Incremental Innovation and Patent Protection for Pharmaceutical Products in India: A Law and Economics Analysis of the Novartis Case

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INCREMENTAL INNOVATION AND PATENT PROTECTION FOR PHARMACEUTICAL PRODUCTS IN INDIA

A Law and Economics Analysis of the *Novartis* Case

Thomas Eger, Petra Ebermann and Padmanabha Ramanujam*

7.1 PATENTS IN INDIA

In 2005, patent protection in India underwent a dramatic change. Whereas the Patent Act of 1970 excluded product patents for food, medicinal drugs, and products of chemical processes from patentability, the 2005 Patents (Amendment) Act allows for product patents also in the pharmaceutical sector, with one important qualification: According to Section 3(d), new forms of existing pharmaceutical substances that do not result in significantly enhanced 'efficacy' or employ at least one new reactant are not patentable. This Act constitutes India's last step towards complete compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

There is some evidence that India is moving away from occupying the post of a mere producer of generics to an innovator developing new drugs and also improving existing drugs in order to make them more suitable for the specific conditions in less developed

* We wish to thank Wolfgang Kerber, the participants of the senior scholar workshop in Hyderabad (February 2008) and an anonymous referee for valuable comments. The usual disclaimer applies.

countries (Chaudhuri;[1] Thomas[2]). This paper presents a study which intends to capture the widely discussed Indian patent policy for the pharmaceutical sector. We describe the legal framework of patent protection in India, which is to some extent determined by the TRIPS Agreement and other international agreements (Sec 7.2). Thereafter, we present the problem of incremental innovation with reference to the recent and controversially discussed Novartis case that centres on Section 3(d) of the 2005 Patents (Amendment) Act (Sec 7.3) and analyse it from a law and economics perspective (Sec 7.4).

7.2 LEGAL FRAMEWORK FOR PATENT PROTECTION

7.2.1 TRIPS as a Legal Framework

One of the problems with patents and international trade is that the principle of territory and independence of patents dictates that a patent can be granted in one country but have no protective effect in another. All intellectual property systems have an element of domestic regulation (Hoeckman and Kostecki)[3]. Patents are territorial rights granted by a sovereign government and valid only within the territory of the granting authority. As a consequence national patent systems focused for a long time on the optimal regulation of the national market. This lead to strong patent systems in countries with much innovative activity and weaker systems in countries with only a few potential innovators (Falvey et al).[4] Trade in goods embodying intellectual property rights has substantially increased in the last decades and crossed national borders. This is one consequence of economic globalization under which national economies are integrated into

[1] Sudip Chaudhuri, 6 August 2004, 'TRIPS, Indian Generic Companies and Accessibility of Medicines', Conference on Global Pharmaceuticals, Biotechnology and Health, Institute for Strategic Biotechnology, Health and Training, Mumbai.

[2] Thomas, J.J. (2006), 'India and China in the Knowledge Economy: Rivals or Allies? Case Studies of Pharmaceuticals and Biotechnology', Paper presented at the Conference on China, India, and the International Economic Order, Singapore, June 23–24.

[3] Hoeckmann, B., Kostecki, M. (2001), *The WTO and Beyond*, 2nd edition, Oxford, p. 274.

[4] Falvey, R.E., Martinez, F., G.V. Reed (2002), 'Trade and the Globalisation of Patent Rights', GEP Research Paper No 02/21, available at http://ssrn.com/abstract=413263.

one global economy (Van den Bossche).[5] With globalization and the growing importance of international trade and international markets the demand for having the same or similar protection in foreign markets as in the national market has increased (Falvey et al).[6] The globalization of the international economy generated a desire for the harmonization of intellectual property rights, including patents, on an international level. There have been attempts to have multilateral cooperation in the field of intellectual property protection, for example the Berne Convention, or the Paris Convention for the Protection of Industrial Property administered by World Intellectual Property Organization (WIPO), but they proved to be insufficient to achieve greater harmonization.

The differences in intellectual property systems that prevailed at the national level with regard to the granting and enforcing of intellectual property rights acted as non-tariff barriers to trade. This led to the formation of TRIPS, which established some level of harmonization in the area of intellectual property rights at the international level (Falvey et al).[7] The TRIPS Agreement was negotiated during the Uruguay round under the auspices of the World Trade Organisation (WTO) and establishes *inter alia* minimum standards for patent protection. These standards apply to availability, scope, and use of intellectual property rights, including enforcement and process requirements. General principles of the General Agreement on Tariffs in Trade (GATT) such as the most-favoured nation clause, national treatment and non-discrimination are part of TRIPS as well (Article 3). The TRIPS Agreement incorporates rules and obligations from existing treaties covering intellectual property and in addition introduces a dispute settlement mechanism (Kamperman Sander).[8] Under this mechanism a country whose rights have been infringed under one agreement may suspend obligations under a different agreement, thus providing for

[5] Van den Bossche, P. (2007), *The Law and Policy of the World Trade Organisation*, Cambridge.

[6] Falvey, R.E., Martinez, F., G.V. Reed (2002), 'Trade and the Globalisation of Patent Rights', 1, p. 15.

[7] Ibid., 2.

[8] Kamperman Sanders, A. (2007), 'Intellectual Property Law and Policy and Economic Development with Special Reference to China', in: Eger, T., Faure, M., Naigen, Z. (eds), *Economic Analysis of Law in China*, Cheltenham, pp. 239–271.

retaliation across agreements and sectors. It is worth noting that the TRIPS Agreement is unique in the WTO context. To effect free trade, the WTO has a provision for excluding of penalizy policies that affect trade negatively. The agreements administered by the WTO have so far concerned with the issue of freeing trade only by providing for the exclusion or penalization of certain policies presumed to affect trade negatively (negative integration). TRIPS, on the other hand, imposes obligations on national governments to adopt a set of substantial rules in a field that is commonly considered to be subject of domestic regulation, having a direct effect on national regulatory and legal regimes (positive integration) (Hoeckmann/Kostecki).[9] The Member States are free only in as far as they can determine how the specified minimum standards are implemented (Article 1 of TRIPS).

With regard to patents, Section 5 Part II (Article 27–34 of TRIPS) regulates the availability, scope, and use of patents. Article 27 (1) states that patents shall be available for any invention, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application. The terms 'non-obviousness' and 'utility' may be deemed to be synonymous with 'inventive step' and 'capable of industrial application' (Article 27 FN 5 TRIPS). Some countries made use of this provision and speak of non-obviousness and utility in their patent laws.

Unlike most other patent laws the TRIPS Agreement does not define what is not of admissible as an invention. Rather, it relies on the eligibility criteria of novelty, inventiveness, and capability of industrial application.

