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The Interplay between Competition Law and Intellectual Property Rights in the Indian Healthcare Sector

Murali Neelakantan

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There has been very little research published on the effect of brands, design, and trade dress on extension of patent monopolies. This paper explores how brand names, design, and trade dress have the effect of creating barriers to competition in the Indian healthcare market. Another consequence of the combination of brands and patents is the compliance risk for doctors to whom these drugs are being marketed. The paper concludes with some recommendations to address these issues and a call for deeper research into the Indian healthcare market, primarily from a competition law standpoint.

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[*] Founder, amicus (formerly Global General Counsel, Cipla Ltd.); B.A., LL.B. (Hons.), National Law School of India University (1996). This paper would not have been possible without research assistance from Suvajit Chakraborty and Anupama Konteti, former colleagues at Cipla Limited, and Dr. Swaraj Barooah of SpicyIP who helped with valuable feedback on an early draft of this paper.

Introduction

Competition law advocates the necessity for free markets, detests monopolies, and aspires to create a perfectly competitive playground that benefits consumer choice. It aims to create an ecosystem oriented towards consumer rights, free trade, and efficient resource allocation. Intellectual property legislation, in essence, creates monopolies. There is therefore a dichotomy between Intellectual Property Rights ("IPR") and competition policy. The former endangers competition and the latter engenders competition.[1] This paper is focused on certain activities of players in the Indian healthcare sector which highlight the conflict between IPR and competition law. While there is a good basis for looking to the rest of the world to understand certain fundamental aspects of IPR and competition law, the Indian healthcare sector operates in a completely different manner from that in the US and Europe, and we should therefore be sceptical of applying the jurisprudence from those jurisdictions to identify and address India's problems.

I. Historical Tension between IPR and Competition Law Continues

The discussion on the interplay between patents and competition law is not recent.

> "The granting [of] patents 'inflames cupidity', excites fraud, stimulates men to run after schemes that may enable them to levy a tax on the public, begets disputes and quarrels betwixt inventors, provokes endless lawsuits...The principle of the law from which such consequences flow cannot be just. The Economist may have put it rather strongly in 1851, but its disapproval of patents represented conventional wisdom at the time. A century earlier, Adam Smith had described them as necessary evils, to be handed out sparingly, and many other economists have since echoed his reservations. Patents amount to temporary monopolies on useful new inventions."[2]

More recently, after the Singapore Ministerial Declaration of 1996,[3] a Working Group on the Interaction between Trade and Competition Policy

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[1] Report of High Level Committee on Competition Policy & Law – Raghavan Committee (Government of India, 2000), available at https://theindiancompetitionlaw.files.wordpress.com/2013/02/report_of_high_level_committee_on_competition_policy_law_svs_raghavan_committee.pdf [hereinafter "Raghavan Committee"].

[2] *Patent Sense*, The Economist, (October 20, 2005), available at http://www.economist.com/node/5015083.

[3] World Trade Organisation, Ministerial Declaration of 13 December 1996, WT/MIN(96)/16 (Dec. 13, 1996) available at http://www.wto.org/english/thewto_e/minist_e/

was created in 1997. This working group discussed competition-related provisions of all existing World Trade Organisation ("WTO") agreements. On the subject of the relation between IPR and competition policy, the view was expressed that the system of protecting technology through IPR could stimulate research and development ("R&D"). However, members were directed to consider the introduction of rules that could control anti-competitive practices related to the use of IPR.[4] The Parliamentary Standing Committee stated that all forms of IPR have the potential to raise competition policy issues.

> "Intellectual Property provides exclusive rights to the holders to perform a productive or commercial activity, but this does not include the right to exert restrictive or monopoly power in a market or society. Undoubtedly, it is desirable that in the interest of human creativity, which needs to be encouraged and rewarded, intellectual property rights need to be provided. This right enables the holder (creator) to prevent others from using his/her inventions, designs or other creations. But at the same time, there is a need to curb and prevent anti-competition behaviour that may surface in the exercise of the intellectual property rights."[5]

During the exercise of a right, if any anti-competitive trade practice or conduct is visible to the detriment of consumer interest or public interest, it ought to be assailed under the competition policy/law.[6] Despite this, when the Competition Act was drafted, this conflict between IPR and competition law was, arguably, not addressed in a comprehensive manner. On the other hand, it may be contended that the omission of exclusions for IPR was deliberate and the only intended protection was clearly set out in Section 3 of the Competition Act, 2002.

II. Indian Competition Act and its Uncertain Interplay with IPR

As one pharma industry expert lamented, "*owing to the blanket exemption under Section 3(5), the square peg of any anti-competitive practise tethered*

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min96_e/min96_e.htm.

4 World Trade Organisation, *Report of the Working Group on the Interaction between Trade and Competition Policy to the General Council* (WT/WGTCP/4, Nov. 30, 2000).

5 Department-Related Parliamentary Standing Committee on Home Affairs, Ninety-Third Report on the Competition Bill, 2001 available at http://www.prsindia.org/uploads/media/1167471748/bill73_2007050873_Standing_Committee_Report_on_Competition_Bill__2001.pdf (Last visited on Jun. 25, 2015).

6 Raghavan Committee, *supra* note 1.

to the use of IPRs must now be brought through the round hole of "abuse of dominant position" under Section 4."[7] While one can sympathise with the emotion, this is perhaps a very narrow and cynical view since the exemption for IPR from the application of Section 3 applies only to agreements. It is a common misconception that IPR has a blanket exemption from all the provisions of the Competition Act. "*Thus, if there is an instance of an abuse of dominant position enjoyed by an IPR holder, the Competition Commission of India ("CCI") would have jurisdiction to inquire into such abuse.*"[8] Exclusions from the applicability of Section 3 have been provided to persons seeking to protect their intellectual property rights as well as agreements for the export of goods. However, the CCI would still be empowered to look into the reasonableness of the restraint while exercising intellectual property rights.[9]

The relationship between IPR and competition policy has been complex and widely debated, and various models exist in different countries to address potential conflicts.[10] The complexity of IPR has deepened since the adoption of legislative reforms in many developing countries as a part of their commitment under the WTO Agreement on Trade Related Intellectual Property Rights ("TRIPS") in 1995. While the importance of IPR in stimulating inventions is widely advocated, by providing legal monopoly it also raises competition concerns, and in certain areas like food and healthcare, it is widely believed that diffusion of intellectual property should have precedence over an incentive to invent.[11] It is noticeable that the discussion about IPR and competition law has remained focussed on patents[12] with very little thought about how other IPR like copyright, trademarks and design can give rise to competition law issues. This paper is an attempt to look at how

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7 Debolina Partap, *Intellectual Competition*, 5(9) LEGAL ERA (November 2014).

8 Vinod Dall, *Injunctions Sought By SEP Holders – Abuse of Dominance or Protection of IPRs?*, 5(9) LEGAL ERA (Nov. 2014).

9 Government of India Report on Competition Policy (Planning Commission, 2007), available at http://planningcommission.nic.in/aboutus/committee/wrkgrp11/wg11_cpolicy.pdf [hereinafter "Planning Commission"].

10 Remedies for abuse of IPR could exist in IPR legislation and/or in competition law. In the United Kingdom, competition law issues are addressed by the Office of Fair Trading but also by specific industry regulators like Ofcom for the telecoms and broadcasting sector, Ofwat for the water industry and Ofgem for the electricity sector. In the United States, it is the Department of Justice, the Federal Trade Commission and even the State Attorney General.

11 This is evidenced in the Doha Declaration which seeks to explain and elaborate on the nexus between IPR and national interest. *See* World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001 (WT/MIN(01)/DEC/W/2), available at http://www.who.int/medicines/areas/policy/doha_declaration/en/.

