Review Article

Do Intellectual Property Rights and Data Exclusivity Encourage Innovation in the Pharmaceutical World?

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ABSTRACT

Today many countries either fail to provide protection or the protection that they provide falls below the levels required by Trade Related Aspects of Intellectual Property Rights (TRIPS). Data exclusivity is one of the most interesting issues in the current discussion on pharmaceutical intellectual property policy making on the global pitch. Data exclusivity, also known as marketing exclusivity, refers to a practice whereby, for a fixed period of time, drug regulatory authorities do not allow the registration files of a pioneer company to be used to register a therapeutically equivalent generic version of that medicine. Only with a clear understanding of the data exclusivity issue and a concerted effort by governments and industries, such as the pharmaceutical industry, that are required to provide registration data to governments have the assurances that their extensive efforts to research, develop, and bring new, innovative products to market will not be subject to unfair business use. Data exclusivity also plays a key role in the development and marketing of new biologics.

Introduction

Data exclusivity is protecting and safeguarding pharmaceutical registration files and the data submitted by pharmaceutical companies to regulatory authorities such as the US Food and Drug Administration (FDA) and the European Agency for Evaluation of Medicinal Products (EMEA) for the purpose of obtaining marketing approval for new drugs. According to North Atlantic Free Trade Agreement (NAFTA, art. 1711) and the World Trade Organization (WTO) agreement Trade Related Aspects of Intellectual Property Rights (TRIPS, art. 39.3), data exclusivity is a relatively new form of intellectual property (IP). Intellectual property rights have evolved over the years with the intention of protecting novelty and innovation of ideas while creating a competitive market at both a local and global level. The strongest tools to achieve this end have arguably been patents protecting inventions that are novel and nonobvious and demonstrate utility. In the field of pharmaceuticals, foods, and agrochemicals, marketing of products requires statutory clearances from the appropriate national regulatory bodies, in order to ensure that the products satisfy certain minimum criteria of quality and safety. Generating such data generally involves elaborate experimentation, trials in various phases, chemical analysis, and an estimation of the impact on the environment, all of which are time-consuming and expensive processes. Thus the intellectual property right of data exclusivity becomes important in this century.[1]

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Impact of Intellectual Property Rights and Data Exclusivity in the Pharma World

Intellectual property rights and data exclusivity play a key role in the pharmaceutical world. The two existing prototypes of data exclusivity at the national level are that of the USA and the EU. Data exclusivity in the USA is provided by Section 355 of the Federal Food, Drug, and Cosmetic Act of 1997. In this section, it is stated that, for the purpose of obtaining authorization for market use, a generic drug does not require the submission of a registration file if it can be demonstrated that it is essentially similar to a medicinal product. The Directive also stated that the period of exclusivity shall be extended to 10 years in the case of high-technology medicinal products and that member states can extend the period of exclusivity to 10 years to all medicinal products. Some details of period of data exclusivity are as follows:

United States of America: In 1984, the USA became the first country

to enact data exclusivity legislation. Under the Hatch–Waxman Act, applications for the approval of new drugs receive 5 years of data exclusivity. Applications for the approval of new indications for an existing drug receive 3 years of data exclusivity.

New Zealand: In New Zealand, the period for data exclusivity is 5 years. New Zealand does not provide data exclusivity for new uses or formulations of old active ingredients.

Japan: A formal data exclusivity regime is not in place in Japan. Instead Japan has a system of "re-examination" under Article 14-4 of the Pharmaceutical Affairs Law which is similar to data exclusivity. In Japan, the period for data exclusivity for new drugs is 8 years, 4–6 years for new indication or routes of drugs, and 10 years for orphan drugs.

China: Under Article 35 of the Implementing Regulations of the Drug Administration Law of August 4, 2002, China provides 6 years of data exclusivity as from the date of marketing approval.

Australia: Australia provides 5 years of data exclusivity for NCE (new chemical entities) only.

Brazil: Brazil grants exclusivity for 5 years.

