

**REVERSE PAYMENT SETTLEMENT: AN AGREEMENT THAT  
CREATES A TUSSE BETWEEN THE INTERPLAY OF IP &  
COMPETITION LAW**

*Shikhar Mishra*

*Gujarat National Law University, Gandhinagar*

**ABSTRACT**

*Competition law and Intellectual property law are always in conflict with each other. The main reason being there antithesis parallel views, competition law ensures free competition in the market by prohibiting monopolies whereas on the other hand intellectual property law ensures some sort of monopolies (in the form of exclusive right) in the market for certain period to encourage the invention or creation. This difference in their approaches leads to the dispute between them. This time it is an agreement most prominent in pharmaceutical sectors where the patent holder transfers some value to the generic drug manufacturers companies in order to delay their entry in the market. So the question arises here is that such an agreement is merely an exercise of the statutory right by the patent holder or it is against the objective of competition law viz. to regulate the free competition in the market. Such an agreement was regarded as anti-competitive in nature from the Competition law perspective whereas the same agreement was labeled as pro-competitive from the intellectual property law perspective. This debate is not limited to only competition law or intellectual property law but the Human Rights Law (viz. right to life, right to health, and right to access medicine) has a vital role to play. In the overall discussion, the two main points which were given preferences and put forward was consumer welfare and development of new inventions. In this article, we attempt to analyze the essentials of reverse payment settlement, their legal aspect in the US and EU, arguments for and against the agreement, and the impact of the reverse payment settlement.*

***Keywords: Competition law, monopolies, pharmaceutical sectors, and reverse payment settlement.***

# DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

## I. INTRODUCTION

The Competition Law has threefold objective viz. to endorse competition in the market, to sustain competition in the market, and to protect the interest of the consumers in its highest possible way. Oppositely, Intellectual Property Rights (IPRs) are monopolistic in nature,<sup>1</sup> and here comes a tussle between the interplay of IPRs and Competition law. However, it cannot be denied that even having parallel views there is the ultimate goal of both the laws viz. consumer welfare.

This debate of superiority between IPRs and the regulation of competition among commercial entities tend to lead an uncomfortable co-existence.<sup>2</sup> It is also generally agreed that in order to put a certain restriction on IP rights for the proper regulation of market Competition law should not be used as a bludgeon against IPRs as this can negatively impact incentives for innovation.<sup>3</sup> It can be articulate that this battle of superiority between competition law and intellectual property law is eternal. This time the conflict has been seen in the context of the patent settlement agreement,<sup>4</sup> especially in the pharmaceuticals industry, called Reverse Payment Settlement or Pay-for-delay agreements.

In such an agreement a patent holder and a patent challenger involves into a settlement where a value is transferred from the originator to the generic company, coupled with a provision to limit

---

<sup>1</sup> Pawan Dutt and Tanel Kerikmäe, 'Reverse Payment Patent Settlements in the Pharmaceutical Sector and Competition Law – Do Lundbeck and Actavis Help to Bridge the Views Across the Atlantic Regarding the Delayed Market Entry of Cheaper, Generic Medicines?' (2013) 13 International and Comparative Law Review <[https://www.researchgate.net/publication/322707385\\_Reverse\\_Payment\\_Patent\\_Settlements\\_in\\_the\\_Pharmaceutical\\_Sector\\_and\\_Competition\\_Law\\_Do\\_Lundbeck\\_and\\_Actavis\\_Help\\_to\\_Bridge\\_the\\_Views\\_Across\\_the\\_Atlantic\\_Regarding\\_the\\_Delayed\\_Market\\_Entry\\_of\\_Cheaper](https://www.researchgate.net/publication/322707385_Reverse_Payment_Patent_Settlements_in_the_Pharmaceutical_Sector_and_Competition_Law_Do_Lundbeck_and_Actavis_Help_to_Bridge_the_Views_Across_the_Atlantic_Regarding_the_Delayed_Market_Entry_of_Cheaper)> accessed 20 April 2020

