INDIAN PHARMACEUTICALS AND COMPETITION ISSUES: A LEGAL ANALYSIS

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INTRODUCTION

"*The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.*"[1]

Various International human rights agreements, significantly the Universal Declaration of Human Rights (UDHR) and the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR) recognize the right to health. The urgency to take action by all governments has been has been expresses in the Declaration of Alma Ata[2]. Right to health in India as a derived fundamental right under Article 21 of our Constitution which is the cornerstone of our Constitution. Access to healthcare is a global problem and India too is no exception in this case .more than one-third of the world populace is deprived of access to healthcare and pays heavy price. A large portion of the developing countries lacks proper access to medicines in developing countries. According to an estimate only some 35 percent of Indians have access to essential medicines.[3] The matter of healthcare, like most other development issues is simply gigantic and it is impossible for the government to do anything single handily without cooperation of the people. It is possible to bring the paper pledges into action only with the support of the people.

Two vital institutions which are of prime importance for ensuring access to medicine and healthcare are health delivery system and the pharmaceutical industry. The healthcare mainly

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[1] Preamble to the WHO Constitution

[2] The Declaration of Alma-Ata was adopted at the International Conference on Primary Health Care (PHC), Almaty (formerly Alma-Ata), Kazakhstan (formerly Kazakh Soviet Socialist Republic), 6-12 September 1978. It expressed the need for urgent action by all governments, all health and development workers, and the world community to protect and promote the health of all the people of the world. It was the first international declaration underlining the importance of primary health care. The primary health care approach has since then been accepted by member countries of the World Health Organization (WHO) as the key to achieving the goal of "Health for All".

[3] World Health Organization Office Of The Who Representative To India & Ministry Of Health And Family Welfare Government Of India , Cuts Centre For Competition, Investment & Economic Regulation (CUTS C-CIER) Cuts International Jaipur, India 2006 ,*Options For Using Competition Law/Policy Tools In Dealing With Anti-Competitive Practices In The Pharmaceutical Industry And The Health Delivery System available*

comprises doctors hospitals (both public and private), diagnostic labs, pharmacists and primary health centres and the pharmaceuticals industry is mainly involved manufacturing and marketing medicines and inventing new medicines.

There are five aspects to access to medicines and healthcare: availability of supply, price, quality, ability to pay and access to proper and affordable consultations. All these aspects are vitiated in our country by a number of factors, which range from poverty and poor infrastructure to corruption, market malpractices and lack of awareness. A market malpractice in general and in particular, anti-competitive conduct in the pharmaceutical industry has serious implications for access to healthcare by people. Examining legal and policy options to effectively curb such anti-competitive practices will be the focal point of this study. Anti-competitive practices in the pharmaceutical sector amongst others, price fixing, abuse of dominance, collusive agreements and tied selling. Even practices such as kickbacks to doctors and pharmacists may be deemed as anti-competitive as they result in depriving patients of best possible medicines and services at the lowest possible prices. The principal effect of anticompetitive practices on the health sector is that medicines and services are rendered expensive.[4] With the advent of India's new patent regime and the increasingly deregulated environment new concerns have arisen particularly in regards to access to medicine and healthcare.

The concerns are enumerated below:

- Will there be rise in prices due to the abuse of the monopoly rights of the patent holder?
- Will relaxation in price controls lead to rising prices?
- Will the inevitable increase in MNC presence, post-TRIPS, usher in the many anti-competitive practices?
- Will the current spurt in mergers and acquisitions create market structures, which may result in abuse of dominance?

INDIAN PHARMACEUTICLS INDUSTRY

The Indian pharmaceutical industry is currently acknowledged as one of the foremost industries. The launching of the new products has led to a significant increase in the growth

[4] CUTS C-CIER, *Supra note* 2, p. 14

rate. According to statistics almost 3000 new products were launched between 2002 and 2004, with sales estimated at US$280mn[5] India is ranked among the top 15 drug manufacturing countries in the world. Globally, the output of India ranks 4th in terms of volume and 13th in terms of value.[6] The Indian pharmaceutical industry, however, only has a one percent share of the world pharmaceutical export market. India's export market is expected to strengthen substantially in the coming years. One vital characteristic of the industry is that drug prices in India are arguably amongst the lowest in the world.

