

Discussion Paper
on
India's IPR Regime

Indian Pharmaceutical Alliance
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1. Preface

Intellectual Property Rights: Is It Time To Pause Or Time To Change?

India ushered in a TRIPs compliant IPR regime from 2005. The changes were far-reaching for the national pharmaceutical industry and had grave implications for the public health. The debate over the issues involved continued even after the amendments to the statute came into effect. They were examined by various committees and discussed threadbare in the media as well as public fora and largely put to rest.

The debate however appears to have been revived. Several newspapers have reported in recent weeks that consequent to a meeting with a group of multinational pharmaceutical companies, the Prime Minister's Office has directed the concerned Ministries of the Government of India to re-examine the issues raised by the multinational companies including data exclusivity, exclusion from patentability under Section 3(d) of the Patents Act, patent linkage and principles for the grant of interim injunctions. The pressure for changes in policy and legislation has created a climate of uncertainty.

IPR issues are contentious. There are usually differences of opinion between generic (largely domestic) and innovator (largely multinational) pharmaceutical companies. There are important implications for public health and protection of private rights and the complex inter-relationship between the two makes the task of reconciling competing interests in the larger national interest so much more difficult. Another important aspect is that even as the domestic industry is emerging from a difficult economic situation, it is now beset with the added burden of uncertainty about policy relating to IPR. Policy stability is in the interest of the industry, whether it be the domestic or multinational companies.

Deeply conscious of the need to facilitate consensus building and decision making on IP issues and mindful of the national interest in the context of IP rights, the IPA has prepared a Discussion Paper to provide relevant background and the IPA views. The discussion of the various conflicting contentions, which provides the basis for the IPA view, follows. Some of the grounds covered in the discussion is familiar, but it has nevertheless been included with the objective of facilitating informed discussion to settle the controversies.

The IPA urges that:

- The Government takes note of the fact that legislation reflecting far-reaching IPR policy changes was implemented only in 2005 and there is a need to carefully evaluate the experience to date, the impact on public health and the national pharmaceutical industry before any changes are contemplated.
- The existing laws are compliant with the TRIPS Agreement and any measure that is TRIPS-plus and raises the bar for generic entry or delays it, will adversely affect the generic industry in India and access to medicines in India as well as other developing countries as India exports a large volume of affordable generic medicines to these countries.
- The Government definitively outlines its position and signals stability of the IPR policy and legislative framework to ensure that there is a stable policy environment for industry.

2. IPA Views

1. Data Exclusivity

- The TRIPS Agreement stipulates the protection of test and other data for new chemical entities required to be submitted for regulatory approval from unfair commercial use.
- Data exclusivity is not mandated by the TRIPS Agreement and this is a TRIPS-plus intellectual property right.
- It would not be violative of the TRIPS Agreement for the regulatory authorities to approve generic drugs that are bioequivalent to drugs approved on the basis of the test and other data submitted by the innovator companies.
- Data exclusivity would no doubt benefit innovator companies, whether multinational or domestic. However these would be a handful. The vast majority of pharmaceutical manufacturers in India are generic companies and they would not be benefited. It cannot therefore be asserted that the pharmaceutical industry would benefit from data exclusivity.
- There is no basis to suggest that data exclusivity will have any impact on the foreign direct investment, technology transfer and consequent employment. On the contrary, available data suggests this is not the case.
- The WHO Commission does not favour data exclusivity for developing countries and specifically recommends that there should be a public health justification for its introduction.
- Public health is ill-served by data exclusivity as it will delay the entry of affordable generics for a significant number of new drugs.
- Finally, it must also be mentioned, that one of the justifications offered for data exclusivity is that drugs submitted with comprehensive safety and efficacy data have higher safety and efficacy than generic drugs approved on the basis of bioequivalence. This is a canard and undoes the significant work done by the Government of India to promote Indian generics. The IPA is apprehensive that his campaign of misinformation will gain in intensity if data exclusivity is granted, to the detriment of public health and the national interest.

2. Section 3(d) of the Patents Act, 1970

- The High Court at Madras has upheld the constitutional validity of Sec 3(d) in *Novartis*.
- Sec 3(d) is not violative of the TRIPS Agreement.
- Sec 3(d) imposes a stricter standard of patentability than that in developed countries. This is widely endorsed, including by the WHO and is justified by the stage of development in India.
- Sec 3(d) strikes the needed balance between encouraging innovation and delaying generic entry, which promotes access to medicine.
- A definition of ‘efficacy’ is not a legal necessity nor is it desirable for the reasons outlined in *Novartis* by the Madras High Court.
- There is thus no compelling justification for legislative changes in Sec 3(d) at the present juncture.

3. Patent Linkage

- The plea for patent linkage has been turned down by the Delhi High Court in *Bayer* and is now pending consideration on appeal to the Supreme Court.
- There is evidence to suggest that the patent linkages have the potential to lead to abuse and delay of affordable generic medicines.
- Patent linkage is an approach shunned even in the EU.

4. Interim Injunctions

- The grievance is that pricing of originator reference products and the attendant impact on public interest should not be taken into consideration while determining the grant of an interim injunction restraining the manufacture and sale of an allegedly infringing drug product in a suit for patent infringement.
- The Delhi High Court has held in *Roche* that the considerations of pricing and public interest are relevant considerations for refusing the grant of an interim injunction.
- In arriving at this conclusion, the Delhi High Court has elaborately reviewed Indian and foreign law which recognize this principle.
- An interim injunction is a discretionary remedy that is decided on a case by case basis and there is no justification for seeking to limit judicial discretion by legislation.

3. Data Protection

All regulatory authorities require the first applicant (usually the innovator) for regulatory approval of a new medicine to submit data on the safety and efficacy of the new drug. The generation of this data requires substantial expenditure and effort including testing in animals and human clinical trials. Usually however, the second or subsequent applicants for approval are not required to duplicate the effort of animal testing and human clinical trials and are only required to establish equivalence to the previously approved drug. Drugs so approved are commonly known as 'generic' drugs and are therapeutically equivalent to the first approved drug.

