

**THE EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND
ASSOCIATIONS**

INTELLECTUAL PROPERTY AND PHARMACEUTICALS

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1. Summary

Every new medicine is the result of a long, painstaking and costly research and development process. Thousands of compounds are tested but very few survive the rigorous testing process. That process and the products it produces must have intellectual property protection. Developing and bringing a product to market is hugely expensive to undertake and very easy to imitate.¹ No industry could survive in the face of free riding by imitators on innovators' investments. But that protection is fundamental in the pharmaceuticals industry, where the investments are measured in billions and the development process in decades.

The portfolio of patents that relates to each product (its uses, forms and manufacturing process) is never granted automatically. They are granted only after expert scrutiny generally from the European Patent Office ("EPO"), a body widely regarded as conducting one of the most rigorous patent examinations in the world. Their expert examiners, well versed in the industry, chemistry, biotechnology and its developments, will conduct a global review of prior art, from patents and scientific literature, testing the claims for novelty and inventive step. The review lasts 44 months on average and just under half of patent applications fail examination.²

Patents that endure that scrutiny are still not secure. Challengers, in addition to the opportunity of offering observations during the patent prosecution process, have a range of risk-free legal tools to "clear the path" if they believe their imitations should not lawfully be restricted by the patent. They can oppose the patent, seek revocation or seek declarations of non-infringement. There is no reason why a well-advised imitator should need to launch "at risk" of infringement proceedings, including damages and pre-trial injunctive relief.

The resulting patent exists only on paper. It is intangible and worthless without judicial protection. Generic entry rapidly and irreversibly takes market share and devalues the price of the patented product. Judicial relief must include not only compensation, to the extent it can be calculated, for the damage caused by illegal generic imitation, but also effective pre-trial relief given the many cases in which compensation is both too little and too late to safeguard the innovator's rights.

The incentives created by the patent system stimulate competition through innovation rather than retard it. The concept of "patent thickets" that prevent follow-on innovation,

¹ Note that ease of imitation applies to chemically synthesised compounds. It is more difficult to copy biotech products.

² The detail of the European Patent Office's scrutiny is illustrated by its statistics: in 2005, it received 128,754 applications, carried out 163,144 searches, 104,433 examinations, and only 53.3% of the patents applied for were finally granted. It took, on average, 44.3 months for a patent application to make it to grant in 2006. See *European Patent Office Annual Reports 2005 and 2006*, available at <http://www.epo.org/about-us/office/annual-reports.html>.

sometimes alleged in other industries, is not one recognized in the pharmaceuticals industry. The patent system creates a race to innovate to produce products that are both first in class and followers that improve upon and differentiate themselves from the class leader. Even there, the innovative competition does not stop, with rivals seeking to improve upon the products they have launched with better, more convenient and efficacious combinations, formulations and delivery systems.

The huge cost, risk and complexity of the development process, in this industry above all others, makes intellectual property protection essential. The pharmaceuticals industry is characterized by precisely those features which economists recognize present the strongest case for protection, and where intervention by regulators will be the most harmful: enormous upfront investments funded almost exclusively by the industry out of current income and profits; the potential for innovations overtaking the incumbent products; speculative prospects of success and many costly failures; and a limited window of commercial exploitation. Where the “*firm has engaged in substantial, high risk investment, and is enjoying the benefits of ‘superior skill and enterprise’, [competition law] claims should be treated with caution.*”³

2. Pharmaceutical Research & Development – An Overview of a Typical R&D Process

2.1 Step 1: Target Identification⁴

The “drug hunting” process begins by focusing on areas of unmet medical need. It seeks to identify a biological “target”, an agent or process in the human body thought to be implicated in a disease and which may be susceptible to medicinal treatment. Examples might be a bacterium, virus, enzyme, growth factor, messenger protein or receptor. Target identification may result from academic or industry basic research, *in vitro* and/or *in vivo*, to understand diseases better. Scientists in the industry are aware of the latest basic research and build on this science with their own ideas and investigations. Publications in respected journals, at conferences and/or in patent literature will often be the stimulus for a number of companies to conduct research into the same or similar biological targets. Typically, it takes up to approximately 6 years from the very start of the research idea before a candidate drug for development exists.

2.2 Step 2: Target Validation

Scientists then carry out studies to try to show that the biological target has an impact on the disease, using *in vitro* and/or *in vivo* models. They try to check whether a promising

³ OFT 377 Innovation and Competition Policy Economic Discussion Paper 3, March 2002, report prepared for the Office of Fair Trading by Charles River Associates, para. 5.106.

⁴ This section addresses the typical steps involved in developing a “small molecule” chemically synthesised drug. The process for biotechnology “large molecule” drugs derived from engineering living organisms will not be the same at each stage.

research path will ultimately turn out to be a dead end. If there is sufficient justification for linking the biological target to the disease for which a treatment is sought, the company will then start to look at chemical compounds.

2.3 Step 3: Hit Identification

A company must make a selection from the possible biological targets to determine which to study using high throughput screening (“HTS”). HTS is an automated system for testing tens of thousands, or even hundreds of thousands, of compounds extremely rapidly. It is a highly effective way of identifying potentially useful compounds amongst a company’s collection of compounds.

The result of this phase is the identification of “hits.” “Hits” are compounds that are active in the initial screens. These compounds must not only be active against the biological target, but must also have some selectivity. In other words, they must not be active against too many targets. They must also have characteristics that make them suitable to be made into drugs. Those compounds - or “hits” - judged to be most interesting in this phase are then selected for further examination.

2.4 Step 4: Lead Identification

HTS will have identified tens or even hundreds of hits. The company will then conduct “hit-to-lead” chemistry, to focus on a few classes of chemical compound which have an influence on the target and have the greatest potential to produce a compound capable of development into an effective medicine.

At this stage, it is possible to file an initial patent application in relation to a class of chemical compounds that exemplifies the lead compounds within that class and any others within the scope of the patent application.

2.5 Step 5: Lead Optimisation

A team of medicinal chemists will synthesise many more compounds relating to the classes identified during “lead identification.” They must seek to identify the compound or compounds which have *inter alia*:

- good efficacy against the target;
- good prospects of being able to be synthesised at a reasonable cost;
- good prospects of being able to be formulated in a satisfactory manner;
- good pharmacokinetics, duration of action; and
- a promising safety profile

Each compound synthesised is tested in biological models and the results are reported to the chemists. This feedback aids them in making new compounds with improved

properties. The new compounds may be within the scope of any initial patent application - in which case they may be added to the application submitted⁵ – or, alternatively, they may be outside the scope of the initial patent application and separate patent applications may need to be filed.

A company will want to have several compounds under review during the development process, as the chances of failure in development are high and it will be necessary to have alternatives. This means that typically several patent applications to classes of chemical compounds are filed in any one project.

Research is necessarily an exploratory process. A company will investigate new areas of interest to it, using new scientific approaches, new mechanisms of action and new screens. So it is quite possible that some of the patent applications filed in one project could cover compounds of interest in another or future project of that company.

2.6 Step 6: Candidate Drug

By this stage, a company has amassed substantial data on classes of compounds and has identified preferred compounds within the class or classes.

Now a significant decision has to be made. The company has to decide whether any of the compounds have the necessary properties to have the potential to be an effective medical treatment – and whether that compound justifies the very substantial cost and effort of the development process.

Different companies will have different procedures. Essentially, a company will generally consider factors such as the potential safety profile of the compound, its potency, bioavailability, stability, process chemistry and method of administration to the patient (such as oral, intravenous or inhalation).

Scientists from many different disciplines will now become involved. There will inevitably be problems associated with the properties of the selected compound that need to be overcome to make it suitable, and commercially viable, as a medicine:

- the process chemists need to find a way to synthesize the compound at an acceptable cost and in a commercialisable manner. The chemical process used in the research laboratory is typically inappropriate for a commercial scale operation. These process chemists may invent an innovative process or process step that solves technical problems. That innovative process may be the basis of a patent application;
- the formulation chemists need to find a formulation that enables the compound to be administered to the patient in an effective manner. Every chemical compound

⁵ If within scope of an existing application, additional compounds may be added by a further patent application within one year of the initial application and claiming priority from that earlier date.

has different properties, and frequently these pose technical challenges to the formulation chemists. For some medical treatments, a simple tablet or capsule taken orally may be sufficient. However, some medical treatments may require more complicated administration (such as sustained release, inhalation or coated capsules). Efforts to identify and develop effective formulations for particular chemical compounds often result in innovations to solve the technical problems. Innovative formulations may be the basis of a patent application (or applications);

- the process chemists and formulation chemists need to identify the best physical form of the chemical compound. This is important, for example, for stability in the end-part of the chemical process, for stability during the formulation process and for ‘shelf-life’ stability. Therefore considerable effort goes into identifying the most suitable salt and/or polymorphic (crystal) form of the compound. Again, this effort and the solving of technical problems may be recognised in patent applications.⁶

The candidate drug stage will generally last a number of years. In parallel, further safety/toxicity testing is performed and testing in humans begins. To start testing in humans, the pre-clinical results are submitted to health authorities to seek permission to conduct clinical studies in volunteers.

2.7 Step 7: Concept Testing

The decision must then be taken as to whether to test the candidate drug(s) in humans. Typically, no more than a few candidates make it to this phase for any given project.

‘Phase I’ then begins. Phase I is the first phase of four clinical trial phases. Phases I – IV of any clinical trial programme may be summarised as follows (Figure 1):

⁶ *Adaptive Innovation, Intellectual Property and the Public Interest: How Patent Extension Leads to More, Better and Safer Medicines*, IFPMA (2006), available at <http://www.ifpma.org/documents/NR4234/AdaptiveInnovationFinal.pdf>.

Figure 1: Clinical Trial Phases

Stage	Typical Number and Type Of Patients	Typical Duration	Purpose
Phase I	20-100 healthy volunteers	Up to 1 year	To ensure the medicine is safe and find the most suitable dose
Phase II	Up to several hundred patients	1-2 years	To assess effectiveness and look for side effects
Phase III	Several hundred to several thousand patients	2-4 years	To confirm effectiveness and monitor any side effects from long-term use
Phase IV	Variable: commonly several thousand	Variable	To develop new treatment uses, compare with other treatments, determine the clinical effectiveness and long-term safety of the medicine in a wider variety of patient types and/or to satisfy conditions of authorisation.

In Phase I, the candidate drug is first tested in a limited number of subjects, generally healthy volunteers, but sometimes in patients, with very close monitoring. The purpose is to determine how well the drug is tolerated, if it has the desired effect in man, to learn about suitable dosage and if the drug has characteristics that would allow it to be made into a medicine.

