The Application of TRIPs to the Authorisation by Health Authorities of the Using, Making and Selling of Pharmaceutical Drugs

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Introduction

The present article analyses whether the granting of authorisations by health authorities for the production, marketing and distribution of pharmaceutical drugs under patent protection violates the Agreement on Trade-related Aspects of Intellectual Property ("TRIPs Agreement 1994"), if the beneficiary of the authorisation is not entitled to use the patent, *i.e.* whether such health authorities are being barred from granting such authorisations. This question is examined independently from the legal remedies to be provided under national laws to the affected patent holders or licensees according to Articles 32 and 41 to 61 of the TRIPs Agreement 1994. Apart from that, this article is based on the assumption that local law does not provide third party rights to the patent holder in the administrative proceeding allowing them to oppose the granting of the aforementioned authorisation. It is also assumed that local law does not provide sufficiently expeditious provisional measures to prevent the patent forfeiter from making, using and selling the patented product, without, however, amounting to a systemic failure.

Legal considerations

The general objectives of the TRIPs Agreement 1994 are set out in its preamble, which reflects to a large extent the mandate given in the Punta del Este Ministerial Declaration (1986) of the Uruguay Round of Multilateral Trade Negotiations and refers to the desire to reduce the distortions and impediments to international trade, the need to promote effective and adequate protection of intellectual property rights and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade. The preamble further recognises the need for new rules and disciplines in the intellectual property rights field, comprising not only adequate principles and standards of intellectual property rights but also effective enforcement measures, as well as a multilateral framework for dealing with counterfeit goods, dispute settlement procedures, and transitional arrangements for developing countries.[1]

The TRIPs Agreement 1994 has also been incorporated in recent trade agreements such as the European Union–Mexico Association Agreement. Article 12 of the Global Agreement[2] of the Association Agreement ("Agreement") between the European Union and Mexico states that specific measures should be taken with respect to the protection of industrial property, taking into account certain international conventions. According to Article 1(c) of Decision 2/2001 of the E.C.–Mexico Joint Council,[3] the Agreement aims at the "adequate and effective protection of the intellectual property rights in accordance with the highest international standards". As such highest international standards, Article 36 of Decision 2/2001 incorporates the TRIPs Agreement 1994.

Before discussing the issue on its merits, it is necessary to examine whether the provisions of the TRIPs Agreement 1994 are applicable without further requirements or whether prior to a claim by a WTO Member, the local remedies available to the patent holder affected have to be exhausted. This, however, is independent from the questions whether the TRIPs Agreement 1994 is directly applicable before national courts, which is outside the scope of this article.[4]

Exhaustion of local remedies

As regards public international law, the International Court of Justice ruled 40 years ago that local remedies must be exhausted before international

1. A.A. Yusuf, "TRIPs: Background, Principles and General Provisions", in Carlos M. Correo and Abdulqawi A. Yusuf (eds.), *Intellectual Property and International Trade: The TRIPs Agreement*, Kluwer Law International (1998), at pp.15–16.
2. Economic Partnership, Political Coordination and Corporation Agreement between the European Community and its Member States, of the one part, and the United Mexican States, of the other part, [2000] O.J. L/276.
3. So-called Free Trade Agreement ("FTA") on Services, [2001] O.J. L/70.
4. See Herfried Wöss, *El Nuevo Orden Económico Mundial y la Ronda Uruguay de Negociaciones Comerciales Multilateriales*, Universidad Nacional Autónoma de México, Revista de la Facultad de Derecho, Tomo XLV (1995), Nos. 203–204, at 130, 136; *ibid., Derecho Internacional Económico y el Acuerdo de Cooperación Laboral de América del Norte (ACLAN)*, Capítulo II, C.1., Oxford University Press, Mexico (forthcoming).

