Statement on Intellectual Property Protection for Pharmaceuticals and the Market Approval Mechanisms in Asia

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

observing that intellectual property protection for pharmaceuticals as a result of obligations arising from multilateral, regional and bilateral trade agreements has an increasing influence on national regulatory sovereignty

emphasizing that the right to property (including intellectual property) and the right to a standard of living adequate for the health and well-being of people and their families, including food, clothing, housing and medical care, are human rights recognized by the Universal Declaration of Human Rights (UDHR, Articles 17 and 25), and that the realization of intellectual property protection for pharmaceuticals should be in compliance with the right to health;

acknowledging the differences in health care systems, development of domestic pharmaceutical industries, domestic market scale and the need for intellectual property protection of pharmaceuticals among states in Asia;

affirming that states in Asia should take full advantage of the regulatory discretion available under the Paris Convention for the Protection of Industrial Property, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and other international law to strike a proper balance

between protection and limitation of intellectual property rights in the pharmaceutical field;

recalling the principle recognized by the "Declaration on Patent Protection — Regulatory Sovereignty under TRIPS"[1] that states in Asia retain some regulatory options to fulfill the need for intellectual property protection of pharmaceuticals as well as to implement public health policy;

stressing that principally the least-developed states have no legal obligation to provide intellectual property protection for pharmaceuticals under international norms; and

in pursuit of **providing** favorable consideration, in terms of accessibility and affordability of pharmaceuticals, to states in Asia while fulfilling the obligations imposed by trade agreements and determining the goals of intellectual property protection for pharmaceuticals,

make the following statement to Asian states:

[1] https://www.mpg.de/8132986/Patent-Declaration.pdf.

General Principles

Article 27 of the UDHR[2] and Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)[3] declare that human right norms should be used to interpret the right to protect intellectual property, ensuring that 1.1

- products of the human mind and creativity should be protected by law, and
- the right to participate in cultural life, and to enjoy the arts and the benefits of scientific progress should be guaranteed.

In the field of public health, states in Asia should adopt proper intellectual property protection for pharmaceuticals, to realize the policy goal of accessibility and affordability of pharmaceuticals. 1.2

The Paris Convention for the Protection of Industrial Property and the TRIPS Agreement preserve the right of states to determine the protection and limitation of intellectual property protection, including pharmaceutical inventions. 1.3

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[2] Article 27 of the UDHR provides: Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits (para 1). Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author (para 2).

[3] Article 15 of the ICESCR provides: (1) The States Parties to the present Covenant recognize the right of everyone: (a) To take part in cultural life; (b) To enjoy the benefits of scientific progress and its applications; (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author. (2) The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture. (3) The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity. (4) The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.

Furthermore, the Declaration on the TRIPS Agreement and Public Health[4] adopted by the Doha WTO Ministerial Conference of 2001 on 14 November 2001 1.4

- recognizes that intellectual property protection is important for the development of new medicines, and
- affirms that the TRIPS Agreement should be interpreted and implemented in a manner to support states to protect public health and to promote access to pharmaceuticals for all.

Differentiation in Asia

With regard to intellectual property for pharmaceuticals, the "one-size-fits-all" approach should not apply in Asia. 2.1

States in Asia face different challenges under differential domestic circumstances, including their 2.2

- health care systems,[5]
- pricing mechanisms for medicine;[6]
- domestic market scale,[7] and
- development of domestic pharmaceutical industries.[8]

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[4] WT/MIN(01)/DEC/2.

[5] For example, everyone has public health insurance in Japan, Singapore and Taiwan. However, in some countries, like India, national healthcare is still developing, and a certain proportion of the population cannot afford basic healthcare yet.

[6] In Japan, Singapore and Taiwan, the price of medicine is mainly determined or influenced by the public sector. By comparison, in India the prices of the drugs are mainly controlled by market mechanisms.

[7] Domestic markets in Singapore and Taiwan are relatively small.

[8] For instance, in Japan, the domestic innovative pharmaceutical industry is developed and capable of manufacturing new drugs. In China, Taiwan and Malaysia the domestic innovative pharmaceutical industry is still developing and merely capable of manufacturing generic drugs and certain types of new drugs like new dosage forms and new routes of administration. By comparison, the generic

Due to these differences, states in Asia might have their respective needs for varying levels of intellectual property protection for pharmaceuticals, to realize the policy goal of accessibility and affordability of pharmaceuticals. 2.3

On the basis that both original and generic drugs are indispensable to maintaining accessibility and affordability of pharmaceuticals, states in Asia should have latitude to determine whether the intellectual property protection for pharmaceuticals should be strengthened or weakened, and whether and to what extent the following measures of intellectual property protection for pharmaceuticals should be adopted: 2.4

- data exclusivity or other measures to protect undisclosed information;
- patent term extension;
- experimental use exemption; or
- Bolar exemption.

Measures to Protect Proprietary Information

Neither the Paris Convention for the Protection of Industrial Property nor the TRIPS Agreement imposes an obligation on states to adopt the measure of data exclusivity to protect undisclosed information submitted to governments or governmental agencies as a condition for approving the marketing of pharmaceuticals. 3.1

industry in India is competitive and capable of manufacturing generic drugs with high quality. In Singapore, both original and generic drugs rely on foreign producers.

