14. A Review on Intellectual Property Challenges in the Field of Agriculture and Pharmaceuticals

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Abstract

The pharmaceutical industry is unusually knowledge-intensive, and the economics of this sector are widely recognized to be unusually sensitive to IPRs. Some progress has been made in documenting and understanding the interactions between IPRs, complementary regulatory and policy provisions, the international expansion of the industry, and the implications of these for pricing and access to drugs, R&D, trade and production. However, opportunities abound for developing and analysing more comprehensive data on this complex and critical sector, particularly in developing countries and countries with economies in transition.

Key words- IPR, Pharmaceutical industry, Opportunities, Policy, Drugs, R&D, Trade.

Introduction

The Indian pharmaceutical industry has dramatically changed over the last half century, from being traders in imported drugs in the fifties, to major bulk drug producers by the eighties(12). During this transitional period our pharmaceutical units have learnt the technology of bulk drug production by their own research(16) and adaptation, and today they produce more than 250 bulk drugs, emphasizing on import substitution and use of indigenous raw materials(4). At present the Indian pharmaceutical industry has about 300 large units, 1700 medium-size units and about 8000 small scale units throughout the country (15).

Intellectual Property Rights

In order to understand the problem properly we need to first familiarize ourselves with the subject of intellectual property rights. Intellectual property rights are a class of legal rights for which the law has provided protection (13). Although originally these rights were contained in the municipal laws of different countries, in recent years the international community has been taking

steps to achieve uniformity regarding the nature of these rights, their enforceability, and sanctions for their breach (41).

Material and Method

On the basis of literature and review, various databases, manuals and different patent act , here collectively define the intellectual property challenges in the field of agriculture and pharmaceuticals.

Basic Forms of Intellectual Property

The five basic forms of intellectual property are (i) Patent (ii) Copyright (iii) Trademark (iv) Trade secret (v) Mask work (design for an element of a semi-conductor chip). Intellectual property is private property to which the law has given public protection (11).

Role of Undisclosed Information in Intellectual Property

Undisclosed information, generally known as trade secret or confidential information includes formula, pattern, compilation, programme, device, method, technique, or process. Protection of undisclosed information or trade secret is not really new to humanity; at every stage of development people have evolved methods to keep important information secret, commonly by restricting the knowledge to their family members (18).

To a layman, property consists of tangible or physical objects like land, buildings, motorcars, clothing, food, books etc. However, the law recognizes even intangible entities as property e.g. the goodwill of a firm (10).

Intellectual properties are also recognized by the law as a form of intangible property. They are recognized and protected by the law because products of the mind can have as much worth, if not more, than physical products (20). The law therefore recognizes that for human progress there should be monetary inducement to make new inventions (5). An invention is creation of a new entity, or a new process, though this usually involves utilization of scientific discoveries.

Intellectual property is different from other kind of property and hence it poses legal problems which other kinds of property do not pose (7). Intellectual property differs from other kinds of property because of uncertainties regarding its value and use. Intellectual property is intangible property which cannot be locked up in a house or kept in a safe deposit vault (9). It is a property which is easily available to the general public, and therefore easier to steal (14). Its registration is nothing more than the recognition of the right of ownership in this property. Since

this property is a product of the intellect, it is very difficult to protect, and commercial piracy is big business (8).

Acts Relating To Intellectual Property Rights

In India there are four Acts relating to intellectual property rights, namely, (1) the Patents Act, 1970, (2) the Copyright Act, 1957, (3) the Trade and Merchandise Marks Act, 1958 and (4) the Designs Act, 1911. These Acts also provide for legal remedies which can be invoked by an aggrieved person in the event of an infringement. While the above laws were made by the Indian Parliament and hence they are municipal laws, after India signed the General Agreement on Trade and Tariff (GATT) and the Trade Related Aspects of Intellectual Property Rights Agreement, 1994 (TRIPS) and has become a member of the World Trade Organization (WTO), the legal position in India regarding intellectual property rights has totally changed (41).

