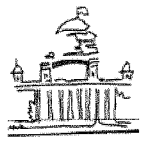

IS COMPETITION LAW THE ANALGESIC FOR THE INDIAN HEALTHCARE SECTOR?

—Murali Neelakantan[1]

Healthcare seems to be in the news in every country, irrespective of whether it is a developed, developing or least developed nation. Even in countries in Western Europe, where the government provides free healthcare, there seems to be no end to the dissatisfaction of all stakeholders.[2] Healthcare reforms seem to always be near the top of the agenda for Presidential candidates in the USA. It seems that India has caught the global bug with the Government announcing a National Health Policy.[3]

Civil servants, public sector employees, armed forces and other para military services, railways and some factory workers who are covered by the Employee State Insurance Scheme have access to free healthcare, in a manner similar to that enjoyed in the USA or the European Union (EU). A vast majority of healthcare cost in India is self-funded by patients and their families[4] and it is they who suffer the most in the Indian healthcare system. The private sector today provides nearly 80% of outpatient care and about 60% of inpatient care, accounting for 70% of the total healthcare expenditure.[5] This paper explores some of the symptoms and suggests a few changes to address the causes that arise from the manner in which Indian intellectual property rights laws operate in this sector.

I. HOW DOES OUR HEALTHCARE SYSTEM HURT PATIENTS?

Due to the complex nature of our healthcare system, there is very little focus on patients for whom the most important issues are access to medicines

[1] Founder, Amicus and former Global General Counsel, Cipla Limited.

[2] See for example, the response by the staff of the National Health Service in the UK to comments by the Secretary for Health, Jeremy Hunt.

[3] Available in draft form at: http://mohfw.nic.in/showfile.php?lid=3014.

[4] Data for the period 1995 – 2013, available with the World Health Organisation indicates that between 86% and 92% of private healthcare is self-funded and government expenditure is between 22% and 32% of total healthcare expenditure, *available at* http://apps.who.int/nha/database/ViewData/Indicators/en.

[5] Draft National Health Policy, 2015, at 10.

and healthcare infrastructure. This is not merely a concern about cost of drugs. Indians have perhaps the most choice in terms of the range of medicines and more and more drugs are being introduced almost at the same time as the rest of the world.[6] With India widely acknowledged as the pharmacy of the world, every generic drug has several substitutes, available at different price points, a sure sign of a vibrant competitive market, which is being slowly killed by irrational price controls.[7] For example, there are over 600 brands of paracetamol manufactured by over 300 entities but do patients really have a choice? How does law affect access to medicines and how can competition law address this? If there is just one product, i.e., a monopoly, and that limits choice, is there a proper mechanism and framework to ensure access for all to this product? Much has been written about the nexus between doctors and pharma companies. Are the ethical guidelines for doctors sufficient to address this issue? The government established and continues to use scarce healthcare budget to fund loss-making public sector pharmaceutical undertakings[8] which do not seem to contribute to the healthcare needs of the nation while seeking private enterprises to tender for affordable generic drugs under the Jan Aushadhi Scheme.

There hasn't been sufficient research published about the effect of Intellectual Property Rights (IPR) on the Indian healthcare sector[9] or the impact of competition law on its structure[10]. The only references to competition law in the context of healthcare occur in the decisions of the Competition Commission of India (CCI) in the series of *AIOCD cases*[11], the Sun Pharma – Ranbaxy merger[12] and the *Hiranandani*[13] case but very little is discussed in these decisions about the

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[6] The recent case of Sofosbuvir, the only known cure for Hepatitis C being introduced in India within a year of it being available in the USA is a good example.

[7] *See* The IMS Institute India, *Assessing the Impact of Price Control Measures on Access to Medicines in India* (2015) for an evaluation of price controls and how it has failed to increase access but has adversely affected the health of the Indian pharma industry.

[8] A recent example is of Hindustan Lifecare Limited, formerly Hindustan Latex Limited, a company owned by the government of India and one of the largest global manufacturers of condoms which exports at a price that is below cost, while there is a scarcity of condoms in India to address the HIV AIDS crisis here.

