Impact patent process on indian pharma industry

Contents

Abstraction

This Seminar Paper focuses on the impact of displacement from process patent to merchandise patent on Indian Pharma industry. The initial portion of this paper gives an overview of the present scenario of Indian Pharma market. Then it tries to develop a basic apprehension of patent Torahs and their pertinence to the Pharma industry. Followed by that, this paper provides an penetration into the alterations that have occurred in the patent jurisprudence and surveies the impact of switching from procedure to merchandise patent on Indian Pharma markets.

Bing an active member of World Trade Organization (WTO) , India needs to follow by certain policies and regulations applicable to all member states. One such set of regulations is defined by Agreement on Trade Related facets of Intellectual Property Rights (TRIPS) . It was under the auspices of TRIPS that India had to follow with certain alterations in its Intellectual Property (IP) ordinances. Switching from procedure to merchandise patent was one such alteration that affected the concern community in general and the Pharma industry in peculiar. This alteration brought about the terminal of India ‘ s aureate age of generic market (reverse-engineering) which had boomed during the procedure patent i. e. pre patent epoch. This period of procedure patent had resulted in development and advancement of Indian Pharma industry to a great extent. Besides the drugs available during this period were of economical monetary values that were low-cost to Indian population and besides to those of other developing states.

If we look on the positive side of this merchandise patent government, it will non merely assist Indian Pharma industry to concentrate more on R & A ; D but besides attract MNCs to do considerable investings in the Indian Pharma market. This may take to new coactions, joint venture, and outsourcing to Indian houses thereby increasing the FDI influxs in state. Owing to better IP protection Torahs, MNCs may open research Centres in India or they may outsource their production demands as Indian houses has maximal figure of FDA approved production installations.

At present the Indian Pharma market is turning at 16 % per annum. The portion of Indian Pharma industries in the market is 70 per centum. The new patent government will take to a batch of positive alterations in the industry viz low production costs, increased focal point on R & A ; D, good trained and advanced work force, first research labs and authorities support. All these will assist Indian Pharma industry to turn and vie with other transnational companies in the long tally.

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Background

An overview of Indian pharmaceutical industry: –

The Indian pharmaceutical sector is one of the extremely organized sectors which is turning at approximately 16 % yearly and is estimated to be deserving $ 4. 5 billion. Worldwide it ranks 3rd in footings of volume and 13 in footings of value. It rank high in footings of engineering, quality and the scope ofA medicinesmanufactured, from simple concern pills to antibioticsA and the complex cardiac compounds, about every type of medical specialty is now made indigenously. A

Indian pharmaceutical sector is an highly disconnected market which faces terrible monetary value competition and besides the monetary value control by the authorities.

The nucleus of Indian pharmaceutical industry is formed by 250 big units and about 8000small graduated table units. a scope of pharmaceutical merchandises is being manufactured / produced by these units these are medical specialties ready for ingestion and around 350 majority drugs. The Indian Pharma industry meet about 70 % of the state ‘ s demand for majority drugs, intermediates, capsules, viva voces, tablets, injectable and different preparations. India is going one of the leaders for API (active pharmaceutical ingredient) production. The strength of Indian Pharma industry is in developing cost-efficient engineerings for drug intermediates and majority drugs in short period of clip and besides without compromising on quality.

As of day of the month India has the largest figure of US FDA (US Food & A ; Drug Administration) approved fabrication installations outside the US.

Besides the DMFs (Drug Master Files) filed by Indian companies with FDA is higher as compared to most of the other states. Indian companies have besides established their bridgehead in abroad markets. India exports to more than 200 states including extremely regulated markets like US, Europe, Japan and Australia. In 2008-09 the exported drugs deserving US $ 8 billion. Besides, there has been a great rush in the figure of patent applications filed in the recent times. A sum of 35, 218 patent applications were filed, 6040 from domestic and 29, 178 from foreign appliers in the last financial twelvemonth (Economic Times, Jan. 7, 2009) . Indian companies have besides increased their R & A ; D outgo in the recent old ages which promote new drug find and doing Indian Pharma industry a planetary hub for R & A ; D activities. Government has allocated a proviso of Rs. 150 crore under the pharmaceutical research & A ; development support fund to promote and back up new drug find by the Pharma houses in the state.