12 Raghavan Committee, *supra* note 1; Planning Commission, *supra* note 9.

the Indian healthcare industry uses IPR, and to identify the competition law issues that arise from it.

III. Are IPR Statutes Self-Contained Codes and Immune from Competition Law?

We have recently noticed a move by IPR owners to resist the application of Indian competition law to IPR[13] on the ground that each IPR statute is a "*self-contained code*" and competition law may not be the appropriate remedy for a right created by each of them.[14] The Supreme Court of India has discussed the term 'self-contained code' in several judgments and held that the following conditions need to be established for a self-contained code:

1. It is a complete legislation for the purpose for which it was enacted;[15]
2. It provides for all possible situations that may arise in relation to that purpose;[16]
3. It contains an adjudicatory machinery;[17]
4. It provides for an appeal;[18]

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[13] Micromax Informatics Ltd., In re, [2013] CCI 77; the suit was filed in relation to refusal by Ericsson to license standard essential patents for GSM technology to Micromax. The CCI rejected this contention and directed the Director General to commence investigation. Ericsson appealed this CCI order and the Delhi High Court granted an interim injunction against the investigation.

[14] *See infra* note 58 for examples. The United States uses antitrust legislation as the basis for measures like compulsory licenses to address patent abuse. *See*, for example, Federal Trade Commission order in Intel Corporation, FTC Docket no. 9288, Final Agency Decision (Mar. 24, 1999), and notification by the Department of Justice in the case of *United States* v. *A.K. Steel Corpn.*, E.D. Mich. 15-cv-11804. For more examples, *see*, James Love & Michael Palmedo, *Examples of Compulsory Licensing of Intellectual Property in the United States*, CPTech Background paper 1 (Sep. 2001), available at http://www.cptech.org/ip/health/cl/us-cl.html. It may well be argued that compulsory licenses and other remedies for abuse of a patent are contained in the Patent Act thereby excluding other legislation from providing measures to counter abuse of IPR. *See supra* note14.

[15] Offshore Holdings (P) Ltd. v. Bangalore Development Authority, (2011) 4 Bom CR 212; Bondu Ramaswamy v. Bangalore Development Authority, (2010) 7 SCC 129.

[16] Offshore Holdings (P) Ltd. v. Bangalore Development Authority, (2011) 4 Bom CR 212; Bondu Ramaswamy v. Bangalore Development Authority, (2010) 7 SCC 129.

[17] The Patent Office can revoke a patent under a post-grant opposition. Similarly the High Court and the IPAB have specific powers of revocation. *See Girnar Traders* v. *State of Maharashtra*, (2004) 8 SCC 505.

[18] *See* for example, S. 115 of the Patents Act, No. 39, Acts of Parliament, 1970 (India) [hereinafter "Patents Act 1970"]; S. 91 of the Trade Marks Act, No. 47, Acts of Parliament, 1999 (India) [hereinafter "Trade Marks Act 1999"]; and S. 36 of the Designs Act 2000, No. 16, Acts of Parliament, 2000 (India) [hereinafter "Designs Act 2000"]. *See also Girnar Traders* v. *State of Maharashtra*, (2004) 8 SCC 505.

5. It contains provisions for offences;[19]
6. It contains comprehensive provisions pertaining to investigation,[20] inquiry, and trial for offences;[21] and
7. It gives power to duly authorized officers to search, recover and arrest, and record statements of witnesses.[22]

The literal meaning of a self-contained code is a law that is complete and exhaustive. While some of the criteria set out by the Supreme Court of India are met by various provisions of India's IPR laws, it is clear that the Patents Act, 1970, the Trade Marks Act, 1999 and the Designs Act, 2000 have not fulfilled all the conditions set out above. Such legislation, though dealing with the creation and maintenance of IP rights, fails to tackle the existence of such rights in the market, where they must co-exist with other rights and the economics of supply and demand.[23]

There is no common theme that runs through all IPR legislation and despite being conceptualised, practiced, and taught as one subject, they have fundamental differences in the jurisprudential and economic basis for their existence and how they are meant to work. For example, if a patent is not worked, the Government can force the patent holder to license it.[24] While a similar provision exists in the Copyright Act,[25] no corresponding provisions exist in the Designs Act. Similarly, if a trademark is not used, its registration lapses[26] but that does not prevent its continued use.

If the IPR laws do not exclude the application of competition law, does the Competition Act, as some apprehend,[27] provide immunity to IPR from com-

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[19] CBI v. State of Rajasthan, (1996) 9 SCC 735.

[20] *See* for example, S. 13, Patents Act, 1970.

[21] *CBI* v. *State of Rajasthan*, (1996) 9 SCC 735. *See* for example, Ss. 123, 124, Patents Act, 1970; Chapter XII, Trade Marks Act, 1999.

[22] CBI v. State of Rajasthan, (1996) 9 SCC 735; Moti Lal v. CBI, (2002) 4 SCC 713 : (2002) 2 ACR 1192 (SC). See for example, S. 115(4), Trade Marks Act, 1999.

[23] One could argue that S. 84 of the Patents Act, 1970 providing a simplified procedure for issuing a compulsory license if the patentee indulges in anti-competitive practices specifically allowing a competition law test refutes this. This is also supported by S. 62 of the Competition Act, No. 12, Acts of Parliament, 2002 (India) [hereinafter "Competition Act 2002"] which specifically states that the remedies provided in the Competition Act are in addition to other laws and remedies. On the other hand, those who advocate the "*self contained code*" theory could argue that by making specific reference to competition law in just one provision, the Patents Act, by deliberate omission, excludes the application of competition law except in S. 84.

[24] S. 85, Patents Act, 1970.

[25] S. 31, Copyright Act, No. 14, Acts of Parliament, 1957 (India) [hereinafter "Copyright Act, 1957"].

[26] S. 47, Trade Marks Act, 1999.

[27] *See* Debolina Partap, *supra* note 7.

petition law? The working group[28] discussed examples of anti-competitive behavior indicating to us that it was contemplated that IPR does have an inherent quality of adversely affecting a competitive market or distorting competition in a market.

A patent cross-licensing agreement that included mutual restrictions on the pricing and output of the patented product, and substantially lessened competition in the market for this product, would constitute an unreasonable restraint of trade (as any other agreement fixing prices and limiting output) and would therefore be illegal under competition law. Similarly, bundling, predatory pricing, and other similar unfair trade practices should be investigated where there is a dominance caused by a patent or other IPR. There are other examples in real life[29] that remind us that this possibility is real and not just the imagination of the working group and academics.

IV. Market is the Starting Point for a Competition Law Analysis

The Competition Act requires that the relevant market be identified in terms of (*a*) relevant geographical market;[30] and (*b*) relevant product market.[31] A relevant product market is assessed on the basis of the following factors:

(*a*) Physical characteristics or end-use of goods;

(*b*) Price of goods or services;

(*c*) Consumer preferences;

(*d*) Exclusion of in-house production;

(*e*) Existence of specialised producers; and

(*f*) Classification of industrial products.[32]

A. Physical Characteristics or End-use of the Goods

Aerospatiale, a French company active in the aerospace sector had a product range that included civil and military aircraft and helicopters, missiles, satellites, space systems and avionics. Alenia was an Italian company also predominantly active in the aerospace sector. Its product range included

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[28] World Trade Organisation, *Report of the Working Group on the Interaction between Trade and Competition Policy to the General Council* (WT/WGTCP/4, Nov. 30, 2000).

[29] *See AZ*, *infra* note 54 and *Actavis*, *infra* note 58.

[30] S. 2(s), Competition Act, 2002.

