

## **INTELLECTUAL PROPERTY AS A MARKET TOOL AND ITS RELATION WITH COMPETITION**

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### ***Abstract***

*Intellectual property rights and Competition Law serves the dual purpose of promoting innovation and ensuring consumer welfare. The paper enquires how seemingly different spheres go along with each other to promote their common goal. Intellectual property rights promote competition by substitution and curtail competition by imitation. Hence the regime balances the loss in allocative efficiency (price competition) with the expected gain in the dynamic efficiency (innovation). Intellectual property laws create exclusive rights that provide incentives for innovation by “establishing enforceable property rights for the creators of new and useful products, more efficient processes, and original works of expression.” Antitrust laws, in turn, ensure that new proprietary technologies, products, and services are bought, sold, traded, and licensed in a competitive environment. Hence the key goal of both regime is to promote economic efficiency. In cases such as the Microsoft case of 2004, the Huawei case (2015), FTC v. Qualcomm Inc, etc., the Courts have taken steps to ensure that both regimes go hand in hand. Further, the Hatch-Waxman Act and Abbreviated New Drug Applications (ANDA) provisions seek to ensure competition in the market by making provisions for checking questionable patents and promoting generic competition.*

*The paper consists of four parts. Part I begins with an introduction to Intellectual Property and Competition and their relationship with one another. Part II tests and analysis the theme of the paper. It begins with analyzing the Intellectual property regime as a market tool and an innovation stimulator. Then moves on to analyze the key ideas of competition and its aim to promote economic efficiency. Thereafter, the paper analyses the intricacies between Intellectual Property Rights and competition policy. The discussion moves on about how IPRs are a trade-off by balancing the loss in allocative efficiency with the expected gain in the dynamic efficiency. In Part III, two special scenarios are investigated. The first is the abuse of*

*dominant position and standard-essential patents, and the second is US scenarios and the Hatch-Waxman Act. The same is studied with the aid of the US Federal Trade Commission Reports and case laws. Part IV is the concluding portion. Here the authors try to draw how IP regime and competition laws are complementary to each other.*

## **INTRODUCTION**

Intellectual Property Law and competition law, though seemingly two spheres different from one another, share the common goal of promoting innovations and enhancing consumer welfare. However, Intellectual Property (hereinafter referred to as “IP”) is a private right, and Competition law is a balancing mechanism for social welfare; both arenas often come into conflict. Until recently, the exclusivity of IP was given predominance over the promotion of competition. However, recently there has been a shift in this trend. Interestingly, as evident from the judicial approaches, FTC reports, and EC commission’s discussions, IP has lately been seen as limited by competition.

While the tryst of IP and competition is being discussed, it is essential to note that IP detains competition by imitation and promotes competition by substitution. The conflicts arise when one supersedes another. The extension of the monopolistic rights to the downstream market would be fatal for competition. Cases wherein such abuse of dominant position, including refusal to license or supply, would curtail healthy competition. There is an abuse of monopolistic rights in such circumstances, which would amount to the anti-competitive practice of Intellectual Property Rights (IPR).

## **IP AS A MARKET TOOL AND ITS RELATION WITH COMPETITION**

Over the past several decades, antitrust enforcers and the courts have come to recognize that intellectual property laws and antitrust laws share the same fundamental goals of enhancing consumer welfare and promoting innovation.<sup>1</sup> Innovation benefits consumers through the development of new products, processes, and services that improve lives and address unmet needs.<sup>2</sup> Intellectual property laws create exclusive rights that provide incentives for innovation by “establishing enforceable property rights for the creators of new and useful products, more

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<sup>1</sup> Fed. Trade Comm’n & Dept. of Justice Antitrust Div., Antitrust Enforcement And Intellectual Property Rights: Promoting Innovation And Competition (April 2007).

<sup>2</sup> Fed. Trade Comm’n, The Evolving IP Marketplace: Aligning Patent Notice And Remedies With Competition (2011).

efficient processes, and original works of expression.”<sup>3</sup> These rights not only prevent others from appropriating the value derived from their inventions or original expressions but also facilitate the commercialization of these inventions or expressions and encourage public disclosure. Antitrust laws, in turn, ensure that new proprietary technologies, products, and services are bought, sold, traded, and licensed in a competitive environment. It fosters competition by prohibiting anticompetitive mergers, collusion, and exclusionary uses of monopoly power.<sup>4</sup> Thus, the two bodies of law pursue the common goal of economic efficiency.<sup>5</sup>

According to Judge Posner, “It is not a violation of [the antitrust] laws to acquire a monopoly by lawful means, and those means include innovations protected from competition by the intellectual property laws.”<sup>6</sup> Even though intellectual property rights may create a monopolistic condition, it is not necessarily true to state that Intellectual Property Rights create monopolies as the consumers may be able to substitute other technologies or products for the protected technologies or products. Moreover, the antitrust doctrine does not presume the existence of market power from the mere presence of an intellectual property right.<sup>7</sup> Antitrust and intellectual property are properly perceived as complementary bodies of law that work together to bring innovation to consumers.<sup>8</sup> Competition among patented technologies at every stage of the innovation process helps generate lower prices, more choices, and higher quality products for consumers.<sup>9</sup>

