

WIPO/ECTK/SOF/01/2.6

ORIGINAL:English

DATE:May2001

THE PRESIDENT OF THE
REPUBLIC OF BULGARIAWORLD INTELLECTUAL
PROPERTY ORGANIZATION

**INTERNATIONAL CONFERENCE ON
INTELLECTUAL PROPERTY, THE INTERNET,
ELECTRONIC COMMERCE AND TRADITIONAL KNOWLEDGE**

organized
under the auspices of
His Excellency Mr. Petar Stoyanov, President of the Republic of Bulgaria

by
the World Intellectual Property Organization (WIPO)
in cooperation with
the National Intellectual Property Association of Bulgaria

**Boyana Government Residence
Sofia, May 29 to 31, 2001**

RECENT DEVELOPMENTS AND CHALLENGES IN THE PROTECTION OF
INTELLECTUAL PROPERTY RIGHTS (IPRS)

UNDER THE TRIPS AGREEMENT:
CONCERNS AND STRATEGIES FOR DEVELOPING COUNTRIES

*Document prepared by Dr. Galal Wafaa Mohamedien, Professor of Commercial Law,
Alexandria University, Egypt, and Legal Advisor, Industrial Bank of Kuwait K.S.C., Kuwait*

I. THE TRIPS CHALLENGE TO DEVELOPING COUNTRIES

Intellectual property such as computers software, medical products, pharmaceutical drugs, know-how, etc., are subject to high risks due to global piracy and infringement. The unchecked continuation of this situation, needless to say, undermines intellectual property rights (IPRs) owners of large volume of expenditures on scientific research, in addition to their effort and invaluable time.¹

A significant challenge of the Uruguay Round of 1994 has been to secure protection for IPRs by the member states. This goal was accomplished through the adoption and implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). However, this goal was not easy to achieve. Arguments have been submitted as to why this goal shall serve the interests of all member states to the Uruguay Round. Intellectual property proponents in the developed world have asserted the economic benefits of enhanced IPR protection, and that a strong system for the protection of IPRs will certainly help the flow of technology from the industrialized nations to developing countries. These assertions, however, have not been accepted by many developing countries which assume that a global IPR protection shall secure the control of IPR entrepreneurs in the industrialized world. In their view, IPR protection is nothing but an extension of the monopolistic prerogatives of the multinational companies. For example, the protection of patented pharmaceutical products shall result in high drug prices.²

These conflicting interests were at stake during the Uruguay Round. Developed countries, such as the United States of America, preferred not to resort to political threat or trade sanctions in order to change the attitude of developing countries on IPR issues. Actually, the Uruguay Round was a unique occasion to eliminate a possible confrontation which was apt to arise between the opposing parties: developed nations vs. developing countries. The TRIPS was concluded to bridge the gap between the two different views on IPR issues.

A middle solution was reached, according to which members of the Uruguay Round have consented to establish transitional periods for developing countries to facilitate their enactment of IPR legislation. Conversely, after the lapse of these transitional periods, developing countries should comply with the rules and procedure in the TRIPS Agreement. Then non-complying member countries shall be subject to the deterrent mandatory sanctions imposed by the TRIPS Agreement itself. In sum, the transitional periods were the basic concessions made by the developed countries in concluding the TRIPS Agreement which would not have been successfully negotiated if those periods were not secured.³

Many writers from developed countries argue, however, that these transitional periods are too long, and their implementation will result to huge losses to IPR owners. Each year the

¹ See for example, Mark Damschroder, Intellectual Property Rights and the GATT: United States Goals in the Uruguay Round, volume 21 Vanderbilt Journal of International Law, No. 2 pp. 367-400 (1988) at pp. 368-369.

² Review: Theresa B. Lewis, Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries, Volume 30, No. 4, The International Lawyer, pp. 835-865 (1996) at pp. 835-837; Robert W. Kastnmeier & David Beier, International Trade and Intellectual Property: Promise, Risks, and Reality, Volume 22, No. 2 Vanderbilt Journal of Transnational Law, pp. 285-307 (1989) at pp. 301-303.