[9] Bishwanath Goldar *et al*, *Effects of New Patents Regime on Consumers and Producers of Drugs/ Medicines in India*, Revised Report Submitted to the UNCTAD (August 2010), after reviewing extensive data of generic drugs, concludes, with very little basis, that a monopolistic patent is unlikely to cause price distortion.

[10] *See* for example, Aditya Bhattacharjea and Fiyanshu Sindhwani, *Competition Issues in the Indian Pharmaceuticals Sector*, *available at* http://www.cuts-ccier.org/compeg/pdf/report-pharmaceutical_sector_study.pdf. This study does not address the monopolistic impact of patents and the extension of the patent by trade mark and trade dress.

[11] See *Santuka Associates (P) Ltd* v. *All India Organization of Chemists and Druggists Assn.*AIOCD, 2013 SCC OnLine CCI 16 at http://www.cci.gov.in/May2011/OrderOfCommission/202011.pdf , *Peeveear* v. *All India Organization of Chemists and Druggists Assn*, Case No. 30 of 2011 and *Sandhya Drug Agency*, *In re*, 2013 SCC OnLine CCI 84.

[12] Combination Registration No. C-2014/05/170 (December 05, 2014), at 14, *available at* http://www.cci.gov.in/May2011/OrderOfCommission/CombinationOrders/C-2014-05-170.pdf.

[13] *Ramakant Kini, In re*, 2014 SCC OnLine CCI 15 : 2014 CompLR 263 (CCI). ("*Hiranandani*").

healthcare market or indeed intellectual property rights[14]. As a result, there has been very little jurisprudence about the definition of a relevant market for the healthcare sector and nothing on the effect of IPR and its interplay with competition law[15].

II. WHY COMPETITION LAW IS UNIQUELY PLACED TO REMEDY THE SITUATION

The common principle with the law is that whatever is permitted to be done by one legislation is usually exempt from being affected by another legislation so that both laws can operate in a harmonious manner is their own exclusive spheres. However, competition law is an exception to this principle and it is explicitly stated that it has an overriding effect over all other laws [16]. There have been extremely interesting examples of both the EU[17] and the US[18] sanctioning companies who, while doing what was permitted by specific law, were held to be in violation of competition law. This allows competition law to have a wider role in the regulation of the market and its stakeholders.

The only case of the interplay between IPR and competition law[19] is currently in suspended animation. Since IPR essentially creates a monopoly, which is an anathema to a market, the ability of competition law to be able to moderate its effects is critical to the growth of the economy. While there are some provisions in the Patents Act[20], Trade Marks Act[21] and Copyright Act[22], to prevent the abuse of the monopoly granted by these legislation, competition law plays a significant role in filling the gaps. A good example of this is the abuse of the dominance by Actavis: "*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*

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[14] There is a passing mention in the Sun – Ranbaxy order of the relevant market for generics being the molecule without any useful analysis or explanation.

[15] The decision in *Micromax Informatics Limited, In re*, 2013 SCC OnLine CCI 78 (Competition Commission of India, November 11, 2013) is still a few years away. The issue is the refusal by Ericsson to licence standard essential patents for GSM technology to Micromax for it to use in mobile phone handsets. The CCI directed the Director General to commence investigation. Ericsson appealed this CCI order and the Delhi High Court granted an interim injunction against the investigation.

[16] *See* Section 60, Competition Act, 2002.

[17] Case T-321/05 *Astra 1Zeneca* v. *Commission,* 2010 ECR II-2805: MEMO/10/294. Significant fines under competition law for abuse of the patent perhaps provided a more effective remedy than revoking the patent under the Patents Act which may well have been at the end of its term.

[18] *State of New York* v. *Actavis Plc and Forest Laboratories LLC*, SDNY 14-cv-4624 (2nd Cir 2015). Here the court granted an injunction against switching patients from a drug which was at the end of its patent term to an 'extended release' version to prevent competition from generics.

[19] *Micromax Informatics Limited, In re*, *supra* note 15.

[20] Section 85, Patents Act, 1970.

[21] Section 47, Trade Marks Act, 1999.

[22] Section 31, Copyright Act, 1957.

then to reverse-commute back."[23] 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[24] revenues from a precipitous decline following generic entry.[25] So long as there is a clear framework to identify the relevant market and how it is being abused by rights holders, competition law is uniquely placed to address abuse of rights granted by other laws.

