

19: Patents: Ordre Public and Morality

Article 27.2 Patentable Subject Matter

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 their law.

1. Introduction: terminology, definition and scope

States have the right to protect the public interest, and patent law is not an exception to this general principle. Based on a long established tradition in patent law (particularly in the European context), TRIPS allows (but not mandates)⁶⁰⁶ two possible exceptions to patentability, based on *ordre public* and morality. The implementation of these exceptions, which need to be provided for under national law in order to be effective, means that a WTO Member may, in certain cases, refuse to grant a patent when it deems it necessary to protect higher public interests.⁶⁰⁷

The term “*ordre public*”, derived from French law, is not an easy term to translate into English, and therefore the original French term is used in TRIPS. It expresses concerns about matters threatening the social structures which tie a society together, i.e., matters that threaten the structure of civil society as such.

“Morality” is “the degree of conformity to moral principles (especially good)”.⁶⁰⁸ The concept of morality is relative to the values prevailing in a society. Such values are not the same in different cultures and countries, and change over time. Some important decisions relating to patentability may depend upon the judgement about morality. It would be inadmissible that patent offices grant patents to any kind of invention, without any consideration of morality.⁶⁰⁹

⁶⁰⁶ See the text of Article 27.2: “Members *may* exclude from patentability...” (emphasis added).

⁶⁰⁷ Note that while Article 27.2 allows not to grant a patent, Article 30 relates to exceptions to exclusive rights, that is, it is operative only when a patent has been granted. See Chapter 23 below.

⁶⁰⁸ The Concise Oxford Dictionary, p. 637.

⁶⁰⁹ See, e.g., Alberto Bercovitz, *Panel Discussion on Biotechnology*, in Kraih Hill and Laraine Morse (Eds.), *Emergent Technologies and Intellectual Property. Multimedia, Biotechnology & Others Issues*, ATRIP, CASRIP Publications Series No. 2, Seattle 1996, p. 53.

Article 27.2 clarifies, unlike equivalent precedents in national laws, that protection of *ordre public* or morality includes the protection of “human, animal or plant life or health or to avoid serious prejudice to the environment”, thereby explicitly allowing for exceptions to patentability when any of these interests may be negatively affected by patent grants. The concept of “health” may be deemed to encompass not only medical care, but also the satisfaction of basic requirements such as adequate food, safe water, shelter, clothing, warmth and safety.⁶¹⁰ The “environment” refers to the “surrounding objects, region, or conditions, especially circumstances of life of person or society”.⁶¹¹

Finally, it should be noted, as examined in more detail below, that WTO Members can provide for the exceptions referred to but they are subject under Article 27.2 to one important condition: non-patentability may only be established if the commercial exploitation of the invention needs to be prevented to protect the interests referred to above. This excludes the possibility of applying such exceptions when, for instance, it would be in the interest of public health to promote the diffusion of an invention (e.g., a medicinal product), since a Member cannot refuse a patent on *ordre public* or morality grounds and, at the same time, permit the commercialisation of the invention.

2. History of the provision

2.1 Situation pre-TRIPS

Ordre public and morality considerations had been taken into account in many jurisdictions before the adoption of TRIPS. In the USA, for instance, traditionally the concept of inventions contrary to *ordre public*, as applied by the courts, referred to an invention that was “frivolous or injurious to the well-being, good policy, or sound morals of a society”.⁶¹²

European laws⁶¹³ and many other civil law jurisdictions had provided for explicit exceptions on terms comparable to Article 27.2. That was the case, in particular, of Article 53(a) of the European Patent Convention, whose wording probably inspired the drafters of TRIPS. After the adoption of Article 4*quater* in the Paris Convention,⁶¹⁴ many national laws were reformed so as to acknowledge that a

⁶¹⁰ See, e.g., Robert Beaglehole and Ruth Bonita, *Public Health at the Crossroads. Achievements and prospects*, Cambridge University Press, Melbourne 1999, p. 45; Fraser Mustard, *Health, health care and social cohesion*, in Daniel Drache and Terry Sullivan (editors), *Health Reform. Public Success. Private Failure*, Routledge, London and New York 1999.

⁶¹¹ The Concise Oxford Dictionary, p. 323.

