

Accommodating Long Term Scientific Progress: Patent Prospects in the Pharmaceutical Industry

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This article examines the recent theoretical justifications of the patent system. The design of the patent system is considered through the lens of the 'prospect' theory of patents, proposed by Edmund Kitch. This theory has much to contribute to the understanding of the actual working of the patent system, particularly in complicated issues such as encouraging research in neglected diseases. It provides a much better insight to the challenges which must be surmounted, in protecting and encouraging private investment in research. However, this theory is yet to be fully explored. Variations of this theory have touched upon some of the challenges within the patent system – but they appear unable to accommodate full impact of patent 'prospects'. For one, the full range of product development processes must be understood. Secondly, the patent regime must be able to include both worlds of organized and unorganized research, commercialized and basic research. This article makes an effort to identify and distinguish between the various implications of this theory, and attempts to bring them together to a simpler formulation. This simpler formulation, of guiding investment *vis-à-vis* the market-pull factors in product development, could probably be satisfied in many different ways. These, however, are outside the scope of this article.

Keywords: Neglected diseases, Kitch theory, commercialization, patent race, patent prospects, rent-seeking, pharmaceutical industry

The patent system has been criticized as a failure based on several grounds including, occurrence of inventive genius independent of the promised reward of patent protection,¹ blockage of rapid technological development in future prospects due to patents,² patent created monopolies which are anti-competitive³ and neglect of the concerns of the developing world. In response to these criticisms, Edmund Kitch put forward his influential proposition of patent law, as being founded not upon reward or return-on-investment, but upon marking out the prospects for organized future technological development.⁴

Kitch contended that any temporary slowdown in the pace of technological development in the industry, as a result of a patent, is justified in the interest of preventing rent dissipation through duplicative research. While this 'prospect theory' has been used to argue for stronger patent protection,⁵ the author hopes to show that Kitch is wrong in suggesting that the prevailing patent system employs an underlying recognition of patent prospects. Instead, it is suggested that the failure of patent law in recognizing such technological prospects is the source of many of its negative effects. Conversely, re-interpreting patent law

in the light of patent prospects could potentially eliminate such negative effects, especially from the perspective of access to medicines and other concerns of the developing world.

Patents, as Kitch predicted, do serve as strong bargaining tools, but are often used anti-competitively, through patent pools. Control over research and development translates into 'blocking' of future development through patent thickets. The anti-competitive effects of patents are most clearly evident in the pharmaceutical industry, because the monopoly granted by a patent is crucial to its commercial profitability: the technology is unpredictable,⁶ requires an expensive commercialization process; and is susceptible to competition from generics.³

This bargaining process between patentees exempts entire countries or researchers from active participation in the bargaining process. For countries, firms and individuals unable to so participate, this process acquires an almost exploitative character. Firstly, their concerns are neglected in research and secondly, in this case, patent law acts as an inadequate incentive to private investment.

There is an urgent need to speed up and diversify patterns of firm-level investment in pharmaceutical research and development for neglected diseases. The

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trade-offs which Kitch suggests may no longer be sustainable – but the prospect theory could possibly provide a solution to induce organization of research within a developing country.

The standard cost-benefit analysis of patent protection, beginning from Kitch's analysis of prospects is first explained, followed by the application of this theory in strategic rent-seeking⁷ (usually by private actors), and in international trade. It is suggested that the patent system crucially neglects the different stages of innovation process, i.e., patent prospects. Further, the benefits of patent protection create varying incentives for different actors in technological development, which cannot all be brought under a one-size-fits-all patent law. The paper concludes by showing that the mismatch between theory and practice is much more fundamental than is conventionally realized. The patent system must provide for more flexibility if it is to truly encourage research in neglected fields.

Kitch Theory

Patent Prospects

Kitch defines prospect of a patent as 'a particular opportunity to develop a known technological possibility'⁴ along the continuum of development towards final commercialization. The act of invention does not pertain to one single identifiable act, but usually comprises a series of incremental developments, i.e., across a continuum.⁸ This continuum exists in practice both for product development,⁹ and for general scientific research. However, under the prevailing 'reward theory' of patent law, each patent is a reward for precisely such an identifiable act, novel and non-obvious in comparison to the preceding developments in the field.