proceedings may be instituted, this being a well-established rule of customary international law.[5] Such principle was confirmed by the International Court of Justice in the ELSI case.[6] However, this does not seem to be valid for the GATT/WTO dispute settlement rules, according to the intention of the drafters of such rules and established state practice. There are a number of cases where GATT dispute settlement proceedings were pursued in parallel with domestic court proceedings, *e.g.* over the same anti-dumping, countervailing duty or other trade measures. In fact no WTO Member country has so far claimed the application of this international law principle which normally applies to cases of "diplomatic protection" of nationals against violations of their individual rights protected under human rights law and investment law on the protection of aliens and their property, as distinguished from cases of "direct injury" to states.[7]

In fact, the only relevant reference to the principle of exhaustion of remedies found in relation to WTO law is with respect to Bilateral Investment Treaties (BITs).[8] However, in the absence of an express requirement to exhaust local remedies in the dispute resolution mechanism of a BIT, it would not apply. The vast majority of BITs do not require exhaustion of local remedies as an express precondition to accessing arbitration, although a practice of accessing local courts for a specific period of time (usually 18 months) is sometimes included, in which case arbitration can be accessed immediately upon expiry of such period, irrespective of whether a final decision has been taken.[9]

In the Grey Portland Cement case, the 1992 GATT Panel report noted

> "that in respect of the domestic administrative proceedings in the United States, there was nothing in the Agreement which explicitly required the exhaustion of administrative remedies, *i.e.* that for an issue to be properly before a Panel, it would have had to have been raised in the domestic administrative proceedings. The Panel considered if such a fundamental restriction on the right of recourse to the Agreement's dispute settlement process had been intended by the drafters of the Agreement, they would have made explicit provision for it."[10]

5. Interhandel case, *USA v. Switzerland*, ICJ Reps 1959, at p.6, cited in: Ernst-Ulrich Petersmann, "International Trade Law and the GATT/WTO Dispute Settlement System 1948–1996: An Introduction", in: Ernst-Ulrich Petersmann (ed.), *International Trade Law and the GATT/WTO Dispute Settlement System, Studies in Transnational Economic Law*, Kluwer Law International (1997), at p.116.
6. Case Concerning Elettronica Sicula S.p.A. (ELSI), ICJ Reps 1989, pp.15–82, cited in Ernst-Ulrich Petersmann *op.cit*, at p.116 n.222.
7. Ernst-Ulrich Petersmann, *op.cit*, at p.117.
8. See WTO, *Trade and foreign direct investment*, Press/57, October 9, 1996.
9. Conversation with Mr Nigel Blackaby of Freshfields Bruckhaus Deringer on November 5, 2001.
10. *United States—Anti-dumping duties on gray Portland cement and cement clinker from Mexico*, ADP/82, 1992 (unadopted).

Therefore, though it may not be excluded that the exhaustion of local remedies principle be brought forward in a dispute resolution proceeding under the TRIPs Agreement 1994, such argument is not very likely to proceed and would substantially change the WTO and similar dispute settlement proceedings. Due to the harmonisation of the WTO dispute settlement proceeding with some differences established in the different multilateral sub-agreements, it is rather unlikely that said principle be applied one day exclusively to disputes under the TRIPs Agreement.

Scope of Article 28.1 of TRIPs (rights conferred)

In the following, the author examines whether a government measure granting the authorisation to produce, market and distribute pharmaceutical drugs under patent protection to a person or entity not entitled to use such patent, violates Article 28.1 of the TRIPs Agreement 1994.

Said Article reads:

> "A patent shall confer on its owner the following exclusive rights:
>
> (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of making, offering for sale, selling or importing for these purposes that product;
> (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."

In order to determine the scope of Article 28.1 of the TRIPs Agreement 1994, said provision has to be interpreted in the light of the WTO law and the Vienna Convention on the Law of Treaties 1968, especially Articles 31 and 32 of the Vienna Convention.[11] From a simple reading of Article 28.1 of the TRIPs Agreement 1994, it appears that the rights of the owner of a patent are limited to prohibit the exploitation of a patent by any unauthorised person or entity. Therefore, acts of government, whether voluntary or involuntary, promoting the violation of the patent owner's rights prima facie seem to be outside the scope or the "ordinary meaning" of the legal provision in question, *i.e.* Article 28.1 of the TRIPs Agreement 1994 does not expressly include rights to prevent others from aiding or participating in the patent infringement, unless the conduct in question consists of the making, using and selling of the patented product.

