# REVERSE PATENT SETTLEMENTS IN INDIA†

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## I. Introduction

Intellectual property law and competition law have been in conflict ever since the advent of competition law. The inherent difference in the approach to generate public welfare itself between these two branches of law makes it the bone of contention. The more recent development in this controversy of competition law and intellectual property law is of reverse patent settlements, particularly in the pharmaceutical industry. Popularly known as 'Pay-for-Delay', it is a strategy through which patent holders[1] seek to extend the exclusivity period of their patented products by making payments to potential competitors, in order to prevent entry of generic suppliers on, or before the expiry of the patents.[2] Contrary to the common understanding of a judicial settlement, where the infringer pays the patentee to settle the lawsuit, in the case of reverse patent settlements, the patentee pays a large amount of money to the alleged infringer to settle the lawsuit and prevent entry of the generic drug in the market. A study undertaken by the American Federal Trade Commission indicates that these settlements are estimated to cost consumers in the United States of America (USA) alone, USD 3.5 billion per year.[3] Similarly, the escalating magnitude of the Indian pharmaceutical industry makes discourse on this issue the need of the hour.[4]

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† This article reflects the position of law as on 31 May 2016.

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1 Hereinafter referred to as 'originators'.

2 Federal Trade Commission 'Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers' (2010) 1.

3 *Ibid*, 2.

4 *See* 'India Pharma 2020: Propelling Access and Acceptance, Realising True Potential' (2010) *McKinsey & Co*, *available at* http://online.wsj.com/public/resources/documents/McKinseyPharma2020ExecutiveSummary.pdf (last visited 31 May 2016).

This article analyses the essential constituent elements and the impact of reverse settlements, in Part II. Part III deals with the stand taken by foreign jurisdictions on reverse patent settlements. It includes a perusal of the regulatory framework and judicial development in USA, the European Union (EU), and the United Kingdom (UK) with emphasis laid on the landmark cases of the respective jurisdictions. Part IV discusses these settlements specifically in the Indian context. The discussion also includes the likelihood of emergence of such settlements in India and the ambit of the Competition Commission of India (CCI) to adjudicate upon/address such issues and the proposed approach to deal with the same.

## II. Analysing Reverse Patent Settlements

### *A. Essential Elements that Constitute a Reverse Patent Settlement*

Reverse patent settlements consist of two basic elements – (1) limitation of generic entry; and (2) value transfer to the generic company.

#### 1. Limitation Of Generic Entry

The entry of generic drug in a competitive market can be restricted either partially or wholly, according to the terms of the license agreement, which the originator controls. The most popular form of limitation of generic entry is an explicit clause contained in the settlement agreement, which specifically lays down that the generic drug maker recognises the validity of the patent of the originator and will desist from entering the market till the validity of such patent expires. Similarly, the originator could also allow the generic drug limited entry in the market by allowing access only to certain patent rights in the license. Due to these reverse patent settlements, the originators are devoid of competitive threats from generic manufacturers and hence, there is an absence of free competition in the market for that particular drug.[5]

#### 2. Value Transfer To The Generic Manufacturers

Value transfers involved in patent settlements agreements take several forms, the most prominent being, payment of a lump sum amount from

5 *See* Competition DG: European Commission '55th Report on the Monitoring of Patent Settlements' (2014) 3.

the pioneer drug company to the generic manufacturer. Other forms of value transfer include compensation for the generic manufacturers' legal cost in a patent dispute, purchase of assets, distribution for agreement by which the generic drug manufacturer obtains commercial benefits by distribution of the pioneer pharmaceutical drug. A newly evolved form also includes 'side-deals' carried out by the originators, in which the generic is allowed to enter the market before the expiry of the patent in a – (i) different geographical boundary; or (ii) with another product altogether. A value transfer could also be in the form of a patent license to the generic manufacturer that would permit the company to enter the market, though restricting its access. The conditions and requisites of a value transfer agreement are vital in determining the level of such a value transfer.[6]

### *B. Impact Of Reverse Patent Settlements*

The global pharmaceutical industry is a USD 300 billion industry, with figures estimated to rise to USD 400 billion by the end of 2016.[7] Legal mechanisms of intellectual property rights and competition law, across the world have scrambled to regulate this sector by protecting rights of patent holders but also ensuring absence of market collusion and promoting growth of the industry. *Prima facie*, it can be observed that reverse patent settlements have a dual negative impact, mainly being – (1) consumer welfare; and (2) *ex ante* effect on innovation.

#### 1. Consumer Welfare

Imbalance in market economic power in any industry could result in creation of monopolies or monopsonies, which tend to decrease consumer welfare. However, unlike other privately traded goods, the pharmaceutical industry bears an ethical burden since healthcare is an established fundamental right. Hence, it is vital for the web of laws to find a policy that protects consumers. The impact on consumer welfare can be explained in two broad categories – (a) *ex post* consumer welfare; and (b) overall consumer welfare.

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6 *Ibid*.

7 Annemarie M, 'The Gray Intersection of Pharma Patent and Reverse Payment Settlement Regulation' (2014) *Pharmaseutical Compliance Monitor*, *available at* http://www.pharmacompliancemonitor.com/gray-intersection-pharma-patent-reverse-payment-settlement-regulation/7703/ (last visited 31 May 2016).

### *a. Ex-Post Consumer Welfare*

It is a direct reflection of the level of consumer welfare that would be lost due to the entering into of a reverse patent settlement by parties rather than the patent being challenged and subsequently being adjudged upon by a court of law.[8] The term *ex post* is utilised in the context since the consumer welfare is calculated assuming that the innovation has already taken place. Reverse patent settlements create an environment in which the originator can exploit the consumer by hiking the prices of the drug significantly while the potential market entrant is barred, leaving the consumer with little choice in case of essential drugs. If the settlement exclusion period exceeds the expected litigation exclusion period, the *ex post* consumer welfare would be mammoth and would lead to heavy loss of consumer welfare.

### *b. Overall Consumer Welfare*

Reverse patent settlements often also cause overall depletion of consumer welfare. The fact that the originators actually pay a lump sum amount to the generic challenger mitigates the chance that the patent will be subject to review in a court of law. This will deprive the legal machinery of the opportunity to 'weed out' the weak patents, thereby preserving unwarranted rights, detrimental to the interest of consumers. While drug companies often argue that reverse patent settlements are in fact pro-competitive, and a viable tool for commercial settlement, sensibly protecting the originator's research and development investment, it does not appear to be so. In practice, it is often seen that generic manufacturers have prevailed in 73 per cent of challenges against the brand name drug owner, in matters computed over a decade.[9] Consumers pay extravagant prices for innovative-patented drugs but very often prices fall rapidly as soon as a generic equivalent enters the market. Therein lies the short-term interest for generic drug makers; the long-term interest being drug discovery encouraged by patent protection regulations.

