PERGAMON

World Patent Information xxx (2003) xxx–xxx

WORLD
PATENT
INFORMATION

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Complying with article 39 of TRIPS... a myth or evolving reality?

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Abstract

In the lengthy process for a new pharmaceutical material to progress from innovation to marketplace, the crucial step of gaining statutory authorisation to offer the product to the public involves the creation of large volumes of data. This article explores the way in which this data is, could, or should be protected. Aspects covered include the relevant articles of TRIPS (39 and 70.9), and the protection potentially provided by official secrets acts, trade secrets and confidentiality provisions and exclusive marketing rights. The article concludes with a tabulated summary of the relevant legislation, and term of protection provided, in over 60 countries worldwide.

Keywords: Pharmaceutical inventions; Statutory authorisation; Proprietary data; Data protection; TRIPS; Official secrets acts; Trade secrets; Confidentiality provisions; Exclusive marketing rights; Worldwide legislation

1. Introduction

Intellectual property rights (IPR) has evolved over the years as a strategic tool to create and sustain competitive positions in the global marketplace. Patents protect inventions that are novel, non-obvious and demonstrate utility. Patent laws in most countries give a protection term of 20 years from the date of filing the complete specification.

In the field of pharmaceuticals, foods and agrochemicals, marketing of products require statutory clearances from National Regulatory Bodies. The mandatory clearances are meant to ensure that the products to be introduced in the public domain satisfy certain minimum criteria of quality, efficacy, safety, environmental friendliness, toxicological clearance, etc. Generating such data generally involve elaborate experimentation, trials in various phases, chemical analysis, and estimation of impact on the environment, which can be time consuming and expensive.

2. Pharmaceutical patentees: protection of proprietary data—general considerations

Thus to carve a competitive position an organisation would seek exclusivity with granted patents in different countries for its business interest and also through protection of its proprietary data generated and submitted by it for the statutory clearances from the appropriate governmental bodies. It may be appreciated that the clearances from the statutory bodies are mandatory for all products to be marketed, whether patentable, patented or otherwise. If patented, protection extends to the invention, but not to the data generated by the innovator. It is therefore clear that the concept of patents and exclusivity of propriety test data are distinctly different, but are complementary to each other in building a competitive platform for the innovators and marketers.

It has been debated for sometime whether it is necessary for the State to provide for a separate statutory platform, since it may be considered that propriety test data generated and submitted to governmental authorities to obtain marketing approvals is protected by the terms of confidentiality in favour of the owner of such data.

Arguments in favour of the proprietor of such data requiring governmental authorities to maintain confi-

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0172-2190/03/$ - see front matter © 2003 Published by Elsevier Science Ltd.
doi:10.1016/S0172-2190(03)00078-4

dentiality of proprietary test data as described above may be justified in economic terms due to the high costs involved in generation of the data. On the other hand several governments have limited the "originator's" proprietary data rights only to a brief period of exclusivity, because of their concern about the repetitive use of animals, humans and other resources for repetitive tests/trials by the "follower" organisations to generate their own data independently.

There are other countries, which do not have any explicit data protection laws and appear to depend upon their National Official Secrets Acts that bind the public servants from disclosing or using confidential information in an unauthorised manner that may affect the security, sovereignty and integrity of the country

3. Official Secrets Acts

A key question is whether the protection under the Official Secrets Acts in different countries provide appropriate and adequate protection to originators of their proprietary test data and whether they mandate the governments not to disclose or rely on the proprietary data for the marketing approval of "generic" ("follower") copies of the pharmaceutical products without the explicit approval of the originator, at least for a reasonable period. Another point to be debated is whether the countries, which tend to believe that the Official Secrets Acts provide the necessary protection, have built in mechanisms within the meaning of such Acts, for the originators to enforce their rights for the proprietary test data. Even the US Trade Secret Laws have proved to be inadequate for protecting proprietary data submitted to regulatory authorities. The position of the courts in exploiting the Trade Secrets Law in the event that the authorities rely on the data submitted to them earlier by the originator, to evaluate the application of the "follower" is not clear. Moreover a few cases have been decided on "public policy" grounds but the difficulties faced by the originators have been inordinately high.

4. TRIPS: Article 70.9 EMR

In the context of TRIPS, one may argue that the "exclusive marketing rights" (EMR) conferred under Article 70.9 for pharmaceutical and agricultural chemical products provides for indirect protection of the data submitted by the "originator" which secured such authorisation, and that designation stops a second applicant for authorisation during the term of the EMR even if the "follower"/generic company generates its own data. However the concept of EMR is organically connected to the originator having obtained a patent and approval to market the drug in at least in one member country of the WTO. It does not protect the test data for items that either is not patentable or for which patents have not yet been granted.

5. TRIPS : Article 39—protection of undisclosed information

Article 39.3 of TRIPS explicitly recognises the significance of "protection of undisclosed information" as another category of IPR. It states:

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

The Article 39.3 should be read in conjunction with Article 39.1 and Article 39.2 for a full appreciation of scope and spirit of the Article 39.3.

