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Anticompetitive Trade Practice and Data Protection in Indian Perspective

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Abstract

This article investigates into the demand for data protection law from a few specific sections of industries in the name of Indian commitment to the TRIPS agreement. The TRIPS Agreement makes it mandatory for the Members to protect undisclosed information. This article looks into the difference between data protection, data exclusivity and trade secret in an attempt to trace undisclosed information provision of the TRIPS Agreement. This article also investigates the anticompetitive trade practice forcefully implemented in the name of a separate legal tool for data protection.

Keywords

data protection, trade secret, data exclusivity, TRIPS, anti competitive trade practices

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In the last decade India has enacted many Acts to fulfil her international commitments. But still the pressure is on for the enactment of a few more laws and data protection is the prominent one in the wish list of a segment of the international community. The expectation of evolution of legal tools indicates the strong currents of globalization. The demand for the enactment of the data protection is industry specific and mainly confined to the pharmaceutical, information technology (IT) and outsourcing (Business Processing Organizations BPO) industries. The demand of IT and BPO industries for the data protection laws is based on expanding their business in European Union (EU) where the transmission of data to the third countries is prohibited by EU official Directive 95/46/EC[1] which further transmitted into their respective domestic law. The global pharmaceutical industry majors are concerned about protection of their clinical trial data. Interestingly the international pressure to enact data protection law is based on another international commitment by India, i.e. the TRIPS Agreement. The Section 7 of the TRIPS Agreement is about the protection of the undisclosed information which is covered under the Article 39[2] and the

1) Article 20: Whereas the fact that the processing of data is carried out by a person established in a third country must not stand in the way of the protection of individuals provided for in this Directive: whereas in these cases, the processing should be governed by the law of the Member State in which the means used are located, and there should be guarantees to ensure that the rights and obligations provided for in this Directive are respected in practice.

2) Article 39(1): In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.
Article 39(2): Natural and Legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices solong as such information:
(a) Is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
(b) Has commercial value because it is secret; and

pressure is to enforce this section on India.

India has no law for the protection of trade secrets or undisclosed information although there is Official Secret Act, 1923 to safeguard classified official information with the Government and the commercial and personal data are protectable through contractual obligations. The non existence of a law on data protection has a very solid reason in India. Once a law is enacted, the enjoyment of one's 'right' is an 'obligation' to rest of the people within the territorial jurisdiction of the country. The pressure to grant a particular 'right' needs an analysis of obligation part on behalf of the subjects of the nation. The reason based law drafting and enactment helps in the enforcement of the law. The other factor to look into this aspect is based in the genesis of the intellectual property (IP) laws. The objective of IP laws is *to promote the progress of science*[3] without making *IP laws barrier to the international trade.*[4] The IP system is based on sharing of private knowledge based on exclusivity to be used in the market to earn the bounty of sharing the knowledge for a particular time and after expiration of the time enhancing the public knowledge pool. The trade secrets do not

(c) Has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Article 39(3): Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

3) Article 1(8) of US Constitution: To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

4) Members desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to ensure intellectualproperty rights themselves become barrier to legitimate trade.

qualify to this genesis and therefore there is no legal protect to trade secrets. The TRISP Agreement, which has emerged as the international IP law instrumental in harmonizing the IP laws across the WTO Member Countries, in its preamble itself warn the Member countries to ensure that the measures and procedures to enforce intellectual property rights do not become barriers to the international trade. This cautious warning needs a wary analysis of the need to enact data protection law. The TRIPS Agreement provides liberty to the Member Countries to determine the implementation of the TRIPS provisions into their domestic legal system.[5] It means that any Member Country is free to choose the method of domestication of the TRIPS provisions into their legal framework. Hence, it is for sure that India has to ensure enforcement of the protection of undisclosed information into her territorial legal system but is free to choose the method of ensuring the same.

There are three wordings trade secret, data protection and data exclusivity which are used interchangeably which have different meanings. As per World Intellectual Property Organization (WIPO), *any confidential business information which provides an enterprise a competitive edge may be considered a trade secret*.[6] The trade secret sustains as long as others fail to decode it. The European Commission says that *the data exclusivity refers to the period during which the data of the original marketing authorisation holder relating to (pre-) clinical testing is protected. Accordingly, in relation to marketing authorisation applications submitted*

5) Article 1(1): Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

6) http://www.wipo.int/sme/en/ip_business/trade_secrets/trade_secrets/trade_secrets.htm

after 30 October 2005 for the applications filed in the framework of national procedures or 20 November 2005 for applications filed in the framework of the centralised procedure, 'data exclusivity' refers to the eight-year protection period during which generic applicant may not refer to the information of the original marketing authorisation holder and 'marketing exclusivity' refers to the ten-year period after which generic products can be placed on the market. However, in relation to marketing authorisation applications submitted before the above mentioned dates, the wording 'data exclusivity' refers to the six or ten-year protection period granted to the original MA holder before generic applicants can file their applications for marketing authorisation.[7] From the definition of trade secret and data exclusivity the difference between the two is clear, i.e. data exclusivity does not claim ownership in data but claiming the exclusivity to be associated with their procedure only before the authority concerned. The wording data protection has very wide connotation and is more acceptable term used in data privacy or information privacy of public data but also includes industrial data. Do trade secret, data exclusivity, data protection are subsets of undisclosed data for that protection under Article 39 of the TRIPS agreement directs the Members?

