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Patent Linkage in FTAs and Indian Position

DR. NANDITA S. PATIL[1]

ABSTRACT

The system of patent linkage links the drugs marketing approval to the status of patent. TRIPS Agreement which sets minimum standards for IPR for the WTO member countries does not provide for patent linkage. This is a TRIPS plus provision which is included in the FTAs and is also found in the domestic legislation of countries such as USA, China, Singapore, Chile, Bahrain, Morocco, Australia. Doha Declaration on the TRIPS Agreement and Public Health affirms that the TRIPS agreement can and should be interpreted and implemented to protect public health and promote access to affordable medicines. There are two separate Acts in India, one Drugs and Cosmetic Act 1940 for granting marketing approval and other is Patent Act 1970 for granting patent. On the issue of Article 39.3 of the TRIPS Agreement Satwant Reddy Committee considers no need for a separate legislation for protecting test data but suggested inclusion of 'data exclusivity' like mechanism in DCA. India does not provide for patent linkage system and the same is maintained by the Courts in India when the MNCs tried to create patent linkage by filing suits.

Keywords: *patent linkage, TRIPS, FTAs, data exclusivity, India*

I. INTRODUCTION

Patent linkage refers to a system by which drug regulatory system is linked with the patent system. In other words it is a regulatory and legislative linkage whereby the drug marketing approval is linked to the status of patent. Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) prescribes minimum standard for protection and enforcement of Intellectual Property Rights (IPR), however, the recent trend is towards introducing TRIPS plus provisions and patent linkage is one of such TRIPS plus provisions being found in the regional and bilateral Free Trade Agreements (FTAs). The reason for inclusion of such standards is due to the weak negotiating positions of the parties especially of the developing countries. USA, China, Singapore, Chile, Bahrain, Morocco and Australia have established patent linkage

[1] Author is an Assistant Professor at Department of P.G.Studies in Law, Dr. Babasaheb Ambedkar Marathwada University, Aurangabad, India.

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system.

In US, the concept of "Patent Linkage" is provided under the Hatch- Waxman Act (1984), FDA does not provide marketing approval for a generic version of a patented drug. A 30 months period stay of marketing approval is engaged in case generic applicants are challenging existing patents. In China State Food and Drug Administration (SFDA) must be satisfied that no patent is being infringed before issue of marketing approval for a new product. There is no formal patent linkage in Brazil. The FTAs of USA with Singapore, Chile, Morrocco and Bahrain had introduced patent linkage system. India do not provide for patent linkage system.

II. TRIPS OBLIGATIONS UNDER ARTICLE 39.3

TRIPS provides minimum standard of protection for Intellectual Property Rights. However, it also provides flexibilities to the WTO members in this regard. In case of patent protection, every country has to balance the interest of patent holders and the public. India's patent regime is formulated as per TRIPS prescribed standards. TRIPS obliges the Members to give effect to the provisions of the Agreement, though Members may provide in their law more extensive protection than is required by this Agreement, but it is not obligatory under the agreement.[2] Looking at the objectives of the TRIPS Agreement,[3] it is provided that the protection and enforcement of intellectual property rights should contribute to:

- the promotion of technological innovation,
- the transfer and dissemination of technology,
- the mutual advantage of both producers of technology and users of such technological knowledge
- a balance of rights and obligations

Also, in formulating or amending their laws and regulations by member states the agreement provides that Members may, adopt measures which are necessary to protect public health and nutrition, to promote the public interest in sectors of vital importance to their socio-economic and technological development[4], but consistency of National Intellectual Property Rights Laws should be assessed in the light of Articles 7, 8.1 and of the preamble of the TRIPS Agreement.

While discussing patent linkage the most important provision which needs to be taken into account is data protection provision of TRIPS Agreement. Article 39.3 of the TRIPS

[2] *See* Article 1.1, The TRIPS Agreement
[3] *See* Article 7, The TRIPS Agreement
[4] *See* Article 8.1, The TRIPS Agreement

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Agreement deals with test data protection relating to pharmaceutical and agro-chemical industries submitted for the purpose of market approval.