Article 39.1 states:

> In the general course of ensuring effective protection against unfair competition as provided in Article 10 bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or government agencies in accordance of paragraph 3.

Article 39.2 states:

> Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practice so long as such information:

- is secret in the sense that it is not as a body or in the precise configuration and assembly of its components, generally known or readily accessible to persons within the circles that normally dealt with the kind of information in question;
- has commercial value because it is secret; and
- has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information to be kept secret.

It may be noted that for the purposes of this provision, "a manner contrary to honest commercial prac-

Table 1
A survey of data exclusivity legislation in over 60 countries worldwide

Country	Protection term	Relevant legislation
Canada	5 years	Food and Drug Regulations, Section C.08.004.1 outlining the conditions under which "the Minister" may or may not issue a notice of compliance in cases where a manufacturer files a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or a supplement to a new drug submission for the purpose of establishing the safety and effectiveness of the new drug for which the submission or supplement is filed
Mexico	5 years	Article 1711. Trade Secrets, NAFTA
USA	5 years	Food and Drug Law. Section 505 (355) (D)
Costa Rica	5 years	Article 9—Abbreviated documentation for the Authorisation of a Pharmaceutical Preparation. Article 10—Mandatory Licenses after the Expiration of the Period. Article 11—Definition of an Essentially similar Medication. Article 12—Documentation and Data Exclusivity compliance
El Salvador	Not specified	Article 177 and 178 of Law of the Development and Protection of Intellectual Property. Essentially protects any information that may be considered as Trade Secrets
Guatemala	15 years	Article 177—Industrial Property Law; protecting "Trade Secrets"; Governmental Agreement no. 89–2002 Article 87 "Protection of evidence or other information" outlining specific requirements from the applicant while submitting the data while seeking protection
Honduras	Not specified	Industrial Property Law, Article 73 and 74 for protection of trade secrets related to the commercialisation or sale of pharmaceutical or agrochemical products that contain a new chemical component
Nicaragua	Not specified	Article 125—of Nicaragua New Law of Patents for implementing regulations for the Drug and Medication Statute
Panama	10 years	Legislative Assembly Law no. 23; Section 7: Protection of undisclosed information—Article 39. Covers all aspects of Article 39 of TRIPS explicitly
Trinidad & Tobago	Not specified	Article 27/1996—Protection against unfair competition
Cuba; Dominican Republic	–	No 39.3 data protection
Bolivia	5 years	Andean Pact Article 266 of decision 486 dated 12/1/2000
Brazil	Not specified	Chapter VI crimes of unfair competition Article 195
Colombia	5 years	Andean Pact Article 266 of decision 486 dated 12/1/2000
Colombia; Mexico & Venezuela	Not specified	Treaty of the group of three. Article 18-22: Data Protection of Chemicals used for Pharmaceutical Purposes or Agrochemicals
Ecuador, Peru, Venezuela	5 years	Andean Pact Article 266 of decision 486 dated 12/1/2000
Argentina, Chile, Paraguay, Uruguay	–	No 39.3 data protection
Austria, Denmark, Finland, Greece, Iceland, Ireland, Norway, Portugal, Spain	6 years	Article 10 (1)(a)(iii) of EC Directive 2001/83
Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, United Kingdom	10 years	Article 10 (1)(a)(iii) of EC Directive 2001/83
Switzerland	5 years	Decree on Medications; Section 3, Article 17
Turkey	Not specified	Annex 8 on Protection of Industrial and Commercial Property of the Customs Union Agreement
Czech Republic	6 years	Section 32 of Law No. 79/1997 Coll. On Drugs
Estonia	6 years	Article 2—Submission of Application for marketing Authorisation Article 2.5 and Article 2.11
Hungary	6 or 10 years based on satisfaction of certain criteria	Health Ministerial Decree 12/2001 on Registration and marketing approval of drugs for Human use—Section 26
Latvia	6 or 10 years based on satisfaction of certain criteria	Normative Documentation of Republic of Latvia Pharmacy Regulations, Article 18-20
Poland	3 years	Act of 6 September 2001, Pharmaceutical Law Article 15.1
Romania	6 or 10 years based on satisfaction of certain criteria	Draft Reglementation Law
Russia	Not specified	Article 39—Civil Code—Business or Commercial Secret
Slovak Republic	6 years	Coll. On Drugs and Sanitation Facilities
Slovenia	6 years	Article 15, Medical Act
Bulgaria, Croatia, Lithuania	–	No 39.3 Data Protection
Egypt	5 years	Peoples Assembly Committees Undisclosed Information—Articles 55–62, Prime Minister Decree No. 1211 Concerning Data Exclusivity of Chemical, Agricultural and Pharmaceutical Products

Table 1 (*continued*)