The pharmaceutical industry avails of global recognition for its following strengths.[7]

- Availability of a large pool of low-cost and highly skilled pool of scientists and medical professionals
- Chemistry and synthesis skills
- Successful scaling up of laboratory processes to plant scale
- Cost effective and commercially viable non-infringing processes
- Manufacturing facilities of international standards
- Quicker adoption of new technology

Despite the all the heartening indicators and the significant promise of the pharmaceutical industry in India, the sector is today in a state of flux. Many domestic companies are being confronted by the very issue of survival in face of the sweeping changes introduced in the patent regime and the increasingly de-regulated environment.[8]

BACKGROUND AND HISTORY

In order to understand the pharmaceutical industry in India it is essential to understand the Indian patent regime. The pharmaceutical industry in India is at the zenith of success and the

[5] Khan, A., & Nanda, N., (2006), Competition Policy for the Pharmaceuticals Sector in India, CUTS International In: Mehta, P.S. (2004) (ed.), Towards a Functional Competition Policy for India, [E-Book] Pp.188-189. Jaipur. Academic Foundation; Available at: http://books.google.co.in/books?id=YrkMLy9Z6OwC&pg=PA189&lpg=PA189&dq=Nitya+Nanda+and+Amirullah+Khan,+Competition+Policy+for+the+Pharmaceuticals&source=bl&ots=L7yN_RgZG_&sig=eAO0R3J1UarJELgy8IwkLbJ_3P0&hl=en&sa=X&ei=juZqT7KfHJGsrAfSo4yfAg&redir_esc=y#v=onepage&q=Nitya%20Nanda%20and%20Amirullah%20Khan%2C%20Competition%20Policy%20for%20the%20Pharmaceuticals&f=false (Accessed on: 20th May, 2020)

[6] Industry Overview: Drugs and Pharmaceuticals; Available at: http://www.directories-today.com/drugs.html (Accessed on: 17th May, 2020)

[7] Nitya Nanda,*supra notes* 4

[8] Ibid.

key factor responsible for this is the transition from the product patent regime for medicines to that of process patent patents in the 1970.The product patenting system protect the patent-holders' rights to the new drug or molecule invented while process patents protect the method used to create a drug or molecule, but not the product itself. A process patent, therefore, permits manufacturers to produce the same or similar molecule, if they are able to devise an alternative method of developing the molecule.

The patent regime gave opportunities to manufacturer to manufacture generics [9]using reverse engineering[10] method .The companies involved in the manufacture of generics did not have to recover any substantial research and development cost therefore they priced in such a manner that it was available at affordable price to the *aam aadmi.* The availability of cheap medicine at affordable price was of utmost significance in a country with such a high percentage of underprivileged citizens.

Based on the flexibilities of the process patent system and a range of protectionist measures, a self-reliant domestic drug industry emerged with the capacity to manufacture and provide at a low cost a wide array of bulk and finished drugs. The milieu against which the industry achieved its success is now set to radically change. The era of liberalisation and integration with the global markets in India has ushered out the earlier protectionist measures. Since 2001, automatic approval has allowed up to 100 percent foreign equity in the pharmaceutical sector and the Indian law now treats TNCs as equal to Indian companies. The process patent regime was fundamentally liable for the domestic industry maintaining its competitive edge.

[9] Unfortunately there is no precise definition. Generics is a term, which is used in a number of different contexts, primarily three. A drugs generic name is the pharmacological name of the compound assigned either by WHO's International Non-proprietary Names Committee or by the US Adopted Name Council. Drugs whose patents have expired are also included in the category of generics. (See Zafrullah Chowdhury, The Politics of Essential Drugs: The Makings of a Successful Health Strategy: Lessons from Bangladesh, Zed Books Ltd. London, 1995, p. 8). Also copies of patented drugs in the erstwhile process patent regime in India were loosely termed as generic copies of patented drugs. Generic drugs are broadly classified into commodity generics and branded generics. Commodity generics, which have been on the market since 1950s are simply generic name products marketed by a wide variety of companies. Branded generics are either unpatented drugs sold under a brand name or patent-expired products sold under a generic name prefixed by the company's initial(s)- a practice which helps differentiation from other generic manufacturers and is supposed to provide an assurance of quality.