III. LACK OF FOCUS ON THE DEFINITION OF THE RELEVANT MARKET

The first pain point while attempting to apply competition law is an understanding of a relevant market and some parameters for us to be able to determine it in each case. Would each of the following be a relevant market since the consumers, suppliers, pricing and procurement process is unique?

1. Central Government Health Service, where civil servants are able to use both public and private infrastructure for healthcare services with the government bearing the costs;
2. Employee State Insurance Scheme where employees of both public and private sector are given free access to healthcare;
3. Retired and serving armed services personnel and their families are provided free healthcare services for life;
4. Hospitals which are "empanelled" by insurers who pay the insured's costs and others which are not and require the patient to pay for services;
5. The Jan Aushadhi Scheme of the government providing low cost generic medicines; and
6. .All those of us who cannot be part of any of the above.

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[23] *State of New York* v. *Actavis Plc and Forest Laboratories LLC*, SDNY 14-cv-4624 (2nd Cir 2015).

[24] 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. 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.

[25] 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 at* http://news.monster.com/a/business/second-circuit-affirms-preliminary-injunction-in-antitrust-suit-against-drug-companies-for-pr-ff8e0f.

If these questions had been asked in the AIOCD cases, we would have had a better sense of why the CCI considered a distribution and sale of medicines in a state as the relevant market. Perhaps the CCI concluded that the relevant market was 'All of us who are not any of the above' without explaining itself since it was of the view that the AIOCD was really a cartel and its members were critical to all the drugs getting to those of us who did not have access to free healthcare provided by the government. A possible explanation for why this analysis was not considered relevant may be because this was not seen in the US and European competition law cases which one reads. One would expect that someone, somewhere, would ask why this issue has never been raised in all those cases and it may then occur to them, that the healthcare systems there are so very different from ours that they have other pains, not this one.

All that we can gather from the decisions of the CCI until now is that (i) in the case of generic drug companies, a single molecule can be the relevant market[26]; (ii) a single hospital can be dominant in the relevant market[27]; and (iii) stockists, distributors and retailers of drugs form a relevant market.[28] All of this may well be correct but does it further the nascent competition law jurisprudence, guiding us in organising our affairs so that we can comply with the law? So, while concluding that a molecule is the relevant market[29], it would have helped if we could be provided an explanation for why a therapy area like oncology is not the relevant market[30] or why the ATC3 classification is not appropriate.[31] After all, when an enterprise has a strong oncology portfolio with many competitors, each having a few drugs to treat that therapy, one should look at the therapy as a relevant market, as the European Union did in the case of Novartis.[32] To be able to evaluate this possibility, one would need to understand how global pharmaceutical companies have evolved and where they are headed. This would

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[26] CCI Order in the matter of the combination of Sun and Ranbaxy, Combination Registration No. C-2014/05/170 (December 5, 2014), at ¶14, *available at* http://www.cci.gov.in/May2011/OrderOfCommission/CombinationOrders/C-2014-05-170.pdf.

[27] *Hiranandani*, *supra* note 13. Would every pharmacy in a hospital be a dominant undertaking since patients have little or no choice but to buy from such in-house pharmacies? Will the hospital and the pharmacy be tested for abuse of dominance? Will such pharmacies be forced to stock all competing products? Or will the CCI fall back on the *Coca Cola case* (*Consumer Guidance Society, In re*, 2012 SCC OnLine Comp AT 175) and hold that the relevant market for drugs is India and hospitals and in-house pharmacies are not dominant?

[28] AIOCD cases, *supra* note 11.

[29] There have been examples where one drug, Namenda, has been treated as dominant in a market and it is possible that one molecule can constitute a market. See *State of New York* v. *Actavis Plc and Forest Laboratories LLC*, SDNY 14-cv-4624 (2nd Cir 2015).

[30] Bhattacharjea and Sindhwani, *supra* note 10. They conclude that the Indian pharma market is really to be viewed as distinct therapy areas where a few companies dominate each therapy.