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8 Einer Elhauge and Alex Kruger, 'Solving the Patent Settlement Puzzle' (2012) 91 *Texas Law Review*, 293.

9 Federal Trade Commission, 'Generic Drug Entry Prior to Patent Expiration: An FTC Study' (2002) 13.

### 2. *Ex-Ante* Effect on Innovation

An important drawback of reverse patent settlements is that it discourages innovation. If a patent legislation system were designed optimally, fostering an environment that encourages efficient amount of innovation, it would in turn benefit the consumers. Reverse patent settlements exceed the exclusivity of a patent beyond the period that it deserves. Economic assessments prove that patent profits that exceed the desired level result lead to excessive investment in innovation, resulting in loss of social welfare, as opposed to an optimal investment.[10] Pay-for-delay settlements encourage generic manufacturers to challenge the branded drug as the computed reward for less deserving patents or unscrupulous inventions are greater than more deserving or genuine innovations. The conditions generated by these settlements, hence, provide greater profits for weaker patents without having to spend large sums on innovation or clinical trials. Hence, if a company is faced with a choice between investing in an arduous genuine innovation that would involve large investments, and an unscrupulous innovation, the artificial and unjust reward obtained *via* reverse patent settlements may distort its choice, causing loss of innovation which would eventually cause grave repercussions to consumer welfare.[11]

## III. Foreign Jurisdiction

In order to fully appreciate the discourse of reverse patent settlements in the Indian scenario, it is expedient to understand certain nuances in development of reverse patent settlements in foreign jurisdictions.

### *A. United States Of America*

#### 1. Regulatory framework

The most prominent legislation in the United States of America is the *Drug Price Competition and the Patent Term Restoration Act of 1984* (Hatch-Waxman Act).[12] In fact the very emergence of reverse patent settlements is a direct consequence of the Hatch-Waxman Act. The Hatch-Waxman

10 *Supra* n. 8, 294.

11 *Supra* n. 8, 284, 294.

12 *The Drug Price Competition and Patent Term Restoration Act, 1984* Pub L 98- 417, 98 Stat 1585.

Act primarily serves to bring lower cost generic equivalents of branded drugs in the market, in turn making essential generic drugs widely available to consumers at low costs.[13] The Hatch-Waxman Act fosters litigation challenging the validity or enforceability of the patents by providing a reward in the form of a 180-day exclusivity period to generic manufacturers that challenge the patent.[14]

Prior to the passing of the Hatch-Waxman Act, generic drug manufacturers were required to undertake a lengthy procedure for approval by the Food and Drug Administration (FDA). However, the passage of this historic legislation metamorphosed the legal mandate imposed on generic manufacturers by shortening the process. The Hatch-Waxman Act now provides that generic drug manufacturers can acquire FDA approval by merely proving that the generic drug is as safe and effective as its brand name drug, *inter alia* by relying on existing data. On obtaining this certification from the FDA, the generic brand will obtain a 180 day exclusivity period during which it will be the only generic manufacturer of the product. However, this is a perk offered only to the first generic manufacturer. Even though the spirit of the Hatch-Waxman Act suggests that it encourages generic manufacturers to file applications and enter the market without exorbitant research cost, in practice it virtually creates a mechanism *via* which the originators delay the release of generic drugs through settlements entered into with the generic drug manufacturers, and extend the exclusivity of their drugs even beyond the patent validity period. These settlements have increasingly gained popularity amongst the pioneer drug patent owners as litigation is onerous for a company, since if the generic manufacturer is successful, the originator risks losing a significant portion of its market. While for the generic manufacturer, regardless the outcome of litigation, the generic will not be subject to any form of substantial damages, as the relief is merely injunctive.[15] Hence, it is quite often contended that reverse payment settlements stemmed from the Hatch-Waxman Act itself.

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13 Olga Gurgula, 'Restrictive Practices in Pharmaceutical Industry: Seeking for a Balance between Intellectual Reverse Payment Agreements Property and Competition Law' (2012) *Global Antitrust Review* 66.

14 *Ibid*, 67.

15 This is so because the Hatch-Waxman Act makes the filing of the Abbreviated New Drug Application (ANDA) a constructive act of infringement.

## 2. Judicial Approach

### *a. The Circuit Split*

Prior to the *Actavis* case,[16] the federal circuit courts were in disagreement as to the suitable approach to analyse reverse patent settlement agreements. The varying approaches of the different circuit courts have been briefly elucidated below:

#### (i) *Per Se* Illegality

The Sixth Circuit Court categorically held reverse patent settlements to be illegal by their very object.[17] The court regarded such a settlement to be, at its core, a horizontal agreement to eliminate competition in the market.[18]

#### (ii) Scope of Patent

Rejecting the *per se* illegality approach developed by the Sixth Circuit Court, the Eleventh Circuit Court developed the 'scope of patent test' wherein it was held that reverse patent settlements would violate competition law only if the settlement exceeded the exclusionary powers granted by the patent.[19] The court laid down the factors to be considered for an effective antitrust analysis of reverse patent settlements, namely– (i) the scope of the exclusionary potential of the patent; (ii) the extent to which the provisions of these settlements exceed that scope; and (iii) whether any provisions that exceed the scope were illegal according to traditional antitrust analysis.[20, 21]

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16 *Infra* n. 25.

17 *Wholesale Drug Co* v. *Hoechst Marion Roussel* (*In re Cardizem CD Antitrust Litig*), 332 F.3d, 896 (6th Cir 2003).

18 *Wholesale Drug Co* v. *Hoechst Marion Roussel (In re Cardizem CD Antitrust Litig*), 332 F.3d, 908 (6th Cir 2003).

19 *See Valley Drug Co* v. *Geneva Pharmaceuticals Inc* 344 F.3d, 1294 (11th Cir 2012); *Federal Trade Commission* v. *Watson Pharmaceuticals Inc* 677 F.3d, 1298 (11th Cir 2003).

20 *Federal Trade Commission* v. *Watson Pharmaceuticals Inc* 677 F.3d 1312 (11th Cir 2012).