India did this introspection of looking into the aspect of data protection by forming a committee headed by Mrs Satnam Reddy, Secretary, Ministry of Chemicals & Fertilizers which presented its report on May 31, 2007. The committee recommended the need for having a minimum legal framework for protecting the undisclosed data related to clinical trials. However, it summarily rejected the need for having a separate legal tool for protecting

7) Pharmaceutical Sector Inquiry Preliminary Report: European Commission DG Competition Commission Staff Working Paper, November 28, 2008
http://ec.duropa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf

the undisclosed data. Since the recommendation was confined to the protection of clinical data, it was recommended to made appropriate amendments in the Drugs and Cosmetic Act, 1940 and the Insecticides Act, 1968. The Committee recommended three years data exclusivity to the data originator from the date of registration with the Regulator under the Insecticides Act, 1968 and for five years protection of the clinical trials data for the pharmaceuticals which provides protection of non-disclosed data to the public and non acceptance of fraudulently obtained clinical trial data. These recommendations were for the transition period of implementing the product patent regime since January 1st 2005 in respect of chemicals and pharmaceuticals in India. The Committee's recommendation further envisages of having a fixed time period of five years post transition period and a model of having the modalities for the same. The caution of wait and watch before making any legal binding for more obligations reflects the commitment of India towards her subjects indulging in lesser obligations.

The selective recommendation for the protection of clinical trials data as undisclosed information under the TRIPS Article 39(3) by the Satnam Reddy Committee needs inspection of the demand of enforcement of Article 39(3) part too. The conceptual acceptance was shown by the Satanm Reddy Committee for the protection of undisclosed information reflects the Government of India view on adhering to the commitment to internalization of TRISP Agreement into the domestic laws. The demand of the IT and the BPO sectors does not seem to invoke any interest in the light of the EU data protection directive 94/46/EC[8] because its conditions can be satisfied with the provision of the same Article by the data receiver in the third country, i.e. India, for data processing. The post product patent regime for the pharmaceuticals and chemicals in the developing countries like India has

8) id 1

changed the market scenario for the pharmaceuticals world. Earlier in the process patent regime the end product was open for all and was out of patent monopoly in case the process for reaching the end product was different from what has been monopolized by the drug inventor by a patent. Under the process patent regime only the process of manufacturing a drug formulation was protected. This was as good as no patent for most of the formulations as the competitors to the invented and patented formulation used tricks like reverse engineering of the formulation and 'invented' another method of reaching the same formulation as the end product. In such a scenario copycat and generic formulations competed with the invented formulations even in the life span of the patent of the invented formulation. There are provisions in the Drugs and Cosmetic Act, 1940 and Drugs and Cosmetic Rules, 1945 for the clinical trials of the new chemical entities (NCE) for taking the marketing approval from the Drug Controller.[9] The NCE owners had no other way but to go through the set

9) Rule 122-A (2), Drugs and Cosmetics Act, 1940: Application for permission to import new drug: The importer of a new drug when applying for permission under sub-rule (1), shall submit data as given in Appendix I to Schedule Y including the results of localclinical trials carried out in accordance with the guidelines specified in that schedule and submit the report of such clinical trials in the format given in Appendix II to the said schedule:
Provided that the requirement of submitting the results of local clinical trials may not be necessary if the drug is of such a nature that the Licensing Authority may, in public interest decides to grant such permission on the basis of data available fromother countries:
Provided further that the submission of requirements relating to Animal Toxicology, Reproduction Studies, Teratogenic studies, Perinatal studies, Mutagenicity and Carcinogenicity may be modified or relaxed in case of new drugs approved and marketed for several years in other countries if he is satisfied that there is adequate published evidence regarding the safety of the drug, subject to the other provisions of these rules.
Rule 122-B(2), Drugs and Cosmetics Act, 1940: Application for approval to manufacture new drug other than the drugs classifiable under schedule C and C(1): The manufacturer of a new drug under sub-rule (1) when applying for approval to the Licensing Authority mentioned in the said sub-rule, shall submit data as given in Appendix I to Schedule Y including the results of clinical trials carried out in the country in accordance with the guidelines specified in Schedule Y and submit the report of such clinical trials in the format given in Appendix II to the said Schedule.