11. See Art.3.2 of the Dispute Settlement Understanding.

Such an interpretation, however, ignores that the government measure inevitably leads to patent infringement. The right of the patent owner "to prevent third parties" from patent forfeiting, necessarily should include the right to stop a government authority voluntarily or involuntarily inducing patent infringement. As one panel ruled,

> "The good faith requirement in [Article 31(1) of the Vienna Convention on the Law of Treaties] suggests … that a promise to have recourse to and abide by the rules and procedures of the Dispute Settlement Understanding, also in one's legislation, includes the undertaking to refrain from adopting national laws which threaten prohibited conduct."[12]

As several GATT panels have recognised, the provisions of the GATT apply not only to laws, regulations and legal requirements but also to *informal government interventions with equivalent effects.*[13]

The Preamble of the TRIPs Agreement clearly states that the parties "recognize the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods". This indicates that Article 28.1 of the TRIPs Agreement 1994 should not be interpreted narrowly and limited to its literal meaning but rather be oriented by the object and purpose of the TRIPs Agreement 1994.

According to the *travaux préparatoires*, the negotiators of the TRIPs Agreement 1994, especially from developed countries, were concerned that the obligations under the TRIPs Agreement 1994 could be circumvented through measures not specifically covered by it, such as high fees for patent registration, or informal administrative guidance.[14]

By granting the aforementioned authorisations to patent forfeiters, the government authority foresees or should have foreseen that it makes patent infringements possible as the purpose of such authorisation is evidently the making, using and selling of pharmaceutical drugs by the applicant not entitled by the patent holder. There is a clear causal relationship between the government measure and the patent infringement, with the consequence that the patent owner is being deprived of his patent rights until he obtains a provisional measure under Article 14 of the TRIPs Agreement 1994 as to be provided under national law. Therefore, the patent owner suffers a temporary suspension of the protection awarded by Article 28.1. Such temporary suspension of patent rights seems to be sufficient to establish a violation of Article 28.1, as the patent owner is deprived of his *exclusive* right to use, make and sell the pharmaceutical products during that period. This is particularly true in case of certain countries that do not provide sufficiently expeditious means to achieve such provisional measures without, however, giving rise to a systemic failure[15] of intellectual property rights enforcement. The situation is aggravated in case the patent holder cannot prevent the granting of such authorisation to third parties because of the lack of legal standing in the administrative authorisation proceeding.

Dispute settlement provisions

In the following subsections, the author evaluates the effect of a probable violation of the TRIPs Agreement 1994 and the consequences of a lack of proof of such violation under the provisions of the Dispute Settlement Understanding. As the dispute settlement provisions in the context of the TRIPs Agreement 1994 have a particular connotation, especially as regards the concept of non-violation nullification and impairment, the exception provision of Article 30 of the TRIPs Agreement 1994 has to be tackled only thereafter.

Nullification and impairment

Article 64 of the TRIPs Agreement refers to Articles XXII and XXIII of the GATT 1994 as applied by the Understanding on Rules and Procedures Governing the Settlement of Disputes ("Dispute Settlement Understanding") contained in Annex 2 of the WTO Agreement. Article XXIII:1(a) reads as follows:

> "If any contracting party should consider that any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as the result of (a) the failure of another contracting party to carry out its obligations under this Agreement."