[31] *See*, for example, ATC-3 therapeutic classification like antiepileptics in Case No COMP/M.4402-UCB/Schwarz Pharma, *available at* http://ec.europa.eu/competition/mergers/cases/decisions/m4402_20061121_20310_en.pdf.

[32] *See* (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.

have been obvious if one notices the trend towards consolidation and domination of therapy areas[33] rather than one-on-one competition by molecule. If each therapy area, cholesterol controlling drugs, for example, is the relevant market and the market share and competitor data for all the 'statins' is aggregated, would the conclusion in the Sun – Ranbaxy case have been different?

The failure to understand and explain the decision on how the CCI determines 'relevant market' has a significant impact on how competition law is applied and how effective it is. If each molecule is a relevant market, would every patented drug be a relevant market in itself and therefore be a monopoly, or will the CCI, in a case of patented drugs, accept therapy area as the relevant market and allow for competition between patented drugs amongst themselves and older generics of the same class that are used to treat the same indications? The same molecule in different forms (intravenous and intraocular, for example), for different uses and with significant price differential (upto 100 fold) may well constitute different markets.[34]

The best example of this in the Indian context is Aspirin. Consider the popular substitutes for Aspirin[35] 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, leading to potentially fatal mistakes in prescriptions.[36] Similarly Crocin and Metacin sound so very much like Aspirin, but are, in fact, similar to Calpol.[37] The use of Crocin and 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.[38] For those cardiac

[33] Bhattacharjea and Sindhwani, *supra* note 10, at 17. *See* also, *Evaluate Pharma World Preview 2014 Outlook to 2020,* EVALUATE GROUP (June 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%.

[34] *See* Jonathan Silver, *Drugs for Macular Degeneration, Price Discrimination, and Medicare's Responsibility Not to Overpay*, (May 23, 2014).

[35] 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.

[36] *See* Priya Yadav, *Disprin is no Longer Disprin,* TIMES OF INDIA (September 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.

[37] 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, establishing the standard for approval of drugs and their trade names pursuant to Section 17-B of the Drugs and Cosmetics Act, 1940. According to the decision: "*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.*"

[38] 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

patients who were taking a daily dose of Aspirin in the name of Dispirin, the change to paracetamol could be fatal. Branding allows pharmaceutical companies to create a segmentation of the market for analgesics, beyond paracetamol – a smaller market than analgesics[39] – and justify the claim that they each have no significant market power in the analgesics market[40] when in fact, it may well be true that each brand is a market by itself since it does not, due to the nature of prescription, have substitutes. This allows each brand to behave independently of the others even though, by all scientific measures, they are identical. This is explained by the manner in which drugs are consumed and choices made. A vast majority of drugs are bought by patients or their families on the basis of doctors' prescriptions or pharmacists' recommending specific brands[41]. "*Much of the actual demand [for drugs] arises from the prescribing behaviour of doctors, and firms' marketing activities are geared to influencing them not just by advertising and publicity, but also through means that many would regard as unethical, such as paying for their conferences, travel and other expenses*"[42]. This practice, although illegal[43], continues to exist. The situation in India is especially serious due to greater lack of awareness, information and education amongst consumers, the limited coverage of health insurance, the relative absence of large, well-informed and cost-conscious institutional purchasers (whether public or private) who can exercise countervailing power against suppliers, and weaknesses in the regulatory framework. On the supply side, the pharmaceutical industry worldwide is dominated by a handful of firms, with their market dominance reinforced by

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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, *The Generic Drug Controversy*, 23(9) INDIAN JOURNAL OF CLINICAL PRACTICE, 485 (February 9, 2013).

[39] 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 relevant market.

[40] It is arguable, based on doctors', pharmacists' and patients' views on substitutability, that combinations containing paracetamol, ibuprofen and diclofenac for example may be treated as being part of the analgesics market, although this conclusion is not supported by the order of the Competition Commission of India in the matter of the Sun – Ranbaxy merger, *supra* note 26, 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 in *Shamsher Kataria, In re*, 2014 SCC OnLine CCI 95, *available at* http://www.cci.gov.in/May2011/OrderOfCommission/27/032011.pdf.

