



Intellectual Property Frontiers

Expanding the Borders of Discussion

A Stockholm Network Publication

Edited by Anne K. Jensen and Meir Perez Pugatch

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Introduction: About the Stockholm Network IP and Competition Programme and this Publication

The Stockholm Network Intellectual Property and Competition Programme was established in January 2005.

By dealing with the field of intellectual property (IP) across the board (including in the monthly bulletin – Know-IP™), the Stockholm Network aims to achieve three key objectives:

First, to make the field of intellectual property more mainstream and accessible to the general public. It seems that currently the field of intellectual property, despite having huge economic, social and political implications for the public as a whole, is considered esoteric, technical and to some extent 'grey'. This gap should be bridged.

Second, to increase the interaction between specialists focusing on different aspects of intellectual property rights (IPRs). A positive effect of the growing importance and impact of the IP field is professionalism and specialisation. This however also leads to an undesirable detachment between different elements and themes of IP, which are becoming increasingly 'divorced' from each other. For example, copyright, patent and trademark specialists, as well as those dealing with the legal, economic and political aspects of IPRs, seem to operate on parallel tracks. A more interactive debate between IP specialists will help us to obtain more comprehensive and up-to-date information about developments in the IP field as a whole.

Finally, and perhaps most importantly, the Stockholm Network IP and Competition Programme aims to encourage discussion, as well as debate, on different burning IP issues. However, such discussions should be as informed as possible. We aim neither to idolise IPRs, nor to demonise them. Rather it is important to see IPRs as a policy toolbox aimed at achieving two social goals: to provide incentives to innovate and develop new knowledge and informational products in the future and to ensure wide public access to such products in the present.

IP is becoming one of the most influential and controversial issues in today's knowledge-based society. The rapid and growing interest in IP reflects the political, economic, legal and moral challenges that characterise this field.

At the macro level, IP affects a wide range of issues, such as international trade, enforcement, foreign direct investments, technology transfer, innovation climates, and competition and rules.

At the micro level, IPRs are strongly embedded in contemporary business models. IP is becoming increasingly critical to the evaluation of intangible assets, the protection and managements of knowledge assets, and to the business strategies of knowledge-based industries and companies, both big and small (SMEs).

In Europe, IP policies and specific forms of IPRs are rapidly capturing the attention of policy makers and the public as a whole. They

touch upon some fundamental issues, such as intra-EU harmonisation, its innovation climate, antitrust and competition rules, and the EU's ability to support specific sectors, such as the pharmaceutical sector; the biotechnology sector and the information technology sector. Moreover, IPRs are also strongly linked to the future ambitions of the EU region. In 2000, European Heads of State established the strategic goal for the EU of becoming the most competitive and dynamic knowledge-based economy in the world by 2010. Innovation was recognised as the key to the success of this strategy, which today is commonly referred to as the Lisbon Strategy or Agenda (depending upon how optimistically one chooses to treat it). However, six years later the EU has yet to produce the anticipated outcome. Different indicators suggest that the innovation gaps between the EU, the US and Japan have not been narrowed and has possibly even increased, especially with regard to patenting activities (see European Innovation Scoreboard (EIS) report for 2004)¹. In this context it is worth noting the November 2004 report of the High Level Group which was asked to conclude about the progress of the Lisbon Strategy:²

'Companies will only invest in innovation and R & D if they have the certainty that they will be able to reap the rewards of that investment. An essential prerequisite for this is a legal framework for the protection of intellectual property rights that is accessible at low cost to Europe's SMEs and academic institutions – something which is manifestly not the case at present.'

But, since the design and execution of different policies in the IP field is far from an easy task, and since the relative importance of IPRs is growing exponentially, there is an urgent need to discuss and debate the various issues and elements concerning the process of IP-policy making.

That is the purpose of this publication!

The publication exposes readers to some of the central issues, as well as dilemmas, currently taking place in the IP field. This is done by way of providing contributed articles from eighteen distinguished scholars, policymakers and practitioners.

In terms of structure, the publication is divided into four sections: (1) the role of IP in the business arena; (2) IP dilemmas; (3) global issues; (4) the European perspective.

We hope that the publication will allow readers to familiarise themselves with the diversity of themes and discussions that are currently taking place in the IP domain. Given its wide scope and rich contents this

publication can also benefit experts in the field of IP, especially those interested in being exposed to some specific IP themes that are outside the scope of their day-to-day activities.

We hope you enjoy it.
The editors.

End Notes

¹ European Commission, *European Innovation Scoreboard 2004 – Comparative Analysis of Innovation Performance* (Brussels: 19 November 2004), Sec 2004(1475)

² European Commission, *Facing the Challenge – The Lisbon Strategy for Growth and Employment*, Report of the High Level Group, Chaired by Wim Kok (Luxembourg: European Commission November 2004), p. 22



The Role of Intellectual Property in the Business Arena

The Role of IPRs in Promoting Innovations

Federico Etro

Since the work of the Austrian economist Joseph Schumpeter, economic research has repeatedly emphasised the positive relation linking patents to investments in innovation and these investments to technological progress and growth. In high-tech sectors (think of hardware, software, pharmaceuticals, biotechnologies,...) firms compete mainly by innovating. This is possible as long as there are well defined intellectual property rights (IPRs), and especially patents, defending innovations and investments, which are ultimately what leads technological progress in our economies.

Even if most economists are used to thinking about market leaders as firms with weaker incentives to invest in research & development (R&D), recent theoretical and empirical research has shown that market leaders play a crucial role in the innovation sector for competitive markets (see for instance: Kresimir Zigic et al., 2005, Innovation, R&D Spillovers and Persistence of Monopoly). Market leaders invest a lot in R&D: in 2000 Microsoft spent more than 16 % of its turnover, Intel spent 11.5 %, Motorola 11.8 %, Nokia 8.5 %, IBM, Hewlett Packard and Xerox between 5 and 6 %. The fact that these companies are pushing forward the technological frontiers in their respective industries is not a sign of a monopolistic position in the traditional sense, but the result of their investments and of the competitive threat deriving from other firms and potential new market entrants. Theoretical research in the *New Industrial Organization* (the industrial economics and policy for the New Economy) has recently clarified the mechanics of these results (Federico Etro, 2006, *Aggressive Leaders*, *Rand Journal of Economics*). In a sense, patents drive competition through innovation in these markets and induce technological progress led by market leaders.

The role of IPRs in promoting innovation can be illustrated with an old argument by William Nordhaus. In general, the argument says that patents create a temporary monopolistic power for the innovators, which creates price

distortions and hence a social cost. But they also create incentives for many firms to invest and try to gain market leadership, and these investments lead to social benefits through technological progress and growth. Clearly, social benefits and costs can be different for different inventions and for different fields of technology. For simplicity and in order to avoid discrimination between fields of technology, patents have typically a uniform length. Nevertheless, from a strictly economic point of view one may question such a uniformity and evaluate the advantages of different levels of protection in different sectors (at least this could avoid having to choose between a complete exclusion of certain innovations from patentability, rather than allowing a more limited protection). More importantly, an evaluation of the social benefits and costs of patents for different fields is essential in judging the net benefit of a patent system.

Let us consider an example concerning the pharmaceutical sector, where the role of patents in new drugs is, to say the least, the basis of competition in the market and for scientific progress in the world. These kinds of patents have often been criticised for jeopardising health defence around the world and especially in developing countries, where Western drugs are very important but very expensive: in other words the social cost of patents on drugs can be high. Nevertheless, one should not forget that those same patents

induced many firms to invest and some of them to invent new drugs which are now available, something that would not have happened otherwise. In other words the social benefit of patents on drugs is very high. Fortunately there are ways to reduce the problems related to the pricing of drugs and their adoption depend mostly on the public sector. For instance, governments can buy drugs and distribute them at lower prices through the medical system, or just pay part of the prices. They may even directly buy the same patents from the innovators, produce the drugs (or outsource their production) and sell them at lower prices. Finally, Western governments could redirect their international aid toward similar initiatives in favour of developing countries. These solutions, widely discussed in the economic literature, may preserve the proper incentives to invest and discover new drugs while spreading their effects globally. Ultimately, this suggests that patents in the pharmaceutical sectors are a crucial determinant of innovations and should be enforced while finding alternative solutions to guarantee health defence for poor people and poor countries.

Consider now another example which is essentially related to the New Economy and the main kind of research which underlies it: that concerning computer based innovations. This is also topical, as the European Union recently tried to complete a process of harmonising the patent system for computer-implemented inventions, with the aim of providing proper incentives to invest and innovate in the New Economy. A similar process was initiated and realised in the United States in the 80s. After a long procedure, the Common Position adopted by the European Council in March 2005 proposed the patentability of computer implemented innovations when they provide a technical contribution to a field of technology. The proposal simply reaffirmed the requirements already used in Europe for the last two decades, and excluded from patentability pure software, business methods and consulting practices (which are patentable in the US). Parts of the European Parliament proposed a number of amendments aimed at radically changing the current situation, which excludes most of the innovations in the Information and Communication Technology from patentability. As a consequence of the confusing situation, the European Parliament ended up rejecting the Directive in July 2005. While this resulted in the EU not introducing unfortunate restrictions on patentability, there is still a need for deeper harmonisation of the European patent system (not just for computer based ones, but for all fields since each Member State still has its own patent system!) and the debate is likely to continue in the near future.

Notice that the rationale for patents on computer based innovations is quite strong. While the main social gain from patents on

Protecting IPRs is necessary to properly promote innovations, but an optimal patent system should trade-off social benefits and costs.

IPRs

computer based innovations is to promote innovation in the most dynamic sectors, the social cost, traditionally associated with market power of patentholders, is smaller than for other patents since the competition in these sectors mainly works through frequent price-reducing and quality-improving innovations. By neglecting these traditional economic insights, opponents of the patent system have often claimed that patents stifle innovation. Even the American experience (addressed by James Bessen) often used to support this view, illustrates that this is not the case. The extension of patent protection to software related inventions started in 1980 (the first patent of this kind was granted by the US Patent and Trademark Office in 1981) and it was associated with a clear increase in R&D investment during the eighties. The R&D/sales ratio for US firms innovating in computer technology, telecommunications and electronic components (the relevant field here) increased from 5.5% to above 8% in 1989. The people working against patentability did not compare investment in computer based innovations with investment in other technologies and did not take into account other (macroeconomic or sector-specific) factors, hence there is no rigorous econometric evidence against patents, which could be drawn from the American experience. Nevertheless a misleading interpretation of this research has created a lot of confusion in the debate.

These examples and the economic research underlying them allow us to draw a number of conclusions and suggestions for the future debate on rules for high-tech patents, with particular reference to the European debate:

1) Protecting IPRs is necessary to properly promote innovations, but an optimal patent system should trade-off social benefits and costs, eventually enforcing more IPRs in those fields, such as the New Economy, where the net benefits of patents are higher or those fields, like the pharmaceutical sector, where social benefits are higher and there are proper policies that can reduce the social costs.

2) Restrictions on the patentability of innovations in high-tech sectors for one country or a group of countries could severely jeopardise investment in innovation and technological progress in the leading high-tech sectors, with negative consequences on growth and competition in the global economy. This will inevitably shift investments towards other countries where IPRs are better protected.

3) Limitations to the enforcement of the current patent system would open doors to foreign low-cost productions which, without patent protection, would be free to imitate even high-tech production, with negative consequences on employment and innovative firms.

4) Improvements to the effectiveness of the current patent systems should rather promote

access to patents especially for small and medium sized enterprises (SMEs), which are traditionally less able to exploit this opportunity (in this sense, it would be helpful to establish institutional ways to provide financial, technical and administrative support to SMEs dealing with patents).

5) Enhancement of the spillovers created by the patent system on the diffusion of knowledge could be obtained through further requirements on a disclosure of the patented invention, which should be sufficiently clear and complete to be carried out by a person skilled in the art.

Biography

Dr Federico Etro is Professor of Political Economy at the University of Milan (UCSC) and President of INTERTIC, an international think-tank focusing on innovation and competition. He is an expert in industrial policy and macroeconomic issues, with publications in the leading journals of economics such as *The American Economic Review*, *The Economic Journal*, *Rand Journal of Economics*, and others. Etro studied at UCLA and Harvard University and previously taught at Luiss University, Rome. He has been a consultant for the Ministry of Economy of Italy and for major international financial institutions and is currently Director of Etro Consulting Group, a company for economic consulting focused on industrial and antitrust issues.

IPRs and Knowledge-Based Companies

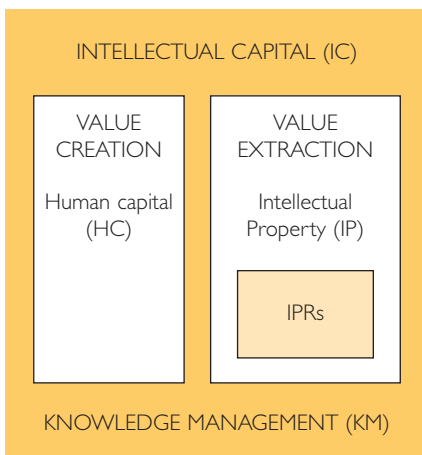
Geoff Gregson

This article examines the creation and strategic use of intellectual property rights (IPRs) for knowledge-based companies. The article describes the creation of IP and IPRs in a knowledge-based company, and then discusses the importance of an IPR strategy for companies and its key elements.

The shift towards knowledge-based industries has placed increasing importance on intellectual property (IP) and intellectual property rights (IPRs) for many companies competing in these industries. In turn, knowledge-based companies are challenged to clearly understand and articulate the role of IP and IPRs as a core strategic function and integral element of their commercial activities.

Companies should be able to first articulate in basic terms how they generate their IP. Figure 1 suggests that the foundational element of IP is *intellectual capital* – defined as new ideas and knowledge generated from the efforts of various sources of *human capital* within the company. Simply put, people usually create the source of potentially valuable knowledge that may be used by a company to generate IP.

Figure 1: IP and IPR Generation within the Knowledge-based Company¹



Most new knowledge generated within a company remains informal and 'intangible', in that its value and use cannot easily be measured or captured. Some new knowledge creates value that becomes formalised in new company routines, procedures or practices. Other knowledge is characterised by its inventiveness, usability, uniqueness and novelty; key traits that identify IP. If IP fulfils the necessary legal criteria, the company is able to generate a particular IPR.

In general terms, an IPR provides a company with a codified, protected and transferable IP

asset that can be exploited by the company itself, licensed to others to exploit or used to generate new partnerships and joint licensing arrangements with suitable partners. A key objective of IPR exploitation and a primary measure of its value is the generation of economic returns for the company.

Figure 1 suggests that creating IP is different from extracting value from it. While IP may emerge in the form of an invention, technology or design that is clearly tangible, the potential value of the IP and the decision to protect it may depend on whether or not there exists a clearly articulated role for IP that is integrated into strategy and commercial activities of the company.

Knowledge management (KM) activities, that may occur within a company and be organised for IP creation are identified in Figure 1. A key objective of many KM initiatives is to renew and maximise the 'company-wide' value of intellectual capital as it develops and to formalise the use of certain knowledge for commercial and operational activities.

Although some companies may include an IPR strategy as part of an overall KM strategy, it is suggested here that a company should have a definitive IPR strategy that focuses on the *value extraction* activities for IP.

IPR Strategy and Commercial Practice

While the importance of IPRs for knowledge-based companies will vary, even a simple IPR strategy is suggested for small companies. Knowledge-based companies, large or small, are challenged not only by the successful creation, aggregation and ongoing generation of new knowledge, IP and IPRs, but often by the need to rapidly exploit them and protect them in a competitive marketplace. At a minimum, a company should be aware of the particular legal benefits of protecting its IPRs, which may include both the protection of its existing products in the market and potential new products about to enter the market.

An IPR strategy should contribute a number of important benefits to a knowledge-based company. An IPR strategy should make explicit the role of IPRs in the company, including the guiding principles of IPR identification, protection, management and exploitation and the justification for and characteristics of existing company IP and IPRs (i.e. patents, trade marks, copyrights, trade secrets). An IPR strategy should also identify the use of IPRs by competitors in the company's immediate market, so that competitors' IPRs are known and respected while the company enforces and protects its own IPRs.

An IPR strategy should articulate the strategic options for the company's IPRs. Companies need to consider the proper 'mix' of IPRs to successfully compete in their market, since an integration of features and benefits of different IPRs into commercial practice can provide significant competitive advantages. For

example, trade secrets can provide natural lead times against competitors while trade marks can link the quality and features of a product and create a distinctive market reputation for the company. A company may also use an IPR to enter into cross-licensing arrangements in order to protect or strengthen their position in a competitive market.

For companies exploiting an IPR through a product, IPRs allow a level of market exclusivity that is most likely based on an improvement on function from competing or substitute products rather than a 'disruption' on function. Nevertheless, IPRs can position a company's technology firmly in a competitive marketplace and make it difficult for competitors to replicate, imitate or in some cases, design around.

One example is Gillette Corporation and its 'Sensor' shaver developed in the late 1980s that is protected by 22 patents. The patents protect the design and function of the Sensor's independently mounted twin blades. On its introduction into the market, the Sensor generated a closer shave than any competitor product by adjusting the blades to the contours of a man's face. The Sensor's introduction into the market in 1989 allowed Gillette to increase its market share in a highly competitive U.S. razor blade market by 6%.²

An IPR strategy may not only provide a significant revenue stream but can also generate new commercial practices that benefit knowledge-based companies. One example involves Texas Instruments (TI), a company that currently earns approximately US\$800 million annually from patent licensing royalties.³ TI's strategy also includes identifying and acquiring companies with 'underused' patents that complement their existing patent portfolio. To support its IPR strategy, TI undergoes continuous in-depth technical analysis of their patent portfolio using a separate partner company – Semiconductor Insights – leaving TI to focus on its core business as one of the world's leading semiconductor companies.

It should be recognised that markets for IPRs can be subject to failure because of uncertainty within the company over the value of an IPR and its potential contribution to a successful knowledge-based product.⁴ IPR value will often change as IP is further developed, market needs are better understood and further commercial resources are determined and committed. Even when IPRs offer significant protection from imitation or replicability, the characteristics of the IP, complementary assets supporting the IP, its performance in comparison to competitive products and its pricing will influence the level of economic return.

In this regard, an IPR strategy should make explicit how IP forms the basis for a marketable product and how the legal

Knowledge-based companies are challenged to clearly understand and articulate the role of IP and IPRs as a core strategic function and integral element of their commercial activities.

monopoly of the IPR – the exclusivity and time for the company to successfully develop the IP – will allow the company to recover any development costs and generate profits. While it is well accepted that monopoly rights are critical for companies competing in sectors such as pharmaceuticals, biotechnology and chemicals, the use of these rights should be explicit in any IPR strategy.

An IPR strategy needs to make explicit the links between company IPRs, the market uses of these IPRs and the company's commercial practices. Commercial practice is a balancing act between the market for a product protected by an IPR and the company resources and capabilities to apply the IPR to market needs. Undertaking the protection of IP and exploitation of an IPR for market use usually occurs only if favourable market conditions are present that ensure a profitable economic return to the company.

Linking IPR strategy with commercial practice requires identification of the capabilities and resources necessary to develop IP and support an IPR. The nature of the IP, its benefits to end users and accurate market assessment are among the factors that will determine the company capabilities required for appropriate IP development. In this regard, an IPR strategy may identify the need to undertake collaboration to solve challenging technological problems facing a company's development of its IP.

One example of IP collaboration is between Texas Instruments (TI) and INRIA (France's national institute for research in computer science and control) to create a Java execution environment for multimedia applications on future mobile terminals.⁵ TI sought the fundamental and applied research expertise in information and communication science and technology (ICST) offered by INRIA that it did not possess. Several joint patents and software packages have been

developed and are registered in co-ownership, benefiting both collaborative partners and strengthening TI's position in its market.

IPR support could include those operational, managerial, manufacturing and marketing capabilities that are related to leveraging the IPR and providing the company with sufficient reach and power in the market. Factors such as learning curve advantages and learning-by-doing will be critical for developing more complex IPRs such as industrial patents, while marketing efforts may be more critical for consumer-based IPRs such as trademarks.

Finally, an IPR strategy should include an ongoing evaluation and assessment of the use and role of IPRs – their value and competitive significance – in the context of changes to a company's internal commercial and/or external market environments. For companies competing in IP-intensive industries, an IPR strategy is critical in protecting IP related investments, leveraging IPRs for economic returns and facilitating sound and timely strategic decisions under dynamic and often unforeseen market conditions.

Biography

Dr Geoff Gregson is a Lecturer in Innovation and Entrepreneurship, Centre for Entrepreneurship Research at Edinburgh University and a member of the AHRC Centre for Studies in Intellectual Property and Technology Law at the Edinburgh Law School. He is also an AIM Scholar (Advanced Institute of Management), the UK's leading business research forum based at London Business School. His research focuses on creation and development of intellectual assets, intellectual property (IP) and IP rights in university spin-outs and new technology-based firms (NTBFs), public and private sector roles in exploiting university patents, regional effects on NTBF growth and systems of innovation, science policy and market intervention programmes.

End Notes

- 1 Adapted from Harrison, S. and Sullivan, P.H. (2000) 'Profiting from Intellectual Capital: Learning from Leading Companies', *Journal of Intellectual Capital* 1 (1): p. 35.
- 2 *Business Week* (2003) Design for Ongoing Revenue Streams, May 9.
- 3 *Harvard Business Review*, January (2000).
- 4 Maskus, K. E. and Reichman, J. H. (2004) 'The Globalisation of Private Knowledge Goods and the Privatization of Global Public Goods', *Journal of International Economic Law*, 7(2): 279-320.
- 5 *INedit* (2004) The Newsletter for the French National Institute for Research on Computer Science and Control (INRIA), January. <http://www.inria.fr/actualites/inedit/pdf/inedit42.en.pdf>

Exploitation of IPRs

Joseph P. Cook

How do firms make the most of their intellectual property rights (IPRs)? Under what conditions might a firm exploit their intellectual property themselves and when might they license it out? While the discussion here of these and related questions has implications for different types of intellectual property, the principal context is that of patents.

Firms can exploit their intellectual property either by exercising the rights themselves for a profit or by selling all or part of those rights to another firm. One can think of a spectrum of possibilities where keeping all the rights and using them in your own operations (or simply holding them) is at one end, while at the other is a full and complete sale of the rights. In between, there are a number of partial interests including a variety of licensing options. One might also include the sale of an interest in a corporation whose principal assets are intellectual property. While in the case of licensing, one would typically expect the licensee to make use of the IPRs, this latter case may offer a means by which the owner can finance its own use of the IPR. Another consideration in determining one's strategy for exploiting an IPR might be in differences in tax treatment. One may well prefer a capital gain from a sale in an interest in IPRs or in the holding company which owns them to royalty income from a licence.

These considerations are generally influenced by the resources with which the firm that owns the IPR is endowed and to which it has reasonable access. Small to medium-sized enterprises (SMEs) will explore the same options but may find their resources are not as well-suited to direct exploitation of the IPRs as a larger firm.

The Decision on the Method of Exploiting an IPR

Under what conditions would we normally expect to find a firm preferring to license or sell IPR rather than use them? The answer, unsurprisingly, has to do with the expected profitability of the alternatives, and IPRs will be acquired in the market by those who expect to make more profit with them.