The findings from these studies are fed back to the formulation chemists and their colleagues. Phase I may show problems with the candidate drug that a different formulation or process (or related compound) may resolve. Again, innovative elements of these solutions may result in patent applications.

2.8 Step 8: Development for Launch

After testing in healthy volunteers, the drug is given to a limited number of patients – this is clinical ‘Phase II’. This phase assesses the efficacy of the drug in the target population. At the same time, further studies of tolerance and safety are carried out.

After successful completion of Phase II trials, the drug is given to larger numbers of patients, comprising anything from 500 to 30,000 patients (‘Phase III’). These large studies provide the most important proof of efficacy, tolerance and safety, and frequently determine whether the project continues or is terminated. These studies also help to establish the permitted uses of the medicine, the labelling and the product information as

well as important commercial information, as to whether the candidate shows added benefits over competing therapies.

Throughout development, scientists are constantly reviewing the optimum use of the new drug for various patient populations. These scientists may consider that the drug has potential use for different diseases than those originally contemplated. *In vitro* and *in vivo* data may support such different and/or additional uses. This may lead to innovative developments that may be covered by patent applications for new medical uses and/or for new combinations of therapeutic drugs.

2.9 Step 9: Regulatory Review, Approval and Launch

All the data from all the pre-clinical and clinical studies are collated and are sent to the regulatory agencies for their review to seek marketing approval.

2.10 Step 10: Post-Launch

If the drug is subsequently approved by the regulatory agencies, it will be launched as rapidly as possible. In this phase, strategies and opportunities for the drug's life cycle are defined, assessed and funded as appropriate. Clinical Phase IV trials are conducted to examine the medical long-term effects and health economic aspects. New indications are closely examined and studies are made to examine new formulations of the substance. Drugs originally intended for the treatment of one disease are sometimes found to have beneficial effects for others. Innovative new formulations and/or uses may constitute patentable inventions.

2.11 The Resulting Portfolio

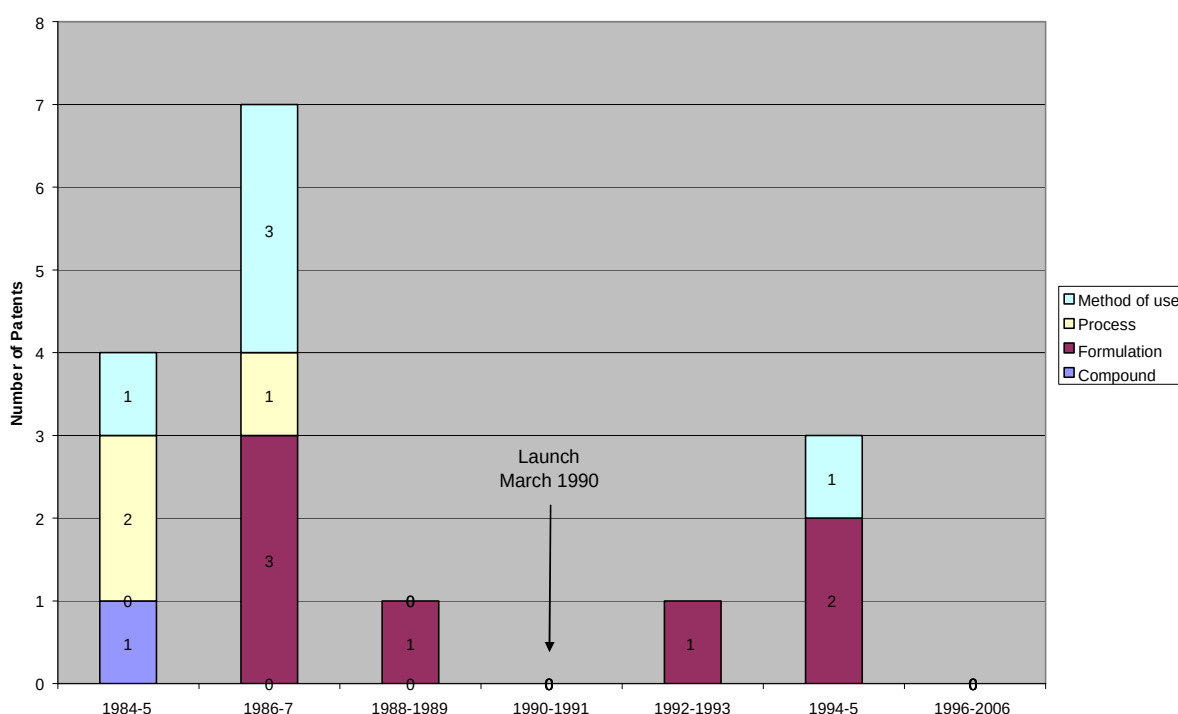
In this way, the compound, related entities, their uses and overcoming the various challenges involved in creating a candidate drug from the lead compounds can be recognised in patent applications as well as improvements and innovations identified post launch. A patent portfolio might comprise 20-40 patents relating to a particular product, but it can be many more (or far less) depending on the compound.⁷ A hypothetical product portfolio illustrating the different patent types applied for over time is set out at Figure 2.

Patent protection is not, of course, automatic. The EPO, where most pharmaceutical applications are made, subjects the application to expert scrutiny for novelty and inventive step. A search of relevant prior art is made. Examiners determine whether the

⁷ The size of patent portfolio from product to product will be as diverse as the underlying molecules, formulations, processes and uses. For that reason, it is impossible to generalise as to the typical portfolio.

claimed invention is novel and inventive in the light of the prior art.⁸ A formulation or process that reflects basic chemistry or common knowledge by those skilled in the art will fail this examination. For later patent applications, the prior art considered by the examiner will include the basic compound, as well as how it is made, formulated, administered and used, as disclosed by the prior patents applied for in relation to the classes of compound under investigation. The patent applications for later improvements, uses, processes or formulations must disclose novelty and an inventive step over all this prior art. For that reason, the claims in such later patents are restricted to limited innovative features.

Figure 2: Illustration of Development of Hypothetical Patent Portfolio Over Time



3. The Need for Intellectual Property Exclusivity

3.1 The Rationale

This innovative activity involves cost and risk. Because an innovator's product may be copied by an imitator who does not incur this cost and risk, protection for that effort is required in order to incentivise innovation. These incentives include a period of exclusivity in order to provide a return on investment. Intellectual property rights

⁸ The patent is also examined to determine whether it discloses patentable subject-matter and sufficiently describes the invention, as noted below.

(“IPR”) are a means of providing that exclusivity. They provide some means of preventing third parties from reproducing the innovator’s product without the innovator’s consent for a limited period of time.⁹

The extent to which IPR protection is an essential part of a particular industry’s business model will largely depend on the cost, risk and time involved in bringing an innovative product to market, and on the cost and risk of imitation.¹⁰

3.2 The Cost and Risk of Pharmaceutical Innovation

There are various studies which seek to analyse cost, risk and time of development of innovative pharmaceuticals.¹¹ However, estimating costs is difficult in this industry given its complexity and the many variables involved.

(a) Cost

A number of studies have considered the cost of bringing a product to market and the range of costs they identify is wide. One study provides an estimate of USD 2 billion for a particular product made by an economist and a research analyst at the Bureau of Economics of the US Federal Trade Commission.¹² Several of the studies report average figures in excess of USD 800m.

There are various reasons for this variation: (i) the studies include different diseases resulting in differences in unit cost, duration, number of compounds studied and number of patients at each stage of development; (ii) the studies have used different attrition rates because they employ either historical data or emergent trends; and (iii) sampling errors are inherent in studying a relatively small number of low probability events, that is to say the prospect of creating a new drug.

⁹ Patents, copyright and other analogous rights are the most obvious examples of time-limited protection against third party imitation of the innovative product. Data and market exclusivity rules also provide a level of protection specifically in relation to generic copying. Trade marks differ in several respects, including that they are not time-limited.

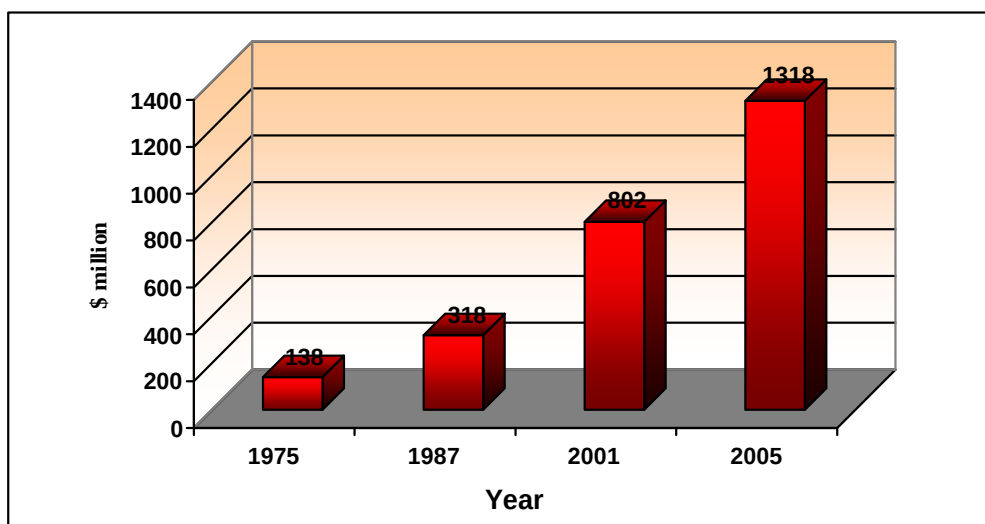
¹⁰ In this section, we examine the position for small molecule products, unless otherwise stated. The position can be very different for biotechnology products where generic copying is more difficult to achieve.

¹¹ See, for example, Tollman et al, *A Revolution in R&D: How genomics and genetics are transforming the biopharmaceutical industry*, BCG Report, November 2001; DiMasi et al, *The Price of Innovation: New Estimates of Drug Development Costs*, Journal of Health Economics, 22, 2003; Gilbert et al, *Rebuilding Big Pharma’s Business Model*, In Vivo, the Business and Medicine Report, 21 (10), 2003; Dickson et al, *The cost of new drug discovery and development*, Discovery Medicine, Volume 4 no. 22, pgs. 172-178, June 2004; Adams et al, *Estimating the cost of new drug development : Is it really \$802 million?*, Health Affairs 25, no. 2 (2006), pgs. 420-428; DiMasi et al, *The cost of biopharmaceutical R&D: is biotech different?*, manage. Decis.Econ, 28, 469-479 (2007). See also all the studies cited in these studies.