[10] Reverse engineering is the process of discovering the technological principles of a device, object, or system through analysis of its structure, function, and operation.It often involves taking something (e.g., a mechanical device, electronic component, software program, or biological, chemical, or organic matter) apart and analyzing its workings in detail to be used in maintenance, or to try to make a new device or program that does the same thing without using or simply duplicating (without understanding) the original.

LAWS REGULATING THE PHARMACEUTICAL INDUSTRY IN INDIA

Laws Pertaining to Manufacture and Sale off Drugs in India[11]

- The Drugs and Cosmetics Act,, 1940
- The Pharmacy Act,, 1948
- The Drugs and Magic Remedies Act,, 1954
- The Narcotic Drugs and Psychotropic Substances Act,, 1985
- The Medicinal and Toilet Preparations Act,1956

The Approval Process for Manufacturing and Marketing

The pharmaceutical industry is regulated by the Drugs and Cosmetics Act 1940 (DCA), and the Drugs and Cosmetics Rules (DCR) made there under. This legislation enjoys jurisdiction in the whole of India and to all products whether they are manufactured in India or imported from other countries. The office of the Drug Controller of India (DCI) has the primary accountability of enforcing the law. Notwithstanding anything enforcement at the field level is done by the individual state government through their Food and drug administration. Matters of product approval and standards, clinical trials, introduction of new drugs, and import licenses for new drugs are handled by the DCI. However, the approvals for setting up manufacturing facilities, and obtaining licenses to sell and stock drugs are provided by the State Governments. There is no requirement for any registration of a drug in India. However, there is need for approval from the DCI to import, market, or manufacture a "new drug." All new drugs (drugs not previously used in India or in use for less than four years) proposed to be introduced must be approved for import or manufacture in India by the DCI. The application for permission to import or manufacture must be accompanied by the appropriate dossier on the following aspects:

- Introduction: description of drug and therapeutic class
- Clinical and pharmaceutical information
- Animal pharmacology
- Animal toxicology
- Human/ clinical pharmacology (Phase I)

[11] Indian Pharmaceutiical Industry and Laws Governing Manufacture and Salle off Drugs D.. Sreedhar Maniipall Collllege off Pharmaceutical Sciences,, Mani pall

- Exploratory clinical trials (Phase II)
- Confirmatory clinical trials (Phase III)
- Special studies
- Regulatory status in other countries
- Marketing information

In case the drug is already permitted and marketed abroad, then only Phase III trials may be mandatory in India. Further, such trials would need to be conducted on at least 100 persons spread over 3-4 locations in the country. However, the DCI may agree to mete out with the need for local clinical trials, if it is in the public interest and if it can use the data of trials carried out in other countries.

All manufacturing of drugs in India requires a license. A license is required for each such location at which drugs are to be manufactured, and also for each drug to be manufactured. The license has to be renewed from time to time.

THE COMPETITION ASPECTS OF THE PHARMACEUTICAL INDUSTRY

The competition aspects of the pharmaceutical industry are very distinct from those in most markets. There are certain exclusive characteristics of the pharmaceutical industry, which account for a distinctive competition scenario, although this is pertaining to primarily the formulations sector and not the bulk drugs industry There is archetypal competition in the bulk drug sector mainly because, there are a large number of players with none enjoying market dominance, and secondly, the sector is characterized by a homogenous product range. Supplementary the buyers in the bulk drug sector are aware consumers and there is lack of asymmetry of information as is the case with the formulation sector:

The Barriers to Effective Price Competition[12]

In a normal market, firms try to improve sales, and accordingly, profits, by reducing prices. Competition between firms to provide the highest quality product for the lowest price ensures efficient allocation of resources in the economy. It also means that the benefits of augmented efficiency are shared between consumers, in the form of lower prices and higher quality; and firms, in the form of profits. However, the scenario changes drastically in the case pharmaceutical sector with specific reference to formulations. The very essentiality of the

[12] CUTS C-CIER ,*Supra note* 2, p. 27

product being sold, namely medicines, is facilitative to distortion in competition in the pharmaceutical market. Consumption patterns are not affected by price and therefore there is absolutely no incentive to keep prices low. In case of developed countries the consumption pattern is untouched mainly because of two reasons. Firstly, the essentiality of the commodity and secondly, due to coverage of the consumers either by private or public insurance companies.

