

## The issue of undeserving patent monopolies in innovation-based businesses and implications thereof for underprivileged consumers

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*Patent system, patentability criteria, undeserving monopolies, high prices, access to drugs, essential medicines.*

### Abstract

*The issue of undeserving patent monopolies is not new. The monopoly rights resulting from patent protection triggered hot debates in different phases of the evolution of patent system. The patent monopolies have been particularly controversial when granted undeservingly. This paper provides a historical background of the issue of undeserving patent monopolies and endeavors to highlight implications thereof for underprivileged consumers. The first part of the paper discusses initial two phases in the evolution of the patent system. In the first phase, the monopolies were granted in the absence of any well-defined patentability criteria. In the second phase, there were patentability criteria but the patent system lacked a requirement of review or examination of patent applications. The second part of this paper discusses the current phase when patents are granted as per well-defined patentability criteria after examination of the patent applications but still many undeserving applications arguably make it to the grant and have serious implications for consumers. Keeping in view the scope of this study, the analysis in this part is confined to ramifications of undeserving patent monopolies in the innovation-based pharmaceutical industry only. The last part sums up the discussion and concludes the paper.*

### Historical background of the issue

A patent is "an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem" (WIPO, 2014). Patents are a monopoly right granted for a limited period (20 years) in respect of inventions or innovations. "The right which they accord is to prevent all others –not just imitators, but even independent devisers of the same idea- from using the invention for the duration of the patent" (Cornish and Llewellyn, 2007).

Patents provide an incentive to innovate. True and genuine innovation by skillful members of the society is necessary for the progress of society. The patent system is supported because of its role in achieving this goal (Jaffe and Lerner). The current well-established principle that patents should only be granted for true innovations evolved with the passage of time. An understanding of the historical evolution of the patent system is necessary in development of a clear understanding of the international patent system in its present form. The idea of offering exclusive rights to inventors emerged from the Republic of Venice in the fifteenth century. In the absence of a general patent law, patents were issued on a case-by-case basis. For instance, a German immigrant printer named John of Speyer (Prager, 1944) was granted a patent by the City Council in 1469 in exchange for introducing the new art of printing. Under the patent, he was granted monopoly rights for five years to exercise his innovative art of printing in Venice and its territories (Biagioli, 2006).

On March 19, 1474, the Venetian Senate enacted Venetian Patent Statute of 1474 as the first general patent law in the history and started to grant monopoly rights for 10 years to inventors and entrepreneurs to attract skilled artisans and smart engineers from different countries. Unlike the modern patent system, the primary objective of the earliest known general patent law was to foster international mobility and to import inventions instead of promoting local innovation (Biagioli, 2006).

Following this Venetian initiative, between 1500 and 1550, France, Germany, England and the Netherlands adopted statutory patent systems (Moser, 2013). In earlier times, English patents were

not granted as property rights or as a recognition of pre-existing natural right; rather patents were granted by the grace of the monarch as privileges that could be revoked at any time at the discretion of the Crown (McEniery, 2010). The granting of monopoly rights as an exercise of the Royal prerogative by the Crown was criticized as an abuse of the power to grant monopolies as favors to Royal favorites (Holdsworth, 1945). Some critics argued that some patentees got undue monopolies by deceiving the Crown that resulted in the abuse of the monopoly system (Walterscheid, 1994). Some critics even blamed the Crown of using the monopoly system as a source of revenue for itself in the form of annual rents from patentees. Others considered the monopoly system a burden on the people because the prices of commodities under monopolies soared significantly.

In the absence of a patentability criteria, the Crown would exercise discretionary powers or Royal Prerogative to grant patents even for necessities of life like salt, starch, and vinegar that involved no innovation at all. The many-fold increase in the price of necessities resulting from unjustified patent monopoly became a source of serious controversy in England (Holdsworth, 1945). In 1601, in the wake of this outrage, Elizabeth I not only revoked several objectionable patents under a proclamation issued in the Parliament but also introduced a system of judicial review which authorized common law courts to determine the validity of monopolies granted by the Crown. The first common law judicial decision on this issue came in 1603 in *Darcy v Allen* (also known as *The Case on Monopolies*) (Corre, 1996). Monopolies in general were stated to be illegal because they block competition and cause price hike (Walterscheid, 1994). However, an exception was made for limited duration monopoly for inventions.