[31] S. 2(t), Competition Act, 2002.

[32] S. 19(7), Competition Act, 2002.

civil and military aircraft, satellites, space systems, avionics, and air and maritime traffic control systems. A concentrative joint venture within the meaning of Article 3 of the European Commission's Merger Regulation was notified. In determining the 'relevant market', the EC decided that aircrafts which have less than 20 seats, 20 - 39 seats, 40 - 59 seats and 60 or more seats are subject to different type certification standards. The certification security requirements such as crash-worthiness, systems reliability, fatigue resistance, damage tolerance and heat release of cabin materials in case of fire differ greatly. It was held that a 60-seat commuter is not interchangeable or substitutable with a 30-seat commuter. Both are used on routes with a significantly different density and their prices vary significantly. The segmentation was made on the basis of physical characteristics, nature and end use of the products.[33]

In *Cellophane*[34] case, the decisions of the Delaware District Court in 1953 and the U.S. Supreme Court in 1956 seemed to attract much comment. The case was about whether Du Pont exercised market power over cellophane. The courts found that cellophane was in a market with other flexible wrapping materials. More specifically the Supreme Court found that there existed a substantial cross-elasticity between cellophane and other flexible wrappings, and that cellophane and these other wrappings had reasonable interchangeability. This seemed to suggest that if two products are not interchangeable or substitutable because of their physical characteristics, they do not compete in the same relevant market.

B. Price of Goods or Services

The Indian automobile industry has major vehicle segments according to the brand and the market positioning of vehicles in different regions. The premium segment (representing highest prices and margins) comprises 10% of the market. The value segment is the mid-price range; this comprises the vast majority of vehicles sold in all markets (70%). The entry segment refers to the least expensive vehicles in the different vehicle classes, making up the other 20%.[35] Creating such differentiation is vital to maintaining a premium perception. Inside the car, premium Original Equipment Manufacturers

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[33] Case No. IV/M053 – Aerospatiale-Alenia/de Havilland, Council Regulation (EEC) No. 4064/89.

[34] United States v. E.I. Du Pont De Nemours & Co., 118 F Supp 41-233; United States v. E.I. Du Pont De Nemours & Co., 100 L Ed 1264 : 351 US 377 (1956).

[35] Mohr, D., N. Müller, and A. Krieg, *The road to 2020 and beyond: What's driving the global automotive industry?* (McKinsey & Company, 2013), available at http://www.mckinsey.com/~/media/McKinsey/dotcom/client_service/Automotive%20and%20Assembly/PDFs/McK_The_road_to_2020_and_beyond.ashx.

could differentiate themselves with the help of design elements, new features in infotainment, and innovations directed at safety and comfort.[36] Even a specific segment in the automobile sector is clearly bifurcated. The electric vehicles category, for example, can be further divided in four types: battery electric vehicles, plug-in hybrids, range extenders and fuel cell vehicles. On the other hand, non-rechargeable Full Hybrid Electric Vehicles tend to belong to the segment of vehicles with internal combustion engines where they play a role in improvement of fuel economy.[37]

Therefore, if a customer wishes to purchase a car, he would normally be interested in one of the distinct segments. For a customer interested in purchasing a Maruti 800, a Maruti Alto or a Tata Nano would be a likely option. It is unlikely that a Bentley would be a viable alternative. Interchangeability of products is therefore primarily based on the price, which may be a proxy for the various features of the product segment and consequently, the market. As a result, products that have a vast price difference do not usually comprise the same relevant market as they are not viable substitutes.

In *Belaire*[38], the Commission stated that there is a distinction between "*high-end*" and "*economy*" or "*low-end*" residential units. "*High end*" is a complex mix of factors such as size, reputation of the location, characteristics of neighbours, quality of construction inter alia. Residential accommodation for Lower Income Group, Middle Income Group and Higher Income Group are standard descriptions adopted by several public sector builders such as Delhi Development Authority and Ghaziabad Development Authority.

> "Apart from the physical attributes, these categorizations also take into account the income or expenditure levels of the customer base. Together, these factors create a distinctly identifiable residential unit that is not substitutable in an economic sense. In other words, a small but significant non-transitional increase in price of a unit in one category [termed SSNIP test often applied in abuse of dominance cases] would not make the customer shift to another category. A 5% increase in the price of a villa would not make the intending customer choose a multi-storey apartment. The purchase may be deferred briefly or the choice may shift to a slightly less comfortable villa but a person who

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[36] *Ibid.*

[37] *See* Heike Proff and Dominik Kilian, *Competitiveness of the EU Automotive Industry in Electric Vehicles: Final Report* (University of Duisburg-Essen, Dec. 19, 2012), available at http://ec.europa.eu/enterprise/sectors/automotive/files/projects/report-duisburg-essen-electric-vehicles_en.pdf.

[38] Belaire Owners' Assn. v. DLF Ltd., (2011) 104 CLA 398 (CCI).

> has made a final consumer choice of preferring a villa for the reasons of family size, need for privacy, demonstration effect etc. would not switch to an apartment for a small increase in price."[39]

In this case, prices create a clearly segmented market. Hence, the Commission was able to identify Belair Housing as high-end housing. For the consumer of such a market, a marginal change in price will not affect his shift to a different category of housing. Hence, due to its inherent quality of not being substitutable with a different category of housing, "*high end*" housing forms its own relevant market. A similar, neatly segmented market is the mobile phone market where price is a distinguishing factor. For an iPhone user, the only likely substitutes would be a high end Android phone. An iPhone user is very unlikely to consider a phone which sells at an 80% discount.

> "It is sometimes argued that two products cannot be reasonably substitutable if they have substantially different prices. Price differences have therefore been used to distinguish between products which may be 'functionally substitutable,' but are not 'substitutable' from a competition assessment perspective. Therefore, defining relevant market solely on the basis of differences in price will be flawed if price differences reflect quality differences (actual or perceived). When such quality differences appear, defining relevant market merely on the basis of absolute price levels, will ignore the possibility of consumers making a trade-off between price and quality. (sic)"[40]

It now seems that price is not the definitive criterion for establishing a relevant market. There are also non-price factors that are considered when a customer buys products. This is particularly significant when we discuss pharmaceutical products and healthcare services where customer choice is very limited because the decision making process for these is complex, with the doctor, pharmacist, and often the hospital,[41] exerting significant influence and excluding competing drugs that are qualitative substitutes. It may

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[39] Geeta Gouri, *Making Markets Work Effectively in India, Experience of the Competition Commission*, (Competition Commission of India), available at http://www.cci.gov.in/images/media/speeches/DrGG.pdf.

[40] Ramakant Kini v. L.H. Hiranandani Hospital, 2014 Comp LR 263 (CCI).

[41] Hospital chains often have pharmacies on their premises and patients are forced to buy drugs and other medical supplies from these "*in house*" pharmacies. Patients are not allowed to buy in drugs or other supplies from external sources. *See* Snehlata Shrivastav, *Hospitals Force Patients to Buy From In-House Pharmacies*, Times of India (Apr. 24, 2015), available at http://timesofindia.indiatimes.com/city/nagpur/Hospitals-force-patients-to-buy-from-in-house-pharmacies/articleshow/47032880.cms.

well be time for the application of the rationale in *Hiranandani*[42] to sales of drugs and other consumables in hospitals to conclude that each hospital and its "*in-house*" pharmacy is effectively a monopolistic market for patients who have no choice of products.

