REQUIEM FOR A DREAM: PRICE CONTROL, IP AND COMPETITION IN THE PHARMACEUTICAL MARKET

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ABSTRACT

The interplay between IP and Competition Law is fascinating. Although the fields may seem to be at polarities with each other, upon closer examination one realises that there exists clear cohesion. Current academic consensus holds that IP and competition law exist in a state of equilibrium vis-à-vis each other through in-built checks and balances, a stringent price control regime represents an altogether new influence that must be factored into any sector-specific examination of the IP/Competition interface. The paper attempts to show that price control is both ineffective and pernicious in the pharmaceutical context, with particular reference to the development and launch of new drugs into the market.

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I. INTRODUCTION

Among the vast variety of interdisciplinary legal studies, the interplay between IP and competition law is particularly fascinating. At first glance, the two discrete fields appear to exist in polar opposition to each other, but deeper analysis reveals clear cohesion between them in terms of the policy goals they seek to achieve. This inherent coherence between IP and competition law has been extensively described,[1] and to reiterate it would amount to little more than a waste of precious ink and paper.[2] In a nutshell, current scholarship holds that competition law fosters innovation by maintaining the market in a static equilibrium, while IP law fosters competition by pushing the market towards a dynamic equilibrium. Thus, in a hypothetical market for ice cream, competition law keeps prices low, pushing producers to innovate to lower their production costs and increase their margins. At the same time, IP law incentivises the creation of new types of ice cream, thus expanding the market and creating new product markets for producers to compete in.

As stated above, the IP/competition law interface has received considerable scholarly attention worldwide, and at least one Indian institution exists for the sole purpose of studying this interplay.[3] In most respects, the IP/competition law interface is globally uniform: most jurisdictions have competition legislation that regulates three aspects of market conduct: anti-competitive agreements,[4] monopolistic and trade-restrictive practices ("abuse of dominance"),[5] and M&A transactions which result in the formation of monopolies or highly dominant players.[6] Similarly, the widespread adoption of the WTO TRIPS framework at the turn of the century has resulted, for better or worse, in the harmonisation of the world's market-oriented IP legislation. Due to these factors, Indian discourse on IP-related

[1]Nuno Pires de Carvalho, IP and Antitrust: The Competition Policies of Intellectual Property in Eighty Cases (WoltersKluwer 2015) 1

[2] Herbert Hovenkamp, et. al., IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law (WoltersKluwer 2001) 1-1.

[3] The Centre for Innovation, Intellectual Property and Competition at NLU Delhi is, to my knowledge, one of India's most advanced research initiatives in the area. http://ciipc.org/

[4] Illustratively, Section 3 of India's Competition Act 2002, which finds parallels in Section 1 of the American Sherman Act.

[5] Again, Section 4 of the Competition Act is analogous to Section 2 of the Sherman Act, along with Sections 2 and 3 of the Clayton Act.

[6] Sections 5 and 6 of the Competition Act perform roughly the same function as Sections 7, 7a and 8 of the Clayton Act.

competition law has trodden a predictable path before inevitably ending up where it is today, with technology standards in the telecoms sector being its primary focus.[7]

Current scholarship seems to have ignored a salient and significant feature of Indian law that differentiates it from most other countries: price control. While current academic consensus holds that IP and competition law exist in a state of equilibrium vis-à-vis each other through in-built checks and balances,[8] a stringent price control regime represents an altogether new influence that must be factored into any sector-specific examination of the IP/competition interface. There are two main ways in which price control may require special treatment when examining the IP/competition interface.

First, in IP-fuelled industries, price control, if properly enforced, achieves many of the short-term objectives of competition law (minimising costs for consumers, preventing any single player from attaining or abusing market dominance, etc.) without necessarily providing the longer term benefits of limited IP monopolies. Policymakers may be tempted to enforce strict price controls on IP-based products, especially when the underlying IP is owned or controlled by foreign nationals. However, this temptation must be resisted since the imposition of price control cannot be a substitute for competition law insofar it does not steer clear of IP monopolies. Because of this, a price control regime cannot promise the static and dynamic market equilibrium that an IP/competition regime can.

Second, price control regimes incentivise cheating or other forms of supply distortion by producers, either through cost inflation (in cost-based controls), price coordination (in market-based controls) or by simply undersupplying the market. This is particularly problematic in regimes such as India, where price control exists as a supplement to IP and competition law. In such jurisdictions, policymakers and regulators may assume that price control renders antitrust law redundant, meaning that antitrust intervention is less likely to occur if price control fails or has been manipulated by market players.

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[7] For example, FICCI's flagship certificate course on IP Rights and Competition Law devotes itself almost entirely and exclusively, after an introduction to the applicable legislation, to Standard Essential Patents and FRAND licensing. *See* Course Outline at http://ficciclipr.ficciipcourse.in/. Similarly, another premier institutional research centre, the Jindal Initiative on Research in IP and Competition at OP Jindal Global University, devotes itself almost entirely to SEP/FRAND work. *See* Events at http://www.jgu.edu.in/jirico/index.php.

[8] Illustratively, compulsory licensing provisions in patent law, nominative fair use in trademark law and the idea/expression dichotomy in copyright law all have a competition-fostering purpose. Similarly, competition law contains exceptions that prevent the antitrust regulator from infringing patent monopolies such as Section 3(5) of the Competition Act 2002.

Over the course of this paper, I examine these themes by evaluating the effectiveness of recent regulatory interventions in the market for pharmaceutical products. IP-indifferent price control which results in a mere static equilibrium is best illustrated through India's regulation of the market for genetically modified seeds. The second theme, of antitrust apathy to price control circumvention, is best illustrated through recent trends in the pharmaceutical industry.

The Essential Commodities Act 1955 permits the union government to control the price at which any essential commodity (which has been defined to include drugs and cotton seeds, among other things) may be bought or sold.

II. PHARMACEUTICAL PRICE CONTROL

Despite an elaborate legal framework with laudable goals, I argue that pharmaceutical price control is little more than the policy equivalent of a wild goose chase. Over the course of this section, I highlight some unique features of the Indian drugs market, after which I describe the prevailing drug price control mechanism. I then argue that pharmaceutical price control is not only ineffective but also comes with tangible harms, which manifest in the realm of competition law. Finally, I argue that a combination of IP and competition law must altogether replace price control as a mechanism for preventing market failure in the industry.