[W]hen any man by his own charge and industry, or by his own wit and invention doth bring any new trade into the realm, or any engine tending to the furtherance of a trade that never was used before; and that for the good of the realm; -in such cases the king may grant to him a monopoly-patent for some reasonable time, until the subjects may learn the same, in consideration of the good he doth bring by his invention to the commonwealth, otherwise not' (Federico, 1929).

James I succeeded Elizabeth I in 1603 and carried on the Royal practice of granting monopolies over existing trades notwithstanding the judgment in *Darcy v Allen*. He had to face continuing political pressure as the Parliament demanded regulation of the monopoly system to curb rampant abuses of the monopolies. In 1610, in the wake of this pressure, James I decided to acknowledge the common-law principles enunciated in *Darcy v Allen* and issued a 'Declaration of His Majesty's Pleasure'. Thereafter, on May 25, 1624, the *Statute of Monopolies* was enacted by the Parliament to restrict already granted monopolies and to prohibit grant of new monopolies, except patent monopolies -for a maximum of 14 years- to the true and first inventor of a new manufacture. For over 200 years, the English patent law was governed by the *Statute of Monopolies (1624)*. Changes were made in the English patent law under the *Patent Law Amendment Act 1852* but the *Statute of Monopolies* was not repealed and formed the basis of English patent laws until 1977. Statutory revisions were made in 1907, 1919, 1932, and 1949 to make changes in the patent law, but no drastic change was attempted (Cornish and Llewelyn, 2007). In 1977, with the adoption of the *Patents Act 1977*, patent law system was substantially changed and the *Statute of Monopolies* based patent regime was abandoned in the United Kingdom.

United States of America's patent system in its early nationhood was shaped by the experience of colonies of Britain in North America (David, 1992). The *Act for the Encouragement of Arts and Sciences*, adopted by the state of South Carolina in 1784, contained a provision related to patents for the first time in the history of the USA. It reads as:

The Inventors of useful machines shall have a like exclusive privilege of making or vending their machines for the like term of 14 years, under the same privileges and restrictions hereby granted to, and imposed on, the authors of books (David, 1992).

With the concept of exclusive rights for authors and inventors already existing in a state legislation, the *United States Constitution* was drafted in 1787 and it authorized the United States Congress: "To promote the Progress of Science and useful Arts, by securing for limited Times to

Authors and Inventors the exclusive Right to their respective Writings and Discoveries” (United States Constitution Article I, § 8, Clause 8). On January 8, 1790, President George Washington, while addressing a joint meeting of Congress, highlighted various matters that required legislative attention, intellectual property protection being one of them (David, 1992). Giving heed to George Washington’s recommendation, the United States Congress adopted its first and second patent statutes in 1790 and 1793 respectively to establish national patent regime. Both these statutes –*Patent Act of 1790* and *Patent Act of 1793*- contained various features of the British patent system like 14 years’ patent term (Walterscheid, 1994). There is, however, one obvious difference; deviating from the English concept of “new manufacture” for patentability, the concept of “new and useful arts” was used to describe the subject matter of patents to broaden the object of the patent system (Lutz, 1948).

At this point in the evolution of the patent system, lack of patentability criteria was no more a concern but the patent laws still lacked a requirement of review or examination of patent applications. The absence of a requirement of review or examination of patent applications in national patent laws emerged as a major source of concern in the 19<sup>th</sup> century. The debate, that instead of automatically issuing monopoly rights to those who meet the basic requirements patent applications must be examined prior to the grant of a patent, triggered in the USA in 1827 in the wake of grant of a patent to Michael Withers for “Winged Gudgeon”- a technology known for several decades (Jaffe and Lerner, 2007). The patent was granted only after ascertaining that requisite paperwork was complete (Jaffe and Lerner, 2007). Before granting of the patent, the patent application was not reviewed or examined to verify the claims. The exercise of unjustified exclusive rights by Withers outraged many mill owners who were using the patented technology and were asked to either negotiate licensing agreements/pay royalties or stop using the technology (Jaffe and Lerner, 2007). As a result of the heated debate triggered by this case, in 1836, the USA had to make changes in its patent laws to introduce the requirement of a systematic review or examination of patent applications to verify the claims prior to granting the exclusive rights (The Patent Act of 1836). Similarly, Britain introduced a systematic examination of patent applications in (The Patents, Designs, and Trade Marks Act) 1883. It is interesting to note that unlike USA and Britain, the Netherlands and Switzerland abolished their patent systems, in 1869 and 1850 respectively, instead of instituting systematic review or examination of patent applications (Schiff, 1971).