Mexico: Data exclusivity rights are mentioned in Articles 82 and 86 of the Mexican Industrial Property Law (MIPL) and in Numeral 167 of the Health Supplies Regulations (HSR). Mexico provides 5 years of data exclusivity.[2-4]

Implication of Data Exclusivity in the Pharma Market and Research

Proponents of data exclusivity at times point out that data exclusivity does not have major implications, since the period of data exclusivity would normally be shorter than the patent duration. Yet, there are some questions as to whether data exclusivity could prevent the registration of medicines produced under a compulsory license. If so, data exclusivity would effectively render the compulsory license useless. Second, if a period of data exclusivity is also granted when an existing medicine obtains marketing authorization or registration for a second or new indication, data exclusivity could extend the period of exclusivity of the originator product. Finally, data exclusivity could prevent the registration of generic versions of medicines even when there is no patent on a medicine, when a country has no patent law or when no patents are granted for pharmaceuticals. The latter situation can arise in least developed WTO member countries, which do not have to grant patents for pharmaceuticals until 2016.[5] Pharmaceutical industry data, although disputed by some, have suggested that the average total development cost of a new drug is on the order of US$800 million, of which about 60% would be incurred in the conduct of trials.[6]

Benefits of Intellectual Property Laws and Data Exclusivity

The purpose of data exclusivity is to ensure that the initial registrants of a new drug can recover the costs of testing the drug for efficacy and safety. Extensive testing directly translates into considerable costs for generating the data necessary to obtain approval of each new active ingredient. Drug developers challenge that they cannot afford to bring drugs to market without data exclusivity because later registrants, who did not have to invest in the high cost of obtaining marketing approval, can free-ride on the initial registrant's approval and sell the same or similar drug at a lower price.[7] Experts argue that data exclusivity offers benefits to domestic innovators in developing countries and, in particular, that it provides incentives for research to identify new uses for the existing unpatented product. Data exclusivity is likely to have the largest effect in countries where for historical or other reasons there are many products with no current patent protection that may gain rights to exclusivity. Today in many developing countries, there are numerous medicines that are not patented. This is often the case in developing countries where TRIPS-based laws have only recently been introduced. In addition, even where there are patent laws, companies may not have considered the market sufficiently valuable to justify the expense and administrative cost of securing patents. In that case, the introduction of data exclusivity laws may bring into exclusivity drugs that would otherwise be open to generic competition. The perceived absence of strong patent protection in India, even after the law was revised in 2005, and the presence of a large number of products without patent protection due to the absence of product patent protection before 2005, is a major reason why the international pharmaceutical industry lobbied very hard for a strong data exclusivity regime in India. In contrast, Indian companies focusing principally on generics argued for a weaker data protection regime.[8] In certain cases it is observed that "data exclusivity" helps innovator companies to recover investments made on discovering and developing a new drug; for example, according to a published article, Aventis's innovative drug Leflunomide for rheumatoid arthritis took 17 years from discovery to commercialization.[9]

Data Exclusivity Plays a Key Role for Biologics

New Economics Research supports 13–16 years of data exclusivity for biologics. A new working paper by Duke University economist Dr. Henry Grabowski, "Data Exclusivity for New Biological Entities," identifies 12.9–16.2 years or about 13–16 years of data exclusivity as necessary to sustain investment in the research and development (R and D) of new biologics in any approach to creating an abbreviated pathway for follow-on biologics (FOBs). The Duke University working paper states that without sufficient data exclusivity, there would be little incentive to develop and market new biologics with uncertain or few remaining years of patent protection. Under this scenario, innovators would be less likely to pursue the development of a molecule if there were uncertainty regarding the possibility of recouping their investments and achieving a positive return.[10]

