2016:19

Changing Dimensions of Company's Enactments

Prof. Vaishali Bankar*

* Assistant Professor, Dept. of Law, Anjuman-I-Islam's Akbar Peerbhoy College of Commerce & Economics, Mumbai, Maharashtra, India.

Abstract - In view of changes in national and international economic environment and expansion and growth of economy of our country, the Central Government after due deliberations decided to repeal the Companies Act, 1956 and enact a new legislation to provide for new provisions to meet the changed national and international, economic environment and further accelerate the expansion and growth of our economy.





Introduction:

Companies Act, 1956 had been enacted with a view to consolidate and amend the law relating to the companies and certain other associations. The said Act has been in force for about sixty-eight years and had been amended several times. Central Government received several suggestions for amendments. Parliamentary Standing Committee on Finance elso made numerous recommendations in its Report. Central Government has accepted in general the recommendations of the Standing Committee and also considered the suggestions received by it from various stakeholders.

Amendment Bill, 2009:

Companies Bill, 2009 was introduced on 3rd August, 2009 in Lok Sabha. The said Bill was referred to Parliamentary Standing Committee on Finance for examination and Committee gave its Report on 31st August, 2010.

Silent features:

- ♦ The composition and powers of the National Company Law Tribunal are similar to those introduced by 2002 amendments to the Companies Act. The constitutional validity of that amendment is being examined by the Supreme Court.
- ♦ The Bill permits certain financial relationships between independent directors



Impact Factor (SJIF) - 5.266

(f) New provisions suggested for allowing re-opening of accounts in certain cases with due safeguards.

(iv) Additional Disclosure Norms:

- (a) New disclosures like development and implementation of risk management policy, Corporate Social Responsibility Policy, manner of formal evaluation of performance of Board of directors and individual directors included in the Board report in addition to disclosures proposed in such report in the Companies Bill, 2009.
- (b) Accounts of Foreign subsidiaries to be attached for filing them with the Registrar. Subsidiary to include "associate" and "joint venture" for the purpose of consolidation.
- (c) Every listed company required to file a return with the Registrar regarding change in the shareholding position of promoters and top ten shareholders of such company.

(v) Facilitating raising of capital by companies:

- (a) Provisions for offer or invitation for subscription of securities on private placement basis revised to ensure more transparency and accountability.
- (b) Companies being allowed to issue equity shares with differential voting rights.
- (c) Central Government empowered to prescribe, through rules, the requirements in connection with provision for accept made by a

company for allowing purchase of company's shares by its employees under a scheme for their benefit. Disclosure to be made in the Board's report in respect of voting rights not exercised directly by the employees in respect of shares to which the scheme relates.

(vi) Audit Accountability:

- (a) Rotation of auditors and audit firms being provided for.
- (b) Stricter and more accountable role for auditor being retained. Provisions relating to prohibiting auditor from performing non-audit services revised independence ensure and accountability of auditor. Subject to the maximum prescribed number of companies, the members of a company may resolve that the auditor or audit firm of such company shall not become auditor in companies beyond the number as may be specified in such resolution.
- (c) National Advisory Committee on Accounting and Auditing Standards(NACAAS) proposed to be renamed as National Financial Reporting Authority(NFRA) with a mandate to ensure monitoring and compliance of accounting and auditing standards and to oversee quality of service of professionals associated with compliance. The Authority shall consider the International Financial other wilcon Reporting Standards and

Impact Factor (SJIF) - 5.266

may be elected in such manner as may be prescribed by rules.