⁶¹² See *Lowell v. Lewis*, 15 (a. 1018 No. 8568) (C.D. Mass. 1817), quoted in Chisum and Jacobs, p. 2.5. In the United States, “the trend is to restrict this subjective public policy approach to utility” (*Idem*).

⁶¹³ See, e.g. Rainer Moufang, *The Concept of “Ordre Public” and Morality in Patent Law*, in Geertrui Van Overwalle (Ed.), *Patent Law, Ethics and Biotechnology*, Katholieke Universiteit Brussel, Bruxelles 1998, No.13, p. 69 [hereinafter Moufang].

⁶¹⁴ Article 4*quater* reads as follows: “The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law.” This provision is thus equivalent to the last part of Article 27.2 TRIPS. However, there is no comparable reference to *ordre public* or morality.

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possible conflict with simple statutory law could not be regarded as a sufficient reason for rejecting a patent application.

2.2 Negotiating History

2.1 The Anell Draft

“1.4 The following [shall] [may] be excluded from patentability:

1.4.1 Inventions, [the publication or use of which would be], contrary to public order, [law,] [generally accepted standards of] morality, [public health,] [or the basic principle of human dignity] [or human values].”

[...]

2.2 The Brussels Draft

“2. PARTIES may exclude from patentability inventions, the prevention within their territory of the publication or any exploitation of which is necessary; to protect public morality or order, including to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement; or to protect human, animal or plant life or health.”

The final text is closer to that of Article 53 of the European Patent Convention. However, the latter refers to conflicts that may follow not only from the exploitation but also from the “publication” of the invention, an alternative that in the view of some authorities would be irreconcilable with Article 27.2 of TRIPS.⁶¹⁵

Article 27.2 makes it clear that an exclusion from patentability cannot be grounded merely on the fact that the existing law of a Member prohibits exploitation. The present wording is a change from the Brussels Draft that read “including to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement”. In other words, an exclusion from patentability must be justified within the terms of Article 27.2 itself.

3. Possible interpretations

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ...

Article 27.2 is concerned with the exclusion of particular inventions, not categories of inventions which are dealt with in Article 27.3 (discussed in Chapter 21 below). It is clear from the wording of the provision that the risk must come from the commercial exploitation of the invention, not from the invention as such. It would also seem, given the wording of Article 27.2, that the likely impact must be within the territory concerned, not that of another Member.

An exception based on this Article can be applied only when it is necessary to prevent the “commercial exploitation” of the invention. Therefore, the condition

⁶¹⁵ See, e.g., Moufang, p. 72.

for the application of the exception would not be met if there is a need to prevent non-commercial uses of the invention (e.g., for scientific research).

It has been debated whether the exception can only be applied when there is an actual prohibition on the commercialization of the invention, or when there is need to prevent it (even if still not done by the government concerned). According to one opinion, an effective ban should exist in order to make the exception viable.⁶¹⁶ It has been held, however, that TRIPS “does not require an actual ban of the commercialization as a condition for exclusions; only the necessity of such a ban is required. In order to justify an exclusion under Article 27 (2) TRIPS, a Member state would therefore have to demonstrate that it is necessary to prevent – by whatever means – the commercial exploitation of the invention. Yet, the Member would not have to prove that under its national laws the commercialization of the invention was or is actually prohibited”.⁶¹⁷

... is necessary to protect ordre public or morality, ...

Article 27.2 introduces a “necessity test” to assess whether protection of an overriding social interest is justified. Though TRIPS constitutes the *lex specialis* for dealing with patent issues in the WTO framework, the GATT/WTO jurisprudence on Article XX of GATT is likely to play a role in the interpretation of said Article.⁶¹⁸

Article XX (a) and (b) of GATT have a similar structure to Article 27.2, and it is clear that, for the purposes of these provisions exclusions must be objectively justified.⁶¹⁹ These provisions permit Members to make exceptions to the basic GATT free trade principle on the ground (a) that it is *necessary* to protect public morals, and (b) that it is *necessary* to protect human, animal or plant life [emphasis added]. Thus, under GATT, quarantine, sanitary and similar regulations must not constitute arbitrary or unjustifiable discrimination or a disguised restriction on trade. A measure is justified only if no reasonable alternative is available to a Member which is not inconsistent, or at least less inconsistent, with GATT.⁶²⁰

⁶¹⁶ Adrian Otten, *Viewpoint of the WTO*, (M. Swaminathan, Ed.), in *Agrobiodiversity and Farmers' Rights Proceedings of a Technical Consultation on an Implementation Framework for Farmers' Rights*, M.S. Swaminathan Research Foundation, Madras 1996.