<sup>2</sup> M. Daniels, 'Review of the Book Critical Concepts in Intellectual Property Law – Intellectual Property and Competition' (2012) 34(4) European Intellectual Property Review (as cited in Pawan Dutt and Tanel Kerikmäe, 'Reverse Payment Patent Settlements in the Pharmaceutical Sector and Competition Law – Do Lundbeck and Actavis Help to Bridge the Views Across the Atlantic Regarding the Delayed Market Entry of Cheaper, Generic Medicines?' (2013) 13 International and Comparative Law Review <[https://www.researchgate.net/publication/322707385\\_Reverse\\_Payment\\_Patent\\_Settlements\\_in\\_the\\_Pharmaceutical\\_Sector\\_and\\_Competition\\_Law\\_Do\\_Lundbeck\\_and\\_Actavis\\_Help\\_to\\_Bridge\\_the\\_Views\\_Across\\_the\\_Atlantic\\_Regarding\\_the\\_Delayed\\_Market\\_Entry\\_of\\_Cheaper](https://www.researchgate.net/publication/322707385_Reverse_Payment_Patent_Settlements_in_the_Pharmaceutical_Sector_and_Competition_Law_Do_Lundbeck_and_Actavis_Help_to_Bridge_the_Views_Across_the_Atlantic_Regarding_the_Delayed_Market_Entry_of_Cheaper)> accessed 20 April 2020

<sup>3</sup> OECD Policy Roundtables, 'Competition, Patents, and Innovation' 2008 <<https://www.oecd.org/competition/abuse/39888509.pdf>> accessed 20 April 2020

<sup>4</sup> Pawan (n 1) 26

# DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

or restrict the generic company's ability to market its own product on the market.<sup>5</sup>This leads to certain interesting areas of conflict between Competition Law and IP Law.<sup>6</sup>

To understand the implication of Reverse Payment Settlements on Competition and IP law this article discusses first in part II about the reverse payment settlement, the regulatory framework in the United States, and the European Union. In part III, we analyze the agreement from both the competition law and IP law perspective. In part IV, we will discuss the impact of the reverse payment settlement and finally, in part V, we will discuss findings and concludes.

## II. REVERSE PAYMENT SETTLEMENT OR PAY-FOR-DELAY SETTLEMENT

No doubt that out of court settlement is an exceptional legal way to end up litigations. Both the parties through out of court settlement can avoid a substantial amount of money in litigation, time, and of course uncertainty in the result. Similarly in a Patent Law, where the patent holder has the right to sue an infringer, may go to court, or to settle, or to accept the entry.<sup>7</sup> In case of settlement there are two forms of patent settlements- first, judicial settlement according to legal provisions and process and second, which deviates from such preferable scenario, namely reverse payment settlement agreements.<sup>8</sup>Reverse payment settlements are different from others out of court settlement in a way that here the brand-name company pays the competitor to delay its entry in the market.<sup>9</sup> It is realities that these agreements emerge essentially in the pharmaceutical industry. This is mainly due to a gap or loopholes provided by the regulatory framework in the pharmaceutical sector.

---

<sup>5</sup>Pawan (n 1) 27

<sup>6</sup>Pawan (n 1) 27

<sup>7</sup> Claude Crampes and Corinne Langinier, 'Litigation and Settlement in Patent Infringement Cases' (2002) 33 (2) The RAND Journal of Economics<<https://www.jstor.org/stable/3087433?seq=1>> accessed 2 May 2020

<sup>8</sup>PetarRumenovRaykov, 'Reverse payment (pay-for-delay) settlement agreements in the Pharmaceutical Industry in the USA and Europe Competition Law Analysis'(Master Thesis,Tilburg Law School)<<http://arno.uvt.nl/show.cgi?fid=129566>>accessed 22 April 2020

<sup>9</sup> Thence, their other appellation – “pay-for-delay” settlements (as cited in PetarRumenovRaykov, 'Reverse payment (pay-for-delay) settlement agreements in the Pharmaceutical industry in the USA and Europe Competition law analysis'(Master Thesis,Tilburg Law School ) <<http://arno.uvt.nl/show.cgi?fid=129566>>accessed 22 April 2020

## DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

In a reverse-payment patent settlement, the patent holder (in this case originator companies) pays the alleged infringer (in this case generic company), who in turn agrees not to enter the market until an agreed date.<sup>10</sup> To explain further, when a generic company creates a generic version of the patented drugs it is a patent holder who files the suit of infringement. Once the suit of infringements is filed the Generic Company will essentially challenge the patent. In such a case, patent holders to avoid litigation and question on the validity of the patent (preferably in weak-patent, where there is the highest possibility of patent gets invalidated by the court) promise to pay something in return for delaying the entry generic drug in the market. In this way, the patent holder gets two things- first, a promise that the validity of the patent will not be challenged, and second, that the patent holder will get extended monopoly rights.