procedure of conducting the clinical trials for collecting the requisite data to secure permission to market the NCE. The generic competitors use to secure the marketing rights relying on the clinical trials data submitted by the first applicant before the Drug Controller on the alibi of taking the approval of marketing the same formulation. The short cut of coming into the competition of the NCE owners frustrated the invented and patented chemical formulation owners on the one hand and on the other hand the Indian generic pharmaceutical industry grew exponentially banking on the knowledge creation of the NCE owners and huge population living in the climate conducive for the growth of most of the bacteria and virus responsible for various diseases. The scenario has changed since the enforcement of the product patent regime in the chemicals and pharmaceutical sector. Now the NCE, as new products, are monopoly of their respective owners who obtain patents for the same. Now the reverse engineering trick to find another method to reach the same chemical formulation is of no use. Now, in the produce patent regime, the patented NCE can remain in market without any competition from the generic manufacturers till the life span of the patent which is twenty years from the date of the filing either the basic application of the PCT application as the case may be. Now the option for the generic chemicals formulations manufacturers is to wait for the expiry of the patent to enter into the market subject to the approval of the Drug Controller. To check the generic drug manufacturers from making their old alibi before the Drug Controller to grant them permission to market the same chemical entity relying on the clinical trails data furnished before the Drug Controller by the patented NCE owner at the time of taking the marketing approval is at the focus of NCE pharmaceuticals majors. If the patented NCE owners could have claim on the clinical trials data submitted before the Drug Controller under the pretext of undisclosed information or data exclusivity, it would force the

generic manufacturers of the same chemical entity to enter into the market only after going through the clinical trials, then Drug Controller' s approval and expiry of the NCE patent. This may further delay the generic manufacturers to come into the competition of the NCE owner in the open market even after the expiry of the patent. This would be an advantage to the chemical entity owner to enjoy the monopoly even after the expiry of patent in the name of having the right over the undisclosed information presented to the Drug Controller. Is this not heading towards the warning in the preamble itself of the TRIPS Agreement about the ensuring that the measures and procedures to enforce the intellectual property rights do not themselves become barrier to the legitimate trade?

The depth of the concern keeps on deepening in the light of the different facets for the protection to the clinical data. The clinical data is nothing just a formality to establish before the Drug Controller that the NCE serves the very purpose for which it was invented/discovered. It is a collection of data from field trials of the NCE. It means it holds sensitive data relating to its action on India' s subjects. It is a data which should be subject to the watchdog to the Drug Controller office and to the Indian population which is ultimately going to use the formulations approved by the Drug Controller. It may be that the clinical trials data provides the short cut to enter into the market to the generic manufacturers banking on the NCE owner supplied clinical trials data but this data should be a public data. The NCE owner is just a collector of the clinical trials data as it gets generated on the basis of the observations made on people after the administration of the NCE. Hence, mere collection of clinical trials data fails the logic of being creator of undisclosed data. If the provision of submission of clinical data is diluted for the generic drugs of the same composition, then perhaps the NCE owners would themselves not consider the clinical trials data as an

undisclosed data. The issue of conducting fresh clinical trials by the generic manufactures for taking the marketing approval for the chemical entity which has successfully sustained for the patent life does not invoke any interest from the neutral parties. Is it not an anticompetitive trade practice to force the generic drug manufacturers to go for the clinical trials of the same chemical formulation which is in market for a long period and successfully served its purpose?

The Satwant Reddy Committee has very strategically recommended for five years of data exclusivity for the Clinical trials data. It at the one hand serves the TRIPS obligation and on the other hand does not provide data exclusivity to the clinical trials data when it is required by the patented NCE owners. But the investigation left a few unanswered questions to ponder upon. One, does really clinical trial data qualify to the undisclosed data protection provision as described in the Article 39 of the TRIPS? Two, are the provisions of undisclosed data protection and control of anti-competitive practices, about which the TRIPS Agreement speaks in the Section 8, conflicting to the extent of becoming barriers to the legitimate trade? The intensity of this question appears melting with the heading of the Section 8 of the TRIPS Agreement itself which says control of anti-competitive practices in contractual licensing. The buyer, seller and regulator are three integral parts of the free market. If copyright is excluded from the intellectual property tool kit, intellectual property becomes industrial property. The data which has been compelled upon to the Government for ensuring undisclosed data protection in the name of Article 39 of the TRIPS is undefined but surely data related to the trade. The EC data protection directive 95/46/EC, which has gradually transmitted into the EU Member Countries domestic law, loudly speaks about personal data relating the same to the basic human rights. Taking consumer or the buyer

as the indispensible part of the market, who will come forward to advocate about the protection of personal data under the same undisclosed data protection provision of the TRIPS? This is the third question which needs investigation in the light of the nascent Competition law.

