



## Standing Committee on Pharma and Biotechnology

### Position Paper

#### Inventions in the pharmaceutical field

In this Position Paper, the AIPPI, through its Standing Committee on Pharma and Biotechnology, urges national governments to remove all laws or regulations which impose restrictions targeting the patenting of subject matter in the pharmaceutical field. The Committee urges national governments to acknowledge that all inventions in the pharmaceutical field, including salts of known chemical compounds, crystalline forms, second medical uses, and formulations of known compounds, are available for patenting, provided that the invention meets all requirements of patentability.

#### **About AIPPI**

The International Association for the Protection of Intellectual Property, generally known under its French name abbreviation AIPPI, is the world's leading international organization dedicated to the development and improvement of legal regimes for the protection of intellectual property (*IP*).

AIPPI is a politically neutral, non-profit organization, domiciled in Switzerland, which currently has over 9000 members representing more than 125 countries. The objective of AIPPI is to improve and promote the protection of IP on both international and national bases. It pursues this objective by working for the development, expansion and improvement of international and regional treaties and agreements and national laws relating to IP. It operates by conducting studies of existing laws and proposes measures to achieve harmonization of these laws on an international basis. Where appropriate, AIPPI intervenes with submissions before major courts and legislative bodies to advocate for strengthened IP protection.

AIPPI has numerous Standing Committees that specialize in various areas of law or technology relating to IP. Each committee is composed of intellectual property professionals with expertise in the Committee subject. The members of AIPPI's Standing Committees reflect the geographic diversity of AIPPI.

AIPPI's Standing Committee on Pharma and Biotechnology was established to monitor, comment and advise AIPPI on policy and legal issues relating to IP protection for

pharmaceutical and biotechnology inventions. The Committee currently has 60 members, from over 25 countries.

### **Executive Summary**

AIPPI acknowledges that various countries have imposed restrictions on the patentability of some subject matter in the pharmaceutical field. These restrictions include the prohibition or heightened standard of review for patents on salts or specific forms (such as polymorphs) of known chemical compounds, or for pharmaceutical formulations of known compounds. AIPPI contends that these provisions violate Article 27 of TRIPS, which 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 “shall be available and patent rights enjoyable without discrimination as to the . . . field of technology.” Moreover, such blanket restrictions are also in violation of Articles 41.2 and 41.3 which require that compliance with patentability requirements must be assessed in individual patent applications on a case-by-case basis. Further, AIPPI asserts that the provisions discourage development of important advances in the pharmaceutical field. AIPPI asserts that countries should generally permit patenting of all subject matter in the pharmaceutical field, provided that the patent applicant meets the country’s requirements of patentability, including novelty and inventive step.

### **Restrictions on Patenting in the Pharmaceutical Field**

Various countries, including India, Philippines, Indonesia, Brazil and Argentina, have enacted laws or regulations that create obstacles to patentability that apply only to pharmaceutical inventions.

India, Philippines and Indonesia have enacted statutes to restrict the patentability of pharmaceutical subject matter. In India, section 3 of the Patent Act lists subject matter that is not an “invention” under the Act. Sub-section (d) to section 3 restricts the patenting of pharmaceutical salts or forms of a known molecule. The section 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 substance, machine or apparatus” is not an invention, “unless such known process results in a new product or employs at least one new reactant.”

Section 3(d) has an additional paragraph, entitled “Explanation” which states:

*For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure forms, 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.*

Section 3(e) provides that “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” is not an invention.

In order for a substance created by an admixture to be eligible for patenting under section 3(e), the substance would have to be more than a mere admixture and thus exhibit some form of surprising result or synergistic effect caused by the aggregation of the properties of the components thereof.

A landmark decision of the Indian Supreme Court in the case of *Novartis A.G. v. UOI & Ors. (2013) 6 SCC 1* invalidated a patent claiming a polymorph of imatinib mesylate, which was commercialized by Novartis as Gleevec™. The Supreme Court ruled that a substance can have enhanced “efficacy” for the purposes of section 3(d) only if its ability to cure a disease is enhanced as compared to a “known” substance in question with known efficacy. The Supreme Court found that imatinib mesylate, which was known in the prior art, was the “known” substance. The Supreme Court found that Novartis had proved that the claimed polymorph has better physico-chemical properties such as more beneficial flow properties, better thermodynamic stability, lower hygroscopicity and increased bioavailability. However, the Supreme Court held that these properties cannot be taken into account for the purpose of the test of section 3(d) since these properties have nothing to do with therapeutic efficacy. The Supreme Court also held that Novartis had failed to prove that the increase in bioavailability will actually lead to an enhanced therapeutic efficacy. The Supreme Court clarified that the questions as to whether or not an increase in bioavailability leads to an enhancement in therapeutic efficacy must be specifically claimed and established by research data.