¹² Adams et al, cited above.

But despite the debate over the figures,¹³ by any measure, it is clear that the costs are extraordinarily high and have risen exponentially over time (Figure 3 below):

Figure 3: Estimated Full Cost of Bringing a New Chemical or Biological Entity to Market (Year 2005 USD millions)



Source: J.A. Di Masi and H.G. Grabowski (2007) (cited above); PAREXEL's Bio/Pharmaceutical R&D Statistical Sourcebook 2006/2007, p. 107.

(b) Risk

There are two types of risk that must be addressed. The first is the risk of having to halt an R&D project (so-called 'attrition'.)¹⁴ It has been estimated that for every 5,000 – 10,000 compounds tested, only 5 ever reach clinical trials and only 1 reaches the market.¹⁵

Attrition can occur for technical reasons (for example, as development progresses, problems relating to safety or efficacy arise) or for commercial reasons (an assessment is made that a product will not succeed in the market because, for example, it shows insufficient differentiation from an existing product.)¹⁶

¹³ An interesting exchange as to methodologies used by the different studies can be found at Parexel's *Bio/Pharmaceutical R&D Statistical Sourcebook 2006/2007*, p. 127.

¹⁴ Rates of attrition also clearly affect the cost of bringing a product to market.

¹⁵ See *Pharmaceutical Industry Profile 2008*, Washington DC, PhRMA, March 2008.

¹⁶ *The Current State of Innovation in the Pharmaceutical Industry*, CRA International, June 2008, section 3.4.4 (Annex 4 to the EFPIA Submission) (evidence of reason for attrition).

The second type of risk is that of post-launch commercial failure. It has been estimated that only 2 out of 10 marketed drugs ever produce revenues that match or exceed R&D costs.¹⁷ Again, those calculations are also much debated, but it serves to show that few of the innovative products that come to market are the commercially successful “blockbusters” that generate a significant amount of the enormous revenues needed to finance R&D in the pharmaceutical sector.

(c) Duration

It is generally accepted that it takes between 10-12 years from the discovery of a compound with biological activity to its launch on the market¹⁸. Indeed, it was this development time that led to the EU adopting the Supplementary Protection Certificate (“SPC”) Regulation.¹⁹ This Regulation recognised the fact that development times led to such a serious erosion of effective patent life (being the patent term remaining at the time of the first marketing authorization) that a 20-year patent would not serve as an adequate incentive for pharmaceutical R&D.

(d) Conclusion

In conclusion, it may be seen that there are three undeniable facts which characterise pharmaceutical innovation. It is enormously costly, very risky and very time consuming.

3.3 The Cost and Risk of Copying by Generic Producers

There is little independent evidence as to the cost of bringing a generic medicine to market.²⁰ DG Shah, the then Secretary General of the Indian Pharmaceutical Alliance (a generic industry association), said in 2003 that “*It will take the Indian company at least two years to reverse engineer the product and will cost anywhere between \$100,000 and \$200,000 to come out with a bio-equivalent drug.*”²¹

¹⁷ Vernon et al, *Drug development costs when financial risk is measured using the Fama-French Three Factor Model*, Unpublished working paper, January 2008, cited in *Pharmaceutical Industry Profile 2008*, cited above.

¹⁸ J. A. DiMasi, *New Drug Development in U.S. 1963–1999*, *Clinical Pharmacology & Therapeutics* 69, no. 5 (2001), 286–296; M. Dickson and J. P. Gagnon, *Key Factors in the Rising Cost of New Drug Discovery and Development*, 3 (May 2004), 417–429; and J. A. DiMasi, R. W. Hansen, and H. G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, *Journal of Health Economics* 22 (2003), 151–185.

¹⁹ Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (as amended) [1992] OJ L 182/1.

²⁰ The European Generic Medicines Association claims - without providing further detail - that “*companies typically invest 6-16% of their revenues (and in some cases up to 30%) into researching and developing new products*”, <http://198.170.119.137/gen-basics.htm>.

²¹ Business Standard, 5 September 2003.

More recently, research by analysts Bernstein Research²² has estimated the cost of US market entry as being between USD 8-30 million²³. Whatever the exact cost might be, the cost to a generic of obtaining approval is orders of magnitude below that needed to bring an innovative product to market. Further, as a general rule²⁴, it is technically easy for a generic company to copy an innovative small molecule product.²⁵

Perhaps more important than the ease and cost of imitation in this industry sector is the fact that there is little commercial risk involved in the generic company developing and launching a new product. It will know that, providing that it can show its product is bioequivalent²⁶ to the originator, it will be able to obtain regulatory approval. It does not risk rejection on grounds of safety and efficacy.

Further, it will be launching into a market created by the innovator. It will know the extent of likely demand for and value of the product and will regard it as being a market of sufficient size to warrant any investment in market entry. It will not risk failure in the market in the same way as an innovator does.

3.4 The Need for Protection

Given the clear disparity between the high cost and risk of innovation in the pharmaceutical sector and the low cost and risk of imitation, it is self-evident that exclusivity and thus protection from imitation is needed if there is to be innovation.

Companies increasingly have a choice in how to invest their research funds. For example, many innovative pharmaceutical companies have already diversified into over the counter (“OTC”) products, consumer healthcare products and own brand generics. If there is a risk of antitrust or other regulatory intervention undermining the patents so vital to innovation, companies will consider further diversification as a means of protecting shareholder investment.

Without strong IPR protection, enforceable through the judicial procedures designed to adjudicate issues of infringement and validity, there is a real risk that innovative companies will reduce their investment in R&D, particularly in the EU. As the EC legislator has stated, “*without effective means of enforcing intellectual property rights,*

²² Bernstein Research, *Biogenerics: Long Rainbow, Small Pot of Gold; Limited Risk for Biotechs*, Weekly Notes, 27 October 2006.

²³ Of which more than 25% represents US litigation costs.

²⁴ This is generally, but not always, true of small molecule products but not true of biological products which are very hard to copy.

²⁵ Sometimes generics will try to avoid patent infringement by using specific salts and/or formulations which fall outside the patent claims. They may be able to do this and meet bioequivalence requirements.

²⁶ Two medicinal products are bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and if their bioavailabilities after administration in the same molar dose are similar to such degree that their effects, with respect to both efficacy and safety, will be essentially the same.

*innovation and creativity are discouraged and investment diminished.”*²⁷ The judiciary has also rightly recognised the importance of IPR protection for research. In a recent judgement, the Düsseldorf Higher Regional Court held that refusing to protect a patent by means of interim relief “*would be contrary to all the intentions of the German legislator and the European Union to strengthen claims for intellectual property, and in particular, the outstanding readiness for investments and risk-taking of research-oriented pharmaceutical producers that are actively involved in research.*”²⁸

4. The Legal Mechanisms for Protecting IPR

In the field of pharmaceuticals in the EU, patents, Supplementary Protection Certificates (“SPC”) and regulatory market and data protection are the principal legal tools which provide a period of exclusivity or protection against imitation²⁹.

4.1 Patents

(a) Patent Rights

Patent legislation is not fully harmonised in the EU Member States. But for present purposes, subject to exceptions identified below, their laws can be understood to be the same³⁰.

The EPO grants a patent only after an extensive review in which it determines whether the invention is patentable. To be valid, a patent claim must be novel,³¹ inventive³²,

²⁷ Recital 3, Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L 195/16–25.

²⁸ *Eli Lilly & Co. Limited / STADApharm GmbH*, Case 4 a O 247/07, Higher Regional Court Düsseldorf, 29 May 2008, part II, 3, e.

²⁹ For completeness, we should also refer to the 10-year period of market exclusivity provided for orphan drugs under Regulation (EC) No 141/2000 on orphan medicinal products [2000] OJ L 18/1 (the legislator noted the need for exclusivity incentives to promote the development of drugs for which there would otherwise have been limited demand. “Some conditions occur so infrequently that the cost of developing and bringing to the market a medicinal product to diagnose, prevent or treat the condition would not be recovered by the expected sales of the medicinal product ... [I]t is therefore necessary to stimulate the research, development and bringing to the market of appropriate medications by the pharmaceutical industry.”).

³⁰ This substantial *de facto* harmonisation is due to a combination of TRIPs, the fact that all EU Member States are members of the European Patent Convention 2000 (“EPC”) and the fact that many have adopted some of the key provisions of the Community Patent Convention provisions (even though the Convention never came into force).

³¹ In order to be patentable an invention must be new, which means that it does not form part of the state of the art. “Prior art” is defined as everything that has been made available to the public before the filing or the priority date of the European patent application by means of written or oral disclosure or by use or in anyway whatsoever. There are some exceptions: (a) if the disclosure was unauthorised and an evident abuse in relation to the applicant or his legal predecessor (for example, a deliberate intention to harm), or (b) if the applicant or his legal predecessor had displayed the invention at an officially recognised international exhibition.

susceptible of industrial application and describe the invention in a way that enables it to be performed by a person skilled in the field³³.

Patent rights are national rights and as such only extend to the territory in which they exist. They last for 20 years from the date of filing³⁴. In essence, they provide, in the country concerned, the right to prevent third parties from manufacturing, selling, using and importing a product, or using a process or selling a product made by the process³⁵. The right is only enforceable when the patent is valid and must be enforced by the owner (or exclusive licensee) in legal proceedings for infringement.

Patent rights are subject to statutory exceptions. To a large degree, these are similar in terms of the legislative provisions in the EU Member States, although differences in national judicial interpretations of similar legislation exist.

Patents claiming the active compounds ultimately used in a pharmaceutical product are generally applied for early in the R&D process (i.e. shortly after the invention is made). The R&D process generally takes between 10 and 12 years and can therefore absorb from at least half of the 20-year patent term. Without some form of adjustment, that would leave a very limited period of effective patent life within which to obtain an adequate return on investment.

(b) The patent application process

The majority of new European patent filings made by pharmaceutical companies are made through the Patent Cooperation Treaty (“PCT”). Some pharmaceutical-related patents are filed directly at the EPO, and a lesser number are filed nationally with Member State patent offices.

The PCT enables the applicant to file a single patent application and designate up to nearly 140 countries. The applicant can postpone the decision on which of the designated countries it wants to enter until approximately 30 months from the priority date. By this time, the invention which is the subject of the patent application will have been searched for relevant prior art, and an international preliminary examination report will have been established regarding the patentability of the invention.

³² An invention is considered to involve an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. The state of the art for the consideration of inventive step does not include the content of patent applications which were filed before the priority date or filing date of the European patent application but which were published after the priority date or filing date of the European patent application. Technical progress is not a requirement for patentability under the EPC. However, the extent of the monopoly conferred by a patent should correspond to and be justified by the technical contribution to the art.