C. Consumer Preferences

In *Belaire*, the Commission cited the example of a consumer who intends to purchase a villa. For such a consumer, the independence, space and privacy are factors in purchasing a place of residence. While consumer preferences, social tastes, and behavioural trends of individuals could govern the demand elasticity of a product, they are relevant only where there is a legitimate choice to make. As seen in *Chemistree, Actavis, AZ* and *Hiranandani*, IPR in the healthcare sector by its very nature may well be monopolistic and may not, give the consumer a choice within that relevant market.

D. Existence of Specialized Producers

Where the producer is required to have highly sophisticated machinery to manufacture the product, or manufacturing techniques are protected as IPR, or that sector has high sunk costs, barriers to entry and competition are high and viable substitutes may well be extremely limited. This is a feature of the pharmaceutical sector where multinational pharmaceutical companies have focussed on certain therapies, creating an oligopoly of sorts.[43]

E. Classification of Products

In the pharmaceutical sector, an important distinction must be drawn between a molecule comprising its own market, and an entire therapy area. In the case of Kaletra, the manner of identifying the relevant market determined that AbbVie did not hold a dominant position and there were several competing products in the same market as Kaletra. A simple example could be of acetylsalicylic acid, more commonly known as Aspirin, an analgesic.

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[42] *Supra* note 40. Surprisingly, the Competition Commission of India had previously held in *Consumers Guidance Society* v. *Hindustan Coca Cola Beverages (P) Ltd.*, [2011] CCI 25 that a multiplex chain that served only one brand of beverages was not a relevant market even though customers could neither bring their own beverages nor leave during a show to buy beverages from outside. No mention is made of this case in the CCI's order in *Ramakant Kini* v. *L.H. Hiranandani Hospital*, 2014 Comp LR 263 (CCI).

[43] *See Evaluate Pharma World Preview 2014 Outlook to 2020,* Evaluate Group (Jun. 1 2014), available at info.evaluategroup.com/rs/evaluatepharmaltd/images/EP240614.pdf, on the projected market share of pharmaceutical companies in the global oncology market, the fastest growing of all therapies. Roche had a market share in 2013 of 34.3%, followed by Novartis with 10.8% and the top 10 companies had a market share of almost 78%.

If these are the only facts, then Aspirin has several well-known substitutes such as paracetamol and ibuprofen. However, if Aspirin is prescribed to help prevent unwanted blood clots from forming within the body, then its substitute may be clopidropel.[44]

The Anatomical Therapeutic Chemical Classification System with Defined Daily Doses ("ATC/DDD") is used for the classification of active ingredients of drugs according to the organ or system on which they act, and their therapeutic, pharmacological and chemical properties. It is controlled by the World Health Organization Collaborating Centre for Drug Statistics Methodology ("WHOCC"), and was first published in 1976.[45] The Competition Commission of India was of the view that "*in generics markets, competition primarily takes place between different brands based on the same molecule. Accordingly, it is appropriate to define the relevant product market at the molecule level,* i.e.*, medicines/formulations based on the same API may be considered to constitute a separate relevant product market*."[46] The CCI relied on sales data provided by the All India Association of Chemists and Druggists, a national body representing most of the retail chemists, and ignored the sales to millions of patients who are treated by hospital chains who procure directly from manufacturers, public sector undertakings, railways and defense services, all of whom provide free healthcare but procure drugs either directly from manufacturers or their selling agents. The CCI also ignored substitutes for a drug which may comprise other molecules which may be effective in the treatment of the same disease or indication – for example, paracetamol and ibuprofen for Aspirin. In the case of *Actavis*, the decision to grant an injunction was based on the monopoly of a single patented molecule dominating a market.[47]

In the United Kingdom, the approach of the Office of Fair Trading to market definition is provided in the competition law guideline market definition which follows a similar approach to that of the European Commission ("EC"). In order to establish which products or geographic areas are included

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[44] *See infra* note 74.

[45] History, WHO Collaborating Centre for Drug Statistics Methodology (Nov. 19, 2011), available at http://www.whocc.no/atc_ddd_methodology/history/.

[46] CCI Order in the matter of the combination of Sun and Ranbaxy, Combination Registration No. C-2014/05/170, ¶ 14 (Dec. 05, 2014), available at http://www.cci.gov.in/May2011/OrderOfCommission/CombinationOrders/C-2014-05-170.pdf. For an example of an ATC-3 therapeutic classification like antiepileptics, *see* Case No COMP/M.4402-UCB/Schwarz Pharma, available at http://ec.europa.eu/competition/mergers/cases/decisions/m4402_20061121_20310_en.pdf. *See also* Case No. COMP/M.7275- Novartis/GlaxoSmithKline Oncology Business, available at http://ec.europa.eu/competition/mergers/cases/decisions/m7275_20150128_20212_4158734_EN.pdf. Here, treatment of ovarian cancer was held to be a relevant market.

[47] *See infra* note 59.

in the relevant market, a conceptual framework known as the hypothetical monopolist test is usually employed.[48] Products are differentiated into different markets primarily on the basis of the relevant product market and the relevant geographical market.

In the United States, market definition focuses on demand-side substitutability, and supply-side substitutability is considered later when the regulator examines existing and potential participants in the market and barriers to entry. Demand-side substitutability focuses on customers' willingness and ability to substitute other products for the products in question. Supply-side substitutability focuses on other firms' willingness and abilities to defeat an attempted price increase by shifting production from one product to the product in question. In contrast to the United States, the EC considers both demand-side and supply-side substitutability when defining the relevant product and geographic markets. It is unclear if the two approaches lead to different results.[49]

V. Competition Law Remedies for Abuse of Patent Monopoly

The Court of Justice of the European Union ("CJEU") upheld the judgment of the General Court, which found that AstraZeneca ("AZ") had abused its dominant position by misleading patent offices and misusing the patent system in order to prevent generic competition against its anti-ulcer medicine, Losec.[50] The EC had established that AZ had provided misleading information to several national patent offices[51] in the EU, resulting in AZ gaining extended patent protection for Losec, and that it had selectively deregistered market authorizations[52] for Losec capsules in certain member

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[48] The Office of Fair Trading Competition Law Guideline on the Definition of Market, S.I. 2004 (OFT403), available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284423/oft403.pdf.

[49] Mark Jamison, *Defining Relevant Markets in Evolving Industries* (University of Florida, Department of Economics, Public Utility Research Center, Working Paper, 2014), available at http://warrington.ufl.edu/centers/purc/purcdocs/papers/1317_Jamison_Defining%20Relevant%20Markets%20in%20Evolving%20Industries%20Final.pdf.

[50] Case T-321/05 AstraZeneca v. Commission, 2010 ECR II-2805: MEMO/10/294. This action in competition law perhaps provided a more effective remedy than revoking the patent under the Patent Act which may well have been at the end of its term.

[51] The Patent Act would have, at best, allowed revocation of the patent, which may not be an effective sanction if the patent term had expired.

