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Patents: An Indian perspective

Jayashree Watal[1]

Introduction

In this chapter, I share my recollections as a representative of India from 1989–90 in the TRIPS negotiations, focusing on India's defensive interests with respect to the patent provisions of the TRIPS Agreement. I also include some relevant background information, as well as some recollections of my interaction with other parties to the TRIPS negotiations.

My role in the TRIPS negotiations began in May 1989, when I was a mid-level official in the Ministry of Industry, Department of Industrial Development. My then supervisor in the government, A.V. Ganesan,[2] chose to have me specialize in IPRs in order to fill a gap in our knowledge, after India was placed on the United States' Special 301 watch list in April 1989 for the first time, and after the mid-term ministerial review decision in Geneva later that month. My active engagement in the negotiations began in mid-May 1990 when I was sent by the then Secretary of the Department of Industrial Development[3] to Geneva on the eve of the presentation of the draft legal text jointly submitted by 14 developing countries.[4] From then onwards, up until the Brussels ministerial meeting in December 1990, by which time most of the TRIPS text was drafted and only some key political issues remained (see Adrian Otten, chapter 3), it became my task, under the close supervision of my seniors in government[5] to safeguard India's interests as best I could, particularly with respect to the patent provisions. As it was for many other authors in this volume, participating in the TRIPS negotiations was a particular highlight of my professional life.

Background to India's negotiating position on patents

A.V. Ganesan provides the reader with much of the background to India's negotiating position on TRIPS (see chapter 11), and his account should ideally be read before this one.[6] He eloquently describes the process of the revision of the

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Plain Packaging and the Interpretation of the TRIPS Agreement

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*Daniel Gervais***

ABSTRACT

Plain packaging of cigarettes as a way of reducing tobacco consumption and its related health costs and effects raises a number of international trade law issues. The plain packaging measures adopted in Australia impose strict format requirements on word trademarks (such as Marlboro or Camel) and ban the use of figurative marks (colors, logos, etc.). As a result, questions have been raised as to plain packaging's compatibility with the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

WTO members can validly take measures to protect and promote public health, but in doing so they must comply with the WTO agreements. In order to determine compliance, a proper method to interpret applicable WTO rules is indispensable for the stability and predictability of the world

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TRIPS Agreement and Bangladesh: Protecting National Interests in Health and Agricultural Sectors

Md. Abbas Uddin*

ABSTRACT

Bangladesh being a member State of WTO is bound to abide by all the WTO agreements in their entirety. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is one of those agreements which was primarily adopted in order to provide legal protection to the interests of the Intellectual Property (IPs) owners. Currently, Bangladesh along with the other LDCs is enjoying an extended period of transition until July 1, 2021 (though there is a debate of its applicability regarding pharmaceuticals for which there is a separate transition period until January 01, 2016 in place) within which period it has to be fully equipped to face the realities of TRIPS and will be required to amend, enact specific laws providing protection to IPRs. This paper mainly focuses on how the national interest of Bangladesh in health and agriculture is going to be challenged by the end transition period, because of the legal imperatives and mandatory directives created by TRIPS. A major query will be how successfully Bangladesh, as a sovereign country, would be able to protect its national interests without making other member states of TRIPS hostile to it. In doing so, the author tends to be very objective to assess the present-day situations with the progress analysis of Bangladesh before TRIPS comes into force.

Key Words: TRIPS, Bangladesh, Public Health, Agriculture, Transition Period, National Interest

1.1 INTRODUCTION

The Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS"/"the Agreement"), which entered into force on January 1, 1995, has always been a matter of great contention between its developed and developing/least developed country Members from its very inception. The agreement was adopted with a view to establishing system of 'one size fits all'. This systematic arrangement has allegedly designed to protect the interests of the developed world to a great extent by providing for a strict protection and enforcement mechanism of their intellectual property rights (IPRs) while ignoring or disregarding the rights and interests of developing world. The Agreement provides relatively high minimum standards for each of the main categories of IPRs,[1] establishes standards of protection and enforcement, and provides for the application of the WTO dispute settlement mechanism to resolve disputes between WTO Members.[2] These protection and strong enforcement mechanisms are meant to benefit both developed,

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SOME CONSEQUENCES OF MISINTERPRETING THE TRIPS AGREEMENT.