For example, suppose the owner of a given patent is able to use that patent to generate \$100 of incremental profit. Unless another firm can earn more profits with that patent, or with some subset of the rights it includes, none of those rights should be sold to another firm, because it is these higher profits that enable the purchaser of the IPR to compensate their owner for the loss. Next, consider two different scenarios. First, suppose a prospective purchaser could only earn \$90 from the patent's use. Because the owner already earns \$100 with the patent, and the prospective purchaser can only earn \$90, no sale will take place. Alternatively, suppose that the prospective purchaser could earn \$110 with the patent. In this case, a voluntary sale is possible because the prospective purchaser can compensate the owner for the \$100

profit it makes from the patent and still have \$10 of profit for itself. The licensing decision for IPR follows similar economic reasoning.

An IPR owner will license IPRs to another party when that party offers some ability to enhance profits from the technology, which can then be shared between them through a royalty. Assume that the enhancement is not one available to the owner of the IPR. A prospective licensee can offer an opportunity to enhance profits in a number of ways. Broadly speaking, we might classify these sources of profit enhancement as: (1) the ability to expand the market, (2) the ability to profitably increase the price of the end-product to existing customers, or (3) the ability to reduce the costs of producing and selling the end-product to existing customers. Let's discuss each of these in turn.

A market expansion by a prospective licensee can be brought about through a variety of means, but generally we can think of those means as deriving from some asset. The asset might be the prospective licensee's sales contacts or a developed sales channel, perhaps in another market, that is difficult to duplicate. The prospective licensee may sell a product that is complementary to the product produced with the IPR at issue. In such a case, the list of these customers provides a ready means of identifying likely sales opportunities for the product produced with the IPR at issue. Without such assets, the IPR owner may find it difficult to otherwise reach the customers for its end-product.

Perhaps the most straightforward example is that of a new field of use. The prospective licensee may be able to use the IPR, likely in combination with assets of its own, to create additional end-products that embody the intellectual property of the IPR at issue. By reaching out to an additional market that the IPR owner finds prohibitively costly to reach, the prospective licensee expands the profit opportunities for the IPR owner and justifies a licence.

Another example might be assets that provide for some form of improved characteristics of the end-product itself. With the improved characteristic profile, the demand for the end-product could increase as the result of stimulating the interest of a wider array of customers. Such might be the case where the prospective licensee can add a brand or trademark, which might include things like the image of a well-known cartoon character or the logo of a popular sports team.

A final example of market expansion would be the case in which the prospective licensee can

actually use some of its assets to improve the physical characteristics of the product and make it attractive or useful to a broader market. For example, if the end-product were a catheter, the prospective licensee may have assets that allow it to make a more flexible catheter that can be used to reach more parts of the body than otherwise and, therefore, have wider applicability and higher demand.

The cases in which the prospective licensee might enable a profitable price increase are not unrelated to these latter examples of market expansion. However, rather than increasing the demand by expanding the base of customers, one can distinguish these cases as those in which the willingness to pay for the product is profitably increased. For example, people might be willing to pay more for the end-product if it includes the logo of their favorite sports team, even if the size of the customer base is not noticeably increased. In effect, the new features, combined perhaps to form positive synergies in addition, create the opportunity for a price premium that the IPR owner does not have available to it on its own.

The complementary case is that of reduced costs. While the prospective licensee may not be able to reach new customers or affect a positive change on the characteristics of the end-product, it may offer a means of producing the same end-product at a reduced cost. These cost savings are then the additional profits that, as above, form the basis for gains from trade and royalties. Of course, in practice the direction of the trade may be in the opposite direction and involve instead the assets that are the source of the market expansion, price premium or cost savings, and the trade may even involve a cross-licence.

In cases where the IPRs are to be shared via a licence rather than sold, the IPR owner will consider the net effect of licensing. The IPR owner must recognize that by licensing another party to use its technology it is creating or enhancing competition for its own sales. The profits that matter most in deciding whether or not to license are those that are truly incremental to the existing profits generated by the IPRs. Sales that would merely be diverted from the IPR owner to the prospective licensee do not encourage licensure, but may help to define the terms of the licence (discussed below).

One additional thought on the licensing decision: while small to medium-sized companies and larger companies approach the problem in the same way, they typically come to different decisions. SMEs, almost by definition, are likely to have smaller distribution networks and fewer assets. Therefore, they are unlikely to be able to reach as many customers and markets as efficiently as a larger company with a more developed distribution network. So, the opportunities for profitable licensing are more plentiful. Similarly, SMEs are less likely to have access to the types of general purpose brands

Growth in production technologies and demand may be providing increased opportunities for the SME to use the IPRs themselves.

that might best serve to promote sales and command a price premium for a new product. So, on the whole we might expect SMEs to more frequently license to another firm.

Nevertheless, there are two other factors to keep in mind that may act to militate against following the general rule. First, one must keep in mind that technological advances can also have the effect of reducing the minimum efficient scale of production. Second, growing markets can also increase the number of profitable niche markets into which an SME could sell a differentiated product protected by IPRs. These types of production cost reductions and demand increases encourage exploitation by the SME more directly, as opposed to licensing.

The Choice of Licence Terms

Having found indications that licensing would be worthwhile, how should the IPR owner set about constructing the licence? Here, we explore some of the considerations that the IPR owner should take into account, which to a large extent are driven by the economic factors that justify the decision to license. When we think about licence terms, a number of questions come immediately to mind, which generally deal with either (1) a description of the rights being licensed or (2) the amount of royalties and conditions upon which those royalties are to be paid.

The source of the incremental profits may play a significant role in the formation of the scope of the licence. For example, if the incremental profits that motivate the licence originate in a planned market expansion via a new end-product, then the licence would likely involve a limitation to that field of use. A similar restriction could be included for sales channels, if a new sales channel were the expected source of the incremental sales and profits. Or, a geographic restriction could be used if the new markets were geographic in nature. These limitations guard against unwanted and unintended competition in the field of use for which the IPR owner is currently exploiting the intellectual property.

Of course, the limitations can be imposed in the other direction as well. If the prospective licensee is to develop a new market

opportunity, it may seek some protection that the owner will not subsequently attempt to compete for those sales. The reciprocal protection could be afforded by a grant of exclusivity, which would prevent any licences to be granted subsequently that would allow competition and even exclude the IPR owner from competing for those sales. The prospective licensee will likely also demand the ability to independently defend the IPRs licensed to it against infringement and to collect any associated damages.

The incremental profits have to be divided between the IPR owner and the licensee, a division that could be a pure bargaining situation or one influenced by the forces of thicker markets. Having decided on the division of those profits, the royalty payments can generally be constructed either as a fixed amount or a running rate based on some performance criteria. A running rate may be expressed as a fixed amount per unit sold or as a percentage of revenues, or less likely, profits. Profits are generally a poor choice because the profits of the licensee may prove difficult for the IPR owner to monitor. Monitoring the units of output may be the least costly, particularly if production machinery provides a ready means of counting the number of units that are produced.

Of course, there is a great deal of flexibility, and fixed amounts may be paid out over time in stages or for each year of the licence with the opportunity to discontinue. Running rates are often laid out in steps so that the royalty payment per unit, say, decreases at higher levels of sales thus providing the licensee with an increased incentive to expand sales.

The fundamental question between running royalties and fixed royalties is one of risk. Which party bears the risk is a function of their expectations and preferences regarding the bearing of risk. All else equal, a fixed royalty payment puts the risk of poor performance on the licensee, for, regardless of how much profit the licensee actually makes, it must pay the IPR owner the same amount. In contrast, a running royalty payment is based on performance. If production and sales are low, then the royalty payments are low.

Conclusion

Every owner of an IPR will seek to exploit it in a manner that maximizes its profit. In cases where another party can add to profitability, a transfer of all or at least some of the IPR will likely follow. The means by which this other party can increase profitability are varied, and we have discussed a number of examples here. However, whatever the source of these incremental profits, their nature, along with the risk preferences of the parties, will play a substantial role in shaping the terms of the licence. For SMEs, a relatively poorer set of resources as compared with larger firms will generally push them toward licensing IPRs more frequently; however, growth in production technologies and demand may be providing increased opportunities for the SME to use the IPRs themselves.

Biography

Dr Joseph P. Cook is Vice President of NERA Economic Consulting where he specialises in law and economics, industrial organisation, and behavioral game theory. He has engaged in research and prepared reports on a variety of issues, including those relating to antitrust and competition policy, economic damages, intellectual property, and auctions and market design. Dr. Cook has written on a variety of topics and has been published in the *Journal of Political Economy* and the *Journal of Economic Behavior and Organization*. He has presented his work and lectured on economics both in Europe and the US. He has also served as a referee for the *Journal of Economic Behavior and Organization* and the *Journal of Risk Research*.

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IPRs and SMEs

Anne K. Jensen

Small and medium sized enterprises (SMEs) play a key role in the European economy accounting for two-thirds of the continent's employment, almost 60% of economic output, and more than 99% of all enterprises. Although most SMEs recognise the importance of intellectual property rights (IPRs), many are still struggling to fully exploit the advantages of the system.

After years of gloomy growth rates and record-high levels of unemployment in the European Union, the European Heads of State decided in 2000 to embark on an ambitious reform agenda. The programme was later to be known as the Lisbon Agenda, and the Member States committed themselves to becoming 'the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social inclusion' by 2010.

Five years after the Lisbon Agenda was agreed upon and with only five years left to go, the prospects of reaching the goals are not encouraging. Europe is still spending a modest 1.96% of GDP on research & development (R&D), a drop in the ocean compared to the huge amounts of money transferred to the European agricultural sector. A step in the right direction would be to increase the spending on R&D to at least match what is being allocated in competing economies such as the USA, where 2.59% of GDP is currently being spent on R&D. This has finally been recognised by the EU and it was agreed under the so-called Sixth Framework Programme (FP6) to increase the Union's spendings on R&D from 1.96% to 3%. The Union has also agreed to create a European Research Area (ERA), with the aim of replacing loose cooperation between researchers and their organisations with programmes that are more integrated across borders and disciplines. Unfortunately the process is very slow and Europe is still struggling to convert its achievements into commercial technologies.¹

Innovation is essential in any knowledge-based economy, and for Europe to become the world's most competitive knowledge-based economy, innovation must be encouraged, nurtured and protected. A report published by the UK Department for Trade and Industry (DTI), defines innovation as 'the successful exploitation of new ideas. Ideas may be entirely new to the market or involve the application of existing ideas that are new to the innovating organisation or often a combination of both.'²

As the report points out, 'innovation involves experimentation and risk taking. Some attempts to innovate will fail, but across the economy the successes outweigh the failures. And the failures themselves generate new knowledge, which if evaluated correctly, can improve the chances for future success.' Furthermore, the risk of failure justifies the potentially high returns from successes, which

provide the incentive to innovate in the first place. This is one of the most important arguments for intellectual property rights (IPRs). IPRs provide a successful tool to incentivise and reward innovation, by granting temporary market exclusivity to the innovator. The exclusivity gives the innovator a completely dominant position in the market and therefore the opportunity to recoup the funds invested in the research and development of the invention. In other words, IPRs function as a guarantee for innovators that their efforts will be rewarded. It is also a guarantee to potential investors in a project, that what they are investing in will not be copied and commercialised by someone else. If the investors are not convinced, the project might not go on in the first place, and a good idea could be lost forever.

SMEs

The links between innovation, intellectual property rights and funding are especially significant for small and medium-sized enterprises (SMEs), for whom IPRs could be a make or break issue. These businesses are at the cutting edge of European innovation and rely heavily on IP protection. First of all, they need IPRs to protect their innovations from being copied and commercialised by other companies. Secondly, but of equal importance, these businesses are dependent on IPRs to attract the investments needed to commercialise their innovation. As described above, potential sponsors are keen to secure their investments and will be reluctant to provide money for an unprotected innovation, which can be commercialised by other companies.

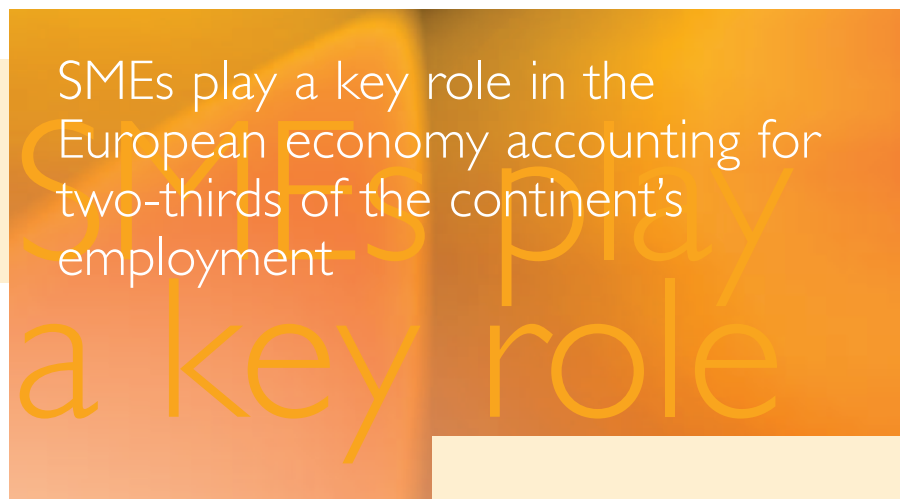
According to the World Intellectual Property Organisation (WIPO), the protection of IPRs is

particularly important to new technology-based firms (NTBFs), 'which are established for the purpose of commercialising new technology or providing an innovative service on the basis of new technology'. Such enterprises, WIPO argues, 'generally have limited capital and tangible assets and largely depend on intangible assets to succeed in the marketplace. The innovative idea is usually the main asset of the company during its start-up phase and the basis on which it will seek investors to take the product or service to market.'³

The European Commission defines an SME as an enterprise with fewer than 250 employees and an annual turnover not exceeding 40 million. There is also a criterion of independence which states that 'independent enterprises are those which are not owned as to 25% or more of the capital or the voting rights by one enterprise, or jointly by several enterprises, falling outside the definition of an SME or a small enterprise, whichever may apply.'⁴

SMEs play a key role in the European economy accounting for two-thirds of the continent's employment, almost 60% of economic output, and more than 99% of all enterprises.⁵ The picture is similar in the USA, where SMEs comprise 40% of employment, one-third of total economic output and roughly 85% of business firms.⁶

With SMEs playing such a dominant role in the European economy, it is absolutely necessary that the EU provides the right environment for these businesses to further flourish. The lack of success in converting innovative achievements into commercial products or services has already been identified by the European Union as a problem that needs to be solved in order to catch up with countries such as the USA and Japan. Yet the Member Countries are still struggling to agree on the most basic thing needed in order to support commercialisation of innovations; a harmonised Community Patent. The idea of an EU-wide patent dates back to the 1960s, but it took the Commission 40 years to propose its creation. In 2003, after years of discussions over the details of the



patent, the Competitiveness Council finally reached an agreement on a common political approach including a centralised court which would rule on disputes, language regimes, rules on the distribution of fees, and the role of national patent offices. The details of the Community Patent are still left unsolved, though, despite regular efforts by the Council to reach an agreement.⁷

SMEs and IPRs

The majority of European SMEs were initially suspicious of intellectual property rights, but it seems now that especially knowledge-based SMEs have realised the benefits of security for their innovations and have therefore started supporting the development of a stronger and better integrated European IP regime. Under the current system each Member State requires that patent applications are translated into its official language for it to be legally valid within their territory, even when an application is filed for an European Patent through the European Patent Office in Munich. These translation costs make patenting in Europe inevitably more expensive than in competing economies and represents a significant barrier to innovation itself and also commercialisation of innovation. This is especially true for SMEs, which often lack the necessary resources to go through the process of applying for a patent, and is an important reason why most SMEs are eager supporters of a harmonised Community Patent.

In the months before the European Parliament voted on the Computer Implemented Inventions Directive (CII) in July this year, the European SMEs displayed an unprecedented level of involvement. The CII Directive was meant to harmonise patent laws concerning software and its interaction with hardware. In other words, the Directive proposed making inventions involving the use of software based technologies patentable, but only if they were new and made a technical contribution, the definition of which proved to be the most politically problematic aspect of the Directive.⁸ Depending on whether their business model relied on existing, but not-patented, software programmes or the innovation of such, European knowledge-based SMEs found themselves either supporting the many campaigns for open-source and against patents on computer implemented innovations or lobbying heavily in favour of the directive. The latter alliance, which included powerful groups such as the European Information & Communications Technology Industry Association (EICTA), argued that the CII Directive was critical to greater European innovation and competitiveness, and therefore a step in the right direction of reaching the goals set out in the Lisbon Agenda. Yet the European Association of Small and Medium-sized Enterprises (UEAPME) disagreed and claimed that the Directive had loopholes, which could lead to the patenting of software at European level, as has already happened in the USA. The end result would be counter-

productive and have damaging effects on innovation in the European Union, rather than boosting it, the Association said, and welcomed the European Parliament's final rejection in July.

Although the CII Directive is formally off the political agenda following the rejection in the European Parliament, there is still talk of reviving a new and improved version of the proposal.

The obstacles facing SMEs

While most SMEs have recognised the importance of a more effective protection of innovation throughout Europe, many are still lacking the necessary awareness and ability to fully protect and exploit their intellectual property assets.

Indeed, a study commissioned by DG Enterprise in 1999 aimed specifically at investigating how knowledge-based SMEs felt about intellectual property rights.⁹ The results showed rather low levels of awareness about patents and how these could protect companies' inventions, which helps explain why some SMEs were hostile to the idea in the beginning. According to the study, patents were seen as 'complex, expensive and difficult to enforce for small entities and therefore less valuable than copyright or informal means of protection'. There is also an interesting difference between the small and the bigger SMEs, as pointed out in a report recently published by the Organisation for Economic Cooperation and Development (OECD)¹⁰. According to the study, SMEs with 500 or more employees are much more active in taking out patents on their innovations than companies with 50 employees or less. 20% of the big SMEs have filed for a patent, whereas only 3% of the smaller companies have done the same.

The two main obstacles facing SMEs, and especially the smaller ones, are financing and enforcement. The cost alone of applying and maintaining a patent is estimated at about 50 thousand Euros, which is twice as much as it costs in the USA. One reason for this is that SMEs need to translate their patent application into the official language of every Member Country they want their patent to be legally valid within. The difficulties increase in the instance of a legal case because the patent holders will have to work in different legal systems. SMEs are also at a disadvantage vis-à-vis large companies in the area of litigation and enforcement, as these companies are equipped with lawyers and the necessary budgets to fight in the court rooms. The time, costs and overall efforts that are typical of IP disputes often deter many SMEs from using IPRs as protection for their innovations.

As a result of the financial burden related to preventing infringement of existing patents, the UK Patent Office established a Patent Enforcement Project Working Group last year to investigate ways of assisting SME patent holders.¹¹ The working group considered several models such as mutual insurance

societies, the current IP insurance market, and commercial companies which would invest in a patent by funding the cost of enforcement in return for a share of any settlement or damages award. The conclusion reached by the group was that the establishment of a mutual insurance association would provide the best solution to the financial challenges faced by SME patent holders. The mutual would be funded by subscriptions and by capital from patent holders whom the mutual has successfully assisted in obtaining favourable settlements or damages in the past.

As SMEs are becoming more strategic in their approach to IPRs, European policy makers have an obligation to provide them with a more IP-friendly environment. Such policies should focus not only on harmonisation of IPRs, but also on financial and technical assistance as suggested by the Patent Enforcement Project Working Group. This would send the signal that the European Union is still committed to the Lisbon Agenda goals set out in 2000.

Biography

Anne K. Jensen works for the London-based market-oriented think tank Stockholm Network, where she specialises in international trade issues and intellectual property rights. Before joining the Stockholm Network in 2004, she studied International Political Economy at the London School of Economics and Politics and Development at the University of Oslo in Norway and Gothenburg University in Sweden. Anne frequently writes about trade-related issues and intellectual property rights in European newspapers and journals.

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What is the Value of Your Patent? Theory, Myth and Reality

Meir Perez Pugatch

Imagine the following situation: A man enters a bank and asks for the loan and mortgage department. 'Hello Sir,' says the clerk, 'how may I be of service?' The man answers, 'I would like to receive a one million dollar loan to be paid in instalments over 10 years.' 'And what assets do you have as collateral, Sir,' asks the Clerk. 'Oh, I have my European patent as an asset and the loan is actually intended to develop the patented technology.' 'In that case,' answers the clerk, 'why don't you go to our IP Valuation Department, who will carry out the necessary appraisal and risk analysis and, provided the analysis is satisfactory, our bank will be delighted to finance your project.'

Now let us return to reality and ask ourselves how many financial houses (perhaps other than venture capital funds) are willing to finance technology-based ventures on the basis of the technology itself. The answer is not many and perhaps none. In reality, a bank would be willing to provide financial support only on the basis of identifiable tangible assets; not on intangible assets. This is particularly evident since the 2000 bust, which forced many banks and financial houses to do a reality check and adopt a much more conservative, less risky, model of financing methods.

The most straightforward question is, therefore, 'what is the value of one's patented invention?' Unfortunately, there is no single answer, as is usually the case with IPRs. Ultimately, it depends upon the person (functionary) you ask: the inventor and patent owner (in many cases they are not the same), the investor, the financier (the bank) or the consumer. Each is likely to have a different perspective on this issue. Each will have a different method of evaluating the patent. And each is likely to provide a different answer. For example, the hired inventor is likely to value the patent on the basis of the income or annual bonus it would add to his fixed salary; the patent owner will value that patent based upon the total income it will generate or the investment it attracts; the financier (in the hypothetical case that one would be willing to provide a loan on the basis of the patent alone) will value the patent at the interest rate it is able to set for the loan and the risk it carries; the investor (such as venture capitalists) will value the patent at the additional profit he is able to make on his investment at the point of exit, and the consumer will value the patent on the basis of the price (or the price addition) he would be willing to pay for the patented product.

Based on the short narrative outlined above, and before going into a more structural discussion there are two immediate methodological distinctions that should be made:

When talking about patent valuation we are actually talking about the technology it protects. In other words, the valuation process considers the patent as a necessary but insufficient condition to the commercial value of a given technology. For example, a non-

patented technology can be extremely valuable to society and yet, since it may be easily copied, worth nothing to the inventor. On the other hand, an invention may be fully patentable (i.e. novel, involving an inventive development and capable of industrial application) and would still be worthless if the market refuses to use it.

We need to be aware (as well as wary) that the business of patent valuation, methodically scientific and advanced as it may be, is ultimately subjective.

Putting relativism aside, it is still very important to highlight, albeit briefly, three elements that are particularly important to the field of IP valuation.

Patents and the lottery – the odds of success are quite similar

A successful utilisation and commercialisation of a patent is akin to playing the lottery: while the reward from a successful patent can be vast, the chance of obtaining a truly successful patent is slim. Indeed, according to Pitkethly (2002: 3) this metaphor is accredited to *The Economist* which, as far back as 1851, argued that 'patents are like lotteries, in which there are a few prizes and a great many blanks.'

The problem primarily derives from the huge gap between the expectations of the individual inventor (patentee) and the overall results of patent exploitation and commercialisation.