Kitch rebuts this misunderstanding by suggesting that patent rights are necessary, not as an incentive to the inventor, but to prevent duplicative research on such incremental development. He compares this to American property rights over oil and other mineral-rich land, where the land is staked out by prospectors before any conclusive evaluation of its prospects. So, the system forces early disclosure of the prospect by following some form of a first-to-file system. Similarly, property law employs ideas of constructive possession, where an unequivocal assertion of property rights is adequate to activate (so to speak) ownership.¹⁰ Kitch argues that such assured property

rights encourage greater investment in the speedy and organized development of the prospect by the original prospector or inventor.

A similar logic is employed to explain the lack of research and investment in neglected diseases, i.e., research in pharmaceuticals when prospective demand is confined to developing countries. The lack of organization of consumers, producers and policy-makers in these countries, it is argued, renders the creation of patent-friendly, research-friendly markets less likely.¹¹ This essentially depicts a tragedy of commons: for each individual developing country, the costs of organizing research, and respecting patent rights are immediate; but the long-term benefits of cooperation could be significant.

Problems and Fallacies

The first-to-file approach propounded by Kitch assumes vesting the management of future prospects 'in the hands of the entity best equipped to handle it.'⁴ This has not been the case in practice, because the person with the resources to conceive the invention does not always have the resources to commercialize the same. Many patents are obtained at stages when research is under-developed, and perhaps even irrelevant, to commercial viability.⁸ These patents are used to eventually 'block' the entrepreneur who attempts to convert disorganized research into a viable product. In other words, the patent is monetized before the exhaustion of all patent prospects. Given the profitability of such blocking, competition to obtain patents in primary inventions has led to 'patent races'; the very form of inefficient duplicative activity which Kitch set out to prevent in the first place.

Kitch's theory has generated literature suggesting that the patent system should reward commercialization process itself, instead the original break-through invention. A 'commercialization patent', it is suggested, would levy a positive duty to commercialize the invention in a time-bound manner, while retaining incentives for the invention.¹² The patent could then be rejected if the subject-matter is not rapidly developed and brought to the market as a commercial product.

The main advantage, obviously, of a separate commercialization patent is that, after a minimal specified time-period, the State is freed from being obligated to respect the rights of the true and first inventor. The patent is quickly brought into the hands of the person/corporate entity with the best capacity for its development (and not for its conception). It is

suggested in the following analysis, that this model would work very well for the development of inventions after conception, but fails to give adequate importance to the research funding - investment nexus. Such a system has even lesser control over the subject-range of scientific research, and might suppress the conception of non-commercial, basic research.

The Pharmaceutical Industry

The reason for the success of patent protection within the pharmaceutical industry is because the industry itself is geared towards high-cost, and high-risk, research and development, rather than rapid commercialization of technological advance. In the physical sciences, scientific development is predictable and rapid;⁶ too fast a pace for adequate return from a new product. These 'market-pull' factors, the need to stay competitive in the market, largely nullify the need for patents as a market incentive.

In the pharmaceutical industry, however, maximum expenditures are not incurred merely in conception of an invention. The stage of invention prior to filing for patent is comparatively less expensive than obtaining regulatory approval, establishing sales and marketing, etc. The introduction of a 'me-too' drug becomes an immensely profitable enterprise. The pharmaceutical industry often seeks protection from generic competition rather than temporal competition.

This approach places some heavy costs on social welfare: firstly, promising drugs are turned away if they are not patentable, or if their prospective market is not adequately profitable.³ Secondly, the inefficient race for control over inventions extends without restriction from product development (which would be within the conventional domains of commercialization), into basic scientific research.¹³ As more and more research comes within the private domain, the division between an invention and an innovation; an academic discovery and product development, has become hazy.

Naturally, incentives in the pharmaceutical industry, as a whole, are stacked against expensive and uncertain basic scientific research. Return on monies invested in research must either be rapid – therefore encouraging investment in lifestyle diseases, over neglected diseases – or must enjoy some form of sustained natural monopoly, with few subsequent innovations in the field. These are the forms of rent-seeking which may, *prima facie*, limit the progress of research.