Novelty requires that a claimed subject matter is not part of the state of the art at the time the patent application is filed. The state of the art encompasses everything that is available to the public. Differences in national laws can be found in regard to the scope of the prior art. While most countries include in the relevant prior knowledge everything that has been made available to the public regardless of the form and place of disclosure, the United States determines prior knowledge of unpublished information on a domestic scale. Unpublished knowledge forms part of the state of the art only if it originates within the United States. A patentable invention must also show an inventive step or

[9] Hoechmann and Kostecki (2001), p. 274.

non-obviousness of the alleged invention. This requirement is met when a person skilled in the art under consideration does not regard the invention as obvious excludes all those inventions that are merely the next logical step or natural consequence of a former invention. Finally, an invention must be capable of industrial application or useful. Industrial application includes trade, industry and agriculture. Usefulness requires the invention to have some current beneficial use to the public.

The minimum term of protection that needs to be provided by domestic patent laws is 20 years from the date of filing. Some exceptions to the general obligation to provide patent protection can be found in Article 27 (2) and (3) of TRIPS. Members can exclude inventions from patentability in case the *ordre public* or morality considerations make such exclusions necessary. Furthermore, diagnostic, therapeutic, and surgical methods for the treatment of humans or animals as well as plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes may be excluded from patentability.

Globalization in general, and the TRIPS Agreement in particular, especially the provisions on obligatory patent protection have been subject to a heated North-South debate. While the developed countries at large demanded strong patent protection in the WTO, most developing and underdeveloped countries were concerned that stronger patent protection would be detrimental to their economic development and welfare. Another point of discussion—the adequate protection of incremental innovations—is discussed in detail in the following sections.

7.2.2 Patent Law in India

Although the objective underlying the Indian Patent Act of 1970 was to encourage inventors to invest in their creative abilities knowing that their inventions would be protected by law,[10] product patents for food,

[10] In the case of *Bishwanath Prasad Radhey Shyam vs. Hindustan Metal Industries* (1979) 2 SCC 511 at 517, the Supreme Court of India ruled that, 'the object of patent law is to encourage scientific research, new technology and industrial progress'.

medicinal drugs, and products of chemical processes were excluded from patentability under Section 5 of the Patents Act of 1970 in order to facilitate access to essential medicine.

Prior to the Patent Act of 1970 the market for pharmaceuticals was dominated by Multi-National Companies (MNCs). By using the existing patent laws, the MNCs prevented home-grown companies from producing new drugs. This led to an increase in drug prices due to a lack of competition. This situation underwent a complete transformation with the introduction of the Patent Act of 1970. The Patent Act introduced a provision which removed product patent protection and thus allowed for process patents only (Watal).[11] This change in patent law brought about significant changes in the Indian pharmaceutical industry as it allowed Indian pharmaceutical companies to 'reverse engineer' the manufacturing process of existing drugs and thus develop generic drugs. As a consequence of this legislation, large scale production of bulk drugs by the native pharmaceutical industry developed particularly in the 1980s. This is considered to be the most important achievement of the Indian pharmaceutical industry (Thakore;[12] Raizada[13]). Further rapid growth and intensification of the pharmaceutical sector took place in the 1990s, which is accordingly considered to be the golden era of the Indian pharmaceutical industry. Today India supplies 8% of the total global output (in volume) of drugs and 22% of the world output of generic drugs (Thomas[14]). There has been a significant increase in exports since the mid 1990s, with the US taking up the role of the most important export partner (Chaudhuri[15]).

Like all other member countries, India entered into trade obligations and agreed to further comply with the provision of the TRIPS Agreement when it joined the WTO in 1995. Accordingly, the Patent (Amendment) Act of 2005 deleted Section 5 of the Patent Act of 1970 and allowed the grant of product patents for food, medicinal

[11] Watal, J. (2008), 'Patents', in Basu, K. (ed.), *The Oxford Companion to Economics in India*, revised edition, Delhi, pp. 400–403.

[12] Thakore (1989).

[13] Raizada (2002).

[14] Thomas (2006), p. 14.

[15] Chaudhuri (2007), p. 10.

drugs, and products of chemical processes in consonance with Article 27 TRIPS.

But the Patent Amendment Act of 2005 also introduced Section 3(d) which is unique in patent law and is the subject of a detailed discussion in this paper. Section 3(d) of the Act deems

'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance or, of the mere use of a known process, machine, or apparatus unless such known process results in a new product or employs at least one new reactant', to be not patentable.

This provisions acts as a barrier to patenting products that differ only slightly from existing products, and is especially relevant with regard to pharmaceutical patents. In the recent Novartis case the Madras High Court order rejected the Novartis challenge of Section 3, (d) thus reopening the debate as to whether disallowing patents on incremental innovation will discourage firms from doing research that builds upon existing inventions.

7.3 INCREMENTAL INNOVATION AND THE *NOVARTIS* CASE

7.3.1 What is Incremental Innovation?

An innovation is generally defined as an idea, practice, or material artefact perceived to be new by the relevant unit of adoption (Zaltmang et al.).[16] The degree of novelty that is captured by the notion of radical innovations in scientific literature also forms an essential requirement for granting patents. The literature on management science studies and classifies innovations under two categories namely (i) radical innovations and (ii) incremental innovations. Radical innovations are defined as innovations with fundamental changes that represent revolutionary changes in technology and show obvious departures from existing practice (Duschesneau et al.;[17] Ettlie[18]). In contrast, incremental innovations

[16] Zaltmang N., et al. (1973) *Innovations and Organizations*, New York.

[17] Duschesneau, T.D., Cohn, S. and Dutton, J. (1979), 'A Study of Innovation in Manufacturing, Determination, Processes and Methodological Issues', Vol. I. Social Science Research Institute, University of Maine.

[18] Ettlie, J.E. (1983), 'Organizational Policy and Innovation among Suppliers to the Food Processing Sector', 26, *Academic Management Journal*, pp. 27– 44.

are minor improvements or simple adjustments on the existing technology (Dewar and Dutton).[19]

The pharmaceutical industry provides an excellent setting to test determinants of incremental and radical innovation. Radical innovation refers to the identification of new chemical entities and their development into potentially useful pharmaceutical drugs. Incremental innovation, on the other hand, works with already known chemical compounds that are merely altered or employed in a different use (Cool)[20].

