Recognising that the practice referred to as evergreening, which includes extending the effective term of protection for a drug by filing secondary patents over minor improvements, or extending patent protection over matters already in the public domain, has a negative effect on access to medicines and promoting innovation,

Affirming that countries have a choice in regulating the granting of secondary patents for pharmaceuticals by incorporating special provisions to check evergreening practices or by utilising the inventive step (non-obviousness) standard,

Understanding that secondary patents in the field of pharmaceuticals would mean higher costs for treatment and health care and greater barriers to entry for competitors,

Acknowledging that some countries have incorporated special provisions to check

evergreening practices for pharmaceuticals by way of amending their patent laws, while others have introduced guidelines,

Emphasising that states in Asia have a choice of absolutely barring patents for minor improvements in the field of pharmaceuticals or of imposing conditions on the granting of patents for such improvements,

Accepting that members of the World Trade Organisation have agreed to offer patents in all fields of technology without discrimination as to the field of technology and that offering different levels of protection for improvements is within the prerogative of the countries,

Stressing the importance of implementing and interpreting the TRIPS Agreement in a way that supports public health and in particular promotes access to medicines for all as agreed in the Declaration on the TRIPS Agreement and Public Health (Doha Declaration[1]),

Desiring to provide favourable considerations, in pursuit of accessibility and affordability of pharmaceuticals, to states in Asia while fulfilling the obligations imposed by trade agreements and determining the goals of the intellectual property protection for pharmaceuticals,

Make the following statement to Asian Countries:

[1] Point 4 of the Doha Declaration.

General Principles

Article 8 of the TRIPS Agreement states that members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Article 27 of the TRIPS Agreement states that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application and that patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

Article 27 also allows members to exclude from patentability certain types of inventions and may provide for an effective sui generis system for the matter excluded.

Differentiation in Implementation in Asia

With regard to anti-evergreening provisions, Asian countries exhibit a wide variance in their implementation due to the absence of an international treaty and the TRIPS Agreement's silence on the same.

Some countries have implemented anti-evergreening provisions by both amending their intellectual property laws[2] and

[2] See, for example, the Philippines, sections 5 and 6, Republic Act No. 9502, an Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic Act No. 8293 or the Intellectual Property Code, Republic Act No. 6675 or the Generics Act of 1988, and the Republic Act No. 5921 or the Pharmacy Law, and for other Purposes https://www.doh.gov.ph/sites/default/files/policies_and_laws/RA9502.pdf (last visited Oct 16, 2018).

introducing Examination Guidelines for patent examiners.[3]

Other countries have implemented anti-evergreening provisions solely by amending their intellectual property laws.[4]

Certain countries have implemented anti-evergreening provisions solely by introducing Examination Guidelines for patent examiners.[5]

The different implementation manners, whether by amendment to existing laws or by guidelines for examiners, may affect the efficiency of such measures.

Factors Affecting Implementation

States in Asia might needs varying levels of patent protection for pharmaceuticals, to realise the policy goal of accessibility and affordability of pharmaceuticals.

Legal capabilities of the local legal system will have a bearing on the implementation of anti-evergreening provisions.

Technical absorptive capacity of the country, including knowledge of basic skills, scientific developments in the field, and executive and judicial measures will also impact the implementation of anti-evergreening provisions.

[3] See, for example, Philippines. Examination Guidelines for pharmaceutical patent applications involving known substances http://www.ipophil.gov.ph/images/Patents/IRRs/QUAMA_EXAMINATION_GUIDELINES_OFFICIALCOPY.pdf (last visited Oct 16, 2018).

[4] See, for example, section 3(d) of the Patents Act, 1970 (India).

[5] See, for example, Thailand. Examination Guidelines for Chemical and Pharmaceutical Patents, 2013 https://www.tilleke.com/sites/default/files/2016_Mar_%20Manual_of_Industrial_Property_Thailand.pdf

Standard of Patentability

With regard to the standard of patentability, Article 27 of the TRIPS Agreement does not detail the standards of novelty, inventive step (non-obviousness) and utility.

Members of the WTO may exclude from patentability inventions, the prevention of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health, or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their laws.[6]

Members of the WTO may also exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals.[7]

Some Members of the WTO have excluded from patentability inventions showing minor improvements over existing pharmaceutical inventions.[8]

On the basis that both original and generic drugs are indispensable to maintaining

[6] Article 27.2 of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

[7] Article 27.3 of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

[8] See, for example, section 3(d) of the Indian Patents Act, 1970 which reads:

3. What are not inventions. -The following are not inventions within the meaning of this Act,-

(d) 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. -For the purposes of this clause, 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.

accessibility and affordability of pharmaceuticals, states in Asia generally should take advantage of the flexibilities in the TRIPS Agreement[9] to determine criteria for patentability, and the types of protection for pharmaceuticals based on their standards of innovation.