It is open to national governments to regulate the use of the data submitted while seeking regulatory approval. Thus, governments can prohibit the unfair commercial use of the data by competitors and provide for protecting the confidentiality of the data submitted.

It is also open to governments to provide by law that new drugs which require clinical data to be submitted for approval will receive a period of market exclusivity in recognition of the expense incurred in generating such data. Such periods of exclusivity typically range between 5-10 years. Data exclusivity can be granted for new drug products irrespective of whether they have patents or not and the period of exclusivity starts from the date of regulatory approval. No generic drug can be approved during the period of data exclusivity resulting in a monopoly for the new drug product, separate and distinct from the monopoly resulting from patents. Unlike in the case of patents which can be challenged as invalid, data exclusivity cannot be challenged.

Data Protection and Data Exclusivity under the TRIPS Agreement

Art 39.3 of the TRIPS Agreement binds member States to *protect* undisclosed data required to be submitted for approval of pharmaceutical and agricultural chemical products against *unfair commercial use*, when such products are *new chemical entities*. The multinational pharmaceutical industry, the US and the EU have interpreted Art 39.3 to require member States to provide data exclusivity, with flexibility only to determine the period of exclusivity.

A plain reading of Article 39 does not suggest that there is any requirement under the TRIPS Agreement to grant data exclusivity to pharmaceutical and agricultural chemical products and this has been acknowledged even by the EU¹:

“It must be admitted that the following of Article 39.3 does not, from a prima facie reading, appear to impose data exclusivity during a certain period of time.”

The EU however asserts that this is merely a “lack of clarity” resulting from a “difficult negotiating process where divergences of views arose between developing and industrialized countries as to the necessity of EC/US like type of data protection” and argues that “the only way to guarantee that no ‘unfair commercial use’ within the meaning of Article 39.3 shall be made is to provide that regulatory authorities should not rely on these data for a reasonable period of time, the determination of what is a reasonable period of time being left to the discretion of Members.” The multinational pharmaceutical companies and the US interpret the TRIPS Agreement similarly.

Prof Carlos Correa, Director of the Centre for Interdisciplinary Studies on Industrial Property and Economics Law at the University of Buenos Aires, has noted the above in his comprehensive and careful analysis of the data protection requirements under the TRIPS Agreement under the aegis of the South Centre, a permanent intergovernmental organisation of developing countries.² The report was published in collaboration with the Department of Essential Drugs and Medicines Policy of the World Health Organisation and the final conclusion was this³:

“In sum, Article 39.3 – interpreted according to the ordinary meaning of the words used, in their context (notably Article 39.1) and taking into account the object and purpose of the Agreement as expressed in Articles 7 and 8 – does not require the granting of exclusive rights. The obligation that it imposes may be satisfied by other means, not specified in the Agreement.”

The ‘obligation’ referred to above is confidentiality, not exclusivity.

Regulatory Approval of Generic Products not ‘Commercial Use’

An important argument used in support of the proposition that data exclusivity is necessary under the TRIPS Agreement is that if the national regulatory authority approves a second or subsequent application for a previously approved drug, it does so on the basis of the safety and efficacy data submitted by the first applicant for approval. Therefore, the argument goes, such data of the first applicant is put to ‘unfair commercial use’ and is violative of TRIPS.

¹ European Union, *Questions on TRIPs and data exclusivity, An EU contribution*, Brussels, 2001, p 19, http://trade.ec.europa.eu/doclib/docs/2006/may/tradoc_122031.pdf

² <http://www.southcentre.org/>

³ Correa CM, *Protection of data submitted for registration of pharmaceuticals: Implementing the standards of the TRIPS Agreement*, South Centre, 2002 Geneva, 2002, p 45-46 , <http://apps.who.int/medicinedocs/pdf/h3009ae/h3009ae.pdf>

This argument does not find favour with Prof Correa, who concluded after an exhaustive analysis that:⁴

“Use by the government to assess the efficacy and toxicity of a pharmaceutical or agrochemical product is not a commercial use subject to Article 39.3. Granting marketing approval to a second entrant, based on the second product’s similarity to a previously approved first product, is not a proscribed “use” under Article 39.3.”

It is noteworthy that UNCTAD holds the same view⁵:

“authorities are not prevented....from using knowledge of such data for instance, to assess subsequent applications by third parties for the registration of similar products.”

The Federal Court of Appeal in Canada had occasion to consider whether the approval of a generic product on the basis of bioequivalence would involve reliance on data submitted by the innovator to obtain marketing authorisation for a new drug product. The Federal Court of Appeal held that while approving a generic product on the basis of bioequivalence, the regulatory authority “will not have to examine or rely upon confidential information filed as part of the innovator’s [New Drug Submission].”⁶ While acknowledging the rationale of the Court, Canada decided to enable market exclusivity for 8 years by an amendment to the law with the following reasoning:

“However, to receive a notice of compliance in Canada, a generic manufacturer need only demonstrate bioequivalence by comparing its generic product to the innovator's product. Therefore, in actual practice, the Minister typically does not examine the data contained in the innovator's submission in order to grant a notice of compliance for a generic product. As a result, data protection does not arise where bioequivalence forms the basis of a generic submission, as affirmed by the Federal Court of Appeal in *Bayer Inc. v. Canada (Attorney General)*, 87 C.P.R. (3d) 293.

While the comparison necessary to demonstrate bioequivalence rarely involves an examination of the innovator's data, it does involve reliance on the innovator's product. Therefore, these amendments are being introduced to clarify that the aforementioned reliance will give rise to an exclusivity period.”⁷

Interestingly, the amendment was justified *not* on the basis that the approval of a generic product involved reliance on the data submitted for marketing approval, but that it involved “reliance on the innovator’s product”. The logic of the Federal Court of Appeal commends itself in the context of a response to the EU position; the logic supporting the amendment in Canada is entirely outside the realm of the TRIPS Agreement.

⁴ *Ibid*, p x

⁵ UNCTAD, *The TRIPS Agreement and developing countries*, UNCTAD/ITE/1, New York and Geneva, 1996, p 48, quoted in Correa, *ibid* p 46

⁶ *Bayer Inc. v. Canada (Attorney General)*, 87 C.P.R. (3d) 293.