In most countries the insurance providers are generally the governments and therefore it's the government that bears the most or all cost of medicines which may result in reasonable drug pricing, since as a monopolist, the government may be able to control drug prices, at least to some extent, and prevent drug companies from exploiting the market [13]. However, in India and most developing countries, the situation is quite different. Majority of people are covered neither by public nor private insurance. The coverage of public provisioning of healthcare services and medicines is also limited.

Consumer Choice –The Dependence Involved due to Asymmetry of information

Another area of concern in this sector is the fact that the consumers in case of formulations are not the decision makers. They are more than often guided by their doctors and pharmacist and this way the doctors and pharmacist assume a significant role in the sale of drugs often leading to manipulation of the system, with drug companies seeking to exploit this influence, sometimes via huge incentives Such practices are detrimental to the interest of the ignorant consumers who are misled into buying expensive medicines .This vitiated dance mentoring by the doctor deprives patients from availing the best possible products at the lowest possible prices, which is a basic competition principle. Empowering consumers is a task fraught with difficulties, since medicine is a highly specialized field in which miscalculations in the decision making process may lead to severe repercussions on health.

Anti-competitive Practices[14]

A number of anti-competitive practices encompass the pharmaceutical industry internationally including in India. Such practices include, amid others, collusive activities, merger and acquisition associated anti-competitive practices and abuse of dominance. To control the distorted competition in the pharmaceutical industry basically all countries in the

[13] Ibid.
[14] CUTS C-CIER, *Supra note* 2, p. 28

world have mechanisms to police the industry, particularly drug prices.

In the Context of Access to Medicines[15]

Skewed competition despite the fact that there is no uncertainty as to the technological sophistication, entrepreneurial flair and export success of the pharmaceutical industry. But in the framework of one yardstick, namely, the contribution of the pharmaceutical industry in facilitating access to drugs, despite significant contribution by the industry, the overall situation has been disappointing. As mentioned previously, only some 35 percent of Indians can access essential drugs. There are a number of factors, which would give explanation for the lack of access to drugs. However, responsibility lies with the industry as well. The health delivery system shares a large part of the responsibility for ensuring access to affordable medicines and healthcare to the people and will be briefly examined hereafter.

COMPETITION CONCERNS IN THE PHARMACEUTICAL INDUSTRY

In the previous chapter it was reflected how the pharmaceutical industry was affected by a range of market failures and as to how the condition was further exaggerated by the prevalence of anti-competitive practices in the market. In this chapter the researcher focuses on the various violations of competition norms in the pharmaceutical industry.

Intellectual Property Rights Related Anti-competitive practices

Patents by nature impose monopoly rights to pharmaceutical companies and the patent-holder is given the exclusive rights to make, use or sell a product for a specified period. Conferment of such rights to the patent-holder very often leads to effects which are detrimental to the interest of the consumers leading to the abuse of dominance by companies which enjoy such patent rights. These companies price their products at monopolistic profit -maximizing levels and restricting access to affordable and essential medicines.

As far as India was concerned the abuse of monopoly power was easily avoided with India following the process patent regime. However with the advent of product patent regime in 2005 any product entering the market is being marketed by a monopolist .Now with this new regime in action there are chances of abuse of dominance which was almost negligible in the earlier process patent regime.

[15] Ibid.

