Exclusions and Exceptions

Asian Regional Course for Judges on Intellectual Property and Public Health 2021

Exclusions from Patentability

Article 27.2 and 3 of TRIPS specifies some of the exclusions to patentability that any country may establish in its domestic law.

The basis for the exclusion under article 27.2 is that the commercial exploitation of those inventions within the territory of the country concerned is felt necessary for protection of public order (ordre public) or morality, including protection of human, animal or plant life or health. Avoidance of serious prejudice to the environment may also be a ground for exclusion from patentability.

Article 27.2 of TRIPS

> Members may exclude from patentability inventions, the prevention within their territory 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 domestic law.

Article 27.3 of TRIPS

> Members may exclude from patentability:
>
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans and animals;
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> (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the entry into force of the Agreement Establishing the WTO.

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Ordre Public

There is no internationally accepted interpretation of the term "ordre public". WTO members have considerable flexibility to define which situations may constitute situations that threaten the "ordre public", based on their perception of the public values that need to be protected. It may be possible, for instance, that a country devastated by an epidemic may consider that measures to combat the epidemic may be a matter of "ordre public".

Protection of human … life or health

The concept of "ordre public" under article 27.2 also includes protection of human, animal or plant life or health. This provides one of the flexibilities that, as confirmed by the Doha Ministerial Declaration on TRIPS And Public Health, WTO members can use to the full to protect public health. Therefore, when it is necessary to protect public health, members can exclude from patentability inventions whose commercial exploitation could undermine the protection of public health.

Article 27.2 permits denial of patentability both before the grant of patent as well as after the grant of a patent.

Implementation of article 27.2 in national laws

All countries in the region have included contravention of public order as a ground of exclusion of an invention from patentability, without elaborating situations that may be considered inimical to public order. However, while some countries have included protection of human life or health as a ground for exclusion of an invention from patentability, some other countries have not stated this specifically. However, as stated in article 27.2, ordre public includes protection of human, animal or plant life or health. Hence, governments, legislatures and courts have substantial discretion to interpret which kind of situations, from a public health perspective, could constitute a threat to public order or human life or health, to justify the exclusion of an invention from patent protection. It is possible that such interpretation be informed by considerations of the primacy of the human right to health, which has been constitutionally and jurisprudentially recognized in many countries.

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Diagnostic, therapeutic and surgical methods for the treatment of humans and animals

Article 27.3 (a) allows WTO members to exclude claims on diagnostic, therapeutic and surgical methods for treatment of humans and animals from patent protection. The exclusion of therapeutic methods may have significant implications in the pharmaceutical sector, in relation to the patentability of the new use of a known pharmaceutical product. As described in the discussion on patentability criteria, it is very common in the pharmaceutical sector to file patent claims on methods of treatment, such as claims on new use of an existing medicine for another therapeutic area, claims on combinations of two or more drugs for the treatment of a condition, claims on specific dosage of a medicine, etc. In effect, there is no real difference between patent claims relating to the use of a substance and those relating to a therapeutic method: in both cases essentially a new way of using one or more known products is claimed. Therefore, patenting of a new therapeutic effect of a known pharmaceutical product would be contrary to the exclusion of methods of treatment. To bypass this exclusion, patent claims on new use of known medicines are sometimes drafted as claims for the use of the known product to manufacture a medicine for the treatment of a new therapeutic condition. Such claims are known as "Swiss claims". However, there is no obligation under TRIPS for countries to allow such claims.

Implementation of article 27.3 (a) in national laws

All countries in the region have implemented the exclusion under article 27.3 (a) of TRIPS. Some countries have implemented such exclusion while providing those products used for delivering the method of treatment (e.g., devices and implements used for administering a drug or conducting surgery) are exempted from such exclusion.

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Plants and animals other microorganisms and essentially biological processes for their production other than non-biological or microbiological processes

Article 27.3 (b) allows countries to exclude, plants and animals, and *essentially* biological processes for the production of plants and animals from being deemed as patentable. However, it exempts microorganisms, and non-biological or microbiological processes from the scope of such exclusion, thereby making them patentable. This clause reflects on the one hand, the strong interests of some developed countries in ensuring protection of biotechnological innovations and, on the other, the important differences existing among such countries with regard to the scope of protection, as well as the concerns of many developing countries about the patentability of life forms.

Article 27.3(b) leaves considerable flexibility for Members to adopt different approaches to the patentability of inventions relating to plants and animals, but unambiguously requires the protection of microorganisms. The exclusion of microorganisms from the scope of article 27.3 (b) raises the question whether microorganisms existing in nature can be patented as such. If this concept were broadly understood, WTO members' obligation would be unjustifiably expanded. Such an obligation should be interpreted as limited to the protection of microscopic or sub-microscopic organisms and exclude cells or sub-cellular parts. Importantly, bacteria, fungi, etc. can also been excluded from patentability whether claimed in their natural form, isolated or genetically modified.