## **INTELLECTUAL PROPERTY AS A MARKET TOOL**

The underlying rationale of granting intellectual property rights is the stimulation of innovation and providing exclusive protection for the innovator’s innovative achievements.<sup>10</sup> Innovations

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<sup>3</sup> U.S. Dep’t Of Justice & Federal Trade Comm’n, Antitrust Guidelines For The Licensing Of Intellectual Property § 1 (1995), Reprinted In 4 Trade Reg. Rep. (Cch) ¶ 13,132.

<sup>4</sup> Ibid.

<sup>5</sup> Competition And Intellectual Property In The European Union: Claude Crampes (Université De Toulouse-Gremaq And Idei), David Encaoua (Eurequa, Paris I), Abraham Hollander (Université De Montréal). Revised Version (February 2005).

<sup>6</sup> Richard A. Posner, Antitrust In The New Economy, 68 Antitrust L.J. 925, 930-31 (2001).

<sup>7</sup> Ill. Tool Works Inc. V. Indep. Ink, Inc., 126 S. Ct. 1281, 1284 (2006) (“[T]he Mere Fact That A Tying Product Is Patented Does Not Support [A Market Power] Presumption.”); Antitrust-IP Guidelines § 2.2 (“The Agencies Will Not Presume That A Patent, Copyright, Or Trade Secret Necessarily Confers Market Power Upon Its Owner.”).

<sup>8</sup> Supra n. 1

<sup>9</sup> Ibid.

<sup>10</sup> Kwok, A New Approach To Resolving Refusal To License Intellectual Property Rights Disputes, World Competition, 2011, P. 262-263.

are essential to sustain economic growth and global competitiveness. The concept of innovation is very elusive. According to OECD's OSLO Manual: "An innovation is the implementation of a new or significantly improved product (goods or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations."<sup>11</sup> It identifies four types of innovations, namely, product innovations<sup>12</sup>, process innovations<sup>13</sup>, marketing innovations<sup>14</sup>, and organizational innovations<sup>15</sup>.<sup>16</sup>

However, the process of innovation is often complex, expensive, risky, and unpredictable. The goal of the patent system is to promote innovation in the face of that expense and risk.<sup>17</sup> The two main mechanisms fulfilled by intellectual property protections are: (i) the prevention of third parties free-riding on the innovator's investments, and (ii) encouraging 'competition by substitution' rather than 'competition by imitation'.<sup>18</sup> The primary tool for encouraging innovation is the prevention of third parties from free-riding on the inventor's innovation. In this way, IP acts as a tool for inventor protection. But in the market sense, IP acts as investor protection. The working of the patent can be expressed as "...*encourage innovation by preventing others from appropriating the value of the patent owner's investment*".<sup>19</sup> The patent being an exclusive set of rights, granting the inventor the economic rights over the inventions, it acts as a mechanism wherein the unauthorised use and misuse of the invention is checked.

Another aim of the Intellectual property system is to encourage competition by substitution rather than competition by imitation. In a situation wherein the protection is not accorded, most of the players would rather copy than create new ideas. Consequently inefficient new ideas would be created.<sup>20</sup> Among various modes, Patents mainly encourage investment in new

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<sup>11</sup> Oecd, Oslo Manual—Guidelines For Collecting And Interpreting Innovation Data (3rd Edn 2005) Para. 146,

<sup>12</sup> Providing New Or Improved Products That Better Respond To Consumer Needs And Preferences.

<sup>13</sup> The Implementation Of A New Or Significantly Improved Production And Delivery Method.

<sup>14</sup> The Implementation Of A New Marketing Method Involving Significant Changes In Product Design Or Packaging, Product Placement, Product Promotion Or Pricing.

<sup>15</sup> The Implementation Of A New Organisation Method In The Firm's Business Practices, Workplace Organisation Or External Relations.

<sup>16</sup> Supra n. 2 Para. 163, Ibid. Para. 169, Ibid. Para. 177.

<sup>17</sup> Ibid.

<sup>18</sup> Käseberg, Intellectual Property, Antitrust And Cumulative Innovation In The EU And The US, 2012, P. 47; Anderman & Ezrachi, Intellectual Property And Competition Law: New Frontiers, 2011, P. 4.