³³ The application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The disclosure must be reproducible by the skilled man without undue burden which means the skilled man must be able to repeat the invention using the disclosure and his common general knowledge.

³⁴ See, for example, Article 63 of the EPC.

³⁵ See, for example, Article 28 of TRIPs.

Negative search and examination reports enable the patent applicant to make the decision to discontinue before incurring the majority of costs associated with the patent filing when entering the European patent system. It also alerts the applicant to potential problems which will be encountered in substantive examination before the EPO. Many applicants choose to have a search and international report established by the EPO even when the receiving office is a different country.

Patents can be obtained in the pharmaceutical field for:

- Generic classes of compounds;
- Specific compounds;
- New salts, polymorphs, optical isomers;
- Novel Metabolites;
- Bio-precursors;
- Intermediates;
- Methods/processes of manufacture;
- Formulations;
- Combination products;
- Therapeutic uses, first and subsequent uses;
- Non-therapeutic uses (such as contraceptives and cosmetics);
- Mechanism for treating disease;
- Dosage administration devices;
- Polynucleotides;
- Vectors;
- Host Cells;
- Polypeptides;
- Antibodies; and
- Screening methods

Regardless of the patent type, the subject matter must be patentable: new, inventive and susceptible of industrial application. It must be a genuine invention.

(c) Filing with the EPO

The patent examination process carried out by the EPO is among the three most comprehensive investigations by patent offices in the world, and many believe it is, in fact, the most comprehensive in the world, resulting in the best quality patents. The examiner conducts a thorough examination of the patent application. Sometimes this examination has been conducted at the PCT level by a European examiner and is adopted completely or with further explanation, citations or objections by the European examiner. An applicant facing objections of lack of patentability can file arguments in support of patentability, including the provision of additional technical data and expert reports to support its claim of an inventive step.

The EPO allows for third parties to file observations on patentability against patent applications during the examination process. These observations may be filed anonymously. The applicant is given an opportunity to respond to the objections, but the third party does not become a party to the examination proceedings. Approximately 5% of patent applications are opposed³⁶.

The applicant may be heard on the patentability of their invention, *inter alia*, in examination before the Examining Division informally or formally. Alternatively, if an application is formally rejected by the Examining Division, the applicant can file an Appeal, which often culminates in an oral hearing with the Appeal Board.

4.2 Supplementary Protection Certificates

Recognising that the period of patent protection is inadequate in relation to pharmaceuticals because of the long lead time before commercial launch,³⁷ Council Regulation 1768/92 created a *sui generis* right, the Supplementary Protection Certificate. This is equivalent to a patent right (and subject to its limitations and to being enforceable only if the underlying patent is valid), and in effect extends the period of patent protection by up to 5 years, subject to a limitation of no more than 15 years of combined patent and SPC protection from the date of first authorisation in the EEA³⁸. Only one patent owned by a company relating to a product can be the subject of an SPC³⁹. SPCs are applied for in each Member State in relation to each relevant national patent.

The policy underlying the SPC Regulation was to enable a patent owner to enjoy a term of 15 years of exclusivity⁴⁰. In fact, the SPC Regulation does not always give full

³⁶ In 2006, 5.4% of applications were opposed, see *European Patent Office Annual Report 2006*, available at <http://www.epo.org/about-us/office/annual-reports.html>.

³⁷ Recitals 2-3, Council Regulation 1768/92 concerning the creation of a supplementary protection certificate for medicinal products (as amended) [1992] OJ L 182/1 (“[M]edicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research ... [A]t the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.”)

³⁸ The eligibility and term of an SPC depends on the date of issuance of the first market authorisation within the EEA. If the first market authorisation is issued less than five years after the filing date of the corresponding patent, no SPC is granted. If the first market authorisation is issued more than five years but less than ten years after the filing date of the corresponding patent, an SPC is granted for a term corresponding to the period elapsed between the five-year point and the market authorisation issuance date. If the first market authorisation is issued more than ten years after the filing date of the corresponding patent, an SPC is granted for a five-year term.

³⁹ In cases where different parties own patents relating to the same product, each can obtain one SPC. See Article 3(2) of Regulation 1610/96 Regulation (EC) of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products. The provisions of this Article are valid, *mutatis mutandis*, for the interpretation of Article 3 of Regulation 1768/92 (for Pharmaceutical Products), according to the Recitals of Regulation 1610/96.

⁴⁰ Recital 8, Council Regulation 1768/92 concerning the creation of a supplementary protection certificate for medicinal products (as amended) [1992] OJ L 182/1 (“[T]he duration of the

compensation for the delays that might be incurred in being able fully to market a product because:

- (i) There are cases where development time is such that the 5-year maximum SPC term and the 15-year maximum period of combined patent and SPC term do not compensate for development delays; and
- (ii) The SPC Regulation does not provide any compensation to take into account the lengthy delays (in some cases in excess of a year) which can occur in some Member States in obtaining relevant pricing/reimbursement approvals. Before such approvals are given, the market for the product will not be fully open and these delays therefore have a significant effect on effective patent life. In contrast, generics following the market that has been created by the originator will not be confronted with similar delays to enter the reimbursement system in the respective market.

Regulation EC 1901/2006, which came into force in January 2007, created a new obligation (unless a waiver or deferral is granted) to submit data relating to the use of a product in children generated as part of a paediatric investigation plan as part of a marketing authorisation application. In such cases, and as compensation for conducting the paediatric research, the holder of an SPC or a patent which qualifies for an SPC is entitled to a 6-month extension of the SPC. This represents further acknowledgement from a policy perspective of the need for exclusive rights against imitation in order to provide incentives for undertaking R&D.⁴¹

4.3 Regulatory Data Protection

Regulatory data protection (“RDP”) is a form of exclusive right enforced through the marketing authorisation procedure. Although an innovator must produce vast amounts of safety and efficacy data in order to obtain marketing approval, a generic does not if it can show that its product is essentially similar⁴² to the innovator product. It does this by relying on the regulatory dossier of the innovator to compare its product to that of the innovator.

protection granted by the certificate should be such as to provide adequate effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains authorization to be placed on the market in the Community.”)

⁴¹ It is notable that the SPC extension is granted even if the paediatric research does not lead to the approval of paediatric indications for the product.

⁴² “*Essentially similar*” is the wording originally used in Directive 87/22 of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products. The terminology has changed under the more recent medicines legislation (Regulation 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Directive 2004/27 of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use). We nevertheless use “*essentially similar*” here because it succinctly conveys the meaning of the obligation.

The generic applicant needs only to show that its product has the same qualitative and quantitative composition in active substance as the innovator product, that it has the same pharmaceutical form and that it is bioequivalent⁴³. Its application for authorisation can be described as “abridged”. This abridged application procedure can only be used after defined periods of time. Prior to 2005, the abridged procedure could only be used:

- (i) If the centralised authorisation procedure was used, 10 years after first authorisation of the innovator product in the EU; or
- (ii) If the mutual recognition procedure was used, 6 or 10 years (at the option of the Member State concerned) after first authorisation of the innovator product in an EEA country.

After revision of the EU legislation in 2005, the period is as follows for applications for approvals made after 30 October 2005 (for the mutual recognition procedure) or 20 November 2005 (for the centralised procedure):

- (i) No valid application using the abridged procedure can be made in the first 8 years from the date of first authorisation in the EEA (the “data exclusivity period”);
- (ii) Thereafter, applications for authorisation of a generic can be made but the generic product cannot be placed on the market until 10 years after first authorisation in the EEA (the “market exclusivity period”);
- (iii) The 10-year period can be extended by one period of 1 year if, in the first 8 years, the innovator obtains approval of one or more new therapeutic indications representing a significant benefit in comparison with existing therapies.

The following should be noted about the exclusivity provided by RDP:

- (i) The RDP period runs concurrently with any patents or SPCs;
- (ii) In the majority of cases, the RDP term will expire before relevant patents and SPCs. It is only in the case of unusually lengthy development times that the RDP period will extend beyond the term of relevant patents and SPCs;
- (iii) When the RDP term expires, approval will be given for the launch of a generic product irrespective of whether relevant patent rights exist. The fact that there may be relevant patents is not a bar to granting marketing approval. If the generic company chooses to launch during the patent/SPC term, it is up to the patent owner to sue for infringement if it wishes to do

⁴³ See Directive 2001/83 (as amended).

so. Indeed, the patent owner will often not be able to find out whether a generic registration has been applied for until after the approval has been given, and may not be able to take action in relation to a generic product which it believes infringes a patent until after it has been launched;

- (iv) RDP is entirely independent of the existence of patent or SPC rights;
- (v) From a practical commercial perspective, RDP is usually only a significant form of protection where there is no effective patent protection, either because patents/SPCs have expired or because there are no patents (or they are invalid). In those cases, however, RDP is the only form of exclusivity which rewards the investment in the product development that has taken place; and
- (vi) Any improvements in formulation (such as the change from a twice-daily to a once-daily formulation) or crystal or salt form of an already existing product will not result in any new RDP period. This is notwithstanding the obligation on the innovator to generate a substantial additional data package for this innovation.

RDP is not a bar to generic entry. It is open to a generic to undertake the trials and testing necessary to prove that their product is safe and efficacious without needing to rely on the innovator's data. However, they generally do not do so.

5. **IPR is the Stimulus, not an Impediment to Competition**

Concerns have been expressed that patents, SPCs and RDP may hinder innovation. Some refer to “patent thickets”⁴⁴ and “bad patents.”⁴⁵ Despite the rhetoric, little evidence, particularly empirical evidence, is put forward to support such claims. On the contrary, EU patent law is designed to prevent patents from being a barrier to innovation.⁴⁶ The empirical evidence that does exist shows that these exclusive rights, limited in time, promote innovation and competition. This is because the exclusive rights which provide incentives for innovation prevent imitation, not innovation.

5.1 Patents Stimulate the Race to Innovate and Articulate the Boundaries of the Invention for Follow-On Competition

Patents stimulate the race to innovate. Companies compete to be first to develop the invention spurred by the knowledge that their investment is not wasted if they file first, but will be protected by patent rights.

⁴⁴ “Patent thicket” is an undefined term and is not recognised in European patent law.

⁴⁵ “Bad patents” is a term that is undefined and is not recognised in European patent law.

⁴⁶ For example, the research exemption and the “Bolar” exemption (the latter also facilitates generic competition).