It is generally accepted that a micro-organism as it exists in nature cannot be patentable. However, in some jurisdictions it is sufficient to isolate a microorganism and identify a use therefore to obtain a patent. This has been the approach in the countries of the European Union as well as the United States. The concept has been applied in an expansive manner to also include human, animal and plant cells, which are not microorganisms in a scientific sense. However, a recent decision of the US Supreme Court in *Association for Molecular Pathology vs. Myriad Genetics,* it was held that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated. WTO members may also opt for a narrower scope of patentability, confining it to microorganisms that have been genetically modified. Many developing countries specifically exclude microorganisms found in nature, even if isolated, from being deemed patentable.

Implementation of article 27.3 (b) in national laws

All countries in the region have implemented the exclusion of plants and animals from patentability under their national laws. While some countries have exempted microorganisms

from the scope of such exclusion, others have qualified such exemption to limit them to man-made, transgenic or not naturally occurring microorganisms. Nevertheless, in the application of this exclusion, the legal provisions would still have to be interpreted to determine what these terms mean. As pointed out in the foregoing discussion, these provisions can be interpreted strictly to exclude microorganisms found in nature, even if isolated, as well as cellular components, genes, etc.

Exclusion	India	Indonesia	Malaysia	Pakistan	The Philippines	Sri Lanka	Thailand	Viet Nam
Public Order	Yes. Term not defined or explained	Yes. Term not defined or explained	Yes. Term not defined or explained	Yes, Term not defined or explained	Yes. Term not specifically defined	Yes. Term not is not defined or explained	Yes. The term is not defined or explained.	Policy not to protect any IP object contrary to social ethics and public order.
Human, animal, plant life or health	Yes. Term not defined or explained	No. However, exclusion applies where implement ation of the invention is contrary to laws and regulations. This could include health laws and regulations	No	Yes. Term not defined or explained	No.	Yes. Term not defined or explained	Yes. The term is not defined.	No.
Diagnostic, therapeuti c or surgical methods of treatment of humans or animals	Yes	Yes	Yes. However products used in method of treatment are patentable	Yes	Yes. However, products or compositio n used in methods of treatment are patentable	Yes. However, products used in such method are patentable	Yes	Yes

Plants and animals other than microorganisms, and essentially biological processes for their production	Yes. The terms "microorganism" and "essentially biological process" not explained in statute	Yes. The terms "microorganism" and "essentially biological process" not explained in statute	Yes. Microorganisms are exempted from the scope of the exclusion only if they are man-made living microorganisms. Hence, naturally occurring microorganisms are clearly excluded from being patentable.	Yes. The terms "microorganism" and "essentially biological process" not explained in statute	Yes. The terms "microorganism" and "essentially biological process" not explained in statute	Yes. However, the exemption of microorganisms from the exclusion is limited to transgenic microorganisms.	Naturally occurring microorganisms and their components, animals, plants or extracts from animals or plants are excluded	Processes of plant or animal production which are principally of biological nature other than microbiological ones

Exceptions to Patent Rights

The TRIPS Agreement does not specify what exceptions to patent rights may be provided under a national law. Rather, article 30 of TRIPS stipulates conditions that must be observed by a WTO member if it provides for any exception.

Article 30

> Members may provide limited exceptions to the exclusive rights conferred by a patent: provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owners, taking into account the legitimate interests of third parties.

In terms of article 30, three conditions must be satisfied by any exception:

1. They must be "limited". However, article 30 does not explain in what sense the exception must be limited – scope, duration or otherwise.
2. The exception must not unreasonably conflict with the normal exploitation of a patent.
3. The exception should not unreasonably prejudice the legitimate interests of the patent owner.

All the three conditions must be applied by taking into account the legitimate interests of third parties.

The indeterminate language in which the conditions under article 30 are written provides ample scope for interpretation of these terms.

In the light of the exceptions generally available under various national patent laws, the following exceptions may be deemed legitimate within the meaning of article 30 of TRIPS:

- Parallel importation of a product that has been put in the market elsewhere by the patentee, with his consent or by an otherwise authorized person
- Acts done privately and on a non-commercial scale or for a non-commercial purpose
- Using the invention for research and experimentation and for teaching purposes
- Seeking regulatory approval for marketing of a product before the expiry of the patent (regulatory review exception)
- Preparation of medicines for individual cases according to a prescription
- Use of the invention by a third party who started or undertook bona fide preparatory acts before the application for the patent (or its publication).

Some of these exceptions such as parallel importation, the research and experimental exception, and the regulatory review (also known as Bolar exception) are particularly important for pharmaceutical innovation, as well as competition and affordable access to medicines.