[52] The drug regulatory system in India works differently from that of the EU and it may well be argued that it may not have been possible for AZ to do what it did here. However, in *Roche* v. *Mylan & Biocon* (Delhi High Court, 2014), it was argued that the clinical trial data submitted by Roche should not be shared with Roche's competitors even though this is the only way that generics can show equivalence with the innovator product to comply

states, in violation of Article 102 of the Treaty on the Functioning of the European Union. In doing so, AZ raised barriers of entry for generic players, as they could no longer rely on AZ's clinical trial data on the original capsule version.[53] The EC imposed a fine of €60 million on AZ for abusing its dominant position. The CJEU held that as under Article 102, an undertaking that holds a dominant position has a special responsibility and cannot use regulatory procedures to prevent entry of competitors in the market. The General Court upheld the EC's decision but reduced the fine to €52.5 million.[54] The CJEU dismissed AZ's appeal.[55] The EC in the EU and the Federal Trade Commission in the US are currently challenging settlement agreements involving 'pay-for-delay', and reverse payment arrangements whereby patent holders pay generic companies to delay or impede the market entry of competing products.[56]

Switching patients from a successful branded product to its next-generation, patent-protected offspring before the onslaught of generics is a crucial tactic in what is often referred to as "*managing the lifecycle of a drug.*" The most common choices for oral solid dosage forms *i.e.*, pills, are modified-release systems (delayed, pulsatile, and extended), fast-dissolving tablets, and bioavailability enhancement technology to improve the onset of action, minimise a fed/fasted effect, or increase overall drug absorption. Two examples of successful dose frequency changes include Merck's Fosamax and Lilly's Prozac which went from daily therapies to weekly medicines for certain well-managed patients. In the extended-release area, GlaxoSmithKline's antidepressant Wellbutrin SR, Pfizer's Procardia XL, Abbott's antibiotic Biaxin XL Filmtab, Biovail's Cardizem LA, and Sanofi-Aventis'Ambien CR are a few of many such formulation changes designed to sidestep generics

with drug regulation. It may be argued that Roche seeking an injunction is itself anti-competitive, based on *AstraZeneca* and the decision of the EU in *Apple* v. *Motorola Mobility* (European Commission Press Release regarding decision on anti-competitive use of standard essential patents by seeking and enforcing injunctions Docket No.IP/14/489 (Apr. 29, 2014), available at http://europa.eu/rapid/press-release_IP-14-489_en.htm).

[53] European Commission Press Release, Antitrust: Commission finds that Motorola Mobility infringed competition rules by misusing standard essential patents (Apr. 29 2014), available at http://europa.eu/rapid/press-release_IP-14-489_en.htm.

[54] *See* AstraZeneca, *supra* note 51.

[55] Case C-457/10 P, AstraZeneca AB and AstraZeneca plc v. European Commission (Dec. 6, 2012).

[56] The lack of a formal patent linkage in India makes it unlikely that this situation should arise. However, a new drug (whether or not patented) introduced in India has a three-year head start since a generic will not be able to introduce a competitive drug during that time. Together with courts being liberal in granting interim injunctions to patent holders, it could be argued that there is *de facto* patent linkage in India.

competition by offering the promise of "*improved patient compliance and convenience*."[57]

However, in an ongoing US case,[58] Actavis was directed to halt plans to pull Namenda, its Alzheimer's drug off the market. Alzheimer's disease is currently treated by five drugs; all the drugs except Namenda are acetylcholinesterase inhibitors ("CI") and work in the same basic manner. Namenda is the brand name for memantine, an N-Methyl D-Aspartate ("NMDA") receptor antagonist and works differently from CIs.[59] The CEO of Actavis made a public statement to analysts that the core of the brand strategy with the new extended release ("XR") version was to convert the existing business to Namenda XR as fast as possible to protect Namenda revenue from generic penetration in 2015 when patent exclusivity expires. "*If we do the hard switch and we convert the patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back*."[60] The judge relied on this statement to establish intent and stated that while the mere possession of monopoly power is not unlawful, monopolists cannot run their businesses in an anti-competitive manner. The purpose of the hard switch was anticompetitive: to put barriers and obstacles in the path of producers of generic memantine and thereby protect Namenda's revenues from a precipitous decline following generic entry.

Although Section 3(5) of the Competition Act provides protection from competition law for enforcement of IPR, it should not be construed to mean that all actions permitted by IPR laws are immune to scrutiny under the Competition Act. In *Chemistree Homecare Ltd.* ("Chemistree") v. *AbbVie Ltd.* ("AbbVie"),[61] AbbVie supplied its HIV therapy drug Kaletra directly to hospitals, without the use of wholesalers. In addition, AbbVie also supplied the medicine to Chemistree to enable Chemistree to provide home-care services to patients treated in the clinics covered by the London HIV consortium. On Chemistree's orders increasing three-fold, AbbVie asked

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[57] *See Dealing with the Generic Threat*, PHARMAFILE (Sep. 15, 2005), available athttp://www.pharmafile.com/news/dealing-generic-threat.

[58] The People of the State of New York v. Actavis PLC and Forest Laboratories LLC, S.D.N.Y.14-cv-4624 (2nd Cir, 2015).

[59] There seems to be a clear acknowledgement of the monopoly of Namenda. *See* Stuart Silverman, *Second Circuit Affirms Preliminary Injunction in Antitrust Suit Against Drug Companies for Product Hopping*, American University WCL, National Law Review (May. 22, 2015) available athttp://news.monster.com/a/business/second-circuit-affirms-preliminary-injunction-in-antitrust-suit-against-drug-companies-for-pr-ff8e0f.

[60] The People of the State of New York v. Actavis PLC and Forest Laboratories LLC, SDNY14-cv-4624 (2nd Cir, 2015).

[61] Case No: A3/2013/0559 – Chemistree HomeCare Ltd. v. AbbVie Ltd., 2013 EWHC Civ 1338.

for an account of Kaletra. On receipt of the account, it was realised that 15% of the sales were home care, 40% of the sales were wholesale and 45% were prescriptions in the European Economic Area. AbbVie stopped supply for everything other than home care, stating that Chemistree's behaviour was disingenuous. The Court of Appeal concluded that if a patient was prescribed Kaletra then the patient required Kaletra alone, and that single drug could be its own relevant market. It was the prescribing doctor, either alone or in consultation with the patient, that made the decision as to whether or not Kaletra should be used and it was that part of the buying chain which was sensitive to increases in price. The Court stated that Chemistree was not the relevant customer. The pharmacist merely acted as a middleman and its role in the economic chain was irrelevant to the determination of the relevant product market. In addition to demonstrating how commercial arrangements can be anti-competitive, this case also highlights the importance of determining the relevant market in terms of product and the test of substitutability for the correct customer.

Testing activities that are permitted by IPR legislation on the touchstone of competition law will be the accomplishment of a milestone for the Indian legal system. Therefore, the decision in *Ericsson* v. *Micromax* will be significant since Standard-Essential Patents are, undoubtedly, monopolies. While the rest of the civilized world has accepted FRAND as the acceptable response to control the monopoly of SEPs, our courts are yet to find a theoretical basis for it in our law. Perhaps, we can then move on to establishing the basis for identifying the relevant market in a more scientific manner than we have done in *Coca Cola*, *Hiranandani*, *Honda Siel*, or *Sun-Ranbaxy*. Once we have been able to establish a good basis for the determination of the relevant market, we will be in a position to evaluate the effect of patents and of the activities of patent holders. Perhaps then, we will be able to look beyond the blinkers of traditional IPR remedies of revocation and compulsory licensing that have been employed to address the abuse of a patent monopoly.

VI. Effect of Trademarks on Market Definition

Trademarks affect both the demand side and the supply side substitutability of products in the Indian healthcare sector. A patent is a legalized monopoly for a specified period of time in relation to a product, whereas a trademark allows a product to be identified with one producer forever. The response to this allegation of an infinite monopoly by trademark owners is that there is no restriction on how many trademarks can exist in a market and it is free for anyone to enter the market with a trademark and compete fairly with

the existing products. There are several instances of brand leaders being displaced by late entrants to demonstrate this. While this is a very persuasive argument in itself, the infinite life of a trademark combined with a monopoly for a patented product in the Indian healthcare sector creates several challenges for competition law. That anyone can compete using their own trade mark assumes that it is possible to compete – which is not possible when there is a monopoly due to a patent, especially in the pharmaceutical sector.