A. Market structure

The market for pharmaceutical formulations is unique, both with reference to other product markets in India, and with reference to pharmaceutical markets abroad. This is because unlike most other geographic or product markets, the Indian pharmaceutical market is characterised by a strong middle player that mediates the relationship between the producers of drugs and their consumers.

Organisations such as the All India Organisation of Chemists and Druggists represent this unique phenomenon, in which a consolidated union of middlemen in the pharmaceutical supply chain have immense bargaining power as against producers as well as consumers. The market features nearly 100% retail consolidation, to the extent that manufacturers must virtually sell their products to a monopsony. This is because the AIOCD and its sister organisations operate to maximise their own interests at two levels, as exposed in two

separate investigations carried into them by the Competition Commission of India.[9] Associations of chemists and druggists (of which the AIOCD is the apex body) have consistently fallen foul of the CCI's rulings, meaning that their anti-competitive market consolidation and monopsonistic practices are not isolated, but form a pattern. In 2011, a range of stockists and other wholesale drug suppliers informed the CCI of anticompetitive conduct by the AIOCD and its sister organisations. In its orders in these matters, the CCI has returned findings that the AIOCD and its members have blatantly violated Section 3 of the Competition Act with impunity, maximising their cash flow at the expense of consumers and manufacturers of drugs.[10] The AIOCD was found to have colluded with associations of drug manufacturers (OPPI and IDMA) to fix retail prices, as well as to fix price margins.[11]

The AIOCD's relationship with pharmaceutical manufacturers is complex. On the one hand, it represents the consolidation of virtually every single retail player in the Indian drugs market, meaning that the manufacturer's market access is entirely dependent on the AIOCD. On the other hand, the AIOCD's all-pervasive influence over its members means that it has immense bargaining power against manufacturers, thus infringing upon their right to set prices for their products. The AIOCD's vast territorial reach and significant influence over its members means that it enjoys a virtual monopsony vis-à-vis manufacturers, as well as a virtual monopoly vis-à-vis consumers. Because of this, it has the ability to squeeze out a lion's share of the revenue arising from the value chain in pharmaceutical products sold in India. In addition, the CCI has recorded instances of the AIOCD and its members organising trade boycotts of manufacturers, wholesalers and retailers that offered discounts or set prices without its consent.[12] These factors indicate that the market for drugs in India is particularly vulnerable to both supply-side dominance (vis-à-vis consumers) and demand-side dominance (vis-à-vis manufacturers), and that such dominance is likely to be exerted against manufacturers, stockists and retailers who disobey the AIOCD's diktats.

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[9] *CCI passes cease-and-desist orders against AIOCD, others*, Business Standard, 11 December 2013, http://www.business-standard.com/article/economy-policy/cci-passes-cease-and-desist-orders-against-aiocd-others-113121100561_1.html

[10] In re: Peeveear Medical Agencies, Kerala, CCI Case No. 30/2011.

[11] "DG has observed that it is apparent that the MOUs between the AIOCD, OPPI & IDMA have directly or indirectly led to the determination of the purchase or sale prices of drugs in the market and the said conduct therefore falls within the mischief contained in Section 3(3)(a) of the Act." Id. Paragraph 14.12.10.

[12] *See, eg., In re: PK Krishnan*, CCI Case No. 28 of 2014, *In re: Santuka Associates*, CCI Case No. 20 of 2011.

Despite cosmetic attempts to comply with the CCI's orders against it,[13] the AIOCD and its sister organisations continue to act in a manner that invites antitrust scrutiny.[14]

B. Price control mechanism

India's political leadership in the years immediately following its independence was famously socialist, and began exercising its expansive powers under the Act from the Third Five Year Plan period.[15] The first instance of pharmaceutical price control occurred in the immediate aftermath of India's military engagement with China, in 1963, with the promulgation of the Drugs (Control of Prices) Order 1963.[16] Passed under the Defense of India Act, this order represented a form of crude market-based price control, freezing drug prices to the prevalent market rate as on April 1 1963.[17] The first price control regime under the Essential Commodities Act was the Drug Prices (Display and Control) Order 1966,[18] which mandated prior government approval for all increases in drug prices, although novel drugs were carved out of its scope through an amendment.[19]

Today, drug price control is enforced through the Drug Price Control Order 2013, issued by the National Pharmaceutical Pricing Authority (NPPA), a body under the Ministry of Chemicals and Fertilisers, and guided by the National Pharmaceutical Pricing Policy 2012.

The DPCO contemplates a two-step process in order to fix a ceiling price for drugs listed in its Schedule. First, the average price of all brands or variants of a formulation whose market share over the last year exceeded 1% is taken. A 16% margin to the retailer is added to this average price to arrive at the ceiling price. In addition, a 3.6% mandatory annual increase in prices has been provided for in the DPCO.[20]

The DPCO's scope extends to all drugs contained in its First Schedule, which has conventionally corresponded to the National List of Essential Medicines, which in turn

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[13] Peethaambaran Kunnathoor, *AIOCD issues circular to members, state assns. urging strict compliance with CCI order*, PharmaBiz, 17 May 2013, http://www.pharmabiz.com/NewsDetails.aspx?aid=75384&sid=1

[14] Shreeja Sen, *Karnataka Chemists & Druggists Association under CCI scrutiny again*, Mint, 3 March 2017, http://www.livemint.com/Industry/hgeyRe7CaVZp50tTS18qbN/Karnataka-Chemists--Druggists-Association-under-CCI-scrutin.html. *See also* MM Sharma, *Pharma firms beware, CCI is inquiring*, Financial Express, 5 April 2016, http://www.financialexpress.com/opinion/pharma-firms-beware-cci-is-inquiring/232609/

[15] Planning Commission of India, Third Five Year Plan 1961-66, Chapter 32.

[16] Subal Basak, *The genesis of drug price control*, PharmaBiz, 9 January 2008, http://pharmabiz.com/PrintArticle.aspx?aid=42905&sid=9

[17] Subba Rao Chaganti, Pharmaceutical Marketing in India (Excel Books 2005) 144

[18] National Pharmaceutical Pricing Policy 2012

[19] Chaganti, *supra*.