Drug enhancements such as new dosage forms may appear at first sight to be unimportant or even trivial but they are important avenues of learning for firms. Incremental progress gives rise to families or classes of related drugs. Although several agents within a class may have the same general action, they often differ significantly in specific actions, side effects, and suitability for individual patients (Levy,[21] Banbury and Mitchell[22]). Consequently, incremental innovation takes many forms, including improved safety and effectiveness, fewer side effects, new formulations allowing greater ease of use and improved compliance, new indications, and new versions of the medicine developed for specific groups of patients (such as children).[23] It can also take the form of greater product stability during storage and transport which can be especially important in tropical climates like some regions of India.[24] Thus in the pharmaceutical sector incremental innovation connotes the continuous improvement of medicines, which also requires large-scale research and development, including clinical trials, along with approval from regulators before the new

[19] Dewar, R.D., Dutton, J.E. (1986), 'The Adoption of Radical and Incremental Innovations: An Empirical Analysis', *Management Science*, 32, pp. 1422–33.

[20] Cool, K. (1985), Strategic Group Formation and Strategic Group Shifts: A Longitudinal Analysis of the U.S. Pindustry, 1963–1982, Unpublished Doctoral Dissertation, Purdue University, West Lafayette, IN.

[21] Levy, R.A. (1990), 'Pharmaceutical Research: Therapeutic and Economic Value of Incremental Innovations', Unpublished Dissertation, National Pharmaceutical Council, Reston, VA.

[22] Banbury, C.M., Mitchell, W. (1995), 'The Effect of Introducing Important Incremental Innovations on Market Share and Business Survival, *Strategic Management Journal*, 16, pp. 161–182.

[23] Pharma Press Release, 2007.

[24] Ibid.

product can be offered to patients. It therefore becomes important to afford protection to such innovations.

7.3.2 The Importance of Incremental Innovation

For many years radical innovation had been the primary goal of research for firms in many areas of science and technology. However, breakthrough innovations are important but rare in medical research. Most medical advances—like in all other technological fields—happen by 'incremental innovation' that is, innovation that builds on previous inventions. In the last 20 years, a number of noticeable changes have taken place in the type of research undertaken in all industries, and pharmaceutical industries in particular. These changes were motivated by the realization that due to long-run time horizons, high failure rates, and a low probability of returns the possibility of discovering new drugs was decreasing (Min *et al*.;[25] Bhaskaran[26]). As a result, the focus of research shifted and concentrated on the discovery of new uses of known substances (Cool;[27] Levy;[28] Banbury and Mitchell[29]). The problem that confronted researchers working in the area of incremental innovation was that traditional patent law refused to recognize the discovery of new advantages of an old product as being novel. Lionel Bently and Brad Sherman conceptualize this problem in the following example. Assume someone discovered and patented aspirin as a drug useful in curing headaches. Later someone else found out that the consumption of aspirin also thinned the blood and was thus useful in preventing blood clots. The second use would be not patentable due to the fact that aspirin is already patented as a drug for curing headaches (Bently and Sherman[30]). The reason for this is that traditional patent law in many countries treated a claim to a 'product

[25] Min, S., Kalwani, M.U., Robinson, W.T. (2006), 'arket Pioneer and Early Follower Survival Risks: A Contingency Analysis of Really New Versus Incrementally New Product-Markets', *Journal of Marketing*, 70, pp. 15–33.

[26] Bhaskaran, S. (2006), 'Incremental Innovation and Business Performance: Small and Medium-Size Food Enterprises in a Concentrated Industry Environment', *Journal of Small Business Management*, 44, pp. 64–80.

[27] Cool (1985).

[28] Levy (1990).

[29] Banbury and Mitchell (1995).

[30] Bently, L., Sherman, B. (2001), *Intellectual Property Law*, New York, p. 8.

for a particular use' as a claim to the product *per se*; consequently the product would lack novelty even if it had previously been employed in a different use.[31]

One of the prominent trends in recent years is the way in which this principle has slowly been diluted in many countries, at least in areas of therapeutic research, highlighting the economic and strategic importance embodied in new use patents. The standard reasoning used by the supporters of new use patents is that the human and economic investment incurred by the industry to discover a new use is comparable to the investment necessary to the development of the product itself (Grubb[32]). It will be interesting to investigate the international position on improvement and on new use patents which provide protection for such incremental innovations.

7.3.3 International Position on Incremental Innovation

In the area of incremental innovation we find different forms of innovations such as the improvement of a known substance, the combination of two inventions, or the discovery of a new use of a known substance. Generally speaking, incremental innovation is, under most patent laws, eligible for patent protection, provided that the requirements of novelty, inventiveness, and industrial applicability are met. The most difficult and decisive hurdle is meeting the inventive step (or non-obviousness) requirement.

7.3.3.1 Improvements

As for improving known and patented subject matter the difficulties lie in the assessment of the degree of inventiveness required to constitute a new patentable product. Ideally patent protection increases with the amount of innovation embodied in an invention (Denicolò).[33] The assessment of inventiveness is thus subject to Patent Office policy,

[31] This applies only if the product was used in the same technical art. Some jurisdictions also allow for second-use innovations in the same art, e.g. the Swiss-claim-formula applied by the European Patent Office.

[32] Grubb, Ph. W. (2004), *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy*, 4th edition, Oxford.

[33] Denicolò, V. (2008), 'Economic Theories of the Nonobviousness Requirement for Patentability: A Survey', *Lewis & Clark Law Review*, 12, pp. 443–59.

guidelines, and caselaw. National laws take different approaches as to how to assess inventiveness.

United States: United States patent law is regulated in the Patent Code 35 U.S.C. Section 101 of the US Patent Act deems any new and useful improvement of a new and useful process, machine, manufacture, or composition of matter patentable if it complies with the criteria that determine patentability. Section 103 incorporates the requirement for an invention to be non-obvious in order to be patentable and states that a patent cannot be obtained 'if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains'. The content of this requirement is determined by case law. The leading case is *Graham vs. John Deere* which determines a test for non-obviousness. The test consists of four factual inquiries. The so called 'Graham Factors' are the scope and content of the prior art, differences between the claimed invention and the prior art, the assessment of whether the differences would have been obvious to a person skilled in the art, and finally, secondary considerations such as commercial success, failure of others, or a long felt need for the improvement. The standard set by *Graham vs John Deere* was subsequently lowered. Instead of relying on the Graham test alone, courts applied the teaching-suggestion-motivation (TSM) test, finding obviousness only if some suggestion or motivation in the prior art suggested the invention (e.g. *Winner Int'l Royalty Corp. vs. Wang*, 202 F.3d. 1340, 1348 (Fed. Cir., 2000)). Recently, however, a return to a tougher standard can be observed. In 2007 the Supreme Court reaffirmed the Graham test in the judgment in *KSR International Co vs Teleflex Inc.* (127 S.Ct. 1727), holding that while *Graham* and TSM are not necessarily inconsistent, it is the Graham test and not the TSM test that is the appropriate basis to determine obviousness. *KSR* concerned a mechanical patent; it remains to be seen whether the reasoning will be applied to the pharmaceutical arts, but there appears to be a tendency that courts will do so. In regard to pharmaceutical patenting the decision in *Bayer Schering AG vs Barr Laboratories, Inc.* (2008 WL 628592 (D.N.J.)) is worth mentioning. The applicant Bayer

held a patent on the formulation for an oral contraceptive consisting of a combination of known agents with an improved coating. The court referred to the reaffirmation of the *Graham* inquiry by the Supreme Court and invalidated the patent on the grounds that the combination of known substances was obvious to try for a person skilled in the art.