Research or Experimental Use Exception

Adoption of the research or experimental use exception may facilitate innovation based on inventing around or improving on the patent protected invention, evaluation of the protected invention to assess whether to request a license, or for other legitimate purposes such as to test whether the invention works, and has been sufficiently disclosed. There is considerable flexibility available in terms of article 30 of TRIPS to determine the scope of the research or experimental use exception. While some countries like the US have adopted a narrow scope of the exception, limiting it to use of the invention without the authorization of the patent holder for scientific purposes only, European and other countries have allowed experimentation on an invention even for commercial purposes, as well as to obtain information about the possible use of a product, side effects or other consequences of its use. Most developing countries, however, have not explicitly used the room left by the TRIPS Agreement to provide for an experimental exception.

Regulatory Review (Bolar) Exception

The regulatory review or Bolar exception deals with the use of an invention relating to a pharmaceutical product to conduct tests and obtain the marketing approval of regulatory authorities, before the expiry of a patent, for commercialization of a generic version, just after the expiry of the patent. This exception is important because it can enable patients to access generic versions of a medicine immediately after the expiry of a patent, without having to wait for an additional number of years for the regulatory approvals to be processed. This exception is called the Bolar exception after legislation was introduced in the US to overturn a ruling in *Roche Products Inc vs. Bolar Pharmaceutical Co.,* where the US court had denied the right to begin the regulatory approval process before the expiry of the patent.

The consistency of the Bolar exception with article 30 of TRIPS was tested in a WTO dispute – *Canada-Patent Protection for Pharmaceutical Products*, when the European Communities challenged the use of a similar provision under the Canadian law which allowed the use of the patented product for development and submission of information required for obtaining marketing approval, and also allowed manufacturing and stockpiling of pharmaceutical products six months before the expiry of the patent. The WTO panel held the exception allowing use of the patented invention for the purpose of development and submission of information for obtaining regulatory approval to be within the scope of exceptions allowed under article 30, but held that the manufacturing and stockpiling exception did not satisfy the conditions under article 30.

The panel adopted a narrow interpretation of the scope of exceptions allowed under article 30 by holding that each of the three conditions under article 30 mentioned above must be observed cumulatively. However, the consideration of the three conditions established by Article 30 as 'cumulative' does not find support in the text of the provision nor is it justified under an interpretation in accordance with the Vienna Convention on the Law of the Treaties. Critiquing the interpretation of the panel, distinguished scholars in the field have observed that

the three conditions under article 30 are not cumulative. The test under article 30 may be understood to require a comprehensive overall assessment rather than a separate and independent assessment of each criterion. Failure to comply with one of the three conditions need not result in the exception being disallowed.

It should be noted in this context that WTO panel decisions do not constitute binding precedents for future WTO panels, or for national courts. Moreover, WTO panels do not have the authority to interpret the provisions of the Agreement. Therefore, the ruling of the panel in this case need not constrain national laws or courts from interpreting a broader scope of the exception possible to allow early working of an invention without the approval of the patent holder.

There can be many alternative approaches to designing or interpreting the scope of a Bolar exception. The broader the formulation of the exception in terms of covered products, sources of samples, type of trials allowed, time to undertake them, and geographical scope, the more competitive environment is ensured that will benefit consumers, health providers and other public agencies. The policy choice for designing a broader Bolar exception is more favourable to the objective of promoting competition.

The Bolar exception may be implemented either as a specific exception or included within a general exception provision. In order to well define the Bolar exception, it may be preferable to design it as a specific exception. The Bolar exception can be crafted, and where possible interpreted, to cover all regulated products, including but not limited to health-related products for human use, such as medicines and medical devices. Other regulated products covered in some Bolar exceptions include veterinary medicines and plant protection products. The scope of the activities that could be allowed under the exception may be those that are related to obtaining marketing approval for generics and biosimilars, but may also extend for acts relating to medical devices (as provided for in the US) and innovative medicines (for example to carry out health technology assessments as in the Bolar exception in the UK Patents Act). It is not necessary to restrict the user of the Bolar exception to the party that would be requesting the marketing authorization. It can also include acts by third parties involved in supplying materials to a company to run tests and trials related to obtaining marketing authorization for a generic or biosimilar. Acts that are related to obtaining marketing approval that should be covered include studies, trials and experiments required for obtaining marketing approval in the country, as well as for obtaining marketing approval in other countries. As noted earlier, third party activity for the company seeking marketing approval, such as delivery of an Active Pharmaceutical Ingredient (API) to carry out tests or trials when the company is unable to produce the API in-house, can also be included.