[20] Drug Price Control Order 2013.

closely mirrors the WHO's List of Essential Medicines. The NLEM does not include patented drugs, but the NPPA has made multiple attempts to expand the ambit of the DPCO beyond the NLEM. Most notably, in 2014, the NPPA invoked emergency provisions in the DPCO (intended to deal with public health crises and other extraordinary circumstances) to pass price control orders against 108 formulations that were not listed in the NLEM.[21] This included cardiovascular drugs, some of which (such as Merck's patented anti-diabetic sitagliptin) were protected by valid patents.[22] Manufacturers immediately filed writ petitions at High Courts in Delhi and Bombay, but were unable to obtain an interim stay on the price control orders.[23] In a sudden and inexplicable development, the NPPA revoked its price control orders within weeks,[24] ensuring that the storm died down amid much confusion.[25] The withdrawal of the orders sparked another round of litigation, which remains unresolved, in which the All India Drug Action Network sought a writ of mandamus from the Delhi High Court seeking the reinstatement of price control over non-essential drugs.[26]

In 2015, the Parliamentary Standing Committee on Chemicals and Fertilisers tabled a report in the House recommending the imposition of price control on all drugs (irrespective of patent status or essentiality) on the Indian market.[27] In addition, the NPPA sought information specifically on patented drugs from manufacturers, in a bid to negotiate a ceiling price.[28]

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[21] Rupali Mukherjee, *Major diabetes, cardiac drugs to become up to 35% cheaper*, The Times of India, 14 July 2014, http://timesofindia.indiatimes.com/india/Major-diabetes-cardiac-drugs-to-become-up-to-35-cheaper/articleshow/38339283.cms

[22] Madhulika Vishwanathan, *NPPA caps prices of non-essential medicines: a policy appraisal*, SpicyIP, 20 July 2014, https://spicyip.com/2014/07/nppa-caps-prices-of-non-essential-medicinesa-policy-appraisal.html

[23] Madhulika Vishwanathan, *Delhi High Court refuses to allow pharma industry's plea seeking stay on NPPA price cap decision*, SpicyIP, 5 August 2014, https://spicyip.com/2014/08/delhi-high-court-refuses-to-allow-pharma-industrys-plea-seeking-stay-on-nppa-price-cap-decision.html

[24] *Non-essential drugs: NPPA withdraws price control order*, The Hindu, 24 September 2014, http://www.thehindu.com/business/Industry/nonessential-drugs-nppa-withdraws-price-control-order/article6439154.ece

[25] "The above said guidelines dated 29.05.2014 and orders dated 10.07.2014 have been challenged in Bombay and Delhi High Court. The Union of India and NPPA which have been made respondents, after careful consideration in consultation with the M/o Law and Justice had decided to convey to the Hon'ble Courts that the guidelines dated 29.05.2014 are to be withdrawn." NPPA Powers not Withdrawn, Press Information Bureau, Government of India, 24 September 2014, http://pib.nic.in/newsite/PrintRelease.aspx?relid=109967

[26] Rupali Samuel, *AIDAN files PIL against NPPA decision to withdraw price control guideline*, SpicyIP, 9 October 2014, https://spicyip.com/2014/10/breaking-news-aidan-files-pil-against-nppa-decision-to-withdraw-price-control-order.html

[27] Anubha Sinha, *Parliamentary committee recommends imposition of price caps on all life-saving drugs*, SpicyIP, 30 April 2015, https://spicyip.com/2015/04/parliamentary-committee-recommends-imposition-of-price-caps-on-all-life-saving-drugs.html

[28] *Patented drugs details sought from Cos for price negotiation*, Business Standard, 29 January 2015, http://www.business-standard.com/article/pti-stories/patented-drugs-details-sought-from-cos-for-price-negotiation-115012901539_1.html

The current Modi government's election manifesto prominently featured the reduction of healthcare costs, and it remains a major aspect of the policy agenda. In 2016, after being chastised for its inaction by the Parliamentary Committee on Government Assurances for its "lackadaisical attitude" and "gross negligence" on this front,[29] the Department of Pharmaceuticals began a consultation process with various ministries on the price control of patented drugs.[30] More concrete change occurred on 1 October 2016, when Mr. Amitabh Kant, the CEO of the NITI Aayog, hosted a meeting with the Secretaries of the Department of Pharmaceuticals, the Ministry of Health & Family Welfare, and the Department of Industrial Policy and Promotion.[31] A decision was made to delink the DPCO from the NLEM, and wrest the price control function from the NPPA (an ostensibly independent body) and vest it directly in the Department of Pharmaceuticals (which functions directly under the political leadership).[32] Despite questions surrounding the authority of the attendees to take such a decision, the fact that the meeting occurred at the Prime Minister's Office makes it amply clear that the Modi government intends to follow through on its promise of cheap drugs via the price control route, regardless of patent status or essentiality.

C. Price control is Ineffective

Two cases must be considered in order to evaluate the effectiveness of the current price control framework: patented and non-patented drugs. The objective of price control is to broaden access to medicines in the short run, thus enhancing consumer welfare, while also ensuring that manufacturers have sufficient incentive to continue supplying the market within the ceiling price. This represents a fine balance, and I now examine whether such a balance is attainable by the current framework (or any hypothetical system of pharmaceutical price control).

1. Case I: Patented Drugs

The DPCO 2013 and the NPPA's guidelines permit price control of novel (and presumably patented) drugs in two ways. First, there exists a provision for setting the price of

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[29] *Parliament panel slams government on regulating prices of patented drugs*, The New Indian Express, 18 August 2016, http://www.newindianexpress.com/nation/2016/aug/18/Parliament-panel-slams-government-on-regulating-of-prices-of-patented-drugs-1510656.html

[30] Arijit Paladhi, *Govt seeks views on pricing patented drugs*, Mint, 23 September 2016, http://www.livemint.com/Politics/kVTTeIKZsy3xLYlNYeKCWO/Govt-seeks-views-on-pricing-patented-drugs.html

[31] Venkat Ananth, *Why India's drug price regulator's fate hangs in the balance*, The Ken, 9 December 2016, https://the-ken.com/why-indias-drug-price-regulators-fate-hangs-in-balance/

[32] RTI responses from the MoHFW and the NITI Aayog available on file with author.

new drugs according to the principles of pharmacoeconomics, which assigns a "fair market value" to new drugs based on their therapeutic effect. However, there exists no universal definition of value in healthcare, and attempts to quantify the value of any particular therapy have been proven to be vague and subjective.[33] More importantly, these principles have not been applied by the NPPA, and it is unclear if a hypothetical price control decision on such vague grounds by an administrative authority would survive judicial review by a writ court.