21 Traditional antitrust analysis factors include likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations.

(iii) Presumptively Unlawful

Dubbing the scope of patent test as an 'almost irrebuttable presumption of patent validity',[22] the Third Circuit Court instead held that reverse patent settlements are 'presumptively illegal'. This approach shifts the onus on the defendants to show that the agreement is not anti-competitive, which can be discharged on two grounds – (i) by showing payment was for a purpose other than delayed entry; or (ii) by establishing pro-competitive benefits of such payment.[23]

*b. The Actavis Case*

The *Actavis* case is considered the single most significant development in the reverse patent settlement conflict in USA, and possibly the world, for it put to rest the controversy regarding such agreements by rejecting both the Eleventh Circuit Court's scope of patent test, and the quick look approach advocated by the Federal Trade Commission. The United States Supreme Court (USSC) appears to have taken the middle path by opting for the 'rule of reason' approach. This approach requires a detailed analysis of the effect on competition within a defined market.[24] USSC, however, refrained from setting forth any guidelines for the lower courts to implement this approach, instead permitting them the flexibility to develop it.[25]

Given the importance of this case, a brief elucidation of the facts would be appropriate. Solvay Pharmaceuticals (Souvay)was the manufacturer of Androgel, for which it obtained a patent in 2003. Subsequently, Actavis Inc (Actavis) and Paddock Laboratories (Paddock) filed an ANDA[26]

22 *In Re: K-Dur Anti-Trust Litigation* 686 F.3d 197, 214 (3rd Cir 2012).

23 *In Re: K-Dur Anti-Trust Litigation* 686 F.3d 197, 218 (3rd Cir 2012).

24 *See National Society of Professional Engineers* v. *United States*, 433 US 679, 692 (1978).

25 *Federal Trade Commission* v. *Actavis*, 570, 21 US (2013).

26 Abbreviated New Drug Applications or ANDA will be certified if they fulfil any one of the following four conditions — (I) No patent related to the pioneer drug has been filed (II); The relevant patent has expired; (III) The patent will expire on a certain date; and (IV) The patent is invalid or will not be infringed by the manufacture, use or sale of the new generic drug. Certification was to be made by declaring that the drug would not infringe any other patent already in existence. It was also mandated that all generic drug manufacturers were required to send notice to all the listed patent owners, who would be affected by the application.

along with paragraph (IV) certifications[27], which resulted in Solvay filing infringement proceedings against them. Another manufacturer Par Pharmaceuticals did not file an independent ANDA, but joined forces with Paddock. Solvay entered into an out of court settlement with Par Pharmaceuticals, Paddock and Actavis for the mammoth sums of USD 60 million, 12 million and approximately 270 million respectively. As consideration, Actavis agreed not to market its generic drug until 2015 and also undertook too promote Androgel[28].

### *B. European Union*

#### 1. Regulatory Framework

Unlike USA, EU has no legislation akin to the Hatch-Waxman Act. The member states individually control the issue and enforcement of patents. As a result, to enforce any patent, the originator/ manufacturer would have to initiate infringement proceedings in the courts of each member state,[29] making patent litigation an expensive ordeal. The branded manufacturer also risks losing a large market share if the patent litigation is adjudicated against it. This onerous nature of patent enforcement for the branded drug manufacturer is considered the root cause of reverse patent settlements.

#### 2. Judicial Approach

##### *a. The Lundbeck Case*[30]

The *Lundbeck* case represents a landmark development in competition law in the EU, as this was the first instance wherein the European Competition Commission (ECC) determined the legality of such agreements, holding the agreement entered into between Lundbeck and the generic manufacturers to be presumptively unlawful. Lundbeck

27 *The Drug Price Competition and Patent Term Restoration Act*, 1984 Pub L 98-417, 98 Stat 1585, § 505(j).

28 The brand name drug of Solvay Pharmaceuticals, Androgel is a daily testosterone replacement therapy.

29 *Convention on the Grant of European Patents* (adopted 5 October 1973, entered into force 7 October 1977) 13 *International Legal Materials* 268 (1974), article 64(3), *available at* http://www.epo.org/patents/law/legal-texts/epc.html (last visited 31 May 2016).

30 *Lundbeck* [2013] COMP/AT 39226 (European Commission: Competition DG) [unpublished].

was the manufacturer of a 'blockbuster'[31] antidepressant –Citalopram, and held patents for both, the Citalopram molecule and the process of manufacturing the molecule. Since the term of Lundbeck's patent was expiring in 2002, it provided an opportunity for generic manufacturers to enter the market; instead of competing, however, Lundbeck entered into agreements with the four groups of generic manufacturers, including the Indian company, Ranbaxy, to defer entry into market, in consideration of a substantial sum of money, amounting to approximately 70 million euros.[32] ECC opined that the agreements entered into between Lundbeck and the generics were presumptively unlawful and hence did not warrant a detailed investigation into the actual anti-competitiveness of the agreements. It further fined Lundbeck 93.8 million euros.[33] An appeal is pending before the General Court (EU).[34]

### *b. The Servier Case*[35]

French pharmaceutical company, Servier, held significant market power of the 'blockbuster' blood pressure control medicine Perindopril, as no antihypertensive medicine other than the generic versions of Perindopril were able to meaningfully constrain its sales. In 2003, when its patent for the molecule expired in most part, except the secondary patents relating to process, the generic manufacturers were determined to enter the market with their versions. Since there were a few sources of technology that were unprotected, Servier acquired the most advanced one to eliminate the use of technology and thereby bar the generics. Cut off from all other directions, the generics chose to challenge Servier's

31 European Commission: Press release IP/13/563 19/06/2013, 'Antitrust: Commission Fines Lundbeck and Other Pharma Companies for Delaying Market Entry of Generic Medicines' (19 June 2013), *available at* http://europa.eu/rapid/press-release_IP-13-563_en.htm (last visited 31 May 2016).

32 James Killick *et al*, The Commission's Lundbeck Decision: A Critical Review of the Commission's Test for Patent Settlement Agreement (2015) *Competition Policy International*, *available at* https://www.competitionpolicyinternational.com/the-commissions-lundbeck-decision-a-critical-review-of-the-commissions-test-for-patent-settlement-agreements (last visited 31 May 2016).

33 *Ibid*.