Intellectual property rights in India are now gradually becoming part of an international legal system relating to such rights and these calls for careful study from the point of view of our national interest (1). The TRIPS Agreement, which is part and parcel of the WTO set-up (it is Annexure 1-C to the Marrakesh Agreement by which WTO was established), has provided a period of 5 to 10 years for the transition from domestic intellectual property regime to an international one (vide Articles 65 and 66 of the TRIPS Agreement) (42). Since we are considering intellectual property rights in special relation to the pharmaceutical industry it may be mentioned that the basic law which governs this field is the law relating to patents. The Indian law on this subject is contained in the Patents Act, 1970 (a law made by the Indian Parliament) as amended from time to time (19).

Basic Requirement for Patentability under the Patents Act

The basic requirement for patentability under the Patents Act is that the invention should be new and useful, that is, it must have novelty and utility, and once an invention is patented the patentee gets exclusive right to use it, though he may sell or lease it to another (46). In fringement of the patent can be prevented by an injunction in a civil suit. Since India was a signatory to the TRIPS Agreement and is a member of WTO, it has had to amend the Patents Act to make it conform to these international agreements (47).

Agreement Regarding Pharmaceutical Industry

Agreement regarding pharmaceutical industry India has the following obligations (17)

(a) To recognize in principle all kinds of inventions in the area of pharmaceutical and agricultural chemical products in accordance with Article 27 of the Agreement.

(b) To provide a mechanism by which applications can be filed for new inventions as understood in Article 27 in these areas from 1-1-1995.

(c) To apply the test of patentability as laid down in the Agreement irrespective of the law of the country on the date of filing, at the time when patent is granted or rejected.

(d) To provide patent protection for a period of 20 years, from the date of filing once the parties decide to grant the patent.

(e) In the case of product patent applications in these areas, grant exclusive marketing rights for five years or until patent is granted or rejected, whichever period is shorter (23).

i. Granting of exclusive marketing rights is subject to three conditions.

ii. Product patent for the invention has been granted by another member country.

iii. Market approval is obtained in such other member country; and

iv. Market approval from the country/member granting exclusive marketing right is granted.

It may be mentioned that Section 5 of the Indian Patents Act, 1970 expressly prohibited product patents and only permitted process patent. Section 5 of the Patents Act states, in the case of inventions (21)

(a) Claiming substances intended for the use or capable or being used, as food or as medicine or drug.

(b) Relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds), no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable (41).

The difference between process patent and product patent is of great importance, and needs to be clarified. Under a process patent, medicines or drugs which have been patented can be manufactured by another manufacturer but by using a different process (22). However, in a product patent drugs which have been patented cannot be manufactured even by adopting a different process (2). Thus, product patent is a much harsher and stringent restriction than process patent.

However, it may also be mentioned that Article 27(2) of the TRIPS Agreement states that members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order among public or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not merely because the exploitation is prohibited by domestic law (44).

Thus it is open to a country signing the TRIPS agreement to exclude from patentability inventions which are necessary to protect morality, order or health or avoid serious prejudice to the environment.But such exclusion can only be in areas where the majority of member states are also prohibiting the commercial exploitation and denying protection (24). Hence, India cannot unilaterally say that it will not accept patent in a particular product or process on the ground that acceptance of the patent will be prejudicial to morality, order or the health of the Indian masses (45).

Only if majority of other countries also make this exclusion can it do so. It may also be noted that under Article 27(1) patent rights must be made available irrespective of the place of invention or the field of technology, and whether the products are imported or locally produced. The invention which can be patented must be new and involve inventive steps which are capable of industrial application (40). One of the objects of the TRIPS Agreement is to discard the notion of patent protection as country-specific and make it international.

According to Article 70(9) of the TRIPS Agreement, a member State is obliged to give exclusive marketing rights if the patent application for product is filed and the claimant fulfils certain conditions (28). The theory upon which the patent law is based is that the opportunity of acquiring exclusive rights in an invention stimulates technical progress by encouraging invention and offering financial reward for the same (26).