Once granted, the patent must clearly articulate the invention and the rights granted. Follow on innovators benefit from disclosure of the invention and the academic literature surrounding it. In due course, after expiry of the patent, they can copy the invention and benefit from the innovator's efforts.

Potential imitators are clearly forewarned of the patent holder's rights and therefore of where they can lawfully concentrate their competitive efforts outside of the patent's claims. In this way, indeed, many generic companies have filed for their own patents in relation to the products of innovators, for example a new process for producing the innovator's basic substance.

5.2 The Reduced Period of Effective Protection

As the EC legislator has noted, the innovator's effective period of protection is limited:

"[T]he period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research."

It was for that reason the SPC Regulation extended patent protection, contemplating a potential maximum period of 15 years:

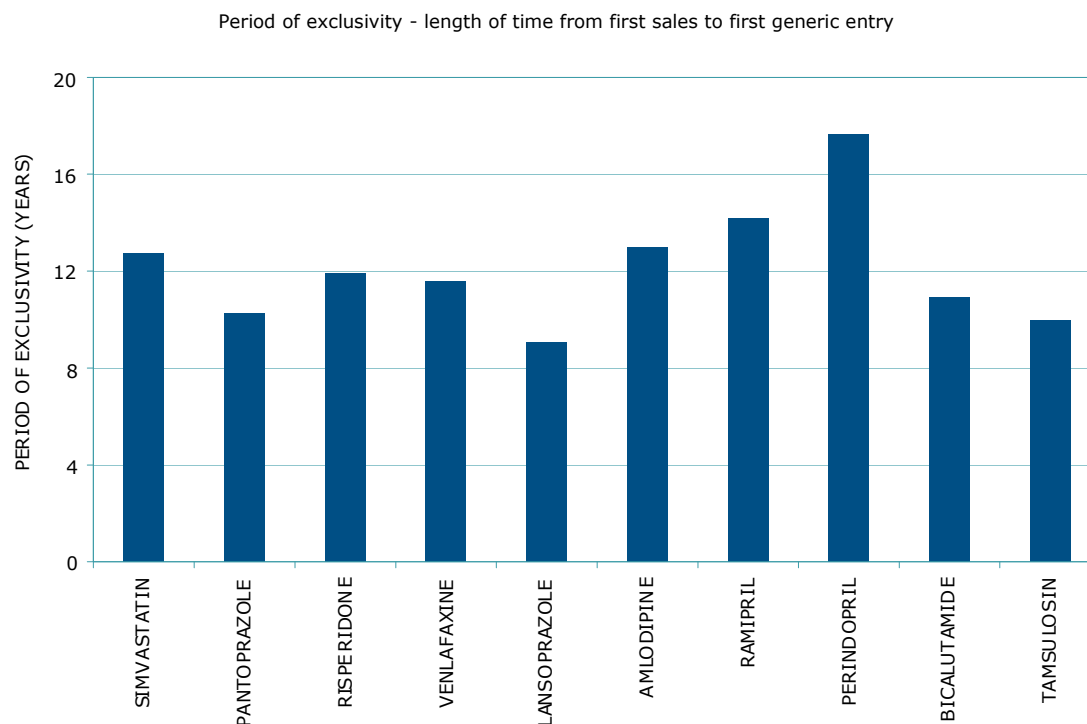
*"[T]he duration of the protection granted by the certificate should be such as to provide adequate effective protection. ... [F]or this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains authorization to be placed on the market in the Community."*⁴⁷

In fact, the evidence shows that even this reduced period, less than the 20 years traditionally envisaged for patent protection, is not achieved in practice. Figure 4 below shows, for the 10 highest value products in 2007, which lost protection during the period 2000-2006,⁴⁸ the duration of protection achieved by those products between first market authorisation in the EU and first generic entry (in any EU state). As may be seen, the periods in question are, in all but one case, less than 15 years, often substantially so.

⁴⁷ Recitals 3 and 8, Council Regulation 1768/92 concerning the creation of a supplementary protection certificate for medicinal products (as amended) [1992] OJ L 182/1.

⁴⁸ We used IMS Health's MIDAS database opinion on the expiry of protection for consistency. Expiry is a complex legal and factual matter. EFPIA members may not take the same view as IMS.

Figure 4: Period of Exclusivity before Generic Competition from First Innovator Sale to First Generic Sale in any of the EU 15, Switzerland and Norway for Top 10 2007 Products by Value Losing Exclusivity Between 2000-2006



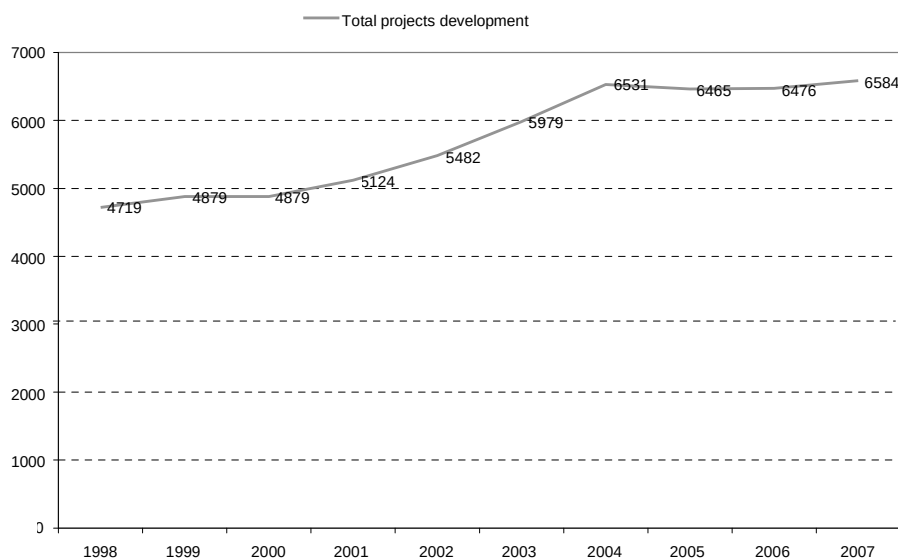
Source: IMS Health MIDAS Database. Note: excludes biologics and combinations

5.3 Data on Development of New Compounds Show no Barrier to Innovation

If, as is sometimes claimed, individual or multiple patents are inhibiting innovation in the pharmaceutical sector, one would expect that there would be few compounds being developed. But that is not the case. As Figure 5 below shows, the number of projects in development, despite the increasing costs discussed above, has increased over the past 10 years from 4,719 to 6,584.⁴⁹

⁴⁹ Adis R&D Insight Database, customized run (December 2007). Attrition in these projects means that an increasing number of projects does not necessarily mean an increasing number of new product launches.

Figure 5: Total number of projects in development



Source: Parexel's Biopharmaceutical R&D Sourcebook 2007-08 and PharmaProjects

5.4 Data Showing that Patents Promote a Race to Compete in Therapy Areas

It is rare to find a therapy area in which there is only one product⁵⁰. When an innovative therapy is launched, it will usually have to compete with existing therapies, whether patented or generic.

Because it is common for several groups of scientists to be working in the same therapy areas and using similar baseline knowledge, launch of an innovative product in one class is often followed by launch of others in the same class. For example, there are more than 15 beta blockers, 9 protease inhibitors, 15 NSAIDs and 10 statins available on the European market. Patents do not, therefore, inhibit development of multiple products in the same class. Indeed, were it not for the availability of effective patent protection, it is extremely unlikely that these multiple competing products would be developed.

These innovative products (both first in class and followers) will compete with each other for prescriptions as well as with any other pre-existing therapies. And each of these innovative products will in time become generic, and the remaining patented innovative products in a particular class will have to compete with newly generic versions in the same class as well as other older and newer therapies. The market is, therefore, highly competitive.

⁵⁰ HIV/AIDS is a recent example of a therapy area for which, some 20 years ago, there were no treatments. Following launch of the first anti-retroviral, many others came to market in a relatively short period of time.

This choice of different therapies is of enormous medical significance. Drugs in the same class differ in, among other things, their side effects and efficacy profiles, adverse drug reactions, drug-drug interactions, dosing schedules and delivery systems. The range of treatments is therefore of enormous benefit to patients. Different drugs will be more or less suitable for different patients. In some cases (such as HIV), the multiplicity of products is absolutely vital to overcome drug resistance (for example, as in the case of HIV, this can be caused by viral mutation).

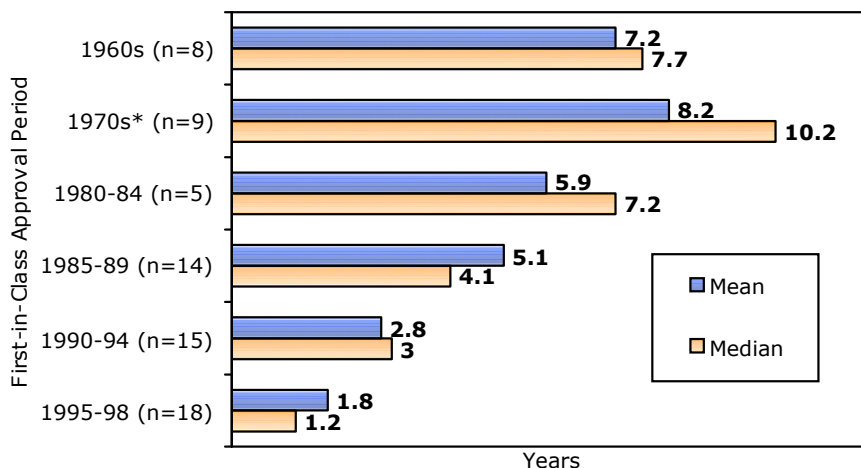
Not only is the innovative market highly competitive, but the speed at which competitive innovative entry occurs has increased significantly in the last 30 years. DiMasi et al⁵¹ examined data on the trends in the speed at which competitive entry has occurred, and concluded that entry barriers have fallen and that the marketplace was increasingly competitive⁵². They studied first-in-class and follow-on new drugs, defining a class as consisting of new drugs that had a similar chemical structure or the same pharmacological mode of action and that were used primarily for the same indications. This definition is of particular significance. If patents were a barrier to innovation, one would expect them to hinder the development of drugs with similar chemical structures and modes of action.

DiMasi studied 72 drug classes where the first-in-class was approved in the US from 1960 to 1998, and 235 follow-on new drugs that were approved in the US through 2003. Their data showed a very significant decline in the period during which a drug was the only member of its therapeutic class by mode of action since the 1970s, as shown in Figure 6 below. The median period fell progressively from a high of 10.2 years in the 1970s to 1.8 years in the period 1995-1998, showing that follow-on innovators with drugs with the same mode of action were quickly able to enter the same therapeutic class. In consequence, it seems clear that the follow-on innovators did not consider themselves impeded by the portfolios of the first-in-class. Indeed, as noted above, patent protection creates incentives necessary for a race by innovators to be the first to develop products to exploit a scientific discovery, knowing that their rivals may be pursuing parallel research.