In this regard it is essential to consider the Novartis case[16] which involved IPR-related issues in the health sector. In this case Novartis filed an application for patenting its cancer drug Gleevac used for the treatment of leukemia which was rejected by the Indian Government[17].Novartis further filed a case at the Madras High Court and challenged this decision of the Indian Government. It is pertinent to mention here that while treatment of leukemia with Gleevac costs around Rs.1,20,000 per month for a patient whereas the treatment of the same with its counterpart generic cost a patient only Rs.8000.The people who supported the decision of the Indian Government have argued that India is a source of cheap medicines and if patent were granted to Novartis then it will lead to a dearth in the availability of affordable medicine in the Indian Market.[18]

In the context of patents and pricing it becomes very important to talk about the grant of exclusive marketing rights (EMRs) [19]in India. Out of the seventeen applications filed for grant of EMR so far, only four have been granted in the pharmaceutical sector to Novartis's Glivec, Wockardt's tropical antibiotic Nadoxin, United Phosphorous' pesticide product Saaf and Eli Lili's Tadalafil.[20] But the conduct in which Novartis exercised these rights gives cause for apprehension with respect to what might be expected in the new patent regime. Novartis' Glivec is used for treatment of Chronic Myeloid Leukaemia ('CML'). There was an increase in the price of the drug from $90 to $2610 after the grant of EMR, which will successfully put the drug out of reach of 24,000 patients in India who suffer from CMLThis

[16] Dea, C.O., (2012) Novartis awaits cancer drug ruling in India [Online] (March, 13) Available at: http://www.swissinfo.ch/eng/business/novartis-awaits-cancer-drug-ruling-in-india/32197530 (Accessed on: 16th October, 2019)

[17] Bennet WJ,(2014), Indian Pharmaceutical Patent Law and the Effects of Novartis Ag v. Union of India [E-Journal] *Washington University Global Studies Law Review* 13(3). Available at: http://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=1500&context=law_globalstudies Pp.535-557. (Accessed on: 22nd October 2019)

[18] Sec 2(m) of the Indian Patent Act

[19] The term EMR means the exclusive marketing rights to sell or distribute the article or substance coverered in a patent or patent application in the country. The purpose of EMRs is to ensure that the innovator can market free copies of his product. To comply with the requirements of TRIPS, pending the transition to a full-fledged product patent regime, provisions relating to exclusive marketing rights in the areas of drugs and agro chemical products were incorporated in the Patents Act, 1970 with cut of date from January 1, 1995. Chapter IVA incorporated the relevant provisions. Section 24 of the Act stipulates that India has to receive applications for patents containing claims for drugs and agro chemical products with the condition that such applications can be taken up for consideration of granting EMR if an application is made.

[20] Centre for Trade and Development. (2010). Competition Law and Indian Pharmaceutical Industry, NEW DELHI, CENTAD. Pp.113-119. See Also: Angell, Marcia, (2005) "The Truth About Drug Companies: How They Deceive US and What to Do About it", New York, Random House. Pp. 56-58. (Centad), New Delhi 2010, *Competition Law and Indian Pharmaceutical Industry*

shows clear abuse of dominance through excessive pricing. It also shows the ramifications of the abolition of the process patent regime. There is another case, which may be noted here. Natco Pharma is now manufacturing a generic version of AstraZeneca's Iressa, which is an anti-cancer drug.[21] The drug priced at Rs 325 per tablet of 250 mg is at 1/10th of the cost of the international brand presently available in the market. It is conceivable that Natco could face a litigation problem as AstraZeneca is considering the drug for EMR and is in consultation with the government agencies to do so. In all likelihood, the price set by Astra Zeneca will be elevated than that at which Natco is presently selling the drug.