The alternative is for the regular average price calculus to be applied to a patented drug, in which market share is calculated depending on the number of variants of a formulation present on the market. In situations where the patentee is the sole manufacturer of the drug, the average price on the market must roughly be equivalent to the price set by the patentee, meaning that price control does little more than freeze the price of drugs set by the patentee at the time of product launch (subject to the mandatory annual upward revision of 3.6%). Such a ceiling price proves spectacularly and almost absurdly ineffective, given that patentees are likely to reduce the prices of patented products over time, meaning that the ceiling price fixed by the DPCO will be marginally higher than the monopolist's price on the market at first, and then progressively increase while the monopolist's price decreases.

Market trends in the pharmaceutical industry have been pointing to a shift in the manner in which originator firms work their patents in India. MNCs historically supplied the local market with patented drugs that their Indian subsidiaries manufactured or (more likely) imported from facilities abroad (such as Bayer's Nexavar, which was imported in low quantities until a compulsory licence was granted to Natco).[34] More recently, however, foreign originators are choosing to license their patents (often on a non-exclusive basis) to Indian generic manufacturers (such as Gilead Sciences' licence to seven companies for the manufacture of sofosbuvir).35 The strategy appeals to originators for several reasons: first, generic manufacturers are (along with NGOs) among the patent's strongest opponents.

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[33] Fernando Antonanzas, et. al., *The value of medicines: A crucial but vague concept*, 34 Pharmacoeconomics 1227 (2016).

[34] "Illustratively, the Form 27 filed in 2009–10 for Bayer's controversial drug Nexavar® (Patent No. IN21578) states that while 4665 units of the drug were imported into India, only 1679 units of the drug were sold." See Shamnad Basheer, Making patents work: of IP duties and deficient disclosures, 7 Queen Mary J. of IP 3 (2017).

[35] Rupali Samuel, *Gilead enters into licenses with 7 Indian generics for manufacture and sale of Sovaldi*, SpicyIP, 7 September 2014, https://spicyip.com/2014/09/gilead-enters-into-licenses-with-7-indian-generics-for-manufacture-and-sale-of-sovaldi.html

Illustratively, BDR Pharma, Natco Pharma[36] and the Indian Pharmaceutical Alliance (whose members are the largest generic manufacturers in the country by market share) had filed pre-grant opposition proceedings against the sofosbuvir patent with the Indian patent office.[37] All of them withdrew their oppositions as a direct consequence of the licensing agreement, perhaps as a result of a clause contained in it.[38] *Second*, licensing the patent and transferring the technology allows the originator to leverage its patent without any further investment in building a manufacturing presence, especially given that the opinion of the patent office[39] and independent scholars[40] is that local manufacture is a pre-requisite to satisfy the patent working requirement in Section 83(b) of the Patents Act.[41]

These situations are typically characterised by wide inter-brand price variation between the originator (which continues to sell the product at its international price) and the licensees (which sell the product at a significantly lower price). Illustratively, a single pill of sofosbuvir is priced at $1,000 by Gilead, while those manufactured by local licensees typically retail at around $4 per pill.[42] The ceiling price would be the average price of all variants of the patented drug, including those imported by the originator. Such an average is overwhelmingly likely to be significantly closer to the originator's price than the generic price. This is because the originator sells the "brand name" version of the drug, carrying with it two unique selling points. First, there exists a perception among patients (especially wealthy ones who can afford to pay for the originator's drug) that the branded drug is qualitatively superior or more efficacious than its generic counterparts.[43] Second, most doctors prescribe drugs under brand names, rather than generic or non-proprietary names,

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[36] PT Jyothi Datta, *More patent-opposition on Gilead's hepatitis C drug sofosbuvir*, The Hindu Business Line, 2 February 2015, http://www.thehindubusinessline.com/companies/more-patentopposition-on-gileads-hepatitis-c-drug-sofosbuvir/article6847904.ece

[37] *Sofosbuvir*, Patent Opposition Database, https://www.patentoppositions.org/en/drugs/sofosbuvir

[38] AN Gireesh Babu, *IPA, Natco withdraw opposition to Gilead's drug*, Business Standard, 14 September 2015, http://www.business-standard.com/article/companies/ipa-natco-withdraw-opposition-to-gilead-s-drug-115091300385_1.html

[39] "Section 83(b) states that Patents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article. Upon a reading of this provision it becomes amply clear to me that mere importation cannot amount to working of the patented invention." Natco v. Bayer, Compulsory Licence Application 1 of 2011 at p. 43.

[40] Basheer, *supra.*

[41] "83. Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely: […] (b) that [patents] are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article."

[42] Ketaki Gokhale, *The same pill that costs $1,000 in America sells for $4 in India*, Bloomberg, 29 December 2015, https://www.bloomberg.com/news/articles/2015-12-29/the-price-keeps-falling-for-a-superstar-gilead-drug-in-india

[43] Jeremy Greene, *Generic drugs: the same, but not*, The Atlantic, 30 March 2015, https://www.theatlantic.com/health/archive/2015/03/generic-drugs-the-same-but-not/388592/

despite consistent pressure to adopt generic prescription.[44] These selling points may allow (but not justify) the originator to command a higher price than its generic counterparts. However, price control regimes are blind to these distinctions, and must fix a single ceiling price for the formulation as a whole. In the example of sofosbuvir, the ceiling price is likely to be close to $800, an absurd and utterly irrelevant outcome in a situation where market forces set the optimal price for generics at close to 0.5% of the ceiling.