Pharmaceutical innovation often occurs by incremental modification of prior art compounds. The development of a pharmaceutical compound with a structure and utility similar to the prior art often establishes a case for obviousness which must be rejected by the patentee, thereby shifting the burden of proof! (Trask[34]) However, in such a scenario it is not *per se* impossible to receive a patent. Rather *prima facie* obviousness can be rebutted by showing that the new pharmaceutical product that combines known compounds, or builds upon existing inventions, and differs only slightly in its chemical structure has unexpected properties, or shows a considerable difference in the degree of the same property, and that this outcome was not suggested by the prior art or could not be anticipated or reasonably expected (Ducor[35]). Here the US approach differs from the Indian patent law that requires for the provision of at least one new reactant.

Europe: European patent law is laid down in the European Patent Convention (EPC). Article 52 (1) EPC states that a patentable invention must involve an inventive step. According to Article 56 'an invention is considered to involve an inventive step if the invention, having regard to the state of the art, is not obvious to a person skilled in the art.'

The European approach to determine inventiveness differs only marginally from the US approach to non-obviousness. The differences relate to the prior art to be included when determining non-obviousness and to the question as to how to assess invalidating prior art. European patent law excludes previously filed but not yet issued patent applications from the prior art (Merges and Duffy).[36] The European Patent Office (EPO) applies the problem-and-solution

[34] Trask, A.V. (2008), 'Obvious To Try: A Proper Patentability Standard in the Pharmaceutical Arts?' *Fordham L. Rev*., 76, p. 2625.

[35] Ducor, Philippe S, (1998), 'Patenting the Recombinant Products of Biotechnology and Other Molecules', The Hague *et al*., p. 30.

[36] Merges, R.P., Duffy, J.F. (2007), *Patent Law and Policy*, 4th Edition, Newark, NJ, p. 773.

approach in assessing inventiveness (see EPO Guidelines). This approach addresses three issues: the determination of the closest prior art and the differences between the invention and the closest prior art, the formulation of the technical problem to be solved, and finally the question whether the claimed invention was obvious to a person skilled in the art starting from the closest prior art and the technical problem. The question is not whether the respective person could have arrived at the solution but rather whether s/he would have done so (could-would approach).

Improving a known substance constitutes a valid patent claim if the requirements for inventiveness are met. The new product must not form part of the state of the art. It must differ significantly from the old product in a technical sense, e.g. by a new formulation, dosage or synergistic combination (Schulte).[37] Furthermore the new improved product needs to be non-obvious in that sense the a person skilled in the art would not have made the improvement because s/he did not anticipate the positive effect (Schulte[38]). The same applies to inventions that consist of a combination of known compounds.

Similar to US patent law, an improved product is patentable under the EPC if the research path or the outcome were not anticipated by the prior art. Consequently, it is not necessary to provide an increased efficacy but rather unexpected and sufficiently different properties.

7.3.3.2 New use

With regard to new (or second) use patents the following observations can be made. The identification of a medical indication of a known medical product cannot lead to patent claim for the product as such under the general principles of patent law. The question is whether the claim can encompass the use itself. The TRIPS agreement does not provide guide lines to Member States regarding patent protection for new uses of known products. Instead it leaves room for interpretation. Comparative law takes different approaches to this question.

United States: In the United States the patenting of new use inventions is possible provided that the purpose of the use is novel and non-

[37] Schulte, R. (2001), *Patentgesetz*, 6th edition, Cologne, 2007, § 1 Rn 190.
[38] Ibid., § 1 Rn 191.

obvious. In the assessment of obviousness, prior art can invalidate the patent only if the technology originated in an analogous art (Thomas[39]). Consequently, new uses can be novel and non-obvious if the invention applies knowledge from a different technical discipline. In the case of method inventions the key consideration to determine patentability is whether the invention could be anticipated by other methods. Patents on uses are confined to a particular 'method-of-use' which does not encompass protection of the product as such (UNCTAD Resource Book on TRIPS and Development[40]).

Europe: Under Article 52 of the EPC patents are granted for new inventions which involve an inventive step and are capable of industrial application. Article 54 (5) of the EPC provides for the patentability of a new purpose of a known product. For instance, the identification of the first medical indication of a known product that did not have a pharmaceutical use before would be eligible for a patent claim for the product itself. Secondary uses of known products are not patentable when the claim concerns directions for the use of a product for the treatment of an illness. Such claims contravenes the directions laid down in Article 52 (4) EPO which deems methods of treatment unpatentable. However, claims directed to the use of a product for the manufacture of a medicament for a new specific therapeutic use can subject to patent protection (so called Swiss-claims, EISAI OJ EPO 1985, 64).

Although the EPC covers European patents some differences in the national laws of the Member States can be observed. New use patents appear to be granted reluctantly in the Member States.

United Kingdom: Courts in the United Kingdom are reluctant to approve new or secondary use patents. Although the principal patentability of secondary use claims is recognized since the decision in *Wyeth & Schering's Applications* ((1985) RPC 545) it has been difficult to maintain the validity of a secondary use patent before the courts. The secondary use of a medical compound may be patentable if the use is sufficiently novel as compared to the known use (Burdon

[39] Thomas, J.R. (2005), *Pharmaceutical Patent Law*, Washington DC, p. 145.

[40] UNCTAD–ICTSD (2004), 'Resource Book on TRIPS and Development', Cambridge: Cambridge University Press, p. 356.

and Sloper[41]). However, there is a tendency that such a new use will be considered a 'method of treatment' which would be excluded from patentability under Article 52 (4) EPC (*Bristol Myers Squibb vs Baker Norton* (2000) ENPR 230). Only few secondary use patents have been approved in recent years, for example *SmithKline Beecham vs Generics* ((2002) 25 (1) IPD 25005) and *SmithKline Beecham PLC vs Apotex Europe Ltd & others* ((2003) 26 IPD 26020).