Patent: –

Explained in most basic footings, “ Patents are the sole rights granted by the province to an discoverer over its innovation ” . These are sole rights as they stop others from importing, merchandising, offering for sale, fabrication or delivering merchandises or services incorporating the patented innovation. These are given for a limited period of clip. The patent ensures merely reward in footings of money and acknowledgment for the discoverer, for all the clip and attempt, cognition and accomplishments, money and other resources invested to come up with the innovation. Patent is valid merely in the state which grants it.

To acquire a patent over an innovation, there are three basic demands: –

1. Novelty- it should be new.

2. Imaginative measure (non-obviousness) – it should be non-obvious.

3. Utility (capable of industrial usage) – it should hold some industrial usage.

All patents are published after 18 months of first filing and are available for public review. There are about 40 million patent paperss worldwide. An extra 1 million are published every twelvemonth. Patents act as an exchange between society and the discoverer.

Need for patents in Pharmaceutical Industry: –

Patents are really much required and are of import for pharmaceutical industries because a immense sum of investing is done in R & A ; D by the houses. Besides, it provides a signifier of protection for the technological being exploited by others besides, as wages to the pioneer for the development of an innovation which it is technologically executable and marketable.

Statement of the job: –

Initially in India there was procedure patent regimen but after the recent alteration made in regimen as per TRIPs, the same was replaced by merchandise patent.

Comparison of India ‘ s Patent Act and TRIPs: –

Harmonizing to India ‘ s patent act merely procedure and non the merchandise is patented while harmonizing to TRIPs procedure and merchandise both are patented.

Harmonizing to India ‘ s patent act term of patent was 14 years, 5-7 old ages for chemicals, drugs but harmonizing to TRIPs its 20 old ages.

Harmonizing to India ‘ s patent act compulsory licensing can be granted while harmonizing to TRIPs there is limited compulsory licensing.

In India ‘ s patent act several countries were excluded from patents like method of agribusiness, method of medicative surgical or any intervention method etc. But in TRIPs about all Fieldss of engineering are patentable excepting works assortments and some countries in biotechnology and agribusiness.

In India ‘ s patent act the authorities is allowed to utilize patented merchandise to forestall scarceness while as per TRIPs there is really limited range for the authorities to utilize patented merchandises.

These alterations lead to a definite impact on Indian Pharma industry and defined the way of growing for the Indian Pharma companies ‘ secret agent in the market over following 5 – 10 old ages.

Purpose/objective of the survey: –

The aim of this survey is to understand the impact of displacement from process patent to merchandise patent on Indian pharmaceutical industry and besides to develop an apprehension of its benefits and restrictions.

Introduction

An Regulation on Patents Amendment was promulgated by the Government on December 26, 2004 to do the Indian patents jurisprudence WTO (universe trade organisation) compliant and to carry through India ‘ s committedness under TRIPS (trade related facets of rational belongings rights) to present merchandise patent protection for Drugs, Food and Chemicals with consequence from January 1, 2005. TRIPs is a pact administered by WTO which sets down minimal criterions for rational belongings ordinances. India being a member of WTO tried to do its patent statute law TRIPS compliant by conveying into force the patents (amendment) act 2005.

Article 27 of the TRIPS Agreement clearly states that the patents are granted for any innovation, whether merchandise or procedure, in all Fieldss of engineering, provided that they are new, involve an imaginative measure and are capable of industrial application. Patent rights are gratifying without favoritism of the topographic point of innovation, the field of engineering and whether merchandises are imported or are produced locally.