On the one hand, the individual inventor or the patent owner considers his patent as a ticket to considerable financial rewards. Indeed, to many researchers and inventors, a patented technology is considered a benchmark of commercial success, merely because it is patented. We all like to believe that our patent could become that next pharmaceutical blockbuster, such as Lipitor, which generated sales of more than \$8.5 billion in 2002 (IMS Health 2003).

On the other hand, a more structural and statistical observation suggests that only a fraction of patented technologies are ever commercialised or utilised. It is estimated that less than 80 percent of patents worldwide are utilised (Pugatch, 2004: 59). Even worse, it

would seem that most of the patented technologies are worth less than their registration and maintenance fee. For example, Schankerman (1998:94), analysing the value of patents in France between 1969 and 1982, found that the median value of patents in different technology fields is surprisingly low: \$1,631 in pharmaceuticals, \$1,594 in chemicals, \$2,930 in mechanical and \$7,933 in electronic patents. Schankerman also reports that only one percent of pharmaceutical patents exceed a value of \$50,000.

Nevertheless, although the above data provides a somewhat discouraging picture about the commercial viability of the patent exploitation process, it says nothing about the value of the single patent. Accurate methods for valuation can thus help us to get a better sense of the value of our patent, as well as assisting us in taking informed decisions about the manner in which we may wish to exploit (or abandon) them.

Methods of patent valuation – cost, market, income and options

The field of patent valuation has evolved quite dramatically over the past decade: from a relatively conservative (some would say primitive) one-factor model to quite sophisticated methods of analysis. This article refers to the various types of valuation in brief as literature on this subject is quite extensive (Smith & Parr 2000; Megnatz 2002, Pitkethly 2002, Rozek & Korenko 2005).

A cost-based approach is the simplest method of patent valuation. A cost approach seeks to capture the value of the patented technology by estimating the cost of replacing it with another technology. In its most straightforward expression, a cost-based approach values the patented technology by calculating the total costs of developing it (and adjusting it to present value). Although simple and easy to use, a cost-approach is also very limited, as it only takes one factor (cost) into account when valuating the patented technology. It is also orientated towards past expenditures and is thus retrospective by nature.

A market-based approach values the patented technology by equating it with recent transactions that involve patented technologies of a similar nature and function. Provided that such a transaction did take place, a market-based approach is quite effective as it represents the 'real' market value of the patented technology. It should be noted however that in order for a market-based approach to be accurate one must acquire inside information about the details and nature of the transaction, as there are many factors – other than the technology itself – that influence the final value of that transaction. Also, if a transaction of this kind is not available, then a market-based approach is of little use.

An income-based approach represents the second generation of IP valuation methods.

Prospective in nature, an income-based approach values the patented technology on the basis of the future income deriving from the successful utilisation of the technology. Calculating future returns from a given patented technology requires sophisticated methods of analysis. These are not discussed in this paper given its concise nature. Suffice it to say that income based-methods aim to capitalise the present value of the patented technology from future income streams, taking three main factors into account: the net cash flow to be derived from utilising the patented technology (or in more simple terms the extra price that can be earned); the duration of income streams, and the discount rate that is needed to be factored in, such as inflation, risk, interest rates etc.. Income-based methods often use discounted cash flow (DCF) analysis in order to arrive at a more reliable – although not necessarily realistic – valuation of a patented technology.

An option-based approach further develops income-based methods by adding flexibility to the calculation process. An option-based approach treats the R&D process, and the IP it generates, as an 'option' to be bought (continued) or sold during the various phases of product development utilisation. One the main advantages of the option-based method is that it allows us to determine the value of our patented technology during the earlier stages of product research and development. It allows IP owners to factor in, at different stages, both the expected costs of developing the patented technology and the expected returns from utilising it, taking into account the level of risk associated with the various phases of product development. Theoretically speaking, by using an option-based method, a research organisation or a company is better able to understand the business prospects of its R&D project, thereby making more informed decisions as to whether to continue investing in it, seek to license or sell it, or perhaps even to terminate the project.

Back to reality

Returning to our earlier example, it is quite understandable why banks and other financial institutions are not keen on financing an R&D project or a business based solely on their IP portfolios.

Previous sections aimed to demonstrate that patents should be treated more cautiously and more systematically when trying to value the worth of a given patented technology. Statistically speaking, in most cases patents would not make their owners rich. We also need to acknowledge that the value of a patent is ultimately subjective.

Despite the evidence, and perhaps because of it, there needs to be a more systematic analysis of the value of a patent. Using such methods, inventors and owners of IP would gain a stronger understanding of the value of the project they are undertaking, as well as being able to present a better case when seeking finance. Who knows, maybe then we will see the establishment of IP valuation divisions in every bank.

Biography

Dr. Meir Perez Pugatch (MSc. Ph.D.), University of Haifa in Israel, is a lecturer in intellectual property policy, management and exploitation of knowledge assets and entrepreneurship. He finished his B.A. studies in 1997 at the University of Tel- Aviv and received his MSc. degree from the London School of Economics in 1998. He was awarded his Ph.D. from the London School of Economics in July 2002. Since 2005, Dr. Pugatch has also headed the Intellectual Property and Competition Programme of the Stockholm-Network.

A successful utilisation and commercialisation of a patent is akin to playing the lottery

to playing the lottery

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Intellectual Property Dilemmas

Challenges to the Contemporary Patent System

Trevor Cook

Patents are more in the news now than for many years, with even the popular press writing about 'hot topics' such as patents for genes, software and business methods. This essay tries to briefly look behind these discussions.

'... an unwelcome and unseemly debate has taken place over the heads of the patent professions, between lobby groups who sometimes seem incapable of cultivating the fruit of any understanding which has not fertilised in the soil of their own self interest.'

One might be forgiven for thinking that, assailed with such challenges, the patent system is reeling. But such controversies do not attack the foundations of the patent system. Instead, as this essay suggests, they are no more than the natural dialectic the system experiences over time and that informs its future development.

That said, those of us in Europe are exposed to the reality of such challenges because the European Commission, in its sometimes mindless drive to harmonise, has decided to tackle the areas of gene patenting and software patenting. And unfortunately, its activities have served only to polarise opinion.

The proposed Computer Implemented Inventions Directive was buried by an adverse vote in the European Parliament in the summer of 2005, to the satisfaction of those on both sides of the debate, freeing up the European Patent Office (EPO) and the national courts in Europe to continue developing the law.

Neither can the Biotechnology Directive 98/44/EC be held up by the Commission as a shining success. By the time the Directive had completed its decade long passage through the Community legislative maze, EPO practices had resolved the areas that the Directive had sought to address. Indeed, it would appear that its only effect to date is to undermine harmonisation in Europe – providing a spurious basis for some of the countries which have implemented it to take differing views about how claims to gene sequences should be written. The result is that, contrary to long established practice, some countries have been forced to include a use limitation², which is a practice that limits the patent claim on a novel product.

The Commission's other interest in this area, the Community Patent, is currently becalmed over disputes about language. While the Commission seeks to hinder the process by claiming exclusive jurisdiction over the matter, attempts are being made by Member States to provide a mechanism for multinational

patent litigation in Europe by means of the European Patent Litigation Agreement.³

These are all narrow European perspectives, and in any event, the EPO, national patent offices and courts will go on. Looking to the wider world, the old aphorism about those who are ignorant of history repeating its mistakes is equally apt when applied to those who 'cry wolf' about the patent system. They are unaware of how wrong such cries have proved before. For a system that is based on rewarding those who devise what is new, it seems ironic that the challenges faced by the patent system today are far from new, and yet they have not hindered its development to date.

The controversies over the rights and wrongs of patenting as a system of incentivising innovation, and doubts over the validity of the economic arguments frequently used to support it are not new. The nineteenth century saw the very foundations of the patent system under attack from people one would believe would have been its greatest proponents, such as the great Victorian engineers Armstrong and Brunel in the United Kingdom. Some countries even tried to do without patents for long periods of time, such as the Netherlands from 1869 to 1912, and Switzerland from 1850 to 1907.⁴ Yet today we have a patent system that is internationally more extensive and harmonised than ever before.

Controversies over what sorts of innovations can be patented are also not new. For a long time, patents were the sole preserve of mechanical engineering, whereas new chemicals, of any degree of utility, were not patentable. Current controversies over the patenting of genetic sequences, to which we in Europe have been particularly exposed, represent a transient, first generation issue⁵. The software and business method controversy, about which we are also aware in Europe, has on an international level long been resolved in favour of a permissive view. Indeed, one might ask what the benefits are to Europe and what we like to call the information society, if we try to limit patenting to 'manners of new manufacture' in the strictest historical sense.⁶ In Europe we may come to pay the price for the interesting experiment we seem intent on conducting, but the international patent system as a whole will not.

Other aspects of the question of patentability are the ones of morality, such as the patenting of gene sequences, and of standardisation, such as the ones set by the developed countries through the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). We may argue over the validity of such concerns, but the flexibility of the exceptions and reservations within the patent system, reflected in experimental use exceptions, regulatory review exceptions and compulsory licensing (the latter as further relaxed by the

WTO General Council Decision of 30 August 2003), meets them anyway.

Disputes over standards of patentability are not new either. In 1952, the authorities in the United States tried to make the courts grant fewer patents. A generation later it decided to centralise the appellate jurisdiction over patents in one court (the CAFC, or Federal Circuit, established in 1982) in order to secure uniformity. Critics however, saw this as yet another attempt to get more patents upheld. The United States' economy does not seem to have done too badly as a result, but some commentators have suggested that the pendulum has now swung too far the other way.⁷ What is significant is that these commentators do not believe their concerns to be so fundamental that they cannot be addressed by specific 'tweaks' to the system. In the United Kingdom the opposite seems to be the case, where even judges have written recognising the unsatisfactory nature of an unrealistic standard of inventive step, rooted more in the perception of invention as only a 'Eureka' type activity.⁸

The debate over patent examination workloads is also not new. We might glance at the inexorable upward trend in patent applications and think this is a new situation, but is the number really any higher than it used to be? Certainly not, at least in that apparent hothouse of patent activity the United States, where the number of such applications, per capita, has dropped since the days of Edison.⁹ Indeed, an increasing proportion of patenting now originates in the vibrant new economies of Asia, particularly China and India. Again, if there is a problem there are solutions, and some have already crept in, such as common search reports and common international preliminary examination reports (such as those issued in relation to the Patent Cooperation Treaty – PCT). The time may come when harmonisation means that formalised mutual recognition between the world's major patent offices can become a reality.

Finally, controversies over cost are also far from new. Patents are not cheap to secure, and they are certainly not cheap to enforce or to defend. But why should they be? The successful English inventor James Dyson might regard patents as a human right that should be funded by the state¹⁰, but perhaps cost can act as an effective 'gatekeeper' both to patenting and to litigation over patents? Indeed one could argue that more time and effort should be put into examining patents than what is being done today, and that the users of the system should pay for this.¹¹ Certainly one answer to those concerned about the upward trend in patenting is that making them more costly would force people to research more carefully what they seek to patent.¹²

No-one suggests that the patent system is ideal. There are situations where innovations

The 'one size fits all,' and technologically neutral approaches of the system that have exposed it to heavy criticism, have also enabled it to weather and to respond to changes in technology far better

are protected too much, for too long, and there are situations where innovations are protected too little, and for too short a duration. But the 'one size fits all,' and technologically neutral approaches of the system that have exposed it to heavy criticism, have also enabled it to weather and to respond to changes in technology far better than any sui generis system of protection.

In summary, the vitality of the patent system is reflected in the degree of controversy that it engenders. Such vitality will only be under threat when that controversy evaporates because it no longer faces the challenges which mould its development.

Biography

Trevor Cook joined Bird & Bird in 1974 with a degree in chemistry from Southampton University. He was admitted as a Solicitor in 1977, joining the Intellectual Property Department of Bird & Bird, where since 1981 he has been a partner. Trevor's practice covers all aspects of intellectual property, technology and regulatory law. He is Treasurer of the UK Group of the AIPPI (The International Association for the Protection of Industrial Property), member of the Council of the Intellectual Property Institute and is Secretary to the British Copyright Council Standing Committee on Copyright and Technology.

End Notes

- 1 Jeremy Phillips IPK at Blog <http://ipkitten.blogspot.com>
- 2 Commission Report COM(2005) 312 of 14 July 2005 on 'Development and implications of patent law in the field of biotechnology and genetic engineering'
- 3 <http://www.european-patent-office.org/epo/epl/index.htm>
- 4 'Industrialisation without National Patents', Eric Schiff, Princeton University Press 1971
- 5 It is also an issue that is, considering the vast amount of academic writing on the subject, of remarkably little relevance to most companies involved in biotechnology – see for example 'Gene patenting and medical research: a view from a pharmaceutical company', Mike Stott and Jill Valentine, *Nature Reviews Drug Discovery* 3, 364-368 (2004)
- 6 This is hallowed wording that was first found in the English Statute of Monopolies of 1623, but which is now only found in the Australian patent statute, and under which, ironically, and on a broad interpretation, business methods were held to be patentable in *Welcome Real Time v Catuity* [2001] FCA 445 (Federal Court).
- 7 See for example 'Innovation and its Discontents – How our Broken Patent System is Endangering Innovation and Progress, and What to do about it', Adam Jaffe and Josh Lerner; Princeton University Press 2004, proposing the creation of incentives to motivate those with information that challenges the validity of patents, to provide multiple levels of patent review, and to limit the role of juries (although in practice the role of juries has already been limited to a large extent, by 'Markman' hearings on matters of construction, and by summary judgement applications, both of which are heard by Judges alone).
- 8 See 'Patents – What's Invention Got to do with it?', Sir Hugh Laddie in 'Intellectual Property in the New Millennium – Essays in Honour of Bill Cornish', Edited David Vaver and Lionel Bently – Cambridge University Press 2004.
- 9 See 'Entering a Dark Age of Innovation', Robert Adler; *New Scientist*, 2 July 2005, reporting on the work of Jonathan Huebner to be published in a future issue of *Technological Forecasting and Social Change*. Although Huebner's analysis of 'Technical breakthroughs per billion of world wide population' can be questioned as inevitably subjective and skewed to the past, his analysis of 'US patents registered per million people in the US' cannot be.
- 10 See 'Against the Odds', James Dyson, *Orion* 1997
- 11 Patent systems in the United States and Europe are however self-funding and more, so that Governments are able to extract money from such patent offices. Such taxation, for that is what it is, is however a matter of political choice, rather than a problem of the patent system
- 12 See for example "Motorola Curbs Chase for Patents" – Mike Hughlett – *Chicago Tribune*, 21 August 2005, noting Motorola's drop from the top ten of patentees in the 1990s to 30th in 2004, to save cost and to focus on the technologies deemed most critical

Huzzah for Kazaa or R.I.P. Kazaa?

Uma Suthersanen

The Supreme Court has pronounced. The manufacturers of the Kazaa-type peer-to-peer software are guilty of secondary liability. Victory for the entertainment industry. The copyright industry has won. Artists and entrepreneurs have won. Even technology has not lost as the two programmers who invented the P2P phenomenon transferred the concept to internet telephony (a.k.a. Skype) and sold it in September 2005 for \$2.6 billion.¹

But the hunt to stop Kazaa is not limited to the US. Over 14000 lawsuits have been taken out in 12 countries to stop the unauthorised downloading of music. Even the Federal Court of Australia has heeded the call and held in September 2005 that Sharman, by merely supplying Kazaa file sharing software in Australia, were liable as having authorised copyright infringement. The court was reasonable – it asked Sharman to stop new users from trading copyright material via Kazaa software and to exert 'maximum pressure' on existing users to upgrade to a new, filtered version that would block copyright material.² And in August 2005, a Korean court required Soribada, a P2P service, to halt unauthorised file-swapping on its network or shut down.

The Chairman and Chief Executive of EMI Music has called these decisions 'pro-consumer' and 'pro-technology' as they recognised that record companies were very keen to work with peer-to-peer distribution software to create legitimate file-sharing models.³ But is this a satisfactory state of affairs? Are there not more stakeholders in this copyright dilemma besides the music industry? What is the dilemma anyway?

American Dreams Inc.

In one sense, it appears to be a battle of two American dreams. On the one hand, we have the US Constitution which demands that authors and inventors be granted property rights for a limited period. On the other, we have the American society's competing constitutional interest in the free flow of ideas, information and commerce. This battle has been fought with respect to diverse intellectual property related subjects, in many areas and in varying degrees of intensity. Nevertheless, the *Grokster* battle is interesting in that it reveals a further dilemma – the technology dilemma.

Technology is simultaneously a threat and an opportunity to the copyright owner. It facilitates the reproduction of works, hence the constant calls for increased protection. Conversely, technology increases the streams of revenue available to an author by allowing a single work to be disseminated all over the world in different formats which elicit different fees – the latter demands an innovation-friendly copyright policy. The technological dilemma simultaneously expands and encroaches a copyright holder's space.

A further fundamental concern is whether the main market players engage in any anti-competitive behaviour.

The Technology Cases

Cases such as *Sony*, *Napster* and *Grokster* are a manifestation of this dilemma.

At issue in *Sony Corp. v. Universal Studios, Inc.*⁴ was the fact that Sony's Betamax home videotape recorders were in widespread usage amongst television viewers who were employing them to record programmes for later viewing. This is known as time-shifting. The plaintiffs claimed that the use of the Sony recorders by private individuals in their homes for their own private use constituted copyright infringement of the works thus taped. They further claimed that defendant Sony, as the manufacturer and seller of the recorders and Betamax tapes, was liable as a contributory infringer. The Supreme Court concluded that Sony was not liable for contributory infringement. In relation to a technology that is used by consumers, an important factor in the *Sony-Betamax* decision was the potential of the technology to be employed for non-infringing uses. Sony supplied an equipment that was generally capable of copying copyright works, or non-copyright works, or copyright works which could be copied without objection from the copyright holder. The Supreme Court then held that the reward aspect of copyright law was a secondary consideration. Instead, the ultimate aim of copyright law is the

achievement of a *public purpose*: to stimulate creative activity for the general public good and to ensure public access to the products of such activity.

But this sort of approach appears to have been reversed first in the *Napster* decision, and then again in the *Grokster* decision.⁵ In the *Grokster* decision, the plaintiffs comprised a majority of the film and sound recording industry in the United States; the defendants manufacture and distribute freely Kazaa-type peer-to-peer software. Although the lower courts agreed that the defendants' software was capable of substantial non-infringing uses and, therefore, the *Sony* doctrine applied, the Supreme Court held otherwise. The majority opinion held that defendants were liable for secondary infringements because both had taken active steps to encourage or 'induce' infringement. The court held that anyone who distributes a device with the object of promoting infringement of intellectual property rights is liable for the resulting acts of infringement by third parties (i.e. the buyers and users of the device). In order to balance copyright with the need not to discourage the development of technologies with lawful and unlawful potential, the court emphasised that mere knowledge of infringing potential or of actual infringing uses would not be enough to subject the manufacturer or the distributor to liability; nor would ordinary acts incident to product distribution incur liability (acts such as offering customers technical support or product updates).

But on closer analysis, is this really the clear ruling that the music industry and the copyright owners wished? The court held that the evidence must be clear – that the technology manufacturer and supplier be shown to have acted purposefully and wilfully. However, how does this affect the normal active, and sometimes vicious, marketing that occurs in relation to any product in a capitalist

Technology is simultaneously a threat and an opportunity to the copyright owner

threat and an opportunity

society? The court seems to be saying that the product may be legal but be careful how you advertise. Rather than a copyright opinion, we appear to have a Supreme Court judgement on marketing.

The Supreme Court was also persuaded by the fact that there was no evidence that the defendants made an effort to filter copyrighted material from users' downloads or otherwise impede the sharing of copyrighted files. The Supreme Court was convinced that networks could have blocked 'anyone from continuing to use its software to share copyrighted files'. Again this is a rather ambiguous statement, and appears like a new version of the now defunct *Brady* rule which came about after the attempted assassination of President Reagan, i.e. gun sellers (and not the manufacturers) have a duty to do a basic psychiatric check on the buyer of the gun.

If the decision is ambiguous in its stance on copyright and music, can we then confidently characterise this decision as being technology-friendly? Well, that is not too clear either. And one only has to read Justice Breyer's intriguing concurring opinion whereby he appears to have painstakingly proven that, despite the 'inducement issue', the *Grokster* facts were indeed very similar to the *Sony* facts. In which case, the Supreme Court, by holding against *Grokster et al*, has also struck the death knell for technology.

Stakeholders

These cases reveal which stakeholders are involved in policy making, and which consumers are ignored in law making. Influential stakeholders include the copyright owners, sound recording companies, and collecting societies. Important stakeholders who may be losing the copyright battle include the information technology sector; especially manufacturers of any technology that allows either reproduction or communication of a copyright work, including all devices with copying or scanning or downloading/uploading technologies such as mobile phones, media players such as iPods, scanners, computer and communications hardware and software. Stakeholders who matter but in truth are largely unheard are the consumers and users of copyright material – which includes, as Justice Breyer reminds us, not only entertainment material but also research, archival and educational works.

A further issue is that of substitutable goods. Tying up distribution routes using copyright laws stifles the availability of substitute goods. Arguably, the Supreme Court in *Grokster* has not held that sharing activities are in themselves illegal but rather the inducement activities of the defendants were. But other courts are not being that finicky with their judgements and the Australian and Korean courts are holding that P2P activities cause market harm. But is this true? Normal economic assumptions are that competitors

ought to be encouraged to introduce new business models, especially where the *de facto* or *de jure* monopolist in that particular market has not satisfied market demand. It is also arguable that the file sharing programs act as new business models and market substitutes. Historically, when the Napster program was launched in 1999, it was the first program which allowed P2P music file sharing. In contrast, there were no legal Internet services offering music from any of the five Majors' catalogues until 2002. In its heyday, the Napster programme facilitated the download of over 1400 songs per minute and attracted over 20 million users. It is not difficult to conclude that there was an unsatisfied market demand here for a different distribution network of entertainment goods, in different mediums. Simply put, the market wanted to download single music tracks and could not. A very different question is: does the market want to pay? File sharing satisfies several types of market demands: browsing, borrowing (or sampling) to create new types of music, free riders (i.e. with no intention to pay), music enthusiasts and fans (who will pay).

The final word

International, US and EU copyright laws and policies now all tend towards widening the scope of copyright protection. But should we introduce more safeguards for technological innovation? Should there be a re-evaluation of the current copyright theory, law and policy so that it better reflects the interests of both copyright and technology sectors?

The Supreme Court has now spoken – however, which version of the alleged unanimity will stand? The apparent pro-property stance of the majority opinion or the apparent pro-technology perspective which one adduces from Justice Breyer's concurring critique?

Biography

Dr. Uma Suthersanen is a reader in Intellectual Property Law & Policy at Queen Mary, University of London. Prior to that she has worked as a consultant for WIPO, EPO, UNCTAD, the Singapore I.P. Academy and the Government of Israel (Patent Office). She has held Visiting Professorships and Lectureships at several institutions including the University of Western Ontario, Verona Intellectual Property Centre, Université Robert Schuman and Southampton University. She is a joint General Editor of the Institute's *Perspectives on Intellectual Property Law & Policy*, the Editor (from 2006) of the *European Copyright and Design Reports* (Sweet and Maxwell). From June 2002 to June 2005, she has authored 16 publications including 2 co-authored books

End Notes

- 1 *Financial Times*, September 16, 2005.
- 2 *Universal Music Australia Pty Ltd and ors v Sharman License Holdings Ltd and ors* (Federal Court of Australia) [2005] FCA 1242.
- 3 Alain Levy, 'A turning of the tide against internet music pirates', *Financial Times*, September 6, 2005.
- 4 *Sony Corp. v. Universal Studios, Inc.* 464 U.S. 417 (U.S. Supreme Court, 1984).
- 5 *Metro-Goldwyn-Mayer Studios, Inc. and ors* 125 S.Ct. 2764 (U.S. Supreme Court, 2005).