Germany: German patent law allows for product patents on products for the first medical use. The second medical use can only be covered by a use-claim (Benkard[42]). In this context it is worth noting that the Federal Patent Court in Germany invalidated a patent on secondary use in a recent decision (Bundespatentgericht 3 Ni 36/05 (EU). The patent had previously been confirmed by the European Patent Office. The Federal Patent Court, however, held that the criteria for novelty set by the European Patent Office cannot bind the German courts. In case this decision is upheld in the higher instances it will be even more difficult to maintain the validity of secondary European Patents in Germany than, for example, in the United Kingdom.

It is difficult to define the degree of inventiveness required in order to patent incremental innovation. The difficulties lie mainly in the fact that much of the assessment is determined by case law and the results of some cases appear to be contradictory, since the individual circumstances matter and are taken into consideration by the courts. Nevertheless the overall trend is to allow patents on incremental innovation in pharmaceuticals but also demand some sort of unexpected and non-obvious result, be it new properties or an enhanced degree of the same property. It appears that Section 3(d) of the Indian Patent Act could suggest a similar approach. However, the Indian Madras court interprets this section in a way that sets a tougher standard with regard to patenting incremental innovation than US and European patent law. This can be concluded from reviewing the recent decision in Novartis vs. Union of India.

[41] Burdon, M., Sloper, K. (2003), 'The Art of Using Secondary Patents to Improve Protection', *International Journal of Medical Marketing*, vol. 3, issue 3, pp. 226–38.

[42] Benkard, G. (2006), *Patentgesetz*, Munich, § 5 Rn 49.

7.3.4 The Novartis Case (*Novartis* v. *Union of India*, 2007 (4) MLJ 1153)

Novartis developed the innovative anti-cancer medicine Glivec®, which is deployed for the treatment of chronic myeloid leukemia. The base compound of Glivec® is Glivec (imatinib), which is patented in 40 countries worldwide. Glivec (imatinib) is merely a research substance with no pharmaceutical form cannot be taken by patients. It was only the first step in the development process of Glivec®. The improvement embodied in Glivec® is the transformation of the base compound into a pharmaceutically useful drug with a greater bioavailability than the base compound and which can more efficiently be employed for the treatment of patients.

Although Novartis did not file a patent application for Glivec (imatinib) at the time of development in India since Indian patent law did not grant product patents for pharmaceutical products at that time, such a claim was made in January 2006 after the introduction of product patents in Indian patent law. However, the patent was denied under Section 3(d) of the Indian Patent (Amendment) Act 2005 because the substance was considered not to possess the required 'improved efficacy'. It was the contention of the Indian Patent Office that Glivec® did not satisfy the requirements of novelty and inventiveness. Novartis challenged the denial of the patent for Glivec® before the Madras High Court on the grounds that the decision lacked legal or factual basis and justification.

The learned senior counsels appearing for Novartis raised two arguments. Firstly, they challenged the constitutionality of Section 3(d) and claimed an infringement of the TRIPS obligations as well as the right to equality as laid down in Article 14 of the Indian Constitution. The second argument refers to the definition of an invention. It was asserted that the amended section is bad in law because the mere discovery of a new property is not treated as an invention unless the discovery of the new form of the known substance results in the enhancement of the known efficacy of that substance. Furthermore, it was argued by the appellants that the amended section, in the absence of any guidelines to determine the enhancement of the known efficacy of the substance on which the discovery relies, vests unguided discretion in the hands of the statutory authority and as a result is bad in law.

The Madras High Court decreed that the said Section 3(d) is not in violation of Article 14 of the Indian Constitution and found that it did not have jurisdiction to decide on the TRIPS issue.[43] Regarding the interpretation of Section 3(d) the Court found that 'if the discovery of a new form of a known substance must be treated as an invention, then the Patent applicant should show that the substance so discovered has a better therapeutic effect.' (Novartis vs. Union of India, 2007(4) MLJ 1153, 1290). The Madras High Court concluded that the amended section sought to prevent 'evergreening' of patents,[44] provide easy access to the citizens of this country to life-saving drugs, and discharge the constitutional obligation of providing good health care to its citizens.

This decision of the Madras High Court removes many innovations that classify as incremental improvements from the scope of patent protection and supports the view that patents on incremental innovations are likely to be used by pharmaceutical firms to 'evergreen' their products by extending their monopoly period products. As a result, under Section 3(d) of the 2005 Patents (Amendment) Act, new uses of known substances cannot qualify as patentable, on the grounds that they do not fulfil the 'inventive step' requirement.

There are examples of other patent applications that were rejected under Section 3(d). In *M/s. Astra Aktiebolag*,[45] for example, the patent controller held that the claimed invention was not patentable under Section 3(d) as the benefit claimed by the applicant did not accrue to the user 'in terms of therapeutic quality of the product but to

[43] This argument is only mentioned for reason of completeness and will not be analyzed in further detail.

[44] 'Evergreening' is a term used to refer loosely to inappropriate extensions in the period of patent exclusivity for a pharmaceutical product.[…] Typically, it denotes a set of practices by patentees, wherein largely trivial or insignificant changes are made to a patented pharmaceutical product and then a secondary patent applied for. If such a patent is granted and if a generic product on the market is modified to include the features mentioned in the secondary patent, the monopoly of the patentee is extended beyond the period of the first patent.' (Basheer, S. (2005), 'Limiting the Patentability of Pharmaceutical Inventions and Micro-Organisms: A TRIPS Compatibility Review', Mimeo, 39). With regard to section 3 (d) Indian Patent Act see ibid., 42, and Basheer, S., Reddy, T.P. (2008), 'The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)', in: *Scripted*, vol. 5, issue 2, pp. 232–66, available at http://ssrn.com/abstract=1086254.

[45] Patent Application No. 1354/Del/1998, decision dated 12 June 2007.

the manufacturer only in terms of consistency in the production of formulation'. In another patent application[46] the patent was refused under the provisions of Section 3(d); it was argued by the patent controller that although the claim possessed some improvement in the physical property of the drug, such improvement did not result in any new therapeutic effect.

In the aftermath of the decision of the Madras High Court the impact of Section 3(d) for the development of the pharmaceutical industry and on public health are still unclear. After the changes of the Patent Amendment Act became effective, the Indian pharmaceutical market experienced an increase in drug prices as well as a decrease in the number of pharmaceutical companies. A detailed survey of this development has yet to be undertaken and it is unclear whether the developments can be attributed to changes in patent policy. Some observers argue that the existence of Section 3(d) of the Indian patent law gives a wrong signal to the domestic as well as the international investing community and as a result will act as a barrier for R&D and innovation in the pharmaceutical sector in India.[47] There are others who argue that Section 3(d) forces firms to focus efforts on innovation and hardcore research instead of trifling with known substances and thereby sought to prevent 'evergreening' of patents.[48] The Madras High Court decision in the Novartis case has already taken the later position, but it is far from clear that this is the 'good position' in law. The way Section 3(d) is interpreted by the courts and patent office clearly demonstrates that the importance of incremental innovation in the pharmaceutical industry is being overlooked by defining 'efficacy' as 'therapeutic efficacy' (Basheer and Reddy;[49] Basheer[50]). Furthermore

[46] Patent application No. 841/Del/1996, decision on 30 August 2007.