³ See: L. Peter Farakas, Trade-Related Aspects of Intellectual Property, in the World Trade Organization "Multilateral Trade Framework for the 21st Century and U.S. Implementing Legislation" by Terence P. Stewart (editor) American Bar Association (1996) at pp. 465-466.

application of the TRIPS Agreement is delayed in a developing country and will cost developed countries billions of dollars because of the infringement of their IPRs.

According to the TRIPS Agreement, developing countries have been permitted to delay the assumption of their obligations for a period of five years commencing from the date the World Trade Organization (WTO) Agreement entered into force on January 1, 1995. Article 65/3 of the TRIPS Agreement provides for the application of the same grace period to those member states in the process of transformation from a centrally -planned into a market, free enterprise economy and which are undertaking structural reform of their intellectual property system and facing special problems in the preparation, and implementation of intellectual property laws and regulations. This grace period expired on January 1, 2000.

Furthermore, Article 65/4 of the TRIPS Agreement provides that developing member countries may elect to delay the application of the provision on product patents of TRIPS part II, section 5, for an additional period of five years where product patent protection in areas of technology is not possible in their territory at the time they became obligated under the TRIPS Agreement. Pharmaceuticals and agricultural products are subject to this exception. Economics in transformation from a centrally -planned into a market free enterprise are not mentioned in Article 65/4. It is, therefore assumed that this exception shall not be applied to this last group of countries.

During this additional grace period, starting from January 1, 2000 until January 1, 2006, developing countries should provide means by which patent applications may be filed (mail box). Applications will be treated as if they had been filed on the actual date of filing, not the first day of complete transition period. Moreover, Article 70/9 provides for exclusive marketing rights in the developing country utilizing this exception. Article 65/5 provides that any country availing itself at transitional period under paragraphs 1, 2, 3 or 4, has an obligation to ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement. This is described by some authors as "a standstill clause" because intellectual property protection may not get worse.⁴

In recognition of the special needs and the intractable problems facing the least -developing countries to create a technological base, Article 66/1 provides that such members shall not be required to apply the provisions of the TRIPS Agreement, except those relating to national treatment, most favored treatment, and multilateral agreements on acquisition or maintenance of protection, for a period of ten years from the date of application as defined under paragraph 1 of Article 65. This period may be extended upon a request by a least -developing country provided that the Council for TRIPS accord that extension. No ceiling or limits have been imposed on additional extensions. The standstill clause is not mandatory in the case of least-developed countries during the mentioned transitional period.⁵

⁴ Ibid. at p. 467.

⁵ Ibid.

II. CONCERNS FOR DEVELOPING COUNTRIES

Despite the fact that few concessions, in the form of transitional periods, have been surrendered to developing countries in an attempt to tempt and encourage them to join the TRIPS Agreement, there are still obvious concerns on the part of those countries to implement the TRIPS rules. The major concerns for developing countries may be explored in the TRIPS Agreement in respect to patentable subject matter, term of a patent and, compulsory licensing.

1. Patentable Subject Matter

Article 27/1 of the TRIPS Agreement provides that "subject to the provisions of paragraph 2 and 3, patents shall be available for all inventions, whether products or process, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

According to this provision all member states to the TRIPS Agreement shall not exclude any field of technology from patentability, except as provided by the TRIPS Agreement itself.

In addition, patents shall be available without discrimination as to the place of invention and as to whether patented products are imported or produced in the local market.

Furthermore, this provision requires as a condition precedent for patentability that the invention must contain an inventive step. In other words, the invention which is eligible for patent protection must be of an authentic and absolute novelty. Inventions which are published or known anywhere in the world shall not be granted patents under TRIPS because of lack of novelty. The requirement of absolute novelty coupled with the requirement of inventive step shall deprive developing countries of an advantage they enjoyed before the application of TRIPS. In the laws of many developing countries, it was possible to grant patents for inventions of relative novelty, e.g. those inventions published or known abroad but not published or known locally.

The grant of patents only to inventions of authentic inventive step is considered an advantage to multinational corporations because they possess enormous investments and scientific capabilities which enable them to develop, create, and execute this type of invention. Conversely, developing countries are banned from granting patents to small inventions of relative novelty, or to improvement inventions which do not satisfy the requirement of the inventive step. Consequently, it is expected that the majority of patents worldwide shall be granted and owned by inventors in the industrialized nations.