It is stated that from a bare reading of the provision, it is evident that section 3(d) can be invoked only if the following conditions are fulfilled:

- a) There is a “known” substance in question
- b) There is a “known” efficacy for that known substance
- c) The claimed molecule(s) or substance(s) is a new form of such ‘known’ substance as clarified by the Explanation to section 3(d)
- d) That the “known” substance and the claimed invention have the same “known efficacy”.

The statute mandates proof of enhanced efficacy only when the above ingredients of section 3(d) of the Act are shown to have been established. Thus, a patent applicant is under an obligation to prove enhanced efficacy of the claimed compound only if the above-mentioned conditions are shown to have been fulfilled.

Both Indonesia and the Philippines have enacted laws similar to section 3(d) in India. In 2016, Indonesia passed a new amendment to its patent law (Law No. 13 of 2016), which required an “increased meaningful benefit” in order to establish patentability for new salts

or new dosage forms of known compounds. As in India, Article 4 of the Indonesian Patent Law lists subject matter that is not an “invention” under the Indonesian Patent Law. Specifically, section f of Article 4 states that:

*Invention excludes:*

*f. Discovery in the following forms:*

- 1. new use of existing and/or known products;*
- 2. new form of an existing compound which no longer shows increased meaningful benefit and has a different chemical structure from known chemical structure of such compound.*

The term “increased meaningful benefit” is defined in the elucidation of Article 4 section f.2., which states:

*What is defined as “meaningful” generally used in pharmaceutical field, is difference of structure of chemical compound, for example Inventions about Penicillin group antibiotics, Ampicillin and Amoxicillin. Difference in one of H (hydrogen) group in Ampicillin and OH (hydroxyl) in Amoxicillin induce anti-microbial effect with wide anti-microbial spectrum and higher stability than Ampicillin, then it can be concluded that Amoxicillin have increased meaningful benefit than Ampicillin.*

Philippines patent law section 22.1 incorporates the language of section 3(d) of India. Thus, the Filipino law excludes from patentability “the mere discovery of a new form or new property of a known substance which does not result in the enhancement of efficacy of that substance.” The Filipino law also includes the “Explanation” section of the Indian section 3(d). Section 26.2 of the Filipino law also establishes a heightened requirement of obviousness for pharmaceutical inventions. Section 26.2 states that “[i]n the case of drugs and medicines, there is no inventive step if the invention results from the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance.”

In Brazil, Article 229-C, which dates from the 1990’s, requires that pharmaceutical applications be examined by ANVISA, the Brazilian Health regulatory agency, as well as the Brazilian Patent Office. Over the years the implementation of the law has changed. Under the current implementation, ANVISA’s approval analysis should be forwarded to the Brazilian Patent Office, and treated similarly to third party submissions. With the advent of the joint Guidelines #1/2017, issued by ANVISA and the Brazilian Patent Office, the review of pharma applications by ANVISA-National Sanitary Surveillance Agency should be limited to whether a patent application contravenes public health. The criterion for conflicting with public health is when a product or process presents a “health risk”. This risk is detected when a product comprises a substance that is prohibited in Brazil, or when a process results in said substance. Accordingly, ANVISA will deny approval when the subject matter of the patent application is found to pose a health risk.

Other countries have enacted patent office regulations or examination guidelines that restrict patentable subject matter in the pharmaceutical sector. In May 2012 the Argentine Patent Office (National Institute of Industrial Property) and the Ministries of Industry and of Health issued a Joint Regulation with new guidelines for the examination of patent applications which severely restricted the patentability of several categories in the pharmaceutical field. The guidelines stated that polymorphs, hydrates, solvates, enantiomers, salts, esters, metabolites, prodrugs, formulations, combinations, Markush structures<sup>1</sup>, selection inventions and processes are not patentable.

In May 2016 Russia's Federal Monopoly Service published a draft Roadmap for Development of Competition in the Healthcare Sector. The finalized Roadmap has been approved by Government Decree of 12 January 2018 no. 9p. The Roadmap proposes restricting to some extent the patentability of new inventions in the pharmaceutical field – in particular, new indications, new treatments, new dosage forms and manufacturing methods. It is noted that the Roadmap, though approved, is only for discussion purposes. Other factors, including fair practice in the pharmaceutical industry, are expected to be taken into consideration.