Article 39.3 of the TRIPS Agreement does not prevent states from authorizing a third party to rely on or use undisclosed information submitted by originator companies, which is necessary for obtaining marketing approval of a generic drug when needed. 3.2

Article 39.3 of the TRIPS Agreement preserves the right of states to adopt a proper measure to protect the undisclosed information, other than the way of data exclusivity. 3.3

When adopting a mechanism for protecting data exclusivity, states in Asia should be cognizant of the impact on market entry of generic drugs.[9] 3.4

States in Asia should have latitude to choose the ways to protect the undisclosed information when the approved pharmaceuticals utilize new chemical entities (NCEs)[10]. In particular, Article 39.3 of the TRIPS Agreement requires only that member states protect undisclosed information when NCEs are involved. In contrast, member states are not obligated to protect the undisclosed information when the approved pharmaceuticals are 3.5

- new indication drugs;
- new combination drugs;
- new routes of administration;
- new dosages; or

[9] Throughout the entire period of data exclusivity, a generics company is not allowed to file for market approval of pharmaceuticals, regardless of whether the original drug is protected by patent right or not.

[10] In Japan, NCE drugs enjoy eight years of data exclusivity protection. New drugs other than NCE drugs enjoy four- to six-year protection of data exclusivity.

- new biological drugs.

Patent Term Extension	Neither the Paris Convention for the Protection of Industrial Property nor the TRIPS Agreement imposes an obligation on states to adopt the legal framework of patent term extension or similar mechanisms[11] for prolonging the protection of a patent claiming a pharmaceutical that requires market approval prior to being sold, or a method of using or manufacturing the pharmaceuticals.	4.1
Experimental Use Exemption	In view of Article 30 of the TRIPS Agreement, states in Asia should have latitude to introduce experimental use exemption, which allows a researcher to use a patented invention without the permission of the patent owner in the course of research and tests for the purpose of regulatory market approval of pharmaceuticals.[12]	5.1

[11] In the European Economic Area (European Union member countries plus Iceland, Liechtenstein and Norway), a supplementary protection certificate (SPC) is a *sui generis* IP right that extends the duration of certain rights associated with a patent. It enters into force after expiry of a patent upon which it is based. This type of right is available for various regulated, biologically active agents, namely human or veterinary medicaments and plant protection products (e.g. insecticides and herbicides). SPCs were introduced to encourage innovation by compensating for the long time needed to obtain regulatory approval of these products (i.e. authorisation to put these products on the market). An SPC normally has a maximum lifetime of 5 years. The duration of the SPC can, however, be extended to 5.5 years when the SPC relates to a human medicinal product for which data from clinical trials conducted in accordance with an agreed Paediatric Investigation Plan (PIP) have been submitted.

[12] An experimental use exemption has been stipulated in many Asian states, including China, India, Japan, Malaysia, Singapore and Taiwan.

States in Asia should have latitude to determine the scope of experimental use exemption, including the circumstance in which the patented invention is used as a research tool.[13] 5.2

Market Approval and Patent Infringement

It is not recommended that Asian countries adopt a type of patent linkage[14] that casts a burden on the regulatory authorities to determine issues of patent infringement in the process of granting market approval for generic drugs. 6.1

If, however, an Asian country has adopted patent linkage, it should be cognizant of the proper balance between the original and the generic companies, particularly in terms of 6.2

- disclosure of patent information by originator companies;
- declaration of the patent status by generic companies;
- notification to the originator companies of filing for market approval by the generic companies;
- stay of market approval of generic drugs by the regulatory authorities in order to allow for settlement of patent disputes.

In determining the length of stay of market approval, states should take the relevant factors into consideration, particularly in terms of 6.3

—the procedure for and duration of market approval;

[13] For example, in Taiwan using the patented invention as a research tool falls under the scope of experimental use exemption, see Article 60 of the Patent Act.

[14] Patent linkage is a system or process by which a country's regulatory approval authorities "link" the granting of market approval to the status of the patents corresponding to the originator's drugs.

—the pricing mechanism of medicine;

—the procedure for reimbursement of medical expenses;

—the procedure for and duration of patent litigation.

6.4 To provide incentive to generic companies to challenge the patent of originators, a limited term of market exclusivity for a qualified generic company can be considered. However, in determining the length of such exclusivity, states should take into consideration the monopoly effect of such exclusivity.

6.5 Under the Paris Convention for the Protection of Industrial Property and the TRIPS Agreement, a patent owner is entitled to exclude others from unauthorized making, using, selling, offering to sell or importing of the patented invention. This includes samples for the filing for market approval of pharmaceuticals, unless otherwise provided by national patent law such as the Bolar exemption.

6.6 Where the application process amounts to patent infringement, states in Asia should have latitude to adopt proper measures beyond patent linkage[15], to exclude certain acts from patent infringement.

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[15] Measures to exclude acts from patent infringement might include the "soft patent linkage" (preliminary injunction) adopted by Australia, according to which a generics manufacturer is obligated to certify the patent status and notify the originator company and patentee, and preliminary injunction, which can prevent the FDA from issuing market approval of a generic drug. Singapore (which, however, lacks an exclusive marketing period for the successful generic drug), South Korea and Taiwan have adopted the mechanism of patent linkage to avoid disputes about patent infringement prior to the marketing of approved pharmaceuticals. In Japan, the Ministry of Health, Labour and

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Welfare has announced a policy not to issue an approval when a related patent may prevent the manufacturing of applied generic drugs.

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