(x) Investor Protection:

- (a) Acceptance of deposits from public subject to a more stringent regime.
- (b) Central Government to have power to prescribe class or classes of companies which shall not be permitted to allow use of proxies. The Bill also to have provisions to provide that a person shall have proxies for such number of members /such shares as may be prescribed.
- (c) Provisions for Class Action Suits revised to provide minimum number of persons who may apply for such suits. Safeguards against misuse of these provisions also being included.
- (xi) Serious Fraud Investigation Office (SFIO): Statutory status to SFIO proposed. Investigation report of SFIO filed with the Court for framing of charges shall be treated as a report filed by a Police Officer. SFIO all have power to arrest in respect of certain offences of the Bill which attract the punishment for fraud. Those offences shall be cognizable and the person accused of any such offence shall be released on bail subject to certain conditions provided in the relevant clause of the Bill. Definition of 'Fraud' provided. Stringent penalty provided for fraud related offences.
- (xii) Woman Director: At least one woman director being made mandatory in the prescribed class or classes of companies.

(xiii) National Company Law Tribunal (Tribunal): Keeping in view the Supreme Court's judgment, on the 11th May, 2010 on the composition and constitution of the Tribunal, modifications relating to qualification and experience, etc., of the members of the Tribunal have been made. Appeals from Tribunal shall lie to National Company

Law Appellate Tribunal.

- (xiv) Mediation and Conciliation Panel: It is proposed to create and maintain as "Mediation and Conciliation Panel" for facilitating mediation and conciliation between parties during any proceeding under the proposed Legislation before the Central Government or Tribunal.
- (xv) Central Government to have power to exempt/modify provisions of the Act for a class or classes of companies in public interest. Relevant notification shall be required to be laid in draft form in Parliament for a period of thirty days.

Amendment Bill, 2013:

- The Bill amends the Companies Act, 2013 in relation to structuring, disclosure and compliance requirements for companies.
- The Act limits the number of intermediary companies through which investments can be made in a company. Similarly, the Act limits the number of layers of subsidiaries a company can have. The Bill removes these limits.

Impact Factor (SJIF) - 5.266

Changes this to permit registration of charges:

(i) within 300 days if the charge is created before the Ordinance, or (ii) within 60 days if the charge is created after the Ordinance. If the charge under the first category is not registered within 300 days, it must be completed within six months from the date of the Ordinance.

Change in approving authority:

Under the Act, change in period of financial year for a company associated with a foreign company, has to be approved by the National Company Law Tribunal. Similarly, any alteration in the incorporation document of a public company which has the effect of converting it to a private company, has to be approved by the Tribunal. Under the Ordinance, these powers have been transferred to central government.

nendment Bill, 2016:

It was introduced in Lok Sabha on March 16, 2016.

- o Bill removes the limit on layers of subsidiaries and intermediaries. This is inline with the Companies Law Committee's (CLC) recommendations which noted that imposing such limits would affect the company's structuring and ability to raise funds.
- Bill permits an Independent Director to have a pecuniary relationship, up to 10% of his total income, with the

company. This is in line with the reasoning of the CLC which had stated that minor transactions may not compromise the independence of such Directors.

- O Certain recommendations of the CLC have not been included in the Bill. These include issues related to: (i) residence requirements for directors; and (ii) compliance requirements for dormant companies.
- o Bill amends provisions related to (i) the qualifications of technical members, and (ii) the composition of the Selection Committee of the National Companies Law Tribunal and the National Companies Law Appellate Tribunal. The amendments bring these provisions in line with a 2015 Supreme Court judgment. It was referred to the Standing Committee on Finance on April 12, 2016.

T

CI

b

ei

re

aı

ir

SI

aı

pi

re

nı

in

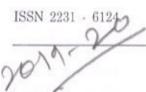
ct

Second Amendment Ordinance, 2019:

It was promulgated on February 21, 2019. It amends several provisions in the Companies Act, 2013 relating to penalties, among others. Note that two similar Ordinances had been promulgated in November 2018 and January 2019. This Ordinance is effective from the date of the first Ordinance, i.e. November 2, 2018.

Conclusion:

The enactment shifts the onus of regulation and oversight over management away from the Government and towards shareholders.