In essence, this provision refers to a violation of a certain obligation (*i.e.* Article 28.1 of the TRIPs Agreement) by another WTO Member. As a consequence the WTO Member suffering nullification or impairment of a benefit under the TRIPs Agreement 1994 may initiate a dispute settlement procedure under the Dispute Settlement Understanding. Nullification or impairment is presumed according to Article 3.8 of the Dispute Settlement

12. Report of Panel on *United States—Sections 301–310 of the Trade Act of 1974*, WT/DS152/R, 1999, para.7.68, cited in Edmond McGovern, *International Trade Regulation*, Globefield Press, Exeter, looseleaf, § 1.1212.
13. BISD 35S/153–155.
14. Frieder Roessler, "The Concept of Nullification and Impairment in the Legal System of the World Trade Organization", in Ernst-Ulrich Petersmann (ed.), *International Trade Law and the GATT/WTO Dispute Settlement System, Studies in Transnational Economic Law*, Kluwer Law International, 1997, at pp.135–138.
15. See Frederick M. Abbott, "WTO Dispute Settlement and the Agreement on Trade-Related Aspects of Intellectual Property Rights", in Ernst-Ulrich Petersmann (ed.), *International Trade Law and the GATT/WTO Dispute Settlement System, Studies in Transnational Economic Law*, Kluwer Law International, at pp.428–429.

Understanding once a WTO-inconsistent measure has been established.[16]

According to Article II:2 of the WTO Agreement, the Dispute Settlement Understanding is an integral part of the WTO Agreement, binding on all Members. Article 1.1 of the Dispute Settlement Understanding specifies that it shall apply, amongst others, to disputes brought pursuant to the dispute settlement provisions of the Multilateral Trade Agreements listed in Appendix 1 to the Dispute Settlement Understanding (*i.e.* the Multilateral Agreements on Trade in Goods in Annex 1A, the GATS in Annex 1B and the TRIPs Agreement in Annex 1C of the WTO Agreement).[17]

Non-violation nullification and impairment

In order to initiate an action under the Dispute Settlement Understanding, it is not necessary to prove a violation of a provision of the TRIPs Agreement 1994. Article XXIII:1(b) of the GATT 1994, applicable since January 1, 2000 due to the transitional period established in Article 64 of the TRIPs Agreement, refers to the "non-violation nullification and impairment" of benefits granted under the WTO Agreement. This concept was originally meant to re-establish the balance of benefits granted under a trade agreement in the form of tariff concessions. However, in the case of the TRIPs Agreement 1994, the non-violation nullification and impairment concept has the character of an anti-circumvention provision.

This provision reads:

> "If any contracting party should consider that any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as the result of (b) the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement, …"

According to Frederick M. Abbott, the application of this principle might lead to transform IPRs from negative rights into *positive rights* providing a powerful tool for the opening of markets.[18] In this regard, Frieder Roessler rightly points out that the application of the nullification and adjustment principle will require a new rationale specific to the TRIPs Agreement such as *non-circumvention* and prohibition of the *abuse of law.*[19]

Under the non-violation nullification and impairment provision, it would be sufficient that the patent owner was deprived of the benefits normally accruing to him as a consequence of patent protection. In the present case and in order to countervail a narrow interpretation of Article 28.1 of the TRIPs Agreement by a panel, the anti-circumvention argument provided by the non-violation nullification and impairment principle would be a suitable alternative.

The patent owner for the pharmaceutical drug is at least temporarily deprived of his patent rights and the economic benefits conferred to him by such patent rights. This can be clearly established by economic data such as the market participation of patent forfeiters and leads to nullification and impairment of the benefits accruing to the patent holder under Article 28.1 of the TRIPs Agreement 1994. In case of a non-violation nullification and impairment, the *burden of proof* is upon the complainant.[20]

Traditionally, even if such nullification and impairment was confirmed by a panel, the consequence was not necessarily a removal of such measure but on some occasions some other kind of compensation. However, in the case of the TRIPs Agreement 1994 and other obligations that are not tariff concessions subject to bilateral negotiation, there does not appear any room for individual renegotiations.[21] Therefore, the result is likely to be a removal of the measure.

Article 30 of the TRIPs Agreement (exceptions to rights conferred)

Even if a violation of the TRIPs Agreement 1994 is being found, the measure may be justified under Article 30 of the TRIPs Agreement 1994. The same is true if a nullification or impairment without such violation occurs, as this exception necessarily extends to the consequences of any rule such as the benefits conferred by Article 28.1 of the TRIPs Agreement 1994.