[47] See Ajit Dangi (Director General, Organization of Pharmaceutical Producers in India) available at http://www.rediff.com/ money /2007/aug/24deb.htm (last visit 18 January 2008)

[48] See D.G. Shah (Vision Consulting Group) available at http://www.rediff.com/ money /2007/aug/24deb.htm (last visit January 18th 2008)

[49] Basheer and Reddy (2008).

[50] Basheer, S. (2008), 'The "Glivec" Patent Saga: A 3-D Perspective on Indian Patent Policy and TRIPS Compliance. Paper presented at the Indo-German Conference on Intellectual Property Law', Freiburg and Munich, May 12–15, 2008, p. 14, available at http://www.atrip.org/upload/files/essays/Shamnad%20Basheer%20Glivec%20Patent%20Saga.doc.

the courts have also failed in laying down proper guidelines as to how to determine the enhanced efficacy.

7.4 A LAW AND ECONOMICS PERSPECTIVE

From an economic perspective there are some good reasons in favour of the grant of patents, especially in the pharmaceutical industry. A patent grants an inventor a legal monopoly in the exploitation of his invention for a limited period of time. This serves the purpose of encouraging innovation and making them available for the public by giving the innovator an instrument to recoup his investment in the innovative activity. The subject matter protected by patents is basically information and as such not rivalled and easy to copy. Without a system that protects inventions there would be inadequate incentive to either innovate or to disclose innovations—to the detriment of the general public. Intellectual property rights are allocated to inventors in order to prevent expropriation and to provide for an environment in which bargaining and market exchange can take place.[51] Innovative work requires the input of large resources. While R&D in this area does not usually only take long, is extremely costly. Patent protection enables innovators to charge a price for innovative products above the marginal cost and thereby to recoup R&D expenses. The protection of inventions is of great importance, especially in the pharmaceutical sector due to the vast efforts and high risks involved in the process of developing a new and useful product. The results of Mansfield's detailed study on how patents affect industries suggested that patent protection was essential for the development of 30 per cent or more of the inventions in only two industries, namely the pharmaceutical and the chemical industry (Mansfield).[52]

However, to achieve the social goal of patent protection, and promote dynamic efficiency by inducing firms to engage in socially beneficial R&D activities, society has to pay a price. The social costs of patent protection consist of the static welfare losses due to the mark up on the marginal cost of producing the product that embodies the invention and, depending on the specific circumstances, the waste

[51] Kamperman Sanders, A. (2007), p. 244.

[52] Mansfield, E., (1986), 'Patents and Innovation: An Empirical Study', *Management Sciene*, vol. 32, No. 2, p. 174.

of resources resulting from patent races and of the increased cost of secondary innovation which builds on the original innovation.

Innovative activity is to a large extent a cumulative process.[53] Present innovations depend on past innovations. How should incremental innovations be treated by patent law from an efficiency point of view? A trade-off has to be solved between inducing investment in the original invention and inducing investment for improvement.

Let us denote the per-period value of some original (first) innovation to all potential final users v_1 and the required R&D investment c_1. Assuming that the innovation is a new product, such as a new drug, and the market for this new good is characterised by the demand function in figure 7.1. For the sake of simplicity, without loss of generality, we assume that the marginal cost of producing the good is zero. In this case, v_1 is measured by the area below the demand function (see e.g.[54]). If the innovation endures forever, its present social value over its entire lifetime is v_1/r, whereby r denotes the discount rate.

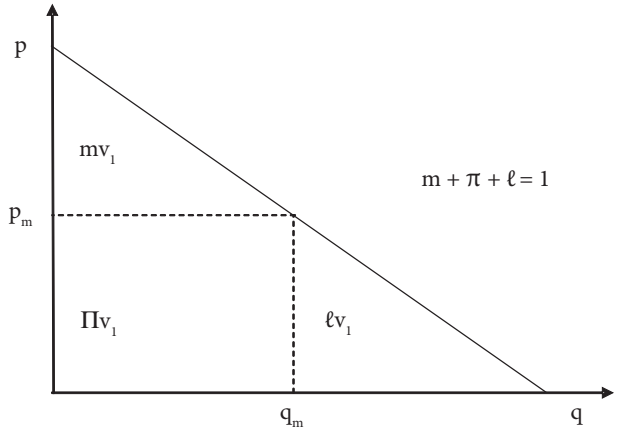

Figure 7.1: Per-period Value of Product Innovations

If the innovation is protected by a patent, consumers will only appropriate part of the social value. During the life of the patent, the consumers' share of the innovation's per-period value is only

53 Scotchmer, S. (2004), *Innovation and Incentives*, Cambridge.
54 Scotchmer (2004), p. 33.

mv_1, with $m < 1$; another part of the social value—πv_1, with $\pi < 1$—is appropriated by the patent owner as per-period profit, which is perceived as the return on the R&D investment. The social cost of inducing innovation by patent protection is the deadweight loss ℓv_1 per period. Consequently, the present social value of the patented innovation is $v_1/r - v_1 \ell T$, whereby T denotes the (discounted) time of patent duration.[55] If the patent holder acts as a perfectly discriminating monopolist he will—during the lifetime of the patent—appropriate the whole per period value of the innovation, so that there is no deadweight loss anymore ($\pi = 1$, $m = \ell = 0$).

Assume furthermore that a secondary innovator, inspired by the original one, invests c_2 in R&D in order to improve the original innovation, and thereby increases the value of the new product to all potential users by v_2 per period and its present social value by v_2/r. We assume, for the sake of simplicity, that the improving innovation emerges with certainty and without any delay. Since the improvement is only possible if the original innovation is made, the (maximal) present social value of the original innovation consists of its stand-alone value (v_1/r) plus the spill-over max $\{0, v_2/r - c_2\}$. Consequently, to induce the original innovator to efficiently invest in R&D he should be allowed to appropriate the stand-alone value plus the spill-over value. However, to induce the second innovator to efficiently invest in R&D he should be allowed to appropriate the total social value of the improvement. Obviously, there is no patent policy available that provides efficient investment incentives for both innovators.[56] An optimal patent regime should minimize the welfare losses from distorting the first and second innovator's investment incentives.[57]

[55] That means T is calculated in a way that $v_1 \ell T$ denotes the present value of the periodical deadweight losses during the lifetime of the patent. See Scotchmer (2004), p. 59.