Are IPRs Scale Neutral?

Grant E. Isaac

The role that small and medium sized enterprises (SMEs) play in the innovation process is significant and an excellent article by Anne Jensen provides a helpful overview of the opportunities and challenges – namely financing and enforcement – that SMEs face when trying to protect their innovations. In a general sense, the issue here is whether or not IPRs – especially patents – are scale neutral. That is, is their effectiveness a function of organisation size? Building on this article, it is useful to consider the strategic decisions faced by innovative SMEs.

To motivate this assessment, we must first examine what is meant by organisation size and innovative organisations. With respect to the former, organisational size refers to the financial resources available to fund the research, development and commercialisation of innovation. Large organisations typically have endogenous financial resources, that is, they have the internal financial resources to fully support their research and development portfolios. SMEs require exogenous resources. That is, they do not have the internal financial resources and must rely upon external investors to fund their research, development and commercialisation project(s). While simple, this assumption creates important differential implications for the strategic management of intellectual property by SMEs. Innovative organisations can be defined many ways. An illustrative, but non-exhaustive list includes definitions such as a required proportion of total expenses spent on basic and applied research, or revenues from the sales of new products, or as the contribution of skilled labour in the production of a good/service according to activity-based costing. Intuitively, all of these definitions share the notion that value comes from an investment in knowledge. Therefore, it is simply assumed that an innovative firm is one actively investing in ideas and seeking to protect the potential economic return from those ideas through intellectual property rights.

Consider the following strategic options facing both large innovative organisations and SMEs. First are the drivers for obtaining intellectual property. Unlike tangible assets like buildings and equipment, intellectual assets are intangible and accounting for their value is the source of considerable debate. What is the proper value of an idea, especially a truly novel idea where significant market development would have to occur before a commercial opportunity is realised? Within this environment, patents have become a proxy for valuing ideas. The logic is that if the scientific community considers an idea to be novel enough to grant it protection, then this connotes that the scientific team has some intangible technical value which can be considered as part of the organisation's asset base. Large innovative organisations are not as beholden to the value of their intangible intellectual assets as their small counterparts are. The former typically have a considerable tangible asset base and a current revenue

stream from products in the marketing phase that is reinvested into a portfolio of research and development projects. Experience and expertise add to not only the likelihood of choosing projects with a higher probability of technical success but also of commercial success. Therefore, these internal resources – both financial and non-financial – mean that large innovative firms can use patents to focus on more long-term strategic resource alignment and to protect those sources of perceived long-term competitive advantage. The strategic implication is that large innovative organisations are freer to invest internal resources in more novel and less incremental knowledge-based products. In contrast, for small innovative organisations intellectual assets may well be all that they have. These assets are used to attract equity investors whose capital is used to fund research and development projects. The strategic management implication of this dependence is that patents are often sought after as a proxy for technical experience and expertise and of the potential future flow of innovative products. Without the internal resources – both financial and non-financial – small innovative organisations typically use patents to secure short-term investment funds. In other words, financial resources are often dedicated to research and development in areas where patents are quicker and more likely to obtain and this may not be congruent with areas more aligned with a long-term competitive advantage. The strategic implication is a bias towards less novel and more incremental innovations that do not require as much financing to investigate. In this sense, patents are not scale neutral with respect to the drivers for patenting intellectual assets.

Second, getting the patent application right is crucial, but not easy, and organisation size impacts the ability to identify optimal patent space. On one hand, an organisation has an incentive to maximize the protection it can obtain in the product space because this represents the potential monopoly profits that can be realized. On the other hand, if the claim is granted such that the organisation either infringes a previous application or the patent cannot actually be enabled for all claimed protection then an expensive legal challenge can ensue. Finding this *optimal* patent space is not an inexpensive proposition in knowledge-based areas such as

biotechnology and nanotechnology. Prior patents must be searched, the filing must be vetted for enablement and a prognostication on future applications and uses must be undertaken. For large innovative organisations there are often financial resources and experienced and expert patent analysts and agents to undertake this work in a manner consistent with the long-term strategy for competitive advantage. In contrast, small innovative organisations with limited financial resources are strategically motivated to minimize the amount of cash spent on these activities. In addition, they tend to lack the experience and expertise to identify the *optimal* patent space to apply for in the application. Yet, the lack of resources to undertake proper application diligence leaves the organisation vulnerable to legal challenge based on either infringement or non-enablement. Again, in comparison, patents as an intellectual property policy instrument are not scale neutral. With respect to patent applications, large innovative organisations are much better positioned to identify *optimal* patents as an intellectual property policy instrument than are small organisations.

Third, when potentially patentable ideas are identified, organisations face an important strategic decision to make with respect to the timing of a patent filing. On one hand, filing right away ensures that the cash spent on ascertaining technical feasibility is protected if the innovation results in a marketable product. However, it also limits the time that monopoly profits can be realized in the marketing phase. Inversely, filing when an innovative product is ready for the marketing phase maximizes the time that monopoly profits can be realised, but also leaves the organisation vulnerable to the possibility that another innovator will patent essentially the same idea. This strategic patenting decision is not scale neutral, organisational size does matter. Recall that small innovative organisations need to protect and then promote their ideas in order to obtain the investment capital necessary to achieve technical feasibility, let alone begin the market development process. Strategically, this means that for a small organisation timing is not really an endogenous strategic variable; they cannot be patient and instead must patent early to attract investors at the expense of perhaps a greater period of time realising monopoly profits. Yet, for a large organisation, internal resources mean that timing is an endogenous strategic resource creating an opportunity for these organisations to move farther along the product development phase before disclosing their idea through a patent application. Provided that such an organisation can maintain their idea as a trade secret during this time, then the opportunity exists to realise monopoly profits longer.

Fourth, in the case of a potential patent infringement it is up to the patent holder to

make a strategic decision to enforce or not to enforce. Indeed, there is much at stake because failure to enforce an infringement essentially dissolves the intangible value of the patent as an intellectual asset. This is a strategic decision because defending a patent requires significant cash to cover the legal expenses and to sustain the organisation while the litigation occurs. Moreover, this decision is going to be made subject to variables such as the financial resources available to enforce and the relative financial resources available to the infringer: Patent enforcement strategy is not scale neutral. For small innovative organisations the financial resources available are targeted toward innovation efforts in order to develop an idea to the stage where it can be patented and to ensure that the patent application is as close to optimal as possible. That is, many small organisations are quite vulnerable to predatory infringement because they simply lack the resources to make the challenge. Large innovative organisations, on the other hand, have the willingness and ability to enforce their patent protection. Therefore, as an intellectual property policy instrument, patents are not scale neutral as strategic patent decisions can again be differentiated based on organisational size.

The comparative assessment above reveals that patents are not scale neutral with respect to their impact upon the strategic options of why an organisation might patent, the patent application, the patent timing and the patent enforcement. Patents are a policy instrument easily employed by large innovative firms with the resources to not only align their patent efforts with long-term competitive advantage, but to ensure diligence in the patent application, effective timing strategy and proper enforcement ability. The same cannot be said for small innovative organisations. For this group, the lack of endogenous resources means that patents are used to secure external funding. Relatively less strategic attention can be paid to the application of the patent while timing is not a strategic variable for this group. Finally, the lack of endogenous resources means that effective patent enforcement is difficult.

This is not to suggest that IPRs are not useful for SMEs, but rather to highlight that different strategic options are available that the organisations, potential lenders and policy makers need to be aware of.

Therefore, as an intellectual property policy instrument, patents are not scale neutral as strategic patent decisions can again be differentiated based on organisational size.

Biography

Dr. Grant E. Isaac is the Chuck and Norma Childers' Chair for Saskatchewan Enterprise in the College of Commerce at the University of Saskatchewan. He is also the Chair of the MBA Specialisation in biotechnology Management and director of the BComm program in biotechnology Management in the College of Commerce; a position affiliated with the University of Saskatchewan's College of Biotechnology. Dr. Isaac is a Research Associate with the Estey Centre for Law and Economics in International Trade and with the London School of Economics' International Trade Policy Unit and he is a member of the Canadian Agri-Food Marketing Council. Dr. Isaac's teaching interests are primarily in the strategic management of the research, development and commercialization of advanced technology products with a specific emphasis upon products of modern biotechnology.

IPRs and Justificationary Dilemmas

Alan Cunningham

During explorations of intellectual property (IP) law issues, one often finds that an important question is placed to the side, or given less analysis than it merits. The question is this: how does one best, or rather properly, justify the existence and nature of IP rights, *per se*. The dismissal of this question is most usually done in order to concentrate on those aspects of IP law considered to be of a more practical and concrete character. It appears to be done on the justificationary basis that such a question is, realistically, let's-be-honest-now, 'of no practical import' and, anyway, 'pretty much settled'. This is extremely unfortunate. Exploring the area of IP rights justification can open up interesting avenues of thought that can re-shape considerations of the character of IP rights and IP legal policy, as will hopefully be illustrated in this article.

When one does come to look at this area of inquiry, one finds that the justifications concerning the existence and nature of IP rights invariably fall into either one of two broadly defined camps. The first type of justification is the economic justification, which attempts to explain IP rights by reference to certain economic problems that affect the goods that IP rights are concerned with i.e. information goods. The second type is the non-economic justification, which attempts to explain IP rights by suggesting that certain fundamental human rights exist concerning both the act of creating information goods and the subsequent ownership of such goods. Within these camps, one also finds that there is a predominant economic justification and a predominant non-economic justification.

The predominant non-economic justification is commonly referred to as the natural rights argument. To briefly elaborate, this argument suggests that the creator of a work, or, to give a more concrete example, the author of a novel, has a natural right to control the distribution, copying, etc. of the work, or novel. This right is, obviously, not justified in terms of producing some beneficial economic effects (even though it may do so). It is justified, rather, as reflecting and effecting the principle that, as Locke would have us believe, the work that one does producing information goods, in and of itself, justifies having a personal and private dominion over that work.

The predominant economic justification is commonly referred to as the incentive argument. This argument requires accepting that information goods suffer certain economic problems, i.e. that they are naturally non-scarce and non-rival. It is commonly suggested that information goods are non-scarce because they (supposedly) cannot be used up to a point in time where they do not exist. It is also suggested that they are non-rival because they can be used (supposedly) by an infinite number of individuals simultaneously. To understand these concepts further, take the example of an artist who creates a new song. If upholding the incentive argument, one could state that the new song is non-scarce because once created, it cannot be used up. In addition, one could also state that the newly created song is non-

rival, because no matter how many people 'use' the song, their use will not rival any others. If an infinite number of people started to sing the song, for example, the quantity of the song would not be diminished by such infinite use. Also, if that infinite number of people could sing the song forever, this event would not affect the availability or quantity of the song. In this respect, it is suggested, information goods are non-scarce and non-rival.¹

the development or creation of such goods. In addition to the points above, this is also because without natural scarcity or rivalry, it is very difficult (although not impossible) to exclude people from unauthorised use of a good that one has spent time and money creating. In other words, it becomes difficult to stop people from free-riding. To go back to the example of the song, once the song is released into the public arena, and people have heard it, they can make whatever use they like of it; they can sing it, play it in a bar, or record it. Such free-riding occurs at the expense of the creator's time and money, and if a good will suffer from such free-riding, it is understandable if individuals are reluctant to invest in the development or creation of such goods.

In the context of information goods IP rights are seen as the answer to this difficulty (the incentive argument suggests), as they offer a conceptual exclusivity in place of the absent actual exclusivity. Exclusive rights of control are granted that allow the creator to charge fees for the licence to do certain things with the work, thus guaranteeing the return of investment costs.

IP rights are perhaps not properly justified as incentive instruments, but are, rather, properly justified as instruments effecting principles of distributive justice.

If information goods are non-scarce and non-rival, this results in an interesting economic difficulty. Such goods lack the natural qualities of scarcity and rivalry that can act as an incentive for individuals to become concerned with their creation. Scarcity can be a natural incentive because if a good is scarce, individuals will realise that if they make or grow that good, they can charge a high price for it. Rivalry can be a natural incentive because if goods are rival, individuals know that if they make or grow such goods, and people buy such goods, not everyone can use them without affecting another's possession. As a result, individual demand for such goods becomes greater and people become prepared to pay for them.

If a good lacks the natural qualities of scarcity and rivalry, which are usually present if the good is physical, individuals thus find it more difficult to see a financial benefit in investing in

The two justificationary arguments outlined above illustrate the Janus-like nature of the IP justificationary 'coin'. Both have their merits and de-merits, and both are reflected, to one degree or another, in actual working intellectual property law regimes, e.g. the natural rights justification is reflected in the civil law Continental tradition; the incentive justification in the common law tradition.

It may be, however, and here we come to the main point of this short article, that there is another *economic* justification concerning the creation of IP rights. Irrespective of whether one favours the economic over the non-economic justificationary argument, or vice versa, a problem remains. As illustrated above, one is only ever presented with one option to pick from (in either camp). What I suggest in this article is that there exists an additional economic justificationary argument: one that

suggests that IP rights are perhaps not properly justified as incentive instruments, but are, rather, properly justified as instruments effecting principles of distributive justice. The existence of such an additional justificatory argument adds to the justificatory dilemma of the title, in that it presents another perspective concerning how we may best explain IP rights. This can only be a good thing, however; dilemmas are useful creatures and their complication a useful activity. They ensure that one thinks with more pressure (and thus more diligence) concerning a subject.

The argument that presents IP rights as being best justified as instruments of distributive justice runs as follows. The first step is to refute a long held notion; that is, the notion that information goods are non-scarce and non-rival. Such a notion needs to be refuted; first, because it encourages society to continue to view IP rights as being justified as incentive instruments²; and secondly because reality tells us that information goods are not non-scarce, nor non-rival. They are, in fact, economically constrained by technologies of information use (the term 'use' incorporates such activities as expression, promulgation, storage, etc.) that are required so that information has a useful existence. It is a matter of existential necessity³ that information goods be constantly allied to physical technologies of information use⁴, of one kind or another, in order that they are both useful to society and capable of use. This is no mere contrivance.

The result of this existential necessity is that information goods, being constantly allied to physical technologies of information use, can be considered as being inherently scarce and rival. They can be considered as scarce because one needs the requisite technology of information use to use the information good, itself a scarce object reliant on physical objects for its construction. They can be considered as rival, because the use by one person of a technology of information use, it being a physical object, will rival the use of it by another.

This reality has important economic implications. If, as it has been suggested, information goods are scarce and rival, one can first question the justificatory argument that suggests that information goods require an incentive, in the shape of the conceptual exclusivity offered by IP rights, in order to ensure they are created. If information goods have an inherent quality of scarcity and rivalry, imparted through their necessary alliance with physical technologies of information use, one can argue that information goods offer to society their own natural incentive quality; that is, they offer their scarcity and rivalry. Such an argument appears to be supported by history, since, prior to the development of IP rights *per se*, society and civilisation created information goods. In order to do so, there must have been a natural and actual incentive

existing (irrespective of any purely artistic incentive, since society has always been aware of the economic significance of information goods), rather than an artificial and conceptual exclusivity.

If, therefore, information goods offer their own incentive for their creation, one can discount the IP rights-as-incentive justificatory argument for the moment.⁵ However, the reality discussed above has a second implication. The fact that information goods are reliant, for useful existence, on physical technologies of information use, and are thus inherently scarce and rival, presents one with a further difficulty. The difficulty is that if information goods are scarce and rival, as other physical goods are, then information goods will suffer problems similar to those suffered by physical goods. One of the problems encountered by physical goods, a problem to which exclusive property rights are viewed as the solution, is what one might term the problem of ensuring distributive justice in light of the fact of scarcity.

The problem is this. Physical objects exist in order to satisfy the needs of society. In this respect such objects can be termed as goods. However, since physical goods are scarce and rival, a certain type of relationship emerges; a quantitative relationship between the availability of goods and the need for those goods. The existence of such a relationship ensures that a certain instability emerges concerning goods and the need for them. Of course, the quantitative relationship between the availability of goods and the need for them might be that certain goods exist in much greater numbers than the need for them. It might also be that certain goods exist in numbers equal to the demand for them. However, two points are relevant. First, as history and reality illustrate, *most* goods exist in number considerably less than the need for them, that is, they are scarce in relation to needs. Secondly, irrespective of whatever the actual availability/need ratio is and because goods are physical and therefore inherently scarce by design, one can suggest that the quantitative relationship between availability and need will always be one illustrating a scarcity of goods in relation to what can sometimes seem like (given the innate greediness of humankind⁶) limitless human needs.

Such a scenario leads to inevitable occurrences in human society. If an inherent quantitative relationship exists concerning the availability of goods and need for goods, and that relationship is one where goods are inherently limited (in stark contrast to limitless needs), it is assured that certain needs of society will go unsatisfied. Human self-interest, a natural instinct not unlike the need to quench one's thirst, or satisfy one's hunger, ensures that if natural circumstance is not sufficient to satisfy needs, individuals will attempt to ensure that their requirements for

survival are met, as much to the exclusion of others as is possible.

Such attempts will produce success and failure. As a result, society comes to be composed of those who have a lot, those who have a little, and those who have nothing. In most cases, those who have a little are envious of those who have a lot, and those who have nothing are envious of both other groups. This leads to what Menger has called a natural 'opposition of interest'.⁷ This opposition of interest ensures the necessity of protecting individuals who possess goods from removal by brute force or other nefarious means. Of course, the real reason why the goods need to be protected is not because people will steal them. It is because the goods exist in a quantitative relationship in relation to the needs of society. If this were not the case, distributive justice regarding goods would be largely assured, nobody would have the (economic) need to steal goods, and protection would not be needed for such a reason.

However, natural circumstance has not assured that distributive justice is effected. Society has to effect such a principle itself. The method of protection that has emerged is a system allowing the exclusive ownership of goods and a system of property rules used to determine the terms and limits of such ownership. The rationale for employing this particular mechanism of distributive justice is rooted in natural self-interest: if one respects what another has, he will also respect what you have, ensuring that even those who have a limited amount are guaranteed protection. In this way, one can see how it is the inherent quantitative relationship surrounding all physical goods, the relationship between availability and need, which explains, and justifies, the use of the principle of exclusive ownership and the property rules that regulate the terms and limits of such ownership.

How does this link back to my initial suggestion that IP rights might not, perhaps, be economically justified as instruments of incentive, but rather as instruments of distributive justice? Well, given the existential necessity for information goods to be allied to physical technologies of information use, and the inherent scarcity and rivalry that is imparted to what were previously considered to be non-scarce and non-rival information goods, two important points become clear. First, information goods have historically supplied their own incentive for their creation, i.e. the technology of information use. This fact acts to weaken the IP right-as-incentive justificatory argument. Secondly, the fact that information goods are tied to technologies of information use means that they suffer from similar problems as physical goods. In other words, they suffer from a lack of distributive justice in light of their scarcity and rivalry. This fact points to the possible

validity of the justificatory argument that suggests that IP rights are actually used in order to effect distributive justice.

The validity of the IP rights-as-distributive-justice argument can be further supported, in part, by considering the effect of new technologies on the validity of IP rights themselves. For example, copyright owners are currently experiencing problems due to digitisation and distributed communications (the Internet). If copyright, however, is properly justified as an incentive instrument, copyright owners should not be experiencing such difficulties. If the conceptual exclusivity offered by copyright was sufficient, that is, if offering an incentive was the true role of copyright, then when copyright owners placed their goods on-line, they should be doing so in the safe and secure knowledge that no one would be free-riding on their investment and that a return on that investment would be guaranteed. This is not what is happening, of course. Copyright owners are not, in most cases, prepared to place their goods on-line to be protected *only* by the conceptual exclusivity offered by copyright. They *are* prepared to place their goods on-line when there are protected by actual exclusivity i.e. technology used to prevent free (meant in either a liberty or pecuniary sense) access to information goods, and technology used to control the use of such goods subsequent to paid and/or permitted access. Why is this the case? Well, these new technologies, or rather their economic effect, illustrate that copyright is not an adequate incentive, and, realistically, this has never been the true function of copyright. Society has had to wait until the relevant technologies came along and coincided in the form of the Internet to point this out to us.

The simple fact is that technologies of information use, up until the technologies of digitisation and distributed communications came along, have been the actual incentive concerning the creation of information goods, because they have provided an actual scarcity, rivalry and exclusivity. Copyright, the law regulating the existence of these goods *ex post* creation, had, and has, a different role. This role, in a serendipitous fashion, results from another economic effect of the incentivising technologies of information use; the creation of distributive injustice. Copyright law tries to alleviate the worst effects of this distributive injustice, and this, I suggest, may be its true role.

Digitisation and distributed communications illustrate the true role of copyright because they remove the assistance that purely physical technologies of information use have historically lent to non-physical information goods, i.e. actual scarcity, rivalry and exclusivity. Without such characteristics, copyright owners have realised that it is these characteristics, and not conceptual copyright laws, that have ensured their investments were

The validity of the IP rights-as-distributive justice argument can be further supported, in part, by considering the effect of new technologies on the validity of IP rights themselves

guaranteed and that free-riding was prevented in the past. As a result, they have rushed to re-establish such scarcity, rivalry and exclusivity, using Digital Rights Management (DRM) systems. If it is these physical technologies of information use that provide the incentive for information good creation, what, then, is the function of the IP right? It reacts to, and attempts to remedy, the disparity that results from the necessary expression of the information good via a physical technology of information use (in the context of the Internet, the physical technology of information use can be viewed as the DRM system). It offers a semblance of distributive justice, by establishing the terms and limits of information good ownership, in the face of scarcity and rivalry.

Other facets of the IP rights regime act to further strengthen the argument. For example, while exclusivity is allowed, IP law regimes also include (and are considered to be ineffectual without the presence of) the means for society to obtain equitable access to information goods where the IP right owner might have prevented such access. Such an objective exhibits the quality of attempting to effect distributive justice, and is indicative of the legal system responding to the knowledge that information goods are subject to, as a result of their existential nature, large degrees of distributive injustice.

As was alluded to earlier, the presentation of the IP rights-as-distributive justice argument is not done with the intention of settling justificatory dilemmas concerning IP rights once and for all. Such a task would be impossible. Rather, the argument is so presented in order to illustrate a different mode of thought on the matter; to broaden the previously set circumference of the dilemma that is: how do we best justify IP rights? As suggested earlier, this can only be a good thing, although the right answer, if there is such a thing, will remain elusive for a long time to come.

Biography

Alan Cunningham is a Herchel Smith Research Fellow at the Intellectual Property Research Institute, Queen Mary, University of London. Prior to joining the Institute, he worked with the Commission for Energy Regulation in Dublin, Ireland, dealing mostly with licensing policy. He commenced doctoral studies at the Institute in September 2002 as a Herchel Smith Research Scholar, and hopes to finalise his Ph.D. in 2006. He lectures at the University of London LL.M. (Intellectual Property in the Digital Millennium), and the Queen Mary M.Sc. in Intellectual Property Management. His current research interests include the problems that occur as a result of using technology to give effect to copyright, (so-called) DRM systems and their justification, justificatory aspects of Intellectual Property law and, generally, all areas where law and technology intersect.