The obligation under Article 39.3 of the TRIPS provides that members, who require, as a condition of approving the marketing of pharmaceutical or other products that utilize new chemical entities, the submission of the undisclosed test or other data to provide protection to such data against unfair commercial use. The controversy is basically relating to the interpretation of this obligation. Article 39.3 of the RIPS only obliges protection of test data for new chemical entities against 'unfair commercial use' leaving the terms 'new chemical entities' and 'unfair commercial use' undefined. Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001, affirms that the TRIPS agreement can and should be interpreted and implemented in a manner which supports the rights of the WTO members to protect public health and promote access to affordable medicines. For this purpose, the Declaration affirms the rights of the member countries to make use of the flexibilities provided in TRIPS Agreement. For interpretation of Article 39.3 of the TRIPS, the ordinary meaning and context of the terms used is to be relied as per Vienna Convention on the Law of the Treaties and the object and purpose of the treaty must be carefully considered along with the history of the negotiation. For test data TRIPS does not provide the nature of protection to be conferred nor that such data be protected through grant of exclusive rights.[5] This Article became disputable due to the ambiguities existing in the text of the Article and also due to the financial interests of pharmaceutical companies.

The TRIPS Agreement does not, mandate data exclusivity as the only option for implementing this provision in the national legislation, In some countries national health authorities are allowed to rely on such test data for registering generic substitutes based on bioequivalence, but they prohibit the disclosure of such data to generic companies or other third parties. India's decision to exclude protection to data exclusivity is in public interest.[6]The TRIPS Agreement avoids providing definition of "new chemical entity" thereby giving Member countries enough room for manoeuvre to implement Article 39.3.

But recent trend shows that some FTAs require the application of a mandatory data exclusivity model.

[5]Carlos María Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* , 28,University of Buenos first published in June 2002 by the South Centre in collaboration with the Department of Essential Drugs and Medicines Policy of the World Health Organisation, South Centre, 2002

[6]Dalal Praveen, *Regulatory Framework for Data Exclusivity in India*, http://iprsi.blogspot.in/2011/07/ regulatory-framework-for-data.html, (last visited December 31, 2013)

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III. PATENT LINKAGE PROVISIONS IN FREE TRADE AGREEMENTS (FTAS)

Free Trade Agreement is an agreement between two or more countries or trading blocs to reduce or eliminate customs barriers that is tariff and non-tariff barriers on substantial trade between them. FTAs normally cover trade in goods or trade in services. FTAs also cover intellectual property rights (IPRs), investment, government procurement and competition policy, etc.[7]

The utilization of TRIPS flexibilities to facilitate access to medicines is affected by FTAs. TRIPS plus provisions are finding their way into Free Trade Agreements. India is having negotiations on FTAs with several countries, some regions were pushing for patent linkage to be included in the FTA. In the area of pharmaceutical patenting FTAs are setting up new rules through TRIPS-plus provisions. EU proposals to Colombia, Ecuador, Peru, India provides for inclusion of exclusive rights in test data.[8] During the negotiations of the India-EU Free Trade Agreement (FTA), the EU insisted on having an exclusive chapter on data exclusivity which India rejected as it would hurt the interest of the domestic generic drug manufacturers. The two sides have not yet reached any agreement.

TPP (Trans Pacific Partnership) is a free trade agreement among 12 countries (USA, Canada, Mexico, Peru, Chile, New Zealand, Australia, Japan, Singapore, Brunei, Malaysia, and Vietnam) signed on February 4, 2016.the agreement provides at least 5 years test data protection from the date of marketing approval of the new pharmaceutical product.[9]

There is no TRIPS obligation to establish patent linkage. However, FTAs appear to upset the balance between patent owners' rights and public interest by elevating the position of patent rights.