The only discernible effect of such a ceiling price would be on the branded drug manufactured or imported by the originator, who would be forced to cut prices by a small but significant percentage to remain under the ceiling. The originator may comply, and marginally enhance the welfare of wealthy consumers who opted for the branded drug over generic counterparts. However, these consumers are irrational actors, given that they have consciously chosen the branded drug over a cheaper substitute. On the other hand, the originator may value its brand equity and opt to pull the branded drug off the Indian market, thereby safeguarding itself from the threat of parallel imports into more lucrative international markets. In doing so, the originator would be immune from Section 84 liability for non-working since it has extensively licensed its patent.

In either case, it is clear that the price control has had no effect on enhancing access to the patented drug.

2. Case II: Off-patent drugs

Here, I only consider the effect (or lack thereof) that market-based price controls have on off-patent drugs. This is because market-based controls are generally seen as superior to cost-based price controls for two reasons. First, cost-based controls eliminate firms' incentive to innovate to reduce their production costs, leading to a stagnation in the state of the art. Second, cost-based controls are vulnerable to misreporting and inflated accounts of raw material costs by firms.

The nature of the Indian drugs market makes it particularly unsuited to market-based price controls. The pharmaceutical industry is one of several sectors which features significant collaboration in the form of advocacy organisations that lobby the government on behalf of their members. The Indian Pharmaceutical Alliance counts about twenty of the

[44] Rakhi Jagga, *Health minister to doctors: prescribe salt name only*, The Indian Express, 26 October 2013, http://archive.indianexpress.com/news/health-minister-to-doctors-prescribe-salt-name-only/1187523/

biggest manufacturers in the country as its members, while the Organisation of Pharmaceutical Producers of India and the Indian Drug Manufacturers' Association represent hundreds of smaller companies. All three organisations have built relationships with regulators, and are known to influence the business decisions of its members. In addition, as discussed previously, intermediaries in the Indian drugs market have disproportionately high bargaining power. OPPI, IDMA and the IPA all have signed MoUs with the AIOCD[45] and its subsidiary organisations regarding price margins and resale price maintenance. These factors ensure that producers have perverse incentives to manipulate any market-based price control imposed on them. In fact, the high degree of collaboration among manufacturers, when coupled with similar levels of demand-side consolidation, ensures that market players (either manufacturers, wholesalers or retailers) who undercut the price set by the associations are unlikely to reach consumers. This is because organisations such as the AIOCD frequently utilise trade boycotts as a means to enforce their terms on the market.[46] While demand-side consolidation has frequently been used as a defence against Section 4-type abuse of dominance claims by market players[47] (who counter the accusation by arguing that the countervailing market power afforded by such consolidation militates against their own dominant position in the market),[48] the issue at hand does not involve abuse of dominance.[49] On the contrary, the circumvention of price control occurs through a coordinated price increase in the period immediately preceding price regulation, so as to raise the market-based ceiling price.[50] In this context, demand consolidation in the form of intermediary associations has an anti-competitive effect, inasmuch as these associations act as gatekeepers of the consumer market and hold manufacturers to ransom.[51]

One study tracked the price of the off-patent anti-diabetic metformin between 2007 and 2015 to study the impact of the DPCO 2013. In an ostensibly competitive market, with an average of 61 manufacturers selling 69 versions of the drug in any given month, the drug was

[45] Peeveear, supra.
[46] Santuka and PK Krishnan, supra.
[47] *See, eg., General Electric v. Commission*, Case T-210/01, European Court of First Instance (Second Chamber) 2005. Although the issue here was primarily one of merger control, the combination's dominance is discussed.
[48] John Lopatka, *Predatory Buying*, in Roger Blair and Daniel Sokol (eds.), The Oxford Handbook of International Antitrust Economics Vol. II (Oxford 2015)
[49] While demand consolidation has been the subject of much academic attention, the current literature primarily focuses on consolidation through managed medical care, in the form of universal insurance and other such schemes. *See* Dranove David, et. al., *Is managed care leading to consolidation in healthcare markets?*, 37 Health Serv. Res. 573 (2002).
[50] Peter Law, Welfare effects of pricing in anticipation of Laspeyres price-cap regulation: an example, 49 Bull. of Econ. Res. 17 (1997)
[51] Warren Grimes, Buyer power and retail gatekeeper power: protecting competition and the atomistic seller, 72 Antitrust L. J. 563 (2005)

priced at INR 1 per 500mg dose in 2007. Given the nature of the market, prices should have remained constant or increased steadily, as they do in the control period (between 2007 and 2009). Upon the initiation of stakeholder consultation by the government to draft the NLEM 2011, manufacturers began a rapid and coordinated price escalation, armed with the knowledge that the 500mg dosage of the drug would fall in the list. The 1000mg dosage did not figure in the NLEM, and was used as a reference in the study. The 2011-2013 period witnessed a steep rise in the average price of the 500mg dosage, without a similar rise in the price of the 1000mg tablet. Upon the fixation of the ceiling price under the DPCO 2013 (at approximately INR 1.6 per 500mg tablet), prices marginally reduced under the ceiling. The market data is conclusive: manufacturers coordinated selectively in the 500mg tablet market between 2011 and 2013 to raise the ceiling price of the drug.[52]

While it is true that backdated market references for the imposition of price control may partially mitigate this form of cheating, such backdating requires accurate data on price trends, inflation, etc., which are not realistically available to the government. In addition, the choice of a cutoff date to determine prevailing market prices is inherently vague and subjective, meaning that it (like the principles of pharmacoeconomics) would be insufficient to base an administrative decision, especially under writ review.