<sup>19</sup> Edith Ramirez And Lisa Kimmel, A Competition Policy Perspective On Patent Law: The Federal Trade Commission's Report On The Evolving IP Marketplace (2011)

<sup>20</sup> Mark A. Lemley, Ex Ante Versus Ex Post Justifications For Intellectual Property, The University Of Chicago Law Review Vol. 71, No. 1 (Winter, 2004), Pp. 129-149

technologies so as to enable the patentee to appropriate the economic value of its innovation by licensing its technology or selling a patented product.<sup>21</sup>

## **COMPETITION**

There is a need to ensure proper development of new technological possibilities wherein any number of firms can pursue the prospect. In order to facilitate this process efficiently, there is a need for a system that will assure efficient allocation of the resources among the prospects at an efficient rate and in an efficient amount.<sup>22</sup> Competition acts as a tool to ensure this efficient allocation of resources.

In order to ensure efficiency and protect a competitive environment in the market, the Competition laws was introduced. The aim of the competition law is the promotion and protection of the competitive process. The competition policy introduces a “*level-playing field*”, where the optimal allocation of resources occurs and would help the market to be competitive. A fair and effective competition system ensures economic efficiency, economic growth and development and consumer welfare. Hence the competition policy applies the competition law to ensure that the companies compete fairly with each other. This, in turn, will encourage enterprises, improve efficiency, creates a wider choice for consumers, helps reduce prices and improve the quality of products.<sup>23</sup>

In a market, the importance of competition is so high that the European Commission’s (EC) Guidelines on Vertical Restraints states: “The protection of completion is the primary objective of EC competition policy, as this enhances consumer welfare and creates the efficient allocation of resources.”<sup>24</sup> Accordingly, it is evident from the EC’s statement that apart from enhancing efficiency, overall consumer welfare also plays a cardinal role in protecting competition.

## **ECONOMIC EFFICIENCY**

Economic efficiency is an indispensable aim of competition law. It amounts to the effective use and allocation of the economy's resources. Most economics foresee efficiency as the ultimate goal of competition. Consequently, the European Union has moved to a ‘more

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<sup>21</sup> Supra n. 19

<sup>22</sup> Kitch, The Nature And Function Of The Patent System, 20 J.L. & Econ. 265 (1977).

<sup>23</sup> See: [Http://Ec.Europa.Eu/Competition/General/Overview\\_En.Html](http://Ec.Europa.Eu/Competition/General/Overview_En.Html)

<sup>24</sup> Guidelines On Vertical Restraints, Oj 2000 No. C 291

economic approach' to analyse and improve their competition policy. The EU competition Commission formulate the goals of European Competition Law in terms of the economic approach, which is in resonance with the efficient approach of the economists.<sup>25</sup> Consequently, the illegality of a specific behaviour within the competition regime was evaluated based on the economic efficiency of the behaviour within the market.<sup>26</sup>

This market-oriented and effect-based approach forces the competition law enforcers to analyse the economic efficiency in individual cases. The EC suggested a cumulative test to evaluate the efficiency-competition coherence and use efficiency defence in anti-competitive practices. It is based on four-factor requirements: " i) that efficiencies are realised or likely to be realised as a result of the conduct concerned; ii) that the conduct concerned is indispensable to realise these efficiencies; iii) that the efficiencies benefit consumers; iv) that competition in respect of a substantial part of the products concerned is not eliminated."<sup>27</sup>

In economic terms, the efficiency is twofold. i) Allocative Efficiency and ii) Dynamic Efficiency. According to Allocative or Static Efficiency, efficiency is achieved by optimal economic use of existing resources. The efficiency builds by relying on available knowledge on existing resources. It concentrated on maximum utilization of particular products. Economically, in allocative efficiency, the production would be determined by consumer preferences. Price would be marginal cost. On the other hand, dynamic efficiency relies on innovations as the decisive factor of innovation. Such a state of efficiency is achieved by the optimal rate of innovation and investments to improve production. They do not merely concentrate on the maximization of the utility of any particular product or innovation. The efficiency coefficient relies on the research and development of new knowledge and marketing. Unlike static efficiency, dynamic efficiency is unable to be measured and quantified.<sup>28</sup> While allocative efficiency involves ex-ante assessment to determine the efficiency, dynamic efficiency relies on ex-post assessment.

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<sup>25</sup> This Concept Was Initially Developed In The Guidelines On Vertical Restrain: "In Applying The Ec Competition Rules, The Commission Will Adopt An Economic Approach Which Is Based On The Effects On The Market; Vertical Agreements Have To Be Analyzed In Their Legal And Economic Context." Guidelines On Vertical Restraints, Oj 2000 No. C 291, Para. 7.