End Notes

- 1 The concepts of non-scarcity and non-rivalry are perhaps better understood if one compares the characteristics of an information good to those of a physical good. For example, while it may be that a song can be sung by an (hypothetically) infinite number of people, for an (hypothetically) infinite amount of time, physical goods could never, either hypothetically or actually, emanate such characteristics. To wit: an apple can only be eaten by a limited number of people; the apple is a rival good, because my use directly rivals another's. In addition, the use of an apple has an established and limited time period, after which I am required to create or purchase a new apple, if I still wish to satisfy my hunger.
- 2 The notion perpetuates this belief because the perception that such goods are non-scarce and non-rival leads to the assumption that people will not naturally create such goods, and thus to the assumption that an incentive is required, that incentive being the exclusivity offered by IP rights.
- 3 The term 'existential necessity' refers to the fact that without technologies of information use, information *per se* would not exist.
- 4 From a reductionist perspective (that is, a perspective that attempts to reduce concepts to their most essential and fundamental core), one could argue that human beings are the ultimate technology of information use, since without their existence, the very concept information goods, let alone information goods themselves (at least as we know such things) would not exist.
- 5 This is not to suggest that IP rights cannot, and do not, act as an incentive for the creation of information goods. They can, and do, but in a supplementary fashion.
- 6 Hume, for example, wrote of 'the selfishness and limited generosity of the human mind'. He also points out that it is this characteristic of human kind, and the 'easy change of external objects allied to their scarcity in comparison to the wants and desires of man' that make up the 'inconvenient circumstances' that point to the need for ownership and property. David Hume, *Treatise of Human Nature*, OUP, Norton, D.F. & Norton M.J. (ed.) (2000).
- 7 Carl Menger, *Principles of Economics*, Libertarian Press (1994).



Global Issues

Global Enforcement of IPRs

Pedro Velasco Martins & Eva Kaluzynska

Ten years ago, intellectual property was an obscure subject understood and discussed mainly by specialists. Lawyers, scholars, civil servants and industry people were the only ones interested. If the general public took any notice, it was usually confined to the sport of buying cheap holiday souvenirs such as Lacoste T-shirts, sometimes with the crocodile facing in the wrong direction, or a Rolex watch which had probably stopped by the time they got home. Since then, the volume of fake goods has increased dramatically, as has their nature and geographical distribution.

There are new risks to buying pirated and counterfeit goods. Customs officials at EU borders are seizing ever-increasing volumes of products such as counterfeit medication, food, bottled water, or spirits such as Scotch whisky made in Turkey, Thailand, China, Vietnam or Australia. Who could resist a bargain bottle of McCarthier? At best, fakes may do no harm. Viagra copycats are a best seller at the moment. But take the case of essential drugs for conditions that may deteriorate rapidly if the patient does not get appropriate medication regularly. In China, the deadly fake baby milk scandal was very well documented, and some hard lessons learnt. There are also fake aeroplane parts, electrical appliances and toys which illustrate the variety of risks at stake. Such fakes are usually made by anonymous entities that take no account of health, safety and quality requirements, not to mention basic consumer rights. Twenty years ago, studies indicated that seven out of 10 firms affected by counterfeiting were in the luxury sector. In 2004, more than 4.4 million items of fake foodstuffs and alcoholic drinks were seized at European Union borders (an increase of 196% over the previous year), while luxury goods accounted for less than 2% of seizures.

Growth in crime

Another major concern is the growing involvement of criminal organisations in the international trafficking of fake goods. This is not surprising, considering the particularly lucrative nature of the trade and the low risk, compared to other criminal activities. The scale of the problem and the money at stake make fighting against piracy and counterfeiting as complex to tackle as drug trafficking or money laundering. Fake DVDs are a good example: profits are higher than for an equivalent weight in soft drugs, while the penalties for offenders are much more lenient. Cigarettes are another good example: a counterfeiter only has to get one in 10 of his containers of fake cigarettes through to make a good return on his investment. Counterfeiting on this scale also provides criminals with a useful means of laundering their criminal proceeds.

Competitiveness

In a globalised world, developed countries are having increasing difficulty competing with certain emerging economies in mass production. The tigers can do it faster and cheaper. This is why operators in markets that traditionally invest in creativity, research, design and quality and count on added-value in return

have a lot to lose if their intellectual property is pirated. Theft of intellectual property deprives legitimate right-holders of rewards for their investment and ultimately puts their viability at risk. Such violations also discourage foreign investment and transfer of technology.

Tax evasion

Illegal, clandestine sales also deprive the state of tax revenues such as VAT, revenue taxes and, customs duties. This issue is particularly sensitive in countries where economic sectors such as tobacco, alcoholic drinks, fuel, etc., are under strict state control.

Why combat faking?

The problem is not as simple as it might seem and it is certainly not a question of honest patent holders in the developed world: this is not a question of 'goodies' in developed countries with intellectual property right holders, and 'baddies' versus dishonest copycats in developing countries. The effects are directly felt in both developed and developing countries. No country, rich or poor, can afford to ignore this problem and allow part of its industrial and commercial resources to become a 'parallel economy, particularly when so many of the goods produced may have a direct impact on the health, safety and security of its citizens.

All countries have an interest in combating piracy and counterfeiting. Some say that if developing countries protect IP rights held predominantly by entities from developed countries, they incur high costs without obtaining direct benefits.

But if developing countries want to attract foreign investment, transfer of technology and know-how, they must offer such protection. What is more, local right-holders in developing and least-developed countries also deserve protection. In the medium to long-term, appropriate protection encourages domestic authors, inventors and investors, and contributes to the development of these countries. This is particularly the case for emerging economies.

But it is clear that IPRs alone are not sufficient. It is only one contributor to innovation, growth and development, and it must be harnessed by rules, accompanied by appropriate national policies and monitored by international institutions, all in a coherent action. But, more importantly, IPRs will only be able to contribute to development and investment if integrated in a system of good governance, respect for property and the rule of law. The Trade Related Intellectual Property Rights (TRIPS) Agreement,

concluded by the World Trade Organisation (WTO) in 1994, was the first attempt at a global, comprehensive, framework of protection and enforcement of intellectual property rights. Since then, it has become applicable to 148 members of the WTO, and there has been significant progress worldwide on the protection of Intellectual Property Rights (IPR). Intellectual property systems have been set up or improved in accordance with international standards in a number of countries, where different types of rights are now protected by law. They include copyright, patents, trade marks, designs, geographical indications and plant breeder's rights, among others. Unfortunately, in parallel with this first multilateral effort to regulate the protection against IP theft, the volume and value of IPR violations, increased dramatically over the last years, to the point where it has taken industrial proportions and now represents a considerable share of the global economy.

Time to take action

Concerns about IPR enforcement worldwide have gained considerable momentum in recent years. To address the problem worldwide, the following initiatives have been launched:

The European Union published an action plan in November 2004 with a comprehensive set of actions aimed at achieving a significant reduction in IPR violations in third countries. The plan called for priority countries to be identified, and for specific measures to be tailored for each circumstance. They must cover fields such as technical assistance, dispute settlement and other sanction mechanisms, political dialogue, partnerships with private entities as well as with international organisations and countries sharing EU concerns.

This strategy is a logical follow-up to recent initiatives such as the Directive on Enforcement that will harmonise enforcement legislation within the European Union, and the revision of the Customs Regulation, which provides action against attempts to ship counterfeit or pirated goods from and into the EU.

The US has made great strides in identifying the evolution and growth of piracy and counterfeiting in the global economy as a top political priority. At the end of 2004, they launched a strategy called the STOP! (Strategy Targeting Organised Piracy), intended to:

Help US businesses, inventors and innovators to secure and enforce their rights in overseas markets;

Secure US borders and the marketplace from fakes;

Work to dismantle criminal enterprises that steal intellectual property; and

Join forces with like-minded trading partners such as the European Union and Japan, also concerned about the growing global IPR piracy problem.

Theft of intellectual property deprives legitimate right-holders of rewards for their investment and ultimately puts their viability at risk. Such violations also discourage foreign investment and transfer of technology.

Japan itself introduced an IP Strategic Plan in mid 2003, which Prime Minister Koizumi hailed an essential element of the global economic plan for the country. The goal is to make Japan an "intellectual property-based nation" and the Plan focuses on the protection and enforcement of IPRs, and on the fight against imports of pirated and counterfeit goods from neighbouring countries.

But developed countries are not the only ones making an effort to combat this trade. Others, such as China, Korea, Brazil, Singapore and the Ukraine, to name but a few, are increasingly aware of the problem too. There is a growing awareness that a solid IPR system is an engine for development and competitiveness. These countries also realise that they need to protect their fledgling research-based industrial sectors against predatory attacks. Pressure from third countries (the 301 Special mechanism put in place by the US being a good example³) and the need to comply with international commitments, such as the TRIPs Agreement, the treaties from the World Intellectual Property Organisation (WIPO), or bilateral free trade agreements also play a role. Furthermore, domestic right-holders demand enforcement of IPRs just as vigorously as foreign right-holders. The problem is that the piracy/counterfeiting industry is still an important element of the economy in many countries. This means that the issue cannot be tackled merely from an IP angle. Consequently, only a comprehensive policy involving authorities at national, regional and local levels can provide a sustainable solution.

Bilateral trade agreements are increasingly becoming another weapon in the war against piracy and counterfeiting. Recent US agreements have detailed sections dedicated to this, and they go beyond the minimum standards required by the TRIPs Agreement. This is notably the case for digital and internet

related infringements, which is natural considering that in the early 1990s, when the Agreement was concluded, concepts such as domestic CD or DVD burning, the internet or p2p file exchanges were either unknown or in their infancy. The EU model, on the other hand, has remained relatively stable and is expressed in quite general terms. The EU usually requires a commitment to the protection and enforcement of IPRs "according to the highest international standards".

On the multilateral side, this topic is also attracting more attention and is on the agenda at the highest political level.

For instance, the G8 leaders approved a statement on the enforcement of intellectual property rights at their last summit. They made a commitment to take steps to reduce substantially global trade in pirated and counterfeit goods, and to combat the transnational networks that support it. Members also agreed to cooperate among themselves in areas such as customs controls, anti-piracy crime strategies, public awareness-raising and in giving assistance to third countries through sharing of best practices, training and technical assistance.

The EU recently tabled a Communication on enforcement at the WTO TRIPs Council, with the aim of helping WTO members to better understand where the main problems, difficulties and shortcomings are and to make recommendations on ways to improve the situation. Paradoxically, though the legal situation has improved, at least formally, the situation in the field has deteriorated. What can be done to close the gap?

For its part, the Organisation for Economic Cooperation and Development (OECD) has decided to conduct an extensive project to assess the impact of piracy and counterfeiting on the global economy. There is broad

consensus on the need to have a truly global and comprehensive assessment of the damage caused by such practices to the industries involving creativity, quality and innovation, but also to consumers and citizens in general. There are few credible overall assessments of the impact of counterfeit on the world economy. When the OECD last carried out a study on the topic in 1998, it concluded that counterfeits accounted for 5 to 7% of world trade. The difficulties of carrying out a credible evaluation cannot be underestimated, and the OECD is certainly the institution best suited to do this.

Conclusion

The misappropriation of creativity, inventiveness or artistic creations is not a new phenomenon. However, it is growing exponentially. It is a problem with serious economic, social and even criminal consequences, for which there are no simple, pre-formatted solutions. To counter this, we need a flexible approach that takes into account each country's specific needs, its level of development, its status vis-à-vis the WTO, and the particular nature of the problem (production, transit and/or consumption of fake goods). But more importantly, any proposed solutions will only be effective if authorities, economic operators and consumers see the benefits of a system that rewards, progress, quality and innovation and become more aware of the risks of free-riding on somebody else's intellectual property.

Biographies

Pedro Velasco Martins has been an official of Directorate-General for Trade of the European Commission (Brussels), since 1996. In 2002, he joined the Intellectual Property Rights unit of DG Trade, where he is responsible for the IPR Enforcement Strategy for Third Countries, as well as for IPR related bilateral and regional relations with North and South America, the Middle East, ASEAN and the South Mediterranean countries.

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End Notes

- ¹ The views expressed in this article are those of the authors and cannot be attributed to the European Commission.
- ² The "Special 301" report is published every year by the US Trade Department. This Report details the adequacy and effectiveness of intellectual property protection in countries throughout the world (and even in private companies, as recently proposed in the below mentioned STOP initiative). The Special 301 report on intellectual property includes allocating "problematic" countries on the "Priority Watch List" or the regular "Watch List". Consequences for countries that are included in this report may vary from unilateral trade sanctions according to US law to dispute settlements in the framework of WTO or of bilateral agreements.

IPRs and Developing Countries: The Trade and Investment Dimensions

Douglas Lippoldt

The past 15 years witnessed a substantial strengthening in the system of international treaties that governs intellectual property rights (IPR) in conjunction with national laws.

Key developments include the advent of the World Trade Organisation's Agreement on Trade-Related Intellectual Property Rights (TRIPS), increased adherence to the series of international IPR agreements administered by the World Intellectual Property Organization (WIPO), and inclusion of intellectual property provisions in a number of regional trade agreements. In moving to implement the commitments associated with ratification of these agreements, developing countries generally needed to reinforce their IPR systems. Previously, many of these countries extended only relatively weak protection for IPRs, sometimes based on poorly adapted systems dating from a former colonial era or sometimes simply lacking an effectual system. Thus, the current wave of IPR reform is a big undertaking and one that is still on-going.

The challenges faced by developing countries in implementing IPR reform have drawn media attention, with some observers questioning the rationale for investing scarce government resources in this area. At the same time, existing economic theory does not provide definitive insights on the economic implications of the strengthening of IPRs. Given this situation, economists have turned to empirical approaches to research that permit assessments based on actual experience with IPR policy. The present article highlights some of the empirical evidence on the international economic implications of IPR reform, taking into account the nature of intellectual property and the potential for the enhanced system to promote technology transfer.

Unlike a material resource, the same bit of intellectual property—say, a patent can be made available simultaneously and repeatedly on a non-exclusive basis to multiple users, generally at a low marginal cost. This characteristic of intellectual property presents a challenge to innovators or subsequent IPR holders who wish to appropriate an international economic benefit from ownership of the underlying innovation. If IPRs are hard to enforce in a particular market, this may discourage foreign rights holders from making their intellectual property available there through merchandise trade, direct investment or licensing. Weak IPR enforcement means rights holders could face difficulty in appropriating returns from the use of their intellectual property or they could risk abuse of their intellectual property by a competitor. This discourages transfer of technology and more broadly—investment in innovation. While some types of IPR can be protected through 'natural' protections (as with products that are difficult to reverse engineer; copy or imitate), many others are vulnerable to abuse. On the other hand, it is possible that IPRs could be made too strong, conferring excessive

market power on the rights holders and thereby unduly limiting access to technologies (e.g., by enabling the rights holders to significantly raise prices to prohibitive levels).

Since many developing countries came into the recent period of IPR reform with relatively weak IPR systems (as of the early 1990s), the risk of conferring excessive market power through moderate IPR reform programmes appeared mild. Intuitively, it seemed feasible that developing countries could encourage trade, investment and licensing by moving to provide adequate IPR protection and in doing so they could encourage rights holders to make their technology available. Success of such efforts could be of critical importance to developing countries because technological progress is a fundamental condition for economic development. Merchandise trade, international licensing and foreign direct investment (FDI) embody intellectual property and are key sources of new technology for developing countries, particularly in regions where the domestic research and development sectors are underdeveloped or non-existent. If the flows in these channels and the associated technology transfer can be positively influenced by the strengthening of intellectual property rights in an economy, then the strengthening of IPRs can be beneficial for development. However, these are complex phenomena and the relationships are not always straightforward.

Seen from a different perspective, a firm holding intellectual property may consider entering markets abroad via alternative channels, including through trade, FDI or licensing technology to local firms. Overall flows via all of these modes may increase in response to stronger IPRs under certain circumstances, but firms may also switch their mode of supply in a given market, moving from exporting to producing locally through affiliates or licensing. In such cases, trade may actually decline or expand more slowly than might otherwise be the case. Where protection of intellectual property is relatively effective and contracts enforceable, firms may opt for licensing and transfer of technology to unaffiliated partners, such as in cases where there are other risks that may dissuade direct investment (e.g. currency risk) or cases where the licensor lacks the capacity to operate in the market.

What does the evidence show?

The scale of trade and investment flows into developing countries is enormous, providing an indication of the potential for technology transfer: As can be seen from the Table, as of 2003 imports of goods and services into the developing regions amounted to about \$ 1.8 trillion and FDI inflows amounted to about \$ 116 billion in 2003. Both sets of flows tended to increase during the 10 years shown, albeit

The strength of patent rights generally was more strongly and positively associated with FDI

with some variation by region. As underscored in a recent World Trade Report (2003), 'Empirical research has found a positive relationship between the size of trade flows and a country's level of total factor productivity.' The effectiveness of trade as a vehicle for transfer and diffusion of technology depends in part on the composition of imports. The same WTO report points out that in 2000 some 30% of developing countries imports were classified as 'high-tech' products, whereas only about 10% of imports by least developed countries (LDCs) fell into this category; the share for developed country imports of these products was a bit more than 20%. (International licensing of intellectual property is an especially interesting element of services trade in that it represents a direct transfer of technology generally intended to be ready for use as a resource.) One question of interest here is the extent to which IPR strengthening has so far influenced these flows and helped to promote increased technology transfer.

As with trade, FDI constitutes an important channel for technology diffusion. A WTO (2002) secretariat report cites four main channels for this to occur via FDI: 1) backward and forward linkages, 2) demonstration effects, 3) competition effects (i.e., FDI may stimulate competing local firms to improve their technological performance), and 4) learning by doing that builds human capital. Although the FDI flows are substantially larger now than they were in the early 1990s, developing countries must still compete in a tough environment to attract investment. A question here is whether increased IPR strength is influencing the FDI inflows.

Economists are still assessing the impacts to-date of strengthened IPRs in both of these areas. Recent OECD studies contribute to this work in progress and some of the key findings are summarised below.

International trade and FDI

Park and Lippoldt (2003) considered the relationship of changes in the strength of patent rights to trade and foreign direct investment during the 1990s, primarily in developing

countries. They used an indicator for the strength of patent rights taking into account such elements as membership in relevant international treaties, restrictions on rights, available means of enforcement, duration of protection and sectoral coverage of patent rights. Similar indicators for trademarks and copyrights exhibited fairly high correlation with the patent indicator. Overall, the OECD study confirms the tendency for a positive relationship between the strength of patent rights and inward trade or FDI. Given the correlation of patent strength with similar indicators for trade marks and copyrights, it is possible that similar relationships exist for these other types of IPR.

With respect to trade, a moderate relationship was found between the strength of patent rights and import flows generally and particularly in some sectors such as textiles, pharmaceuticals and industrial chemicals. For certain other sectors, such as computer and office equipment, patent rights appeared to be important primarily in markets where there was a threat of imitation. The estimates for the LDCs were generally not statistically significant.

With respect to FDI, the OECD study found that the strength of patent rights generally was more strongly and positively associated with FDI. A 1% increase in the patent rights indicator was associated with a 0.5% increase in the stock of FDI. The results indicate that variation in FDI in relation to strengthened patent rights is largest for the LDCs (where initial IPR regimes tended to be weakest). There was some indication that patent rights may have a positive but diminishing association with increased FDI as the strength of those rights increases. The strength of patent protection appeared to be relatively important for FDI in such sectors as computer services, finance, chemicals, petroleum and pharmaceuticals; this may be due to the relative ease with which competitors can imitate the technology embodied in those sectors.

While the OECD study confirms the tendency for a positive relationship between patent strength and trade or FDI, it should be noted that other factors, such as market scale, often appear to play a determinant role and may attract investment or imports despite shortcomings in the IPR environment. In an investment issues survey of the world's largest 1,000 firms conducted by the consulting firm A.T. Kearney (2003), business leaders characterized the most critical risks to their corporations as they invest abroad. At the top of the list were such issues as government regulation, country financial risk, currency risk, or risk of political and social disturbances (each of which cited by 60% or more of respondents). Theft of intellectual property was cited by 17% of the respondents and ranked 12th on the list of concerns. At the same time, among many of those citing IPRs as a significant concern, weak IPRs could be seen as a 'deal breaker' condition.

The case of licensing

In a further OECD study, Park and Lippoldt (2004 and 2005) examined the relationship between international licensing and the strengthening of IPRs in developing countries during the 1990s. International licensing activity is considered to be part of services trade, but was given separate consideration because of its important role in technology transfer. Licensing transactions are a means by which technology and expertise can be acquired by licensees, saving them the expense of independent research and development. At the same time, licensors not only derive fees and royalties, but may also be able to capitalise on the licensee's local reputation and knowledge.

The OECD study finds general support for the proposition that the strengthening of intellectual property rights has had a net positive effect on technology transfer via licensing. Taking into account other explanatory factors (such as gross productivity, corruption, tariff rates, and country risk), patent rights and effective enforcement of statutes in particular are positively associated with licensing. In addition, stronger patent rights were associated with increases in licensing relative to FDI in developed regions and at the same time increased FDI relative to licensing in developing regions. This finding may indicate that a critical level of patent protection is needed before firms have an incentive to relinquish direct control and engage in licensing (as opposed to FDI). Across sectors, patent rights are found to be influential in the services, electrical and electronic, and transportation industries, while not influential in the machinery and wholesale trade industries. Enforcement effectiveness is especially important in the chemicals, electrical and electronic, and services industries.

Conclusion

Can IPR reform help to boost trade, foreign direct investment and licensing in developing countries? In this review of the developing country context, the answer tends to be 'yes'. From the evidence cited above, it appears that recent strengthening of IPRs in developing countries has tended to have a positive influence on FDI and licensing and a moderate influence on merchandise trade. These effects vary across sectors and countries, depending on such factors as the risk of imitation and the importance of other factors to rights holders (such as market scale). The reform of IPR regimes may also influence the pace of technological progress, a fundamental condition for economic development. To the extent that technology is embodied in traded goods and services (including licences) and FDI, developing countries may be able to accelerate technology transfer by enhancing their IPR regimes. This can also help to stimulate domestic innovation.

The results do not imply that stronger protection for patents or other IPRs will always increase trade and FDI and the associated transfer of technology. IPR protection is not a 'silver bullet' development solution. Rather, a general policy

implication of the OECD studies for developing economies is that IPR reform should be one part of a broad strategy for promoting economic development. In order to reap the full benefits from IPR reform and ensure the capacity to absorb technology inflows, developing countries must also move to develop a coherent policy framework that provides complementary conditions such as appropriate regulation, an environment conducive to enterprise, essential physical infrastructure (e.g., for communications), and effective educational systems, among other elements.

