THE TRIPS AGREEMENT: A ROARING LION OR TOOTHLESS TIGER:

A CRITICAL ANALYSIS

Abhishek Singh[93]

INTRODUCTION

In India, under the Patents act of 1970, a patent means the exclusive right of the inventor to use his invention for a particular period.[94] The basic principle underlying the grant of patents is that the invention must be new and useful and capable of industrial application.[95] The Indian Patent act recognizes only process patents in pharmaceutical and agro-chemical inventions.[96] Only process patents can be granted for the food products, medicines and chemicals. This means that only the method of production can be patented and not the end product.[97] The general term of a patent is for 14 years. However, for certain process patents used for medicine, food and drugs, the term varies from 5 to 7 years. In addition the state can impose any condition on the grant of patent. Further, The central Government can use a patented invention in specific circumstances without the payment of royalty.

As a matter of fact, Pharmaceuticals enjoy a special place as a major research-oriented and knowledge-based industry.[98] Numerous drug formulations for various ailments are invented, patented, produced and marketed throughout the world every year.[99] The Indian Pharmaceutical Industry plays a major role not only as a contributor to the economy but also by providing drugs at affordable prices.[100] Nearly 95 percent of the domestic demand for pharmaceuticals in India is met through indigenous production.[101] Import are limited to a few lifesaving drugs like anti-cancer, cardiovascular, anti-hypertension and other newer drugs that are not yet cleared for indigenous production.[102]

Under the Indian Patents act, 1970, India recognizes only process patents for pharmaceutical products.[103] This allows Indian companies to reproduce and market newly invented drugs in the Indian market through a different production process, typically within one or two years of its invention, and at only

---

93 Student, NALSAR University Of Law, Hyderabad

94 Suman Sahai, Indian Patents Act And TRIPS, *Economic And Political Weekly*, Vol. 28, No. 29/30 (1993), Pp 1495 – 1497.

95 *Id.*, P.1495

96 *Id.*, P.3787

97 *Id.*, P.1496

98 Pradeep Agarwal, P Saibaba; TRIPS And India's Pharmaceuticals Industry, *Economic And Political Weekly*, Vol. 36, No. 39 (2001), Pp 3787 – 3790

99 *Id.*, P.3787

100 *Id.*, P.3788

101 *Id.*, P.3788

102 *Id.*, P.3789

103 *Supra* Note 3, P.1496

a small fraction of the cost of patented drugs in developed countries.[104] The idea behind granting only process patents for food products, chemicals and medicines is to keep down the price of these items, as the majority of Indian population is poor and does not have enough food and basic health care.

PRE TRIPS ERA

Pharmaceutical patents were first introduced to India by the British in the colonial era.[105] In 1970, concerned about the dominance of foreign pharmaceutical firms and the high price of medicines, India changed course, passing a patent law prohibiting product patent on medicines.[106] at that time, foreign firms controlled about 70 percent of Indian market,[107] and Indian drug prices were among the highest in the world.[108]

The 1970 act served as a substantial driver of three decades of growth in the domestic pharmaceutical industry.[109] In the years that followed it, the number of patents granted in India dropped quickly.[110] although the law permitted process patents related to medicines, they were very limited in scope[111] and rarely sought. The law thus created significant space for the entry of local pharmaceutical firms,[112] and they rapidly increased their share of the Indian market.[113]

Indian firms also became more technically sophisticated. For example, they first produced active Pharmaceutical Ingredients (aPIs) in the mid-1970s, with production steadily increasing over the next three decades.[114] Indian companies became skilled in reverse engineering and developing new processes for drug production.[115] Some launched foreign drugs locally before the originator did, apparently even in cases where the originator sought to be the first in the market.[116] Over time, the Indian industry also evolved to become

104 *Supra* Note 3, P.1497
105 P. Narayana, **PATENT LAW**, P.5, 4th Ed., 2006
106 The Patents Act, 1970, No. 39, 5 (India), Reprinted In P. Narayana, **PATENT LAW**, P.546, 3rd Ed., 1998
107 *Infra* Note 18, P.341
108 Amy Kapczynski, Harmonization And Its Discontents: A case Study Of TRIPS Implementation In India's Pharmaceutical Sector, *california Law Review*, Vol. 97, No. 6, Pp.1571-1649, (2009)
109 Jean O. Lanjouw, *The Introduction Of Pharmaceutical Product Patents In India: "Heartless Exploitation Of The Poor And Suffering"?* 3, National Bureau Of Economic Research, Working Paper No. 6366, Available At *Www.Oiprc.Ox.Ac.Uk/EJWP0799.Pdf* Last Visited On May 5, 2013
110 *Id.*, P.3
111 *Supra* Note 15, P.563
112 *Infra* Note 28, P.133
113 *Infra* Note 28, P.18, Tbl. 2.2
114 *Infra* Note 28, P.40-41
115 *Infra* Note 28, P.52
116 *Infra* Note 28, P.54

extraordinarily competitive and diverse.[117] Further, numerous surveys indicate that Indian drug prices by the 1990s were among the lowest in the world.[118]