Currently, national patent laws provide a clearly defined patentability criteria and patents are granted after examination or systematic review of the patent applications. Undeserving patent monopolies are still a cause of concern because low-quality patents are arguably granted by patent offices owing to various factors, unsatisfactory standard of examination being most prominent of them (McEniery, 2010). The following examples of grant of patent monopolies, after examination of patent applications, illustrate this issue:

- A patent was granted in the US in 1977 for a hair styling method that involved dividing a partially bald person’s hair into three sections and carefully folding one section over another in order to conceal the partial baldness (Patent No. 4,022,227).
- A patent was granted in the US in 1995 for a ‘method for inducing cats to exercise by directing a beam of invisible light produced by a hand-held laser apparatus onto the floor or wall or another opaque surface near the cat’ (Patent No. 5,443,036).
- A patent was granted in the US in 1999 for a sealed crustless sandwich which could be stored for longer periods of time (Patent No. 6,004,596).
- A patent was granted in the US in 1999 for a method for fashion shopping. Under this method, the customers were to provide personal information for selection of fashions from a plurality of clothes items based on the personal information provided by the customers (Patent No. 5,930,769).
- A patent was granted in the US in 2000 for a method of shaving with a razor dipped in a bath of astringent liquid (Patent No. 6,014,975).

- A patent was granted in the US in 2001 for a method of making a reservation to use a bathroom (Patent No. 6,329,919).
- A patent was granted in the US in 2002 to a five-year old boy who, with the help of his father, claimed a unique method of swinging on a swing involving 'side to side motion by pulling alternately on one chain and then the other' (Patent No. 6,368,227).
- A patent was granted in the US in 2007 for a method of designating dating status which was designed to limit the embarrassment of rejection and to minimize the costs of implementation. This method involved a market recognition of an external sign, such as a color-coded bracelet, to be associated with a dating status (Patent No. 7,255,277).

These few examples of poorly granted patents from merely one jurisdiction represent just a tip of an iceberg. It is argued that examples of such cases are disappointingly commonplace in different jurisdictions. These examples clearly illustrate how the original intent or rationale of the patent system, to promote innovation and advancement in technology for common good of the society, has been ignored while granting patent monopolies. In order to maintain an equitable balance between interests of the inventors and the society, patents need to be granted as a bargain between the inventors and the society only for genuine innovations that meet the strict standards of patentability.

### **Undeserving patent monopolies in the pharmaceutical industry and their implications**

The issue of access to drugs is a relatively modern issue which came to the limelight only after global harmonization of intellectual property protection standards. By the mid of the 19<sup>th</sup> century, various countries had adopted national patent laws, but to patent inventions abroad was not only extremely costly but also cumbersome because of discrimination against foreign patentees (Moser, 2013). The *Paris Convention for the Protection of Industrial Property* of (1883)(hereinafter the Paris Convention) was the first major step towards internationalization of intellectual property law. It enshrined the principle of national treatment and reciprocity to address the problem of discrimination against foreign patentees. The Paris Convention was controversial and uncertain because of its broad provisions and use of undefined/vague key terms. Nonetheless it contributed towards evolution of minimum international intellectual property protection standards (Abbas and Riaz, 2013).

While patents are granted under domestic law, enforced in national courts, and have no effect beyond national boundaries, the national patent laws must comply with the minimum standards set by the international treaties on intellectual property protection. Other multilateral treaties aimed at harmonizing global patent protection standards include the *Patent Co-operation Treaty* of 1970, the *Convention on the Grant of European Patents* of 1973, the *Agreement on Trade-Related Aspects of Intellectual Property Rights* of 1994 (hereinafter the TRIPS Agreement), and the *Patent Law Treaty* of 2000.

The TRIPS Agreement for the first time introduced intellectual property law into the international trading system. This WTO Agreement not only provided for stringent patent protection for innovations in all fields of technology (TRIPS Agreement, 1995) but also had teeth because of its enforcement (Article 41-61) and dispute settlement (Article 63-64) provisions for effective implementation of the agreed minimum standards (Reichman, 1997). Prior to TRIPS Agreement, pharmaceuticals were excluded from patent protection in patent regimes of over fifty countries, including some of the developed countries of the today's world (Abbas and Riaz, 2014). The TRIPS Agreement had serious implications for access to essential drugs, especially in the third world countries, because pharmaceuticals were no more excluded from patent protection.