⁵¹ The economics of follow on drug research and development – trends in entry rates and the timing of development; *Pharmacoeconomics* 2004, 22 Suppl. 2: 1-14.

⁵² Although DiMasi studied US data, there is no reason to suggest that their conclusions are not equally applicable to the EU.

Figure 6: Average Period Between Market Entry of First Drug in a Therapeutic Class and Entry of Class Followers (US Data)



Source: DiMasi, J., and Paquette, C. 2004 “*The Economics of Follow-on Drug Research and Development: Trends in Entry Rates and Timing of Development*”, *Pharmacoeconomics* 2004;22(2)1-14.

DiMasi also found that (i) 80% of the first-in-class drugs received an FDA priority rating (meaning that they addressed an unmet medical need),⁵³ (ii) nearly one-third of the follow-on drugs also received an FDA priority rating and 57% of all classes studied had at least one follow-on drug which received a priority rating, and (iii) nearly all of the follow-on drugs for classes where the first-in-class was approved in the 1990s had initially undergone pre-clinical testing and were in clinical testing before the first-in-class was approved. In their words, “[t]hese results suggest a development race for drugs in a new therapeutic class, rather than a scenario where firms engage in low risk imitation of a proven breakthrough.”

These data simply would not exist if patents were a barrier to innovation. Further, it is inconceivable that the multiple follow-on products identified would have been developed were it not for strong and effective patents.

It can therefore only be concluded that as a practical, evidence-based matter, patents do not impede innovation but play a key role in competitive innovation and in contributing to a competitive market.

⁵³ See <http://www.accessdata.fda.gov/scripts/cder/onctools/Accel.cfm>.

6. The Enforcement of Patents in Europe

Patent rights only extend to the territory in which they exist and last for 20 years from the date of filing⁵⁴. They provide, in the country concerned, the right to prevent third parties from manufacturing, selling, using and importing a product, or using a process or selling a product made by the process.⁵⁵ Patents are of little or no value unless they can be enforced.

The scope of the exclusive right is defined by the patent claims, which are numbered paragraphs at the end of the patent. It is the patent claims that set out the boundaries of the exclusive rights conferred by the patent, which can then be enforced in court. The claims are interpreted in light of the description and drawings of the patent⁵⁶. The claims must be clear and concise⁵⁷. The EPC provides that the protection of the patent should not be understood as confined to the strict literal meaning of the wording of the claims - nor should the claims be seen only as a guideline. Instead, the EPC seeks to provide a *“position between these two extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.”*⁵⁸

Because patents are nationally granted rights, they extend only to the countries for which they are granted. Any enforcement must occur in each relevant Member State⁵⁹.

6.1 The Need for Strong Patent Enforcement

The entry of generic products into a market swiftly and significantly erodes the income to the innovator. Once the period of regulatory data protection has expired, the only means by which an innovator can be protected against copying is to enforce its patent rights.

A single patent can be of enormous commercial value in each country (indeed, it is likely that individual patents in individual Member States are of more commercial value to a pharmaceutical company than in any other industry). Typically, sales of an innovative pharmaceutical product peak after expiry of the regulatory data protection period and the patent is thus of most value late in its life. Further, failure to enforce a patent in one

⁵⁴ See, for example, Article 63 of the European Patent Convention (“EPC”).

⁵⁵ See, for example, Article 28 of TRIPs.

⁵⁶ See, for example, Article 69 of the EPC.

⁵⁷ See, for example, Article 84 of the EPC.

⁵⁸ Protocol on the Interpretation of Article 69 of the EPC.

⁵⁹ Until fairly recently, some Member States granted cross-border injunctions whereby the courts of country A (e.g., the Netherlands) would order that infringement of corresponding other “parts” of the European patent (e.g., the UK part of a European patent) should cease. However, this practice (and the analogous “torpedo” practice, in which attempts were made by potential infringers to start national proceedings for revocation of declarations of non-infringement in one country in order to delay or prevent infringement proceedings in others) have, in essence, halted, following the decisions of the Community courts in Case C-4/03 *GAT v. LuK* [2006] ECR I-6509 and Case C-539/03 *Roche v. Primus* [2006] ECR I-6535.

country can have significant impact in others; for example, because of national pricing and reimbursement rules. For example, if a company were not to enforce a patent against a generic company in one Member State, this could force it to reduce its prices in that Member State. As has been acknowledged by the English courts⁶⁰, this in turn can lead to a reduction of the prices in other Member States, which use international price referencing to fix prices, causing significant damage to commercial operations in those other Member States. That is the case even if the equivalent national patents in those other Member States are successfully defended.

6.2 European Patent Enforcement at Member State Level

Differences in national judicial procedures (which can lead to substantial differences in how the case is heard, for example the length of trial, whether witnesses will be heard and cross-examined, and what kind of evidence will be admissible) and, in particular, divergent national judicial approaches to certain patent law issues (for example, the interpretation of claims and obviousness) can sometimes result in different conclusions on the question of whether the sale of a generic product infringes the different national parts of a European patent or whether the national patent is valid or not.

However, it seems that different conclusions on infringement or patentability among national courts are a rare occurrence. It has been estimated that no more than 5-10% of patents are litigated in more than one jurisdiction⁶¹, and not all of those will reach trial or result in apparently conflicting decisions⁶².

It should always be borne in mind that in seeking to enforce a patent, the patent owner or beneficiary is relying on a right provided by an expert body trained and empowered to reach a conclusion on patentability and to grant patents on behalf of European countries. Pharmaceutical companies, just like all other companies, have the right to assume that the granted patent is valid and that it is reasonable to assert the patent. By taking enforcement action, pharmaceutical and other companies are thus merely using judicial processes to determine whether their legal rights have been infringed and whether sales or other activities by the defendant are unlawful.

⁶⁰ See *Leo Pharma v Sandoz*, UK Patent Court, [2008] EHC 541, at paras. 36 and 37.

⁶¹ “Workload and cost of the European patent judiciary” EPO paper WPL/4/03, p. 8, http://www.european-patent-office.org/epo/epl/pdf/wpl_0304.pdf.

⁶² It is also possible for conflicting decisions to be reached between national courts and the EPO in the case where validity is being litigated in a national court, and the patent in question is being opposed in the EPO. However, the English Court of Appeal has recently stated that this is “*not a frequent occurrence*”, *Glaxo Group Ltd. v Genentech Inc.*, unreported decision of 31 January 2008. There is no reason to suppose that this is different in other Member States.

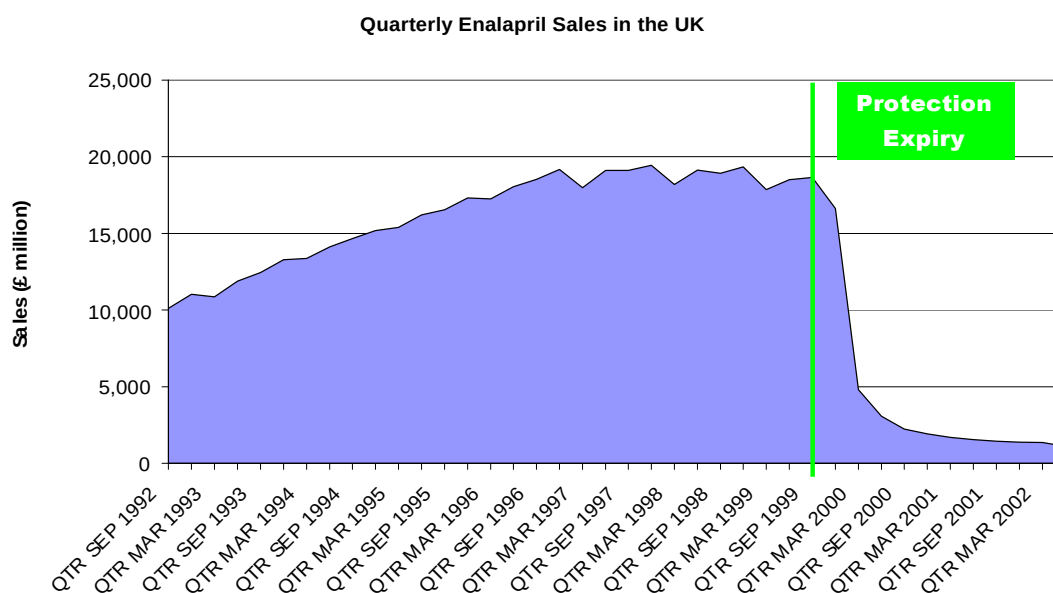
7. Pre-trial injunctions in pharmaceutical patent cases

7.1 The Need for Pre-Trial Injunctions

The report prepared by CRA⁶³ describes in detail the market impact of the launch of a generic product. It makes clear that the impact varies from country to country due to the interplay between various factors having nothing to do with intellectual property. Nevertheless, in terms of volume and value, the impact of generic launch on the sales of the innovative product can be very significant in a very short period of time.

The chart below is an example of the impact of generic launch on the innovator's sales of one product, Enalapril, in the UK. As can be seen, in the period Q3 1999 – Q1 2000, sales dropped by around 70%.

Figure 7: Impact of generic launch on innovator's sales - Enalapril



Source: IMS Health MIDAS Database (Retail Panel)

The time it takes generally to bring a patent case to trial (without any appeal) varies from nine to twelve months (in the UK and Germany) to up to four or more years (in Denmark), with most cases in most countries taking in the region of one to two years or more. As illustrated by the above example of Enalapril, if the patent owner has no

⁶³ CRA Generics Report, (Annex 5 to the EFPIA Submission).

opportunity to prevent sales of the infringing product until trial begins, it can suffer significant damage.

If the patent owner is successful at trial, it will typically be entitled to an injunction preventing future sales of the infringing product during the term of the patent, and compensation for the harm done in the interim period.