Legal System, IPR and Economic Prosperity

Vaishali Bankar

Akbar Peerbhoy College of Commerce and Economics, Grant Road, Mumbai, E mail: vaishalibankar358@gmail.com

Abstract

The copyrights, patents, trademarks and similar rights upon which the lion's share of creative and innovative products and services has played a vital role in grooving the economics of developed and developing countries all over the world in spurring innovations, in giving large and small firms a range of tools, so that to provide benefits to consumers and society through a continuous stream of innovative, competitive products and services, as well as an expansions of societies overall state of knowledge. It's protection is an important detriment of economic growth. It helps entrepreneur to recover cost of their innovative expenses and undoubtedly IP system must be developed so as to bring in socio economic wellbeing. IP has in extricable nexus with issues like traditional knowledge, foreign investment, geographical indication and competition law. To receive the financial rewards of IPR organization ought to proactively execute licensed innovation arrangements. As business livelihood develop IP engineers can make techniques to insure the special parts of their manifestation.

Keywords: Copyrights, patents, trademarks, consumers, society, beneficiary, etc.

Introduction

Globalization and competition word wide headway the ideas from inventors and creators to withstand the competitions in the market. India is rich with knowledgeable and talented people in all the areas of life sciences and technology which drive India to enter in the field of Intellectual Property Rights (IPR). The biodiversity and the traditional knowledge Intellectual Property Rights (IPR) denotes the creation of the human idea viz., inventions literary/creative works, symbols, names, pictures and styles employed in business holding rights defend the interests of creators by giving them property rights over their creations. The intangible intellectual property rights (IPR) give exclusive rights to

the creator for their creation. To withstand the competition in the market globally these rights boost the innovative thinking and research which give recognition and economic benefits to the creator. The lack of knowledge about IPR is the main hitch with developing countries like India. Intellectual property laws offer individuals the proper way to have and exploit their creative scientific and technological creations for an outlined amount. Holding rights defend the interests of creators by giving them proper rights over their creations or intellectual property laws offer individuals the proper to have and exploit their creative scientific and technological creation. IPR is monitored by world Intellectual Property Organization (WIPO). With the

IMPACT FACTOR SJIF 2020 (7.551)

- government has resulted in drastic reduction in pendency in IP applications. Automatic issuance of electronically generated patent and trademark certificates has also been introduced
- Patent filings have increased by nearly 7% in the first 8
 months of 2018-19 vis-à-Vis the corresponding period
 of 2017-18. Trademark filings have increased by nearly
 28% in this duration.
- IP Process Re-engineering Patent Rules, 2003 have been amended to streamline processes and make them more users friendly. Revamped Trade Marks Rules have been notified in 2017.
- IPR Awareness programs have been conducted in academic institutions, including rural schools through satellite communication, and for industry, police, customs and judiciary.

Challenges in international markets:

- A. Groups working on healthcare access in India have said the proposed U.S.- India MoU on Intellectual Property Rights (IP) is a matter of serious concern. The groups including the All India Drug Action Network (AIDAN), the National Working Group on Patent Laws, the WTO Campaign for Access to Medicines and Devices-India and the Third World Network (India) Drug Action Forum, Karnataka (DAF-K) have approached the Central government saying the U.S. had been pressing India to make changes in its IP legislation, rules and procedures through the annual United States Trade Representative (USTR) Special 301 reports and was also interested in getting the Indian IP management officials to opt for a stronger IP regime. "India's IP laws especially the Patents Act, Copyrights Act and Protection of Plant Varieties and Farmers Rights Act contain robust public interest safeguards against the abuse of IP monopolies. These public health provisions in the Patents Act are crucial for ensuring affordable generic medicines for the people. Therefore, we caution that such a move may undermine the legislative intent behind our Patents Act," the group noted. They urged a review of the IP laws which should be in accordance with the needs of the country.(4)
- B. India also further restricted the transparency of information provided on state-issued pharmaceutical manufacturing licenses, continues to apply restrictive patentability criteria to reject pharmaceutical patents, and still has not established an effective system for protecting against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for

- pharmaceuticals and certain agricultural chemical products," the report said.
- C. The report also mentioned high customs duties on medical devices and Information and Communications Technology. These goods categories were have been persistent challenges in trade talks between the two countries last year the language used in the 2020 report in this context is the same as in the 2019 report." Despite India's justifications of limiting IP protections as a way to promote access to technologies, India maintains extremely high customs duties directed to IP-intensive products such as medical devices, pharmaceuticals, Information and Communications Technology (ICT) products, solar energy equipment, and capital goods," it said.