⁷ Canada Gazette, Vol. 140, No. 21, October 18, 2006. <http://www.gazette.gc.ca/archives/p2/2006/2006-10-18/html/sor-dors241-eng.html>

Data Exclusivity is a TRIPS plus Measure

Notwithstanding the stand of the multinational pharmaceutical companies, the EU and the US, the TRIPS Agreement does not require the grant of data exclusivity.

Prof Correa is of the view that data exclusivity is TRIPS plus measure⁸:

“Members may also opt, but are not obliged to, grant ‘TRIPS-plus’ protection on the basis of data exclusivity, as some countries currently do.

In making such choices, policy makers will have to weigh the protection of interests of originator companies against the importance of creating a competitive environment in order to increase access to medicines that are outside patent protection. From a public health perspective, the introduction of TRIPS-plus standards does not seem the best approach for developing countries.”

The negotiating history of the TRIPS Agreement also makes it clear that the data protection required by it is basically confidentiality and the concept of data exclusivity is entirely different and was rejected during the negotiation process. The idea originated from a US submission in 1987 under the heading ‘Trade Secrets’. Thereafter, the ‘Business Communities’ in the US, Japan and EU issued a ‘Joint Statement of Views’ in 1988 which noted that the registration of new pharmaceutical products required the submission of information that takes many years and much expense to generate. It went on to state that some “governments permit local interests to have the benefit of this registration information enabling them to compete without suffering the high costs of the original registrant in developing the information” and the “ability of local interests to get such a free ride operates as a trade barrier to markets.”⁹

Despite the clear articulation of the business view early in the negotiation process, it is clear from the legislative history of Art 39.3 and an authoritative interpretation of the final text by Carlos Correa (also shared by others) that the notion of market exclusivity was rejected in the final text of Art 39.3.¹⁰

Data Exclusivity: A Public Health View

As is evident, the choice of adopting a TRIPS plus measure such as data exclusivity has to be made carefully as it impacts access to medicines and public health. The issue was specifically considered by an independent commission established by the WHO in 2004 (the WHO Commission), pursuant to a resolution by its member States to consider the relationship between

⁸ Correa, *op cit*, p 46

⁹ See Cook, TM: *The protection of regulatory data in the pharmaceutical and other sectors*, Sweet and Maxwell, 2000, p 10

¹⁰ Correa, *op cit*

intellectual property rights, innovation and public health. The recommendation of the WHO Commission was:¹¹

“Developing countries need to decide in the light of their own circumstances, what provisions, consistent with the TRIPS Agreement, would benefit public health, weighing the positive effects against the negative effects. A public health justification should be required for data protection rules going beyond what is required by the TRIPS Agreement. There is unlikely to be such a justification in markets with a limited ability to pay and little innovative capacity. Thus, developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS.”

The basis of the above conclusion and the factors relevant to weighing the pros and cons are best stated by the Commission itself, reproduced extensively below:

“Article 39.3, unlike the case of patents, does not require the provision of specific forms of rights. But it does oblige Members to protect undisclosed test or other data against unfair commercial use. It does not create property rights, nor a right to prevent others from relying on the data for the marketing approval of the same product by the same party, or from using the data except where unfair (dishonest) commercial practices are involved.

Thus, the TRIPS Agreement does not refer to any period of data protection, nor does it refer to data exclusivity. In some countries, however, such as the United States, a *sui generis* regime was adopted prior to the TRIPS Agreement under which, for a period of five years from marketing approval, no other company may seek regulatory approval of an equivalent product based on that data without the approval of the originator company. In the European Union the period has now become up to 10 years, during which generic companies are allowed to develop the product and may submit an application for authority to market it after eight years. Some developing countries have also adopted this regime in one form or another.

If the patent period has expired, or there is no patent on the product, this *sui generis* data exclusivity may act independently of patent status to delay the entry of any generic companies wishing to enter the market. This is because the regulators cannot use the data in the period of protection to approve a product, even if the product is demonstrated to be bio-equivalent, where required. The only alternative for a generic company would be to repeat clinical trials, which would involve replicating tests in humans to demonstrate what is already known to be effective. These *sui generis* regimes, which provide for data *exclusivity*, need to be clearly differentiated from the TRIPS agreement’s requirement for data *protection*.

According to its proponents, the claimed benefits of data exclusivity relate, to a great extent, to the additional incentives offered to companies in the long and expensive process of pharmaceutical R&D. They note that data exclusivity gives companies an incentive to extend the original use of the product (e.g to a wider population by age or geography and in new indications for therapeutic use) and provides an additional opportunity for originator companies to recoup their investment where marketing approval occurs late in the patent life, so that the protection afforded extends beyond patent expiry. They also argue that it offers benefits to domestic innovators in developing countries. Further, it is argued that data

¹¹ WHO, *Public health, innovation and intellectual property rights, Report of the commission on Intellectual property rights, innovation and public health*, Geneva, 2006, p 126
<http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>

exclusivity provides an incentive for research identify new uses for existing unpatented products (e.g. paediatric formulations) and an incentive for originator companies to introduce products into developing countries, which they would not otherwise do because of the possibility of generic competition.

Opponents note that, for developing countries, there are no benefits of data exclusivity, since it would not promote R&D in those countries, and the benefits to the companies themselves will be small because of the limited market potential in most developing countries. It will not add materially to R&D incentives for companies more generally. They argue that its purpose is to allow additional periods of exclusivity for originator products, and it therefore correspondingly delays the onset of generic competition and thus prevents possible reduction in the cost of medicines. Therefore, they argue, the principal result will be added health-care costs. For instance the United Nations Special Rapporteur on the Right to Health commented on the possible additional health-care costs of the proposed Free Trade Agreement between the United States and Andean Pact countries relating to the introduction of data exclusivity.”