Implementation of the Research Exception and Bolar Exception in National Laws

The research exception has been implemented in all countries in the region. However, the scope of the exception may vary between different countries. While in some countries the exception is very broad and may be interpreted as including within its scope both commercial as well as non-commercial research and experimentation, in some other countries the exception is limited to non-commercial research and experimentation. In some countries the

exception is only for scientific research but the statutes do not provide any guidance on whether the scientific research on how the term is to be interpreted, while in some countries scientific research may be limited to non-commercial research by implication through extending the patent rights to acts done for commercial purposes. Statutory silence may permit interpretation of scientific research in broad terms to include scientific research for commercial ends within the scope of the exception.

Most countries in the region except Sri Lanka specifically provide for the Bolar exception, albeit with different scope. In Thailand, the Bolar exception is included as part of the general provision on exception that allows both research and the Bolar exception. In some countries the exception is extended to acts done for obtaining marketing approval in its own territory as well as in other countries (e.g. India, Philippines) while in some other countries this is not expressly mentioned in the statutes. In case of statutory silence it may be possible to interpret the scope of the Bolar exception as applicable to the obtaining and submission of information for regulatory approval in other countries.

The scope of a broad Bolar provision was tested in a recent case in India in *Bayer Corporation vs. Union of India* where the Delhi High Court held that the Bolar provision under the Indian law allows export of a patented product for generation or submission of information for seeking regulatory approval in India or other countries, without such export constituting an act of patent infringement. The court established an indicative list of factors to determine whether the export is 'reasonably related' to the research purpose or not.

Exception	**India**	**Indonesia**	**Malaysia**	**Pakistan**	**The Philippines**	**Sri Lanka**	**Thailand**	**Viet Nam**
Research Exception	Yes. Section 47(3) states that a patented product or process may be used, by any person, for the	Yes – Article 19(3). Use of the patented product or process for the purposes of education, research, experimentation, or analysis is exempted, as long as	Rights conferred by a patent do not extend to acts done only for scientific research	Section 30 (5) – exempts acts done only for experimental purposes relating to a patented invention;	Acts of making or using exclusively for experimental use of the invention for scientific purposes or	Patent rights do not extend to acts done only for scientific research purposes (patent rights are extended	any act for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with a normal	Use of invention for noncommercial purposes, or for purpose of evaluation, analysis, research, teaching, testing, trial

	purpose merely of experiment or research, including the imparting of instructions to pupils. There is no distinction between commercial and non-commercial research.	they do not harm the legitimate interests of the patent holder and are not commercial in nature.		acts done for teaching purposes in educational or research institutions.	educational purposes and other related purposes are exempted	to only acts done for industrial or commercial purposes)	exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner	production or information collection for carrying out procedures of application for licenses for production, importation or circulation of products
Bolar Exception	Yes – section 107A. Any act of making, constructing, using, selling or importing patented invention for development and submission of information for regulatory approval in India or any other country. In *Bayer vs. Union of India*, Delhi High Court interpreted "selling" to include sales for export.	Yes – Section 167. The production of a patented pharmaceutical product by a third party within 5 years before the expiry of patent protection is exempted from civil and criminal liability, provided that the manufacturing is made for the purpose of licensing and marketing after the patent protection is expired.	Rights conferred by a patent do not extend to acts done to make, use, offer to sell or sell a patented invention soley for uses related to the development and submission of information to the relevant authority which regulates manufacture, use or sale of drugs.	Section 30 (5) – exempts acts, including tests, necessary for commercial approval of a product after the expiry of a patent.	In the case of drugs and medicines, acts of testing, using, making or selling the invention including any data related thereto, solely for purposes reasonably related to the development and submission of information and issuance of approvals by government regulatory agencies required under any law of the Philippines or of another country that regulates the manufacture, constructio	No specific provision	Patent rights do not extend to any act concerning an application for drug registration, the applicant intending to produce, distribute or import the patented pharmaceutical product after the expiration of the patent term.	General research exception includes Bolar exception

					n, use or sale of any product			

Exercise

- In your opinion, what is the scope of exclusion of an invention from patentability on the ground of public order in a public health context?

- Do you agree with the following statement:
  - A naturally occurring DNA sequence, isolated in a laboratory, is a patentable invention.

- What specific ground of exclusion from patentability would apply to the following patent claim:
  - Use of substance or composition X for the treatment of disease Y
- What is the scope of the research and experimental use exception to a patent right?

- From a public health perspective, what is the public policy objective of a Bolar exception?

- Do you agree with the following statements
  - Under the TRIPS Agreement, the Bolar exception must be limited only to pharmaceutical products
  - The Bolar exception can be used only when a short period of time remains for the term of a patent to expire
  - The Bolar exception can be used for the purpose of developing and submitting information required for marketing regulatory approval in both domestic and foreign markets.
  - Export of a patented pharmaceutical product without the authorization of the right holder for the purpose of developing and submitting information required for regulatory approval in foreign markets can be allowed under a Bolar exception.