IV. INDIAN SCENARIO RELATING TO PATENT LINKAGE

India does not provide for patent linkage. There are two separate Acts dealing with separate aspects of new drugs. Drugs and Cosmetic Act 1940 (DCA) regulates marketing approval, manufacture, sell, distribution and import of drugs, agricultural chemicals and cosmetics. New drugs are required to establish their safety and efficacy through test data which has to be submitted to the Drug Regulatory Authority that is Drugs Controller General of India (DCGI) for the purpose of getting marketing approval. The requirement of the test data for new drug is

[7]http://commerce.nic.in/trade/FAQ_on_FTA_9April2014.pdf?id=9&trade= i, (last visited September 10, 2015)
[8]*See* Christopher Spennemann, *Protection of Pharmaceutical Test Data under TRIPS & FTAs*, available at https://www.tralac.org/images/docs/4755/spennemann-test-data-under-trips-and-ftas-presentation.pdf
[9] *See* wtocenter.vn/tpp/full-text-and-summaries-tpp, (last visited August 4, 2017)

specified by DCA Rules 1945.[10] New drug means a drug not previously approved in India.For subsequent marketing approval the bio-availability/ bioequivalence study is to be submitted.

It is the Patent Act 1970 which deals with patenting of pharmaceutical drug. The Bolar type provision provided under of the Act allows the generic manufacturers in India to experiment with any patented drug so that they can generate data that could then be submitted to a drug regulatory authority.[11] The aim of this Bolar type provision is to speed up entry of generic drug in the market so that people could have access to cheaper generic medicines.

There is no provision for protection of undisclosed test data submitted to the regulatory authorities in either of the above acts and also no separate legislation for the same. By not giving exclusive protection to undisclosed test data the Indian government has used TRIPS flexibility. The Declaration of TRIPS agreement on public health (14 November 2001) states that the TRIPS provisions should not prevent member countries from taking measures for protecting public health rather it's provisions should be interpreted to support protection of public health and access to medicines.

For dealing with the issue of Article 39.3 of the TRIPS Agreement Satwant Reddy Committee was appointed in 2004 which submitted its report in 2007. The committee considers no need for a separate legislation for protecting test data but suggested inclusion of 'data exclusivity' like mechanism in DCA and DCA rules to prevent unfair commercial use of the undisclosed test data of patent owner by others. For protecting undisclosed test data of Pharmaceuticals and Traditional Medicines it suggested a model to be implemented after the transition period specified in the TRIPS Agreement. For patented drugs, it recommended that the period of data protection should in no case go beyond the 20-years patent protection in India. And that if the product is not marketed within six months of the grant of marketing approval and if not marketed for twelve consecutive months, the new drug will lose its validity.

Even the Ranjit Roy Committee recommended that first time manufacturers in India should undergo bridging Phase III trials and bioequivalence (BE) studies on humans. Similar biologics (biosimilars) should undergo both pre-clinical development and bridging Phase III clinical trials as per the guidelines of Department of Biotechnology (DBT) and Central Drugs Standard Control Organization (CDSCO).[12]

The recommendations of the Satwant Reddy Committee were dealt with in the case of

[10] Schedule 'Y', and Rules 122A, 122B, 122D, 122DA, 122DAA and 122E.
[11] Section 107 A, The Patent Act 1970
[12] Report of the 47th Meeting of the Drugs Consultative Committee held on 30th and 31st July, 2014 at New Delhi, available at www.cdsco.nic.in/write read data/ Report of 47th DCC Meeting(1).pdf, (last visited August 25, 2017)

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Syngenta.[13] In this case Syngenta claimed that Article 39.3 of TRIPS mandated protection for the test data submitted by the pharmaceutical and agrochemical industries for market approval. The petitioner expresses concern about vulnerability resulting from data disclosure, in the absence of a protection regime, and its utilization by applicants for the same product, for the purpose of their claim to registration. The petitioner also alludes to a "Reddy Committee" report concluding that the Act and the Rules should be amended to ensure that undisclosed test data of the originator is not put to unfair commercial use by others. However, the court rejected the claim of Syngenta and held that the court was being invited to make a policy declaration and it could not do so under any circumstances.