Certain compensatory steps and strategies are given by TRIPS to avoid the negative impact of monopolisation of merchandise patents particularly in wellness and pharmaceutical sectors. Such steps are: –

aˆ? Transition periodA

aˆ? Compulsory LicensingA

aˆ? Public, non-commercial usage of patentsA

aˆ? Parallel importsA

aˆ? Exceptions to patent rightsA

aˆ? Exceptions from patentability andA

aˆ? Limits on informations protection [1]

Outstanding characteristics of the Patents (Amendment) Act 2005 related to merchandise patents:

a) Extension of merchandise patent protection to merchandises in sectors of drugs, nutrients and chemical. A

B) Term for protection of merchandise patent shall be for 20 years. A

degree Celsius) Introduction of a proviso for enabling grant of compulsory licence for export of medical specialties to states which have insufficient or no fabrication capacity ; provided such importing state has either granted a compulsory licence for import or by presentment or otherwise allowed importing of the patented pharmaceutical merchandises from India (in conformity with the Doha Declaration on TRIPS and Public Health) .

A vitamin D) A new proviso has been introduced that provides that the mere find of a new signifier of a known substance which does non ensue in the sweetening of the known efficaciousness of that substance or the mere find of any new belongings or new usage for a known substance or of the mere usage of a known procedure, machine or setup unless such known procedure consequences in a new merchandise or employs at least one new reactant, shall non be patentable. [1]

The purpose of these amendments is to do Indian Pharma industry competitory with the transnational companies. The generic drug industry will confront restrictions whereas MNCs are traveling to bask the monopolistic rights. However it besides attracts the contract R & A ; D and the joint ventures with MNCs.

Impact

Initially when the regulative system was focused merely on procedure patents, a strong and extremely competitory domestic pharmaceutical industry was established with a stiff monetary value control model. It helped the industry to go universe provider of majority drugs and medical specialties which are at low-cost monetary values in India and in the underdeveloped universe. The Process patent and the reverse-engineering made the Indian Pharma industry world-class generic industry. Product patent government will convey terminal of this aureate epoch and will prefer the participants with constitutional scientific and proficient resources. The new ordinances will non discourage the Indian Pharma big leagues who are already making howling concern in states with rigorous patent Torahs.

In merchandise patent epoch Research & A ; Development act as the “ survival kit ” for Indian pharmaceutical industry. To back up this, the Government of India extended 10 twelvemonth revenue enhancement vacation to Pharma sector and the planning committee has earmarked $ 34 million for the drug industry R & A ; D publicity fund.

(a) A Product Patents and Prices of Medicines: –

With merchandise patent the monetary value of drugs are decidedly traveling to increase. In hapless states, drug monetary values are closely connected to sole selling rights (EMRs) , merchandise patents, or inexpensive imports that put drugs beyond the range of the common people. For illustration, Flucanazole, an ARV (antiretroviral) which was n't patented in Thailand. Was being sold by Pfizer for US $ 6. 2 while the local Thai maker was selling it for US $ 0. 3, which is 207 times cheaper than Pfizer. Besides, the same drug was sold at US $ 21. 4in South Africa because no generics were available.

The monetary values of drugs are much higher in other states where merchandise patent is in force as compared to India. Ranitidine sold by Glaxo at Rs. 7. 20in India, while the same merchandise sold in Pakistan at Rs. 65 and in the U. S. A. at Rs. 545.

To get the better of this and maintaining in head the low buying power of Indian people, the Government of India should convey certain indispensable drugs under the monetary value control and protect consumer against high monetary value. Drug monetary value control is applicable on patented drugs besides.

(B) A Product Patents and Research and DevelopmentA

Because of the high cost incurred in the R & A ; D and the high fiscal hazard and failure rates acts as barrier to the entry of new houses in R & A ; D sector. In developing states, merely a few houses have sophisticated R & A ; D installations while the others are benefited chiefly from the spillovers of

the end point R & A ; D. Studies showed that 1 out of 5000 compounds synthesized during the applied research finally reaches the market, out of 100 drugs that enter the stage I, approximately 70 completes it, and out of that merely 33 complete stage II, and merely 25-30 clear stage III. And merely two-thirds of the drugs that enter phase III finally reaches the market.