It is important to note that the structure of the drugs market in India makes it extremely difficult for firms to cheat their way out of horizontal agreements to circumvent price controls through coordinated price increases. This is because any deviation by a manufacturer would likely be met with swift retribution from industry associations in the form of a sales boycott and the accompanying denial of market access. These factors severely disincentivise cheating horizontal agreements, meaning that the game theoretical foundations of cartel-busting simply fail to work in the context of the Indian drugs market.[53]

The fact that price control in the drugs market today is entirely ineffective appears to be the subject of a careful cover-up by industry players. Associations such as the IPA are known to frame victim narratives[54] in which they hold price control squarely responsible for

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[52] Ajay Bhaskarbhatla, et. al., Mitigating regulatory impact: the case of partial price controls on metformin in India, 32 Health Pol. & Plg. 194 (2016).
[53] Christopher Leslie, *Antitrust amnesty, game theory, and cartel stability*, 31 J. of Corporation L. 453 (2006).
[54] *IPA punches holes into drug pricing policy implementation*, Economic Times, 4 April 2017, http://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/ipa-punches-holes-into-drug-pricing-policy-implementation/articleshow/58010089.cms

the pharmaceutical industry's stunted growth in recent years.[55] More insidious is the fact that they do this despite well-documented internal statistics dispelling this claim. In fact, an internal report drafted by the IPA in February 2017 admits that the majority of the market is effectively out of price regulation, and an estimated 2-4% of its members' revenue was hit by price control. Price regulation, to quote a senior executive of an IPA member company, is not one of the industry's primary problems.[56]

D. Price control harms consumer welfare by acting as an antitrust vaccine

I have established that pharmaceutical price control on the Indian market does not enhance consumer welfare by lowering prices, both for patented and off-patent products. The reasons may vary, but in all cases, the ceiling prices imposed by price control fall at or above the prices set by the manufacturer of the drug. However, mere redundancy may not prove to be a strong enough argument against pharmaceutical price control, since there exist a number of laws that are unenforceable, redundant or simply pointless.[57] In contrast to these laws, I argue that pharmaceutical price control has the potential to cause active harm to consumer welfare. Although I have attempted to show previously that all forms of price control in the Indian drugs market will fail, here I confine myself to the current model of price control as mandated by the DPCO 2013. This is for two reasons: having shown that all price control is ineffective, I no longer shoulder a burden to show that alternative, hitherto untested models of price control are harmful – lack of efficacy is sufficient to refrain from legislating new policies, but the additional element of harm is only necessary to overcome the inertia of policies already in place. More importantly, criticisms of price control must necessarily depend on the precise model of regulation employed. Consequently, it would be impossible to catalogue the harms of vague and hypothetical models.

I have established that in an overwhelming majority of cases, the ceiling price is likely to be well above the price set by the market in equilibrium. I argue that the imposition of such ceilings effectively immunises manufacturers from antitrust scrutiny for at least some of their actions on the market.

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[55] *See, eg.,* DG Shah, *A chill pill that India needs*, Economic Times, 13 April 2017, http://blogs.economictimes.indiatimes.com/et-commentary/a-chill-pill-that-india-needs/ (note that the author is Secretary General of the IPA and speaks in his official capacity)

[56] Ruhi Kandhari, *What is hurting Indian pharma more – misinformation or price control?*, The Ken, 20 April 2017, https://the-ken.com/indian-pharma-misinformation-price-control/

[57] Suicide legislation is one such example. *See, eg.*, Gerry Holt, *When suicide was illegal*, BBC News, 3 August 2011, http://www.bbc.com/news/magazine-14374296

This is because a price control model of this sort effectively gives manufacturers free licence to do as they please as long as they stay beneath the ceiling price. While this would ordinarily pose no significant problem, it results in concrete harms in situations where the ceiling price is substantially supra-competitive in and of itself.

A unique chain of circumstances allows manufacturers to take advantage of pharmaceutical price control at the expense of consumer welfare. To begin with, the price control regime (effectively acting as an administrative determination that supracompetitive pricing, to a point, is acceptable) permits sub-ceiling price increases by manufacturers. In any other country or any other market, the first supplier to carry out such a price increase would be severely undercut by competitors, and forced to return to the equilibrium market price. In ordinary circumstances, even a relatively small lone supplier holding out at the equilibrium price would suffice to combat a coordinated price increase by the rest of the manufacturers. However, another factor unique to the Indian market prevents this failsafe from kicking in: intermediary demand consolidation through organisations such as the AIOCD. Since these intermediaries act as retail gatekeepers, any manufacturer that cheats or holds out from a coordinated price increase is likely never to see a consumer at the end of the tunnel. Finally, when the entire act does finally come before the antitrust regulator, it is unlikely to be treated as a serious infraction of antitrust law, since the burden of proof for the regulator increases manifold when it needs to show that a sub-ceiling price increase adversely impacted consumer welfare.

To illustrate, we need only examine the CCI's treatment of sub-ceiling pricing policies in the drugs market. In *Peeveear*,[58] the CCI examined allegations that the OPPI, IDMA and AIOCD colluded to fix trade margins and allocate value among manufacturers, wholesalers and retailers. The DG's report, and subsequently the CCI order, extensively referenced paragraph 19 of the DPCO 1995, which provided as follows:

> "*19. Price of formulations sold to the dealer – (1) A manufacturer, distributor or wholesaler shall sell a formulation to a retailer unless otherwise permitted under the provisions of this order or any order made there under, at a price equal to the retail price, as specified by an order or notified by the government, (excluding excise duty, if any) minus sixteen percent thereof in the case of Scheduled drugs*."

[58] Peeveear, supra.

In interpreting paragraph 19, the DG and the CCI committed a crucial error by holding that the DPCO imposed a *statutory obligation* to pay a sixteen percent margin to retailers in respect of scheduled drugs.[59] On the contrary, the framers of the DPCO only intended to fix a *ceiling* on the prices and margins charged on drug sales. The CCI, in its wisdom, interpreted the DPCO to mean that it had fixed a statutory price from which no deviation was permissible. This interpretation is significant, since the CCI's order held that the provision of a 20% retail margin amounted to an anticompetitive vertical agreement between manufacturers' and retailers' associations, while refraining from interrogating a "statutorily provided" margin that was merely 4% lower. I submit that the existence of a ceiling on retail margins rendered the AIOCD, the OPPI and the IDMA immune from antitrust proceedings, as long as they did not overstep such a ceiling. In situations where the ceiling is substantially and significantly supracompetitive, firms have no incentive to overstep (or even closely approach) the ceiling price. Hypothetically, if the price of generic insulin in the market today is 60% of the ceiling price, then a coordinated price increase to about 80% of the ceiling price would enrich manufacturers and retailers immensely at the expense of consumer welfare, while simultaneously staying below the antitrust radar.

Price-fixing by generic drug manufacturers is a global phenomenon, as evidenced by the fact that no fewer than twenty states in the US have initiated antitrust proceedings in this respect.[60] The fact that leaders in the Indian generic industry such as Aurobindo Pharma and Emcure Pharma have been implicated in the suits (with the latter being named as the "ringleader")[61] must come as no surprise, given the results of the metformin study discussed above.