In the wake of outbreak of HIV/AIDS in Africa, the fourth Ministerial Conference of the World Trade Organization (hereinafter the WTO) was held in Doha, Qatar in November 2001 to discuss public health issues. In this meeting, the *Doha Ministerial Declaration on TRIPS Agreement and Public Health* (hereinafter the Doha Declaration) was adopted to reaffirm the right of the WTO

member states to use the public health safeguards (TRIPS Agreement, 1995) provided under the TRIPS Agreement such as parallel imports and compulsory licenses (Abbas and Riaz, 2014).

Doha Declaration was a success for third world countries who achieved this negotiation win with the help of civil society, human rights activists, and Non-Governmental Organizations (NGOs). Doha Declaration frustrated the expectations of the pharmaceutical industry and developed countries realized that the WTO was not a friendly forum for expansion of intellectual property protections. Bilateral or regional free trade agreements provided a viable alternative for enhanced intellectual property protection agenda because of weaker bargaining position of individual third world countries and their eagerness to get market access and other trade advantages under free trade agreements (Correa, 2015).

Some of the notable free trade agreements that seek TRIPS-plus intellectual property standards are as under: *Central American Free Trade Agreement (CAFTA)*; *North American Free Trade Agreement (NAFTA)*; *Jordan-US Free Trade Agreement (JUSFTA)*; *U.S.-Singapore Free Trade Agreement*; *U.S.-Australia Free Trade Agreement*; *U.S.-Malaysia Free Trade Agreement*; and *U.S.-Korea Free Trade Agreement* (Abbas and Riaz, 2013). The *Trans-Pacific Partnership* (hereinafter the TPP) is the most recent development. The TPP is an ambitious free trade agreement that the United States has negotiated with 11 other countries (New Zealand, Australia, Canada, Japan, Singapore, Brunei Darussalam, Chile, Malaysia, Mexico, Peru, and Vietnam). The TPP is being criticized by the public health activists because it has numerous serious implications for public health in general and for access to medicines in particular (Luo et al, 2015).

In short, patent protection for pharmaceutical drugs is a reality and WTO member states have accepted this reality by signing up to TRIPS. Ever since the adoption of TRIPS, the issue of pharmaceutical patents and access to drugs has remained a controversial issue. There are arguments both in support of and against drug patents. It goes beyond the scope of this paper to go into detail of this debate. The crux of the debate is that the cost of patented drugs set by pharmaceutical companies far exceeds the cost of production. Monopoly rights accruing from patent protection enable pharmaceutical companies to charge high prices for drugs in the absence of competition. Pharmaceutical companies, on the other hand, argue that innovation in the drug industry is extremely risky, costly and time consuming (Bela et al, 2016). A successful formula is developed after thousands of failed attempts. Drug companies charge high prices in order to recoup expenditures spent on failed projects (DiMasi et al, 2016). Another strong argument in the favor of patent protection for drugs is to provide incentive for further research in this sector because monopoly rights provide incentive to make huge and risky research and development (R&D) investments in the pharmaceutical sector.

It is argued that instead of channeling their efforts towards genuine R&D for development of novel and effective drugs, the brand-name pharmaceutical companies attempt to find loopholes in the existing regulatory framework and play safe by adopting different tactics or strategies to prolong their period of exclusivity by exploiting those loopholes (Dwivedi et al, 2010). Moreover, the declining quality of patent examination is a serious concern in this context. Even if the drug patent protection is accepted as a reality, without going into merits of the debate, low-quality or undeserving patents in the pharmaceutical sector cannot and should not be tolerated given the social cost thereof. There is a serious need to improve standards of examination of patent applications to make sure that only deserving patent applications make it to the grant

## Conclusion

The patent system has serious conflicts with competition laws, consumer protection laws, and certain human rights laws. Despite all its demerits and controversies attached to it, the patent system has been accepted as a necessary evil to promote innovation by incentivizing innovators through grant of absolute monopoly rights. This rationale of the patent system can be justified only when patent monopolies are granted for genuine innovations meeting all requirements of

patentability. It is argued that undeserving patent monopolies are sometimes granted by patent offices because of lacunas in the examination standards. Undeserving patent monopolies granted in the field of pharmaceuticals are a cause of serious concern because of their implications for access to affordable medicines. Unjustified drug patents have a huge social cost because the issue of access to drugs is a matter of life and death. Keeping in view the lethal consequences of low-quality drug patents for poor patients, concerted efforts must be made to improve standards of patent examination so that only deserving patent applications make it to the grant.

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- Patent No. 6,014,975 titled 'Shaving method'.

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