The agreement was explained by an author in a very lucid manner as- *“this deal implies that the pharmaceutical company holding a patent on a drug enters into an agreement with the potential generic competitor to settle the dispute and to fix some kinds of restriction on its market entry (e.g., a non-challenge or non compete clause where the generic company refrains from entering the market until the originator’s patent expires), where the latter, in return for withdrawing its market entry, benefits either from a direct monetary payment or other forms of valuable agreements (e.g. an authorized licensed entry at a specific date, distribution agreements, favorable terms in a side-deal in which the originator company grants a commercial benefit to the generic company) or both.”*<sup>11</sup>

That means value transfer flow from patent holder (plaintiff in infringement suit) to generic company (defendant in infringement suit) rather than from generic company to patent holder and thus called as Reverse Payment Settlement. The agreement was entered with the object to delay the entry of the generic company in the market and thus also known as the Pay-for-delay agreement.

---

<sup>10</sup> Thomas McGuire and others, ‘Resolving Reverse-Payment Settlements with the Smoking Gun of Stock Price Movements’(2016) 101(4) IOWA Law Review 1581 <<https://ilr.law.uiowa.edu/print/volume-101-issue-6/resolving-reverse-payment-settlements-with-the-smoking-gun-of-stock-price-movements/>>accessed 22 April 2020

<sup>11</sup> Margherita Colangelo, ‘Reverse Payment Patent Settlements in the Pharmaceutical Sector under EU and US Competition Laws: a Comparative Analysis’ (2017) 40 (3) World Competition: Law and Economics Review<[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3070189](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3070189)>accessed 22 April 2020

# DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

## *Regulatory Framework for the Pharmaceutical industry and rise of the Reverse Payment settlement*

### **1. UNITED STATES**

The Pure Food and Drug Act (PFDA) 1907 is the first statute to regulate pharmaceuticals industry in the United States which was later on repealed by the Federal Food, Drug, and Cosmetic Act (FFDCA) 1938. However, even then there are some difficulties to regulate the medicines in the market of which the prominent difficulty is of disputes between the patent holder and generics company which was highlighted in the case of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*<sup>12</sup> The Court, in this case, highlighted that “*unlicensed experiments conducted with a view to the adaption of the patented invention to the experimenter's business is a violation of the rights of the patentee to exclude others from using his patented invention*”<sup>13</sup>

Thus, the generic manufacturers are not entitled to conduct any research work with patented drugs before the expiry of the patent. That means even after the expiry of the patent, the patent holder gets an additional exclusivity period till the time any generic company comes up with a generic version of the patented drugs. So, in this way, the consumer benefits are kept at risk. To elucidate this problem and to launch generic medicines effectively in the market the US enacted new statute the Drug Price Competition and the Patent Term Restoration Act of 1984 (Commonly known as Hatch-Waxman Act). The act was enacted in response to the judgment given in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*

The Act was introduced with the purpose to permit rapid access of inexpensive generic drugs on the market by shortening the procedure for their approval before the Food and Drug Administration (FDA).<sup>14</sup> The act demonstrates two types of application: first, New Drug Application (NDA) for a new drug that has not previously been approved by the FDA, and second, Abbreviated New Drug Application (ANDA) for a drug that previously has been

---

<sup>12</sup>Roche Products Inc v Bolar Pharmaceutical Co, 733 F2d 858 [Fed Cir1984]  
<[http://biotech.law.lsu.edu/cases/ip/patent/roche\\_v\\_bolar.htm](http://biotech.law.lsu.edu/cases/ip/patent/roche_v_bolar.htm)>accessed26 April 2020

<sup>13</sup>ibid

<sup>14</sup>Petar(n 7) 9

# DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

approved by the FDA.<sup>15</sup> Thus under the ANDA application now the generic company can get approval for marketing their generic version of drugs from the FDA relying on the existing data. The objective of the act is to encourage generic drug manufacturers to file an application before the FDA and enter the market for the ultimate benefit of the consumer. However, in practice, it virtually creates a mechanism via which the originator's companies 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.<sup>16</sup> Thus, it can be contended that the reverse payment settlement is a direct outcome of the Hatch-Waxman Act.