Impact of Intellectual Property and Data Exclusivity: An Indian Perspective

Indian Government has planned to allow data exclusivity to pharmaceutical companies, which may effectively offer a monopoly to develop a new drug, even without a patent and restrict cheaper versions of the drug for several years, and data protection and data exclusivity, which would have a far-reaching impact on the Indian pharma industry. Many multinational pharma companies are with a view that India should provide an effective period of exclusivity for clinical dossiers that is autonomous of patent protection. The TRIPS agreement not only for the patent but also related with other forms IPR like copyright, trademark, industrial, design and geographical indication. Article 39.3 of TRIPS requires countries to

protect registered clinical trials data about NCE, against disclosure and unfair commercial use. Thus, regulatory authorities may not publish registration data, or share them with third parties or generic competitors. According to WHO, there is no unfair commercial use by a generic company. A generic manufacturer never uses the originator's data and does not even have access to them. Thus data exclusivity guarantees additional market protection for originators or pharmaceutical companies by preventing health authorities from accepting applications for generic medicines during the period of exclusivity.[11]

Global Model to Give Instant Patent Relief to the Indian Pharma Market: Future Outlook

For the global pharma industry to obtain patents in India easily, the United Nations' arm on IP is planning to implement a global patenting model that will mandate all member countries including India to grant patents to drugs approved by any two international patent offices. The World Intellectual Property Organization (WIPO) recognizes patent offices of 11 countries including the USA, United Kingdom, Germany, and Japan. The Indian patent office is not among those recognized by the organization. But with this proposed patent regime, India will have to grant patents to a drug patented at any 2 of the 11 offices. The proposal was debated at WIPO in Geneva, and also circumvents safeguards in the Indian patent laws that prevent companies from patenting drugs with incremental innovation. The safeguard has resulted in many key patent applications of innovator companies being shot down by the Indian patent offices. If this proposal is implemented, it will be easier for global drug companies to get patents of their drugs in India that will give them marketing monopoly for 20 years. Developed countries are trying to extend laws globally suitable to the USA and EU countries. This means, "India is a not a sovereign country which cannot decide for itself and if implemented, it will be a disaster." According to Indian Pharmaceutical Alliance (IPA) secretary general DG Shah, "This system will dilute our sovereignty in determining patentability of applications for inventions and does away with flexibility negotiated under the WTO TRIPS agreement." India has been a major prickle in the developed countries attempt to impose their IPR eco-system on the developing countries. The new global patenting model is proposed by the United States Patent and Trademark Office (USPTO) for a comprehensive revision of the international patent system and establish a new patent co-operation treaty (PCT).[12]

Arguments in Favor of Data Exclusivity in India

According to analysis of the pharmaceutical market by Satyanarayana *et al.*, one of the most significant problems for developing countries like India is the formulation of products directed at diseases or conditions that are not normally found in developed countries. Drugs catering to the needs in India will only be developed if data exclusivity laws exist in India. It is only when sufficient protection is accorded to drug manufacturers that they will come to India and spend their resources and time to develop drugs for diseases endemic to India. Data exclusivity will make India an attractive destination and a huge pool for research and development work.[8]

Why Indian Pharmaceutical Industries Say No to Data Exclusivity?

The Patent Act is one of the reasons for drug manufacturers in India saying no to data exclusivity. Most drug manufacturers in India work only on generic drugs. If data exclusivity is approved, domestic enterprises would be prevented from obtaining marketing approvals on the basis of the data submitted by the first enterprise that had generated and submitted the data. There are various reasons why data exclusivity rights should not be granted in India. Many reasons to say no to data exclusivity are as follows:

1. The Patents Act 1970 was recently amended by the Patents (Amendment) Act 2005. It introduced many changes to the pharmaceutical industry including product patents for drugs, medicines, and foods including products of chemical reactions.[13] If the generic industry in India is curbed further, a large amount of cheap supply of medicines at very competitive prices will be seriously affected. If Indian law granted data exclusivity for 5 years, this would mean that a patent granted for a product in 1995 would be valid until 2015 under the amended Patents Act. On the other hand if this product were introduced in the Indian market only in 2011, then data exclusivity in Indian law would protect the regulatory data submitted by the company until 2016 thus delaying the entry of generics, and extending the product monopoly for another year beyond the patent period.[14]
2. India is a major supplier of generic medicines in the world and exports two-thirds of its generic drugs to developing countries. These exports are critical for addressing and treating a great number of public health illnesses and in the global fight against AIDS.[15] India has been largely responsible for reducing the prices of antiretroviral drugs by as much as 98%.[15] Thus, Indian generic manufacturing clearly plays a vital role in the global fight against diseases. If data exclusivity rights are granted, this respectable status that India enjoys in the eyes of the developing world would certainly be lost and new data exclusivity provisions may have a disastrous affect on health conditions worldwide.[16]
3. The research-based pharmaceutical industry claims that data exclusivity provides incentives for companies to generate the necessary data, since without marketing exclusivity, brand-name companies would not want to conduct expensive preclinical tests and clinical trials. Preclinical testing and clinical trials are a requisite for any new drug marketing application. In India, Preclinical and clinical data have to be submitted to the Drug Controller General of India (DCGI), whether or not marketing exclusivity is granted.[17]
4. The notion that data exclusivity laws will encourage the introduction of new medicines into the Indian market deceives a misunderstanding of their implications. In fact there is a possibility that data exclusivity would actually provide incentives to delay the entry of new products for MNCs would prefer to keep prices high in developed markets by delaying their entry into the developing world at lower prices.[18]
5. In order to enter even small and marginally profitable markets, generic competitors would be required to duplicate expensive and time-consuming clinical trials in order to establish safety, quality, and efficacy. Another concern is that animals and other research subjects are dangerously exploited if the second applicant has to replicate studies already performed by the pioneer company. If the same agency has approved a drug

based on clinical data provided by one company, there is no logical reason why the same drug should be refused marketing approval if another company produces it.[18]

6. Data exclusivity would turn into the use of a compulsory license. A compulsory license is the tool in India used to curb the abuse of monopoly by multinational companies. The government can issue such a license after 3 years of the grant of the patent, if it is found that the patented drug is not available or it is too expensive or the development of domestic industry or an expert market is hindered. However, if data exclusivity laws are introduced, they may act at cross-purposes with compulsory licenses, because the DCGI may have to ask Indian companies to conduct fresh clinical trials before getting the marketing approval. There is a possibility that the domestic sector may not be able to duplicate even its own data for getting the marketing approval even when the companies may be granted a compulsory license for meeting the demands for some patented products.[18]
7. According to Digital Communications Associates Inc. (DCA), a "new drug" requires a regulatory approval as something much wider in scope than a "new chemical entity," including drugs "proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form and route of administration." If the data exclusivity law is enacted as mandatory for all "new drugs" as presently defined under the DCA, drug companies will be able to enjoy in effect monopoly rights over minor changes that may not even be patentable under patent laws for lack of inventiveness, but still qualify as new drugs under the DCA. This can arguably constitute protection to an unreasonable extent for pioneer pharmaceutical companies. The extension of intellectual property beyond its boundaries, so as to protect investment and not intellectual contributions, disrupts the essence of a system conceived to reward the creators of original ideas and new inventions.[18]

Conclusion

Under Indian law, to introduce data exclusivity provisions is an essential issue. In this review we discussed several reasons why data exclusivity laws should not be brought into India at this stage. TRIPS give freedom to choose the nature and extent of protection. This interpretation of TRIPS finds support from most Indian pharmaceutical companies. Developed countries like the USA and the EU try to enforce provisions of data exclusivity in the form of free trade agreements with developing countries. Developing countries need to maximize benefits of this flexibility accorded to them and put patients' rights of access to economical healthcare ahead of economic rights of patents. At present India is a global supplier of quality generic medicines. Thus India must take a more liberal view of data exclusivity provisions and ensure that flexibilities in the TRIPS agreement are utilized fully. Also, data exclusivity will provide sufficient protection when drug manufacturers will come to India and spend their resources and time to develop drugs for diseases endemic to India.

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