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The Agreement on Trade-Related Aspects of Intellectual Property Rights (or TRIPS Agreement) set the standards for intellectual property protection in the world today. It came into force on 1 January 1995 and is binding on all members of the World Trade Organization (WTO). TRIPS: a one-size-fits-all approach The TRIPS Agreement sets minimum standards in the international rules governing intellectual property, including patents on medicines. Countries that are members of the WTO (today, more than 150 countries) agree to certain general common rules in the way they enact and implement their intellectual property laws. These standards include, amongst others, that patents be given for a minimum of 20 years; that patents may be given both for products and processes; and that pharmaceutical test data be protected against 'unfair commercial use'. But the question of what deserves to be patented is left for countries to determine. The Agreement only says that patents should be granted for new, inventive and useful inventions - but it does not define these terms. Deciding whether a new formulation (producing a pill version of a drug that formerly came as a powder, for instance) or a new combination (combining two or more existing molecules into a new pill) deserves a new twenty-year patent for example is a prerogative of countries, and is not determined by the WTO texts. Countries should therefore determine what kind of inventions deserves patents in the area of pharmaceuticals, in light of their own social and economic conditions. Some governments, such as Brazil, Thailand or India, have done precisely that. In today's world, for many patients, that decision can be a question of life or death. In other words, though there is not such thing as a single international patent law, TRIPS represents a harmonisation of patent laws. The industry had been pushing for this kind of move for decades. It's a one-size-fits-all policy that aims at extending the stricter patenting laws previously used in industrialised countries to developing countries, regardless of their radically different social and economic conditions. Developing country members of the WTO generally had until the beginning of 2000 to implement TRIPS. Some countries were given a longer transition period – those like India that did not grant patents on pharmaceutical products were given until 2005, and least-developed countries were initially given until 2006. The Doha Declaration: restoring the balance Implementation of the TRIPS Agreement's intellectual property standards is having a considerable impact on access to medicines and public health. By limiting competition and local manufacturing, the danger is that TRIPS extends high drug prices and worsens the access to medicines crisis. With TRIPS, life-saving medicines are considered in the same vein as mere consumer goods and the devastating impact of high prices is mostly ignored. The balance between the private interests of the patent holder and the larger interests of society is severely skewed. It didn't take long for the issue to come to a head. In 2001, at the annual ministerial meeting of the WTO in Doha, Qatar, countries agreed to redress that imbalance, and firmly restated the primacy of health over commercial interests. The Doha Declaration reaffirmed countries' right to use TRIPS safeguards such as compulsory licences or parallel importation to overcome patent barriers to promote access to medicines, and guided countries in their use. One final significant achievement of Doha was to extend the deadline by which the least developed countries had to grant and enforce pharmaceutical patents, from 2006 to 2016. This deadline needs to be further extended or they will face the same difficulties that other developing countries already contend with in accessing medicines. » Read the text of the Doha Declaration TRIPS Plus: going even further than TRIPS Despite the Doha Declaration, in recent years, many developing countries have been coming under pressure to enact or implement even tougher or more restrictive conditions in their patent laws than are required by the TRIPS Agreement – these are known as 'TRIPS plus' provisions. Countries are by no means obliged by international law to do this, but many, such as Brazil, China or Central American states have had no choice but to adopt these, as part of trade agreements with the United States or the European Union. These have a disastrous impact on access to medicines. Common examples of TRIPS plus provisions include extending the term of a patent longer than the twenty-year minimum, or introducing provisions that limit the use of compulsory licences or that restrict generic competition. One of these provisions is known as data exclusivity. This refers to exclusive rights, granted over the pharmaceutical test data submitted by companies to drug regulatory authorities for obtain market authorisation. It means that information concerning a drug's safety and efficacy is kept confidential for a period of, say, five or ten years. If a generic manufacturer wants to register a drug in that country, it is not allowed simply to show that their product is therapeutically equivalent to the originator product. Instead, it must either sit out the exclusivity period, or