

FOREIGN TRADE AGREEMENTS AND ACCESS TO MEDICINE

by

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INTRODUCTION

The issue of access to affordable medicine is seeing some interesting times in India, especially in the context of intellectual property. A few events close on the heels of one another, viz., granting of first compulsory license over So rafenib, a drug for cancer by Intellectual Property Appellate Board,¹ followed by the Supreme Court judgment rejecting plea of Novartis to grant patent protection to its anti-cancer drug sold in the name of Glivec or Gleevec, India being put again on the US priority watch list in the latest USTR Special 301 Report, May 2013 for allegedly tweaking with uniform patent standards to the disadvantage of their pharmaceutical companies and not the least, the EU India BTIA negotiations reflect intense turbulence and shifting of fault lines in the access to medicine debate. While issues concerning the Novartis judgment and compulsory licensing are being well discussed, our concern for EU-India negotiations should be no less. This article seeks to draw attention to issues incorporated in the negotiation document between EU and India and their impact on access to affordable medicine, if accepted.² WTO's trade-related aspects of intellectual property rights or TRIPS - establishing a universal minimum protection for intellectual property-has been adopted in the domestic Intellectual property regimes of most countries of the world. However, perception with respect to its efficacy varies. For developed countries who still are the leading innovators, TRIPS was only a battle half won as their demand for some of the more stringent provisions of protection remained unheeded. On the other hand, according to the developing and least developed countries, TRIPS laid down stringent conditions of protection which could prove stalling for local innovation. The debate on access to medicine is inextricably intertwined to these counter views.³

¹ *Bayer Corp. v. Union of India*, Order No. 100/2009 (Intellectual Property Appellate Board, Mar. 4, 2013), <http://www.ipab.tn.nic.in/Orders/100-2009.htm> (last visited Sept. 28, 2026).

² *Novartis AG v. Union of India*, (2013) 6 SCC 1, <http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212>.

³ *U.S. Trade Pressure on India Drug Patents Threatens Access to Life-Saving Medicines: Report*, HuffPost (May 1, 2013), http://www.huffingtonpost.com/2013/05/01/india-us-drugs-trade_n_3196458.html

The issue of access to medicine has several dimensions to it intellectual property rights being one of them. In fact, access to medicine is the ground on which the developed and developing countries have fought the battle between protecting innovation versus making available affordable medicines to the poor the underlying issue being whether intellectual property rights is an instrument of public policy or a property right.⁴

To be fair, TRIPS has some rudimentary flexibility built into it and many of these have been creatively used by developing countries to pursue public health objectives mainly access to affordable medicines. These flexibilities however, in the perception of the developed countries, have proven disadvantageous to their pharmaceutical companies.

In order to guarantee more elaborate intellectual property protection to them therefore, developed countries have found a way around TRIPS- through 'forum shifting' that is 'transferring a negotiating agenda from one setting to another to increase opportunities for pursuing their overarching objectives (here, greater protection to intellectual property rights)'.⁷ Such 'forum shifting' have severe implications to the access to medicine debate as these countries have entered in to bilateral or regional trade negotiations, which is a new setting outside the WTO-and have successfully persuaded governments to voluntarily accept conditions leading to substantial broadening of IPRs,⁸ in return to concessions on market access.⁵

These conditions effectively kill the flexibilities embedded in TRIPS regime.¹⁰ These agreements also set standards in other policy areas which have several implications on access to medicine, notably standards established on government procurement and competition policy, as well as preferential tariffs in pharmaceutical products.¹¹

India has not remained untouched to this phenomenon. In fact, India has also in recent past, entered into and is negotiating many bilateral and regional trade agreements, some of which

⁴ World Health Organization, World Intellectual Property Organization & World Trade Organization, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade* 171–75 (2012) (Note: Textual proposition re-formatted as standard Bluebook textual footnote citing background TRIPS-plus flexibility restrictions).

⁵ Off. of the U.S. Trade Representative, 2013 Special 301 Report (2013), <https://ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf>.

include stipulations with respect to intellectual property rights in the pharmaceutical sector.¹² Currently intense negotiations are on between the European Union and India for a broad based trade and investment agreement, wherein certain provisions shall have immense ramifications on the local generic drug companies.⁶

The European Union views seriously, its responsibilities to protect the patent rights of its pharmaceutical companies. According to it, in view of the scarce natural resources, it is the 'innovation, creativity, quality and exclusivity' of the European companies on which it thrives.¹³ Enlisting its priority area European Commission's policy document 'Protection of Intellectual Property in Free Trade Agreements' states that provisions on patents in Free trade Agreements would primarily focus on pharmaceutical products, especially patent term restoration mechanism to recover term that was lost due to delay in marketing authorization and protection of regulatory test data (data protection).¹⁴ Hence it very much follows the 'forum shifting' trend discussed above and not surprisingly therefore has raised the issue of data protection in its negotiations with India.