THE TRIPS AGREEMENT

Major changes were seen in the pharmaceutical industry in India after 2005, as a result of TRIPS agreement, which endeavored to protect the rights of inventors.[119] The agreement has been the result of active lobbying by multinational pharmaceutical firms and strong pressure from the US and other developed countries.[120]

Under this agreement, norms and standards were provided in respect of seven categories of intellectual property rights, which include copyrights, trademarks and product patents in all areas of technology.[121] all member of WTO were expected to comply with the provisions under TRIPS from January 1, 1995.[122] However, the agreement provided a transition period of 10 years for developing countries *i.e.* until January 1, 2005 to enact a bill incorporating product-patent protection.[123] accordingly, the patents will provide the rights of production and marketing solely to the inventor in all the member countries of WTO for 20 years.[124] Further, all member countries are also required to take steps to provide for the receipt of exclusive marketing rights (EMR) for 5 years or till the patent is granted, whichever is earlier.[125]

INDIAN PATENTS ACT AND THE TRIPS AGREEMENT

India already grants product patents in most fields.[126] However, the Indian Patent act 1970 as stated above recognizes only process patents in pharmaceuticals and agro-chemicals, while the TRIPS agreement requires both product and process patents in all fields. as a result of which, India had to change its patents law. However, this was proved difficult, as the immediate and severely adverse impact of the bill on Indian consumers makes it politically inappropriate. On a complaint by the US to WTO, India was asked to take steps to amend its patent laws to meet WTO obligations by april, 1999. Subsequently, the Rajya Sabha passed the amended bill in December 1998 but the government could not bring it for consideration in the Lok

---

117 Aradhana Aggarwal, *Strategic Approach To Strengthening The International competitiveness In Knowledge Based Industries: The Indian Pharmaceutical Industry*, 16, Research And Information System For Developing countries, Discussion Paper No. 80 (2004)

118 K.Bala & Kiran Sagoo, *Patents And Prices,* Hainews, April 2000, Available At *Www.Haiweb.Org/Pubs/Hainews/Patents%20and%20prices.Html* Last Visited On May 5, 2013

119 Sudip chaudhari, Patents And Pharmaceuticals In India, *The WTO And India's Pharmaceuticals Industry: Patent Protection, TRIPS And Developing countries*, P.341, Oxford University Press, New Delhi (2005)

120 *Id.*, P.341

121 Jayashree Watal, Implementing The TRIPS Agreement: Policy Options Open To India, Available At *Www.Jstor.Org/Stable/4405898* Last Visited On May 5, 2013

122 *Ibid*

123 *Supra* Note 7, P.3790

124 *Supra* Note 7, P.3790

125 *Supra* Note 7, P.3790

126 *Supra* Note 26

Sabha due to resistance from both the treasury and the opposition benches. Finally, in order to fulfill its obligations, the government of India promulgated the Patents (amendment) Ordinance in January 8, 1999 changing the Indian Patents act, 1970 in line with the WTO norms. The ordinance provided for:-

1. Filling of applications for product patents in the field of agro-chemicals and pharmaceuticals.
2. Grant of EMRs for the applicant after a set of conditions is fulfilled.

One immediate consequence of TRIPS agreement would have been the sharp increase in the prices in drugs invented after the new product patent laws came into force in 2005. Thus, the TRIPS agreement initially would affect only a small portion of drugs available in India. However, the impact would increase gradually over time as virtually all new drugs entering the market in future would be patent protected and many of the old drugs would be expected to become ineffective over time as disease causing bacteria develop resistance to them, thereby forcing people to switch to the new, more expensive drugs.

On the other hand, some parties benefited from the TRIPS agreement. In particular, it is clear that the large pharmaceutical firms based largely in developed countries benefited by being able to charge much higher prices on their patented drugs by virtue of the monopoly they gained in the markets of developing countries as a result of TRIPS agreement. This also benefited the developed countries through a larger tax base and more jobs, among others.