The Satwant Reddy Committee in 2007 recommended that it will not in India's interest to grant data exclusivity. A parliamentary report has also confirmed the same position as that of the Satwant Reddy Committee not to provide data exclusivity at this juncture. Foreign pharmaceutical companies are strongly lobbying for the same issue and have also been at the heart of debate in FTAs India which is being negotiated with European Union (EU).

Bayer filed a writ petition in the Delhi High Court against Union of India[14], praying that DGCI be restraint from granting any drug approval to Cipla's 'Soranib' which is a generic version of their drug Sorafenib contending that such approval would violate the patent rights of Bayer.

It prayed that Cipla's application for marketing approval should not be processed or entertained. The Court, however pointed out the disparity between DCA and Patent Act the court held that both are separate codes with different objectives and are enacted for different purposes and hence there is no patent linkage. It further held that though important amendments were made to the patents act in 2005, but never was any intention expressed by the parliament to place patent superintendence, or policing powers, with drug agencies. Bayer appealed against this decision to the Supreme Court by filling Special Leave Petition. The appellate court also held that if it was the intention of the parliament to link the entry of information in respect of patent status with the grant of marketing/manufacturing approval, then the definition of 'new drug' under rule 122E of Drugs and Cosmetics Rules ought to have been amended.[15]The appellate court thus concurs with the decision of the single judge of Delhi High Court that the Patent Act and the DCA are distinct and separate and that the attempt by Bayer to establish a linkage cannot be countenanced.

In a similar case Merck questioned the marketing approval given to Glenmark for Januvia

[13] Syngenta India Ltd v. UoI 161(2009) DLT413
[14] Bayer Corporation and Anr. Appellants v. Union of India (2010) 2010-(DL2)-GJX-0305-DEL,e-jurix
[15] *Ibid*

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(sitagliptin phosphate) for treatment of type II diabetes thus reviving the demand of patent linkage. The Supreme Court of India has restrained Glenmark by a permanent injunction from making, using, selling, offering for sale or dealing with the generic version (Merck v. Glenmark case (20 March 2015)).[16]

Thus, we see that the MNCs are trying to pressurize Indian government to amend regulations to bring in patent linkage. This TRIPS-plus provision will become a barrier for generic drug entry in the market which resulted in saving of expenditure and health costs.

V. CONCLUSION

Patent linkage is a TRIPS Plus concept and as India has signed TRIPS Agreement, it is obliged to comply with TRIPS obligations only. Moreover, the policy on patent linkage is not uniform, it differs from country to country.

At international level TRIPS Agreement provides for minimum standards to be followed by the WTO member countries in their national IPR regime. Patent linkage is a TRIPS Plus provision, also there was a growing opinion, in developed countries, including those of the European Union cautioning against patent linkage. The patent linkage would result into transformation of patents rights which are private property rights into public rights, whose enforcement depends on publicly funded statutory authorities. Such linkage would have tremendous implications for entry of generic drugs till the expiry of the patent.

For introducing a new pharmaceutical drug in the Indian market, approval from the Drugs Controller General of India (DCGI) is required as per Drugs and Cosmetics Act, 1940. Moreover, patent infringement provision is provided in the patent act 1970, hence DCGI is not a competent authority to assess the possibility of infringement of a patent as there is no specific statutory provision authorizing it to do so. There is no patent linkage in India and the same is maintained by the Courts while dealing with the cases which attempted to create patent linkage. The recent trend of inclusion of chapter on IPR mostly includes TRIPS plus provisions. The inclusion of patent linkage provision in FTA will have implications on access to medicine. India should not succumb to outside pressure and should not include patent linkage provision in FTA. As this is a TRIPS plus provision India is under no obligation to include such provision.

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[16]Merck Sharp &Dohme Corporation &ors. Vs. Glenmark Pharmaceuticals Ltd, decided on 7th October 2017

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