[41] In violation of guidelines requiring doctors to prescribe the International Non-proprietary Name of the drug and not brands. *See* Indian Medical Council (Profession Conduct, Etiquette and Ethics) Regulations, 2002, Gazette of India, at ¶1.5 (April 6, 2002). For a summary of the viewpoints of the various players in the Indian healthcare sector on competition between brands, see, Aggarwal, *supra* note 38.

[42] Bhattacharjea and Sindhwani, *supra* note 10, at 26.

[43] Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. Regulation 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 5 free units for every one unit of a drug purchased. The doctor would therefore be able to sell 6 units at the retail price and make an astonishing profit without the patient ever knowing this.

patent protection (whose scope they continually try to enlarge), mega-mergers, large advertising and marketing budgets directed at the healthcare providers who actually influence consumer 'choice[44].

Is there therefore a case to argue that each brand, being independent of its chemical substitutes, is relevant in itself and therefore vulnerable to the test of abuse of dominance?

IV. TRADE MARKS AND TRADE DRESS: EXTENSION OF PATENT MONOPOLIES

While patents have been devised to create incentives for innovations and R & D, its very design creates "*market power positions that can adversely affect the economic performance of the system*".[45] The traditional view held by economists that patents and other such arrangements are a way of rewarding the successful innovators and, therefore, such measures are a kind of necessary evil one has to put up with despite their market-distorting characteristics has now been repeatedly questioned.[46]

When combined with an unlimited life of a brand protected by a trademark or trade dress, the patent monopoly which is limited to 20 years could extend to perpetuity. Take for example, an inhaler which is purple in colour[47] and is protected as trade dress or a blue rhomboid shaped pill. It will be virtually impossible for competitors who wish to enter the market after the expiry of the patent term to introduce a product that looks the same. As a result, patients who have been used to taking the purple inhaler will resist any change to a competing product which has another colour. Similarly, patients who have been taking a blue rhomboid shaped pill will resist changing over to another coloured or shaped pill. This phenomenon has been recognised in recent studies and acknowledged by the USFDA as a significant issue[48]. As a result, a patented drug which is branded or otherwise protected by trade dress creates barriers to entry for generics at the end

[44] Bhattacharjea and Sindhwani, *supra* note 10, at 8.

[45] Langinier, Corinne and Moschini, *The Economics of Patents: An Overview*, Working Paper 02-WP 293, Center for Agricultural and Rural Development, Iowa State University (2002).

[46] *See* Tirole, J., *The Theory of Industrial Organisation*, (MIT Press, 1995) ; Cohen *et al, R&D spillovers, patents and the incentives to innovate in Japan and the United States*, 31(9) RESEARCH POLICY, 1349-1367 (December 2002).

[47] GSK has attempted this, with mixed results, in Europe.

[48] *See* Aaron S. Kesselheim, *et al, Variations in Pill Appearance of Antiepileptic Drugs and the Risk of Nonadherence*, 173 (3) JAMA INTERNAL MEDICINE, 202 (February 11, 2013); Brady Dennis, *If Color or Shape of Generic Pills Changes, Patients May Stop Taking Them*, THE WASHINGTON POST, (July 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* (December 2013), *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm377938.pdf.

of the patent monopoly period to the detriment of the market. If one applies the rationale in *Actavis,* trade mark and trade dress protection should not be allowed beyond the term of the patent. This issue becomes critical when generic competitors are not allowed to state that their products are the equivalent of the innovator product[49] when that has been scientifically established to the satisfaction of the drug regulator and is a regulatory requirement for the drug to be approved for sale in India.

V. COPYRIGHT AS A BARRIER TO COMPETITION

In a recent case[50], a drug[51] which was first in the market tried to create barriers for competition on the basis that its competitors were using the goodwill of the brand that it had created and established globally. This argument was successful before the Delhi High Court, much to the disappointment of health activists and doctors. The court seems to have misunderstood the Indian drug regulatory process which requires generics to establish equivalence with the earlier drug. Having established that, the requirement of copyright law that they cannot use the text of the packaging to describe the drug, its side effects, etc., seems to defeat the whole purpose of establishing that all the competing products are substitutes. If one is allowed to insist that the text on the packaging and the "insert" containing important information about the drug is protected by copyright, it will result in substitutable products having different texts and could result in confusing doctors and pharmacists who may think of these products as different.