Different Types of Anti-evergreening Provisions

Anti-evergreening provisions, which introduce restrictions on procuring patents, including secondary patents, over pharmaceutical inventions, may be of different types:

1. Restriction with regard to patenting new forms of known substances.[10]
2. Restriction with regard to patenting new uses or properties of a known substance.[11]
3. Restriction with regard to patenting uses of a known process, machine or apparatus.[12]
4. Restriction with regard to patenting combinations of known substances

[9] Declaration on Patent Protection – Regulatory Sovereignty under TRIPS (available at https://www.mpg.de/8132986/Patent-Declaration.pdf) and the Statement on Intellectual Property Protection for Pharmaceuticals and the Market Approval Mechanisms in Asia (available at https://arciala.smu.edu.sg/vipp-statement)

[10] See, for example, the first part of section 3(d) of the Indian Patents Act, 1970. Section 3(d) has three parts. The first part of section 3(d) stipulates that the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of the known substance cannot be granted a patent. Thus, in order to patent new forms or derivatives of known substance, the applicant should show improved efficacy by submitting substantive relevant data. The explanation to section 3(d) further makes it clear that the new form and the known substance should differ significantly with regard to efficacy, i.e., the efficacy of the known substance should be significantly different from the efficacy of the new form of the known substance. The second part of section 3(d) states that the mere discovery of any new property or new use for a known substance is not patentable. The third part of section 3(d) states that 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, shall not be a subject matter of a patent. The first and the third parts are conditional exceptions to patentability, and the applicant can overcome the objections raised by fulfilling the requirements mentioned under each part. For instance, the applicant can show enhancement of "efficacy" or use of a "new reactant" to get over the bar in those provisions, hence they are conditional exceptions. Compared to the first and third part, the second part is an absolute exception, as it cannot be overcome under any circumstances.

[11] See, for example, the second part of section 3(d) of the Indian Patents Act, 1970.

[12] See, for example, the third part of section 3(d) of the Indian Patents Act, 1970.

resulting only in the aggregation of properties of their components.[13]

5. Restriction on patenting methods of treatment.[14]

6. Restriction on patenting invention based on traditional knowledge in medicines.[15]

New Forms of Known Substances

Countries may exclude from patentability new forms of known substances, as they are deemed to be minor improvements over known substances.

Countries have a choice of granting patents for new forms of known substances which demonstrate enhanced efficacy over the earlier known efficacy of the substance in cases where the applicants are able to show advancement in the form of increased efficacy. [16]

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[13] See, for example, section 3(e) of the Indian Patents Act, 1970 which reads:

3. What are not inventions. -The following are not inventions within the meaning of this Act,-

(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance.

[14] See, for example, section 3(i) of the Indian Patents Act, 1970 which reads:

3. What are not inventions. -The following are not inventions within the meaning of this Act,-

(i) any process for the medical, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

[15] See, for example, section 3(p) of the Indian Patents Act, 1970 which reads:

3. What are not inventions. -The following are not inventions within the meaning of this Act,-

(p) an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

[16] Section 3(d) of the Indian Patents Act, 1970. The Philippines was the first country to do so, when the Cheaper Medicines Act, 2007 amended the country's Intellectual Property Code. Sections 5 and 6, Republic Act No. 9502, An Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic Act No. 8293 or the Intellectual Property Code, Republic Act No. 6675 or the Generics Act of 1988, and the Republic Act No. 5921 or the Pharmacy Law, and for other Purposes. https://www.doh.gov.ph/sites/default/files/policies_and_laws/RA9502.pdf (last visited Oct 16, 2018). The

	Countries may also choose to have an absolute bar on patenting new forms of known substances.[17]
New Use of Known Substance	Countries may exclude from patentability new uses of known substances, such as a second medical use, on the ground that the grant of patent for the first time covers all uses.
New Use of Known Process	Countries may exclude from patentability new use of a known process, unless such process results in a new product or employs a new reactant.
Combination of Known Substances	Countries may exclude from patentability combination of known substances as the level of improvement deemed to be a minor one when known substances are combined.[18]
Method of Treatment	Countries may exclude from patentability methods of medical treatment.
Traditional Knowledge	Countries may exclude from patentability inventions based on traditional knowledge in medicines.

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Philippines also introduced Examination Guidelines for pharmaceutical patent applications involving known substances, which clearly show that it is inspired by section 3(d) of the Indian Patents Act.

[17] Like India, Argentina had introduced provisions to bar the patentability of new forms of known substances by incorporating a provision into its guidelines for examination of patent applications of pharmaceutical and chemical inventions. In comparison to the Indian laws, the Argentinean guidelines are stringent, as they could deny patents for derivatives of pharmaceutical substances even if they demonstrate enhanced efficacy. The Argentinean provisions create a blanket ban on grant of patents for derivatives of known pharmaceutical substances. This means that even if an applicant shows an enhanced or improved efficacy, a patent cannot be granted.

[18] Section 3(d) of Indian Patents Act, 1970. Section 3(d) also covers combinations of known substances.

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