## **2. EUROPEAN UNION**

In the EU the pharmaceutical industry is not regulated by any statute like in the United States. In EU medicines regulatory system is based on a network of around 50 regulatory authorities, the European Commission, and EMA.<sup>17</sup> In EU the states control the pharmaceutical sector by keeping in mind two objectives- first, promotion of innovation and invention and second, consumer welfare. Since innovation is crucial for the sector, an important role is played by the intellectual property law and patent law, however, the grant of intellectual property protection for pharmaceuticals and its enforcement are not harmonized in Europe as distinct from the homogeneous regime in the US.<sup>18</sup> As a result, in the EU patents are granted by each member state and a patent holder who wants to initiate an infringement suit would have to bring patent litigation in the court of each member state individually. Also, if anyhow the generic company enters the market can subsequently affect the price of the drug not only in one state but in all the other member states in the EU. In this situation, it is very difficult and expensive for a patent

---

<sup>15</sup> Michael Clancy, Damien Geradin, and Andrew Lazerow, 'Reverse-payment patent settlements in the pharmaceutical industry: An analysis of US antitrust law and EU competition law[2013] SSRN <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2345851](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2345851)>accessed 22 April 2020

<sup>16</sup> RohilBandeekar and Maithili Parikh, 'Reverse Patent Settlements In India' (2017) 9(5) The Law Review Government Law College <<http://glcmumbai.com/lawreview/volume9/05RohilBandeekarandMaithiliParikh.pdf>>accessed 25 April 2020

<sup>17</sup> European Medicines Agency, 'The European regulatory system for medicines-A consistent approach to medicines regulation across the European Union [2016] <[https://www.ema.europa.eu/en/documents/leaflet/european-regulatory-system-medicines-european-medicines-agency-consistent-approach-medicines\\_en.pdf](https://www.ema.europa.eu/en/documents/leaflet/european-regulatory-system-medicines-european-medicines-agency-consistent-approach-medicines_en.pdf)>accessed 25 April 2020

<sup>18</sup> Petar (n 7) 23

holder to adequately enforce their patents to prevent generic entry.<sup>19</sup> This arduous nature of patent enforcement is studied as the principle cause of reverse patent settlements in the EU.<sup>20</sup>

### **III. TUSSLE BETWEEN THE INTERPLAY OF IP & COMPETITION LAW**

There is always a debate that Reverse Payment Settlement is an antitrust violation or is a proper exercise of pharmaceutical patent rights. Competition law is invoked since reverse payment settlements are deemed to preclude the possibility of the generic manufacturer to enter the market and compete with the brand-name company<sup>21</sup> which is argued as anti-competitive in nature since it has adverse effect on the competition.

On the other hand, one of the basic ideas of Patent Law is to give an exclusive right to the patent holder and to encourage them for further invention. So, in this way, patent holders by the way of exclusive rights provided to him prevent the others from getting the benefit of his patented invention. In this way, it was argued that the Originator Company can also restrict the entry of generic manufacture company in the market who is doing nothing but trying to get benefit from the patented invention. Thus, any such settlement to avoid litigation will not anyhow violate competition law.

The very such nature of Reverse Payment Settlement can be analyzed from both the perspective in landmark judgments in the US and EU.