Biography

Douglas Lippoldt is a senior trade policy analyst with the Organisation for Economic Co-operation and Development in Paris, where he has worked since 1992. His present assignments target a variety of trade and development issues, with trade-related intellectual property rights as one area of focus. He has produced a series of articles in recent years on the economic impacts of strengthened IPRs in developing countries. Prior to coming to the OECD, he worked 10 years for the United States Government as an international economist covering economic development issues in light of trade policy and labour market perspectives.

End Notes

- 1 The views expressed in this chapter are the responsibility of the author; they do not necessarily reflect the views of the Organisation for Economic Co-operation and Development (OECD) or its member countries. The findings cited in this note draw, in particular, on OECD studies prepared by Park and Lippoldt 2003-2005. Thanks are due to Raed Safadi for his helpful comments on an earlier draft.
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Resurrecting the TRIPS Agreement

Meir Perez Pugatch

A decade has passed since the General Agreement on Tariffs and Trade (GATT) was turned into the World Trade Organisation (WTO). A decade has passed since the WTO was described and perceived as the ultimate neo-liberal clearing house for international trade – an institution with a clear pro-free trade agenda (though not an extreme one), solid consultation mechanisms and most importantly – the ability to litigate as well as enforce its members' obligations. A decade has passed and the WTO is now at a crossroad as is its agreement on trade related aspects of intellectual property rights – TRIPS.

At the outset it should be noted that any discussion on trade-related intellectual property agreements is far from being straightforward. Unlike other trade agreements, the international regulation of intellectual property rights ultimately deals with a very unique commodity – knowledge. It is therefore subject to a set of constraints and interests that differ substantially from the 'conventional' challenges of international trade agreements.

Signed in Marrakesh, (15 April 1994) as annex 1C to the Final Act establishing the WTO, the TRIPS agreement came into effect in January 1995. It was one of the most innovative and important subjects to be included in the multilateral negotiations of the Uruguay Round. Indeed, some scholars considered TRIPS to be a revolution in international intellectual property law.¹

To all intents and purposes TRIPS was established as a right-holders' agreement. It was envisaged, advocated and lobbied by the developed countries, in particular the US, seeking to maintain the vital interests of their knowledge-based industries. The linkage between the TRIPS Agreement and business interests, such as the pharmaceutical, music and film industries is also clear. No one denies that these industries were the main driving force behind the agreement. However, when adopting a more international systemic view, one can explain the formation of TRIPS as an attempt by the developed countries to secure their competitive advantage in a rapidly interconnecting world. The clearest threat to the vital interest of the leading knowledge-based economies was the ability of some developing countries to engage in reverse engineering activities (or in other words – counterfeit).

And so TRIPS was created and along with it came a promise that, over time, TRIPS would not only serve the interests of developed countries but also those of developing nations. After all, Article 7 stated that: *'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge...'*

Before concentrating our attention on the problems and to some extent the crisis that the TRIPS Agreement is currently experiencing, it is worth providing a brief overview of some of its underlying features.²

First, as part of the WTO agreements, the TRIPS Agreement incorporates the principles of National Treatment and Most-Favoured-Nation (MFN) treatment. The former (TRIPS, Art. 3) requires all members to treat nationals of other members no less favourably than their own nationals, on all issues concerning IPRs, subject to the exemptions laid down in previous IPR conventions and treaties. The MFN principle (Art. 4) requires that any advantage, favour, privilege or immunity granted by a member to the nationals of any other member must be extended unconditionally to the nationals of all other members.

Second, the TRIPS Agreement specifies the minimum protection standards that member countries must adopt under their domestic IP legislation. More importantly, the Agreement provides a detailed 'technical guide' for member countries with regards to the protection of IPRs. The TRIPS articles refer specifically to copyright and related rights (Art.9-14), trademarks (Art.15-21), geographical indications (Art. 22-24), industrial designs (Art. 25-27), patents (Art. 27-34), layout designs of integrated circuits (Art. 35-38) and the protection of undisclosed information, so-called data exclusivity. (Art.39).

Third, the TRIPS Agreement specifies the minimum measures necessary for the adequate enforcement of its provisions (Art. 41 to 61). Each WTO member must provide civil and judicial procedures in order to prevent, or at least inhibit, the infringement of IPRs (Art. 41). Members' remedies must include injunctions – 'to prevent the entry into channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right' (Art. 44), damages for injuries (Art.45), and the destruction of infringed goods without compensation of any sort (Art. 46). Member countries are also required to adopt adequate border measures, aimed at preventing the importation and circulation of counterfeit and pirated IP-related goods (Art. 51-60). Finally, in order to combat the illegal trade in pirated products involving copyright or trademark rights infringements, WTO members are required to adopt criminal procedures, and to allow for penalties to be applied, under their domestic IP legislation (Art. 61).

Fourth, the TRIPS Agreement is subject to the dispute settlement procedures governing the

WTO. These provisions are designed to make the WTO, including the TRIPS Agreement, an institution with 'teeth'. Indeed, to date, the WTO has witnessed about 140 wide-ranging disputes associated with the TRIPS Agreement, such as on Irish music, pharmaceutical patents, geographical indications, motion pictures and sound recordings. Some of these ended in mutual agreements, while others were litigated at the WTO's dispute settlement body.³

Fifth, the Council for TRIPS is the primary body responsible for the Agreement's administration, operation and timely implementation (Art. 68), and functions as a major forum for information and consultation on IP-related issues. Two elements are particularly important to the work carried out by the Council: (1) notifications-aimed at helping the Council to monitor members' compliance with TRIPS obligations. (2) TRIPS built-in agenda - negotiations and discussions between WTO members on specific provisions that require further development starting from the year 2000, to which the TRIPS Council acts as the focal point.

Finally, implementation dates of the TRIPS agreement are subject to the 'developmental' status of WTO members (Transitional Arrangements, Art. 65), and exclude the principles of National Treatment and MFN Treatment, which were to be implemented by January 1996. Developed countries were required to implement TRIPS provisions within one year of its date of coming into force, i.e. January 1996. (Art. 65.1). Developing countries and countries in transition, mainly centrally-planned countries moving towards market orientated economies, were entitled to an additional period of four years (January 2000), (Art. 65.2-65.3). Least-developed countries (LDCs) were required to implement TRIPS over a period of 10 years from its date of coming into force (2006), but this deadline was extended with regards to pharmaceutical patents.

The decade of TRIPS can roughly be divided into three periods. The first period – 1995 to early 1999 – may be described as the period of 'determination'. Developed countries were positively convinced about TRIPS' ability to provide a long-term platform for the protection and enforcement of their IP rights world-wide. One need only look at the different WTO disputes between the US/EU and India/Pakistan on the so-called patent 'mailbox' provisions in order to understand why such optimism was in place.⁴ It was also a period in which developed countries underestimated the growing opposition to TRIPS by developing countries, and particularly the least developed countries.

The second period – November 1999 to November 2001 - may be described as the period of 'resentment'. Developing countries, backed by a new wave of anti-IP sentiment within the NGO community, expressed a growing sense of antagonism about their

The TRIPS Agreement should therefore be strengthened and expanded in a manner that would represent the growing importance of knowledge-based factors in the global economy

obligation to implement TRIPS as of 2000. Briefly put, some developing countries felt that the TRIPS agreement was too one-sided, with limited prospects for the interests of their own nationals. This resentment was fuelled, in part, by two separate events – the colossal failure of the Seattle Ministerial Conference in late 1999, and the case of patented AIDS medicines in South Africa.

The third period – November 2001 to date – may be described as the period of 'flexibility', though not necessarily in a positive sense for all parties concerned, as will shortly be argued. This period brought two major changes. First, the subject matter of the discussion on TRIPS has narrowed down to an almost exclusive focus on pharmaceutical IPRs. Second, discussions no longer focused on the implementation of TRIPS, but rather on the 'flexible' interpretation of TRIPS, in other words on the manner in which developing and least developed countries could essentially avoid or bypass the Agreement. The epitomes of this era are the 2001 Declaration on the TRIPS Agreement and Public Health (as part of the Doha Development Agenda), and the August 2003 Agreement on the implementation of Paragraph 6 of the declaration (focusing on the manner in which least developed countries with no manufacturing capacities can import generic substitutes to existing patented pharmaceutical drugs).⁵

But the era of TRIPS flexibilities, while celebrated in the media and by some NGOs, has proved to be the most dangerous period in the existence of the Agreement and to its future prospects. To a large extent, TRIPS flexibilities has proved to be too flexible, leading to two different yet interconnected outcomes.

The first outcome is the surge of regional and bilateral agreements led by the US and also the EU. These agreements establish IP commitments of a TRIPS+ level, which means that the parties, including developing countries, are required to implement stronger and more detailed IP provisions than those stated by TRIPS.

With regards to the protection of pharmaceutical IPRs, which as explained above became synonymous with the TRIPS

Agreement as a whole, it would seem that the multilateral, bilateral and regional levels are currently subject to opposite trends.

On the one hand, the TRIPS pharmaceutical patent regime has become weaker ever since 2000. The 2001 Doha Ministerial Declaration on TRIPS Public Health and the August 2003 Deal led to an overall reduction of protection for patented medicines, especially with regard to the use of compulsory licenses. Without getting into the specifics of the above mentioned agreements, it is the author's view that they are primarily political, and apart from diluting the level of IP protection provided under TRIPS, they do little, if anything at all, to promote public health in the least developed countries.⁶ Patents are probably the least problematic aspect of the issue of access to essential medicines for poor people. In fact, of the 300 drugs listed by the WHO on its Model List of Essential Drugs (2001), less than five percent or fewer than 20 are under patent protection anywhere in the world.

On the other hand, regional and bilateral trade agreements led by the US or the EU, such as the The Central American Free Trade Agreement (CAFTA)⁷, establish a level of pharmaceutical IP commitment, that is clearly higher than the level provided by TRIPS, such as in the areas of data protection, patent term extensions, parallel imports, etc.

The second outcome is the (almost) complete stagnation in the negotiating agenda of TRIPS. In the decade that has passed, we have experienced vast and rapid technological developments, such as in the World Wide Web, mobile and digital mediums. These fields encompass highly complex and important IP issues, most of which are not covered in TRIPS. Some may argue, with a certain degree of certainty, that this proves that TRIPS has been forsaken. Others again may argue that the recent changes in India's patent regime do prove its continued vitality.

Over the long run, the phenomena of 'TRIPS flexibilities' and 'TRIPS+' may prove incompatible with the interests of both developing and developed countries. Aside from the general

economic critique of the long term utility of regional and bilateral trade agreements, their overall political legitimacy is also weaker compared with the multilateral level.

The TRIPS Agreement should therefore be strengthened and expanded in a manner that would represent the growing importance of knowledge-based factors in the global economy – both in developed and developing countries, such as India, and even China. Significant technical assistance, as well as some concessions, should also be given to those countries that have yet to experience greater innovation and technology transfer. Put briefly – and in advance of the WTO Ministerial Meeting in Hong Kong (December 2005) – it is time to resurrect TRIPS!

Biography

Dr. Meir Perez Pugatch (MSc. Ph.D.), University of Haifa in Israel, is a lecturer in intellectual property policy, management and exploitation of knowledge assets and entrepreneurship. He finished his B.A. studies in 1997 at the University of Tel-Aviv and received his MSc. degree from the London School of Economics in 1998. He was awarded his Ph.D. from the London School of Economics in July 2002. Since 2005, Dr. Pugatch has also headed the intellectual property and competition programme of the Stockholm-Network.

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The European Perspective

The Community Patent

Elizabeth M. Coleman

This article aims to explain the substance and progress of negotiations to establish a Community patent system since the Commission's proposal of 2000, while highlighting very briefly the long history of the subject.

Patent protection is most useful for inventions which involve high research and development costs but are easily copied. The ability to exclude competitors for a limited time period gives the patent holder an opportunity to recoup his investment by commercialising the invention himself, by licensing its use to others against payment or by selling the patent outright. Once the patent lapses or expires then the invention becomes free for anyone to use. Moreover the technical description of the invention is published in the patent specification and adds to the sum of knowledge available for future inventions.

Given the role of patents in fostering innovation and growth, and the rise of global markets and competition, it is important for inventors and businesses in the EU to have patent protection which is as good as the patent system available to those in other countries. Now under the existing system in Europe, patent protection must be applied for in respect of every individual state where coverage is required. Not only can this be costly and burdensome, but states may interpret the same basic patent under national law in different ways, so that a product which is protected in one state may fall outside patent protection in another. Moreover the need to pay for translations, since the patent documents must be filed in the language of the state concerned, adds considerably to the official fees and professional charges incurred. The result is that patent protection in Europe can be significantly more expensive than in the USA or Japan.

Small and medium sized enterprises operating outside their domestic market are particularly affected by the cost and complexity of the non-integrated system in Europe for two reasons. Firstly, the cost for protection of a single invention may be significant in relation to the company's overall budget, and secondly small firms are less likely to be able to rely on market power instead of patent protection, so they may well seek coverage in several or all EU member states where a large firm would rely on patents in only a few.

The background

In fact, discussions between governments aiming to set up a single European patent system began in the late 1940s. They led eventually to the European Patent Convention or Munich Convention of 1973. This established the existing European Patent Office, granting patents for all the states party to the Convention, according to substantive rules which were also incorporated in national patent laws. From the same beginnings also sprung the Community patent convention (Luxembourg Convention) of 1975. This was subsequently amended in 1989, but for various

reasons did not attract sufficient national ratifications to come into force, although some of its provisions were likewise taken over into national laws.

The 1975 Community patent convention would have established a single patent right, covering all the contracting states (the then members of the EU), rather than the bundle of national patents granted by the European Patent Office, which are governed by national laws for the states where they have effect. It was in the spirit of revisiting the failed Community patent convention that the European Commission issued a Green Paper in 1997 on the future of the patent system in Europe.¹

Responses to the Green Paper showed very clearly that interested circles still wanted a single patent right covering the whole of the EU. And a firm political signal was given by EU Heads of State and Government in the European Council at Lisbon in March 2000, when they called for a Community patent to be available by the end of 2001 'so that Community-wide patent protection in the Union is as simple and inexpensive to obtain and as comprehensive in its scope as the protection granted by key competitors.'² From the beginning, the principles of affordability, efficiency and legal certainty were established as key.

The EU proposals

In the summer of 2000 the Commission issued its proposal for a Regulation on the Community patent.³ As for the earlier Community Trade Mark and Community design

proposals, which similarly set up unitary intellectual property rights covering the whole EU, the proposal was for a Regulation rather than a Directive. Only a Regulation can establish a supra-national IP right; a Directive which harmonises Member States' national laws could not have that effect. Moreover a Regulation is directly applicable without implementation by national governments.⁴ The legal base for the proposal was Article 308 of the Treaty establishing the European Community.⁵ This requires that the Council of Ministers act by unanimity after consulting the European Parliament.

The Commission's proposal envisaged a Community patent which would be granted by the European Patent Office in Munich, but have effect for the whole EU rather than equating to a bundle of national patents as is granted under the current system. Once a patent had been granted, the rules governing validity and infringement of the patent would be those set out specifically in the Community patent Regulation, while issues such as entitlement to the patent (e.g. rules on employee inventions) and treatment of the patent as an item of property would be governed by national law. Translations of the granted patent specification would not be required, except in the case of disputes. And the patent would be renewed for the whole Community through single annual payments rather than payments to individual states. The Regulation provided for adoption of implementing regulations determining fees and other practical issues.

This system of grant by the European Patent Office would require a link to be established between the Community and the European Patent Office, which is not a Community institution or agency – it has no legal relationship with the EU. A simple contract

Given the role of patents in fostering innovation and growth, and the rise of global markets and competition, it is important for inventors and businesses in the EU to have patent protection which is as good as the patent system available to those in other countries.

arrangement was not considered to give the necessary legal certainty as regards the granting of Community rights. Instead the Commission envisaged accession of the Community to the European Patent Convention, so that relevant provisions of the Convention would apply to the Community and Community patents just as for the contracting states and 'bundle' patents. This would mean that the Community as a supra-national entity would become a party to the Convention and a member of the European Patent Organisation just as if it were a nation state. It would require a decision by the Council of Ministers approving the Convention on behalf of the Community.

However the European Patent Convention does not provide for accession by an organisation like the Community. Even though Part IX of the Convention already envisages unitary patent arrangements it does not match the specific circumstances of the EU and the Community patent. So the Commission had to prepare proposals for amending the Convention to allow accession by the Community. Once agreed in EU circles, these amendments would then have to be adopted by a Diplomatic Conference of the contracting parties to the Convention, be ratified and enter into force, before the Community patent could become available. Initial ideas were set out in a Commission services working paper of April 2001.⁶

Besides the Regulation setting out substantive law, and the link with the Convention allowing grant by the European Patent Office, the third crucial pillar upholding the Community patent system was to be a unitary Community jurisdictional system for settling disputes between parties concerning the validity and infringement of a Community patent. This was to be a key feature of the Community patent by comparison with the existing system, where the same basic patent or application can be subject to different interpretations in the different Member States. But jurisdiction over private party disputes was a new departure for the Community, and there was no legal base provided in the existing Treaty.

This meant that the founding Treaty establishing the European Community had to be amended to allow for the Community patent jurisdictional system. Fortunately the process of Treaty revision was gathering pace during the latter half of 2000 and two relevant amendments were adopted in the Treaty of Nice signed in February 2001, which came into force in February 2003.⁷ These are Articles 225a and 229a.

Once the new legal bases were available, and taking account of discussions on the initial ideas presented in a Commission staff working document,⁸ the Commission was able to present its proposals for the specialised Community patent court. The proposed Council Decision under Article 229a confers jurisdiction over Community patent private

party disputes to the European Court of Justice,⁹ while the proposed Council Decision under Article 225a sets out in detail how the Community patent court would be constituted as a specialised panel, with expert judges having access to technical expertise.¹⁰

The Community patent court would rule with EU-wide effect, so that there would be no possibility of differences of interpretation of the scope of the granted patent. This should ensure legal certainty for patent holders and their competitors alike. A Community patent would stand, or fall, for the whole Community, and a business activity would constitute infringement, or not, wherever it was carried out in the EU.

The negotiations

The Commission proposals were sent simultaneously to the Council of Ministers and to the European Parliament so that both institutions could begin their work, and also to the advisory European Economic and Social Committee for its opinion. The jurisdictional proposals were additionally sent to the Court of Justice for an opinion as foreseen in the new Treaty Articles.

In the case of the proposed Regulation, negotiations in the Council of Ministers (the Council working group on patents, COREPER or the Committee of Permanent Representatives, and the Internal Market Council, later the Competitiveness Council) testified to the complexity and political sensitivity of the proposal. Controversial issues included the respective roles of the European Patent Office and national patent offices, language arrangements including translations of patent specifications, whether jurisdictional arrangements should be centralised or in Member States, and redistribution of annual fee income to the national offices as foreshadowed in the Luxembourg Convention. Experts in the working group met for something like three days every month over four years; the file was put to at least 12 meetings of EU Ministers, and on more than one occasion Deputy Permanent Representatives in COREPER continued discussions till the early hours of the morning.

Meetings of the Council working group began under the French Presidency in the autumn of 2000. Initially work focused on the jurisdictional arrangements for disputes, given the need to contain appropriate provisions in the Nice Treaty then under negotiation. The Swedish Presidency took over in 2001, and achieved agreement at the 31 May Internal Market Council on guidelines for future work on the proposal.¹¹ These included a new role for national patent offices in the delivery of the Community patent and a commitment that the annual payment for maintaining the patent would not exceed the fees payable for an average European 'bundle' patent. Given that this covered only around eight states, the commitment represented a considerable saving over existing patent arrangements covering the 15 states of the Community.

Next the Belgian Presidency, mindful of the Lisbon target of end-2001, raised the file to the level of Heads of State and Government at the Laeken summit of December 2001. This resulted in an extraordinary Internal Market Council meeting on 20 December devoted solely to the Community patent. Twelve Member States signalled agreement to a compromise package, but unanimity among the then EU 15 was required. Under the Spanish and Danish Presidencies in 2002 extensive discussions continued on the different aspects with the language arrangements proving particularly difficult to resolve.

It was in March 2003 that agreement was reached under the Greek Presidency on a common political approach which set out key principles of the Community patent system, covering the roles of the European Patent Office and national patent offices, fees, jurisdiction and language arrangements.¹² In particular the central role of the European Patent Office was confirmed; the Community patent court would be a specialised panel under Article 225a of the Treaty; and the compromise on languages was that the patent holder would be required to file translations of the claims of the patent into all Community official languages 'upon grant of the patent.' Commission calculations showed this agreement would result in a competitive Community patent.¹³

This document then served as the basis for new Presidency texts of the Regulation and the proposal for revising the European Patent Convention; work took on new impetus given that many political questions had been resolved and it was mainly technical detail that had to be finalised. Experts from the candidate countries joined the working group as observers from 2003 in preparation for accession to the EU on 1 May 2004 and were also able to contribute to the fine-tuning of the texts.

Indeed the Italian Presidency in November 2003 was very close to achieving agreement in the Council. However one point appeared to be incapable of resolution. Yet again this was the language question, and concerned a point which the common political approach had glossed over – what was the legal effect of the translations that were required to be filed? For some Member States the translations were for information and should have no legal effect as far as their substance was concerned, while for other Member States the translations should be taken into account in determining the scope of the patent. This divergence of views also impacted on the time to be allowed for filing the translations – if they were to have legal effect then arguably they would need to be more precise than if they were to be used for information only, and this would add to the time needed to obtain them.

The Irish Presidency continued efforts to resolve this question, looking for different compromises between the two positions which

would allow for translations to be taken into account but with limited effect.¹⁴ But when at the May 2004 Council five states still could not accept the proposals before them, the Presidency announced their intention to refer the issue once again to Heads of State and Government.¹⁵ This was to no avail, and while subsequent Presidencies continued bilateral contacts and informal discussions, no further progress has been possible despite the large measure of agreement on the texts both of the Regulation and of proposals for amending the European Patent Convention.

The European Parliament also played its part by adopting an opinion on the Commission's proposal as required under the legislative procedure.¹⁶ However discussions in the Parliament focused very much on the same issues as in the Council, although with slightly different results. In particular influences within the Parliament pressed hard for the first instance jurisdiction over disputes to be at national level, rather than Community level, and the language arrangements suggested included a five-language processing regime like that of the Community Office for Harmonisation in the Internal Market, rather than the three-language system under the European Patent Convention. Now the OHIM deals with trade marks and designs, for which very little text is involved, as opposed to patents which may have lengthy and complex technical specifications, so the comparison is not obvious. Such an arrangement could have had significant practical and economic consequences if somehow imposed on the European Patent Office, and it was not a suggestion taken up by the Council.

Mention must be made of the work of the European Economic and Social Committee, which adopted its opinion on the Community patent regulation in March 2003.¹⁷

The Commission's proposals for setting up the Community patent court were affected by the impasse on the Regulation to the extent that neither the Council nor the Parliament began substantive work. On the other hand the Court of Justice did give its opinion on the proposals at the end of 2004.¹⁸

The outcome

Progress on an affordable, efficient and legally certain Community patent has often been cited as a litmus test of the EU Member States' commitment to meeting the goals of the Lisbon agenda they set themselves in March 2000. It can be said that there is a long history of failure of attempts to achieve a Community patent, for example not only the Luxembourg Convention of 1975 but also the amended version in 1989 which did not attract sufficient ratifications. Moreover, the current proposals piggyback on the existing European Patent Convention and have to fit into the existing Community legal order including the long established arrangements of the Court of Justice. These conditions naturally have an

impact on the content and progress of the proposals.