Article 30 of the TRIPs Agreement 1994, the so-called "limited exceptions provision", reads:

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

An extensive interpretation of the meaning of this Article can be found in the Report of the Panel on *Canada—patent protection of pharmaceutical products* ("Canada Panel report").[22] The issue of

16. See also GATT Basic Instruments and Selected Documents ("BISD"), 11S/99–100 (1960).
17. Ernst-Ulrich Petersmann, *op.cit*, at pp.54–55; see also Herfried Wöss, *El Nuevo Orden Económico Mundial y la Ronda Uruguay de Negociaciones Comerciales Multilateriales*, Universidad Nacional Autónoma de México, Revista de la Facultad de Derecho, Tomo XLV (1995), Nos.203–204, at 131, 137–138, 146–149.
18. Frederick M. Abbott, *op.cit*, at 433–434.
19. Roessler, *op.cit*, at 138.
20. Art.3.8 of the WTO-Dispute Settlement Understanding.
21. Roessler, *op.cit*, at 137–138.
22. WT/DS114/R of March 17, 2000.

the report was a dispute between the European Communities and their Member States, on the one hand, and Canada, on the other hand, about two provisions of the Canadian Patent Act, the "regulatory review exception" and "the stockpiling exception", that create exceptions to the exclusive rights of patent owners. The latter allowed competitors to manufacture and stockpile patented goods during a certain period before the patent expired, but the goods could not be sold until the patent expired. Under the pharmaceutical regulations, the period during which pharmaceutical products could be made and stockpiled was six months immediately prior to the expiration of the patent.

Article 30 establishes three criteria that must be met in order to qualify for an exception: (1) the exception must be "limited"; (2) the exception must not "unreasonably conflict with the normal exploitation of the patent", whether or not "taking into account the legitimate interests of third parties"; and (3) the exception must not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".

According to the Canada Panel report, the three conditions are cumulative, each being a separate and independent requirement that must be satisfied. Failure to comply with any one of the three conditions results in the Article 30 exception being disallowed.[23] The three conditions must be interpreted in relation to each other. Each of the three must be presumed to mean something different from the other two, or else there would be redundancy.[24] Normally, the order of listing can be read to suggest that an exception that complies with the first and second can still violate the third. The syntax of Article 30 supports the conclusion that an exception may be "limited" and yet fail to satisfy one or both of the other two conditions. The ordering further suggests that an exception that does not "unreasonably conflict with normal exploitation" could nonetheless "unreasonably prejudice the legitimate interest of the patent owner".[25]

The Panel further held, that the three limiting conditions attached to Article 30 of the TRIPs Agreement testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement.[26]

Limited exceptions

The term "limited exceptions" derives from Article 9(2) of the Berne Convention. However, according to the Panel the wording in the Berne Convention and the TRIPs Agreement is different and concluded that "[t]he term 'limited exception' must therefore be read to connote a narrow exception—one which makes only a small diminution of the rights in question".[27]

The Canada Panel report also stated that the "market advantage gained by the patent owner in the months after the expiration of the patent" can only be considered a purpose of the patent owner's right to exclude "making" and "using" during the term of the patent. In both theory and practice, the Canada Panel concluded that "such additional market benefits were within the purpose of these rights". The Panel stated that the rights of the patent owner are generally viewed as a right to prevent competitive commercial activity by others and manufacturing for commercial sale is a quintessential competitive commercial activity.[28]

The granting by the health authorities, without restriction, of authorisations to laboratories not entitled under the respective patent to use, make or sell the pharmaceutical drugs in question deprives the patent holder during a certain period and until a provisional measure has been issued of the benefits provided for by the patent. The temporary curtailment of such benefits is quite similar to the effects of the foreclosing of commercial benefits after patent expiry caused by the Canadian stockpiling exception that was deemed not to satisfy the first condition of Article 30 of the TRIPs Agreement 1994 and to be inconsistent with Article 28.1 of the TRIPs Agreement. As already mentioned, it is not relevant whether the measure in question has the form of a law or a regulation or whether it consists of a discretionary government measure. This situation is aggravated when the patent owner is not being granted legal standing in the drug authorisation procedure initiated by the patent forfeiter.