In the long run, the TRIPS are also expected to bring benefits to developing countries like India in the form of increased research and development expenditure in inventing drugs for diseases that are specific to developing regions (such as tropical diseases). The major reason, why Indian firms have not tried to invent better cures for malaria or tuberculosis is that, the patent protection in India makes it unprofitable to do so, any such invention will be readily copied by other firms in India and the original inventor will not be able to recover the research costs. Thus, changes in patent laws may encourage many firms in India and in other developing countries to undertake more research in finding cures for diseases common in their countries, rather than mere focusing on cheaply reproducing drugs invented in industrialized countries. This should bring benefits to developing countries in the medium to long run. However, the cost that is being demanded appears to be too large to pay for such benefits. There exists alternative ways to achieve these ends. For example, the pharmaceutical industry could be persuaded to invest more on R&D for inventing drugs for disease prevalent in developing countries either by moral suasion or by sharing of costs by developing countries. Developing countries with a relatively developed pharmaceutical industry, such as India, can also achieve this by providing sufficient rewards to their own firms (such as tax incentives for undertaking research and development of new drugs, reimbursement of research cost for specific discoveries, and provisions for product patents for firms operating within the country and subject to its sovereignty) that are willing to argument their research efforts, possibly in collaboration with foreign firms.

These measures could provide similar long-term benefits but without imposing the severe price increases for medicines.

SUGGESTIONS

There exists some specific problems with the TRIPS agreement that may harm the interest of developing nations, including India. The authors can mention one of the problems related to the patent regime of WTO regarding the dispute over the domestic biodiversity legislation. There is a need to provide appropriate legal and institutional means for recognizing the rights of indigenous communities on their tradition knowledge about their biological resources and traditional remedies, many of which are not documented yet in written form. It will be a gross abuse of patent laws if such knowledge of, say, various traditional herbal treatments of one country are given patent rights in other countries where such knowledge may not be well known.

It seems that some western firms have been trying to take advantage of the fact that the traditional medical knowledge of many indigenous communities is not well documented in written form, and they take out patents on products based on such knowledge. Proper rules should be formulated to prevent such abuse. India has proposed that patent application should mention the origin of biological material utilized in the invention and the countries providing such materials should get a share of commercial benefits out of such patents. Similarly, traditional remedies of one community or country should either be not patentable at all, or should share such commercial benefits with the community where the knowledge originated. There is an urgent need to forge a consensus of this issue.

The authors feel that in its present form the TRIPS agreement is tipped too far in favor of multinational pharmaceutical firms and the developed countries. For example, today's economic superpowers, the US and Japan, developed rapidly during the late 19th and early 20th century, largely by copying European technology. Switzerland refused to have product patents for pharmaceuticals until 1978 in a largely successful effort to develop its pharmaceuticals by copying patented drugs invented elsewhere. Developed countries, concerned over their declining competiveness in a large array of manufactured products, are now trying to snatch away this right from the developing countries, thereby making technological catching-up more difficult so as to be able to preserve their own supremacy as long as possible. Some have equated this to an attempt by the developed countries to recolonize the developing countries. The latter should be wise enough to see through this game. It is quite clear that there is nothing trade related about TRIPS except that the right trade is being exploited by the developed countries to impose trade restrictions on developing countries. Industrial countries are making similar attempt in other direction as well, such as by linking trade with environment and labor standards in an effort to protect their manufacturers.

This exploitation should not become the norm for interaction among communities of nations. Instead, the developed helping to uplift the developing should be the idle for the human race. Sadly, the TRIPS agreement is closer in spirit to the former than to the latter and major changes in this agreement are called for. The developing countries act unitedly, the developed countries will have no choice but to compromise more reasonably.

Ideally, the TRIPS agreement should not be part of the WTO regime at all. There is no reason for developing countries to compromise on their sovereignty and agree to police the patent rights of multinational firms at a huge cost to their own people.

At the very least, the industrialized countries should accept some changes in the TRIPS agreement in favor of developing countries. a more appropriate agreement need to be drafted to balance much more evenly the commercial interest of inventors and needs of the poor in developing countries for access to cheap medicines.

The authors believe that a more reasonable compromise would be to reduce the patent life from 20 years to 10 years and a right for developing countries to enforce compulsory licensing and price controls after the first 5 years of an invention, at least in case of life saving drugs and drugs of mass consumption. The authors believes that this is a reasonable compromise that will safeguard the essential commercial interests of multinational pharmaceuticals firms without unreasonably distressing the poor in developed countries.

In the meantime, we must try to make the best of the present scenario. India is relatively better off than many other developing countries because it has a reasonably well developed pharmaceutical sector. We must do our best to help make Indian firms more capable of undertaking research and development and to be more competitive in export. This can be facilitated by providing generous tax incentives for undertaking research and development, and by allowing liberal imports of raw materials with minimum import duties.

Export procedure should also be further simplified so that they do not become a hindrance in the growth of exports. We should also actively encourage technological collaboration with foreign firms and the inflow of foreign direct investment in the pharmaceutical industry as way to bring new technology, research, and managerial capabilities into this important sector of the economy.