Rent-Seeking on Patent Prospects

Under the prevailing typology, a distinction is drawn between the 'commercial value' or 'social value' of an individual patent, and the technology's function as a 'signal' for future inventions. Theoretically, investment in research is dependent on immediate commercial value,¹⁴ and therefore, 'primary inventions'—those which need to undergo a long commercialization process, and further innovation, before reaching the consumer market—usually attract very little investment. When primary inventions signal future developments in industry, this trend is reversed - rent-seeking at the secondary level demands grant of wide patents, to block the entry of newcomers in the industry as far as possible.

However, this merely explains, not resolves, the typical patent-race scenario mentioned above: if rent-seeking occurs at both the primary and the secondary stages of invention, the only alternative is to (arbitrarily) suspend patent protection altogether.¹³

This catch-22 situation occurs because the original oil-prospecting analogy offered by Kitch is inherently flawed: tangible property is pre-existing, requiring only mechanical exploitation within exhaustible limits.¹⁵ Intangible property is, by its very nature, involves three-steps including conception, commercialization/exploitation, and unlimited future development.¹⁶ At present, only some aspects of commercialization find legal protection, which appears to encourage rent-seeking and strategic attempts to extend protection to all three steps. For instance, 'patent trolls' employ legal redress to obtain compensation (against commercialization) on the basis of conception alone. Rights arising from conception or commercialization are extended to control future, or after-arising, technology. The extent and scope of predictable after-arising technology can in turn, cause a patent race even if the primary technology is not socially useful or commercially valuable.

Thus, in the absence of adequate demarcation between the stages of technology development, it would be impossible to influence the flow of technological development through the patent system. Further, the opportunity cost of granting a patent to the wrong person¹⁷ is disproportionately higher than the opportunity cost of an inefficient distribution in physical property, as its prospects impact of the technological matrix in future.

Identifying the Inventor and Commercializer

Invention is a concept so distinct from innovation that the laws regulating each ought to be

correspondingly different. Invention occurs at the moment of conception,¹⁸ while innovation or commercialization¹⁹ depend upon a process of construction²⁰ – making adjustments to suit the market, obtaining requisite regulatory permissions, sale and marketing, etc. Financial investment, skill and effort might be immaterial in the creation of patentable technology, but are inevitably crucial to commercialization.

But, since an invention originates from an abstract idea²¹ rather than a concrete product, the inventor must necessarily be (one or more) identifiable individual person(s). A corporate entity can only invest in research, and obtain patent rights by assignment, but cannot conceive of the abstract invention independent of its employees. Moreover, patent law continues to entertain the notion of the inventor as one with special creativity or genius and hence, employees cannot be mechanically replaced with others of similar skill in the art, the proverbial PHOSITA (person having ordinary skill in the art).

Conventionally, this inventor is expected to also carry out the role of commercializer, after a sufficient period of product development. But patent law itself unwittingly becomes an obstacle to this transformation. Firstly, as mentioned above, ex-post reward for invention is not *per se* an incentive-to-commercialize as usually argued, on account of the scarcity of financial resources at the disposal of the inventor. Patent law also refuses to take into account disclosures made in the conventional method of publication in scientific journals, etc., which are economical and accessible to an individual.²² Consequently, some stronger form of moral-rights protection, may also be desirable.

Even if this hypothetical ‘individual’ inventor is replaced with groups of individuals or firms, there is no significant difference made to the argument itself. A firm which is focused on basic research would receive very little direct protection within the patent system, if it lacks a simultaneous capacity in commercialization. Obviously, these researchers usually lack in organization of research – but could greatly benefit from the same.

The relevant conclusion, from this discussion, is that there are few or no known barriers, preventing individuals and pure research oriented firms from undertaking research on neglected diseases. In fact, given the moral and personal incentives, one would expect that such researchers would be more

motivated, in general, to invest their time and energy in researching neglected diseases. This has been observed, to some extent in open source development – particularly in the information technology industries, and also to a small extent, in pharmaceutical industry.

Besides, such research is liberated from national and local restrictions – it is international in nature. This does not serve as an argument for immediate globalization of intellectual property, because, the processes of commercialization usually demand direct or near-direct engagement in local markets.

The reasons for expecting non-investment in neglected diseases, when research is dominated by the commercialization goals of drug development, are analysed below:

A Cost-Benefit Analysis of ‘Patent Races’

Though, the patent system remains theoretically committed to protecting the inventor,²³ any cost-benefit analysis attempted on the inventor’s behalf is misplaced. Product development driven by the corporate entity or other commercializer commanding considerable resources (in accordance with Kitch’s assumptions) invariably renders theoretical presumption of low competition in primary inventions fallacious. The small-scale inventor is driven out of any lucrative inventive activity altogether.