It is also very relevant at this point of time to look into two provisions of the Patent law of the country. The patent law spells a few principals which are the guiding source of spirit with which the rest of the provisions have been enacted. The guiding patent principles spell out in the Section 83[10] make it very clear that the intention behind granting patent monopoly is merely to encourage inventions and their commercialization in India, socio-eco welfare of the subjects with the rights reserves with the Central Government for the protection of the public health. The principles further make it very clear that in relation to the public health that patents granted do

10) Section 83: General Principles applicable to the working of patented inventions: Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely:–
(a) That patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
(b) That they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
(c) That the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of the producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to balance rights and obligations;
(d) That patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio–economic and technological development of India;
(e) That patents granted do not in any way prohibit Central Government in taking measures to protect public health;
(f) That the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
(g) That the patents are granted to make the benefit of the patented invention available at reasonably affordable prices to public.

not impede protection to the public health and should act as an instrument to promote public health. Monopoly is bad for open market system. This concern is reflected in the guiding principles. It was further added in it by warning the patentees that they should reap the benefit of their inventions by making their invented patented products or processes at a reasonable price to public.

There is another provision spell out in the section 107-A[11] which is relevant in reference to the clinical trials data fight between the NCE owners and the generic drug manufacturers. This section has been particularly drafted and incorporated by an amendment in the year 2005 to dissuade all fears of jeopardising the public health system of the nation. It in a very clear language says that act of making a chemical entity, which is otherwise a patented product, for the purpose of developing the same for the purpose of securing approvals from the Indian as well as foreign government agencies (read Drug Controller). Hence, the generic drug manufacturers are free to do their homework for entering into the market soon after the expiration of the NCE patents.

This is one aspect of the Indian Patent law which clears the decks for completing the formalities for entering into the pharmaceuticals market by making the formulations and conducting the clinical trials. The other aspect

11) Section 107–A: Certain acts not to be considered as infringement: For the purpose of this Act:–
(a) Any act of making, constructing, [using, selling or importing] a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other thanIndia, that regulates the manufacture, construction, [use, sale or import] of any product;
(b) Importation of patented products by any person from a person [who is duly authorized under the law to produce and sell or distribute the product], shall not be considered as an infringement of patent rights.

of the Patent law permits the patent monopoly only for the complete disclosure of the invention. If the person pertinent in the relevant art of the patent disclosure fails to reach the desired results with the help of the invention disclosure in the patent specification, he can approach the patent office for the revocation of the patent on the ground of not disclosing the invention completely by the patentee. This provision is of great help if the others are permitted to further develop the disclosed invention in the patent document; the development of the patented invention after the expiry of patent makes the provision to cancel the patent on the ground of insufficient invention disclosure.[12] In short the growth of science and technology development is not hampered by the patents.

The provisions of the Patent Act, The Drug and Cosmetics Act and TRIPS provisions in totality provides a picture which is as encouraging in practice as envisaged in theory. The process patent regime was tilted towards the generic drug manufacturers and the post product patent regime is being tried to manoeuvre in favour of the NCE manufacturers under the pretext of providing protection to the undisclosed information. But in both the cases the stand taken by the Government of India is in favour of her subjects. The repetition of a lengthy, time consuming and costly process of clinical trials can take a twist if the requirement of clinical trials for the generic manufacturers for the same formulation is do away with. This will pave the way for a swifter clearance of drug approval for marketing the

12) Section 64(1)(h): Revocation of Patents: The Patent Act, 1970: that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection.

same in India relying on the clinical trials data submitted by the NCE owner and the results of the NCE in the real life scenario after the grant of the approval. This will destroy the demand for protection of clinical trials data, which in principle should be a public data accessible to all without objection from even the creator of the data. India has worked brilliantly to minimize the obligation part on behalf of her subjects but has yet to realize the sensitivity of privacy and the respect of data protection. The data protection right under the right to privacy may pave the way for the fresh thinking on integrating the data protection rights to the industrial property.

인도의 관점에서 본 반경쟁적 거래행위와 데이터 보호

Rahul Dutta

국문초록

본문은 인도의 TRIPS 협정 준수 노력을 위한 일부 산업 부문의 데이터보호법 요구를 조사한다. TRIPS 협정에 따라 회원국은 공개되지 않은 정보를 보호해야 한다. 본문은 TRIPS 협정의 비공개 정보 조항을 조사하기 위해 데이터 보호와 데이터 독점, 영업비밀의 차이를 살펴본다. 본문은 또한 데이터 보호를 위한 별도의 법률 도구로써 적용된 반경쟁적 거래행위에 대하여 조사한다.

주제어

데이터보호(data protection), 영업비밀(trade secret), 데이터 독점(data exclusivity), TRIPS, 반경쟁적 거래행위(anti competitive trade practices)