MERGERS & ACQUISITIONS

The Indian pharmaceuticals industry at present is highly fragmented. However it is anticipated that in the years to come it will witness intense consolidation activities. In fact, most of the top global pharmaceutical companies are consolidating their market positions, either through product rationalisation, brand acquisitions, or company acquisitions. Sun Pharma, Nicholas Piramal and Dr. Reddy's Labs have opted for brand/company acquisitions to increase their therapeutic extent and market diffusion. Large Indian pharmaceutical companies are also intensifying their reach overseas through acquisitions abroad. Examples include Ranbaxy's acquisition of RPG Aventis; and Wockhardt's acquisition of CP The primary reason which has led the companies to resort to mergers and alliances is the increasing pressure to trim down drug prices .The mega-mergers in the global pharmaceuticals industry, in the last few years, have been Sanofi-Aventis, Glaxo-Wellcome-SmithKline Beecham; Hoechst-Marion-Merrell Dow-Roussel; Pfizer-Warner Lambert; Ciba-Sandoz (to form Novartis); and Hoechst Marion Roussel-Rhone Poulenc (to form Aventis).[22] It is anticipated that the trend is likely to continue and such mega-mergers in the global market are likely to raise competition concerns in several markets, including India. Indian pharmaceutical industry has witnessed quite a few cases of M&A over the last few years, both as a direct fall out of mergers of global players, as well as M&A of domestic players, and in some cases between global and domestic players. Several of these cases involved companies that had medicines that were used for the same therapy and hence were competing directly.

Now the question that arises is how can we say mergers and acquisitions are anti-competitive

[21] CUTS C-CIER, *Supra note 2*
[22] CUTS C-CIER, *Supra note 2* ,

in nature? Mergers are not necessarily anti-competitive and may lead to creation of efficiencies. The trends of mergers and acquisitions in the global pharmaceutical market seem to reveal that for the pharmaceutical industry, these transactions are an appropriate way of counteracting competition and achieving more profitable returns and high market shares. However, the concern is whether the mergers, the acquisitions or the joint ventures will enable parties to achieve or strengthen a dominant position n in the markets in which they compete and whether there will be abuse of dominance leading to higher prices, reduced output or less innovation. In a mega merger case[23] two large pharmaceutical giants merged to become GlaxoSmithKline (or GSK). This merger produced a leading global pharmaceutical company, with sales of £18.1bn in the year 2000. Headquartered in the United Kingdom, GSK supplies products to 140 markets in the world. Evidently, the merger created competition concerns in several countries, yet it went uncontested in most of them. India did not have a merger review provision in its extant competition law, the MRTPA, so the merger was not investigated. In Sri Lanka, the competition authority did not even take up the case of merger between Glaxo Wellcome and SmithKline Beecham, saying that that it did not have jurisdiction, even though both the companies had commercial presence in the country.

The handling of the merger case by South Africa is quite illustrative. Upon investigation and evaluation of the merger, the Competition Commission reached the conclusion that the transaction should be prohibited, on competition and public interest grounds. In particular, the Commission was concerned that the merger would result in the merging parties having high market shares in two therapeutic categories. The Commission stipulated that there would be unacceptable levels of concentration with respect to Bactroban, Zelitrex and Famir, and there were no appropriate substitutes to counter any price gouging, or ease of entry, to offset the concern.

Upon prohibition of the merger by the Commission, the merging parties volunteered to out license some of their products identified, by the Commission, to be the cause of the competition concerns. The merging parties, and the Commission, reached an agreement and the merger was allowed, conditionally. Interestingly, the conclusion of the Commission, in making its recommendations to the Competition Tribunal, was substantially the same as the conclusions of the EC, in so far as the overlap of products was concerned. This may partly be due to the fact that the Commission sought, and received, extensive cooperation from both

[23] Involving Glaxo Wellcome and SmithKline Beecham

the US and EC. However, it may be noted that the Commission completed its investigation long before the case was decided by the EC.

COLLUSIVE PRACTICES IN THE PHARMACEUTICAL INDUSTRY

Collusive practices in the pharmaceutical industries can vary from cartelisation to bid-rigging. Although there haven't been evidence of existence cartels in the Indian Pharma Industry but the existence and operation of the same cannot be denied keeping in mind the fact that India has been a prey to the International Vitamins Cartel for quite some. According to one estimate, this vitamins cartel cost India about US$25mn, in the 1990s, due to overcharging.[24]

Therefore, the subsistence of a tendency towards collusive behaviour in certain segments, where there are just a few manufacturers, cannot be altogether neglected specifically looking into the fact that India has been affected by the Great Global Vitamins Cartel.