<sup>26</sup> Josef Drexl, Is There A 'More Economic Approach' To Intellectual Property And Competition Law? Research Handbook On Intellectual Property And Competition Law Edited By Josef Drexl, (Pages 27-53)

<sup>27</sup> Dg Competition Discussion Paper On The Application Of Article 82 Of The Treaty To Exclusionary Abuses (Para 84)

<sup>28</sup> Supra n. 26

## **IPRS AND COMPETITION POLICY: INTRICACIES**

Conflicting views about the relationship between Intellectual property rights and competition have emerged over time. Among economists, no concurrency has been reached as to whether one complements or contradicts another. IPRs are treated as ‘exceptions’ from competition resulting in the use of competition law only in instances where the entrainment in the competition went beyond the scope of the exclusive rights.<sup>29</sup> However, such understanding’s folly lies in the fact that they merely consider IPR rights as granted without considering the economic rationale behind the grant.<sup>30</sup>

There are two views on the interconnections of IPRs and Competition. One of the views argues that IP and Competition are independent entities and that the enforcers shall refrain from one another. The view propounds that competition law enforces should not interfere with the exclusive rights even if they might create market dominance. On the other hand, a second view propounds that both IPRs and Competition share the common goal of enhancing dynamic efficiency and should be read to be complementary to each other.<sup>31</sup> Hence it could be understood that the function of competition policy is to enhance dynamic efficiency, as opposed to mere allocative efficiency. Moreover, antitrust or competition policy moulds the nature and value of intellectual property rights. This is furthered by placing restrictions on the acquisition of intellectual property, refusals to deal, and the terms adopted in licensing agreements.<sup>32</sup>

According to the US Antitrust Guidelines for the Licensing of Intellectual Property (2017), intellectual property laws and antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare.<sup>33</sup> Further, the guidelines identify that the IPRs incentivize innovations, dissemination and commercialization through a mechanism of enforceable rights. The antitrust laws also work to promote innovation and consumer welfare. They do this by prohibiting certain actions that would harm competition with regard to either existing or new technologies.

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<sup>29</sup> This School Of Thought Gave Raise To Inherency Theory.

<sup>30</sup> Initially IPRs Were Granted To Bring In New Trade And Technology.

<sup>31</sup> Supra n. 26

<sup>32</sup> Michael L. Katz , Intellectual Property Rights And Antitrust Policy: Four Principles For A Complex World

<sup>33</sup> Antitrust Guidelines For The Licensing Of Intellectual Property, Issued By The U.S. Department Of Justice And The Federal Trade Commission January 12, 2017

According to the EU commission, a theory of complementarity comes into the picture when IP promotes dynamic competition by encouraging undertakings to invest by developing new or improved products and processes, and competition compliments this by putting pressure on the companies to innovate. The ECJ in *IMS Heath*<sup>34</sup> had devised three cumulative conditions as a test of abuse of IPRs to curtail competition. The three conditions read as, i) the refusal is preventing the emergence of a new product for which there is potential consumer demand, ii) this refusal is unjustified and, iii) it excludes any competition from the secondary market. The court further stressed that the interest of consumers in having access to a new product that would otherwise not be offered by the right holder in the secondary market has to be given predominance while striking a balance between the exclusivity of proprietary rights and protecting free completion.<sup>35</sup>

### **DYNAMIC COMPETITION AND IPR**

From the above, it is clear that Intellectual property rights and competition share the common goal of enhancing consumer welfare and promoting innovations. Certain tools such as competition laws act as a complementary tools to intellectual property laws and provide an important market-stabilizing effect on anti-competitive behaviour.<sup>36</sup>

However, granting the monopolistic rights in IP in the economic efficiency assessment can be regarded as a trade-off by balancing the loss in allocative efficiency (price Competition) with the expected gain in the dynamic efficiency (innovation).<sup>37</sup> According to Robert. P. Merges, competition law, should attempt to favour competitive environments for improvements marginally, but without extensively reducing the incentives to innovators. He further concludes that in many industries, the efficiency gain from innovator's ability would outweigh the loss of competition for improvements to the basic inventions.<sup>38</sup>

IPR mechanism is this balancing approach. IPR excludes price competition by excluding imitation, even when the competitor may be better placed to produce the good or service in

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<sup>34</sup> Case C- 418/01, *Ims Health*, [2004] Ecr I-5039

<sup>35</sup> The Court Here Has Stressed On The Fact That The IPR Rights Should Not Be Accessed So As To Curtail Dynamic Competition. According To Drexl, Dynamic Competition Is A Process Oriented Concept.

<sup>36</sup> Report Of The United Nations Secretary-General's High-Level Panel On Access To Medicines: Promoting Innovation And Access To Health Technologies (September 2016): [Http://Www.Unsgaccessmeds.Org/S/Unsg-Hlp-Report-Final-12-Sept-2016.Pdf](http://www.unsgaccessmeds.org/S/Unsg-Hlp-Report-Final-12-Sept-2016.Pdf)

<sup>37</sup> *Supra* n. 26

<sup>38</sup> Robert P. Merges, On The Complex Economics Of Patent Scope, 90 Colum. L. Rev. 839 (1990)



question. However, allowing such production would negatively affect the IP system's incentive structure. But the question remains as to where to strike a balance, given that dynamic efficiency is impossible to measure.<sup>39</sup>

In the absence of IPRs, the cardinal issue remains that the competitors can compete by imitations and minor innovations rather than investing in better products. This would be a loss in dynamic efficiency. On the contrary, there is no guarantee that the firms will reinvest the monopoly profit earned from IP without competition. Due to competition pressure, the firms may reinvest the monopoly profit for more profits. In monopolistic situations, since the firm already has a dominant position, such reinvestment does not occur. Hence intervention under competition law is not advocated for the sake of mere efficiency but rather to safeguard the competitive pressure needed for the maintenance of the overall incentive structure of innovation.