The protection of the inventor is not, however, the primary focus here. An excessive emphasis on the commercialization goals of drug development also displays some negative side-effects, diverting the progress of science in neglected diseases.

Commercial exploitation of patent rights, obviously, is focused on monopoly control over the market. For a corporate body to undertake the prohibitive expense of research in primary inventions, the expected reward must not only compensate this expense – the aim of patent law – but must also offset the risk of investing in the uncertain outcome from a patent race. In other words, if a patent race is taking place, the returns guaranteed are, almost certainly, inefficiently high.

Moreover, given the high reliance on future expectations of profit, the commercializer’s primary motive is to minimize enablement of patents as far as possible. Enablement is the disclosure which allows the PHOSITA to re-create the invention; and, by definition, the grant of monopoly is believed to provide enablement with the least rent dissipation through organized research. Organized research will,

when concentrated in the hands of one commercializing entity, take the form of ever-greening,²³ where the pace of technological development is deliberately slowed with a view to extending the period of monopoly. Any technological development occurring within the period of monopoly is usually necessitated by the push of the market, rather than the pull of technological capacity.

Conclusion

The paper summarizes two challenges in regulating research in neglected diseases.²⁴ Firstly; the patent system must cover, separately, the whole gamut of product development. Multiple-level rent-seeking must be prevented. Thereafter, specific incentives to the inventor and commercializer must be accommodated in the patent system.

There have been several proposals to break this deadlock. For instance, one could liberally interpret a research exemption to patent protection.¹³ Rapid progress of knowledge in an industry would eventually create the demand-push required to speed up the commercialization process, as is evident in the energy and IT industries. While this might reduce 'blocking' at the primary level, it would not impact, or maybe even intensify, patent races. To avoid rent dissipation through a patent race, any incentives for invention must further be, in some way, specifically encouraging to diversity in research.

Another method of achieving the objectives is to reduce the costs of commercialization.²⁵ Reducing costs is integral to any attempt at efficiency; diversity in research, for instance, cannot be achieved if unavoidable regulatory costs are prohibitive. The drawback of this method is that it does not impact pre-existing competition at the primary stage of invention.²⁶

The 'commercialization patent' mentioned above, is also obviously not a solution to clustering of research. Firstly, it fails to consider financing of basic research – which is significantly lower than commercialization, but considerable by itself. Releasing the patent system from the first-to-file system would be a welcome achievement; but it might nullify any incentive to conduct pure research.²⁷

All these methods either recognize the product development process, or the inventor-commercializer distinctions. But the problems plaguing research in neglected diseases are a combination of both.

At the risk of over-simplifying the issues involved, the task of the patent system is that of diverting

resources from areas of intense competition, suffering from patent races, to those neglected by commercializers. Unless this linkage between competition and patent rights is drawn, the patent system cannot protect the inventive 'genius' adequately, and cannot support pure scientific research.