Country	Protection term	Relevant legislation
Jordan	5 years	Article (8)—Unfair Competition Law
Saudi Arabia	Not specified	Provides de facto Article 39.3 protection; no separate legislation
South Africa	Not specified	Medicines Control Act 101 of 1995, Section 34
Kenya, Morocco, Nigeria	–	No 39.3 Data Protection
Australia	5 years	Data Exclusivity Provision of the Therapeutic Goods Act(Cth) 1989 (Australia). 25A
China	6 Years	Implementing Regulation of Drug Administration Law of China Article 31—Draft of February 19, 2002; Report of Working Party on Accession of China to WTO
Hong Kong	Not specified	Pharmacy and Ordinance Act
Japan	6 years	Japanese Drug Regulation Article 18-3
Korea	4 or 6 years based on satisfaction of certain criteria	Article 26-2 of the PAL; Article 5, Paragraph 11 of the KFDA Regulations Regarding the Safety and Efficacy Examination of Drug Products
New Zealand	5 years	23B. Medicines Act 1981
Pakistan	Not specified	Section 43 of the Drugs Act 1976. The Act provides de facto 39.3 protection. It permits the Federal Government to frame the necessary secondary (subordinate) legislation to carry out the purposes of the Act. The relevant rules are the Drugs (Licensing, Registering and Advertising) Rules 1976. Section 40 of the Act lays down the conditions under which the Government can publish the result of test or analysis or public information or in public interest
Singapore	5 years	Medicines (amendment) Act of 1998; New Sections 19A and 19B. These deal with the protection of confidential supporting information about innovative medicinal products. It requires the government to take reasonable steps to ensure that the confidential supporting information is kept confidential by the licensing authority during the period and that it shall not use that confidential supporting information for the purposes of determining whether to grant any other application
Thailand	Not specified	Trade Secret Act Chapter 3, Section 15
India, Indonesia, Malaysia, Philippines, Taiwan	–	No 39.3 Data Protection

Source: Generated by the author based on the text in a publication of the International Federation of Pharmaceutical Manufacturers Association, July 2002.

tices'' shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who know, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

In practice, to get national laws compliant with Article 39 the following steps are needed:

- Pass independent legislation related to the protection of undisclosed information with exception provisions for public use.
- Explore the possibility of introducing subordinate legislation appropriately in an existing law such as the Drug and Cosmetic Act 1940 as is applicable in India.
- Explicitly define the nature of information that is protectable under the legislation and the term of such protection.
- Define the role and conduct of the Appropriate Statutory Authorities clearly with respect to their activities in the formal marketing approval process.
- Respect and recognise the considerable effort of the originator in the development of the test data and give the originator data exclusivity.
- Protect data against disclosure by the authorities and treat the originator's submitted data as secret information.
- Define the legitimate rights of the originator who submitted the test data in the dossier to the statutory authorities.
- De-link the issue of protection of proprietary data from any of the articles in TRIPS dealing with patent or other forms of intellectual property rights such as design registration, trademarks, geographical indications, etc.
- Build-in the framework for effective enforcement in the event of infringement or violation of the provisions of the enacted law.
- Construct an effective competition law with in-built provisions for data exclusivity and enforcement against unfair commercial use.

5.1. Protection against unfair commercial use

Though the Article does not explicitly define "unfair commercial use", one is expected to interpret it by keeping in mind the spirit and principle of the Article by referring to the development process of this Article. The discussions while formulating this Article were directed towards setting up a framework to prevent any direct or indirect reliance by the statutory authority in any country on the originator's proprietary data in the submitted dossier, without the originator's consent, in the consideration/review of a "follower's" application for registration of a generic drug.

6. In practice—worldwide

It may be appreciated that there is no uniform standard that is followed by the countries while introducing and implementing the laws related to exclusivity of test data and protection of undisclosed information. However there is a common principle that is followed in that the laws generally specify the conditions under which data exclusivity can be sought and the period for which the "originator" can enjoy the exclusivity after the marketing approval is granted in the country, which is typically between 5 and 10 years. For example in some European Countries in their implementation of the European provisions conferring protection of regulatory data in relation to medicinal products do not confer such protection "after patent expiry". The regime for medicinal products in the USA confers a shorter period of protection on a second applicant who challenges any patent, which also protects the product. In the USA there are specific procedures for notifying the patent holders who wish to be alerted to a third party request for approval of a product covered by a patent. Article 1711 dealing with Trade Secrets of the North American Free Trade Agreement (NAFTA) paragraphs 5 through 7 have also incorporated provisions that broadly cover protection of undisclosed information.

The brief survey below (Table 1) illustrates the approaches taken by various countries while implementing their domestic laws related to data protection and granting exclusivity to proprietary data and information.

7. Conclusion

The considerations discussed above and the existing legislation could serve as a guide for the legislators in various developing and least developed countries while formulating their own national laws related to this issue. Whatever the form of the protection offered it is imperative that that all member states of the WTO comply with the provisions of Article 39.3 to protect the interest of the innovators and originators and provide a healthy platform to encourage investments and innovation for societal benefit. It is relevant to note that according to the timetable set by TRIPS for WTO member countries, the Developed and the Developing Countries (with the exception of the least developed countries) were expected, with certain exceptions—such as product patent protection, to have their TRIPS legislation in place by 1 January 2000.

Acknowledgements

This article is closely based on an article by the author in Express Pharma Pulse and is published here with permission from that journal's publishers—Indian Express Newspapers, Mumbai, India.

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