Benefit to Industry and Patients

Apart from the issue of whether or not data exclusivity is required to be granted under the TRIPS Agreement and the public health perspective, as discussed above, the debate between the proponents and opponents of data exclusivity are commonly around a few issues:

- Data exclusivity would benefit the pharmaceutical industry; the counter argument:
 - it is true that data exclusivity could benefit the originator or innovator pharmaceutical industry;
 - such benefit is however restricted to a handful of pharmaceutical companies who develop new chemical entities. On the other hand, the vast majority of the pharmaceutical industry in India is engaged in the manufacturing generic drugs and the vast majority will be benefited if the entry of generic drugs is not delayed;
 - however, benefits to individual pharmaceutical companies or even the industry has to be weighed against the impact on public health as urged by various individuals and organisations, including the WHO Commission.
- Data for obtaining regulatory approval is generated at considerable cost and to allow regulatory authorities to rely on such data for approval of subsequent applications for generic products would be unfair to the originators of the data; the counter argument:
 - this reasoning has not found acceptance among a number of individuals and organisations, including international organisations such as UNCTAD and the WHO Commission;
 - the alternative of requiring generic applicants to generate their own preclinical and clinical data of safety and efficacy is completely untenable as it would needlessly increase the cost of generic products and entails unethical duplicative testing on animals and humans.

- Data exclusivity would provide an incentive for the wide dissemination of data relevant to the safety and efficacy of the drug to doctors which would ultimately benefit patients; the counter argument:
 - this argument is difficult to justify as the dissemination of information to doctors on new drug products is required by law as a condition of approval;
 - the dissemination of information is also a commercial imperative and the core activity of marketing of a drug. The reward is commercial return;
 - the most important benefit to patients is access to medicine at affordable prices. This is best achieved, as the experience of India shows, by promoting generic competition, not by awarding market exclusivity to a single manufacturer.

Increased Foreign Direct Investment

Another principal argument of the proponents of data exclusivity is that it would result in increased foreign direct investment, employment opportunities and technology transfer.

It would be appropriate to give this issue careful consideration and base the policy perspective on relevant data, but unfortunately no data seems to be readily available to support this contention. A general perception is that the relevant data prior to 1970, when medicinal products were patentable in India, does not support this contention.

One indicator of whether data exclusivity could impact investments may be the distribution of global R&D expenditure of major multinational companies. The US has 5 years of data exclusivity. While various countries in Europe had differing periods of data exclusivity, the EU adopted a uniform period of data exclusivity of 10 years for applications for approval submitted from November 2005 onwards. This is double that of the US and the longest period of data exclusivity available globally. Several other countries have also introduced data exclusivity provisions. The question therefore is whether this has resulted in a shift in R&D expenditure from the US into other countries, including the EU.

The data suggests the introduction of data exclusivity in other countries has not resulted in any greater proportion of R&D expenditure being incurred in these countries by members of the Pharmaceutical Research and Manufacturers of America (PhRMA), who account for a substantial portion of the R&D expenditure for new drug discovery and development globally. The PhRMA companies have consistently spent around 80% of their R&D expenditure in the US over the last 30 years and no significant change in this pattern is observable.¹² If the R&D spend, which is the most proximate to the impact that data exclusivity can have, has not been discernibly affected in the US despite data exclusivity being provided in other countries and for

¹² Computed from data available in the PhRMA website
http://www.phrma.org/sites/phrma.org/files/attachments/Profile_2010_FINAL.pdf

longer periods, it is unclear on what basis it can be asserted that the distribution of investments is influenced by provision of data exclusivity. On the other hand, it is logical that such investments and the consequent employment as well as technology transfer are largely dictated by normal commercial considerations such as profitable pricing, market size, availability of skilled manpower, infrastructure and costs.

Delay in Generic Entry

The opponents of data exclusivity have principally argued that it would delay the entry of affordable generics.

An analysis¹³ of new drug approvals by the EMEA for 3 years, (2007-2009) shows that:

- Of the 113 drug products approved (including biologicals, but excluding vaccines), 92 drug products were granted data exclusivity.
- Of these 92 drugs, 32 drugs did not have subsisting patents for the actives as on the date of approval. The patents for the actives had either expired or the actives were not patentable but as they were used in new drug products, they were eligible for data exclusivity.
- The remaining 60 drug products are new chemical or biological entities with subsisting patents for the actives as on the date of approval. The data exclusivity for 38 of these products expires subsequent to the date of expiry of the patent. In fact data exclusivity extends even beyond the period of the supplementary protection certificate (i.e. patent term extension) for 18 of these products.

This analysis suggests that 70 of the 92 products approved in the EU in 2007 to 2009, the data exclusivity period of 10 years extended beyond patent expiry. It is noteworthy that even if a data exclusivity period of 5 years is considered, the period of exclusivity will extend beyond patent expiry for 50 products.

Clearly data exclusivity provides an additional period of market exclusivity beyond that provided by patents for a significant number of new products. The proponents of data exclusivity would argue that this is the reason why data exclusivity is needed as the cost of expensive clinical trials would otherwise not be recovered. The opponents of data exclusivity would argue that where there is no patent protection at all, the cost of clinical trials would generally be of a lower order of magnitude and the available period of exclusivity for products with a patent would be adequate; in both cases, the commercial returns would be reasonable.

In any event, it cannot be disputed that data exclusivity delays generic entry for a significant number of new drug products. The WHO Commission has specifically recommended that such a

¹³ Ramakrishna V, personal communication

TRIPS-plus measure requires a careful weighing of pros and cons and a public health justification.

Satwant Reddy Report

The Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, Government of India was entrusted with the task of suggesting measures to be adopted in the context of data protection provision as outlined in Article 39.3 of TRIPS in February 2004. The report authored by the then Secretary, Mrs Satwant Reddy and Joint Secretary, Mr GS Sandhu, was submitted in May 2007.

The Satwant Reddy report¹⁴ recognizes that the TRIPS Agreement is a minimum standards agreement and Article 39.3 relates to the minimum standards of data protection, namely confidentiality and non-disclosure of test data. The report also recognizes the need to effectively implement these standards by making the necessary legal changes to “explicitly provide for the minimum requirements under Article 39.3 of TRIPS” and cautions that “any higher standards of data protection should be done after a careful study of its impact on the sector and public to avoid any adverse repercussions in the long run.”