⁶¹⁷ Dan Leskien and Michael Flitner, *Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System*, Issues in Genetic Resources No. 6, IPGRI, Rome 1997, p. 15.

⁶¹⁸ In the *India- Patent Protection for Pharmaceutical and Agricultural Chemical Products* case (WT/DS50) the panel held that the TRIPS Agreement has a “relatively self-contained, *sui generis* status within the WTO.” However, it also held that the Agreement is “an integral part of the WTO system, which itself builds upon the experience of over nearly half a century under the GATT 1947” (para. 7.19).

⁶¹⁹ See *GATT Analytical Index*, Vol. I, p. 518 *et seq.*

⁶²⁰ See 1990 Panel Report on *Thailand 'Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes'* BISD 37S/200, adopted November 7, 1990. A contracting party cannot justify a measure inconsistent with GATT provisions as ‘necessary’ in terms of Article XX(b) if an alternative measure it could reasonably be expected to employ not inconsistent with GATT is available to it. Thus a Thai government restriction on the importation of cigarettes could not be justified in terms of the desirable objective of stopping people smoking, given that alternatives such as anti-smoking campaigns are available, and have been shown to be effective in a number of countries around the world. Similarly, a United States measure prohibiting the importation of tuna under

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Ordre public encompasses, according to European law, the protection of public security and the physical integrity of individuals as part of society.⁶²¹ This concept includes also the protection of the environment, but is deemed to be narrower than ‘public order’, which appeared in some drafts of the Agreement. Though European law may be an important source for the interpretation of that concept, there is no generally accepted notion of “*ordre public*” and no reason for other WTO Members to follow the European approach. Members have a considerable flexibility to define which situations are covered, depending upon their own conception of the protection of public values.

Ordre public should be contrasted with the exclusion from patentability on morality grounds. Morality seems to depend, for the purposes of this Article, on the particular culture of a country or region.⁶²² While it is possible to give a meaning to “morality” which is not culturally dependent, it would seem likely that the provision was drafted from a more relativist viewpoint and could include, for instance, religious concerns in a particular Member. According to Ladas, morality

“... reflects customs and habits anchored in the spirit of a particular community. There is no clearly objective standard of feeling, instincts, or attitudes toward a certain conduct. Therefore, specific prescriptions involving uniform evaluation of certain acts are extremely difficult.”⁶²³

The jurisprudence of the European Patent Office (EPO) has distinguished between *ordre public* and morality (Decision T.356/93). Under the Guidelines for Examination of the EPO, “*ordre public*” is linked to security reasons, such as riot or public disorder, and inventions that may lead to criminal or other generally offensive behaviour (Part C, chapter IV, 3.1). This concept also encompasses the protection of the environment.⁶²⁴ Under the morality clause, the Office has to establish whether

the Marine Mammal Protection Act to save dolphin life and health (they often get caught in the nets used to catch tuna) was held not to be fully consistent with the GATT obligations, because other means of protecting dolphins were available—see *United States – Restrictions on Imports of Tuna* BISD 29S/155. On the other hand, the Appellate Body held that a French prohibition of manufacture, processing, sale, import and marketing of asbestos and asbestos containing products was “necessary” to protect human life in terms of GATT Article XX(b) (See *European Communities – Measures Affecting Asbestos or Products Containing Asbestos [EC – Asbestos]*, WT/DS135/AB/R of 12 March 2001). In particular, the Appellate Body denied the availability of alternative and equally effective measures such as “controlled use” of asbestos as advocated by Canada (see *EC – Asbestos*, para. 174. For a detailed analysis of this jurisprudence, see Jan Neumann, Elisabeth Türk, *Necessity Revisited – Proportionality in World Trade Organization Law After Korea – Beef, EC – Asbestos and EC – Sardines*, *Journal of World Trade* 2003, vol. 37, No. 1, pp. 199 – 233.). See also Carlos Correa, *Implementing National Public Health Policies in the Framework of the WTO Agreements*, 34 *Journal of World Trade* 2000, vol. 34, No. 5, 2, p. 92-96.