Issues in India's IPR regime:

- A. Section 3(d) of the Indian Patent Act 1970 (as amended in 2005) does not allow patent to be granted to inventions involving new forms of a known substance unless it differs significantly in properties with regard to efficacy,-
- a. this means that the Indian Patent Act does not allow ever greening of patents.
- this has been a cause of concern to the pharma companies. Section 3(d) was instrumental in the Indian Patent Office (IPO) rejecting the patent for Novartis' drug Glivec.
- B. Issue of Compulsory licensing (CL): CL is problematic for foreign investors who bring technology as they are concerned about the misuse of CL to replicate their products. It has been impacting India-EU FTA negotiations,-
- a. CL is the grant of permission by the government to entities to use, manufacture, import or sell a patented invention without the patent-owner's consent. Patents Act in India deals with CL.
- b. CL is permitted under the WTO's TRIPS (IPR) Agreement provided conditions such as 'national emergencies, other circumstances of extreme urgency and anti-competitive practices' are fulfilled.

In its latest Special 301 report released by the United States Trade Representative (USTR), the US termed India as "one of the world's most challenging major economies" with respect to

protection and enforcement of IP.

C. Foreign investors and MNCs allege that Indian law does not protect against unfair commercial use of test data or other data submitted to the government during the application for market approval of pharmaceutical



Implementation of Forest Rights in PESA Area of Maharashtra

¹Prof. Vaisḥali Bankar and ²Prof. Dr. Tejaswini Malegaonkar ¹Research Scholar, Indian Law Society, Research Centre, Pune, Maharashtra ²Research Guide and Assistant Professor, Indian Law Society Research Centre, Pune Maharashtra

ABSTRACT

This paper investigates the provisions of FRA enactments and its implementation in Maharashtra. Tribal customary rights, community rights, ownership of land, cultural activities and their livelihood are discussed. Implementation of education, sanitation, livelihood, housing, compensation policies are discussed. Prevention of deforestation against the consent of villagers is pointed out. To provide speedy settlement of claims, right to hearing, allotment of alternate land, transportation and marketplace for selling minor forest produce, etc. are considered.

Keywords: Community, compensation, deforestation, minor forest produce, traditional, tribal land.

INTRODUCTION

Maharashtra is the third largest State by area and second most populated. Konkan coastal area and Deccan plateau by Sahyadri range of Western Ghat, Satpura hills and Bhamragad-Chiroli-Gaikhuri ranges are divided the forest lands amongst 36 administrative districts throughout the State of Maharashtra. Mainly, the forest areas are located at Western Ghats, Satpura hills and Gondwana regions. Total population of Tribal is nine percent.

To provide speedy settlement claims, customary and traditional rights, livelihood, housing and education and other essential services to the tribal, etc., the Parliament has enacted the Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006 (2 of 2007) (for short "Forest Rights Act") and the Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Rules, 2007 made thereunder by the Ministry of Tribal Affairs, Government of India, so as "to recognise and vest the forest rights and occupation in forest land in forest dwelling Scheduled Tribes and other traditional forest dwellers who have been residing in such forest for generations but whose rights could not be recorded and also to provide for a framework for recording the forest rights so vested and the nature of evidence required for such recognition and vesting in respect of forest land".