### **AIPPI's Position**

AIPPI contends that any practices that restrict patentable subject matter in a single field, such as pharmaceuticals, violate Article 27 of TRIPS. TRIPS Article 27 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.” The TRIPS provision requires that member states apply the patent laws consistently across technologies, and do not set barriers to patentability that apply to one technology but not to others.

The referenced statutes in India, Brazil, Philippines and Indonesia, which impart substantive or procedural impediments to patents in the pharmaceutical field, are not compliant with TRIPS. The regulations and practices in Argentina, and the proposed new laws in Russia, also violate TRIPS Article 27, by singling out the pharmaceutical field for restrictions on patentability. Furthermore, such blanket restrictions also violate Articles 41.2 and 41.3 which require a case-by-case basis assessment.

AIPPI has previously acknowledged TRIPS Article 27(1) and its principle of non-discrimination. In its Resolution on Gene Patenting (Sydney, 2017) ([aippi.org/wp-content/uploads/2017/10/Adopted-Resolution-Gene-Patenting\\_English.pdf](http://aippi.org/wp-content/uploads/2017/10/Adopted-Resolution-Gene-Patenting_English.pdf)), AIPPI stated that TRIPS Article 27(1) “provides that patents shall be available for any inventions, whether products or processes, in all fields of technology provided they are new, involve and inventive step and are capable of an industrial application.” In a 2016 Report on Computer Implemented Inventions ([aippi.org/wp-content/uploads/2016/09/AIPPI-paper-2016-06-28.pdf](http://aippi.org/wp-content/uploads/2016/09/AIPPI-paper-2016-06-28.pdf)), the AIPPI Standing Committee on Information Technology and Internet stated that Article 27 of TRIPS does not permit excluding any subject matter from

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<sup>1</sup> A representation of chemical structure used to indicate a group of relate chemical components.

patentability, with the exception of “exclusions based on public order or morality, or for diagnostic, therapeutic and surgical methods, as well as for plants and animals.”

AIPPI acknowledges that patents on pharmaceutical subject matter have the potential to impact the costs of medicines, and has made statements about the intellectual property rights and public health. AIPPI’s Resolution on Q202 – "The impact of public health issues on exclusive patent rights" (Boston, 2008) (**Resolution Q202**) – and the Summary Report<sup>2</sup> on which Resolution Q202 is based recognizes that countries may permit exceptions to infringement to benefit public health, including experimental use and individual prescription exceptions to infringement. In Resolution Q202, AIPPI also acknowledges that countries may permit parallel importation of patented medicines, and in the face of a public health emergency may permit compulsory licensing.

Further, AIPPI supports rigorous examination of patent applications, and a strict interpretation of patent laws so that patents in all fields, including pharmaceuticals, are granted only for qualifying inventions. AIPPI urges countries to support strong intellectual property systems, with the quality of examination that is necessary in order to have high quality assessment of novelty and inventive step, thus leading to stronger patents. AIPPI strongly believes that the patent offices must be allowed to use and invest resources in better training, databases and infrastructure in order to secure patent quality.

AIPPI asserts that these provisions which enact impediments to pharmaceutical patenting discourage development of important advances in the pharmaceutical field. AIPPI recommends that countries permit patenting of all pharmaceutical subject matter, provided that the applicants meet all requirements of patentability, including novelty and inventive step, that are required for all inventions.

Consistent with this Position Paper, AIPPI has also urged countries to recognize the patentability of new medical uses for known compounds. AIPPI’s Resolution on Q238 – "Second medical use and other second indication claims" (Toronto, 2014) called for countries to acknowledge the patentability of “second medical uses”, i.e. any “new therapeutic use(s) of known compound and substances”.<sup>3</sup> The Resolution noted that second medical uses require significant investment in research and development, and often cover important and valuable medical innovations.

## **Conclusion**

AIPPI asserts that patents have shown to be a tool for fostering innovation, precisely because they are an incentive to develop new treatments and drugs. Improvements on pharmaceuticals can improve health outcomes and reduce health care costs. In order to encourage all forms of innovation in the pharmaceutical field, countries must allow innovators to obtain patent protection on novel and inventive developments in

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<sup>2</sup> See <http://aippi.org/wp-content/uploads/committees/202/RS202English.pdf> and <http://aippi.org/wp-content/uploads/committees/202/SR202English.pdf>.

<sup>3</sup> <http://aippi.org/wp-content/uploads/committees/238/RS238English.pdf>.

pharmaceutical forms or dosages. Restrictions on patenting will discourage innovation in the health sector, and thus negatively impact public health.

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