34 As of 31 May 2016.

35 *Perindopril (Servier)* [2014] COMP/AT 39612 (European Commission: Competition DG) [unpublished].

patents before the court, but virtually every time a generic came close to entering the market, Servier and the concerned company would adopt an out-of-court settlement procedure with the generic manufacturers. Taking into account the long duration of limiting the market entry of generics, several anti-competitive practices that were adopted, and the gravity of the offence, ECC fined Servier and five generic manufacturers, a whopping 427.7 million euros.[36] This clearly suggests that a multitude of generic manufacturers do not necessarily serve as an effective bar to eliminate the possibility of a reverse patent settlement.

### *C. United Kingdom*

#### 1. Legislative Approach

Similar to EU, UK has no specialised legislation akin to the Hatch-Waxman Act.

#### 2. Judicial Approach: The *Glaxo Smith Kline* Case

Currently pending final order by the Competition and Markets Authority (CMA) of UK, Glaxo Smith Kline could be fined a massive 2.6 billion pounds if it is found guilty of the alleged offence of delaying entry of generic anti-depressant Seroxat through a reverse patent settlement.[37] The body responsible for enforcing competition law in UK, the Office of Fair Trade (OFT), began investigations in 2011, being of the opinion that Glaxo Smith Kline had violated the Competition Act of UK as well as the treaty between the EU member states.[38] However after the disbandment of the OFT, the responsibility has been passed onto CMA to further investigate whether the generics–AlphaPharma, Generics UK and Norton Healthcare, were transferred value by Glaxo Smith Kline to exit the market of the concerned anti-depressant, which is also its best-selling drug.

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36 *See* European Commission, 'Antitrust: Commission Fines Servier and Five Generic Companies for Curbing Entry of Cheaper Versions of Cardiovascular Medicine', EU Press Release IP/14/799 (2014), *available at* http://europa.eu/rapid/press-release_IP-14-799_en.htm (last visited 31 May 2016).

37 *See* Adam Hill, 'GSK Faces £ 2.6 Billion Fine' (2013) *Pharmafile*, *available at* http://www.pharmafile.com/news/178972/gsk-faces-26-billion-fine (last visited 31 May 2016).

38 *Ibid*.

## IV. Reverse Patent Settlements In India

### *A. Emergence Of Reverse Patent Settlements In India*

Close analysis of reverse patent settlements in USA might lead to the erroneous conclusion that such settlements have originated as a direct consequence of the Hatch-Waxman Act, would not have arisen but for the enactment of such legislation, and hence would be confined to USA alone. The European and the UK experience prove otherwise. It appears that reverse patent settlements occur when–generic challenges to patents are incentivised, and/or the patent litigation is more onerous for the patentee, ie the patentee risks losing more in the patent litigation as compared to the generic company.

Although the overall Indian pharmaceutical industry data suggests that there are a large number of active generics in the market, thereby resulting in intense competition, the actual scenario in a specific market appears to be otherwise due to several factors as follows:

1. Market Concentration

As of 2010, the organised sector (which is primarily responsible for the formulation production in the country) was comprised of 250–300 players and accounted for 70 per cent of the industry in terms of value.[39] Amongst them, Cipla continued to have the largest market share of 5.2 per cent, followed by Ranbaxy (now a subsidiary of Sun Pharma) with a 4.7 per cent share.[40] These numbers at a cursory glance might suggest intense competition; however the actual scenario is quite contrary because pharmaceutical products are not single homogenous goods, and there are several 'relevant markets' within the industry known as therapeutic segments.[41] It is within these therapeutic segments that competition takes place. In the case of many drugs, there are only a few large suppliers in a particular therapeutic category, even

39 *See* 'India Pharma Inc.: Capitalising on India's Growth Potential' (2010) *PWC*, 15, *available at* https://www.pwc.in/assets/pdfs/publications-2011/pwc_cii_pharma_summit_report_22nov.pdf (last visited 31 May 2016).

40 *Ibid*.

41 'Competition Issues in The Pharmaceutical Industry' (2007) *CUTS International*, *available at* http://www.cuts-international.org/pdf/ICRR07_%20Pharma.pdf (last visited 31 May 2016).

in the case of non-patented drugs. However, in the case of patented drugs, with the patent-holder companies exercising monopoly rights over those drugs, substitutability is often close to zero, especially after the implementation of *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS)[42].[43] The table below illustrates the oligopolistic structure of different therapeutic segments despite generic competition:[44]

| Name of the Drug | Therapeutic Category | No of Brands | Share of Top 4 rands (Per Cent) |
|---|---|---|---|
| Ciprofloxacin | Quinolones | 200 | 60 |
| Levofloxacin | Quinolones | 45 | 48 |
| Chlorogquine | Anti-Malaria | 43 | 93 |
| Quinine | Anti-Malaria | 24 | 85 |
| Rh Adults | Anti-Tuberculosis | 63 | 79 |
| RHEX FD (Rifampicin + Isoniazid+ Pyrazinamide) | Anti-Tuberculosis | 40 | 70 |
| RHE (Rifampicin + Isoniazid + Ethambutol) | Anti-Tuberculosis | 42 | 65 |
| Atorvastatin | Stantins | 75 | 47 |
| Simvastatin | Statins | 25 | 84 |
| Lovastatin | Statins | 15 | 98 |
| Note: The drugs' categories include all dosages and forms of individual brands. | | | |

42 *Agreement on Trade-Related Aspects of Intellectual Property Rights* (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299.

43 *See* 'Competition Law and Indian Pharmaceutical Industry' (2010) *CENTAD*, *available at* http://www.cci.gov.in/sites/default/files/PharmInd230611_0.pdf (last visited 31 May 2016), paras 2.10.23 and 3.4.21.

44 *Ibid*, table 2.34, 65.

Therefore, it is can be seen that the mere presence of a large number of generic manufacturers in the pharmaceutical industry as a whole does not always result in a competitive industry.

2. Asymmetric nature of Industry: The consumer is not the chooser

The Indian pharmaceutical market is unique and differs largely in consumer pattern from the pharmaceutical markets across the world. The Indian consumers are not involved in the decision making process of their purchase of goods because these are usually dictated by the doctors, pharmacists and hospitals. This dependence of patients is due to the complicated nature of healthcare and the trust instilled in healthcare professionals. The significant role assumed by doctors, pharmacists and hospital staff leads to manipulation of the market, as drug companies tend to exploit this influence by providing lucrative incentives and consumers are induced into buying drugs that are more expensive.[45] Below is an analysis of the distorted market pattern:

*a. Doctors*

Driven by the desire to capture larger market share and maximise profits, drug companies engage in intense promotional strategies aimed at doctors. Doctors are routinely wooed with electronic gadgets, sponsored weddings, sponsored holidays, conferences at five star hotels, and even establishment of nursing homes. Therefore in the prescription-drug industry, companies tend to exert commercial influence on the prescribing habits of doctors and indirectly violate the spirit of competitive principles.[46] Since only large drug companies have the financial resources to resort to such practices, competition is effectively limited. This makes the prospect of reverse patent settlements more lucrative.