Constitutional Provisions

Directive Principles obligate the State to take certain directions to promote the welfare of the people and achieve economic democracy as well as give directions to the Legislature and Executive to exercise their power. In the Constituent Assembly, "Dr. Ambedkar had said that a party which failed to implement these principles would stand to lose in the next elections." As a part of such Directive Principles, Art. 40 of the Constitution of India provides that the State shall take steps to organise village panchayats and endow them with such powers and authority as may be necessary to enable them to function as units of self-government. "The expression 'village' connotes ordinarily an area occupied by a body of men mainly dependant upon agriculture or occupation subservient thereto". Article 40 of the Constitution requires the State to take steps to organise village panchayats and to confer on them powers and authority as may be necessary to enable them to function as units of self-government. Article 40 does not give guidelines for organising village panchayats. The village panchayats however organised have to be equipped with such powers and authority as may be necessary to enable them to function as units of self-government.

To provide effective legal instruments so that to develop and uplift the tribal, the Government of India had appointed a number of Committees to survey thoroughly. Amongst them the Balwant Rai Mehta Committee was appointed in January 1957, and the said Committee has recommended to establish the scheme of 'democratic decentralisation', which ultimately came to be known as Panchayat Raj. subsequently, the National Development Council in January 1958 Ashok Mehta Committee, G V K Rao Committee, L M Singhvi Committee, Thungon Committee and Gadgil Committee, appointed, time to time. The Rajiv Gandhi Government introduced the 64th Constitutional Amendment Bill in Lok Sabha in July 1989 but Rajya Sabha was not approved. Then V P Singh Government introduced the Bill in Lok Sabha in September 1990, but it lapsed. Thereafter, Narasimha Rao Government introduced it in Lok Sabha in September 1991 and finally it was passed as the 73rd Constitutional Amendment Act, 1992, which come into force on the 24th April 1993.

To give effect to the said Article 40, the Parliament has enacted the Constitution (Seventy-third Amendment) Act, 1992, after ratification by the State Legislatures as required by Art. 368 and by that amendment, a new Part

Asian Journal of Organic & Medicinal Chemistry Vol. 7 No. 2 (April - June, Special Issue - VI 2022)

ISSN Online: 2456-8937 UGC CARE APPROVED JOURNAL

- (d) other community rights, such as fishing, traditional seasonal resources, etc.;
- (e) community tenures of habitat and habitation;
- (f) on disputed lands of any nomenclature;
- (g) convert of patta or leases or grants on forest lands to titles;
- (h) settlement and conversion of all forest villages, old habitation, surveyed villages and other villages in forests;
- (i) protect, regenerate or conserve or manage any community forest resource;
- (j) recognised by any traditional or customary law;
- (k) access to bio-diversity and community right to intellectual property and traditional knowledge related to bio-diversity and cultural diversity;
- any other customary or traditional rights excluding hunting or trapping or extracting a part of body of any species of wild animal;
- (m) rehabilitation including alternative land.

Sub-section (2) of the said section has imposed the duties on the Government to provide schools, dispensary or hospital, anganwadis, fair price shops, electric and telecommunication lines, tanks and other minor water bodies, drinking water supply and water pipelines, water or rain water harvesting structures, minor irrigation canals, non-conventional source of energy, skill upgradation vocational training centres, roads and community centres.

The Governor of Maharashtra has by issuing notification in pursuance of his legislative powers conferred by sub-paragraph (1) of Paragraph 5 of the Schedule Vth of the Constitution, and accordingly modifies the provisions of the Forest Rights Act, in its application to the State of Maharashtra, providing that "to enable tribal and other traditional forest dwelling families to build houses in the neighbourhood forest area". This provision was inserted with a view to prevent the migration of forest-dwelling families outside their native villages and to provide them housing by extending the village site into forest land in their neighbourhood.