#### **A. Reverse payment settlement and competition law perspective**

##### **1. *United States***

The Federal Trade Commission, which is an authorized body to regulate antitrust law in the US, is of the view that Reverse Payment Settlement is anticompetitive in nature. The FTC was constantly trying to stop such agreement but the ambiguity in the law stood as a barrier until the

---

<sup>19</sup> Michael (n 14) 9

<sup>20</sup> Rohil (n 15) 102

<sup>21</sup> Petar (n 7) 6

# DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

Supreme Court showed its clarity on it. Before the Supreme Court judgment in the Actavis case, different views were made by the Circuit Courts. Like, the sixth circuit court is of the view that, if the object of the agreement is illegal everything is illegal. This view is popularly regarded as *per se illegal* that means the agreements are illegal if the object of the agreement is illegal. Eleventh Circuit Court applies the rule of Scope of the Patent test. According to this view, Patent Law has got its limitation and if by any such agreement you are exceeding such limitation you are exceeding antitrust law, you are exceeding the scope of the patent and thus the settlement is not acceptable. Third Circuit Court is of the view that agreements were presumptively held to be illegal unless rebutted by the defendant that it is not against the Competition Law

Finally, all this debate was put an end to by the Supreme Court in Actavis Case. The Supreme Court in Actavis Case had taken the middle path opting for the Rule of Reason Approach.<sup>22</sup> This approach requires a detailed analysis of the effect of the Reverse Payment Settlement Agreement on competition within a particular defined market.<sup>23</sup> The dissenting view of the Chief Justice about the ‘scope of the patent test’ was rejected and held that even if the agreement falls within the scope of the patent it cannot be exempted from the anti-trust law.

## ***2. European Union***

The European Competition Commission (ECC) is regulating body in the EU to regulate Competition Law. They are also of a similar view of the FTC in the US. Like in the US where the view of FTC was scrutinized by the Supreme Court, General Court securitized the view of the ECC in Lundbeck Case. The court is of the view that it is necessary to analyze the context in which the payment was made under the Reverse Payment Settlement. The General Court affirms the commission assessment on Reverse Payment Settlement that the payment was made to exclude any competition in the market which being anti-competitive in nature is not acceptable.<sup>24</sup>

## **B. Reverse payment settlement and intellectual property law perspective**

---

<sup>22</sup>Rohil(n16) 101

<sup>23</sup> ibid

<sup>24</sup> Jonas Frank, ‘Patent Settlements in Europe and the Lundbeck Case: A Competition Law and Economics Perspective’ (Dissertation, University of Marburg 2017) <<https://ssrn.com/abstract=3054358> or <http://dx.doi.org/10.2139/ssrn.3054358>> accessed 27 April 2020



# DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

## 1. *United States*

It was argued by the many scholars that the Reverse Payment Settlement be analyzed from the Intellectual Property law perspective i.e. Patent Policy rather than from a Competition Law Perspective. They further explained that whether the payment made in the settlement is to withdraw the case since the patent is invalid and whether there is infringement by the generic company is a question of Patent Law rather than Competition Law.

Again the dissent opinion of Chief Justice Roberts with two other judges in Actavis Case compelled the scholars to think from Patent law perspective. Chief Justice Roberts said that -

*“A patent carves out an exception to the applicability of antitrust laws. The correct approach should therefore be to ask whether the settlement gives Solvay monopoly power beyond what the patent already gave it. The Court, however, departs from this approach, and would instead use antitrust law’s amorphous rule of reason to inquire into the anticompetitive effects of such settlements. This novel approach is without support in any statute, and willIs courage the settlement of patent litigation. I respectfully dissent.”<sup>25</sup>*

To support his view, he cited many precedents set out by the US Supreme Court. He cited a case of *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp*<sup>26</sup> where it was held that- *“A patent . . . is an exception to the general rule against monopolies”*<sup>27</sup>. He further made emphasizes the fact that such an agreement must be within the scope of the Patent Law. That means exceeding the scope of patent law will ultimately lead to antitrust assessment. He highlights the point as-

*“If its actions are within the scope of the patent, they are not subject to antitrust scrutiny....”<sup>28</sup>*

---

<sup>25</sup> *Federal Trade Commission v Actavis Inc* 570 US 136 [2013] <[https://www.supremecourt.gov/opinions/12pdf/12-416\\_m5n0.pdf](https://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf)>accessed 27 April 2020

<sup>26</sup> 382 US 172, 177 (1965)

<sup>27</sup> *FTC v Actavis* 570 US 136 [2013] <[https://www.supremecourt.gov/opinions/12pdf/12-416\\_m5n0.pdf](https://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf)>accessed 27 April 2020