We have always had trademarks for drugs and they have arguably made them more accessible, since the name Aspirin is easier to remember than acetylsalicylic acid. Why has this suddenly become an issue? Trademark law has come a long way and it is perhaps important for us to retrace its history to understand how far we have come from its roots and ask ourselves if we really want to be where we are.

While we are all taught that the origin of trademarks was for goods to be easily identifiable with their makers – originally the artisan guilds in medieval England – this quickly morphed into a right for the maker rather than a protection for the consumer. There is some evidence of Harappan marks embossed on goods traded with foreign countries such as Mesopotamia and Babylonia. The legal recognition of the trademark as a species of incorporeal property was first accorded by the Court of Chancery in the first half of the 19th Century. In *Millington* v. *Fox*[62], it was decided that it was not necessary to establish any intention to deceive on the part of an infringer against whom an injunction to restrain his use of another trademark is sought.

> "The concept of distinguishing goods or services of the proprietor from those of others was to be found in the requirements for a mark to be registrable. Essentially, whatever the wording used, a trademark or a service mark was an indication which enabled the goods or services from a particular source to be identified and thus distinguished from goods or services from other sources. In adopting a definition of 'trademark' which simply describes the function in terms of capability of 'distinguishing the goods or services of one undertaking from those of other undertakings' the new law is really saying precisely the same thing. (sic)"[63]

Thus, the most critical object of a trademark is to clearly identify the origin of the good.[64] The function of a trademark is to give an indication to

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[62] Millington v. Fox, (1838) 3 My & Cr 338.

[63] Ramdev Food Products (P). Ltd. v. Arvindbhai Rambhai Patel, (2006) 8 SCC 726 : (2006) 33 PTC 281, 299.

[64] S. 2(1)(zb), Trade Marks Act, 1999.

the purchaser, or a possible purchaser, as to the manufacture or the quality of the goods,[65] to give an indication to his eye of the trade source or trade hands through which they pass on their way to the market. Thus, it is to be distinguished from a property mark which denotes that a movable property belongs to a particular person.[66] While registration confers a permanent and exclusive right in respect of a registered mark, it does not create a monopoly in the mark in the true sense of the word 'monopoly.' Trademarks give rise to exclusive rights as indications of the source and quality of goods; it is only when related to goods that they have life or value. A trademark is not a type of copyright.[67] It cannot exist in vacuum and should not therefore be considered property.[68] It can only exist in connection with the goods in relation to which it is used or intended to be used.[69] The proprietary rights in the trademark/service mark are not acquired merely on account of registration in India but on account of priority in adoption, use, and even on account of trans-border reputation spilling over to India.[70] For a drug, this means that it is possible, given the barriers to substitution in India by either the pharmacist or the patient, that a brand could well be treated as Kaletra was in *Chemistree*.

VII. Why Don't We Name Drugs Like Other Products?

All cars have light bulbs and no automobile company has its own special name for a light bulb in a car that it makes, but there does not seem to be a simple name for every drug or class of drugs.[71] As drugs come out of patent

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[65] Quality is not relevant for pharmaceutical brands since all drugs having the same chemical composition are approved before being allowed to be sold and it is a requirement of the Drugs and Cosmetics Act that a generic is the chemical and bio-equivalent of the innovator (patented) drug.

[66] Sumat Prasad Jain v. Sheojanam Prasad, (1973) 1 SCC 56 : AIR 1972 SC 2488, 2490.

[67] Glaxo Group v. Dowelhurst Ltd., 2000 FSR 529, 539.

[68] *But see* the recent reports of Phillip Morris claiming expropriation of property in respect of tobacco plain packaging laws of some countries, which highlights this issue once again. *See* M.C. Porterfield & C.R. Byrnes, *Philip Morris v. Uruguay: Will Investor-State Arbitration Send Restrictions on Tobacco Marketing up in Smoke,* Investment Treaty News (Jul. 12, 2011), available at http://www.iisd.org/itn/2011/07/12/philip-morris-v-uruguay-will-investor-state-arbitration-send-restrictions-on-tobacco-marketing-up-in-smoke/; Aylin A. Sahin, *Philip Morris v. Uruguay: Intellectual Property Debate in International Investment Arbitration*, Berkeley Tech. L.J. (Nov. 7, 2014), available at http://btlj.org/2014/11/philip-morris-vs-uruguay-intellectual-property-debate-in-international-investment-arbitration/.

[69] American Home Products Corpn. v. Mac Laboratories (P) Ltd., (1986) 1 SCC 465 : AIR 1986 SC 137, 154.

[70] McAtee v. Chem Shengula, (2007) 34 PTC 298.

[71] One may argue that there are families of drugs and they together with the International Non Proprietary Names are well known amongst the cognoscenti. For example, "*statins*"

protection and become open to competition, the use of a trade name for that drug is so prevalent that no one remembers the generic chemical name[72] – for instance, acetylsalicylic acid has always been overshadowed by the brand name Aspirin. This phenomenon of not having common names for products does not seem to prevail in any other industry. When brand names became common nouns like in the case of Yo-Yo (a children's toy), cellophane[73] (the plastic wrapping material), photocopying (Xerox[74]) or instant photography (Polaroid), there developed a theoretical basis for these trademarks to be genericized. But pharmaceuticals seem to have managed to sidestep this issue. In fact, the generics established their own pharmaceutical brands, rather than challenge the basis for innovators to name a product and then appropriate it to own the brand. The justification was patient safety – it is easier to prescribe and consume drugs which have simple, memorable names than having to remember the generic chemical name.

VIII. Brand Names for Drugs Cause Confusion

Consider the common substitutes for Aspirin[75] as an analgesic – Disprin, Crocin and Metacin. Disprin was initially a brand name for a generic version of Aspirin but the chemical composition of the drug sold as Disprin was later changed to paracetamol in India alone, leading to potentially fatal mistakes in prescriptions.[76] Similarly, Crocin and Metacin sound so very much like Aspirin, but are, in fact, similar to Calpol.[77] The use of Crocin and

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as a family of drugs which help control cholesterol.

[72] I have chosen to use the term "*generic chemical name*" rather than International Non-Proprietary Name ("INN"), the term of art used by the healthcare industry. International Non-Proprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognised and is public property. *See* Essential Medicines & Health Products: International Nonproprietary Names, World Health Organization, available at http://www.who.int/medicines/services/inn/en/ (Last visited on Jul. 3, 2015).

[73] *See* What you don't know about trademarks, World Intellectual Property Organization (Nov. 2009), available at http://www.wipo.int/wipo_magazine/en/2009/06/article_0010.html.

[74] *But see* the decision of the IPAB rejecting the genericisation of Xerox and its criticism by Prashant Reddy, *Xerox is not Generic … Yet?!,* SpicyIP L. Blog (Oct. 16, 2012), available at http://spicyip.com/2012/10/guest-post-xerox-is-not-genericyet.html.

[75] Aspirin is also used to treat coronary thrombosis for which clopidogrel is a possible substitute. *See* Increasing the Knowledge & Understanding of Aspirin, Aspirin Foundation, available at http://www.aspirin-foundation.com.

[76] *See* Priya Yadav, *Disprin is no Longer Disprin,* Times of India (Sep. 12, 2001), available at http://timesofindia.indiatimes.com/city/Disprin-is-no-longer-disprin/articleshow/1020224953.cms. There are more than 630 brands of paracetamol (with significant price difference) made by over 300 pharmaceutical companies in India. For a listing, *see* www.drugsupdate.com.