Therefore, government measures voluntarily or involuntarily inducing patent forfeiture can hardly be considered as limited exceptions to the exclusive rights conferred upon a patent owner by the patent as it curtails such rights in essence, independently of the duration of such curtailment.

The Canadian Panel report did not provide any determination with respect to the notions of exceptions that do not "unreasonably conflict with the normal exploitation of the patent" or must not "unreasonably prejudice the legitimate interests of the patent owner, taking account of

23. Report of Panel on *Canada—Patent protection of pharmaceutical products* WT/DS114/R, para.7.20.
24. See *United States—Standards for Reformulated and Conventional Gasoline,* WT/DS2/AB/R, para.23 (adopted May 20, 1996).
25. Report of Panel on *Canada—Patent protection of pharmaceutical products* WT/DS114/R, para.7.21.
26. Report of Panel on *Canada—Patent protection of pharmaceutical products* WT/DS114/R, para.7.26.
27. Report of Panel on *Canada—Patent protection of pharmaceutical products* WT/DS114/R, para.7.30.
28. Report of Panel on *Canada—Patent protection of pharmaceutical products* WT/DS114/R, para.7.35.

the legitimate interests of third parties", as the finding of the lack of a "limited exception" was sufficient to declare the stockpiling exception inconsistent with Canada's obligation, *inter alia*, under Article 28(1) of the TRIPs Agreement 1994. However, in order to be exhaustive, said notions will be discussed briefly.

Normal exploitation of the patent

According to the second condition of Article 30 of the TRIPs Agreement, the measure in question must not be in conflict with the normal exploitation of the patent. As it is notorious, the granting of authorisations to use, make and sell pharmaceutical drugs by health authorities to applicants not entitled under patent law, substantially reduces the exploitation by the patent owner. This is due to the importance of the patent rights curtailed and given the unlimited extent and the considerable duration in certain jurisdictions until the violation of patent rights be stopped through judicial proceedings. Therefore, the measure in question would normally unreasonably conflict with the normal exploitation of the patent.

Legitimate interests of patent owners and of third parties

The interest of consumers to obtain cheaper medicines are purely economic and are the same with respect to public health or health insurance enterprises.[29] No legitimate interests of patent forfeiters or third parties, of a legal, economic, moral or other kind can be identified that could outweigh the legitimate interest of the patent owner to prevent health authorities from voluntarily or involuntarily causing patent infringements.

Conclusions

The issuing of authorisations by health authorities to use, make or sell pharmaceutical drugs to applicants not entitled to do so under the respective patent is likely to be inconsistent with and definitely nullifies and impairs the benefits granted by Article 28.1 of the TRIPs Agreement 1994. Provided that no third party rights are granted to the patent owner during the authorisation procedure before the health authority and that provisional measures are not being granted sufficiently expeditiously, the limitation of market benefits during the time between the granting of the authorisation and the effects of court actions to prohibit the use, making and selling of the patented drug is similar to the one found inconsistent in the Panel report on *Canada—Patent protection of pharmaceutical products*. However, it has to be admitted that the issue at stake in the present case is not the same as in the Canada Panel report.

In case a panel interprets Article 28.1 of the TRIPs Agreement 1994 too narrowly, recourse to the non-violation nullification and impairment provision referred to in Article 64 of the TRIPs Agreement should be sought. In neither case may a violation of Article 28.1 of the TRIPs Agreement 1994 or nullification or impairment of the benefits accruing from such Article be justified under Article 30 of the TRIPs Agreement 1994.

29. Report of Panel on *Canada—Patent protection of pharmaceutical products* WT/DS114/R, para.4.30, (2)(c)(iii).