<sup>28</sup> *ibid*

# DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

In a nutshell, the dissenting view is that majority opinion “*accommodated antitrust principles and struck a balance between patent and antitrust law.*”<sup>29</sup>

## **2. European Union**

Nearly the same arguments were made in the EU by Lundbeck in *H. Lundbeck A/S and Lundbeck Ltd v European Commission*<sup>30</sup>. However, the court held that-

“*The scope of a patent is not, it appears, immune to antitrust laws; on the contrary, antitrust laws and patent laws should work together to define that scope. Setting aside the scope of the patent test, and allowing competition law to intervene along with patent law in the definition of the scope of the patent, would seem like the best solution.*”<sup>31</sup>

## **C. Findings based on the arguments**

The patent holder enjoys the right as an owner because the state has granted him such legal status in relation to his invention and such ownership has nothing to do with the rules relating to Competition Law, per se.<sup>32</sup> However, Competition law will be applicable against such rights if in the preview of legal rights the act is anti-competitive in nature. It can be concluded that though an exclusive right to exploit his invention may be given by the states, the connotation that this would mean that IPRs are in some way or manner immune from intervention by Competition law authorities is incorrect.<sup>33</sup>

## **IV. IMPACT OF REVERSE PAYMENT SETTLEMENT AND HUMAN RIGHTS AS A THIRD PERSPECTIVE**

The reverse payment settlement has an adverse impact on human rights and intellectual property. It directly affects the consumer on the one hand and innovation on the other hand. From the

---

<sup>29</sup> ibid

<sup>30</sup>EU: T: 2016:449

<sup>31</sup>Sandra Marco Colino and others, ‘The Lundbeck Case and the Concept of Potential Competition’ (2017) Concurrences Review 2The Chinese University of Hong Kong Faculty of Law Research Paper <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2931411](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2931411)>accessed 01 May 2020

<sup>32</sup> Parke, *Davis v Probel* [1968] ECR 55; [1968] CMLR 47

<sup>33</sup> Pawan (n 1) 25

## DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

consumer viewpoints, as internationally recognized that “the right to access to medicines is an essential element of the right to health and the right to life”.<sup>34</sup> Even access to medicines is well-founded in international law under the International Covenant on Civil and Political Rights (ICCPR) or in the International Covenant on Economic, Social and Cultural Rights (ICESCR).<sup>35</sup>

As far as the relationship between Competition, Intellectual Property, and Human Rights are concerned they are interlinked with each other with the two same policies commonly seek to safeguard and promote the economic interests of consumers in the pharmaceutical industry.<sup>36</sup> The Human Rights and Competition law ensures the access of medicine to the public at lower prices but with higher quality. Whereas, the Intellectual property act as a catalyst to encourage the invention of new technology in the pharmaceutical sector which ultimately has social and financial values.

However, the pharmaceutical industry has encountered loopholes in the regulatory framework which led to the reverse payment settlement. These reverse payment settlements result in a hike in the price of medicine. For instance, the originator company now adds the value paid to the generic company into the price of a drug. On the other hand, we as a consumer are going to pay a high price for the weak patent (which might be invalidated in the court). As a result, if these weak patents did not get challenged in the court, the standard of prior art would not be as high as it would have been and this ultimately led to a weak invention again that is not going to serve the social and financial value at the end.

Thus it can be concluded that pay-for-delay settlement that constitutes an antitrust violation indicates that parties to such a settlement, a brand-name drug manufacturer and a generic manufacturer, have fallen afoul of the fundamental human rights responsibility in relation to

---

<sup>34</sup>Joo-Young Lee, ‘A Human Rights Framework for Intellectual Property, Innovation and Access to Medicines(1<sup>st</sup>edn Routledge 2015) 204 (as cited in KwanghyukYoo, ‘Interaction of Human Rights Law and Competition Law: The Right To Access to Medicines and Consumer Welfare in the US Pharmaceutical Sector’ (2018) 43(123) Vermont Law Review<[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3250392](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3250392)> accessed 02 May 2020)