Hence in an ideal situation by excluding imitations, the competitors compete by better products that can be marketed in the same market without infringing the pre-existing IP rights, i.e., it would lead to competition by substitution. The competition by substitution mechanism would further pressure the right holder to invest in innovation further. The role of competition law, in such scenarios, would be then limited to protect the competitive mechanism of the IP system against distortions. It is when the firms use their monopolistic rights to further curtail innovations in the secondary market that the competition mechanism comes into play.

## **IP AND COMPETITION: AN ANALYSIS OF SPECIFIC SCENARIOS**

### **ABUSE OF DOMINANT POSITION**

A dominant position exists when an undertaking is in a powerful position in the market and has a de-facto monopoly over such a market.<sup>40</sup> The de-facto monopoly may be the result or the consequence of the absence of alternatives to compete. The de-facto monopoly may be achieved due to the investment in research and development and IP protection. Such undertakings are entitled to continue to compete by the exercise of their exclusionary rights.

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<sup>39</sup> Supra n. 26

<sup>40</sup> Haris Čatović: Refusal To License Intellectual Property Rights As Abuse Of Dominant Position In EU Competition Law: The Implications Of The Huawei Judgment.

However, the conflict arises wherein the exercise, or rather over the exercise of the rights, would curtail competition in the neighbouring downstream market.

According to the theory of complementarity, as advocated by the EC Commission, the intervention of the competition commission is limited to exceptional circumstances, i.e., instances where dynamic competition is distorted. The distortion is caused by the behaviour of the right holder, either or not due to the IPR itself hampering or even excluding competition by substitution. Two circumstances can cause hindrance of competition by substitution as a consequence of IPR. In the first circumstance, IPR itself excludes substitution.<sup>41</sup> While in the second circumstance, the market circumstances external to the IPR exclude substitution.

The instance wherein IPR itself is excluding substitution can be seen in RTE and ITP v. Commission (Magill, 1995).<sup>42</sup> In this case, copyright was granted to television program listing under the British and Irish Law. This allowed the companies to monopolize the information. The EC Commission, while addressing the issue of whether the refusal to license copyright-protected television program schedules would amount to an abuse of the dominant position, held in affirmation. The Commission held that the Television channels were in a dominant position and withholding the license to compile the program schedule would amount to an abuse of the dominant position. Here the IPR itself went beyond the line of mere promoting creativity and monopolized the downstream product market. Hence, in such an instance, the IPR is said to be in conflict with the competition law and would negatively affect the market. Monopolization of the downstream or the secondary market is not the purpose of IPRs, the same, in fact, goes beyond the scope and purpose.

Hence, IPR grants the right holder to prevent competition from exploiting the subject matter of protection. However, it does not prohibit the development and use of competing technology. In fact, promoting innovation can be said to be the main purpose of granting monopolistic rights. But IPR holders' refusal to deal<sup>43</sup>, including refusal to supply and license, would constitute inordinate restriction in the development of competition in the secondary market. Such behaviour would create a barrier to competitor's entry into relevant markets, which would

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<sup>41</sup> Here IPR Itself Counteracts The Very Goal Of Granting Of IPR, I.E., Promoting Further Innovations.

<sup>42</sup> Joined Case C-241 And 242/91 P, Rte And Itp V. Commission ('Magill'), [1995] Ecr I-743

<sup>43</sup> There Is A Wide Collection Of Commercial Conduct That Can Be Categorized As A Refusal To Deal: Refusal To Supply Key Input Products And Services, Refusal To Provide Essential Interoperability Information, Refusal To Grant Access To Indispensable Facilities Or Networks And Refusal To License Intellectual Property Rights.

constitute an abuse of dominant position. Therefore, even though hindering in the upstream market is facilitated by IP, any hindrance, including constructive hindrance in the downstream market, would amount to an abuse of the dominant position.

Another issue comes into play in the instance of Pay-for-delay, also called as Reverse-payment Settlement cases. Here the branded drug makers sidestep competition by offering patent settlements by paying the generic companies not to bring lower-cost alternatives to market. Since 2001, the FTC has filed various suits to end pay-for-delay settlements. In 2013, the US Supreme court in *FTC v. Actavis*<sup>44</sup>, held that the monopolistic rights do not stand beyond the antitrust attack. This further hinders the competition and would amount to an abuse of the dominant market.