The report suggests that “in the long run it may be in India’s interest to move towards higher standards of data protection” and recommends a “transition period” to enable the needed careful evaluation. No time frame for the transition period is recommended and the report notes that it should be determined “after further discussions”.

The report notes in the recommendation section that a model for data exclusivity emerged during its deliberations for consideration post the transitional period¹⁵:

“The feasibility of providing a fixed period data protection at a future date was deliberated upon. This could be for five years with the Drug Regulator not placing reliance upon the data submitted by the Originator while approving second and subsequent applications for the same product. After examining the views expressed for and against fixed term data protection by various stakeholders and experts a model has emerged which can be applicable with adequate safeguards in the post-transitional period. It is perceived that this model will help in early introduction of new drugs in India as also provide an impetus for R&D. However further analysis of the implications of this model is required.”

The report therefore recommends legislative changes to strengthen data protection in consonance with the TRIPS Agreement and a possible ‘model’ for data exclusivity that could be considered in the future¹⁶:

¹⁴ Reddy S and Sandhu GS, *Report on steps to be taken by Government of India in the context of data protection provisions of Article 39.3 of TRIPS Agreement*, New Delhi, 31 May 2007

¹⁵ *Ibid.* p 46

¹⁶ *Ibid.* p v

“The initial steps to be taken should be to implement the minimum standards of data protection i.e. [prevention] of unauthorized disclosure and unauthorized use through explicit legal provisions in the Drugs and Cosmetics Act, 1940 and the Insecticides Act, 1968 and the Rules framed under these. Liability of the third parties in case unauthorized use of test data of the Originator should be made explicit in these laws and it should be enforceable through courts.... There is no need for separate statute for data protection in India.

In the [post-transition] period, higher standards of data protections can be considered for adoption. This may include a fixed period data protection for a period of five years with [non-reliance by] the Drug Regulator [on] the data submitted [by the] Originator. Several safeguards have also been suggested to take care of any adverse effect on public health or situations of [health] emergency. The duration of the transition period as well as the [model] needs to be discussed further before any decision to adopt is taken.”[typographical errors corrected]

Views of the Parliamentary Standing Committee

The Parliamentary Standing Committee on Commerce had occasion to consider the issue of data exclusivity and recommended as follows¹⁷:

“5.47 As a condition for registering pharmaceutical and agro-chemical products, National authorities normally require the applicant to submit data relating to quality, safety and efficacy of the product. The Committee were informed that the MNCs are demanding ‘Data Exclusivity’ on their data, so that its use could be prevented for allowing generic manufacturers to take marketing approval. The Committee is aware of the fact that there is considerable pressure on the Government to accede to this demand. The Committee feel that conceding to demand for Data Exclusivity would amount to agreeing to TRIPS plus provisions. Once such a demand is agreed at bilateral forum, there will be additional demands, which may relate to higher level of intellectual property right, such as extension of patent period, restriction on compulsory licences, restriction on parallel imports, and may be on R&D activity on patented subject matter. Data Exclusivity may result in delay in ensuring role of domestic enterprises through compulsory licensing system, and in preventing other parties from developing similar data.

5.48 Since the consequences of Data Exclusivity are quite serious, the Committee strongly recommend that the Government should not fall prey to such demands of MNCs. The Government must thwart such attempts, being made at the behest of certain vested interests. It should also guard against moves to enter into FTA with USA, as the developed countries, particularly the USA, are trying to bring in certain TRIPS Plus measures through Bilateral and Regional Agreements.”
(emphasis in original)

¹⁷ Parliamentary Standing Committee on Commerce, *Eighty Eighth Report on Patents and Trademarks Systems in India*, New Delhi, October 2008, Rajya Sabha Secretariat

4. Section 3(d) and Patentability

There have been suggestions that Section 3(d) of the Patents Act be amended. The disquiet over Section 3(d) is fundamentally because it introduces limitations, unfamiliar to western countries, on patentable subject matter. The result of this disquiet is a campaign for the amendment of section 3(d) for two main reasons:

- The terms “efficacy” and “significantly” in Sec 3(d) are said to be ambiguous and need to be defined.
- The limitations on patentability imposed by Section 3(d) allegedly adversely affect innovation and should be removed.

Legislative History

Sec 3(d) defines what are not inventions under the Act. Sec 3(d) existed prior to 2005 and the changes brought about by the amendment in 2005 are highlighted below:

“3. The following are not inventions within the meaning of this Act,-

(d) **the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or** the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one known reactant.

Explanation.-For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered the same substance, unless they differ significantly in properties with regard to efficacy.” (Emphasis added to the language of the amendment)

The amendment was enacted in 2005 to comply with the TRIPS Agreement and to strengthen the safeguards against “evergreening” – a device adopted to increase patent life of a product by successive patents, with the effect of delaying generic entry.

The amendment was challenged by Novartis¹⁸ before the High Court at Madras on two grounds:

- That it was not compliant with the TRIPS Agreement, mainly Article 27.
- That it was violative of Art 14 of the Constitution as it was vague and arbitrary, mainly because the term ‘efficacy’ in Sec 3(d) is not defined.

The High Court declined to go into the question of whether Sec 3(d) was compliant with the TRIPS Agreement on the ground that it had no jurisdiction to do so. This note therefore briefly discusses this issue subsequently, based on other authoritative commentaries and views.

It also held that the amended Sec 3(d) was not violative of Art 14 of the constitution. As there appears to be a persistent view that it is desirable to provide a definition of the term ‘efficacy’, (generally without reference to the decision in *Novartis*), this is also discussed below in the context of the reasoning of the High Court.