*b. Pharmacists*

In India, where thousands of drug companies compete for market shelf in pharmacies, a few companies that offer spectacular discounts to pharmacists wield great clout as more often than not, pharmacists

45 *Supra* n. 43, para 2.10.7.
46 *Supra* n. 43, para 2.10.13.

advise the consumers regarding purchase of a drug.[47] These discounts intensify the gap between wholesale price and retail price and in fact a study found that all but one of the top 25 drug companies in India offer heavy discounting deals at least once a month, which could be up to 103 per cent[48].[49] This enables large drug companies to control the market and exclude smaller manufacturers as well as generic manufacturers; making reverse patent settlements very profitable.

*c. Hospitals*

As an integral part of the healthcare system, hospitals also play a role in influencing consumer pattern. A case brought forth in a consumer forum in Andhra Pradesh revealed that a private hospital had entered into a contract with a drug manufacturing company, wherein the company agreed to sell the particular drug to the hospital above market price, which was detrimental to the trusting consumers who would buy the prescribed drugs from the hospital pharmacy.[50] Hospitals often have their own pharmacies, which are incorporated under different companies, which in turn lead to spatial monopolies.[51] This is the role that hospitals play in limiting competition.

Tied selling is a frequently used anti-competitive measure involving the above three players of the health care delivery system. It restricts the choice of consumer by engaging in collusive activities resulting in monopolistic dominance as noted above.

3. Increased presence of MNCs due to the product patent regime

The return of the product patent regime as a result of the *Patent Amendment Act, 2005* has raised concerns regarding the future of the generic pharmaceutical industry in India.[52] The dynamics of the

47 'Competition Law and Indian Pharmaceutical Industry' (2010) *CENTAD*, *available at* http://www.cci.gov.in/sites/default/files/PharmInd230611_0.pdf (last visited 31 May 2016), paras 2.10.13 and 3.4.21.

48 *See generally* Daniel Pearl and Steve Stecklow, 'Drug Firms' Incentives Fuel Abuse by Pharmacists in India', (2001) *Wall Street Journal*, *available at* http://www.wsj.com/articles/SB997910373349012375 (last visited 31 May 2016).

49 *Supra* n. 41, 11.

50 *Supra* n. 41, 14.

51 *Supra* n. 43, para 2.10.17.

52 *Supra* n. 43, para 2.1.5.

pharmaceutical industry prior to the introduction of the *Patents Act, 1970* is crucial to fully appreciate the concern raised. Prior to 1950, the indigenous sector dominated the pharmaceutical industry in India.[53] Post 1950, multinational companies (MNCs) began to improve their presence in the Indian markets with the introduction of new medicines. A strong product patent system then prevailing under the *British Patents and Designs Act, 1911*, led to increasing influence of MNCs in the Indian pharmaceutical market reducing the share of indigenous companies to 32 per cent in 1970 from 62 per cent in 1950 and the share of MNCs increased to 68 per cent in the 1970s from 32 per cent in 1952. The Ayyangar report[54] examining the legislation concluded that foreign patent holders dominated the industry through large number of filing and grants. Therefore, the *Patents Act, 1970* was introduced, which limited patents only to process patents in the case of pharmaceuticals and agricultural chemicals, and reduced the term to seven years. It was this effort of the Government that led, once again, to the growth of the generic industry in India. However, in order to make the Indian patent law fully compliant with the TRIPS[55], the government introduced the *Patent Amendment Act, 2005*.[56]

It is not a mere coincidence that MNCs have now renewed their interest in India. The Indian pharmaceutical industry has attracted USD1707.52 million worth of foreign direct investment (FDI), exclusive of investments in shares of Indian firms in the period between April 2000 and April 2010.[57] Acquisitions of local players by large MNCs illustrate the increasing level of interest that they have shown in the Indian market.[58] History appears ready to repeat itself with the MNCs likely to succeed in capturing a larger pie of the Indian markets.[59] The implications of these mergers on competition are significant since many

53 *Supra* n. 43, para 2.2.2.

54 Shri Justice N Rajagopala Ayyangar 'Report on the Revision of the Patents Law' (1959), *available at* http://spicyip.com/wp-content/uploads/2013/10/ayyangar_committee_report.pdf (last visited 31 May 2016)

55 The TRIPS agreement envisages product and process patent.

56 *Supra* n. 43, 7.

57 *See* 'India Pharma Inc.: Capitalising on India's Growth Potential' (2010) *PWC*, 17, *available at* https://www.pwc.in/assets/pdfs/pharma/PwC-CII-pharma-Summit-Report-22Nov.pdf (last visited 31 May 2016).

58 *Ibid*.

59 *Supra* n. 43, para 2.7.1.

of the merging MNCs and generic companies have pharmaceutical products used for the same therapy, and therefore are competitors. For example, both Nicholas Piramal (India) and Boehringer Mannhein were major players with competing products in various therapeutic segments, namely cardiovascular system, hormones, vitamins and nutrition, before they merged.[60] Increased MNC presence, accompanied by market entry tactics such as mergers, acquisitions and exclusive licensing deals with generics, reduce the number of competitors within the concerned therapeutic segment even in the case of non-patented drugs,[61] creating fertile grounds for reverse patent settlements.

Furthermore, with the CCI taking notice of several possible reverse patent settlements and investigating them, it is clear that reverse patent settlements are now beginning to make their way to India. It is pertinent to note that in a study commissioned by the CCI on issues relating to competition in the Indian pharmaceutical industry,[62] there were glaring observations about patent settlement deals in EU and USA. However, the study failed to provide suggestions to overcome such practices based on the experiences of EU and USA. The point of pertinence is that these settlements are extensively used in scenarios such as the above, wherein the generics in the operating market are few and the research and development costs are high.

## MODEL SCENARIO

A model scenario may be where 'X', an originator operating in a market for a unique drug with a high cost of research and development, with a few major generics, files a patent infringement suit on a major threatening generic manufacturer, thereafter reaching a mutual settlement with the generic. With the product patent regime now applicable in India, the frequency of scenarios, wherein there are increased patent challenges which would eventually lead to reverse patent settlements, are likely to increase. Thus, obtaining patents on newly developed drugs and the high cost of research and development[63] of the drug would serve as an entry barrier for generic manufacturers, thereby limiting competition to a few big generics only.