PROVIDING INCENTIVES

Often we will find companies giving incentives to doctors and pharmacists which lead to an absolute violation of free and fair competition. This might be motivated by longing to generate a bigger market share or to gain better profits by pushing overpriced drugs and the same is achieved through insistent promotional strategies designed at doctors, and by providing well-paid margins to chemists. In India pharmacists are given incentives to buy large quantities of prescription drugs and thousands of drug manufacturers compete for shelf space, and the country's half-million pharmacists wield an unusual amount of clout.[25]

In a recent study conducted by Interlink Healthcare Consultancy it was found out that all but one of the top 25 drug companies, in India, presented heavy discounting deals at least once a month. A correspondence to pharmacists from Blue Cross Laboratories Ltd, a Mumbai company, outlined agreement that offered pharmacists up to a 103 percent profit margin on assortment of prescription drugs[26]

MISDIAGNOSIS

Certain companies also make assistance of anti-competitive practices to make a market for

[24] CUTS C-CIER, *Supra note 2*
[25] CUTS C-CIER, *Supra note 2*, p. 53
[26] ibid

their products. For example, Novartis, a company that has a large market share in India has been recently accused of fuelling the misdiagnosis of Attention Deficit Disorder (ADD) through its close relationship with psychiatric associations and its presentations at their meetings, and conspiring thereby to shape a niche in the market for Ritalin, their drug for ADD through expanding the use of the drug by being responsible for millions of children being misdiagnosed with ADD.[27]

AVAILABLE LEGAL OPTIONS

There are numerous legal and policy options, which may be utilized to deal with anticompetitive practices in the pharmaceutical industry .These options, are to be considered in light of facilitating access to medicines and healthcare by the poor. Competition law apart, patent law and drug price control are essential for successful eradication of competition violations in the health sector.

Using competition law is an obvious legal remedy to deal with anti-competitive practices in the pharmaceutical, industry. The key element in successfully enforcing the provisions of competition law is building the capacity of the competition agencies.

The three central areas of anti-competitive conduct covered by the Indian Competition Act, 2002, as amended by The Competition (Amendment) Act, 2007, relate to: anti-competitive agreements; abuse of dominance; and combinations – all three of which bestow competition concerns in the pharmaceutical industry and the health delivery system. The specific anti-competitive practices of the pharmaceutical system, covered by the Act are collusive agreements including cartels, tied-selling, exclusive supply agreements, exclusive distribution agreements, refusal to deal, and resale price maintenance.

The Competition Act, 2002, as amended by The Competition (Amendment) Act, 2007 prohibits the abuse of dominance and, therefore, if pharmaceutical companies do engage in overpricing patented products or are unreasonable with respect to licensing terms and so on, the competition law may be resorted to for redressal.

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[27] *See Generally:* Anonymous (2013), *Fraud and the Pharmaceutical Industry*. Available at: http://www.uow.edu.au/~bmartin/dissent/documents/health/pharmfraud.html#Novartis (Accessed on: 22nd December 2019). See Also: Kesselheim A.S., (2010), *Whistle-Blowers' Experiences in Fraud Litigation against Pharmaceutical Companies*, Available at: http://www.nejm.org/doi/full/10.1056/NEJMsr0912039#t=article (Accessed Date: 15th May, 2020)

The Patent (Amendments) Act, 2005 introduces product patents in India, invalidating Section 5 of the Indian Patent Act, which granted only process patents for food, medicines and other drug substances. Under the Patent (Amendments) Act, 2005, monopoly status is awarded to patent-holders. The Indian Patent (Amendment) Act, 2005, also provides compulsory licensing under Section 84 and 90. Generally, three years after a patent is granted (sealed), any interested party can allege that the invention is not reasonably available to the public and can request the grant of a compulsory licence.

Price control is a tool that is used in a situation when maintaining a competitive market is extremely difficult. India has been following a price control regime for pharmaceutical products since the 1960s. However, there has been significant decontrol in this regard since the 1990s, with the effect that prices of many medicines have seen an unprecedented rise. Under the Drug Price Control Order (DPCO) 1995, only 74 drugs are under price control. The DPCO is to be succeeded by the National Pharmaceutical Policy of 2002, which contains several important policy changes.