<sup>35</sup> Alicia Ely Yamin, ‘Not Just a Tragedy: Access to Medications as a Right Under International Law, (2003) 21 Boston University international law journal 325  
<[https://www.researchgate.net/publication/7262748\\_Not\\_just\\_a\\_tragedy\\_Access\\_to\\_medications\\_as\\_a\\_right\\_under\\_international\\_law](https://www.researchgate.net/publication/7262748_Not_just_a_tragedy_Access_to_medications_as_a_right_under_international_law)> accessed 02 May 2020

<sup>36</sup>J. JanewaOseiTutu, ‘Human Development as a Core Objective of Global Intellectual Property’ (2016) 105(1) Kentucky Law Journal<[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2896342](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2896342)> accessed 02 May 2020

# DROIT PENAILE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

access to medicines in terms of availability, accessibility, acceptability, quality, transparency, and monitoring and account ability.<sup>37</sup>

## V. CONCLUSION AND FINDINGS

As discussion made in part II, the essentials that constitute Reverse Payment Settlement are limitations on the entry of generic drugs in the market and some form of value transfer from originator to the generic drug manufacturer. We have observed that this settlement was preferably initiated in case of weak-patent. Further, it was highlighted that both in the US and EU the ultimate importance was given to the consumer welfare (viz. right to life, right to health and to access medicine) and the inventions. However, in the US it was not appropriate to say that reverse payment settlement is a result of Hatch-Waxman Act as we have seen in EU (and even in the US) that root cause which led to the development of the reverse payment settlement is to avoid patent litigation, challenges made to the validity of the patent and of course challenges against the inventions of the patent holder. We have further observed that how the patent holder gets an additional exclusivity period till the time any generic company comes up with a generic version of the patented drugs. In Part III we have observed the argument rose for and against the reverse payment from IP and Competition Law perspective respectively. On one hand, where reverse payment settlement was argued to be within the scope of patent holder exclusive rights, on the other hand, it was regarded as anti-competitive in nature. The detailed analysis of both views leads to the conclusion that though it may be regarded within the scope of patents right it is anti-competitive in nature. We have further observed that Competition law authority in both the US and EU is of strict view to declared such settlement illegal regardless of any tests. However, courts in both the jurisdiction adopted some liberal views and held not per se illegal but must be examined through the rule of reason approach. In part IV we have observed that the debate is not limited to the IP and Competition law but Human Rights have also a vital role to play. Since reverse payment settlement affects consumers and invention it directly affects the

---

<sup>37</sup>KwanghyukYoo, 'Interaction of Human Rights Law and Competition Law: The Right To Access to Medicines and Consumer Welfare in the US Pharmaceutical Sector' (2018)43(123) Vermont Law Review<[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3250392](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3250392)> accessed 02 May 2020

## DROIT PENALE: INDIAN LAW JOURNAL ON IPR

(A Unit of Droit Penale Group, Prayagraj)

ILJIPR, ISSN: 2582-8762

VOLUME 1 ISSUE 1

right to life, right to health, and the right to access the medicines. We have further noticed that due to reverse payment settlement we as a consumer had to pay a high price for the weak patents.

Thus, finally it can be observed that even having parallel views there is the ultimate goal of both the laws viz. consumer welfare. At the same time, we will have to keep in mind the well-established legal principle all over the globe that patent law which provides exclusive rights is not immune from the intervention of the competition law. Competition law puts pressure on innovation without reducing competition by restricting the market player's anti-competitive conduct.<sup>38</sup> Even if we analyze the reverse payment settlement it violates the basic objective of the intellectual property mainly to encourage inventions. The tussle is not between the Competition law and Intellectual Property rather it is scuffle within the intellectual property where on one hand, patent holder (with a weak-patent) called this reverse payment settlement as pro-competitive and on the other hand, it discourages the good quality of inventions.

In this way it is necessary to scrutinize such an agreement with proper care and cautions that it does not violate Competition law only but also did not affect Intellectual property and Human Rights. It is also to be referred that since the inventions are not limited to the pharmaceutical sector so there is always a chance that such an agreement could also arise in other sectors.

---

<sup>38</sup> Christine-Jane Selenhag, 'Pay-for-delay: A competition law analysis of settlement agreements in the pharmaceutical sector' (Independent Thesis, Stockholm University, Faculty of Law 2019)