Sec 3(d) is TRIPS-compliant

Prof Correa has specifically endorsed Sec 3(d) of the Patent Act as a measure which avoids the vice of extending patent life by ever greening and blocking generic competition¹⁹:

“The best policy for developing countries would rather be to establish high standards of inventive step, in order to avoid ‘evergreening’ and other patenting strategies aimed at blocking genuine competition and follow on innovation. For instance, the recent reform (2005) of the Indian Patent Law has incorporated an antievergreening provision, which tightens the inventive step requirement as applied to new forms or modifications of existing pharmaceutical products.” (internal citations omitted)

The IPA had argued in *Novartis* that amended Sec 3(d) was compliant with the TRIPS Agreement. In substance, as is clear from the amendment of Sec 3(d) marked out above, all that the amendment does is to exclude a new form of a known substance from patentability, if it does not result in enhanced efficacy. The Explanation is clarificatory and provides guidance on the new forms that should be so excluded. Further, the IPA had argued that for an invention to be patentable, under the TRIPS Agreement or any national law, the invention in question should not be obvious to a person skilled in the art. ‘Obvious’ is nowhere defined in the TRIPS Agreement or indeed any other legislation anywhere in the world. Many countries in the world have set out through rules, regulations or procedures, as well as through judicial pronouncements, their own interpretation of what constitutes an inventive step and what is the standard of obviousness that negates it. These are standards of obviousness that have evolved over time and in the context of

¹⁸ *Novartis v Union of India*, (2007) 4 MLJ 1153

¹⁹ Correa CM, *Intellectual Property and Sustainable Development: Revising the agenda in a new context*, Paper for the Bellagio Dialogue, International Center for Trade and Sustainable Development (ICTSD), September 2005, Bellagio, Italy, p 7. http://www.wipo.int/meetings/en/2006/scp_of_ge_06/presentations/scp_of_ge_06_correa.pdf

the state of technology or development and differ from country to country. Sec 3(d) sets out certain standards of obviousness in the statute itself. In other words, what other countries have done through their rules, regulations or through judicial pronouncements has been incorporated into the statute. This is expressly permitted by the TRIPS Agreement. Article 1(1) of TRIPS in relevant part reads:

“[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”

The TRIPS Agreement enshrines within itself the concept of flexibility in implementation and recognizes the sovereign right of member States to make use of these flexibilities in implementing the TRIPS Agreement in consonance with the status of their economic and technological development. The stated objective of the TRIPS Agreement in Article 7 is that:

“protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, **to the mutual advantage of producers and users** of technological knowledge and in a manner **conducive to social and economic welfare, and to a balance of rights and obligations.**” Further, Article 8 adopts the principle that “[m]embers may, in formulating or amending their laws and regulations, adopt **measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development**, provided that such measures are consistent with the provisions of this Agreement.” (emphasis added).

Further, the Doha Declaration which is issued in the context the implementation of the TRIPS Agreement specifically recognized the concerns of the effects of intellectual property protection on prices and specifically affirmed that the:

“[A]greement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, **in particular, to promote access to medicines for all.**” (emphasis added)

It may be that because of Sec 3(d) or otherwise, the standard of the inventive step is higher in India, but as is clear from the above, it is permissible under the TRIPS Agreement and is justified by the state of socio-economic development in India as also the imperative of ensuring that generic competition is not stifled and access to affordable medicine is promoted.

This view is strengthened by a relatively recent and remarkably comprehensive and scholarly treatise by Amy Kapczynski, Assistant Professor at the Berkeley School of Law at the University of California, on the nature and utility of the flexibilities in the TRIPS Agreement. Prof Kapczynski notes the enormous domestic and global pressure on India not to enact a patent law that went beyond TRIPS requirements and the similar insistence in Parliament.²⁰ This resulted in

²⁰Kapczynski A, *Harmonization and its discontents: A case study of TRIPS implementation in India’s pharmaceutical sector*, California Law Review, Vol 97, No 6, December 2009, 1586-87 , <http://www.californialawreview.org/assets/pdfs/97-6/2KapczynskiFINAL.pdf>

India's 'creative' use of TRIPS flexibilities, consistent with the TRIPS Agreement. Characterizing Sec 3(d) as providing for 'subject matter exclusion', Prof Kapczynski points to the consequence of limiting patents for medicines:²¹

"India has adopted a set of exclusions to patentability unknown elsewhere in the world and which could sharply limit the number of patents granted in the pharmaceutical context. It has also adopted an exceptionally high threshold for inventive step (or obviousness), which if applied rigorously would have the same effect. These two moves alone could invalidate a substantial percentage of the patents on medicines that would be granted in a jurisdiction such as the United States. And yet they appear to be fully TRIPS compliant."

After an exhaustive interpretation of the TRIPS Agreement, Prof Kapczynski concludes:²²

"Each interpretive tool thus points to the same conclusion: India's subject matter exclusions and inventive step standard appear to be consistent with the terms of the TRIPS Agreement. They thus map out a novel set of flexibilities that developing countries could adopt that would, if applied rigorously, substantially reduce the scope of exclusive rights in medicines in such countries."

India's "innovative lawmaking", says Prof Kapczynski "creates a potential model for other developing countries."²³ Any change would potentially have implications beyond India.

Is There a Need to Define 'Efficacy'?

The 'subject matter exclusion' in Sec 3(d) is not absolute, as it permits patentability of new forms of known substances that result in the 'enhancement of the known efficacy'. The interpretation of 'efficacy' is therefore crucial. As Prof Kapczynski notes:²⁴

"Whether India ultimately interprets "efficacy" in section 3(d) as the more demanding "therapeutic efficacy" standard, and whether it interprets its inventive step standard as more stringent than inventive step standards in, for example, Europe, remains to be seen."

The Madras High Court has however answered this question in *Novartis*:²⁵

"The position therefore is, if the discovery of a new form of a known substance must be treated as an invention, then the Patent applicant should show that the substance so discovered has a better therapeutic effect."