CONCLUSION AND SUGGESTIONS

Thus, after carrying out this study we try to look for some strategies which can be used for the elimination of anti-competitive practices from Indian pharmaceuticals industry. The healthcare market suffers from a peculiar feature which is invisible in other industrial sectors and which is particularly exclusive to the pharmaceuticals. If a patient needs emergency healthcare services then he lands up at the nearest hospital leaving him completely at the hands of that particular hospital and the doctors available therein. In such a case the authorities have all the discretion as to what kind of treatment is to be given, what type of diagnostics tests are to be carried on and what type of medication is to be given to them. Now in such a case the hospitals might take and advantage of such a position and thus leading to financial exploitation of the ignorant patients who have submitted themselves at the mercy of such authorities. Thus it would be better to promote competitive results and efficiency rather than promoting competition *per se*. After carrying out a study on the prevalence of anti-competitive practices in the Indian Pharmaceuticals the researcher has come to the following conclusion and suggestion:

- *Generics have to be promoted:* The doctors often indulge in accepting incentives from pharmaceutical companies and help the companies in selling their products

which are often more expensive than the other alternatives available in the market and this is a gross violation of the competition principle of "best possible goods and services at the least possible prices". This primarily happens due to the existence of the traditional system of drugs by prescription. In order that the consumers avail of the "best possible goods and services at the least possible prices" it is essential to break the nexus between doctors and companies and to further promote the use of generics. This promotion may be done by de-branding prescriptions for essential generic medicine.

- *IPR Related issues need to be dealt efficaciously:* One very effective method for the elimination of IPR related anti-competitive practices from the pharmaceutical industry is compulsory licensing. Compulsory licensing can prove to be the most efficacious to deal with the abuse of monopoly rights by the pharmaceutical companies. It is suggested that it would be more apt to give the competition authority the responsibility of granting compulsory licences in consultation with the patent office, rather than doing it the other way around. , Bureaucratic delays in the grant of compulsory license have to be eliminated .In this regard India may look up to the policies of other countries such as Canada, France and the UK.

  The IPR related agreements have been exempted in the Indian Competition Act, 2002, as amended by The Competition (Amendment) Act, 2007, even if they contain anti-competitive provisions which are reasonable, without defining what is reasonable. This will create confusion. Moreover, some of the provisions can be purely anti-competitive and cannot be justified in the interests of promoting innovation and hence should not be exempted even with a rider of reasonableness. Subjects like abuse of dominant positions relating to IPRs like monopoly pricing, exclusive dealing, tied sales, restrictions on end users, etc have altogether been exempted from the Indian Competition Act, 2002, as amended by The Competition (Amendment) Act, 2007.

- *Presence of Collusive Activities needs to be scrutinized:* Collusive activities among Indian manufacturers of pharmaceuticals have not yet been discovered. However, their pervasiveness cannot be ruled out. Pharmacies engage in collusive practices in India to ensure higher trade margins. The government has created deterrence mechanisms, though these have limitations and need to be re-examined. There exists a strong need to eliminate collusive practices by pharmacies to ensure growth of the

industry, including that of ensuring a fair deal for consumers.

- *Health Insurance:* The most significant way for the elimination of anti-competitive practices from the Indian Pharmaceuticals is the pervasive introduction and assimilation of health insurance services. The most evil effect of almost all anti-competitive practices in the health sector is the ensuing hike in the prices of medicines and health services therefore the best thing that can be done in these circumstances is insurance and thus shifting the financial burden on the insurance companies which may be private or public or PPP. More awareness needs to be spread about insurance facilities which can be availed by the consumers.
- *Creating Awareness:* The Central Government, State Governments, and all interested non-governmental organisations (NGOs) need to be drawn in creating awareness. The Clinical Establishments (Registration and Regulation Bill), 2007, has been introduced in the Indian Parliament, which proposes for the creation of a National Council for Regulation and Standardisation of Clinical Establishments. Once enacted, it can change the scenario relating to availability, accessibility, quality of service provided in the Indian health sector.