Initially the investing done by little local Pharma companies in R & A ; D in India was for contriving new procedures or engineering, fundamentally change by reversal technology procedures and non the new drug find. Now, with passage in the new government many Indian companies are mobilising their resources both human and fiscal to increase in their R & A ; D processes and doing them better and progress so as to be in competition with MNCs. Government of India has allocated financess to advance and promote Indian Pharma houses to come in in the R & A ; D sector.

R & A ; D Expenditure of the taking Pharmaceutical Firms (Rs in Crores) [2]

Year

Ranbaxy

DRL

Sun

Workhardt

Cadila

Glenmark

Downpour

Cipla

Aurobindo

1998

43

11

10

25. 6

19. 2

3. 1

4. 2

23

9. 2

1999

55

13. 27

18

36. 24

21. 27

5. 2

10

30

14. 4

2000

57

23

20

32

25

10. 2

20

23

8

2001

77

51

25

30

42

12

22

22

6

2002

192

74

34

34

38

31

31

52

14

2003

276

141

97

60

88

37

40

57

22

2004

331

199

127

69. 3

103

48. 7

67. 3

98. 4

49

2005

486

254

143

81. 1

119

46. 7

87. 4

155

54

2006

386

215

202

138

124

45

74

176

77

2007

460

246

279

152

134

43

91

232

97

2008

471

353

287

165

133

51

113

244

118

Growth Ratess

2. 23

2. 35

2. 69

2. 85

2. 20

1. 82

2. 13

2. 86

3. 03

It can be seen in this tabular array that the R & A ; D investing /expenditure of taking pharmaceutical houses has been increased over the old ages. Maximal investing is done by Ranbaxy.

R & A ; D should be the chief focal point in the merchandise patent epoch.

(degree Celsius) A Product Patents and Foreign Direct Investment

One of the expected consequence of beef uping the Intellectual Property Rights is the addition in foreign direct investing (FDI) in R & A ; D, direct fabrication, outsourcing, in-licensing, out-licensing or joint ventures. The flows of FDI depend on the available accomplishments, present engineering, R & A ; D capacity, the competency and institutional and other back uping engineering and the substructure. it has been observed that the flow of FDI in some underdeveloped states is non much even with strong rational belongings ordinances while in others it is increased after the execution of patent ordinances. It shows that patent ordinances do n’t hold important impact on the trade benefits, the investings and the flow of FDI.

(vitamin D) A Product Patents and Technology Transfer

The high cost of development and rapid obsolescence may forestall the transportation of engineering and the patent holder may prefer direct development or import of merchandises than reassigning the engineering or know-how. Fear of competition besides dissuades the transportation of engineering or demands a high royalty for the transportation, but immense royalties may hold a negative impact on the outgo on R & A ; D. In the instance of India, though in the pre’70s epoch, the engineering transportation by the large TNCs did non back up the autochthonal technological abilities, yet in the station ’70s, a big figure of little and average size houses have besides been reassigning their drug engineerings to India, therefore promoting an ambiance of competition in engineering transportation. But India has encountered troubles in acquiring entree to engineering for a constituent known as HFC 134 A, which is considered the best available replacing for certain CFCs. Patents and trade secrets cover this engineering, and the companies that possess them are unwilling to reassign it without bulk control over the ownership of the Indian company. [3]

Decision

During The period of the 1995 to 2008, the strong public presentation of the Indian pharmaceutical industry can be seen. The assorted factors that contribute to the public presentation are: -the improved production public presentation. the foreign exchange earner during this period. India emerged as a power house of API production. R & A ; D Expenses have increased at a higher rate during this period. It has been shown in the tabular array above

besides that Ranbaxy has ever spent higher outgo as compared to other Pharma companies in research & A ; development. Besides, India ‘ s portion in drug maestro filing with the USFDA has increased to 50 per centum in 2007 from that of 14 per centum in 2000.