More significantly, the Community patent debate has raised rather fundamental issues of importance across the board for the EU; one is the possibility of Court rulings on private party disputes, and another is the question of language arrangements for documents which may directly affect individual business decisions in an EU of 25 states. Similar language issues have been resolved in rather pragmatic ways in specific commercial sectors, and clearly this is a question which will assume greater importance as the EU expands. But agreement on all the aspects of the Community patent system will be needed, if we are ever to achieve a single patent for the single market, with a single interpretation decided by a single court.

Biography

Elizabeth M. Coleman has a chemistry degree from Cambridge University and joined the UK Patent Office in 1983 as a patent examiner. She moved within the Office to work on corporate policy from 1993 and intellectual property policy from 1995, becoming Deputy Director of IP policy in 2000, and spending four years on secondment to the European Commission in Brussels. Over the last 10 years she has been involved in the negotiation of copyright and industrial property legislation at EU level as well as bilateral and international agreements covering IP. At present she is working in the industrial property unit within the Internal Market and Services Directorate-General of the Commission, where her responsibilities include computer-implemented inventions, the Community patent, and access to medicines.

End Notes

- 1 http://europa.eu.int/comm/internal_market/en/indprop/patent/558.htm
- 2 http://europa.eu.int/comm/internal_market/en/indprop/patent/ec/lisbon03-00.htm
- 3 http://europa.eu.int/comm/internal_market/en/indprop/patent/2k-714.htm
- 4 http://www.europa.eu.int/scadplus/glossary/community_legal_instruments_en.htm
- 5 http://europa.eu.int/abc/treaties_en.htm
- 6 http://europa.eu.int/comm/internal_market/en/indprop/patent/sec01-744en.pdf
- 7 http://europa.eu.int/abc/treaties_en.htm
- 8 http://europa.eu.int/eur-lex/en/com/wdc/2002/com2002_0480en01.pdf
- 9 http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0827en01.pdf
- 10 http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003_0828en01.pdf
- 11 http://ue.eu.int/ueDocs/cms_Data/docs/pressData/en/intm/09120.en1.html
- 12 <http://register.consilium.eu.int/pdf/en/03/st07/st07159en03.pdf>
- 13 http://europa.eu.int/comm/internal_market/en/indprop/patent/docs/2003-03-patent-costs_en.pdf
- 14 See, for example, <http://register.consilium.eu.int/pdf/en/04/st07/st07119.en04.pdf> and http://europa.eu.int/comm/internal_market/en/indprop/patent/docs/2004-05-faq_en.pdf
- 15 http://ue.eu.int/ueDocs/cms_Data/docs/pressData/en/intm/09120.en1.html
- 16 See <http://www2.europarl.eu.int/oeil/file.jsp?id=198752>
- 17 http://europa.eu.int/comm/internal_market/en/indprop/patent/prop01c155en.pdf
- 18 <http://register.consilium.eu.int/pdf/en/04/st14/st14349.en04.pdf>

Note: further information and documents are available on the Commission, Council and European Parliament websites accessible via <http://europa.eu.int/>

IP and Anti-Trust – A European Perspective

Duncan Curley

Competition law is intended to preserve the functioning of a free market economy and to keep prices down for consumers. Intellectual property rights ('IP' or 'IPRs') such as patents, copyrights and trade marks are monopoly rights conferred by the state as a reward for innovation and creativity. Being state-endorsed monopolies, IPRs may confer immunity to certain products from the downward pressure of ordinary market-driven pricing. One of the difficult questions facing IP and competition policy makers is how to balance the degree of monopoly protection given by IPRs to inventors and artists on the one hand against the desirability of maintaining open and competitive markets, on the other.

The main European competition rules are laid down in Articles 81 and 82 of the EC Treaty. The two provisions can affect IP rights-holders in different ways.

Article 81

Article 81 regulates aspects of jointly agreed conduct between companies. Its main purpose is to catch serious anti-competitive practices, such as cartels and price-fixing agreements, but it can render illegal any agreement between companies that has an adverse effect on competition in the common market. As such, Article 81 can catch what otherwise might appear to be relatively benign legal agreements containing apparently inoffensive contractual provisions (such as no-challenge clauses and limited territorial exclusivity).

For IP rights-holders, the main impact of Article 81 is on IP licence agreements, whereby one company agrees to licence its IP to another company, in order (for example) to enable the company receiving the benefit of the licence to operate within the licensor's monopoly. Licensing deals are often done so that companies can benefit from synergies arising out of their respective technological expertise. It is generally an effective way of disseminating technology, leading to innovation and ultimately new and better products for consumers.

Competition regulators have no wish to burden companies involved in licensing with onerous competition law compliance obligations, since licensing activity is usually pro-competitive. The European Commission has recognised that IP licensing usually has positive economic effects that are beneficial to consumers. It has therefore issued a special regulation which provides an automatic exemption from Article 81 for technology licensing agreements between two parties (including licences of patents, know-how and software copyright). This piece of legislation is Commission Regulation (EC) No. 772/2004, known as the Technology Transfer Block Exemption Regulation, or the TTBER. It came into force at the end of April 2004.

The exemption in the TTBER provides what is often called a 'safe harbour' or 'safety zone' by way of an automatic exemption from Article 81 for certain IP licence agreements. If an agreement comes within the scope of the

TTBER, it is within the safety zone and it is deemed to be exempt from the prohibition against anti-competitive agreements in Article 81. This is important for two main reasons. First, it ensures that the agreement is legal and enforceable. Second, it avoids the risk of fines after an investigation by a regulator, such as the European Commission.

Article 82

Article 82 applies to companies acting unilaterally that abuse a dominant position on a relevant market. It has been said to place a special responsibility on dominant firms – that is, firms with a strong market position, with (say) a 40%+ market share of a particular market not to behave abusively towards others. Over the last half century, Article 82 has been applied to companies supplying or owning products and services as diverse as bananas, cash registers, sugar, telecoms networks, travel agency services and software. There are four aspects to proving an abuse of a dominant position under Article 82:

- 1) an undertaking must have a dominant position on a relevant market;
- 2) the undertaking must have engaged in abusive behaviour;
- 3) the abuse must have affected trade between Member States of the EC; and
- 4) the abusive conduct must not be capable of objective justification by the undertaking that has been accused of the abuse.

It is important to note that although IPRs are monopoly rights, mere ownership of an IPR is not sufficient to establish a dominant position on a relevant market, for the purposes of Article 82. This is because the relevant market will often consist not just of products covered by a particular patent, copyright or trade mark. It is often the case that other products may compete on a market with a product that is protected by IPRs. Market dominance on the part of an IPR owner will only usually arise if there are no or only few non-infringing substitute products available for consumers to buy.

Article 82 and the compulsory licensing of IPRs

Many decisions of the Commission and of the

European Community courts have been taken under Article 82. Decisions ordering the compulsory licensing of intellectual property rights – *Magill* and *IMS Health* – are amongst the most controversial of these decisions. The compulsory licensing of IPRs under EC competition law developed from the European Court of Justice's judgment in 1974 in the case of *Commercial Solvents*. *Commercial Solvents* was the dominant supplier of a raw material used in the manufacture of a drug to treat TB. *Commercial Solvents* ceased supply of the raw material to Zoja, a company active in the downstream market for supply of the anti-TB drug. The dominant company cut off supply to Zoja because it wanted to supply the anti-TB drug itself. The Commission held that *Commercial Solvents* had abused its dominance by refusing to supply Zoja and ordered the resumption of supplies of the raw material.

In 1988, the European Court of Justice considered the case of *Volvo v Veng*. *Volvo* had alleged that the import and sale in the UK by *Veng* of front wing components for *Volvo* cars infringed one of *Volvo*'s UK IP rights (a registered design). *Veng* alleged that *Volvo* was abusing its dominant position on the market for spare parts by refusing to grant *Veng* a licence. The ECJ held that any obligation imposed by Article 82 and competition law upon the proprietor of an IPR to grant a licence would take away the very substance of the exclusive monopoly right. The court did however say that the exercise of an exclusive right by the proprietor of an IPR could infringe Article 82, if the dominant undertaking had carried out other culpable acts in addition to the refusal to license, for example, an arbitrary refusal by the dominant undertaking to supply spare parts to independent repairers, or the fixing of prices for spare parts at an unfair level.

The first case in which IPRs were the subject of a compulsory licence order under EC competition law came in 1995 with the *Magill* decision. Mr *Magill* wished to publish a composite TV programme guide for Irish viewers. Until Mr *Magill* arrived on the scene, consumers had had to buy separate TV guides for each channel. The Irish broadcasters sued Mr *Magill* for infringement of copyright subsisting in the list of TV programmes contained in their individual guides. On appeal, the ECJ confirmed that each broadcaster was dominant in the market for TV scheduling information. Furthermore, the refusal of the broadcasters to license Mr *Magill* infringed Article 82. In particular, the ECJ held that the exercise of an exclusive right such as copyright may in exceptional circumstances infringe Article 82. The exceptional circumstances in this case included the fact that the refusal to license Mr *Magill* prevented the launch of a new product for which there was proven consumer demand.

Some IP rights-holders believe that any competition law remedies which impinge upon the otherwise lawful exercise of IPRs are wrong in principle, since they take away the very reason for granting the IP rights in the first place.

All was then quiet on the compulsory licensing front until the relatively recent *IMS Health* case. IMS Health owned a copyrighted database containing German pharmaceutical marketing data. It sued a new market entrant, NDC, for copyright infringement in relation to NDC's similar product. In October 2001, the German national court referred questions to the ECJ on a preliminary reference. These included the question of whether IMS Health could obtain injunctive relief under German copyright law if IMS Health's refusal to grant a copyright licence to NDC infringed Article 82. Following *Magill*, the ECJ held that in order to compel a copyright owner to grant a licence, the owner's refusal must prevent the emergence of a product for which there was potential consumer demand. Commentators have noted that the ECJ's decision in *IMS Health* is not precisely in accordance with its previous decision in *Magill*. The *IMS Health* decision seems to suggest that a compulsory licensing order can be made provided only that there is potential consumer demand for a product, without the requirement that this 'product' be a new product that is not already being sold by the IP rights owner.

Finally, in 2004, the Commission issued a decision stating that Microsoft Inc. had infringed Article 82 by leveraging its near monopoly in the market for PC operating systems on to the market for work group server operating systems (and by bundling its media player with 'its ubiquitous Windows operating system'). The Commission undertook its economic market analysis and found that Microsoft had a near-monopoly in client PC operating systems, with a market share that was in excess of 90%. According to the Commission, Microsoft had abusively refused to supply Sun Microsystems and other rivals with specifications for communication protocols that allow work group servers to

interoperate with Windows PCs. Microsoft's conduct was said to threaten to eliminate competition in the market for work group server operating systems, even though there were several existing players in this market with their own product offerings.

In order to remedy the alleged adverse effect on competition, the Commission ordered Microsoft to disclose complete and accurate interface documentation, thereby allowing non-Microsoft work group servers to achieve full interoperability with Windows PCs and servers. Microsoft had previously justified its refusal to disclose this information by relying on its IPRs. It claimed that its patents and copyright could be used to prevent the use of the interface information by others. The Commission said that if the interface information was protected by IPRs, it relied on the *Magill* case as justification for a compulsory licence, citing 'exceptional circumstances', these being Microsoft's overwhelming dominance, the indispensability of the interface information to competitors and the risk of elimination of competition. The Commission believes that its decision in the *Microsoft* case accords with the ECJ's earlier decision in *IMS Health*, namely, that the suppression of a brand new product by the assertion of IPRs is *not* a necessary condition in order for competition law to apply and to force a compulsory licence of IPRs. However, Microsoft disagrees and the case is now on appeal to the Court of First Instance.

What is the right balance between competition law and IPRs?

The European Commission wishes to use competition law as a way of facilitating new and innovative products and encouraging dynamic markets. Unfortunately, it is sometimes the case that intervention by the competition authorities is appropriate in order

to regulate certain behaviour of companies that does or may have an adverse effect on markets and consumers. IP-based companies are no more immune to an investigation of their business practices than any other companies, although they will frequently allege in defence of their behaviour that their acts must be legitimate, when performed within the scope of legal monopoly IP rights. The Commission says that it is always careful to ensure that the imposition of an order under the competition rules is fair and proportionate to the scale of the infraction, although some IP rights-holders believe that any competition law remedies which impinge upon the otherwise lawful exercise of IPRs are wrong in principle, since they take away the very reason for granting the IP rights in the first place. IP rights owners are also concerned that the criterion laid down in the caselaw in the 1990s for the imposition of a compulsory licence has recently been eroded with the decisions in *IMS Health* and *Microsoft*. The debate and the case law continue to evolve.

Biography

Dr Duncan Curley is a partner in the Intellectual Property, Media and Technology Group at the international law firm of McDermott Will & Emery UK LLP. Duncan represents clients in a variety of sectors, including large and small companies, charities, individuals and universities. He advises on all aspects of IP, including patents, trademarks, designs, copyright and confidential information. Duncan has a particular interest in the impact of European competition (antitrust) law on the exercise of IP rights and he is the author of the leading textbook on the European Technology Transfer Licensing Block Exemption. He has also published in *European Intellectual Property Review*, *The Journal of BioLaw & Business*, *The Solicitors' Journal* and *The Times*.

Interoperability, IPRs and the Computer Implemented Inventions Directive

James Killick & Vincent Artis

During the past two years, the subject of interoperability has received close attention in the EU, notably during the debate on the proposal for a directive on the patentability of software, which became known as the Computer-Implemented Inventions (CII) Directive. As the proposal went through the adoption process, more attention was paid to its provisions on 'interoperability'.

This issue became prominent in the discussions over the CII Directive because of the broader debate in IT circles over the merits of open source, as opposed to proprietary, software. Advocates of open source software (OSS) believe that software should not be protected against unauthorised copying, and decompilation, but instead should be free in the sense that anyone should be able to make unlimited copies of the software and to access and read the underlying source code and to modify all or parts of the software. The increased awareness of the issues underlying this debate on the part of Members of the European Parliament (MEPs) goes a long way towards explaining the arguments which arose over interoperability during the second reading of the proposal.

This paper examines the issues that arose in relation to interoperability during the debates on the CII Directive.

Interoperability in the IT sector

In the field of information technology (IT), the term interoperability is generally understood to mean the ability of heterogeneous IT networks, applications, or components to exchange and use information, i.e., to 'talk' with each other. In simple terms, when two computer programs interoperate, the information generated by one can be used by the other. Interoperability is of course a continuum, and more expansive definitions are sometimes advanced. At the extreme, interoperability is defined by some to require that the two programs should be interchangeable. For two programs to be interchangeable they would have to mimic each other in the sense that each program could access and use all of the other's features. In commercial reality, interoperability means that two programs can communicate with each other; it does not mean that they should be able to copy all of the other's features and functionality.

The IP rights at issue

The information needed to achieve interoperability with a particular computer program will generally be protected by intellectual property rights (IPRs). Three different types of IP protection may be available.

First, the program can be protected by copyright, which gives the rightholder protection against literal copying and publication of derivative works and unfair imitation based upon decompilation that reveals how the program is designed, engineered and implemented. The rightholder has strong commercial and legal incentives to

enable interoperability by publishing the application programming interfaces (APIs) and implementing industry standards. Copyright does not prevent third parties from interoperating through APIs and industry standards. And subject to the restriction on decompilation, third parties are not prohibited by copyright from independently developing their own software programs that are similar to the original program.

Second, the program may contain patented inventions. Patents offer an exclusive right to use the invention for a limited period of time, in exchange for publishing the invention as part of the patent process. Some areas of technologies are extensively patented, such as digital rights management (DRM), and a program to make two DRM systems interoperable could require a patent licence.

Third, the program's software design, engineering and implementation methods could also be trade secrets, unless the rightholder chooses to make the information public, e.g., to publish the source code. Trade secrecy protects against unlawful disclosure of a secret, but it does not prevent someone from achieving interoperability as a result of his or her own endeavour. In other words, it does not grant the rightholder exclusivity in the same way that patents do.

The current rules on copyright and interoperability

Existing EU law already reflects a careful balancing of intellectual property protection with interoperability. Directive 91/250/EEC on the legal protection of computer programs by copyright (the 1991 Software Directive) aims both to stimulate innovation by guaranteeing copyright protection for software, and to encourage interoperability. One of its fundamental goals was to prevent unfair imitation of an innovator's computer program, while avoiding unacceptable barriers to interoperability. It therefore contains a compromise which allows a licensee unlimited rights to study and observe a program and limited rights to decompile a program in order to investigate its interfaces. The decompilation right is subject to certain very specific conditions. Firstly, the act of decompilation must be limited in scope, i.e. it must be undertaken only to achieve interoperability with an independently created program and must be confined to the parts of the original program that are necessary to achieve interoperability. Secondly, the information necessary to achieve interoperability must not previously have been

readily available to the licensee. Lastly, the decompiled source code may not be made public and the information cannot be used to create a computer program substantially similar in expression.

The context in which the CII proposal was brought forward

The CII proposal aimed to harmonise national laws on the granting of patents for inventions which operate through the use of computer software. (Software itself is, of course, protected by copyright in the EU.) Some Member States and the European Patent Office already grant patents of this kind, and they are common in the US and Japan. Online consultations held by the Commission in 2001, before the proposal was finalised and published, revealed concerns in some quarters that the competitiveness of EU industry would suffer if harmonised patent protection of this kind was not available.

Supporters of software patents argued they were needed to protect companies which had spent time and money on developing their innovations. They wanted EU legislation to stop competitors from appropriating their technology and using it in their own products without risking any legal consequences. They argued that copyright protection is difficult to apply in this context and that patent protection would give innovators much greater security, as well as the means to attract the investment needed to take products to market.

On the other hand, small software producers expressed very strong opposition, on the ground that large firms would misuse patents to maintain their dominant positions. At the time of the 2001 consultations, the OSS community was less numerous and vocal than it has since become, but the arguments made by small producers then were not dissimilar to those of the OSS community now. They claimed that small software developers would be unable to afford the costs of obtaining patent protection, that patent protection would limit innovation by forcing programmers to spend time checking for patent infringements, and that it would trap ideas developed in the IT world in the hands of large (and, it was said, non-European) corporations. The need for new products to be interoperable with existing and possibly patent-protected technology was among the arguments raised by opponents of software patenting, but it was not then at the core of the debate.

Interoperability in the CII Proposal

The Commission initially proposed similar checks and balances for the CII Directive as had been in the Software Directive. Article 6 of its original proposal of February 2002 expressly followed the same provisions on decompilation and interoperability as in the Software Directive. The Commission proposed extending the same decompilation exception to patent protection in order to

The interesting debate over interoperability and IP rights in the CII proposal is now a matter of history.

a matter of history

make the holder of a patent covering a computer-implemented invention unable to interfere with the freedoms granted under copyright law to software developers. The Commission also recognised the desirability of the interoperability exception to ensure that computers could talk to each other, and the proposal sought to create a safety net against use of patents to hinder communication between computers. Where patent protection was used to abuse an existing dominant position, recourse to competition law would remain available.

Thus interoperability was not initially perceived as a controversial element of the CII proposal. However, during the first reading of the proposal in September 2003, the Parliament effectively undermined the patent protection by adopting an amendment stating that the use of a patented technique to ensure communication between computers was not a patent infringement, whether or not the patent holder had consented and received compensation. This exemption went beyond simply promoting interoperability as it effectively ignored any potential infringement of patent protection and eliminated the need to obtain the patent holder's consent before using a patented technique. The Parliament adopted the amendment because MEPs were afraid that software firms which obtained patent protection for a dominant proprietary standard might 'lock in' the market and make it impossible for other programs to interoperate and thus to compete.

The European Council of Ministers did not follow the Parliament's approach, but it too chose to modify the proposal by redrafting the exemption in the original text. It rejected the Parliament's proposed amendment as too open-ended, and as contradictory to the Trade Related Intellectual Property Rights

(TRIPS) Agreement. This suggests the Council believed the interoperability issue was already sufficiently covered by the original Commission provision and the general competition rules. However, the Council proposed to add a recital stating that the Directive was without prejudice to the competition rules, especially if a dominant player tried to block interoperability through patent protection. Opponents of the CII proposal in general objected that the recital would leave a patent holder free to block interoperability as much as he wanted, provided he did not violate antitrust law.

By the time the Council Common Position was adopted in March 2005, public awareness of the issues involved had spread far beyond information technology specialists and intellectual property lawyers. The OSS community continued to highlight what it perceived to be the risks to interoperability in the proposed Directive, and its views won considerable support in the European Parliament. Certain Member States, led by Poland and Denmark, also found the Council text unacceptable, notably with regard to interoperability.

The Commission's views also shifted. In a 'Communication on the Common Position of the Council', it moved from the basically neutral attitude on interoperability of its original proposal to the voluntary promotion of interoperability as '*a mean of fostering innovation and competition*'. Apparently the Commission had come to consider that current patent laws, which have no infringement exceptions for interoperability reasons, should be modified to provide an interoperability exemption regime for infringements like that for copyright in the Software Directive.

The Parliament's second reading discussions were steered by an openly pro-OSS *rapporteur*, Michel Rocard and fierce debates took place on whether patents were justified in the IT world. Mr Rocard and his supporters clearly felt that this matter should be resolved by the legislation, and he therefore decided to re-table the wide interoperability exemption amendment from the first reading. Despite this, however, the Parliament did make an attempt to reach a compromise with the Council. During informal discussions between the *rapporteur* and the Council, the Council showed some willingness to consider MEPs' arguments on the interoperability issue. However, a suggestion from MEPs that patented technology should be submitted to standards-making organisations was not accepted as a viable solution by the OSS community and their spokesmen in the Parliament, because standards would carry licence fees, which the OSS community argued would be an unacceptably heavy burden for SMEs and individual programmers.

In addition, some MEPs thought this was a good opportunity to incorporate the TRIPS provisions into EU law, by specifying that an interoperability exemption did not prejudice the legitimate rights of patent holders. Patent supporters objected to what they saw as an attempt to water down the TRIPS provisions. They argued that preventing a patent holder from enforcing his patent was not compatible with TRIPS, particularly Article 27, which prohibits any discrimination of protection between fields of technology. They also pointed out that the interoperability amendments did not incorporate the TRIPS requirement that a proposed licensee must first make '*efforts to obtain authorisation from the rightholder on reasonable commercial terms*'. They added that the rightholder should receive an adequate recompense, determined by a judicial authority and took account of the economic value of the use made of the interoperability facility.

For patent supporters, the main problem was how to prevent situations where a developer requested a licence under the guise of interoperability, but then used the patented information for entirely different purposes. A developer might claim that any invention should be licensed because it was indispensable for achieving interoperability. This would create serious risks unless the licence required the developer actually to use the patented technology/invention for the purpose indicated, i.e. to interoperate with other programs.

Patent supporters also recalled that if competitive forces on their own were not sufficient to promote interoperable products, competition law was there to protect the public interest. The Commission and the European Courts, notably in the *Magill* case, have already accepted that dominant companies may be subject to a compulsory licence of their intellectual property rights.