In fact, since 1990s, EU has entered into numerous trade associations, agreements, partnerships wherein it has contracted with governments to impose levels of intellectual protection practiced within the European Union members (and which are all TRIPS plus). Further, some of the agreements entered into by EU contain commitment to apply, for example the 'highest international standards' in protection of intellectual property. The agreements however nowhere elaborate the precise meaning of this standard.⁷

One bone of contention between India and European Union in these ongoing negotiations has been intellectual property in pharmaceutical products. A cursory look through the document of India- EU BTIA negotiations reveal that a few TRIPS plus provisions have been put on table here too. For instance, under Article 14 of the draft document, provisions have been made for protection of pharmaceutical data submitted to obtain a marketing authorization. When read carefully effectively translates into providing 'data exclusivity'.¹⁷

⁶ Ruth Lopert & Deborah Gleeson, *The High Price of "Free" Trade: U.S. Trade Agreements and Access to Medicines*, 41 J.L. Med. & Ethics 199 (2013).

⁷ World Health Organization, World Intellectual Property Organization & World Trade Organization, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade* (2012)

'Data exclusivity', seeks to provide a period of exclusivity to the testing data (clinical and field trial data collected to establish the product's safety and efficacy) submitted by the pharmaceutical and agro chemical companies to the relevant authority for receiving marketing approval. The period of exclusivity means that these data cannot be relied upon by the regulator to grant generic pharmaceutical companies marketing approval to generic versions of the same drug for a specified period of time (as discussed below, Indian law permits reliance on clinical data submitted by the patentee company to give marketing approval to generics). By doing so, data exclusivity allows the first mover, who has conducted the extensive testing, to recover the cost of the clinical trials or field trials, failing which there would be no incentive for any of the other firms to conduct extensive testing for any of their products.⁸

Article 39.3 of the TRIPS agreement also makes provisions for protection of undisclosed data on pharmaceutical and agrochemical products which may be submitted for marketing approval, but the protection is against unfair commercial use to prevent unfair competition only. Jurisdictions like the US and the EU have interpreted it to mean granting data exclusivity as discussed above, to the concerned entity.

On the other hand, in India, the rule with respect to data exclusivity differs from industry to industry. While in agro chemical industry it has been interpreted to mean 'data exclusivity' and incorporated in the Pesticide Management Bill 2008, with respect to pharmaceutical industry it has meant merely confidentiality that is 'protection through nondisclosure' that is prohibiting others 'from accessing this test data for unfair commercial use'.¹⁹ It means that clinical data can still be used by approving authorities to grant approval to generic versions provided confidentiality is maintained.

This approach has also been supported by many authors including Charles Correa according to whom when correctly interpreted, Article 39.3 does not oblige members 'to grant exclusive rights over data, as is done under the sui generis regimes established in the USA, the EU, and in other countries'

The issue of data exclusivity is relevant for the access to medicine debate because the Drugs & Cosmetics Act, 1940 and The Drugs and Cosmetic Rules 1945, (under which marketing

⁸ *Id.*; see also Off. of the U.S. Trade Representative, 2013 Special 301 Report 24 (2013), <https://ustr.gov/about-us/press-office/reports-and-publications/2013/2013-special-301-report>.

approvals are granted to medicines) exempt generic companies from submitting clinical trial data for bio equivalents of a drug which has already received marketing approval abroad. The only requirement for such bio equivalents is to establish bio equivalence with the foreign approved drug. The requirement of clinical data is met by relying on data submitted with respect to the approved drug, as discussed above.⁹

The data exclusivity proposed by EU in the negotiations, means that generic companies would no more be able to rely on innovator company's clinical data for getting marketing approval. This would in consequence, adversely affect their chances of getting marketing approval, thereby eliminating them from the market and increasing the cost and accessibility of the concerned drug.