[56] With patent protection, and absent perfect price discrimination by the patent owner, the maximal present social value is not achievable any more since the deadweight loss has to be taken into account. Thus, the actual present social value of both innovators reduces to $(v_1 + v_{2)}\ ((1/r) - \ell T)$. The balancing of the innovation incentives between primary and secondary innovator is a function of the design of the patent law which allocates total profit $\pi T(v_1 + v_2)$ to both innovators.

[57] See the elaborated model by Chang (1995) who takes the uncertainty of the first innovator over the value and the cost of the second innovator into account.

When an improvement satisfies the normal requirements of patentability (novelty, non-obviousness, and industrial application) the secondary innovator can obtain a patent. Here, two cases are possible. If the secondary innovator is entitled to use his patent without obtaining a license from the primary innovator, that is, if he owns a *competing patent*, he would be enabled to appropriate part of the stand-alone value of the original innovator, thereby undermining his incentive to invest in R&D.[58] If the secondary innovator can use his patent only with the consent of the primary innovator, that is, if he owns a *subservient (dependent) patent*, both parties can block each other and the primary innovator may appropriate part of the value created by the secondary innovation.[59]

Basically, there are two policy levers available to taiylor both parties' incentives by patent law: the requirement for patentability of the secondary innovation, i.e., for example, the distinction between (non-patentable) 'minor improvements' and (patentable) 'significant or radical improvements' (Lemley),[60] and the breadth of the original patent, i.e., the distinction between improvements that infringe or that do not infringe on the original patent. Consequently, we can distinguish four cases:

Case 1: Broad Protection of Original Innovation, Patent for Improving Innovation

In this case, both innovators hold a patent, but the secondary innovator can use his patent only with the consent of the primary innovator. The secondary innovator owns a *subservient (dependent) patent* and is only able to market the improved good if he buys a license from the original innovator (Scotchmer)[61]. Let us start with the simple case of an *ex post license*, that is, the bargaining about the license takes place after the secondary innovator has invested c_2 in R&D. Since c_2 is sunk, the bargaining surplus is the present value of the periodical profits the secondary innovator earns by selling the improved product: $v_2\pi T$. According to the Nash bargaining solution each party to the license

[58] See Ibid. (1995, 44 f.).

[59] Ibid.

[60] Lemley, M.A. (1997), 'The Economics of Improvement in Intellectual Property Law', *Texas Law Review*, 75, p. 1007ff.

[61] Scotmer (2004), p. 135.

agreement receives the amount of the threat point, that is, the pay-off without cooperation, plus half of the bargaining surplus. Thus, ex post licensing leads to the following result:

	Threat point	*Cooperative pay-off*
First innovator	$\pi Tv_1 - c_1$	$\pi Tv_1 + ½\ \pi Tv_2 - c_1$
Second innovator	$- c_2$	$1/2\ \pi Tv_2 - c_2$

With ex post bargaining, the first innovator is able to hold-up the owner of the subservient patent whose R&D costs are already sunk. This constitutes a problem when $1/2\ \pi Tv_2 < c_2 < \pi Tv_2$, because in this case the secondary innovator has no incentive to engage in some socially valuable R&D activities before agreeing upon a license with the primary innovator.

Basically, this problem could be solved by agreeing on an ex ante license, before the secondary innovator has spent c_2. In this case, the bargaining surplus is $\pi Tv_2 - c_2$, and ex ante licensing will be in the mutual interest of both parties, even if $1/2\ \pi Tv_2 < c_2 < \pi Tv_2$. Thus, ex ante bargaining on a license leads to the following results:

	Threat point	*Cooperative pay-off*
First innovator	$\pi Tv_1 - c_1$	$\pi Tv_1 + 1/2\ \pi Tv_2 - c_1 - 1/2c_2$
Second innovator	0	$1/2\ (\pi Tv_2 - c_2)$

Consequently, more socially valuable improvements will be made if we allow for ex ante licensing. However, this solution might not be feasible because of high transaction costs or because this type of cooperation conflicts with antitrust law (Chang).[62]

In general, the combination of broad patent protection for original innovators and patents for improvers creates blocking patents and thereby incentives to disclose new knowledge and to allow rivals to build on the current state of knowledge.

Case 2: Narrow Protection of Original Innovation, Patent for Improving Innovations

In this case, the secondary innovator is allowed to sell the goods that embody the secondary innovation without asking the primary

[62] Chang (1995).

innovator for a license ('competing patents'). This enables the secondary innovator to compete with the original innovator, thereby lowering his profits from the original innovation. Instead of earning the monopoly profit πTv_1 during the lifetime of the patent, he will only earn the oligopoly profit $\pi' Tv_1$, with $\pi' < \pi$. Consequently, narrow patents for original innovations discourage investment in R&D by primary innovators and induce them to delay the disclosure of their innovation until they have improved the original innovation themselves.

From this reasoning it follows that there are two classes of primary innovations that should receive a broad patent protection in order to efficiently trade-off between primary and secondary innovator's incentives: First of all, those basic innovations which have a high stand-alone value relative to possible improvements (which is intuitively clear). Secondly, basic innovations with a very little stand-alone value relative to the high value of expected improvements. The reason for a broad protection in the second case is the existence of large spillovers that are created by the basic innovation and that require a strong incentive for the primary innovator to invest in R&D. There is a special need to protect primary innovations with little stand-alone value when there is a large combined welfare effect resulting from both the primary and secondary innovation (Cooter & Ulen).[63] If $v_2(1/r - \ell T) > 0$ and $v_1(1/r - \ell T) + v_2(1/r - \ell T) - c_1 - c_2 > 0$, but $\pi' Tv_1 - c_1 < 0$, competing patents will discourage investment in the original innovation, thereby also destroying the options for secondary innovations. Broad patent protection of primary innovators will enable them to appropriate part of the spillover via licensing, encourage investment in R&D, and see society better off.

This result contradicts the 'reverse doctrine of equivalents' which is applied by some US courts and also supported by Merges and Nelson.[64] 'Under that doctrine, if the contribution made by the improvement *greatly* exceeds the contribution made by the original patented invention, the improver is allowed to practice his invention

[63] Cooter, R., Ulen, T. (2004), *Law and Economics*, fourth edition, Boston *et al.*, p. 126.