Moreover, the TRIPS Agreement provides protection for almost all kinds of inventions. An invention which satisfies the inventive step criteria shall be patented. There is a room, however, for few exceptions. The inventions shall not be protected by a patent if commercial exploitation of a patent is prohibited for reasons of public order or morality, or the protection of human, animal or plant life or health, or the avoidance of serious prejudice to the environment. Diagnostic therapeutic, surgical methods, animals other than micro-organisms,

plants, and essentially biological processes for the production of animals or plants may also be excluded from patentability.⁶

The enlargement of the scope of the patentable subject matter under the TRIPS Agreement shall have a direct impact in the field of pharmaceutical industries which are of very vital importance to developing countries. Before TRIPS, many developing countries, like India, did not grant any patent protection to medicine and drugs. In other developing countries, pharmaceuticals are granted limited protection. For example, the Egyptian Patent Law of 1949, protects pharmaceuticals through process patents only. Process patents are directed at protecting the means or the method of obtaining an end result. The majority of developing countries are reluctant to grant product patents for pharmaceuticals.⁷ This is because product patents refer to the chemical structure defining a chemical compound, or composition which is the product consumed by consumers. Conversely, multinational companies prefer product patents for pharmaceuticals because they confer protection regardless of the method employed to produce the compound. Multinational companies shall gain huge profits because of product patents in the field of pharmaceuticals.

Thus, developing countries should, under their TRIPS commitments, grant product patents for pharmaceuticals. It is admitted that TRIPS has conferred grace periods for those countries in order to make arrangements to fulfill their obligations to grant product patents for drugs, nevertheless, the adverse effects shall be severe. The most serious impact shall be the unavoidable increase of pharmaceutical prices for local consumers.

2. Term of a patent

Under the pressure of multinational companies, the industrialized nations have advocated a long-patent term which shall prolong the patent monopoly for inventors. According to the TRIPS Agreement, a universal patent term of twenty years from the date of filing for a patent shall be applied to all kinds of inventions regardless of their patentable subject matter.⁸

In the laws of many developing countries, the patent term is relatively short. A short term is advantageous because it allows developing countries, upon the expiration of patents, to make use of inventions that might still have viable technological value. Under the TRIPS Agreement, developing countries are deprived of this advantage. Taking into consideration the complexity of inventions and the fast development of technology, the requirement of twenty years for patents shall render many inventions as obsolete after the expiration of that term, and hence deprive developing countries of an advantage that they enjoyed before TRIPS.

In any case, developing countries are under an obligation to amend their national laws to conform with the newly stipulated patent term.

⁶ Bernard Hoekman, Services and Intellectual Property Rights, in The New GATT, Implications for the United States (Susan M. Collins & Barry Busworth - editors - 1994 - The Brookings Institutions) at pp. 101 - 102.

⁷ Julio Noguez, Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries, Volume 24, No. 6, Journal of World Trade, pp. 81 - 104 (1990); M. Adelman & Sonia Baldia, Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India, Volume 29, No. 3, Vanderbilt Journal of Transnational Law, pp. 507 - 533 (1996).

⁸ Peter Farakas, Trade Related Aspects..., Supra note 3, at p. 488.

3. Compulsory License

Generally, the doctrine of compulsory license is applied if the patentee abuses his exclusive rights conferred by the patent system. Normally, a compulsory license is granted if the patentee refuses to work his patent locally or abstains from granting licenses to others on reasonable grounds and thereby hinders industrial development and the national welfare. Another form of abuse occurs when the patentee refuses to supply the national market with sufficient quantities of the patented invention, or demands unreasonable prices for such inventions.⁹

According to the TRIPS Agreement, foreign patentees are not obliged to work their patents locally. In addition, compulsory licenses have very limited application. They are allowed in few cases. Article 31 of the TRIPS Agreement permits compulsory license if the patentee refuses to authorize the use of the invention on reasonable commercial terms. In other words, a compulsory license shall be allowed only when negotiating a license on fair commercial terms has failed. A compulsory license is not granted if a developing country attempts to exploit the invention without giving the inventor an adequate compensation which is measured by reasonable commercial term. Conversely, a compulsory license is obtained failing such negotiations with the patentee, provided that an equitable compensation is paid. This requirement may be waived in case of national emergency or other circumstances or extreme emergency in cases of public non-commercial use.¹⁰

In any case, the licensee, obtaining a compulsory license, should not exploit the invention on commercial basis to reap economic benefits. For example, the licensee is not authorized to export products manufactured under compulsory license, nor is he allowed to exclude a foreign patentee from subsequently working the patent locally in direct competition with the licensee.