take the route of repeating lengthy clinical trials to demonstrate the safety and efficacy of the drug – trials that have already been undertaken. This happens even when the originator product is not patented. In other words, data exclusivity is a backdoor way of preventing competition, so that even when a medicine is not protected by a patent, a pharmaceutical company will receive a minimum period of market monopoly when artificially high prices can be charged. Data exclusivity and other TRIPS plus provisions are frequently pushed as a part of free trade agreements between developed and developing countries. Under the Paris Convention, the national treatment principle allowed for what was usually called the "asymmetries", i.e., the adoption of different standards of protection by different countries in accordance with different levels of national development (provided national treatment was secured). The TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement of the World Trade Organization (WTO) established minimum standards of protection that each government has to give to the IP of fellow WTO members, thus limiting the former scope for flexible national approaches. However, the TRIPS Agreement incorporates certain "flexibilities." These aim to permit developing and least-developed countries to use TRIPS-compatible norms in a manner that enables them to pursue their own public policies, either in specific fields like access to pharmaceutical products or protection of their biodiversity, or more generally, in establishing macroeconomic, institutional conditions that support economic development. Government offices in charge of drafting laws frequently request advice from WIPO regarding how to use the TRIPS flexibilities so as to accommodate particular national interests or resolve issues that are specific to their countries. Advice is provided only after careful consideration of the flexibilities, TRIPS-consistency and their legal, technical and economic implications. The ultimate decision regarding the choice of legislative options lies exclusively with each individual Member State. The WIPO Secretariat, in tandem with Member States, has identified four clusters of flexibilities: Flexibilities as to the method of implementing TRIPS obligations These result from the language of Article 1.1 of the TRIPS Agreement. Under these flexibilities, WTO Members can exploit creative solutions to transpose into national law and practice those concepts that the TRIPS Agreement simply enunciates but does not define. Examples of those flexibilities include concepts such as novelty and inventiveness; or of situations of extreme urgency for the purposes of compulsory licenses. Flexibilities as to substantive standards of protection These flexibilities can operate either downward or upward, i.e. they may permit measures that reduce or limit the rights conferred; or measures that raise the level of protection above the minimum standards established by the TRIPS Agreement. (The latter are sometimes referred to as TRIPS plus). Examples of the former are the introduction of exceptions to rights conferred (such as experimental use and the "Bolar" exceptions; and the limitation to the use of trademarks in packages and advertisement of products considered prejudicial to health, like alcohol and tobacco). Examples of raising the level of protection are the introduction of temporary protection of industrial property rights before the grant of protection; the extension of the term of patents to compensate for delays in granting the marketing approval of products; or the extension of the scope of patentability and/or registrability of trademarks beyond the minimums established, respectively, by Articles 27 and 15 of the TRIPS Agreement. Flexibilities as to mechanisms of enforcement In the field of enforcement, the TRIPS Agreement (in Part III) identifies the mechanisms that Members are obliged to adopt in order to make enforcement rights available to IP owners; and prohibits Members from adopting stricter measures against defendants than those that are established. Nevertheless, Members can resort to their own legal system and practices to implement enforcement obligations. WTO Members are, for example, free to maintain their own judicial system. They also can use enforcement measures to implement flexibilities as to the standards of protection. Flexibilities as to areas not covered by the TRIPS Agreement The TRIPS Agreement does not cover a number of areas of IP subject matter, either because there was no consensus at the time the Agreement was negotiated, or because the areas in question had not yet emerged, or simply because the negotiators of the TRIPS Agreement did not consider that problems of barriers to trade existed in those areas. Some of those areas are of particular interest to developing countries, such as utility models, traditional knowledge and handicrafts. Unlike the "upward" standards of protection mentioned above, these flexibilities lie outside the TRIPS Agreement. Therefore, countries legislating on those subjects do not need to conform to the principles and provisions of the Agreement. For example, the protection of traditional knowledge can be extended to foreigners on a basis of reciprocity only.

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