Guidelines on Forest Rights Act

The Government of India, Ministry of Tribal Affairs, vide No. 23011/32/2010-FRA [Vol.II (Pt.)], dated the 12th July 2012 has issued the Guidelines on the implementation of the Forest Rights Act, with a view to ensure effective implementation the provisions of the Act and rules made thereunder and for the purpose issued in this regards, the following guidelines,-

- (1) Process of Recognition of Rights.- Officials of Revenue and Forest Department should remain present when the Forest Rights Committee visit site for verification of claims; in case of rejection or modification of claim by the Gram Sabha or Sub-Divisional Level Committee or District Level Committee, communicate the aggrieved person so that he should be enable to file petition before the appropriate Committee within sixty days; Sub-Divisional Level Committee or District Level Committee should remand such rejected or modified claim for reconsideration, etc.;
- (2) Minor Forest Produce.- All non-timber produce of plant origin, including bamboo, brush wood, stumps, cane, tussar, cocoons, honey, wax, lac, tendu or kendu leaves, medicinal plants and herbs, roots, tubers, etc. of the Minor Forest Produce should be provide market, remuneration, transport, processing by the State Government;
- (3) Community Rights.- State Government may convert all forest villages, unrecorded settlements and old habitations into revenue villages, and also provide land for schools, health facilities, public spaces, etc., and to maintain its records;
- (4) Protection against Eviction, Diversion of Forest Lands and Forced Relocation.- Ministry of Environment & Forest, vide letter No.11-9/1998-FC(pt), dated the 30th July 2009, directed State Government to complete the process of settlement of rights under the Forest Rights Act relating to the diversions of forest land for non-forest purposes under the Forest (Conservation) Act, 1980;
- (5) Awareness-Raising, Monitoring and Grievance Redressal.- State Nodal Agency should plans to conduct trainings for revenue, forest, tribal welfare department's field staff, officials, Forest Rights Committees.

16

ISSN Online: 2456-8937 UGC CARE APPROVED JOURNAL

Environment and Forests, SC held that the provisions of the Scheduled Tribes and Other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006, are protecting the tribal autonomy, cultures and economic empowerment, to attain social, political and economic justice, and good governance for all. An issue involved in Biological Diversity Ac, 2002 and Regulations 2014 require Indian entities, and not only those with a foreign element, to pay a fee for fair and equitable benefit sharing with tribal communities for the use and development of bio-products constituting their traditional knowledge.

Review Meeting

Minutes of the Review Meeting held between 7th June 2021 to 14th June 2021, under the Chairmanship of Secretary, Tribal Affairs, Government of India, has been communicated vide F.No.11015/02/2019-Grants, Ministry of Tribal Affairs (Grants Division), on the 7th July 2021. In the said meeting, on behalf of the State of Maharashtra Shri Anup Kumar Yadhav, Secretary of the Rural Development Department, had represented. In the said meeting discussed various issued under the schemes of the Ministry, such as, Sharing of Best Practices which can be adopted, Status of submission of proposals for 2021-22 financial year after due approval of (www.grants.tribal.gov.in), Empowered Committee, Uploading data on Diagrams (www.emrs.tribal.gov.in) and Scholarship Portal, Identification of land for EMRS sanctioned between 2018-19 and 2020-21 and to be sanctioned during 2021-2022, Progress of construction of EMRSs under State Board, Adoption of RR framed by NESTS to be adopted by State Societies, Scholarships, Initiatives taken in tribal areas in view of Covid 19 crisis, Invitation to National and International achievers/celebrities as "Special invited Guests" to the Republic Day Parade, 2022, Integrated village development scheme, FRA, NCST Annual Reports Compliances, Status of National Tribal Policy and Xaxa (HLC) Committee, Monitoring of State TSP,

Agenda 9 on FRA directs all the States that the petition in Supreme Court still is pending, therefore, requested to all State Governments "to ensure that the contents of their respective affidavits filed in the Court be adhered and also keep in mind the timelines that have been submitted to the Court" and also discussed on the "data on rejection of cases should be thoroughly examined and reasons for rejection should be documented for each case".

The "State Government of Maharashtra has been uploading the implementation of FRA in FRA Portal. However, discrepancies [declining titles/land figure (CFR) in MPR found after May, 2020 to April 2021. The State Government was, therefore, advised to send correct MPRS for the said period".