[64] Merges, R.P., Nelson, R.R. (1990), 'On the Complex Economics of Patent Scope', *Columbia Law Review*, 90, pp. 839–916.

without being deemed an infringer, even though he is making use of the prior invention without a license from the patentee' (Landes and Posner).[65]

If 'minor improvements' are patentable more general problems may arise. There might be a tendency to patent small improvements too early, thereby depriving potential future innovators of the opportunity to develop a better innovation (Denicolò).[66] If many minor improvements without a remarkable value added are protected by patents, a patent thicket (Shapiro)[67] would be created which would require developers to negotiate with many patent holders and discourage companies from developing more valuable improvements. Also, transaction costs of licensing increase and the 'tragedy of the anticommons' (Heller and Eisenberg)[68] may arise.

Now, assume that secondary innovations are not patentable since they do not meet the requirements of patentability. This corresponds to Section 3(d) of the Indian Patent (Amendment) Act 2005 which determines specific restrictions on patenting secondary innovations.

Case 3: Broad Protection of Original Innovation, No Patent for Improving Innovation

This constellation discourages investments in the improvement of original innovations and also the disclosure of improving innovations in due time. The secondary innovator's best strategy is to wait and hide the information, and (if it is profitable) to continue with R&D until a level of improvement is achieved which makes the product patentable. Consequently, technical progress is retarded and investment in R&D for primary innovations with large expected spillovers might be discouraged.

[65] Landes, W.M., Posner, R.A. (2003), *The Economic Structure of Intellectual Property Law*, Cambridge.

[66] Denicolò (2008), p. 444.

[67] Shapiro, C. (2001), 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting', in: Jaffe, A., Lerner, J., Stern, S. (eds), *Innovation Policy and the Economy*, vol. I, Cambridge, pp. 119–150.

[68] Heller, M.A., Eisenberg, R.S. (1998), 'Can Patents Deter Innovation? The Anticommons in Biomedical Research', *Science*, 280, pp. 698–701.

Case 4: Narrow Protection of Original Innovation, No Patent for Improving Innovation

When the improving innovation is not patentable, but does not infringe on the original patent, the secondary innovator faces two options (Scotchmer)[69]: The first option is to market the good which embodies the non-patentable improvement, provided it can be protected by trade secrecy or first-mover advantages. In the latter case, some of the new knowledge may be revealed to the public. In the process, the original innovator's profits will be eroded, which discourages his investment in R&D in the first place. The second option is to cache the improvement and wait for further (patentable) improvements (see case 3).

Will there be any change when the original and the incremental innovation are provided by the same party? Since all spillovers are internalized, the problem of coordinating the R&D activities between primary and secondary innovators vanishes. But proponents of a restrictive policy with respect to improvements of patented innovations, such as the creators of Section 3(d) of the Indian Patent Act, argue that another problem will arise: 'evergreening'. Evergreening generally refers to the strategy adopted by patentees who seek to extend their period of patent protection by applying for secondary patents over related or derivative technologies (Chambers).[70] However, does evergreening really constitute a practical problem? Imagine that a pharmaceutical company invents a new drug which is patented so that the residual lifetime of the patent after approval of the drug by the regulatory authority is, for example, fifteen years. After some time, it develops a minor improvement of this drug which is also patented, even though it does not create any remarkable value added, so that the residual lifetime of the new patent after the expiry of the original patent is ten years. Does the new patent extend the patent protection of the original innovator? Obviously not. After the original patent has expired and after the producers of generics have gained access to the relevant product data disclosed by the original innovator to the regulatory authorities the imitators will be entitled to produce

[69] Scotchmer (2004, p. 150.

[70] Chambers, R. (2006), 'Evergreen or Deciduous? Australian Trends in relation to the "Evergreening" of Patents', *Melbourne University Law Review*, 30, pp. 29–61.

generics of the original drug and sell them at a low price. Since the original drug and the newer ones with minor improvements are close substitutes, the price of both drugs will approach the marginal cost of production. This implies that no extension of the original patent and no increase of the deadweight loss is possible.

Only under very special circumstances will the patenting of minor improvements lead to 'evergreening' of the original patent: (i) If the producer of a generic from the original drug infringes on the claims related to the new (improvement) patent. However, in this case the producers of generics would challenge the new patent (which does not comply with the requirements of novelty and/or non-obviousness). (ii) When the pharmaceutical company is able to convince doctors and health insurance systems that the improved drug is much better than the original even though they are in fact close substitutes. However, from our point of view, there are no convincing arguments that this hypothesis will exist. In high income countries, there are elaborated checks and balances to keep health costs down, so that the health insurance systems would refuse to cover high-price-drugs that could easily be replaced by low-price-drugs of the same quality. In low income countries, people simply could not afford to pay the high prices.

Of course, the original innovators are typically also very innovative with respect to delaying the entry of generic drugs.[71] However, this does typically not result from the overprotection of marginal improvements, but to a large extent from infringements of antitrust law.

7.5 IMPACT OF RESTRICTIVE INTERPRETATION OF LAW ON INNOVATION

At first glance, the restrictive interpretation of Section 3(d) of the Indian Patent (Amendment Act 2005 by the Madras High Court, which identifies 'efficacy' with 'therapeutical efficacy', seems to reflect the old conflict between producers of original drugs, located in developed countries, and producers of generics, located in developing countries.

[71] In July 2009, the European Commission presented the final report on its competition inquiry into the pharmaceutical sector. It found out 'that originator companies use a variety of instruments to extend the commercial life of their products without generic entry for as long as possible.' http://europa.eu/rapid/press ReleasesAction.do?reference=IP/09/1098&format=HTML, last visit: 17.07.2009.

However, this is not necessarily true. As it has become clear from the economic analysis, the narrow interpretation of Section 3(d) severely restricts innovation through incremental steps, and this restriction holds for pharmaceutical companies from developed countries and from India as well.

There is some evidence that India has developed a huge innovative potential in the field of pharmaceutical research and development. In the last years more and more Indian pharmaceutical companies have spent larger fractions of revenues in research and development (R&D). Whereas in 1992–1993 seven major spenders invested only 1.78% of sales in R&D, the investment of twenty-eight major spenders amounted to 8.79% of sales in R&D in 2005–2006 (Chaudhuri).[72] Some big pharmaceutical companies like Ranbaxy Laboratories and Dr. Reddy Laboratory Ltd. have now started taking R&D seriously (see the corresponding Annual Reports).

Under these conditions, the restrictive interpretation of Section 3(d) also works against the Indian pharmaceutical companies that have the potential to make existing drugs more useful for patients under the specific conditions of countries with tropical climates, high rates of illiteracy, etc.

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[72] Chaudhuri (2007), p. 22.

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