Thus it seemed certain until the eve of the Parliament's vote in second reading on the CII proposal that some form of amendment relating to interoperability, however worded, would win broad support, both from MEPs, the Council and the Commission. In the end this was not the case, as the Parliament voted to reject the entire proposal. Ironically, the interoperability issue was not the cause of the proposal's demise. The fatal blow was struck by the inability of Parliament and Council to agree on a definition of what was patentable under the Directive. Because there was no solid parliamentary majority on the other main elements in the proposal, Parliament could not make the Council take its view on patentability into account, and therefore decided that the only solution was to reject the proposal in its entirety. With it died all the solutions to interoperability put forward during the debate.

Conclusion

The interesting debate over interoperability and IP rights in the CII proposal is now a matter of history. But, despite the fears that were raised during the debate, there is interoperability in the marketplace today. Market forces, recourse to common standards, reverse engineering, the Software Directive and the EU competition rules have been effective in enabling undertakings to achieve interoperability.

Biography

Vincent Artis works for the law firm White and Case and advises in the area of EU regulatory affairs, public affairs and advocacy. He focuses on Internal Market legal issues such as intellectual property law, audiovisual policy, consumer and health law, public procurement and environmental liability, with a particular emphasis on legislative and decision-making procedures, comitology and political developments in the EU institutions and Member States.

James Killick works for the law firm White & Case and regularly advises clients on the compatibility of agreements with EU law. He has also been involved in pleading a number of leading cases in the European Courts, including *Microsoft v Commission* (abuse of dominant position, compulsory licensing), *Hanner* (Swedish retail monopoly on pharmaceuticals), *Pfizer v Council* (precautionary principle), *IMS Health* (compulsory licensing) and *Servier v Commission* (banning of pharmaceuticals).

End Notes

¹ White & Case, Brussels. The views expressed herein are personal and do not reflect the views of our law firm or of our clients.

The State of Pharmaceutical IPRs in Europe

Manuel Campolini

The present paper aims to provide a short synthesis of some recent developments in the European Union. Even though it is difficult to draw a final conclusion, it seems at this point that the EU authorities have not fully understood under which conditions Europe will be able to maintain a top level innovative pharmaceutical industry.

The pharmaceutical industry is characterised by two segments: the research and development (R&D) based pharmaceutical industry, also known as the innovative industry, and the generic industry, which markets copy products. In practice, however the situation is less clear-cut.

Many R&D-based companies such as Pfizer, Johnson & Johnson and MSD don't have generic activities. At the same time, a number of innovative companies do have strong generic activities: Novartis with its generic subsidiary Sandoz is one example. Excluding pure generic companies such as Ratiopharm or Randbaxy, some generic companies also develop research programmes and market innovative products. One example is Copaxone, a successful product for the treatment of multiple sclerosis currently marketed by Teva, the largest generic group worldwide.

One should not neglect the fact that the innovative industry includes an increasingly important biotech sector with an adapted regulatory framework and requirements. This specific environment may affect the quality of the protection granted to innovative biotech products.

As with other innovative products, pharmaceuticals can benefit from various forms of intellectual property rights (IPRs) such as copyrights, trademarks or patent protection. The key element is to determine when a protected innovative product can be 'genericised'. This may depend on four interconnected factors: patent protection and supplementary protection certificates (SPCs), data exclusivity (or data protection), registration rules and competition rules. This article discusses these factors in the context of the European Union (though not necessarily in the above order).

Data Exclusivity and registration issues

Any pharmaceutical company interested in marketing a new medical product is required to submit a dossier to the regulator, including relevant information such as pre-clinical and clinical data that demonstrate the quality, safety and efficiency of the product. These data are both costly and time consuming to generate. Data Exclusivity relates to the period of time after which a generic company can register its copy product on the basis of an abridged application, i.e. without submitting these data but rather relying on the originator's registration dossier. Data Exclusivity is important when there is no patent available or when the innovative drug is only partially protected by a patent. In the

EU, this period was previously six or ten years after the first marketing approval of the originator's product.

As a result of various decisions made by the European Court of Justice (*Generics case C-368/96*, *Novartis case C-106/01*; *APS case C-36/03*), the data relating to any new drug development (e.g. a new indication or a new delivery system) registered by the innovative company during or after the 6/10 years period are not protected as such. In the US, on the other hand, a specific Data Exclusivity might protect these types of new developments. In the *SKB case (C-74/03)*, the Court confirmed in substance that a generic product does not have to be strictly identical to the original one and may use a different salt provided that the change does not significantly affect the safety or efficacy of the copy product.

The new EU pharmaceutical legislation adopted in 2004 has a harmonised Data Exclusivity period of eight + two years, which can be extended to 11 years. After eight years, a generic company can submit an abridged application in order to obtain approval, and after 10 years it can market its own copy product. The 10-year period can only be extended to 11 years if the innovator registers a new important indication. This new system is likely to be valuable for generic companies wanting to copy biotech products (bio-generics or bio-similars). Biotech pharmaceutical products contain complex molecules where small changes can have huge impact on their safety and efficiency. The products are extremely process dependent and the generic companies might not have the process know-how of the originator. Therefore, a generic company cannot simply refer to the innovator's dossier and provide only a bio-equivalence study. Indeed, the registration of such copies requires the submission of a number of specific studies in order to ascertain their safety and efficiency. The assessment process is likely to be longer compared to traditional generic products. In the past, applications for bio-generic products could only be submitted after 10 years. The new law however, allows generic companies to apply after only eight years.

Pharmaceutical Patents and Commercial Testing by Generic Companies (Bolar)

The new EU legislation has also introduced a Bolar-type provision, which allows generic companies to conduct bioequivalence studies in the EU before a patent expires.

Bolar aims at allowing generic companies to obtain registration of its product before patent expiry and for the product to be on the market day one after patent expiry. Registration normally requires the conduct of a bioequivalence study to demonstrate that the generic product is essentially similar to the original one. In the absence of the new provision, such studies would be considered patent infringement.

The EU provision also allows the conduct of any clinical trials for registration purposes before patent expiry. This might be more valuable for the registration of bio-generic products, which requires such additional studies.

However, it has been argued that the new provision only allows the conduct of trials by a third party but not their submission to the authorities before patent expiry for generic registration purposes.

IPRs, parallel trade and competition

Due to the divergent pricing policies of EU-members, significant price differences within the EU have arisen and boosted the parallel trade of patented pharmaceutical products.

Parallel trade occurs when an independent company exports an original product from a low price country (e.g. Greece) to a high price country (e.g. UK).

The process usually generates huge profit for the parallel traders. R&D-based companies have consistently argued that the trend is negatively affecting their innovation capacities without benefiting patients (in terms of lower prices) or the Member States.

Consequently, research-based pharmaceutical companies have undertaken numerous steps in order to avoid, or at least curb the effect of parallel trade particularly on high priced patented products. These actions, however, raised the question of their compatibility with competition rules, something the Commission is particularly sensitive about these days.

Two examples may be given;

The GSK case

The main aspects of the *Syfait vs. GSK C-53/03* can be summarised as follows: GSK in Greece was providing a limited supply of pharmaceuticals to wholesalers in order to avoid the parallel trade of patented products from Greece, a country where low prices are imposed by the authorities, to EU countries where prices reflect the value of pharmaceutical innovation more accurately. The Greek competition authority therefore asked the European Court of Justice to clarify whether a pharmaceutical company, which is in a dominant position with respect to a

While the EU has strengthened its pharmaceutical IP environment in areas such as Data Exclusivity, such improvements are always adopted years after the implementation of their equivalent by the US.

pharmaceutical product, is breaking Article 82 of the EC Treaty (abuse of a dominant position) by refusing to meet wholesalers' orders in full, with the aim of limiting parallel trade. For the Advocate General Jacobs the refusal might be considered acceptable, particularly because of the unique characteristics of the pharmaceutical industry, such as Member States' intervention in the pricing of pharmaceutical products and the negative consequences of parallel trade for pharmaceutical innovation and for consumers. However, the Court has refused to answer these questions, on the grounds that the Greek competition authority was not entitled to ask for a preliminary ruling. Even if national courts still have full competence to request a preliminary ruling on similar issues, the economic operators remain confronted with legal uncertainty on the European market in the absence of any guidance from the Court.

The AstraZeneca case

On 15th June 2005 the Commission indicated that it would fine AstraZeneca 60 millions for abusing its dominant position in the treatment of its blockbuster anti-ulcer drug Losec.

The Commission said AstraZeneca was breaking Article 82 EC and imposed the fine because the company was *giving misleading information to several national patent offices ... resulting in AstraZeneca gaining extended patent protection for Losec through so-called ... SPCs' and for 'misusing rules and procedures applied by national medicines agencies ... by selectively deregistering the market authorisations for Losec capsules in Denmark, Norway and Sweden with the intent of blocking or delaying entry by generic firms and parallel traders.'*

The Commission's decision concerning the so-called *selective deregistration* of Losec capsules to prevent parallel trade, relates, in particular, to the Court decision in case C-15/01. Losec *tablet* (MUPS) was launched in Sweden on the basis of a new and separate approval and AstraZeneca withdrew the Swedish marketing authorisation of the previous Losec *capsules*. As a consequence of the withdrawal, the Swedish authority decided that the parallel import licence for Losec capsules belonging to Paranova was no longer valid. This decision was challenged and the European Court of Justice ruled the subsequent withdrawal of the parallel import licence to be in opposition to the principle of free movement of goods.

The Commission's argument that *deregistration* of Losec was being used as a tool to abusively block generic entry, refers to the Court decision in case C-223/01. The Danish marketing authorisation of Losec capsules was also withdrawn and the new Losec tablet was launched. Generics UK Ltd had submitted an abridged application for Omeprazole capsules before the withdrawal of the marketing authorisation of Losec capsules. However, the approval of the generic Omeprazole was given after the withdrawal of Losec capsule authorisation. AstraZeneca challenged this approval, but the Court argued that a national approval based on an abridged application could be granted in such cases.

AstraZeneca contended that it had acted in good faith and that Losec was not in a dominant position. The company announced its intention to challenge the decision before the European Court of First Instance in what

may well be a landmark case for the pharmaceutical industry. AstraZeneca argued that *'the matter was so unclear'*, that the issue *'was ultimately decided by the [European Court of Justice] after several years of legal arguments'*, that the withdrawal of marketing authorisations was a legitimate business decision, and that Losec tablets *'offers significant benefits over capsules for certain categories of patients'*.

The decision of the Commission might raise the question of whether competition rules have primacy over intellectual property rights in certain circumstances.

SPC extension and medicinal products for paediatric use

Regulation EC 1768/92 provides pharmaceutical innovators with a Supplementary Protection Certificate (SPC), the aim of which is to extend pharmaceutical patent protection by an additional period of up to five years (while limiting the combined maximum period of market exclusivity of the basic patent and the SPC to 15 years from the date the patented product is authorised for market use).

Similarly to the practice in the US, SPC was given in the EU in order to compensate companies for the development time needed before the product approval would be obtained (from eight to 12 years).

Last year the Commission submitted a proposal aimed to increase R&D on products for the treatment of children (so called paediatric drugs). This complex piece of draft legislation argues that any future application for a first marketing approval of a pharmaceutical product will need to include the results of all studies and information collected by the originator in accordance with a *paediatric investigation plan*. A waiver will be granted for a medicinal product or for classes of medicinal products in a number of situations, in particular if there is evidence that the product is likely to be ineffective or unsafe in part or all of the paediatric population. The company may also request a deferral of the initiation or completion of the measures set out in the plan, when it is appropriate to conduct studies in adults prior to initiating studies in the paediatric population or when studies in the paediatric population will take longer to conduct than studies in adults.

The proposal establishes that a six months extension of the SPC term will be granted when the paediatric indication is labelled. If this is not the case, the extension will nonetheless be granted, provided the results of the studies completed are reflected in the labelling of the product.

Paediatric studies already submitted for evaluation in non-EU countries will not qualify for the incentive. That is because the EU does not wish to reward studies completed before

the adoption of this regulation. As a matter of fact most of them have been completed in the US, whereas a six-month extension period of any type of protection (patent, patent term restoration, data exclusivity, etc.) has already been in place for years in order to encourage paediatric research. The regulation will anyway impose the submission in the EU of all previous studies meaning these studies already submitted in the US.

On 7th September 2005, the European Parliament adopted MEP Françoise Grossetête's report on the Commission's proposal in its first reading. It is noticeable that the European Parliament has accepted the Commission proposal of a fixed six-month SPC extension without any amendments, when it has previously rejected suggestions allowing the granting of a variable and reduced period of extension. The proposal will now go back to the Council of Ministers before the second reading of the European Parliament and the final adoption.

In conclusion

Today, the EU is at a crossroads. While the EU has strengthened its pharmaceutical IP environment in areas such as Data Exclusivity and will possibly strengthen it in granting additional SPCs in the context of paediatric research, such improvements are always adopted years after the implementation of their equivalent by the US. This situation, combined with the current uncertainty regarding the scope of competition rules on patented products, is not a factor likely to make Europe a natural home for pharmaceutical innovation. This is particularly true in a context where the Union is rapidly losing its competitive edge in this key area of R&D. Even though there are more reasons for this than IP protection, it is evident that this element plays an important role and needs to be addressed.

Biography

Manuel Campolini is a member of the Brussels Bar and has been working since the end of the 1980s in the area of intellectual property rights including patent, trademarks, data exclusivity at national, European and international levels. Within the Law Firm Janson Baugniet, he is member of the *Intellectual Property and Life Science department*, with a practice that focuses on legal assistance, advice and litigations related to IP and to pharmaceutical issues such as regulation and registration, pricing and reimbursement, parallel trade, etc. As a specialist of IP and pharmaceutical law, he is also a frequent speaker and author of articles and other publications on his areas of expertise.

Biotechnology and IPRs in Europe

Graham Dutfield

In July this year, the European Commission admitted that trying to impose common European Union-wide patenting rules and practices for biotechnological inventions had gone about as far as it could go. With persisting divergencies among the laws of EU member states (including two of the most economically powerful ones) in the areas of gene and stem cell patenting, the Commission accepted that harmonisation had limits that could not be overcome.

The Commission's admission may be a surrender or just a tactical retreat. Either way it is significant, politically if not economically. As long ago as 1989, the Commission drafted a Directive on the Legal Protection of Biotechnological Inventions. In doing so, the Commission sought to counter legal uncertainty concerning the patenting of such inventions which it considered prejudicial to the growth of commercial biotechnology in Europe. The aim was to harmonize patent law relating to biotechnology around high minimum standards, while preventing member states from backsliding by, for example, banning or restricting patents on living organisms and genes. The Commission showed great determination in finally getting the Directive approved by the European Parliament nine years later; as it did when so many countries took much longer to implement it than Community law allowed. It now appears that EU members can interpret the Directive as they see fit, safe from legal challenge from the Commission.

This article discusses what is currently the most important area of divergence and assesses the implications of lack of harmony for Europe and its biotechnology industry. Such an assessment can benefit from comparisons with other countries having advanced biotech sectors. Therefore, we consider the case of the United States where the biotechnology industry is more mature than in Europe, where the patent system generally has been more accommodating to new technologies including biotechnology, and, again unlike Europe, presents us with a single patent jurisdiction. It is argued, admittedly without offering any overwhelming evidence, that the differences in biotech patent regulation within Europe and between Europe and the United States are unlikely to have much effect on the competitiveness of the European biotech industry compared to the United States. Neither will they have much influence on where biotechnological research is carried out within the continent of Europe. There are of course counter-arguments, some of which are presented in this article.

The differences in biotech patent regulation within Europe and between Europe and the United States are unlikely to have much effect on the competitiveness of the European biotech industry compared to the United States.

The first of the two controversies, and to date the most important one economically, concerns the proper scope of DNA patents. The view of many if not most businesses and patent practitioners is that DNA is a chemical, no more or less. As such, it should be possible to claim a disclosed DNA sequence in the same way as a newly characterised chemical can be claimed for all known and yet to be discovered uses. However, France and Germany have opted, in the case of human sequences, for so-called 'purpose-bound protection' according to which DNA can only be claimed in respect of a specified use. Let us suppose there is a gene that codes for proteins A, B and C. The company that finds the gene discovers only that it codes for A and patents it on that basis. In the United Kingdom and the United States, that company can control use of the gene for any application or function subsequently discovered while the patent remains in force. But in Germany and France, another company that discovers the gene's role in producing proteins B and C can independently patent the gene in relation to those functions (but only those functions).

So what is the appropriate position to adopt: full product protection or purpose-bound protection? The only honest answer is the underwhelming one of 'it's difficult to say for sure.' Nonetheless, to this author the purpose-bound approach makes much sense.

Certainly, supporters of the French and German positions could deploy some persuasive scientific and economic arguments. Scientifically speaking, the state of the art in molecular biology is whizzing forward. If the recent past is even a halfway decent guide to the near future, much of what we assume to be true today will seem pathetically misguided in a few years. Scientists now believe that as much as 98.5 percent of human deoxyribonucleic acid (DNA) is non protein-encoding even though much of it is still transcribed into ribonucleic acid (RNA) for reasons that we hardly

understand (but probably will in the coming years).¹ The conundrum is that 'either the human genome ... is replete with useless transcription, or these nonprotein-coding RNAs fulfil some unexpected function.'² Apparently, 'these RNAs may be transmitting a level of information that is crucial, particularly to development, and that plays a pivotal role in evolution'.³

The widespread assumption till recently, and one generally held by patent applicants, agents and examiners, that genes operate independently and perform single functions is now demonstrably false. Indeed, the 'gene' itself is beginning to look like a rather shaky concept. A scientist at the Karolinska Institute in Sweden admitted that 'we tend not to talk about 'genes' anymore; we just refer to any segment that is transcribed to RNA as a 'transcriptional unit'.⁴ Admittedly, it has been known for some time that a gene can produce more than one protein, for example by means of a process called 'alternative splicing' in which coding sections of the gene are selectively deleted. But it is now more apparent than ever that genomes consist largely of multiple intersecting 'mini-ecosystems' forming one larger one (i.e. the genome itself). They are definitely not single collections of separately functioning 'Lego bricks' (i.e. the individual genes) that can be combined and recombined precisely, predictably and with no possibility of unintended consequences.⁵

Consequently, one can argue on sound scientific grounds that treating genes as patentable inventions on the basis of a single disclosed function or discovery such as that it codes for a particular protein, or that it is associated with a disease, is a rather generous interpretation of the 'inventor's' relatively modest addition to the state of the art. This is not to say that such discoveries are necessarily easy or inexpensive to attain and undeserving of any reward. The point is that there may well be much more to be discovered about the

gene of both scientific and commercial interest, and such future discoveries may well be a whole lot more important.

Such a practice may also be anti-innovation. Broad patent protection can stifle innovation in new industries such as biotechnology, where the learning curve is particularly steep. Broad protection potentially hinders opportunities for follow-on researchers to carry out further investigations on genes and find out much more interesting things about them, including how they interact with other parts of the genome and with what effects.

Of course, there is much more to biotech patenting than gene patents. As in the USA, microorganisms, cell lines, plants and animals are patentable in all European Union member countries. And while morality and other public considerations may come into play to assess the validity or scope of certain patents, subject matter exceptions are more or less limited throughout the continent to human beings, human totipotent stem cells – which are those capable of developing into human beings – and plant and animal varieties. So while the United States has no statutory subject matter exceptions to patentability and is generally considered more accommodating to discoveries arising from new technologies like biotechnology, one should be careful not to exaggerate the differences in European and US patent law with respect to biotechnological inventions, even less those between European countries.

As to patent office rules and examination practices, there are differences in the sense that the US patent system tends to be relatively permissive in terms of applying the non-obviousness criterion with the result that inventions patented in the US may be too obvious to be patentable in Europe. This is worth bearing in mind when patent filing or granting statistics are used to measure levels of innovation. Indeed, a recent study in *Science* found that of 74 US human gene patents examined by researchers, 73% of them contained one or more claims considered to be 'problematic'.⁶ Such permissiveness hardly seems like the right way to encourage genuine innovation.

So will biotech investors take their money out of Germany and France, where only purpose-bound protection is available for genes, and put it into Britain or other European countries where full product protection is available, or into the US, where it is also available and (despite a recent tightening up of the rules) patent examination standards are rather lax by European standards? And can we expect European scientists to follow this money trail?

They may well do so. Indeed, it may be happening already. But are patents responsible? Probably not. Recent reports indicate that several European life science corporations are moving some of their research and development operations to the United States.

The size of the US market is clearly a factor as is the existence of an active biotech sector. But the biggest attraction of all may be the magnitude of the public research infrastructure which these companies can tap into including the world's best universities. Government spending on medical research is now more than five times greater than the European Union countries combined. The patent system does not appear to be a significant factor in these corporate decisions, at least in any direct sense.

On the other hand, unfriendly regulations and discouragement, both official and unofficial, of research in controversial areas are undeniably a hindrance to corporate research investment. This becomes apparent when one hears of US scientists doing stem cell research fleeing to Europe,⁷ European firms no longer working on genetically modified crops resulting in scientists crossing the Atlantic in the other direction,⁸ and of British medical researchers who experiment on animals being driven away to work in other countries by animal rights terrorists.⁹

The European Commission decision not to push aggressively for biotech patent law harmonisation is pragmatic and sensible. The German and French DNA patenting rules appear on the face of it in any case to be scientifically and economically sound. It is hard to see why these countries or the European biotech industry will be harmed in any way by the present impasse. Admittedly, securing Europe-wide continues to be expensive, often prohibitively so for small companies. Moreover, having to draft different DNA-related claims for different jurisdictions hardly helps reduce costs or legal uncertainty. In addition, the morality and Europe's confusing exceptions to patentability lead one to wonder if the rather more simple US patent system may be better in certain respects, at least from the view of those of us who actually support biotechnology research. Of course, the overly permissive application of non-obviousness in that country is not something that Europe should imitate.

All things considered, though, in any assessment of Europe's continuing inability to catch up with the United States in commercial biotechnology, the present state of Europe's patent regime is probably much less relevant than some of the other factors discussed in this article.

Biography

Graham Dutfield is Herchel Smith Senior Research Fellow at Queen Mary, University of London. His latest books are *Intellectual Property, Biogenetic Resources & Traditional Knowledge, Intellectual Property Rights & the Life Science Industries: A Twentieth Century History*, and *Trading in Knowledge: Development Perspectives on TRIPS, Trade & Sustainability* (edited with Bellman and Melendez). He is currently writing *Global Intellectual Property Law: Commentary & Materials with Maniatis and Suthersanen*, which will be published in 2006.

End Notes

- 1 In brief, each gene contains within its DNA the instructions for the synthesis of one or more proteins. Just as proteins consist of chains of amino acids, each gene may be sub-divided into units called codons that comprise three nucleotide base pairs and code for (by way of a closely related chemical called ribonucleic acid) the preparation of a particular amino acid. These amino acids are then combined in a specified way to form the required protein (that is, the one 'expressed' by the gene). However, RNA appear to perform many functions unrelated to protein manufacture.
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- 3 *Ibid.*, at 32-3.
- 4 Quoted in Gibbs, W.W. (2003) 'The unseen genome: gems among the junk', *Scientific American* 289(5): 26-33, at 29.
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- 6 Paradise, J., Andrews, L. and Holbrook, T. (2005) 'Patents on human genes: an analysis of scope and claims', *Science* 307, 1566-1567.
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