60 *Supra* n. 41, 9.
61 *Supra* n. 41, 5.
62 *Supra* n. 43.
63 *Supra* n. 43, table 2.23, 55.

### *B. Would Reverse Patent Settlements Come under the Purview of Competition Law in India?*

The analysis of reverse patent settlements involves an amalgamation of settlement law, competition law and intellectual property law. The *Competition Act, 2002* (Act) aims to promote and sustain competition in markets and protect interests of the consumers. Hence, an agreement between two competitors which results in one of them delaying entry in the market appears to fall within the provisions of the Act. However, in light of the intersection with the aforementioned branches of law, the following issues must be addressed:

1. Whether the CCI can scrutinise a compromise entered into between an originator and a generic drug manufacturer?

The CCI is empowered to scrutinise any agreement that allegedly causes or is likely to cause an appreciable adverse effect on competition.[64] Reverse patent settlements have the potential to raise competition concerns such as creation of entry barriers, hampering innovation and adversely affecting consumer welfare,[65] which are factors that the CCI shall have due regard to in order to determine an appreciable adverse effect on competition.[66] *Prima facie* there appears to be a conflict between the powers of the CCI to scrutinise such agreements and the order 23 rule 3 of the *Civil Procedure Code, 1908* which mandates that the court which has recorded the compromise must determine whether the compromise is lawful, or alternatively unlawful.[67] However, section 61 read in conjunction with the *non obstante* clause in section 60 of the Act resolves the conflict; the justification for the aforementioned lies in the fact that the term 'unlawful' has a broad scope of application. Since reverse patent settlements could be unlawful because they may produce an appreciable adverse effect on competition, the CCI is the appropriate forum to seek such remedy, as its very formation was aimed to correctly adjudicate complex and technical anti-competition matters.[68]

64 *The Competition Act, 2002*, section 19.

65 Part II (B), *Impact of Reverse Patent Settlements*.

66 *The Competition Act, 2002,* sub-section (3) of section 19.

67 *See also Banwari Lal* v. *Chando Devi* AIR 1993 SC 1139.

68 *See* Government of India, 'Report of High Level Committee on Competition Policy & Law' (2000), para 7.2.4 and *FICCI Multiplex Association* v. *United Producers and Distributors Forum* Case No 01 (2009) Competition Commission of India, para 23.37.

Further, section 32 of the Act empowers the CCI to investigate into extra-territorial conduct by companies which have the potential to cause an adverse appreciable effect on competition in India. The investigation of Indian generic manufacturers such as Unichem Laboratories Ltd, Matrix Laboratories Ltd and Lupin Ltd by ECC in the Servier case[69] could serve as a reason for the CCI to institute a *suo moto* investigation into the practices of such pharmaceuticals and their effect on the Indian market.

2. Whether the presence of a patent would exempt a reverse patent settlement from anti-competition scrutiny?

The exemption provided under section 3(5) of the Act is by no means a blanket exemption,[70] since it has 'reasonable conditions' as its fulcrum.[71] Although the term 'reasonable conditions' has not been defined under the Act, jurisprudence in USA suggests that acting within the monopoly powers conferred by the patent would be considered reasonable.[72] By implication only unreasonable conditions attached to intellectual property rights would attract provisions of the anti-competition law.

### *C. Proposed Approach:*

Jurisdictions around the world make use of different approaches to scrutinise reverse patent settlements, in tandem with their country's public policy, competition policy and patent policy. In this regard, the authors propose that the following method and steps may be adopted for examining reverse patent settlements in the Indian scenario:

1. Mandatory reporting of all patent settlements to the CCI

In USA, the Hatch-Waxman Act provides an incentive to the first generic challenger by allowing him a 180 day exclusivity period post filing an ANDA as prescribed. This in turn makes challenges by subsequent generic companies less lucrative and serves as a deterrent to

69 *Ibid*, 32.

70 Government of India, Report of High Level Committee on Competition Policy & Law 2000, para 5.1.7.

71 *See FICCI Multiplex Association v. United Producers and Distributors Forum* Case No. 01 (2009) Competition Commission of India, para 23.31.

72 *United States v. General Elec. Co.*, 272 U S 476, 485 (1926); *Simpson v. Union Oil Co. of Cal.*, 377 U.S 13, 24 (1964).

subsequent challenges. However in India, EU and UK, where no such legislation granting special incentives to the first challenger is in place, a large payoff to a single generic company might signal to others that the patentee lacks confidence in the validity of the patent, thus, resulting in an increase in the number of generic challenges. In order to avoid this, the originator may often conclude such settlements in secrecy.

In such a scenario, mandatory reporting to the CCI would serve a dual purpose, namely:

- Serve as a natural deterrent to reverse patents:

  Mandatory reporting would ensure that such settlements do not go unnoticed and may result in an increased number of generic challenges to the patent. This would act as a deterrent for a patentee to enter into such agreements *ab initio*. It is, however, doubtful whether this mandatory reporting of reverse patent settlements would entirely negate its emergence; and

- Provide the CCI reasonable opportunity to comprehensively scrutinise such settlement agreements.

2. Which approach of competition analysis should be undertaken by the CCI?

The most suitable approach for reverse patent settlement analysis that can be adopted by the CCI in the Indian scenario, in the opinion of the authors, is the 'presumptively unlawful' approach that has been advocated by the Federal Trade Commission of USA and ECC. The presumptively unlawful approach would lead the courts to presume that these settlements are unlawful, unless otherwise demonstrated by the parties. The parties can rebut this presumption by showing pro-competitive effects of the settlement and proving that the payments constitute a reasonable assessment of the litigation success. However, if they fail to do so, the courts can safely conclude that the particular settlement violates anti-competition law and creates an appreciable adverse effect on competition in India as envisaged under the Act.[73] This approach rests on the logic that the mere payment from a brand name manufacturer to a generic drug manufacturer for agreement by the

73 *The Competition Act,* 2002, section 3.

latter to delay its market entry for such consideration, serves as a *prima facie* evidence of unreasonable restraint of trade. Hence, even though the court would presume them to be anti-competitive, the settling parties would have the opportunity to rebut the presumption by leading clear evidence that the pro-competitive benefits of the settlement outweigh the anti-competitive benefits. The *Preserve Access to Affordable Generics Act* provides that the Trial Court would be prudent to consider the following factors[74] before making a fair conclusion in such matters– (i) comparison between the deferred entry date agreed upon by the generic drug manufacturer and remaining life of the existing relevant patent; (ii) the amount of consideration obtained by the generic drug manufacturer while settling the dispute; (iii) the potential earnings of the generic drug manufacturer had it succeeded in the litigation proceedings; (iv) potential earnings lost by the originator had the generic manufacturer succeeded in such litigation proceedings; (v) time period between date of value transfer to the generic manufacturer and date of settlement; and (vi) the value the consumers would have gained via competition in the market between the generic drug maker and originator. Hence, these factors would serve as a six-prong test for the court to adjudicate on the lawfulness of such settlements.