III. ENGAGING THE IP/COMPETITION INTERFACE

Price control can prove especially disastrous in IP-fuelled industries, as evidenced by the market's reaction to a recent decision by the Indian government to bring genetically

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[59] "Thus, while working out the price of scheduled drugs, the National Pharmaceutical Pricing Authority (NPPA) makes an allowance for 16% margin on price to retailer (as per DPCO, 1995) and 8% margin to wholesaler as per practice. However, DG also noted that for non-scheduled drugs (drugs not under price control), there is no statutory obligation to pay any specified margins to either the retailers or the wholesalers." Id. at paragraph 5.3.3.

[60] Katie Thomas, *20 states accuse generic drug companies of price fixing*, The New York Times, 15 December 2016, https://www.nytimes.com/2016/12/15/business/generic-drug-price-lawsuit-teva-mylan.html

[61] Zeba Siddiqui, *Aurobindo Pharma shares hit nine-month low on US price-fixing lawsuit*, Mint, 16 December 2016, http://www.livemint.com/Money/SGgSIaxPImqi7VHyLU6YfJ/Aurobindo-Pharma-shares-hit-ninemonth-low-on-US-pricefixin.html

engineered cotton seeds under price regulation. The government invoked the Essential Commodities Act[62] to fix the trait value that Monsanto (which owned patents and related know-how covering the technology)[63] could charge to sell bollworm-resistant cotton seeds to Indian companies.[64] The move met mixed response from activists[65] and experts, [66] but its most significant impact was Monsanto's decision not to launch the latest generation of its cotton seed technology in India.[67] In a market where the monopolist's product has little in the way of equivalent competition, this was a catastrophic result for Indian agriculture, and serves as an illustration of the manner in which price control can elicit the worst out of the market.

Regulatory intervention in the form of ineffective price control also has adverse implications for the delicate balance that currently characterises the relationship between IP protection and antitrust intervention. It is undoubted that price control of patented drugs would meet stiff challenges in the form of TRIPS compliance,[68] but that is not the focus of this paper. The essential question that must be asked is whether there are in-built safeguards in IP and competition law that enable policymakers to achieve similar or better results with respect to access to patented drugs than price control.

A. Test cases in the market for patented drugs

As explained previously, Indian patent law contains sufficient safeguards through the threat of compulsory licensing against patentees who fail to "work" their invention, and patentees who fail to meet reasonable market demand.[69] Consequently, supracompetitive

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[62] Cotton Seed Price (Control) Order 2015. *Fix a uniform price of Bt cotton seeds across the country for the benefit of farmers*, Press Information Bureau, Government of India, 9 March 2016, http://pib.nic.in/newsite/PrintRelease.aspx?relid=137599

[63] Sanjeeb Mukherjee, *Seed pricing: cottoning on to controls*, Business Standard, 22 March 2016, http://www.business-standard.com/article/economy-policy/seed-pricing-cottoning-on-to-controls-116032201241_1.html

[64] Sayantan Bera and Shreeja Sen, *Govt cuts Bt cotton royalty fees by 74%*, Mint, 10 March 2016, http://www.livemint.com/Politics/NdDYRxsayfh2655qOqy7mI/Centre-notifies-Bt-cotton-seed-prices-slashes-royalty-fees.html

[65] Vandana Shiva, *Why the government is right in controlling the price of Monsanto's Bt cotton seeds*, Scroll, 22 August 2016, https://scroll.in/article/814476/why-the-government-is-right-in-controlling-the-price-of-monsantos-bt-cotton-seeds

[66] Vivian Fernandes, *Bt cotton price control against R&D*, Financial Express, 12 December 2015, http://www.financialexpress.com/opinion/column-bt-cotton-price-control-against-rd/177690/

[67] *Monsanto pulls new GM cotton seed from India in protest*, The Hindu, 25 August 2016, http://www.thehindu.com/business/Monsanto-pulls-new-GM-cotton-seed-from-India-in-protest/article14588852.ece

[68] Article 31's extensive focus on fair remuneration to the patentee might be one of many stumbling blocks.

[69] Section 84 of the Patents Act 1970 states: "*Compulsory licences.* -

pricing can only occur in situations where the patentee is able to singlehandedly supply the drug to the Indian market. In the overwhelming majority of cases, the originator is an MNC with little or no local manufacturing capacity, meaning that licensing arrangements of the form mentioned previously are the only sure-shot strategy to avoid compulsory licensing. Consequently, the challenge for Indian IP and competition law is to prevent supracompetitive pricing at the level of licensing agreements.

B. Safeguards in competition law

Patentees enjoy a lawful monopoly under Indian law that appears, at first glance, to be exempt from antitrust scrutiny.[70] Upon deeper examination of the CCI's orders dealing with patent protection, however, it is clear that nothing could be further from the truth.

The CCI's analysis of IP suggests that it is open to inferring dominance from the mere fact that a market player holds patents over certain technologies.[71] Going further, the CCI has also recognised that the threshold for abuse of IP-induced dominance in the market is not high. In the Auto Parts case,[72] for example, the CCI has held that unilateral refusals to license patents would violate Section 3 of the Competition Act if they foreclosed market access to downstream players such as independent service providers and small mechanics.

More pertinent for our purposes is the CCI's treatment of vertical agreements between licensors and licensees of patents, since this is the nature of the relationship between large foreign originator MNCs and local Indian drug manufacturers. In such circumstances, the

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At any time after the expiration of three years from the date of the 170 [grant] of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:-
that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
that the patented invention is not available to the public at a reasonably affordable price, or
that the patented invention is not worked in the territory of India."