In respect of review of rejected claims, the State Government was advised to ensure that due process of law (communication of reasons for rejection at each leve, etc.) has been followed in the process to be prepared before the Supreme Court hearing. 1752 cases under FRA were reported to be pending in the State. Success stories of bamboo plantation/fishing on FRA land Community Forest Management success stories were brought out and the State was requested to formally share these stories with FRA Division of MOTA".

CONCLUSION

The implementation of the provisions of the CFR rights in Maharashtra are quite satisfactory insofar as the Gadchiroli District is concerned. But, the rest of Maharashtra needs to implement the CFR rights more effectively with the help of Gram Sabhas, Adivasi Movements, Civil Society Groups, Tribal Development Department, Governor's office, Block and District administration. Needs to spread the awareness programme throughout Maharashtra at all levels, so that every Tribe must know its provisions and importance. Needs to provide livelihood, food and water security together with socio-cultural integrity. To provide information relating to convention on Biological Diversity and climate change. The Government institutions are crucial to provide good governance, mobilization and resource management. Necessary to stop the conflicting policies of notification on Village Forest Rules, leasing out forest lands to FDMC without Gram Sabha's consent, supporting JFM committee in recognised CFR villages and diversions of forests for non-forest purposes against the wish of the affected Gram Sabha's consent, etc. The Tribal Development Department of the Government of Maharashtra is a nodal agency, and therefore, this nodal agency implements its policies effectively, in the interest of the Tribal.

7. BIBLIOGRAPHY:

BOOKS

(1)	Jain, M. P.	Indian Constitutional Law, Fifth Edition 2003, Wadhava and Company, Nagpur
(2)	Professional Book Publishers	Constitution of India, Bare Act, 2021, Professional Book

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL INDUSTRY

Prof. Vaishali Bankar

Akbar peerbhoy college of commerce and economics

Introduction

In the globalised era, new and improvised drugs are being introduced in the market driven by rapid changes in technology. Over the past couple of decades, many advances in the pharma sector had led to introduction of blockbuster drugs, thus saving lives of millions of people. Most of the revenues from these commercially successful drugs are invested in research and development (R&D) and innovating new drugs.(1) The pharmaceutical is one of the sectors where the innovation makes a dramatic impact on the bottom line of the drug manufacturers, thus these companies are focusing more on Research& Development to survive the competition and gain market share. Innovation is the key element that defines the success of the pharmaceutical sector while the risk associated with launch of new drugs can threaten its survival in the marketplace. Besides this, innovation help pharma companies to distinguish themselves from generic manufacturing company to research-based company.

HISTORY:

The history of the Indian pharmaceutical industry dates back to 12 April 1901 when Bengal Chemical and Pharmaceutical Works Pvt. Ltd, Kolkata, was started by Acharya Prafulla Chandra Ray(2) with certain eminent medical practitioners. There is mention of at least of two other Indian companies ,which made significant contribution in the production of allopathic medicines , founded earlier than 1901 -B K Paul &Co, Kolkata, and N Powell & Co, Mumbai, which pioneered essentially in the imports and distribution of allopathic medicines along with production of certain others local medicines; although details of the local production could not be authenticated. Setting -up of Bengal Chemical was followed by the establishment of Alembic Pharmaceutical Works 3, Baroda, in 1907, Zandu Pharmaceutical Works Ltd4 Kolkata, in 1910, Calcutta Chemical Company(3), Kolkata, in 1916, and Bengal Immunity7, Kolkata, in 1919. These companies had started Indian companies were not yet technologically rich, and could not freely produce and supply "patented medicines" to the people of India because of legal barriers. But Indian entrepreneurs continued to show their enthusiasm to capture a part of the business, which grew. During 1930s and 1940s, several other Indian companies came up. Noteworthy among them were Cipla8, Mumbai (established in 1935); Amrutanjan Health Care, Chennai(4) (registered in 1935); East India Pharmaceuticals Ltd, Kolkata (formed in 1936) FDC Ltd, Mumbai (established in 1940); Dey's Medical Stores, Kolkata (started as a retail medical store in 1941 followed by factory in 1957) Indoco Remedies, Mumbai (incorporated in 1947); and IPCA Labs, Mumbai (established in 1949) Based on the scattered information left by these companies in their history-sheets as obtained from the sites of the companies on the net, it was observed that Indian entrepreneurs initially produced pharmaceuticals dispensed in various formulated forms such as tablets, dry powders, capsules, liquids, ointments and other forms, dispensed as alkalizers, digestives, immune boosters based on traditional herbal medicines, disinfectants based on coal- tar products, plant-based astringents, balms for pain relief and alcoholic herbal extracts of different kinds. The Second World War (1939-45) caused severe scarcity of modern medicines in India. At that time microbial diseases created considerable distress among people, and were the principal cause of death. The prevalent diseases included typhoid fever, tuberculosis, small -pox, malaria, measles, cholera, plague, dysentery and diarrheal diseases, a host of conditions of sepsis, respiratory diseases, including pneumonia and broncopneumonia, venereal diseases, kala-azar, leprosy, infection from hook- worm and other parasitic worms in the or addressed by adopting effective patent strategy by branded pharma companies through obtaining patents for methods of manufacture and active ingredients.