### **STANDARD ESSENTIAL PATENTS**

In general terms, standards as technology-specific are regarded as voluntary quality or technical specifications with which current or future products, production processes or services may comply.<sup>45</sup> This standardisation may have occurred due to widespread use or through official endorsement by a standard-setting organization.<sup>46</sup> Over time, standards have developed in multiple technical areas, including agriculture, foodstuffs and medicines.

The inherent tension between the technology innovators who seek economic benefits and the users who seek access has been aggravated once standards came into play in technology.<sup>47</sup> It occurs when the implementation of a standard would necessitate the application of the proprietary property.<sup>48</sup> The philosophies of both systems, at the core, are different. While patents are private rights, standards are intended for collective use. Standards, hence, foster harmonization and compatibility through shared and common systems. This tension has increased, especially once essentials came into play.<sup>49</sup>

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<sup>44</sup> 12-416 Ftc V. Actavis, Inc. (06/17/2013) (Supreme Court)

<sup>45</sup> Regulation 1025/2012 Of 25 October 2012 On European Standardisation [2012] Oj L 316/12, Rec. (1) And (3).

<sup>46</sup> A. Fitzgerald And K. Pappalardo, 'Moving Towards Open Standards' (2009) 6:2 Script-Ed 467, 468

<sup>47</sup> E.J. Iversen, E. Øversjøen And H.T. Lie, 'Standardisation, Innovation And IPR' (2004) 100 *Teletronikk* 65.

<sup>48</sup> J. Verbruggen And A. Lorincz, 'Patents And Technical Standards' (2000) 33 *Int'l Rev. Of Indus. Prop. And Copyright Law* 125.

<sup>49</sup> Larouche, P., & Van Overwalle, G. (2015). *Interoperability Standards, Patents And Competition Policy*. P. Delimatsis (Ed.), *The Law, Economics And Politics Of International Standardisation* (Cambridge International Trade And Economic Law, Pp. 367-393). Cambridge: Cambridge University Press.

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A Standard-Essential Patent (SEP) is a patent whose claims would be infringed by the implementation or adoption of the standards.<sup>50</sup> It would also encompass both patents that are essential to the use of a standard and the essential claims of such patents.<sup>51</sup> There are three main issues concerning SEPs. They are: i) Deceptive behaviour on the part of the SEP holder ('patent ambush; ii) Unwillingness of SEP holder to license or dispute regarding license terms ('patent holdup'); iii) Accumulation of SEPs ('patent thickets').<sup>52</sup> Our concerns for the present discussion would be limited to the second and third concerns. The unwillingness to license and patent thickets play havoc in the market in regard to competition. In either situation, it would amount to an abuse of dominant position and hinder competition in the secondary market and would be fatal for dynamic efficiency.<sup>53</sup>

In order to counter the issue of unwillingness to license, FRAND commitment has coped up. It is the most popular form of ex-ante requirement. Under this, a prior commitment is undertaken by the eventual SEP holder to grant licenses to implementers of the standard on fair, reasonable and non-discriminatory (FRAND) terms. However, the implementations, negotiations and mechanism of its working are still disputable. To tackle the issue of patent thickets, patent pools may be suggested. Here the patent holders are huge in number and the relevant patents are so dispersed among the many patent holders that users must first hack their way through a dense web of overlapping patents before they can implement technology and commercialize their product.<sup>54</sup>

In the Microsoft case of 2004,<sup>55</sup> EC Commission took into account the instance wherein the refusal to disclose sufficient interface information to another group who was working on the Microsoft desktop to create an operable 'workgroup operating system' was considered. The commission affirmed the dominant position occupied by Microsoft and that it has become a de-facto market standard for interoperability in workgroup networks. The court has ordered

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<sup>50</sup> The Common Definition Relating To Standard Essential Patents Can Be Found At K. Blind And T. Pohlman, 'Trends In The Interplay Of IPR And Standards, Frand Commitments And Sep Litigation' [2013] *Les Nouvelles* 177

<sup>51</sup> K. Maskus And S. A. Merrill (Eds), *Patent Challenges For Standard-Setting In The Global Economy: Lessons From Information And Communication Technology*, National Research Council (2013), 16 (Available At [Http://Www.Nap.Edu/Catalog.Php?Record Id=18510](http://www.nap.edu/catalog.php?record_id=18510)).

<sup>52</sup> *Supra* n. 48.

<sup>53</sup> *Supra* n. 48.

<sup>54</sup> C. Shapiro, 'Navigating The Patent Thicket: Cross Licenses, Patent Pools And Standard Setting'; E. Jaffe Et Al. (Eds), *Innovation Policy And The Economy*, Vol. I (2001) 119–150.

<sup>55</sup> Commission Decision Comp/C-3/37.792, Microsoft [2004] 24 March 2004

the disclosure of the information, as it would be impossible for the rivals firms to compete on equal footings otherwise.