[77] This continues to occur despite the clear direction from the Supreme Court in *Cadila Health Care Ltd.* v. *Cadila Pharmaceuticals Ltd.*, (2001) 5 SCC 73 : AIR 2001 SC 1952,

Calpol, different trade names and marks for the same drug, paracetamol, by one company, GlaxoSmithKline ("GSK") in this case, creates significant confusion for doctors, patients, and chemists.[78] From a competition law perspective, it allows pharmaceutical companies to create a segmentation of the market for analgesics, rather than just paracetamol – a smaller market than analgesics[79]– and justify the claim that they each have no significant market power in the analgesics market.[80] It is significant that paracetamol is covered by the Drug Price Control Order[81] and as a result, it is easily argued that by this measure, the government has ensured that no paracetamol manufacturer has significant market power, thereby negating the effect of brands causing any disruption to the working of market forces.[82] This does not however explain why patented drugs, which are very likely to have a monopoly, are not covered by price control in India, when a vibrant competitive market with over 300 producers, like generic paracetamol, is. Evidently, the economic basis for this policy of the Indian government is extremely difficult to understand.

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establishing the standard for approval of drugs and their trade names pursuant to S. 17-B of the Drugs and Cosmetics Act, 1940: "*Exacting judicial scrutiny is required if there is a possibility of confusion over marks on medicinal products because the potential harm may be far more dire than that in confusion over ordinary consumer products.*"

78 There is also a brand called Krocetamol, presumably a take on both Crocin and paracetamol and several variations on the Calpol brand – Calpol Plus which has paracetamol and ibuprofen, and Calpol T which has paracetamol with tramadol. These combinations are one of the reasons cited by Indian doctors to prescribe brands rather than generic chemical names. *See* K.K. Aggarwal, *infra* note 95.

79 While it may seem like the relevant market is either analgesics or paracetamol in India, there are other aspects like price and substitutability that affect the definition of market.

80 It is arguable based on the views of doctors, pharmacists, and patients, on substitutability, that combinations containing paracetamol, ibuprofen, and diclofenac for example, may be treated as being part of the analgesics market. However, this conclusion is not supported by the order of the Competition Commission of India in the matter of the Sun – Ranbaxy merger, *supra* note 46, where for example, atorvastatin and rosuvastatin were each considered as separate markets, although the family of statins all treat the same condition and act in a similar manner and are similarly priced by Sun. Interestingly, the Competition Commission considered spare parts for each car brand as a relevant market *Shamesher Kataria* v. *Honda Seil*, [2014] CCI 26 , available at http://www.cci.gov.in/May2011/OrderOfCommission/27/032011.pdf.

81 Issued under the Essential Commodities Act, 1955. It has been and continues to be the subject matter of challenge before the Delhi and Bombay High Courts and the Supreme Court of India.

82 *See* paragraph 23 of the order of the Competition Commission of India in the matter of the Sun-Ranbaxy merger, *supra* note 46 for an example of this concept being accepted, with little explanation, by the Competition Commission of India.

IX. Trade Dress is the Next Barrier to Competition

Another aspect of trademark law is trade dress. In a country like India, colour plays a significant role in patient retention and customer loyalty. For example, the use of a purple-coloured inhaler[83] is a sure way of keeping an asthmatic patient handcuffed to a brand for life if the colour of the inhaler is protected as a trade mark,[84] even after the patent on the drug expires and other cheaper and perhaps even more effective alternatives are available, albeit in different coloured inhalers.[85] "*The importance of colour-coded asthma treatment in patient education is well accepted. Traditionally, reliever medication inhalers are blue in colour and preventer inhalers brown. This custom is not always followed and the inconsistencies in the colour of inhalers create a lot of confusion.*"[86] It is unlikely that when an asthma attack comes on, a patient will read the label of the different inhalers in a medicine cabinet or bag. By force of habit, a patient will not risk changing the brand since a colour is strongly associated with relief from a feeling of certain death by suffocation. When a colour and/or a shape is associated with a drug or a device, the patent monopoly naturally gets extended for the life of the trademark and design. This principle also extends to the colour and shape of pills that need to be taken routinely or when several pills need to be taken by a patient. It is now widely acknowledged by empirical studies that changing the colour of pills has an extremely adverse effect on patient compliance making it difficult for competing products, usually significantly cheaper generics to enter the market.[87] As a consequence, the combination

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[83] The definition of trade mark was amended in 1993 to include "*shape of goods, their packaging and combination of colours*" to follow global norms on trademarks. *See* S. 2(1)(m) and S. 2(1)(xb), Trade Marks Act, 1999.

[84] See the decision of the Court of Appeal in *Nestle* v. *Cadbury*, 2013 EWCA 1174 where Cadbury was refused registration of its distinctive purple colour which it has used for over a century.

[85] The battle between GSK and Sandoz on the inhaler from Sandoz that competes with purple coloured inhaler sold as Advair (the multi-billion dollar blockbuster from GSK) is being keenly watched. GSK was granted CTM registration for the purple colour combination on the inhaler. While a Danish court refused GSK an interim injunction, a court in Cologne granted an interim injunction but the case was eventually settled.

[86] Dr. B. Jayakrishnan, *Asthma Inhalers And Colour Coding: Universal Dots*, 60(578) Br J. Gen Pract 690–691 (Sep. 1, 2010), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2930224/.

[87] *See* Aaron S. Kesselheim, *et al*, *Variations in Pill Appearance of Antiepileptic Drugs and the Risk of Nonadherence*, 173(3) Jama Internal Medicine 202 (Feb. 11, 2013); Brady Dennis, *If Color or Shape of Generic Pills Changes, Patients May Stop Taking Them*, The Washington Post (Jul. 14, 2014), available at http://www.washingtonpost.com/national/health-science/if-color-or-shape-changes-patients-more-likely-to-stop-taking-much-needed-drugs/2014/07/14/60e687f4-0b8c-11e4-8341-b8072b1e7348_story.html. *See also* U.S. Federal Drug Administration, Guidance for Industry Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules (Dec. 2013), available at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm377938.pdf.

of a patented drug with a trade name, unique shape and colour is a potent combination of IPR to keep competition out forever.

The use of a colour, shape, or trademark extends a patent monopoly for every patient who either has really no choice once the doctor prescribes a drug or device,[88] or suffers from such a medical condition that a change would be extremely disruptive of his treatment regimen, causing him to reject the choice of cheaper alternatives.[89] However, a Danish Court in *GSK* v. *Sandoz* (2014) attached importance to the fact that GSK had not proved to a sufficient degree that the purple colour served as a distinctive sign for its inhaler or could in any other way influence consumers' purchasing decisions. It concluded that the inhaler was a prescription medicine, and it could be assumed that the doctors who prescribed it would emphasise the special functionality of the product for the patient and his or her needs, while the patient would mainly consider the price. Since this was a decision on an interim injunction in a healthcare market which has rules on generic substitutability, it may well not apply in the Indian market.[90]

X. Trade Mark extends Patent Monopoly

It is perhaps time to question whether trademark law contemplated the extension of patent monopoly. The judgment in *Philips* v. *Remington*[91] establishes that trademark law cannot be used to protect from competition a shape marketed by one undertaking if the essential characteristics of that shape perform a technical function. Such shapes are excluded from registration and there are no ways to circumvent this prohibition. Does it not follow that this limitation ought to be applicable to drug and device colours as well, where there is a compelling patient interest to have uniformity to reduce confusion and mistakes?[92]

Despite there being a well-established understanding of the essential elements of a trademark and its role in a market economy, it was interesting that the CJEU sought to clarify the basis for a trade mark:

> "…to guarantee the identity of the origin of the marked product to the consumer or end-user by enabling him, without any possibility

[88] *See* Chemistree, *supra* note 61.
[89] *See supra* note 86.
[90] A similar reasoning is offered by Indian doctors to prescribe brands rather than generic chemical names of drugs. *See* K.K. Aggarwal, *infra* note 94.
[91] Case C-299/99 – Koninklijke Philips Electronics NV v. Remington Consumer Products Ltd., 2003 RPC 2.
[92] See *supra* note 85.