The severe anti-competitive effects of reverse patent settlements warrant the presumptively unlawful approach since the various competitors virtually divide the market, restricting all forms of competition between the market players and on all grounds; this form of market control could result in consequences more serious than price control. In price control, only one factor of the market is being controlled, while in reverse patent settlements, all the factors are controlled to benefit a few competitors. In cases where generic drug manufacturers have been paid to stay out of the market, it could be construed as market allocation of time. Furthermore, putting the burden of proof on the settling parties fits in the Indian scenario, where the lack of first challenger benefits leads to secrecy of settlements, which may make the process of proving reasonable grounds cumbersome for the CCI. This especially holds

74 *See Preserve Access to Affordable Generics Act*, section 369, 111th Cong. § 2(b) (as reported and amended by S Comm on the Judiciary, October 15, 2009); *Protecting Consumer Access to Generic Drugs Act*, 2009, HR 1706, 111th Cong. § 2(a) (2009). It is pertinent to note that this bill has not yet been enacted.

true in an industry such as pharmaceuticals, where intellectual property licenses, raw material incentives and promotional aids have replaced the typical cash payments.

More importantly, a sheer perusal of the Indian economy and health care scenario suggests that this approach is more suitable in the present context. Dubbed the 'global pharmacy of the south', India exports life-saving drugs to developing countries and also supplies quality drugs to the rich nations at affordable prices. Despite this seemingly commendable performance, millions of Indian households do not have access to vital drugs. Despite the availability of adequate knowledge, technology and skills to innovate and develop new drugs, India faces tremendous challenges in prioritising and delivering essential medicines to the millions vulnerable and in urgent need of these drugs. Since the initiation of market friendly economic reforms, drug prices have risen significantly. India's drug market structure is presently vulnerable to control by multinational companies, which are beginning to take over the dynamic domestic generic drug industry.[75] With the government likely to increase financial investments substantially in the healthcare sector[76] and take various measures in order to increase availability of low cost generic medicines[77] through the Universal Health Coverage (UHC) and Jan Aushadi Scheme, reverse patent settlements which attempt to delay generic entry into the market, in order to maintain supra-competitive prices would certainly be antithetical to such schemes, greatly inhibiting their success. Therefore, in the Indian context it would be prudent to adopt a rule that is more restrictive as compared to the approach taken in USA. However, it is conceded that a rule that is excessively restrictive ('*per se* illegality') would subject competitors to

75 *Supra* n. 2.

76 High Level Expert Group (HLEG) has recommended that the Government (both Central and state governments) should increase public expenditures on health from the current level of 1.2 per cent of GDP to at least 2.5 per cent by the end of the 12th plan, and to at least 3 per cent of GDP by 2022 and specifically increase expenditure on medicines from around 0.1 per cent to 0.5 per cent of GDP. Furthermore, HLEG has recommended using general taxation as the primary source healthcare financing, *supra* n. 2.

77 HLEG for UHC has recommended enforcement of price controls and price regulation on essential and commonly prescribed drugs, reviving public sector units (PSUs) that manufacture generic drugs and vaccines, measures to retain and ensure self-sufficiency in drug production and setting up of a national and state level Drug Supply Logistics Corporation for the bulk procurement of low-cost, generic essential drugs.

vexatious litigation, potentially discouraging innovation, therefore the presumptively unlawful approach would be best suited in India.

There is an absolute legislative vacuum with regard to identification and addressing reverse patent settlements in India. It would be prudent for the legislature to take due advantage of the clean slate, and provide for these settlements in the Act itself. Under the Act, the presumptively unlawful approach already finds its place in the provisions of sub-section (3) of section 3 which lays down the provisions dealing with cartelisation. The same provisions could also be suitably modified to apply to reverse patent settlements in India. While it has been previously mentioned that the presumptively unlawful approach will be the most apt to examine such agreements, we further aim to explain the other possible methods and reasons supporting our suggestion herein.

3. Why the scope of patent test may not be suitable in the Indian context?

The scope of patent approach was utilised by the 11th Circuit Court in the *Actavis* case[78] and lays precedence on patent over antitrust law. This approach does not seem to strike a balance between the two bodies of law as envisaged by the Act[79] and tends to disagree with the spirit and purpose of the Act. The patent is presumed to be valid, which in turn, virtually rejects the purpose of the patent infringement case. The crux of reverse patent settlements is that in such agreements, settling parties agree to uphold patent validity even when none exists as was seen in the case of *Valley Drug Company*,[80] where the district court also ruled against the patentee. Similarly, the 11th circuit court relied on the scope of patent approach based on its exclusionary power and created a new patent right, unfairly, through mutual agreement between parties which in turn would harm the consumers. This approach allows parties to create a contractual patent, which excludes that particular competitor. Subsequent contracts with various generics may be entered into by the patentee for their exclusion from the market. It may be inferred that the scope of a patent forms only a part of the required analysis to be made while setting out the criteria for identifying reverse patent settlements

78 *Supra* n. 25.

79 *The Competition Act, 2002,* sub-section (5) of section 3.

80 *Valley Drug Co* v. *Geneva Pharmaceuticals Inc* 344 F.3d 1295 (11th Cir 2012).

since it neglects important aspects such as the relevant market and the pro- competitive effects of the settlement, if any.

4. Why the rule of reason approach should not be applied?

After exploring all alternatives, perhaps the most tempting approach to adopt may seem 'rule of reason', adopted in Actavis case and remains a settled law in USA. Even though USSC did record the rule of reason approach as the desirable method of analysis, in spirit it seems to have adopted the presumptively unlawful approach.[81] It is commonly known that the rule of reason used in practice is quite different from the rule of reason laid down by Justice Brandeis in the old *Board of Trade* case.[82] Instead, it revolves around a regulated structure. Here a reference may be drawn to the criteria laid down in Professor Hovenkamp's hornbook:[83]

- Consider first whether there is a 'contract, combination, or conspiracy' that restrains trade.
- Consider whether this restraint poses any kind of risk to competition.
- Consider whether this risk is likely to generate any perceivable pro-competition benefits in the market.
- Consider if the defendant has market power or whether there is a presence of proof of actual anti-competitive damage.