In 2015, again in the Huawei case,<sup>56</sup> SEP was the centre of the discussion. The European Court of Justice held that it was necessary to strike a balance between the general interests of (i) maintaining free and undistorted competition within the internal market and (ii) safeguarding the (enforcement of the) proprietor's intellectual property rights and its right to effective judicial protection.

The Federal Trade Commission (FTC) challenged Qualcomm Inc, in the case *FTC v. Qualcomm Inc.*<sup>57</sup> in federal district court under section 5 of the FTC Act alleging that the company used anticompetitive tactics to maintain its monopoly position as the world's dominant supplier of baseband processors – devices used to manage cellular communications in mobile phones. In June 2017, the Northern District of California rejected Qualcomm's motion to dismiss

Even then, standardization can be understood as pro-competitive as it stimulates competition between standard-compatible products. However, the issue arises when the companies withhold the patent covering certain technologies included in the standards.<sup>58</sup> Moreover, steps are to be taken to ensure that the obligation to license based on competition law is balanced so that the potential risks of decreasing firms' ex-ante incentives to innovate and invest in research and development and the promotion of free and effective competition are balanced out.<sup>59</sup>

### **THE US SCENARIO AND HATCH-WAXMAN ACT**

The US Federal Trade Commission has taken a keen interest in addressing the IP and competition matrix. It is evident from the sheer number of FTC reports and guidelines that the commission has repeatedly published. The recent 2017 Antitrust Guidelines for the licensing of Intellectual property<sup>60</sup> have reaffirmed that both IP and Antitrust law shares a common purpose. The FTC has been conducting regular studies and according to a recent study, the

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<sup>56</sup> Case C-170/13, Huawei Technologies (Huawei), 16 July 2015

<sup>57</sup> Case No. 17-Cv-00220-Lhk: United States District Court, Northern District Of California, San Jose Division

<sup>58</sup> Geradin, Damien, European Union Competition Law, Intellectual Property Law And Standardization (January 29, 2017). Forthcoming In J. Contreras Ed., Cambridge Handbook On Technical Standardization Law (2017). Available At Ssrn: <https://ssrn.com/abstract=2907632>

<sup>59</sup> Faull & Nikpay, P. 466

<sup>60</sup>[https://www.ftc.gov/system/files/documents/public\\_statements/1049793/IP\\_Guidelines\\_2017.pdf](https://www.ftc.gov/system/files/documents/public_statements/1049793/IP_Guidelines_2017.pdf)

commission found out that due to anti-competitive agreements, a 3.5 billion dollar is seen as a higher drug cost every year.

The immediate history of the Hatch-Waxman began in 1984, following the decision of the Roche v. Bolar<sup>61</sup> case in April 1984. In the Bolar exception case, Bolar, a generic company, produced and stockpiled the generic version of Roche's branded drug, Dalmane. This was challenged by Roche. The court held that taking steps to get market approval during the subsistence of the patent was a violation of patent laws. The generics are obliged to wait till the expiry of the patent term. The judgment implied that the generics market entry was delayed even after the patent expired. An estimated three to four years was necessary for the generics to conduct the requirements for New Drug Approval (NDA) and FDA approval. It further elevated the generic companies' difficulties in gaining market entry, for example, filing an NDA or waiting until a patent expired to begin testing, etc. This prompted public policymakers to create a mechanism that eased approval and entry of generic drugs. Following the Roche v. Bolar case in April 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.

The Drug Price Competition and Patent Restoration Act of 1984 (Hatch-Waxman Act) was thought to be the answer to the rising drug prices and was deemed to be a compromise between the two competing players in the pharmaceutical market-generic manufacturers and brand name manufacturers.<sup>62</sup> The Act was designed to balance two countervailing tasks: facilitating greater market entry of lower-priced generic imitations of brand-name drugs while at the same time preserving brand-name pharma's incentives to continue discovering and developing new drugs.<sup>63</sup>

To further address the issue of questionable patents, and promote competition, the Act further incorporated the provision for Abbreviated New Drug Applications (ANDA). A questionable patent of poor quality is likely to be invalid or contains claims that are likely overly broad.<sup>64</sup> The effect of such patents is that they effectively block competition and harm innovation. It

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<sup>61</sup> 733 F.2d 858 (Fed. Cir. 1984)

<sup>62</sup> James J. Wheaton, Generic Competition And Pharmaceutical Innovation: The Drug Price Competition And Patent Term Restoration Act Of 1984, 35 Cath. U. L. Rev. 433, 434-36(1986)

<sup>63</sup> Alfred B. Engelberg, Special Patent Provisions For Pharmaceuticals: Have They Outlived Their Usefulness?, 39 Idea 389, 389 (1998-99)