Today invention in new products in the field of medicine generally involves the collective efforts of many highly skilled professionals and expenditure of considerable amount in research which only the big corporations and institutions can afford(6). Besides, the manufacture of the article or product on a commercial scale requires a great deal of effort and money. Hence, under modern conditions only big corporations or institutions can afford to engage in research and development of new drugs or medicines (37).

Even if an individual research scientist or technologist invents a new product he will seldom have the financial resources for developing the invention for commercial use and protecting his invention against infringement by competitors (27). It is therefore seen that almost all the major patents relating to new inventions in the medical field are usually held by big transnational corporations (3). The beginning of the product patent regime will pose the greatest challenge to the Indian pharmaceutical industry (34). It is feared that as a result of product patent a large number of pharmaceutical industries in India, which manufacture drugs patented in the west, may have to close down, and drugs may become too costly for the Indian masses (25).

The important changes which are then expected are-

i. Grant of patents for pharmaceutical, chemicals and food substances which are at present unpatentable.
ii. Enlargement of the term of a patent from 14 years to 20 years from the date of filing;
iii. Recognition of micro-organism as a patentable subject-matter;
iv. Reversal of burden of proof in cases of infringement of a process for producing a novel compound (33).

Many of these standards are similar to those found in existing international conventions (39). The conventions which have been formulated under the auspices of the World Intellectual Property Organization (WIPO), such as the Paris Convention, cover patents, trademarks and industrial designs (50).

Two basic principles provided by TRIPS are that each member shall accord nationals of other members treatment no less favourable than it accords to its own nationals and any advantage, favour, privilege or immunity granted by a member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other members (35) (most-favoured nation treatment).

It may be clarified that under the patent law, the earliest applicant gets the patent, and all other applications have to be rejected. The rapidly growing international trade makes it imperative that intellectual property rights are properly recognized and managed by the authorities concerned in India (36). National protection is no longer adequate to safeguard intellectual property rights which can easily be pirated or copied by nationals of other countries, exploited in their own market, and even in the international market (31). Hence, international remedies for such infringement are necessary, but care should be taken that our national interest does not suffer.

The conventions which are administered by WIPO and TRIPS Agreement grant international protection of intellectual property rights (32). Suitable laws protecting such rights internationally and giving adequate compensation to the owner without creating any undue monopoly in the property can and are being formulated as standards for laws to be enacted by the different countries in the world (38). These standards reflect the experience of various countries in protecting such rights while taking care of the public interest. At this stage, it will be relevant also to point out some dangers inherent in the grant of certain patents which affect human life.

A balance has to be struck between the need to give monetary inducements to new inventions, and making available these inventions to the broad masses in the underdeveloped countries at affordable prices (30). At present it is felt that many of the medical drugs available in the market are too costly for the poor people in India (48). Ways and means should therefore be thought out for making these drugs available to the masses at affordable prices, while at the same time giving inducement to the inventors to continue their research (29).

Conclusion

It is obvious that management of IP and IPR is a multidimensional task and calls for many different actions and strategies which need to be aligned with national laws and international treaties and practices. It is no longer driven purely by a national perspective. IP and its associated rights are seriously influenced by the market needs, market response, cost involved in translating IP into commercial venture and so on. In other words, trade and commerce considerations are important in the management of IPR.

Different forms of IPR demand different treatment, handling, planning, and strategies and engagement of persons with different domain knowledge such as science, engineering, medicines, law, finance, marketing, and economics (49). Each industry should evolve its own IP policies, management style, strategies, etc. depending on its area of specialty. Pharmaceutical industry currently has an evolving IP strategy (28). Since there exists the increased possibility that some IPR are invalid, antitrust law, therefore, needs to step in to ensure that invalid rights are not being unlawfully asserted to establish and maintain illegitimate, albeit limited, monopolies within the pharmaceutical industry. Still many things remain to be resolved in this context.

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