⁶²¹ “*Ordre public*” is a legal expression with a long tradition in the area of international private law, where it serves as a last resort when the application of foreign law leads to a result which would be wholly unacceptable for the national legal order. See, e.g., Moufang, p. 71.

⁶²² Gervais, p. 149.

⁶²³ Stephen P. Ladas, *Patents, Trademarks, and Related Rights. National and International Protection*, Harvard University Press 1975, pp. 1685–1686.

⁶²⁴ In case T 356/93 the Board of Appeal of the European Patent Office observed “It is generally accepted that the concept of ‘*ordre public*’ covers the protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is likely

an invention would be so abhorrent for the public that its patenting would be inconceivable. Morality includes the totality of the accepted norms which are deeply rooted in a particular culture.

The analysis of the application of Article 53.b) of the EPC is made case-by-case. The EPO has employed two methods for that purpose: the balancing of interests at stake⁶²⁵ and the opinion of the vast majority of the public.⁶²⁶ In all the cases where these methods were applied, the EPO affirmed the patentability of the inventions under examination.

... including to protect human, animal or plant life or health or to avoid serious prejudice to the environment,...

Article 27.2 includes *examples* of permissible exceptions to patentability, for the protection of human, animal or plant life or health, and avoiding serious prejudice to the environment within the relevant Member.

As mentioned, some decisions by the EPO show that the effects of an invention on the environment may constitute a valid ground for denying patentability. However, the EPO refused to assume a *regulatory role* on the introduction of genetic engineering inventions. In dealing with this issue, one of the opposition decisions argued that

“A patent does not give a positive right to its proprietor to use the invention but rather only confers the right to exclude others from using the invention for a limited period of time. If the legislator is of the opinion that certain technical knowledge should be used under limited conditions only it is up to him to enact appropriate legislation.”⁶²⁷

As noted by Moufang, patent examiners “are not specifically trained in ethics or in risk assessment. Since patents do not give a positive right to use the protected inventions, other bodies have to shoulder the responsibility for the decisions of society whether certain technology can and should be put into practice.”⁶²⁸

to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to ‘ordre public’”.

⁶²⁵ The balancing of interests takes into consideration the advantages and disadvantages of an invention, including the possible environmental risks due to the eventual dissemination of genes in nature (Decision T.19/90). In the area of plant technology, the Board of Appeals of the EPO has argued that plant genetic engineering is not a technical domain that, as such, may be deemed contrary to morality or public order. In decision T 356/93 (Plant Genetic Systems), it reasoned that it needed to be established in each individual case whether a particular invention relates to an improper use or has destructive effects on plant biotechnology. The Board held that “inventions the exploitation of which is likely to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to ordre public”.

⁶²⁶ The opinion of the majority of the public was considered by the Opposition Division of the EPO in a decision of 8.12.94 in the case of “Relaxin”. The patent related to a DNA fragment codifying for a human protein. The Office examined whether the invention would appear immoral for the vast majority of the public.

⁶²⁷ Decision T0019/90, in the “oncomouse” case.

⁶²⁸ Moufang, p. 72.

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... provided that such exclusion is not made merely because the exploitation is prohibited by their law.

The last sentence of Article 27.2 establishes that the sole fact that the exploitation is prohibited by law is not sufficient reason to exclude patentability. This is in line with Article 4*quater* of the Paris Convention, which contains a rule equivalent, though not identical, to the provision contained in the last part of Article 27.2: it stipulates that the grant of a patent shall not be refused (or the registration of a patent not be invalidated) for the sole reason that the sale of the patented product is restricted or limited under domestic law. Thus, mere marketing restrictions as such cannot justify exclusions from patentability. There has to be a specific link between the commercial exploitation of the patent and the respective Member's *ordre public* or morality: Article 27.2 requires that this commercial exploitation would represent a particular danger to either *ordre public* or morality.

4. WTO jurisprudence

There is no specific WTO jurisprudence on this provision. It might be of interest, however, noting the discussion about the concept of "exploitation" in the *EC - Canada* case. Canada took the position that "exploitation" of the patent "involves the extraction of commercial value from the patent by "working" the patent, either by selling the product in a market from which competitors are excluded, or by licensing others to do so, or by selling the patent rights outright. The European Communities also defined "exploitation" by referring to the same three ways of "working" a patent" (para. 7.51). Since the parties differed primarily on their interpretation of the term "normal", the panel defined "normal exploitation" as

"The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices" (para. 7.55).