References

- 1 Eisenberg Rebecca S, Proprietary rights and the norms of science in biotechnology research, *Yale Law Journal*, 97 (2) (1987) 177-231.
- 2 A typical example of this is the pace of innovation following the patenting of the steam engine; the pace of innovation upon the engine remained constant during the period of patent, but increased by a factor of five in the 25 years following the expiry of the patent, Boldrin Michele and Levine David K, *Against Intellectual Monopoly* (Cambridge University Press, Cambridge), 2008, p. 1.
- 3 Roin Benjamin N, Unpatentable drugs and the standards of patentability, *Texas Law Review*, 87 (3) (2009) 503-570.
- 4 Kitch Edmund W, The nature and function of the patent system, *Journal of Law and Economics*, 20 (2) (1977) 265-290, 266.
- 5 Abramowicz Michael, Underdeveloped patent prospects, *Cornell Law Review*, 92 (6) (2007) 1065-1123.
- 6 Collins Kevin E, Enabling after-arising technology, *Journal of Corporate Law*, 34 (1) (2009) 1094.
- 7 'Economic rent-seeking is defined as the manipulation or exploitation of economic or political environment, without adding value through production/investment. This could include, for instance, costs/benefits associated with securing licences', Krueger Anne O, The political economy of the rent-seeking society, *The American Economic Review*, 64 (3) (1974) 291-303.
- 8 Sichelman Ted, Commercializing patents, *Stanford Law Review*, 62 (2) (2010) 341-413.
- 9 Product development is defined to denote innovations improving the efficiency or quality of one product line, rather than an industry as a whole.
- 10 Holbrook Timothy R, Equivalency and patent law's possession paradox, *Harvard Journal of Law and Technology*, 23 (1) (2009) 1-48.
- 11 Sykes A O, Public health and international law: TRIPS, pharmaceuticals, developing countries, and the Doha 'solution', *Chicago Journal of International Law*, 47 (3) (2002) 47-68.
- 12 Keiff Scott F, Property rights and rules for commercializing inventions, *Minnesota Law Review*, 85 (2) (2001) 697-754.
- 13 Grady Mark F and Alexander Jay I, Patent law and rent dissipation, *Virginia Law Review*, 78 (1) (1992) 305-350.
- 14 Kitch presents protection for intellectual property as a method of efficiently distributing the scarce physical resources required for commercializing intellectual property. Thus, capacity to research in unknown technology is assumed to be limited by financial constraints.
- 15 However, retrospectively, when faced with exhaustion of known reserves, the efficiency in purification and distribution of the resource might have been considerations in the grant of prospecting rights. The long-term

- sustainability of a resource, whether tangible or intangible, necessarily requires calculation of the opportunity cost in the development of the resource.
- 16 'Literal claim scope is not limited to the technologies that are already in existence at the time a claim is filed. It routinely encompasses technology that is beyond the competence of the PHOSITA of ordinary creativity to make and/or use at the time a claim is filed and that can be realized only after a post-filing technological advance has occurred. This type of technology is called after-arising technology (AAT) because it arises only after the claim has been filed', Collins Kevin E, Enabling after-arising technology, *Journal of Corporate Law*, 34 (1) (2009) 1087.
 - 17 Abramowicz Michael, The uneasy case for patent races over auctions, *Stanford Law Review*, 60 (3) (2007) 803-863.
 - 18 Invention requires 'a flash of creative genius', *Cuno Engineering Corp v Automaczi Devices Corp*, 314 US 84, 91 (1941).
 - 19 Innovation and commercialization need not be synonymous; commercialization encompasses a wider range of activity, and more market-oriented activity, than innovation. However, this distinction is not very relevant for the purposes of this paper, as both are incremental in nature and undertaken, not by the original inventor, but by the commercializer.
 - 20 'By [the act of conception] inventive genius, so far as it relates to this particular invention, is exhausted; all that remains to be accomplished . . . belongs to the department of construction, not creation', *Hybritech Inc v Monoclonal Antibodies Inc*, 802 F.2d 1367, 1376 (Fed Cir 1986)
 - 21 Conception is 'formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice', *Burroughs Wellcome Co v Barr Lab Inc*, 40 F.3d 1223, 1228 (Fed Cir 1994); Perelman Michael, *Steal This Idea*, (Palgrave, New York), 2002, p. 25.
 - 22 US law also considers disclosure in the course of private negotiations as subject to limitation: if product development is outsourced, the patent application must be filed within a time-bar to be eligible for protection, Whitman Daniel J, The 'on-sale' bar to patentability: Actual reduction to practice not required in *Pfaff v Wells Electronics Inc*, *Akron Law Review*, 32 (2) (1999) 397-427.
 - 23 Boldrin Michele and Levine David K, *Against Intellectual Monopoly* (Cambridge University Press, Cambridge), 2008, p.19.
 - 24 Though this article uses neglected diseases as its primary example, any scientific field, suffering from similar dearth in investment, due to misdirection into inefficient strategic investment, would probably display similar challenges.
 - 25 Benjamin Roin suggests that the costs of commercialization be borne by a special monopoly granted by the FDA instead of by the patent system. This, essentially, reduces the costs of commercialization from the perspective of the patent system.
 - 26 Martin Donald L, Reducing anticipated rewards from innovation through patents: Or less is more, *Virginia Law Review*, 78 (1) (1992) 352.
 - 27 Eisenberg Rebecca S, Patents and the progress of science: Exclusive rights and experimental use, *University of Chicago Law Review*, 56 (3) (1989) 1017-1086.