In principle, the use of inventions under compulsory license is not exclusive, and such use is authorized mainly for the supply of the domestic market of the country authorizing such use. The only exception to the compulsory license available under Article 31 of the TRIPS is for patented semi-conductor technology which "shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive."

It appears, therefore, that the TRIPS Agreement eliminates the possibility that lack of local working of a patent is a sufficient ground for obtaining a compulsory license. That is because importation satisfies the patent working requirement. Thus, developing countries shall fail to obtain compulsory licenses if foreign patentees sufficiently provide the local markets with the patented products. Nevertheless, developing countries may increase the pressure on foreign patentees to negotiate compulsory licenses if reasonable terms are proposed.

⁹ J.H. Reichman, Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement, Volume 29, No. 2, The International Lawyer, pp. 345-388 (1995) at pp. 355-357.

¹⁰ Ibid., Bernard Hoekman, Services and Intellectual Property, supra note 6 at pp. 102-103.

III. STRATEGIES FOR DEVELOPING COUNTRIES

The value of implementing the patent TRIPS in developing countries is controversial. Developing countries shall face hardships because of their growing dependence on foreign patents. This fact is based on the grounds that the TRIPS Agreement has emphasized and expanded patent protection without assuring the enhancement of solid technological base in developing countries.

In order to cope with the expected consequences following the implementation of the TRIPS Agreement, developing countries should develop strategies to avail themselves of some benefits. In particular, they should take full advantage of the grace periods given under the said Agreement in order to introduce regulatory as well as technical improvements to their patents systems. Taking into account that the TRIPS Agreement does not require retroactive protection for patents, and that it does not give rise to obligations in respect of facts which occurred before the date of application of the Agreement for the member state in question, many developing countries may continue the use of thousands of pharmaceutical products in consumption in the local markets.

Another suggestion is proposed by an eminent writer according to which there would be a fee for patent acquisition and maintenance, especially in pharmaceutical and semiconductor inventions, that would be adequate to fund the patent granting agency in the country. The proposed fee may be employed in establishing and developing a technological base. ¹¹

It has been also suggested that developing countries should make use of few provisions in the TRIPS Agreement which could be of vital importance to them. One of these provisions is Article 29 which mandates that member countries should require applicants for a patent to “disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention.” Developing countries should impose on patentees an obligation of complete disclosure which will enable the making of the invention in that country. It is also suggested that developing countries should require that the patent applicant should disclose the (best) mode for the making of his invention in that developing country. ¹²

Last but not least, it is recommended that developing countries shall grant or continue to grant utility patents for small inventions in specific fields. Utility patents fit the needs of developing countries as they enable inventors, usually local inventors, to obtain patents based on other basic patentable inventions. TRIPS itself does not expressly prohibit the practice of utility patents. Therefore, and until the matter is resolved, developing countries may continue to grant this type of patent.

[References follow]

¹¹ A. Samuel Oddi, TRIPS Natural Rights and a “Polite Form of Economic Imperialism,” Volume 29, No. 3, Vanderbilt Journal of Transnational Law, pp. 415 -470 (1996) at pp. 461 -463.

¹² Ibid. at pp. 463 -466.