> of confusion, to distinguish the product or service from others which have another origin, and for the trademark to be able to fulfill its essential role in the system of undistorted competition which the Treaty seeks to establish, it must offer a guarantee that all the goods or services bearing it have originated under the control of a single undertaking which is responsible for their quality… (sic)"[93]

This reaffirms the legal basis for a trademark to be the clear identification of the source of the goods, and no more. It also reminds us of the potential risk of trademarks distorting competition. In the Indian healthcare context, each brand seems to be a market in itself since doctors prescribe brands, not drugs by their generic chemical name,[94] and patients don't consider them substitutable because they would not be able to make the decision based on information available to them from pharmacists who are incentivized to sell more expensive drugs.[95] This is not much of an issue in the United Kingdom or most of Europe where healthcare is virtually free at the point of use and patients pay very little for drugs or devices, all of which are primarily funded by a national health service. In the United States, the oligopoly of insurers negotiates the price of drugs with pharmaceutical companies and it may well be argued that there is a fair balance of power. Brands therefore have little effect of distorting competition where the buyer, the national health service, or an oligopoly of insurers, with sufficient information and choice is able to evaluate (both on a cost-benefit basis as well as medical need) before listing the drugs that a doctor can prescribe. There is virtually a monopoly buyer negotiating with a potential monopolist patent holder, and the patient is rarely given a choice of the brand of the drug. In most of Europe, the patient is often only aware of the generic chemical name on the label of the container printed by the pharmacist.

Conclusion and Recommendations

While the Indian healthcare market is rapidly developing, there is a need to study it in much greater detail as a market than has been done until now.[96]

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[93] Case C-299/99 – Koninklijke Philips Electronics NV v. Remington Consumer Products Ltd., 2003 RPC 2, ¶ 30.

[94] *See* Dr. Ganapati Mudur, *Doctors in India Defy Guidelines on Generic Drugs*, BMJ 347 (2013) available at , http://www.bmj.com/content/347/bmj.f4244#.

[95] For a summary of the viewpoints of the various players in the Indian healthcare sector on competition between brands, *see* Dr. K.K. Aggarwal, *The Generic Drug Controversy*, 23(9) Indian Journal of Clinical Practice 485 (Feb. 9, 2013).

[96] As a part of the Drug Price Control Order, the Indian government is now requiring all manufacturers to register all products with details of price and sales. The Competition Commission of India relied on sales data from the All India Association of Chemists and Druggists who do not list all sales for all drugs. Information on direct sales to hospital

This will help us understand the impact of various regulations on the market and the operation of market forces. There is clear evidence of the disruption of the market by brands, especially with several combinations[97] which are used as reasons for doctors to prescribe them in clear violation of their ethical and legal obligations.[98] The natural consequence of the existence of brand names is their promotion by the brand owners. Since the doctor, being the decision maker, is the real customer, pharmaceutical companies are incentivized[99] to use corrupt practices to influence them to prescribe brands, rather than the generic chemical names of drugs.[100] As a result, the elimination of protection of brand names for drugs addresses several market distorting issues.[101] Corruption creates barriers to competition for those who are unwilling to participate in corrupt practices, and increases the cost of doing business which, in turn, is borne by patients. The belief that regulation of drug prices is an easy fix to overcome potential dominance of brands is a misconception that is disrupting the market by creating other barriers to competition and incentivizing brands to game the system.

It is possible to prevent the distortion of the healthcare market by brand names without any legislative measures. Section 13 of the Trade Marks Act clearly prohibits the use of the international non-proprietary name or any name deceptively similar to it from being registered as a trademark. If any attempt is made to use a mark without registration to overcome this

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chains, government, public sector undertakings, railways and defence and paramilitary services and the like, for example, where millions of patients are treated every year are routinely missed.

97 *See supra* note 78.

98 Indian Medical Council (Profession Conduct, Etiquette and Ethics) Regulations, 2002, Gazette of India, ¶1.5 (Apr. 6, 2002).

99 Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, ¶6 prohibits doctors from accepting gifts. Often, to overcome this stipulation, "*free samples*" or "*special schemes*" are provided to doctors by pharmaceutical companies. An example of a "*special scheme*" would be giving a doctor five free units for every one unit of a drug purchased. The doctor would therefore be able to sell six units at the retail price and make an astonishing profit without the patient ever knowing this.

100 A common definition of corruption is *the abuse of public or private office for personal gain*. *See* Asian Development Bank, *Anti-Corruption: Policies and Strategies, Description and Answers to Frequently Asked Questions* 1 (Manila, 2000).

101 *See* Corruption Explained, International Chamber of Commerce, available at http://www.iccwbo.org/advocacy-codes-and-rules/areas-of-work/corporate-responsibility-and-anti-corruption/corruption-explained/ (Last visited Jul. 3, 2015), for the position of the International Chamber of Commerce; Guidance Note of the International Monetary Fund, "*Role of the IMF in Governance Issues*." *See* The IMF and Good Governance, International Monetary Fund, (Apr. 9, 2015), available at http://www.imf.org/external/np/exr/facts/gov.htm (Last visited Jul 3, 2015); Business and Governments Against Corruption: Factsheet, United Nations Office Against Drugs and Crime, available at http://www.unodc.org/documents/congress//background-information/Corruption/4._Factsheet_-_An_Anti-Corruption_Ethics_and_Compliance_Programme.pdf.

prohibition, Section 17-B of the Drugs and Cosmetics Act, 1940 can be used to disapprove the sale or marketing of a drug or product. Since limitations can be placed on the use of a mark,[102] the trademark registry can very easily restrict the use of the name for the period of the patent,[103] with the express condition that the name be then made available thereafter to every competitor to use, so long as the source is clearly identified on the product or packaging. Therefore, if Aspirin is a trade name for acetyl salicylic acid during the term of the patent, the name "*Aspirin*" and the generic chemical name should be used by every manufacturer or seller (after the patent on Aspirin expires) together with the name or mark of the manufacturer clearly stated, in order to distinguish products of different manufacturers of Aspirin. Similarly, the colour of pills, devices, and packaging should be uniformly used and industry standards established so that there is consistency and confusion is avoided,thereby ensuring patient compliance. With the elimination of competing brand names, it will be easier for ethical pharmaceutical companies to compete, and for doctors to comply with their legal and ethical professional obligations.[104]

Each drug name could automatically be listed under Section 23(1) of the Trade Marks Act[105] upon patent expiry so that they become generic, instead of being registered. The colour of the drug or device, the text on the packaging, and the design elements, all of which have a functional element, should not be allowed to be owned separately from the product. This prevents the composition of the drug from being changed while selling it under a well-known brand name,[106] and further ensures that patient interest is not compromised and patients have real choice of products in a market that allows competition to thrive.

While we can look to the West for ideas on how to regulate our markets, we need to be very vigilant about how different India is and why we need to be wary of blindly implementing western models of market regulation. Instead, we should focus on leapfrogging them to avoid the regulatory challenges that they have created in the process of their learning and growth.

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[102] S. 18, Trade Marks Act, 1999.

[103] S. 2(1)(l), Trade Marks Act, 1999 defines "*limitations*" to mean any limitation of the exclusive right to the use of a trade mark given by the registration of a person as proprietor thereof, *including limitations of that right as to mode* or area of use within India or outside India.

[104] *See supra* notes 98, 99.

[105] So far, the Central Government has listed names and pictures of gods and goddesses.

[106] *See* for example, *supra* note 76.