Volume-IX, Issues-I

An effective strategy should be developed to obtain patents for the broadest possible scope in the R&D process, whereas methods of use and formulations patents can be filed at the clinical trial stage that defines the product use and attributed. As the cost involved in the R&D is too high, majority of the pharma companies rely on patents and apply for patent protection right from research stage i.e. prior to clinical trials, thus shortening the time to market the drug and increase return on investment. Inventions in many technology-based industries can be kept a secret till the time it reaches the market and utilize the patent term of 20 years whereas inventions in the pharma industry has to be disclosed and protected prior to foraying into the market.

Extending patent protection

Pharma companies extend the patent term for commercially successful drugs by obtaining patents for new formulations of the known compound through ease of use or reduced dosage, thus making it superior to the previous drug. This provides an advantage to the branded companies to compete with generics competitors and protect market share. Furthermore, the drug takes less time to obtain an approval from Food and Drug Administration (FDA).

Future of pharma industry

Pharma companies are focusing on drugs that increase the sales volume and improve market share, thus boosting profits instead of developing life saving drugs.

As the drug discovery is becoming time consuming and expensive for the pharma companies, they have limited time to market their drugs. As a result, the industry is facing expiry of the patents on the commercially proven drugs. Without extended patent protection, the company will not be able to fund their R&D efforts. Also, extension of patent product lifecycle can help companies to invest more time in research and development and novel medications. On the contrary, extended patent protection means these drugs will be expensive for a longer period of time.

In the absence of adequate patent protection, pharma companies have to limit their patent portfolio resulting in erosion of market share. In order to compete with the pharma companies globally, Indian pharma companies have to focus on developing new drugs and protecting their intellectual property. It is imperative to protect intellectual property for commercialization in near future. As patents are crucial for pharma companies, they should focus on maintaining and developing patent portfolio. Indian companies can also produce patented drugs through licensing from foreign companies or earn revenues from generic drugs. High cost of research and development and lack of stronger product patent regime can stifle the growth of the pharmaceutical industry. To sum up, patents are necessary to promote innovation and economic growth. They help in gaining competitive edge in the market, and increase revenues and market share. Adequate patent protection can provide pharma companies a platform for future growth and produce new drugs. Also, protecting new inventions help pharma companies recuperate skyrocketing costs incurred in R&D and maximize the commercial product lifecycle. Therefore, it is critical to devise an effective IP strategy in order to maximize the returns and realize the true potential of intellectual property(5)

CONCLUSION:

The current state of the pharmaceutical industry indicates that IPR are being unjustifiably strengthened and abused at the expense of competition and consumer welfare. The lack of risk and innovation on the part of the drug industry underscores the inequity that is occurring at the expense of public good. It is an unfairness that cannot be cured by legislative reform alone. While congressional efforts to close leapholes in current statutes,