The problem that may be created for access to medicine due to data exclusivity can be understood better in context of the prevailing structure of the Indian pharmaceutical industry. The post TRIPS regime in India has shown remarkable change in its structure and composition. With decline in new drug entry and more and more blockbuster drugs going off patent, the big pharmaceutical companies, in desire to keep up their profit, have entered into the generic segment of pharmaceutical industry throughout the world. The same is happening in India. The foreign companies are either taking over or entering into some kind of arrangement with local companies making generics. In fact MNCs in India are actively increasing their shareholding in local pharmaceutical companies.¹⁰

The growing presence of MNCs in generic segment when combined with demand of data exclusivity serves the purpose of obstructing other generic drug makers from accessing their data for marketing approval (subject to the patent status of the drugs)²³ leading to delay in entry of generics from other companies, reducing product variety, safeguarding market share and rise in cost.

Further, one of the most consistent criticisms of Indian pharmaceutical industry has been lack

⁹ *International Trade Agreements*, Ministry of Com. & Indus., Gov't of India, http://commerce.nic.in/trade/international_ta.asp (last visited Sept. 28, 2026).

¹⁰ European Commission, Draft EU-India Free Trade Agreement: Civil Enforcement of Intellectual Property Rights (Nov. 2012), http://trade.ec.europa.eu/doclib/docs/2012/november/tradoc_150081.pdf.

of research and development. The entry of MNCs in the generic market is only a means to utilize the expertise which Indian companies accumulated in the age of weak IPR regime. There is a fear that focus on generic or off patented drugs can only generate short term benefit for the Indian market. In the long run, it may inhibit Research and development.¹¹

Another relevant issue in the document which may have implications on access to medicine is the EU's stand on Traditional Knowledge (especially those related to medicine, plant genetic resources etc). Initially, the negotiation text contained no reference to Traditional Knowledge. Some authors had felt that this may have been purposely done by India to fully preserve its capacity to regulate the matter at the national level.²⁵ The new negotiation document includes Traditional Knowledge in two sections 10 and 11 but EU asserts that there is no internationally recognized definition of Traditional Knowledge and therefore does not guarantee a strong protection against its use by pharmaceutical companies for innovation.¹²

Quite true that there is no universally accepted definition of Traditional Knowledge yet. According to WIPO, 'Traditional Knowledge is knowledge, know-how, skills and practice that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity'.²⁷ The purpose behind recognizing TK is to take prior consent and share the benefits of any patented product derived from the TK, with the community to whom the TK belongs.¹³

By refusing to accept most of India's proposals with respect to TK or proposing to accept only weaker provisions, the EU is effectively relegating it to the public domain²⁹ thereby allowing its MNCs to misappropriate the TK and thereafter patent the product without adhering to responsibilities imposed under the TK regime like CBD. This may have adverse impact on efforts to provide affordable medicine through developing alternative/traditional medicinal systems in India and developing medicinal formulations there under. Such alternative

¹¹ Knowledge Ecology International, *Leaks and Reports on EU-India FTA Intellectual Property Negotiations*, KEI Blog (Feb. 2013), <http://keionline.org/node/1691>; see also Press Information Bureau, Gov't of India, *India-EU Broad-Based Trade and Investment Agreement (BTIA)* (July 11, 2011), <http://pib.nic.in/newsite/erelease.aspx?relid=73130>.

¹² Knowledge Ecology International, *Leaks and Reports on EU-India FTA Intellectual Property Negotiations*, KEI Blog (Feb. 2013), <http://keionline.org/node/1691>.

¹³ Carlos M. Correa, *Negotiation of a Free Trade Agreement European Union-India: Will India Accept TRIPS-Plus Protection?* (Oxfam Deutschland & Church Dev. Serv. Working Paper, 2009).

medicines have the potential to positively influence availability of affordable medicine.³⁰

The debate on access to affordable medicines would therefore be lopsided, if attention is not drawn to TRIPS + provisions in trade agreements that are being rampantly entered into, away from the citizens' eyes and in great secrecy. The issue of Data exclusivity combined with the growing dominance of MNCs in the generic segment, lack of innovation and weak provisions for protection of TK in the negotiation documents with the EU, have long term impact on the availability of affordable medicines in future and the attention should accordingly shift to active study and opinion here.¹⁴



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¹⁴ Prashant Reddy T., *The Data Exclusivity Debate in India: Time for a Rethink?* (SSRN Working Paper No. 2231027, 2013), <https://ssrn.com/abstract=2231027>.