Entree to drugs is the primary and major concern of the populace in any hapless or developing state like India, which has introduced merchandise patent regimen. The generic drug industry of India will be affected by the Patent Amendment Act 2005. As The Act has failed to protect the involvement, of the generic manufacturers who were bring forthing and selling drugs would hold to pay “ sensible royalty ” for fabricating drugs for which the patent applications made in “ letter box ” . The term sensible royalty is non decently defined in the act which leaves the pick to the patentee to make up one’s mind it without any fixed criterions. For this Canada has fixed it at 2 per centum and left no range for any confusion/problem.

In the merchandise patent epoch for easy entree to medication few points are to be considered, these are: –

Use of TRIPS flexiblenesss including compulsory licensing, without give uping to MNCs ‘ force per unit areas and to vouch drug production by generics at low cost.

Develop India ‘ s rich traditional cognition on Ayurvedic and other options to promote aggregation of ancient literary plants to protect the same from being patented by other states.

Introduce drug monetary value control mechanism.

Promoting new innovation by proper R & A ; D activities. [4]

The alteration in regimen or the new Torahs should non come in manner or impact the economic advancement of the state and besides should non go against the constitutional right to wellness and life to people. Therefore, proper steps should be taken by the government/law to protect the involvement of the populace which is the eventual aim of the Patent.

The Indian Pharma market is the taking generic market whose strength is in reverse-engineering. Indian Pharma sector comprises of 250-300 companies which account for 70 per centum of the entire Pharma market. Besides, the 75 per centum India ‘ s demand for medical specialty is been served by the local makers. Initially in the pre Patent epoch the India ‘ s patent act follow procedure patent which benefitted the Indian Pharma companies and resulted in the roar of generic market. These generic drugs are priced low-cost to common adult male. Not merely this, the growing of Indian Pharma sector is been recognized in this period merely. But this aureate epoch will now come to stop because of new regimen. This new regimen will pull MNCs to come in Indian market and sell their merchandises ; this will advance the construct of joint venture, outsourcing, besides amalgamations and acquisitions. Research and development will move as survival kit as a consequence there is addition in R & A ; D outgo by the Indian houses, besides authorities of India is besides raising financess to advance and promote R & A ; D in state.

The issues which have to be taken attention of during the station patent epoch is the increased monetary value of drugs-

India being a developing state and bulk of its population is below poorness line who ca n’t afford the drugs or for whom medication/treatment is by and large out of their range, the monetary value of drugs should be kept in control. The societal duties should non be neglected, as for success and advancement of state both the socio and economic factors are to be taken attention of and should be balanced. Therefore, the authorities should go on the monetary value control ordinances on branded merchandises besides. Basic drugs needed should be included in the indispensable drug list.

The patent epoch will promote the Indian Pharma industry to concentrate and put in R & A ; D, besides will convey more coaction, joint ventures, partnerships with MNCs, as MNCs are attracted by low R & A ; D cost in India, advanced scientific work force, low cost of production etc. This will convey net incomes, FDI flow as transnational companies will outsource put up their research and development Centres in India.

But the authorities should besides maintain an oculus to that MNCs do n’t bask the monopolistic in the manner which harm the society or take control over local houses.

The promising factors which can lend to success and development of Indian Pharma industry/market are: –

Low R & A ; D cost

The addition in R & A ; D investing

Addition in patent filing

Addition in figure of FDA approved installations

Well educated -trained & amp ; advanced work force

Improved and progress engineering

Generic hub

Excellent and first national research labs.

Patent ordinances and

Government support

All shows the Indian Pharma industry will maintain turning and using and will vie with other MNCs. increased amalgamations and acquisitions will strength the R & A ; D in new merchandise development. The R & A ; D and fabrication installations set up which meet the international criterions will be approached by multinationals for carry oning research and set abouting fabricating on their behalf. This all will turn out good for Indian Pharma market.