[70] Section 3(5) of the Competition Act, for example, states that *"Nothing contained in this section shall restrict—*
the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights which have been or may be conferred upon him under:
the Copyright Act, 1957 (14 of 1957);
the Patents Act, 1970 (39 of 1970); […]"

[71] *Micromax v. Ericsson*, CCI Case No. 50 of 2013, http://www.cci.gov.in/sites/default/files/502013_0.pdf

[72] *Shamsher Kataria v. Honda Siel, et. al.*, CCI Case No. 3 of 2011, 25 August 2014, http://www.cci.gov.in/sites/default/files/032011_0.pdf?download=1

CCI has leaned perilously close to holding "restrictive" vertical agreements as *per se* anticompetitive:[73]

> "*...a non-dominant enterprise may enter into a vertical agreement which forecloses the market but enhance certain distribution efficiencies, and in such conditions the Commission on balancing the factors provided in section 19(3), may conclude that such agreement does not cause an AAEC in the market. However, where such agreements are entered into by a dominant entity, and where the restrictive clauses in such agreements are being used to create, maintain and reinforce the exclusionary abusive behavior on part of the dominant entity, then the Commission should give more priority to factors laid down under section 19(3)(a) to (c) than the pro-competitive factors stated under section 19(3)(d) to (f) of the Act, given the special responsibility of such firms not to impair genuine competition in the applicable market*."

In essence, the CCI's stance appears to be that while restrictive vertical agreements entered into by non-dominant players are subject to a "rule of reason" analysis, those entered into by dominant players are subject to a modified form of scrutiny in which the anti-competitive factors are weighed heavier than pro-competitive ones.

Dominance is easily established from the mere existence of a patent monopoly, especially in the market for cutting-edge pharmaceutical preparations. In the example of sofosbuvir, the product drug has no substitute insofar as its ability to treat Hepatitis C Virus without its myriad side effects is unique. Once a finding of dominance is returned, the modified inquiry in Auto Parts will necessarily mean that restrictive conditions (such as exorbitant royalties, resale price maintenance, etc.) are particularly vulnerable to antitrust intervention.

It is important to note that the liability here would be under Section 3 for the licensing agreement that causes an AAEC, rather than under Section 4 for abuse of dominance. The CCI's reasoning in the Auto Parts test seems to hold dominance as a necessary but not sufficient factor – liability is attracted by the licensor for entering into a restrictive licence which poses appreciable anticompetitive effects and distorts the market. However, the

[73] *Id.* at paragraph 20.6.35.

dominant or non-dominant position of the licensor will play a role in deciding the relative weight of the evidence that AAEC has occurred.

The only question left to answer from a competition perspective is whether the CCI has formulated an appropriate test to detect supracompetitive pricing. The jurisprudence on this point, primarily illuminated in *HT Media v. Super Cassettes*,[74] where it has noted that "*determining whether a price is excessive is an uncertain and difficult task*:"[75]

> "*The Commission notes that in the absence of the cost data it will be difficult, neigh impossible, to term the price charged by the opposite party at 661 INR per needle hour as unfair being excessive solely on the basis that it is higher than the price charged by the competitors of the opposite party. In view of all factors discussed in the preceding paragraphs above, the Commission holds that a case of excessive pricing has not been made out against the opposite party*."

However, supracompetitive royalty rates have, in fact, been addressed by the CCI and the Delhi High Court in SEP/FRAND cases such as *Micromax v. Ericsson*,[76] resulting in market players abiding by court or regulator-ordered royalty structures.[77] In addition, the subjective determination of whether a licensor's asking price is supracompetitive can be best answered by competitors on the market. As will be shown below, Indian patent law provides competitors an opportunity to do so.

C. Safeguards in IP law

The Patents Act contains unique compulsory licensing provisions in Section 84, which provide that any interested party may apply to the patent office (after meeting some threshold criteria such as making an attempt to obtain a voluntary licence on mutually agreeable terms) for a licence to practice the patent. In *Natco v. Bayer*,[78] one of the grounds pleaded by the applicant was Section 84(1)(b), which tackles the question of affordability (rather than competitive pricing). Applicants for licences under Section 84(1)(b) are typically required to furnish information to the patent office as to their intended pricing policies in the

[74] CCI Case No. 40 of 2011, http://www.cci.gov.in/sites/default/files/C-2011-40_0.pdf
[75] *Id.* at paragraph 199.
[76] Supra.
[77] *Ericsson v. Intex*, [2015] SCCOnline Del 8229
[78] Compulsory Licence Application 1 of 2011

event that they receive the licence. Section 84(1)(b) filing information may prove valuable information for an antitrust regulator, since it may point to a competitive price that market player is willing to offer the patented product to the market at. In addition, the price offered in the Section 84 application is typically awarded without modification upon the success of the application, meaning that successful applicants may not subsequently raise the prices of the patented product.

However, it is equally important to note that the exact calculus utilised for price determination under Section 84 may not be suited to detect supracompetitive pricing. In *Lee Pharma v. AstraZeneca*,[79] the patent office denied a compulsory licence to the applicant on the ground that the patentee's anti-diabetic drug (saxagliptin) was priced in the same range as other patented drugs of the same class. The patent office refused to consider generic drug (either licensed or infringing products) prices in the same class since the patentee may be justified in charging a higher price to recoup its research costs. A vast divergence between the patentee's price and an applicant's offer, as in the case of Natco, would nevertheless be a strong indicator of supracompetitive pricing by the patentee.

Another provision in the patent law that could be used to mitigate anticompetitive licensing structures is Section 140, which prohibits and renders void restrictive covenants in patent licences. These include some forms of tying and exclusive grant-back clauses that may distort downstream innovation in the market. However, Section 140 has never been used in the competition context, and it is unclear whether it is enforceable by the competition regulator.

IV. CONCLUSION

Over the course of this paper, I have attempted to show that price control is both ineffective and pernicious in the pharmaceutical context, with particular reference to the development and launch of new drugs into the market. Price regulation amounts to nothing more than a ham-handed attempt to preserve short-term interests at the expense of long-term market stability. As such, it can be justified in a narrow set of circumstances, such as epidemics and military engagements. Its use by the Indian government as a peacetime policy instrument is alarming, and must immediately cease in favour of a combination of IP and

[79] Compulsory Licence Application 1 of 2015. *See* Balaji Subramanian, *Examining the rejection of Lee's Saxagliptin CL application*, SpicyIP, 22 January 2016, https://spicyip.com/2016/01/examining-the-rejection-of-lees-saxagliptin-cl-application.html

competition law. Indian antitrust jurisprudence has shown itself to be more than enthusiastic to break down IP-enabled abuses, and IP law offers an opportunity to tackle supracompetitive pricing and restrictive licensing.