However, as a practical matter, in many cases neither the injunction nor any compensation payment order will have the effect of properly compensating the patent owner for the damage it has suffered by virtue of the infringement. There are a number of reasons for this, such as:

- (i) the patent may have expired by the time the case reaches trial. Any growth in the market which the pharmaceutical company might have achieved during the last months or years is lost;
- (ii) the types and measure of damages which will be awarded by a court varies from Member State to Member State⁶⁴, and some Member States will not regard certain types of actual damage that occur as being recoverable in legal proceedings⁶⁵. Also sales in one country can cause damage in another through the interplay of international price referencing and parallel trade⁶⁶;
- (iii) the damages that will be ordered by the Member State courts will often not reflect the patent owner's loss of profit, but will be calculated as a notional royalty which will be far less;⁶⁷
- (iv) where there are multiple generic products on the market, it may not be possible to determine with precision which generic has caused what degree of loss to the patent owner;

⁶⁴ This is recognised explicitly by paragraph 7 of the preamble of Directive 2004/48/EC on the enforcement of intellectual property rights. Although the objective of Directive 2004/48/EC is to “*approximate legislative systems so as to ensure a high, equivalent and homogeneous level of protection in the internal market*” (preamble, para. 10), as a practical matter, that will take some years to achieve.

⁶⁵ For example, if a generic product comes to the market it will often cause the price of the innovator product to be reduced either voluntarily, or through pricing and reimbursement schemes. If the generic product is ultimately found to infringe, the loss of profit caused by the reduction in price of the innovative product is clearly a direct result of that infringement. But it is open to significant doubt whether some Member States would allow recovery of these elements of damage.

⁶⁶ The fact that a lower-priced generic product is available pending trial in one country (e.g., the UK) can have effects on the price of the innovative product in another country (e.g., Spain) – see, for example, the case *Leo Pharma v Sandoz*, UK Patent Court, [2008] EHC 541 at paras 36 and 37.

⁶⁷ This appears often to be the case in at least Austria, Germany and Portugal – see *Patent litigation: Jurisdictional comparisons*, Calame & Sterpi (eds), European Lawyer Ltd, London (2006), pgs. 35, 133 and 277. Article 13 of Directive 2004/48/EC expressly refers to this.

- (v) market entry by the generic may have caused reimbursement prices to fall in a manner that cannot be reversed even if the generic product is removed from the market; and
- (vi) even if compensation which truly reflects the loss of profit caused by the infringer is ordered, the sums may be so large that the infringer - which may be a manufacturer or a distributor - is unable to pay.

Therefore, because the patent owner often cannot be adequately compensated for the damage caused by the presence on the market of one or more generic products in the period between the commencement of infringement proceedings and the trial of the action (which may occur years later), it will often have no realistic alternative to seeking a pre-trial injunction from preventing sale of the generic product until trial.⁶⁸

Therefore, in many cases the damage done by the generics will be irreparable. In contrast, the generic can be adequately protected by a cross-undertaking or security for damages. As stated, most recently, by the Düsseldorf Higher Regional Court:

“If [the originator] were referred to waiting for the appeal decision in the nullity proceedings, it would be likely – considering the length of time presently needed for nullity appeal cases – that a final judgment would only be rendered towards the end of the legal duration of the patent-in-suit. It would not have any more value for the remaining duration of several years because the [originator] would not be able to enforce its legally protected monopoly position, which weighs even more severely, since due to [generic’s] market entry (as well as that of other generics manufacturers) a dramatic price erosion is to be expected, as [the originator] will not be able to uphold its prices against those offered by cheaper generics companies (which are not as burdened with costs for development and approval as [the originator], being a researching pharma company).

This would amount to a denial of law that would be contrary to all the intentions of the German legislator and the European Union to strengthen claims for intellectual property, and in particular, the outstanding readiness for investments and risk-taking of research-oriented pharmaceutical producers that are actively involved in research. The patented invention is of particularly outstanding importance, having made great progress in the treatment of schizophrenia. It has been unequivocally acknowledged by experts all over and has also been recognized by all the other courts, except for the German Federal Patent Court.

The drawbacks to be asked of [the generic company] lie only in having to wait with the market introduction of its olanzapine generic until either the patent protection for the substance according to the invention has expired, or until the Federal Court of Justice is going to confirm its revocation by the Federal Patent

⁶⁸ The need for “measures for immediate termination of infringements before a decision on the merits, particularly where irreparable harm would otherwise be caused” is acknowledged in para. 22 of the preamble to Directive 2004/48/EC.

Court. It is sufficiently secured against the financial drawbacks arising thereby by damages according to § 945 Code of Civil Procedure, particularly since the Senate additionally decreed that [the originator company] shall provide a high security payment for securing this entitlement to damages before enforcement of this injunction.”⁶⁹

7.2 Pre-Trial Injunctions in Practice

(a) Lack of uniformity between Member States

There is no uniformity among Member States as to when pre-trial injunctions will and will not be granted,⁷⁰ which can lead to different courts giving different decisions in apparently identical cases. This can arise for many reasons, including:

- (i) the legal test for granting an injunction differs between Member States;
- (ii) the different civil litigation procedures in the Member States may mean that different courts have different evidence before them;
- (iii) the facts may be different. Different generic companies may be selling different products, for example. This impacts on infringement arguments; and
- (iv) even if the national patents and products are identical, other relevant facts may differ between Member States. For example, differences between the pricing and reimbursement rules of Member States, and the length of time it takes to bring a case to trial, can have a significant impact on the extent and nature of the harm that will be done to the patent owner if it does not obtain a pre-trial injunction and then succeeds at trial.

In many cases, because of this complex matrix of factors, even where a company considers significant and irreparable harm will occur prior to trial, they are advised that interim relief is unlikely to be available.

(b) Timing

Even if the remedy is available, obtaining the injunction expeditiously so as to be able to protect the value of the market for the innovator can be challenging.

⁶⁹ *Eli Lilly & Co. Limited / STADApharm GmbH*, Case 4 a O 247/07, Higher Regional Court Düsseldorf, 29 May 2008, part II, 3, e.

⁷⁰ This is acknowledged in para. 7 of the preamble to Directive 2004/48/EC.

(i) Delay in being able to bring proceedings

Although national laws are required to allow courts to prevent “imminent” infringements⁷¹, the application of this principle in the pharmaceutical patent area is problematic. The application for a marketing authorisation by a generic company is not usually publicly-available knowledge, and is not an act of patent infringement. Indeed, in many Member States in which there have been judicial decisions, even the fact that a marketing authorisation has been granted is not sufficient to allow proceedings for an actual or imminent patent infringement to be brought. In some Member States, even the act of applying for or obtaining pricing or reimbursement approval may not be enough to allow proceedings to be brought.⁷²

In other cases, the patent owner may need to obtain and analyse a product before he can assess whether there is patent infringement. This means that proceedings will not be possible until after the product is available on the market unless there is some form of pre-trial disclosure or investigation.⁷³

So, in effect, it will often not be possible for a patent owner to bring proceedings for infringement until just before or even after the generic product is sold or offered for sale on the market. The fact that the generic product is close to or even on the market can in itself influence a court to decide that the *status quo* should be maintained and sale of the product should be allowed to continue until trial.

(ii) Delay in obtaining a decision on a pre-trial injunction application

Although applications for pre-trial injunctions are of necessity confined to cases of urgency, there can be significant delays in the time it takes for an application to be heard, even after the proceedings have started. In many countries, delays of three months are common, although in some countries it can take significantly longer, particularly if the case is complicated. In Portugal, delays of nine to twelve months are not uncommon⁷⁴.

The delay not only has an impact on the market if the generic product has been launched, but can in some cases impact on the court’s decision, as it can be persuaded that it is correct to leave on the market a product that has been there for several months.

⁷¹ Article 9(1), Directive 2004/48/EC. This had been a principle in the laws of many Member States before the Directive was adopted.

⁷² Hungary is an example of this. Further, the grant of a generic price will not allow proceedings to be brought but will lead to a reduction of the price payable to the innovator even if the generic product has not been launched.

⁷³ For example, the pre-trial orders for seizure of product or evidence such as *saisie contrefaçon* (France) or *diligencias* (Spain).

⁷⁴ The President of the Commercial Court of Lisbon (where patent cases are heard) has described the workload of the Court as being so severe that the court is in a state of “*complete rupture*”; *Jornal de Negócios*, Quarta Folia, 9 April 2008, pgs. 24-25.

- (iii) Technical complexities can lead to a reluctance to grant patent pre-trial injunctions

Because of the technical complexity of the issues, some Member State courts are reluctant to grant pre-trial injunctions in patent cases, especially if it is clear that genuine issues as to infringement and validity exist. In all cases, it is necessary for the patent owner to establish at least an arguable case that the patent in question is infringed. In some cases, if a generic is able to raise even an arguable case of non-infringement or invalidity,⁷⁵ that alone can appear to be enough to defeat an application for a pre-trial injunction.⁷⁶

- (iv) National damages rules can favour refusal of a pre-trial injunction

As noted above, different Member States regard different types of damages as being recoverable or irrecoverable, and in some cases courts prefer to award damages based on notional royalties instead of loss of profit. Where the type or extent of damages awarded under national rules is relatively limited or can be easily calculated by a royalty based on the defendant's sales, it is far more difficult for a patent owner to establish that it will suffer irreparable harm if the infringement is allowed to continue until trial. This will often favour the accused infringer, because the need for irreparable harm is generally a pre-condition for grant of a pre-trial injunction.

- (v) Generic companies can take steps to obstruct proceedings, reducing the likelihood of a pre-trial injunction being granted

Steps can be taken by generic companies to reduce the likelihood of an injunction being granted, whatever damage might be caused in the period to trial. For example, in Hungary and Italy, if a generic company brings revocation proceedings before the patent owner brings infringement proceedings (which - as noted above - may not be possible until just before or after product launch), the prospects of obtaining a pre-trial injunction are significantly reduced. In Portugal, the risk of a pre-trial injunction can be significantly reduced simply by posting a bond or other guarantee for damages.

Other steps, which may well be legal, can be taken as "*a deliberate tactic*"⁷⁷ to try and obstruct the attempts of patent owners to stop the launch of infringing products. Although those steps may be legal, they should not influence whether pre-trial injunctions are granted.

⁷⁵ In some cases, generics claim that they have their own patent relating to the product in question. Although some courts have been sympathetic to this claim, it is clearly not a valid reason for asserting that another patent is not infringed.

⁷⁶ In the French and, until recently, in the German courts, if validity is put into question (as is usually the case), a preliminary injunction is unlikely to be granted unless the patent has been upheld in, for example, EPO opposition proceedings or, in the case of France, in the courts of a country such as Germany or the UK. In some cases, if the national part of a patent has been revoked by, for example, the courts of the UK or Germany, that will raise sufficient doubt as to its validity to make it impossible to obtain a preliminary injunction in other countries.

⁷⁷ See the case *Leo v Sandoz*, cited above at footnote 60.

7.3 The Consequences of a Pre-Trial Injunction

If a pre-trial injunction is granted, and the patent owner wins at trial, the infringer has no cause for complaint as it has merely been prevented from acting unlawfully.