²¹ *Ibid*, p 1589

²² *Ibid*, p 1598

²³ *Ibid*, p 1594

²⁴ *Ibid*, p 1594

²⁵ *Novartis, op cit*, para 13

There has however been a persistent demand that ‘efficacy’ needs to be explicitly defined so that it is free from ambiguity. The Parliamentary Standing Committee on Commerce made the following recommendation to this effect:²⁶

“However, even Section 3(d) is not free from ambiguities. The Government should clarify the usage of terms ‘significantly’ and ‘efficacy’, which form part of Section 3(d), to clear the ambiguities involved in the interpretation of the said section. It needs to be ensured that the laws are not TRIPS-plus but just TRIPS compliant.” (emphasis in original)

The challenge in *Novartis* was also that in the absence of a definition, ‘efficacy’ is vague and ambiguous and therefore violative of Art 14 of the Constitution of India. The High Court rejected this contention:²⁷

“We have already held that the amended section cannot be said to be vague or ambiguous. We reiterate here at this stage that the amended section with its Explanation is capable of being understood and worked out in a normal manner not only by the Patent applicant but also by the Patent controller. In other words, the patent controller would be guided by various relevant details which every patent applicant is expected to produce before him showing that the new discovery had resulted in the enhancement of the known efficacy; the derivatives differ significantly in properties with regard to efficacy and therefore it cannot be said that the patent controller had an uncanalised power to exercise, leading to arbitrariness. The argument that the amended section must be held to be bad in Law since for want of guidelines it gives scope to the Statutory Authority to exercise its power arbitrarily, has to be necessarily rejected since, we find that there are in-built materials in the amended section and the Explanation itself, which would control / guide the discretion to be exercised by the Statutory Authority.”

The High Court also held that there was no legal necessity of having a definition for efficacy’:²⁸

“Therefore it is clear from the case laws referred to above that Parliamentarians expresses its object and purpose in general terms when enacting a Statute and does not foresee the minute details that are likely to arise in the future and provide a solution for the same at the time when the Act itself is enacted. On the other hand, they would be acting wiser if they make only general expressions, leaving it to the experts / Statutory Authorities and then courts, to understand the general expressions used in the Statute in the context in which they are used in a case to case basis depending upon the facts available in each case.”

The logic of the Madras High Court bears careful consideration. Clearly, the question of efficacy has to be determined on a case by case basis. The experience in determining this question is evolving and if anybody has a grievance about its determination, there is always recourse to appeal. The alternative of defining efficacy could well be an exercise in futility, for the reasons laid out in the *Novartis* case. It is significant that no definition of efficacy has been suggested by those who desire one.

²⁶ Parliamentary Standing Committee on Commerce, *op cit*, para 5.35

²⁷ *Novartis*, *op cit*, para 16

²⁸ *Ibid*, para 14

‘Sec 3(d) Discourages Innovation’: The Logic and the Fallacy

The Logic

Apart from the view that Sec 3(d) is violative of the TRIPS Agreement and that ‘efficacy’ needs to be defined to remove ambiguity, several other policy considerations supporting its legislative review have been advanced. These are probably dealt with most comprehensively in a report commissioned by the US-India Business Council (USIBC), a business advocacy organization “carrying forward a strong program in regard to IPR protection” comprising American companies investing in India and some Indian companies.²⁹ The report was authored by White and Case LLP,³⁰ an American law firm with international operations and Dua Consulting,³¹ an Indian consulting firm for business and public affairs.

The USIBC report³² is of the view that the exclusion from patentability under Sec 3(d) “appears *prima facie* to be in conflict with the international consensus reflected in the TRIPS Agreement”.³³ This is incorrect for the reasons outlined earlier.

Apart from issue of compliance with the TRIPS agreement, the USIBC report argues that:

- ‘incremental innovation’ which “involves technical modifications of an existing product, process or system that results in some improvement or enhancement thereto..... has been an important source of India’s recent economic growth and the recent success of Indian companies.”
- the National Knowledge Commission study of 2007, “determined that while 37.3% of Indian companies have introduced breakthrough innovations in recent years, no fewer than 76.4% have introduced incremental innovations.”
- “a study conducted in 2007 of the medicines on the World Health Organization’s (WHO) Essential Drug List found that over 60% of the drugs on the list reflect incremental improvements of older drugs.”
- “incremental pharmaceutical innovation can improve the usefulness and effectiveness of existing drug products and result in less expensive and more accessible treatments.”

²⁹ <http://www.usibc.com/usibc/about/default>. For membership list see

<http://www.usibc.com/usibc/membership/default>

³⁰ <http://www.whitecase.com/about/overview/>

³¹ <http://www.duaconsulting.com/>

³² White & Case LLP and Dua Consulting, *The value of incremental pharmaceutical innovation: Benefits for Indian patients and Indian business*, USIBC, June 2009

³³ *Ibid*, p 14

- “incremental pharmaceutical innovations can reduce employee absenteeism and mitigate the impact of illness on labor productivity.”
- “[i]ncremental pharmaceutical innovation can also increase competition within the pharmaceutical industry and reduce drug prices.”
- “the clinical, social and economic benefits of incremental pharmaceutical innovation suggests that such innovation can have important advantages for Indian patients and Indian businesses.”
- “By restricting patentable subject matter to those incremental pharmaceutical innovations for which an inventor can demonstrate significant therapeutic enhancement over a known pharmaceutical substance, Section 3(d) excludes from patentable subject matter the vast majority of highly useful incremental pharmaceutical innovations.

The Fallacy

It may well be, as the USIBC has argued, that incremental innovations are very useful, but largely unpatentable in India because of the exclusions under Sec 3(d). The fallacy is in reasoning that enabling patents for the *products* of such innovations is very useful.

Firstly, patentability is predicated upon novelty and the inventive step. If it is novel, but merely an obvious improvement, however useful it may be, no patent can be granted in any jurisdiction.

Second, as the USIBC report itself notes incremental innovations in pharmaceuticals are often new formulations (eg once-daily dosage, or different dosage forms), combinations, polymorphs and the like. The *processes* for preparation of these forms are patentable under Indian patent law if they satisfy the novelty and inventive step criteria. It is only the *products* that are not patentable unless they enhance efficacy. It is not unreasonable to argue that such innovation is protected appropriately in this scheme of things. It is therefore incorrect to state as the USIBC has done that “India’s patent law regarding incremental pharmaceutical innovation provides little, if any, incentives for Indian companies to undertake such effort and investment.”

Third, patents grant monopolies and monopolies prevent competition that reduces prices. It is difficult to appreciate the USIBC argument that patenting *products* of incremental innovation (which use known active substances) and delaying generic entry can reduce prices, when it is self evident that it is generic availability of pharmaceuticals ensures the highest competition and the lowest prices.