Different text implies different products and hence, a misleading effect. The decision in *Roche* v. *Biocon & Mylan* is wrong since it is true that generics are bioequivalent of the Roche product which is not patented. The decision causes segmentation of market and the Roche product is therefore a dominant monopoly for the therapy which should be forced to promote market access by referencing which is a regulatory requirement and has been sanctioned by the drug regulator. If herceptin is not a brand but trastuzumab is used, market access is assured and confusion in the market will be eliminated.

VI. POSSIBLE SOLUTION

A possible solution would be to allow competitors to use the same trade dress and trade mark of the patented drug at the end of the patent term along with a clear indication of the manufacturer so that there is no confusion regarding the source of the product, the primary reason for a trade mark. So, for example, everyone who needed acetylsalicylic acid would be able to buy aspirin

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[49] As a result of the injunction granted by the Delhi High Court in *Roche* v. *Mylan & Biocon* (2014).

[50] *Roche* v. *Drugs Controller,* 2016 SCC OnLine Del 2358.

[51] It is very interesting that there was no patent for the drug trastuzumab, sold as Herceptin.

manufactured by a variety of drug companies, all of whom could use the name 'Aspirin'. Each of them will however have to identify themselves clearly. This would eliminate the various brands trying to be substitutes to the 'Aspirin' brand. Another consequence of the brand being available to all producers of Aspirin will be severing the nexus between drug companies and doctors.[52] Even if doctors prescribe a brand, they will have no control over the product actually dispensed to the patient and there will therefore be a level playing field for drug companies to compete fairly.

VII. HOSPITALS' IN-HOUSE PHARMACIES – ABUSE OF DOMINANCE

It seems to be a common practice that hospitals choose to stock only certain drugs in their in-house pharmacies and insist that hospitalised patients buy drugs only from the hospital pharmacy. Drug companies sell drugs to hospitals at a price much lower than what the patient is charged, further incentivising the hospital to stock their products. This is further exacerbated by hospital chains promoting brands that they own. As a result, cheaper and other competing brands often get left out in this game[53] and do not have access to the hospital patient market. If the rationale in *Hiranandani* is applied to this scenario, every hospital must treat all competing products fairly and allow patients full choice of products.

VIII. CONCLUSION

Healthcare is too important a sector of the economy to be neglected by government. On the other hand, bad policy choices like price control of generics have hurt the industry and not benefited patients[54]. While there has been a decline of the 'License Raj' in India since the early 1990s, the government can and should intervene in other ways so that the market forces work as they should. So, rather than having price control for generics, competition law ought to be enforced to ensure that there is a vibrant market by addressing demand and supply side issues for each product. In addition, direct intervention by having public sector pharma undertakings manufacture essential drugs should be considered. For drugs, where there is patent, the government could use public sector undertakings to manufacture these drugs under the "government non- commercial use" flexibility in TRIPS[55] and provide patients a choice between the patented drug manufactured by a private sector company and a cheaper alternative. To ensure

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[52] It is fairly common in Europe for generics to add their name to the INN used by the patent holder.

[53] *See* Sanjay Nagral, *The Cost of Drugs: Beyond the Supreme Court Order*, 48(17) ECONOMIC AND POLITICAL WEEKLY, 13 (2013).

[54] *Supra* note 7.

[55] Implemented by Section 84 of the Patents Act, 1970.

that the poor patients are able to buy these affordable government manufactured drugs, they should be able to debit the universal health insurance programme for the cost of these drugs. The creation of competition on the supply side as well as creating demand will go a long way in making healthcare affordable and accessible. Similarly, centralised procurement of drugs by all government, public sector, railways, ESI and other entities where government provides benefit will create a significant counter force to monopolies. The government should tender for both generic drugs and also for licensed manufacture of patented drugs. This will not only ensure that there is competition for all products but could well result in technology transfer, a promise on which India and other developing countries agreed to in the provisions of the TRIPS agreement.

All of these suggestions can be implemented easily without any legislative changes but none of this can happen unless there is sufficient data, an understanding of the healthcare sector and the various 'relevant markets' and a commitment to data-driven, rather than ideology-led, policy making.