However, if a pre-trial injunction is refused, the effect on the market is often devastating to the innovator and the damage is irreparable. It faces the prospect of not being adequately compensated even if it wins at trial. Indeed, there are cases in which the irrecoverable damage done in the period leading up to the trial means that there is no commercial advantage to be gained by pursuing a case. This type of financial analysis may result in a patent owner being advised by experts that it is unlikely to obtain a pre-trial injunction, so it does not even bring an infringement proceeding, or a patent owner failing to obtain a pre-trial injunction, and subsequently settling or even withdrawing a case which it would otherwise have taken to trial.

If a pre-trial injunction is granted but the patent owner fails to establish its case at trial, the defendant can argue that it has wrongly been prevented from trading in the period to trial. It is as a result of this that it is common practice in the Member States to require that a patent owner seeking a pre-trial injunction guarantees that it will compensate the defendant for any loss it may suffer should the patent owner not succeed at trial⁷⁸ (and in some countries such guarantees can be required to be reinforced by provision of a bond or bank guarantee). Generic companies therefore have commercial protection if a pre-trial injunction was granted.⁷⁹

7.4 Pre-Trial Injunctions are a Necessary But Insufficiently Applied Means of Protecting Against Patent Infringements

As illustrated above, because of the nature and extent of damage that can be caused in the period between the launch of a generic product and trial, pre-trial injunctions are an essential tool to protect against the consequences of patent infringement. Indeed, without the protection of a pre-trial injunction, there may be no commercial point in launching - or continuing - infringement proceedings.

It is therefore essential in the pharmaceutical sector for a patent owner to be able to seek pre-trial injunctive relief. If it has no arguable case, the action can be dismissed. On the other hand, if it has an arguable case, the balance of competing interests and consequences should favour granting a pre-trial injunction. One of the biggest hurdles, however, remains the unjustified reluctance of many Member State courts to grant injunctions in patent cases.

⁷⁸ This is explicitly contemplated by Article 1(a) of Directive 2004/48EC.

⁷⁹ *Eli Lilly & Co. Limited / STADapharm GmbH*, Case 4 a O 247/07, Higher Regional Court Düsseldorf, 29 May 2008, part II, 3, e.

8. Avoiding Infringement Suits by Taking Early Action to “Clear the Path”

It is sometimes alleged that it is somehow “unfair” that generic companies launch products at risk of being sued for patent infringement and of being subject to pre-trial injunctions. Such fears are unfounded. There are legal means by which a generic (or any other) company can avoid the risk of litigation.

8.1 EPO Opposition Proceedings

Any patent granted by the EPO can be “opposed” within 9 months of grant on the grounds, essentially, that it should not have been granted⁸⁰. Approximately 4-5% of patents granted by the EPO are opposed⁸¹. The opposition and appeal procedures together take generally 4-6 years (and sometimes much longer, particularly in cases of multiple opponents).

If contested, the opposition will involve an exchange of evidence and arguments and will be followed by a decision which has effect in all EPC member states. The decision may be to:

- (i) maintain the patent in the form in which it was granted; or
- (ii) maintain the patent in an amended form; or
- (iii) revoke the patent⁸².

Oppositions between innovative companies are not uncommon. They can prove to be a very useful tool for determining the scope of third party patent rights relevant to research projects. Oppositions can be useful too in relation to patents which are granted relatively late in the product lifecycle. Generic companies will be able to identify these patents and if, having assessed them they think they are likely to be relevant to their commercial plans, either design around them (thus avoiding infringement) or oppose them. By way of illustration, Teva currently has 51 active oppositions ongoing.

8.2 National Revocation Actions

A generic company concerned as to whether it will be sued for patent infringement can also seek revocation of the national patent. This step is available in almost all Member States and can be taken even if the patent in question has been subject to opposition

⁸⁰ See Articles 99 – 100 of the EPC 2000.

⁸¹ See EPO Annual Report 2006, pgs. 98–99, at [http://documents.epo.org/projects/babylon/eponet.nsf/0/82162336C20C094BC12572F9003C3188/\\$File/entwicklung_zahlen_split.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/82162336C20C094BC12572F9003C3188/$File/entwicklung_zahlen_split.pdf)

⁸² As a generality, one third of those patents that are opposed are maintained as granted, one third are amended and one third are revoked. In 2006, 62,780 European patents were granted, and 2,641 decisions in opposition cases were rendered by the EPO (see EPO Annual Report 2006, pg. 19).

proceedings in the EPO. National revocations often happen because (i) the evidence before the Court is different to that before the patent office, for example because the challenger has brought additional evidence, and there is a greater reliance on the parties' expert witnesses and/or court appointed experts, and (ii) case-law in national proceedings sometimes differs from the case-law and approach of the EPO.

Depending on the Member State concerned, the action can be brought in either the national patent office or the courts. Extensive analysis of the validity of patents is commonly undertaken in Germany and the UK, two of the major pharmaceuticals markets and also common venues for patent litigation. A successful action will result in the patent being revoked for that Member State⁸³. If that happens, the generic product can be launched in that country without fear of patent infringement proceedings.

8.3 Declaratory Actions on the Question of Infringement

Nearly all Member States⁸⁴ allow a party, in advance of selling a product, to seek a court determination on whether the sale of that product would constitute patent infringement. In some countries (for example the UK), the question of the validity of the patent can be raised in the same proceedings. By using this procedure, a company can determine ahead of launch whether it is free to sell the product.⁸⁵

8.4 "Clearing the Path" in Practice

There are therefore at least three ways for a generic company to minimise the risk of wasted development of a product and of liability for patent infringement arising from its launch by "clearing the path". These are judicial proceedings created as tools to minimise risk. This is something that is happening more frequently, proving that there are significant benefits to such an approach.

The courts are beginning to refer to such proceedings in the United Kingdom. In several cases⁸⁶, the fact the generic companies have not taken steps to clear the path has influenced the court to grant a pre-trial injunction or a pre-trial order requiring the disclosure of information as to the distribution of the allegedly infringing product.

⁸³ The decisions of some Member State courts may be very influential in others.

⁸⁴ For example, Austria, Belgium, Denmark, Finland, France, Germany, Italy, Ireland, the Netherlands, Portugal, Spain, Sweden and the UK.

⁸⁵ For various reasons, it may not always be possible to reach a final determination of whether a defined product will infringe a patent as early as a generic company might wish. However, it will always be as possible for a generic company to launch an early action seeking a judicial ruling on whether a defined product will infringe, as it will be for a patent owner to sue for actual or imminent infringement.

⁸⁶ See, for example, cases *SmithKline Beecham v Apotex* [2003] FSR 524, *Laboratoires Servier v KRKA* [2006] EWHC 2453, *Leo v Sandoz* (cited at footnote 60 above), and *Eli Lilly v Neopharma* [2008] EWHC 415.

The following words of Mr Justice Jacob in the *SKB v Apotex* case⁸⁷ are instructive:

“The defendants have known for a long time about this patent. You would have to be very naïve in the pharmaceutical industry to think that the patentee, with a product as important as this would not, if it had anything other than a frivolous chance of success, take action. So the defendants knew, when they set out upon this project in 1997, that if the patentees could cause trouble they would.

The defendants could, so soon as they settled upon the product they were intending to sell, have launched a petition for the revocation of the patent and started a claim for a declaration of non-infringement. Or, since there are certain difficulties with the latter (for example onus of proof goes the other way round), they could simply have said to the patentees, “We intend (we are not saying when but it is a settled intention) to launch our product within the next five years. If you intend to sue us, sue us now.” If they had taken such a course, having settled upon the product they intended to sell, the whole of this dispute would have been got out of the way before their date of intended launch.

It is purely commercial common sense. If there may be an obstacle in your way, clear it out It was something that could have been avoided by the defendants; they chose not to do it.

Where litigation is bound to ensue if the defendant introduces his product he can avoid all the problems of an interlocutory injunction if he clears the way first. That is what the procedures for revocation and declaration of non-infringement are for.”

Although these words were written in the context of whether a pre-trial injunction should be granted, they apply with equal force to those who claim they are put at undue risk of infringement proceedings if they launch a product. It is not true: means exist that allow them to clear the path.

Despite this, some have argued that patent owners bring patent infringement cases which are so frivolous that a generic company could not have reasonably foreseen that a case would be brought and could therefore not have taken steps to clear the path. By definition this is not true, because patent proprietors are fully justified in concluding that a patent that is granted by the EPO is valid and enforceable⁸⁸.

The fact is that there are very few cases where issues of patent infringement and validity can be deemed frivolous, as they are based on a patent granted by a trained experienced

⁸⁷ *SmithKline Beecham v Apotex* [2003] FSR 524, p. 542 *et seq.*

⁸⁸ Furthermore, there is no reason why a frivolous or unfounded case cannot be quickly rejected by the court concerned. In the case *Leo v Sandoz* cited at footnote 60 above, the defendant argued in the context of an application for a pre-trial injunction that there was no arguable case on infringement. The judge said that: “[If the defendant’s argument is correct], it ought to be a short matter for experts so to opine and a matter for summary judgment if it is that easy”, para. 28.

body authorized to do so. Most cases are dependent on determination of questions of fact, law and a mixture of fact and law. In nearly all cases, each party has an arguable case, and if it does not, procedures exist at national level to dispose of the case quickly. Indeed, this is well recognised judicially. As the court concluded in the case *Leo v Sandoz*⁸⁹, in response to the defendant's argument that there was no arguable case on infringement and so no pre-trial injunction should be granted:

"[If the defendant's argument is correct], it ought to be a short matter for experts so to opine and a matter for summary judgment if it is that easy."

A patent owner whose patent has been substantively examined by one of the best patent offices in the world should be able to test arguable cases before judicial authorities. It is a principle of Community law that in principle the bringing of an action, which is the expression of the fundamental right of access to a judge, cannot be characterised as an abuse unless an undertaking in a dominant position brings an action one of the features of which is that it cannot reasonably be considered as an attempt to establish its rights.⁹⁰ Patent infringement cases which cannot be disposed of on grounds that there is no arguable case are a reasonable attempt to establish the rights of the patent owner and cannot therefore constitute an abuse of a dominant position. Indeed, in circumstances where the judicial system itself provides a quick and efficacious remedy in relation to claims which have no arguable basis, antitrust intervention is unwarranted.

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⁸⁹ Cited above at footnote 60, at para. 28.

⁹⁰ Case T-111/96, *ITT Promedia NV v. Commission* [1998] ECR-II 2937, para. 30.