5. Relationship with other international instruments

5.1 WTO Agreements

Article XX, letters (a) and (b) of the GATT 1994 authorizes WTO Members to deviate from GATT obligations through measures necessary to protect public morals; as well as human, animal or plant life or health, subject to further requirements.⁶²⁹

⁶²⁹ This provision reads: "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

(a) necessary to protect public morals;

(b) necessary to protect human, animal or plant life or health;"

5.2 Other international instruments

6. New developments

6.1 National laws

The approach expressed in Article 27.2 was retained in post-TRIPS developments in Europe,⁶³⁰ and can be found in many other national laws. Moreover, some recent legislative changes in patent law have defined specific exceptions based on ethical considerations in relation to inventions consisting of parts of the human body or techniques applied to human beings. Thus, as a result of a comprehensive legislative initiative in the field of bioethics, the French domestic patent law, as amended in July 1994, provides that the human body, its elements and products as well as knowledge relating to the overall structure of a human gene or elements thereof may not, as such, form the subject matter of a patent. The Australian Patents Act stipulates that “human beings, and the biological processes for their generation, are not patentable inventions”. The European Directive on Biological Inventions, similarly, provides that the human body and its elements in their natural state shall not be considered patentable inventions. However, patents over human genes or cell lines have been granted as a matter of routine by the EPO, whose Opposition Division has not found any reasons why the patenting of human genes should be intrinsically unethical.⁶³¹

6.2 International instruments

6.3 Regional and bilateral context

A number of regional and bilateral free trade agreements such as CAFTA, USA-Jordan, USA-Singapore, and USA-Australia contain exceptions to patentability similar to Article 27.2, TRIPS. On the other hand, the USA-Chile FTA does not expressly provide for such exception.⁶³²

6.4 Proposals for review

There have been no proposals for review of this Article.

7. Comments, including economic and social implications

A patent is simply a grant of exclusive rights. It does not of itself authorise the exploitation of the patented invention, and this can be regulated in separate

⁶³⁰ The 1998 European Directive on Biotechnological Inventions contains a provision (Article 9) similar to Article 53 of the European Patent Convention. See, e.g., Vandergheynst, Dominique, *La notion d'ordre public et des bonnes mœurs dans la proposition de directive européenne relative à la protection juridique des inventions biotechnologiques*, in Geertrui Van Overwalle (Ed.), *Patent Law, Ethics and Biotechnology*, Katholieke Universiteit Brussel, Bruxelles 1998, No. 13, pp. 82–92; Deryck Beyleveld; Roger Brownsword and Margaret Llewelyn, *The morality clauses of the Directive on the Legal Protection of Biotechnological Inventions: conflict, compromise and the patent community*, in Richard Goldberg and Julian Lonbay (Eds.), *Pharmaceutical Medicine. Biotechnology, and European Law*, Cambridge University Press 2000.

⁶³¹ Moufang, pp. 75–76.

⁶³² For details, see Roffe, 2004, who in this context discusses a TRIPS non-derogation clause contained in the U.S.-Chile FTA.

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legislation provided this is consistent with Article 27.2 (that is, for example, that it is necessary to protect human, animal or plant life or health or to avoid serious prejudice to the environment). In the case of pharmaceutical inventions, for example, separate marketing approval is usually required before the invention can be prescribed by doctors for their patients. This marketing approval can sometimes take several years after the grant of the patent. A classic example of an invention contrary to *ordre public* would be a novel kind of letter bomb. It would clearly be permissible to exclude such devices from patentability under Article 27.2. The non-disclosure of the mechanism of the device in a patent specification is a necessary first step in such prevention.

One important point to be considered is the extent to which the role of a patent office in judging and eventually denying a patent on the basis of moral or public order grounds may be sufficient to prevent the harmful effects from taking place. Given the limited competence of a patent office, non-patentability would only ensure that an invention is not the subject of property rights, but by no means would this be sufficient to prevent the use of the invention by any interested person, since it would remain in the public domain.