

Data Protection vis-à-vis Data Exclusivity

2 September 2010

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.”

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

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.

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.”

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>

⁴ *Ibid*, p x

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.

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.

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>

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

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*

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>

“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 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 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.

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

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

¹³ Ramakrishna V, personal communication

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