Fourth, the USIBC report fails to recognise that patents are only one of many possible incentives for innovation. The market is the major incentive, even if it is not a monopoly market. The experience in India is that investments have been made in developing many incremental

innovations and these have achieved commercial success in the face of generic competition and without the need for patent monopoly.

Fifth, the grant of patent monopolies is always a balance between the incentive for innovation and affordable access. The state of economic development influences this balance. The weight of opinion from the developing country perspective (including those of the UK Commission on Intellectual Property Rights and the WHO) is overwhelmingly on the side of adopting stricter standards of patentability than in the developed countries.³⁴

³⁴ James TC, *Patent protection and innovation: Section 3(d) of the Patents Act and Indian pharmaceutical industry*, Indian Pharmaceutical Alliance, Mumbai, 2009, p 22-26

5. Patent Linkage

The demand from a section of the multinational pharmaceutical companies is to ‘harmonise’ laws so that patents granted for drugs under the Patents Act are not ‘defeated’ by the approval of drugs under the Drugs and Cosmetics Act during the term of the patent. In effect, what is sought is to link the regulatory approval of a drug product to its patent status - a practice that is referred to as ‘patent linkage’ in industry parlance. The Drugs Controller General (India) would therefore be required to deal with patent issues while processing applications for drug approval.

Bayer Corporation sought to achieve this end by seeking a direction to this effect in a writ petition before the Delhi High Court. A single Judge of the Delhi High Court dismissed their writ petition with costs.³⁵ Bayer filed an appeal which was also dismissed by a Division Bench of the Delhi High Court.³⁶ Bayer then preferred a Special Leave Petition to the Supreme Court which is now pending consideration.

It would obviously be inappropriate to consider any legislative review of the Drugs and Cosmetics Act while the matter is under consideration by the Supreme Court, particularly when submissions have been made by the Drugs Controller General (India) that they cannot be asked to enforce the private rights of a patentee and that they lack the “institutional expertise to deal with complex patent issues.”³⁷

Even otherwise, it is pertinent to point out that the single Judge of the Delhi High Court explicitly relied upon finding of the EU Directorate General for Competition that “to delay competition, originator companies had intervened before national authorities” in “a significant number of cases”, arguing that “marketing authorizations could violate their patent rights, even though marketing authorization bodies may not take this argument into account.” Further, the single Judge has also noted the finding of the EU Directorate General of Competition that “patent-linkage is considered unlawful” under the EU regulations.³⁸ Clearly, patent linkage has the danger of abuse and delaying generic entry. Even the EU has not chosen to tread this path and there does not appear to be any reason for India to consider such a measure at this stage.

³⁵ Bayer Corp v Union of India, 162 (2009) DLT 371

³⁶ Bayer Corp v Union of India, LPA 443 of 2009 dt February 9, 2009

³⁷ Bayer Corp v Union of India, 162 (2009) DLT 371, paras 28-29

³⁸ *Ibid*, para 44

6. Interim Injunction

Another issue that has irked a section of multinational companies is the consideration of the price of the originator product while refusing an interim injunction restraining the sale of an allegedly infringing generic product.

The issue arose when Roche sued Cipla³⁹ for infringement of its patent for erlotinib and sought an interim injunction restraining Cipla from manufacturing and selling its allegedly infringing product. The single Judge of the Delhi High court refused the injunction but bound Cipla to furnish an undertaking to pay damages to Roche in the event of the suit being decreed and file quarterly accounts of the sales of its product in Court. Roche filed an appeal against the refusal of the injunction. A Division Bench of the Delhi High Court dismissed the appeal. In doing so, the Division Bench noted the finding of the single Judge that:⁴⁰

“The court cannot be unmindful of the general access to life saving products and the possibility that such access would be denied if injunction was granted. If the Court was of the opinion that the public interest in granting an injunction in favour of the plaintiff during the pendency of an infringement action is outweighed by the public interest of ensuring easy and affordable access to a life saving drug, the balance should tilt in favour of the latter. In the instant case irreparable injury would be caused to the public if the injunction was granted as they would be deprived of the defendant’s product. Several unknown persons who are not parties to the suit and who would be deprived of the life saving drug would not be able to be restituted monetary terms for the damage that would be caused to them if the injunction were granted.”

The Court held on appeal that the aspect of balance of convenience was not even reached as Roche had failed to make out a *prima facie* case in their favour which was the first requirement for the grant of injunction.⁴¹ However the Court dealt with the attack on the judgement of the single Judge for linking the issue of pricing with public interest, which according to Roche, was a principle unknown to law for refusing an injunction.⁴²

The Court noted that the price of the Roche product was Rs 3200 per tablet as against the price of the Cipla product of Rs 1600 per tablet. The Court also referred to a catena of Indian and foreign judgments that held that pricing is relevant to the public interest and cannot be ignored while determining where the balance of convenience lay in determining whether or not to grant an interim injunction restraining the manufacture and sale of an allegedly infringing drug product, particularly if it is a life saving drug.⁴³ Specifically, the law as laid down by the Court is as follows:

³⁹ F. Hoffman La Roche v Cipla, CS (OS) No 89/2008

⁴⁰ F. Hoffman La Roche v Cipla, 159 (2009) DLT 243, para 24(vi)

⁴¹ *Ibid*, para 69

⁴² *Ibid*, paras 72-73.

⁴³ *Ibid*, paras 72-84

- “[I]n a country like India where the question of general public access to life saving drugs assumes great significance, the adverse impact on such access which the grant of injunction in a case like the instant one is likely to have, would have to be accounted for.”⁴⁴
- “Whether indeed the public interest in the availability of the drug to the public interest at large is outweighed by the need to encourage research in the invention, would obviously differ from case to case and depend on a host of factors.”⁴⁵

Interim injunctions are a matter of discretion and should remain so in patent matters as it necessarily has to be determined on a case by case basis. The consideration of pricing of a drug and the public interest is not ‘unknown’ in law as suggested by the multinational companies. The law on interim injunctions is not static and has evolved over time and continues to evolve. There does not appear to be any warrant to change the present course through legislation.

⁴⁴ *Ibid*, para 81

⁴⁵ *Ibid*, para 83