<sup>64</sup> To Promote Innovation: The Proper Balance Of Competition And Patent Law And Policy A Report By The Federal Trade Commission Federal Trade Commission October 2003

may lead its competitor to forgo R&D in the areas that the patent improperly covers. The implication of such patenting is that it would further deter market entry and follow-on innovation by competitors and increase the potential for the holder of a questionable patent to suppress competition.<sup>65</sup>

According to the ANDA provision<sup>66</sup>, a company may apply for regulatory approval by establishing that the generic drug effectively duplicates the branded NDA drug, which would be listed in the Orange Book. The generic company need only show the similar active Pharmaceutical ingredient is used in the generic version and the route of administration, strength, dosage form and intended use are the same. The generics need to submit either of the four types of certificates, as prescribed within the act, along with the application. The certificates state any one of the following conditions, i.e., i) that the drug has not been patented; ii) that the patent has already expired; iii) the date on which the patent will expire, and that the generic drug will not go on the market until that date passes, and iv) that the patent is not infringed or is invalid.<sup>67</sup>

Certificate IV specifically deals with questionable patents. Once the application along with the fourth certificate is submitted before the regulatory authority, the act also requires the applicant to send notice to the patent holder. In the case of judicial intervention, the approver has to wait till the case is finally settled or till the expiry of thirty months, whichever is earlier, to issue the approval. The Hatch-Waxman Act hence seeks to ensure competition in the market by making provisions for checking questionable patents and promoting generic competition.

However, the fallacy of the Act lies in the fact that the high cost of brand-name pharmaceutical innovations and the prices that consumers pay for that innovation has nothing to do with either patent protection or even lack of competition within the pharmaceutical marketplace. The fact that lower prices at which generic manufacturers can offer their drugs can only mean that generic manufacturers are horizontal competitors to brand-name pharma, i.e., except for generic market entry, there would be no price competition for brand manufacturers.<sup>68</sup> This is

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<sup>65</sup> Ibid.

<sup>66</sup> 21 U.S.C. §355

<sup>67</sup> Gerald J. Mossinghoff: Overview Of The Hatch-Waxman Act And Its Impact On The Drug Development Process; Food Drug Law J. 1999; 54(2):187-94.

<sup>68</sup> Emily Michiko, The Myth Of Generic Pharmaceutical Competition Under The Hatch-Waxman Act (September 22, 2011). 22 Fordham Intell. Prop. Media & Ent. L.J. 245 (2012).; Indiana University Robert H. McKinney School Of Law Research Paper No. 2012-12. Available At Ssrn: <https://ssrn.com/abstract=1932461> Or <http://dx.doi.org/10.2139/ssrn.1932461>

based on many factors, such that the pharmaceuticals could never be a competitive market unless there are significant changes far beyond those contemplated by the Hatch-Waxman Act.

Moreover, an argument can also be raised that the ANDA is delaying the market entry of generics, given the time and the procedural formalities. In countries like India, a generic can infringe the patent without needing to go through the process. Though this might be seen as a risk, considering the huge cost likely to be incurred if the patent is held valid by the courts, this risk factor of failure to establish the questionability of patents also exists under ANDA. But even then, the risk factor is low under ANDA rather than India, as the cost of failure would include the production cost, apart from any fines that may be incurred. The safe harbour provisions further allows generics to conduct certain activities to develop the generic drug without significant risk of patent infringement liability. According to statistics, in the year 2016 alone, seventy-three ANDA's were approved.<sup>69</sup>

## **CONCLUSION**

From the above discussions, it is clear that IP and competition go hand in hand. While patents and copyrights provide their holders with certain rights that allow the holders to exclude others (including competitors) from exploiting their inventions, intellectual property rights do not provide blanket immunity from the antitrust laws. However, IPRS and competition are not inherently in conflict with one another. IP and antitrust law "are complementary, as both aim to encourage innovation, industry, and competition".<sup>70</sup>

Though the functions of both regimes are similar, their modes are divergent, often bringing in divergent results. This discussion has summed up that the competition must be promoted. However, emphasis is laid on the dynamic competition. The conflicts occur when these monopolistic IP rights impair the dynamic efficiency and block follow on innovations. That would constitute a clear case of abuse. The FTC conjointly issued the Antitrust Guidelines for the Licensing of Intellectual Property power and stressed that the market power conferred by IPRs does not by itself offend the antitrust laws. However, illegal acquisition and maintenance of market power would distort competition. Hence there is a need to strike a balance between

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<sup>69</sup><https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandgenerics/>

<sup>70</sup> Atari Games Corp. V. Nintendo Of Am., 897 F.2d 1572, 1576 (Fed. Cir.1990).



the two and ensure that such market power does not prohibit or hinder development in the secondary market.

Looking into the US scenario, we can draw how the system has tackled the issues to promote competition in the pharmaceutical field. The system pulled it outside the patent regime to address the competition issue. ANDA applications are certainly a positive push in the promotion of competition.