BACKGROUNDER ON IP RIGHTS: Indian Perspective

Patents, Data Exclusivity and Regulatory Approval of Generic Drugs

1. Patents

Patents are granted under the patent legislation of each country. Such legislation is expected, at the minimum, to conform to the provisions of the TRIPS Agreement and India has accordingly amended the Patents Act, 1970 with effect from 1.1.2005.

Patents are granted for a term of 20 years from the date of application to novel (ie previously unknown) innovations involving an inventive step (ie it should not be obvious to a person skilled in the art).

Patents were granted to all eligible inventions in India till 1970. However, after an extensive review of its working, the statute was revamped and a new Act replaced the earlier statute. One of the main changes brought about by the new Patents Act, 1970 was that medicines and agrochemicals were excluded from patentability, though the process to manufacture them could be patented. This was done to ensure that an adequate number of manufacturers could make and sell new and effective medicines and pesticides to provide for adequate availability at prices that are determined by market competition and not as a privilege of monopoly.

The change in the Patents Act, 1970 had far reaching implications for the pharmaceutical industry. A number of Indian manufacturers developed generic medicines cost effectively and India is now well known as the 'pharmacy of the developing world'. In fact, India is also emerged a very significant supplier of generic medicine to the US and Europe. The domestic market has widespread availability of generic medicines at perhaps the lowest prices in the world, which is particularly important as most of the Indian population pays for its medicines.

The Patents Act which was amended with effect from 1.1.2005 reintroduces patent protection for medicinal products and agrochemicals in conformity of the TRIPS Agreement and strikes a balance between the need to provide patent protection to incentivize innovation and prohibiting grant of patents to specified 'innovations' that are really intended only to prolong patent monopolies and delay entry of affordable generic versions of patented products.

2. Data Exclusivity

Patents and Data Exclusivity are two entirely different concepts and are independent of each other.

All regulatory authorities require the first applicant for regulatory approval of a new medicine (usually the innovator) to submit data on the safety and efficacy of the new drug. The generation of this data requires 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 (most often bioequivalence will satisfy this requirement) 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. India protects these data.

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 data – or market - exclusivity. Such periods of exclusivity typically range between 3-10 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.

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 EU[1]:

> "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 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 this[3]:

> "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."

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[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

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' by the regulator 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."

It is noteworthy that UNCTAD holds the same view[5]:

> "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."

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 measure[6]:

> "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."

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

[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] Correa, *op cit*, p 46

between intellectual property rights, innovation and public health. The recommendation of the WHO Commission was:[7]

> "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."

3. Patents and Regulatory Approval (Patent Linkage)

There is nothing in the Patents Act that would prohibit the grant of regulatory approval for a generic drug even if it is protected by patent. The remedy of a patent holder in case of infringement is to sue the infringer and obtain an order prohibiting the manufacture and sale of the infringing product and damages.

There is no link in India between patents and regulatory approval. In fact, there is no such link in most other countries including Europe.

The US has such a linkage between patents and regulatory approval. The innovator company holding the patents to a drug 'lists' the relevant patents and their expiry date in the 'Orange Book' (a compilation of the drug products in the US approved by the CDER, a division of the FDA). Every applicant for approval of generic drug will have to certify that the listed are not infringed or that the patents are not valid (a patent challenge) and communicate such certification to the patentee. If the patentee sues the generic applicant within 45 days of receipt of such notice, the FDA will not approve the application of the generic drug applicant for a period of 30 months or disposal of the suit in favour of the generic applicant, whichever is earlier. Thus, the FDA can approve the application of a generic drug even if it is patent protected, after the specified period. To encourage generic industry to challenge patents by incuring legal expense, the US law provides 180-day exclusivity to the first applicant.

The linkage of regulatory approval for the marketing of a drug and its patent status is not desirable, as it has the potential to delay availability of affordable generics. Indian laws do not currently provide for such a mechanism. Bayer, a multinational company filed a writ petition in the Delhi High Court seeking the imposition of such a requirement. The writ petition was dismissed by the High Court and so was the appeal. The company subsequently filed a Special Leave Petition in the Supreme Court which is pending.

4. Data Exclusivity and Regulatory Approval

The purpose of data exclusivity is to prevent applications for approval of generic drugs for a specified period of time reckoned from the date of approval of the first application for a drug product. Thus, in the US the period of data exclusivity for a new chemical entity is 5 years and a new formulation with a previously approved active chemical is 3 years. The periods of

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[7] 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

data exclusivity in Europe are longer. No drug can be approved for marketing within the period of data exclusivity.

Data exclusivity prevents regulatory approval for a specified period irrespective of whether it has patent protection or not. Unlike patents, whose validity can be challenged, data exclusivity is absolute and cannot be challenged.

Data exclusivity is a TRIPS-plus measure and is not provided for in Indian law. The multinational pharmaceutical companies as well as the US and Europe have mounted considerable pressure on India to adopt this TRIPS-plus measure, mainly arguing that it is just reward for investments in innovation.

It may be pointed out that patents usually have a longer term than data exclusivity and both run concurrently in the developed countries. Thus data exclusivity is of practical value only when there is no patent or the remainder of the patent term on approval is shorter than the period of exclusivity. If there is no patent, as for example when an application is rejected because the invention claimed is not new or does not involve an inventive step, then data exclusivity confers a period of monopoly.

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