81 Thomas F Cotter, 'FTC v. Actavis, Inc.: When is the Rule of Reason Not the Rule of Reason?' (2014) 15 *Minnesota Journal of Law, Science and Technology* 41, 43.

82 *See Board of Trade of Chi* v. *United States*, 246 US 231, 238 (1918). Justice Brandeis wrote for the Court: 'The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question, the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences.'

83 Herbert Hovenkamp, *Federal Antitrust Policy*: *The Law of Competition and its Practice* (4th edn West Academic Publishing 2011) 279–80.

- Consider whether the restraint of trade creates any actual pro-competitive benefits and not just perceivable or plausible benefits.
- Consider whether the restraint is the least restrictive means of attaining those benefits.
- Balance the pro-competitive benefits against the anti-competitive harm.

Following this step-by-step analysis, we can safely assume that typical Pay-for-Delay settlements satisfy the first four steps of this analysis, on primary glance itself. The first step is satisfied since these settlements include a value transfer from the originator to the generic manufacturer in return for the generic manufacturer to settle the case and temporarily exit the market. Here lies a contract that restrains trade, which is indisputable. A contract of such nature would pose an obvious potential risk to competition, which satisfies the condition laid down by the second step. The third step is satisfied by a perusal of these settlements since even though they are potential risks to competition in a market, they have their share of possible pro-competitive benefits as they would mobilise social resources that would otherwise be utilised in the expensive process of litigation. The fourth step would also be satisfied, if in litigation the patent could be proved invalid or not infringed by the generic drug, the loss in revenue that would be experienced by the originator would then flow to the consumers in the form of lower prices.

Hence, for reverse patent settlements, the analysis would only essentially begin at the fifth step, at which point, the burden of proof has shifted to the defendant, who has to produce exonerating evidence and discharge his burden. Therefore, it seems that the rule of reason approach in the case of reverse patent settlements functions in the same manner as the presumptively unlawful approach.[84] However, despite the in-depth analysis in the similarities, *prima facie* the rule of reason approach seems unsuited for India. This case specific approach would result in considerable delay in litigation result keeping in mind the existing judicial backlog of cases.

84 *Supra* n. 81, 41, 45 and 46.

## 5. Compulsory Licensing

Compulsory licensing is a well-recognised remedy in cases of patent abuse.[85] It is defined generally as the granting of a license by the government of a state to use a patent without the patentee's permission.[86] Competition authorities around the world have resorted to compulsory licensing to effectively combat patent related issues.[87] Furthermore, various international covenants too endorse compulsory licensing. For instance, TRIPS although does not mention the term, but it does, in spirit, support the concept under article 31.[88]

In India, compulsory licensing as a remedy for competition law violations is a nascent concept, with the competition authorities yet to explore this avenue. The Act, if construed liberally does confer upon the CCI, powers to issue compulsory licenses under sections 27 and 28. As per section 27 of the Act, if the CCI after inquiry finds that any agreement is in contravention of section 3 or section 4 of the Act, it can pass such other order or issue such directions as it may deem fit.[89] The CCI is further empowered to transfer the property of a firm that has abused its dominant position.[90] Keeping in mind the primary objective of the Act–to promote consumer interests and competition in the markets,[91] we believe that such a liberal interpretation of the aforementioned sections should be taken. The CCI too has in its decisions laid emphasis on the interests of the common man, than on the competitors or competitive processes.[92]

Presently, granting of compulsory licenses is governed by the *Patents Act, 1970*.[93] The Controller of Patents (Controller) can grant a compulsory

85 *United States* v. *Besser Mfg Co*, 343 US 444 (1952), 447.

86 Sara M Ford, 'Compulsory Licensing Provisions under the TRIPS Agreement: Balancing Pills and Patents' (2000) 15 *American University International Law Review* 942, 945.

87 *The Canadian Competition Act* RSC 1985, C-34, section 32.

88 *Agreement on Trade-Related Aspects of Intellectual Property Rights* (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299.

89 *The Competition Act*, 2002, sub-section (g) of section 27.

90 *The Competition Act*, 2002, section 28.

91 *The Competition Act*, 2002, preamble.

92 Naval Sataravala Chopra, Dinoo Muthappa, 'The Curious Case of Compulsory Licensing in India' (2012) 8 *Competition Law International*, 37.

93 *The Patents Act*, 1970, section 84.

license after expiry of three years from the grant of patent–(i) if the reasonable requirements of the public with respect to the patented invention have not been satisfied; (ii) the patented invention is not available to public at affordable price; or (iii) the patented invention is not worked in the territory of India. Presently, the procedure for availing this remedy in cases of reverse patent settlements would be to first seek redressal from CCI and then separately file for compulsory licensing before the Controller,[94] making it a tedious and long drawn ordeal. Therefore we believe that pursuing this remedy before the CCI would be most suitable. The overriding effect of the Act over other statutes ensures that no conflict between the provision regarding compulsory licenses in the *Patents Act, 1970* and the Act can arise.[95] Moreover, the CCI can make a reference to the Controller before granting a compulsory license. Certain groups of scholars opine that a policy favouring compulsory licensing would tend to hamper innovation and deter investment. However, this consequence is not inevitable as royalty payments can be granted along with such licenses, which would in fact incentivise innovation.

## V. Conclusion

Reverse patent settlements that were earlier restricted to the West are likely to emerge in India, making it an urgent issue to be settled by Indian law. Despite the fact that this settlement strategy seems to be catching on in the Indian pharmaceutical industry, the legality remains incoherent owing to the nascent nature of competition law in India. Expected to reach a mammoth figure of USD 55 billion by 2020,[96] the legal stance to be taken on reverse patent settlements is crucial. Recognising that a rule that is too permissive, would lead to risk allowing competitors to collude and one that is excessively restrictive, would subject competitors to vexatious litigation, potentially discouraging innovation and burdening an already taxed judicial system with a new species of litigation. In this regard, we are of the opinion that the presumptively unlawful approach would be most suitable to the Indian scenario.

94 As explained in Part III, an anti-trust approach before the commission is the most suitable to analyse reverse patent settlements

95 *The Competition Act*, 2002, section 60.

96 *Supra* n. 4, 2.