References

1. Adrian Otten & Hannu Wager, "Compliance with TRIPS: The Emerging World View," Volume 29, No. 3, Vanderbilt Journal of Transnational Law (May 1996), pp. 391 - 413.
2. Amede Turner, *The Law of Trade Secrets* (Sweet & Maxwell London), (1962).
3. Arthur Kuflik, "Moral Foundations of Intellectual Property Rights" (in *Owing Scientific and Technical Information*, editors: Vivian Weif & John W. Snapper, editors, (1989).
4. Arvind Subramanian and Jayashree Watal, "Can TRIPS Serve as an Enforcement Device for Developing Countries in the WTO?," Volume 3, No. 3, Journal of International Economic Law, pp. 403 - 416 (2000).
5. Bernard Hockman, "Services and Intellectual Property Rights, in the New GATT, Implications for the United States" (Susan M. Collins & Barry Bushworth, editors, (1994).
6. Carlos Brager, "The Economics of Intellectual Property Rights and The GATT: A View from the South," Volume 22, No. 2 (1989) pp. 243 - 264.
7. Donald F. Turner, "The Patent System and Competitive Policy," Volume 44, New York University Law Review, pp. 450 (1969).
8. Douglas F. Greer, "The Case Against Patent Systems in Less - Developed Countries," Volume 8, Journal of International Law & Economics (1973).
9. Eric H. Smith, "World Wide Copyright Protection under the TRIPS Agreement," Volume 29, No. 3, Vanderbilt Journal of Transnational Law (1996), pp. 559 - 578.
10. Harold C. Wagner, "TRIPS Boomerang - Obligations for Domestic Reform," Volume 29, Vanderbilt Journal of Transnational Law (1996), pp. 535 - 558.
11. J.H. Reichman, "Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement," *The International Lawyer*, Volume 29, No. 2 (Summer 1995), pp. 345 - 388.
12. Julio Lacarte and Petina Gappah, *Developing Countries and the WTO, Legal and "Dispute Settlement System: A View from the Bench,"* Volume 3, No. 3, Journal of International Economic Law, pp. 560 - 601, (2000).
13. Julio Nogues, "Patent and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries," Volume 24, No. 6, Journal of World Trade Law (December 1990), pp. 81 - 104.
14. L. Peter Farkas, *Trade Related Aspects of Intellectual Property: What Problems with Transition Rules? What Changes to U.S. Law? How has Congress Salvaged, Sec. 337: The World Trade Organization Multilateral Trade Framework from the 21st Century and U.S. Implementing Legislation,* by Terence P. Stewart, editor (1996) pp. 463 - 521.

References (cont'd)

15. Mark L. Danschroder, "Intellectual Property Rights and the GATT: United States Goals in the Uruguay Round," Volume 21, No. 1, *Vanderbilt Journal of Transnational Law* (1988), pp. 367 -400.
16. Martin J. Adelman & Sonia Baldia, "Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India," Volume 29, No. 3, *Vanderbilt Journal of Transnational Law* (1996), pp. 507 -533.
17. Monique L. Corday, "GATT v. WIPO," 16 *Journal of Patent & Trademark Office Society* (1994).
18. Neil J. Wilkof, *Trade Mark Licensing* (Sweet & Maxwell, (1995).
19. A. Samuel Oddi, "TRIPS Natural Rights and a (Polite Form of Economic Imperialism)," Volume 29, No. 3, *Vanderbilt Journal of Transnational Law* (1996).
20. Oppenheim & Weston, *Unfair Trade Practices and Consumer Protection* (West Publishing Co., (1974).
21. Paul J. Heald, "Trade Mark and Geographical Indications: Exploring the Contour of the TRIPS Agreement," Volume 29, No. 3, *Vanderbilt Journal of Transnational Law* (1996), pp. 635 -660.
22. R. Michael Gadbow, "Intellectual Property and International Trade: Merger or Marriage of Convenience?," Volume 22, No. 2 (1989), pp. 223 -242.
23. Robert A. Choate & William H. Francais, *Patent Law* (West Publishing Co., (1981).
24. Robert Kastenmeier & David Beir, "International Trade and Intellectual Property: David Beir, "International Trade and Intellectual Property: Promise, Risks and Reality," Volume 22, No. 2, *Vanderbilt Journal of Transnational Law* (1989), pp. 285 -307.
25. Roger M. Milgrim, *Trade Secrets* (Mathew Bender), New York (1981), part II.
26. Ruth L. Gana, "Prospects for Developing Countries under the TRIPS Agreement," Volume No. 4, *Vanderbilt Journal of Transnational Law* (1996), pp. 735 -775.
27. *The TRIPS Agreement and Developing Countries* (United Nations Publications) (1996).

[End of References and of document]