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Competition Law as a Patent 'Safety Net' in the Biopharmaceutical Industry

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The present paper examines the relation and interaction of competition and patent law as tools for innovation in the biopharmaceutical industry. The paper starts by positing the concern that has been raised in the biotech industry relating to restricted access to essential tools for innovation due to the increase in patenting of essential upstream research. While the implications of such a trend are not clear, the need to ensure the presence of adequate 'safety nets' is seen as paramount. In view of that, the paper proceeds to examine certain patent law provisions to address such concerns. It is argued that patent law does not provide a remedy in all such cases and that hence a remedy needs to be sought outside the patent system. Competition law then is examined as a complement to the patent system in the innovation 'balance'. The relation between the two bodies of law is examined both from a competition law and a patent law perspective. Adopting the view that there is no reason to treat IP differently from other property, the paper concludes by suggesting the viewing of the essential facilities doctrine as a potential safety net to address the concern of access to essential upstream technology.

> We often talk about how important patent are to promote innovation, because without patents, people don't appropriate the returns to their innovation activity, and I certainly very strongly subscribe to that … On the other hand, some people jump from that to the conclusion that the broader the patent rights are, the better it is for innovation, and that isn't always correct, because we have an innovation system in which one innovation builds on another. If you get monopoly rights down at the bottom you may stifle competition that uses those patents later on, and so … the breadth and utilization of patent rights can be used not only to stifle competition, but also [can] have adverse effects in the long run in innovation. We have to strike a balance.[1]

Innovation has assumed a particularly important role in our society, especially in industries such as the biopharmaceutical. Competition law and patent law are two of the main propellers and determinants of innovation, but the relation between the two bodies of law as applied to strike the innovation 'balance' has been a highly contentious issue.

[*] European University Institute.

[1] J Stiglitz, in http://www.ftc.gov/speeches/other/dvisraelin.htm

The present paper examines the relation and interaction of competition and patent law as tools for innovation in the biopharmaceutical industry. The paper starts by positing the concern that has been raised in the biotech industry relating to restricted access to essential tools for innovation due to the increase in patenting of essential upstream research. While the implications of such a trend are not clear, the need to ensure the presence of adequate 'safety nets' is seen as paramount. In view of that, the paper proceeds to examine certain patent law provisions to address such concerns. It is argued that patent law does not provide a remedy in all such cases and that hence a remedy needs to be sought outside the patent system. Competition law then is examined as a complement to the patent system in the innovation 'balance'. The relation between the two bodies of law is examined both from a competition law and a patent law perspective. Adopting the view that there is no reason to treat IP differently from other property, the paper concludes by suggesting the viewing of the essential facilities doctrine as a potential safety net to address the concern of access to essential upstream technology.

ACCESS TO ESSENTIAL UPSTREAM RESEARCH IN THE BIOPHARMA INDUSTRY

Pharmaceutical Industry R&D: The increased importance of cumulative innovation and the concern

Recent changes in the nature of research in the pharmaceutical industry have given rise to new concerns regarding innovation. Particularly in the US, the industry has been fragmented into a two-tier system where small biotech firms conduct all the innovative research that the large pharmaceutical companies then produce, prepare and market. Much of the research conducted by small biotech firms involves upstream innovative research that is fundamental to the development of downstream research on products and processes. Hence, research has increasingly become dependent on access to other fundamental research. While this in the 1980s was mainly government-sponsored research, with the increased privatization this came in the hands of private firms who were found with the right to exclude others from their findings. As more stages, actors and inter-connectiveness, complemented the drug development process patenting made commercial sense where before there was nothing to patent. This led to an increase in patenting and in the patentable subject-matter.[2] Research became more cumulative and guided by prior scientific findings[3], and Acts such as the Bayh Dole Act in the US simplifying patenting and containing provisions allowing universities to patent their inventions where before they were open to the public, led to the grant of even more patents.[4]

These two trends immediately raised fears that patents would deter innovation. In an article published in Science magazine, Heller and Eisenberg postulated a theory

[2] See for example the debate on the patenting of genes.

[3] J Walsh & J Cohen, 'Research Tool Patenting and Licensing and Biomedical Innovation', Forthcoming in Cohen & S Merill (eds) *Patents in the Knowledge-Based Society*, Washington DC, National Academies Press, p 5.

[4] *Ibid.*

whereby too many patents on upstream innovation could lead to two eventualities.[5] Firstly, the grant of too many fragmented patents may lead to a situation identified as the tragedy of the anti-commons, whereby too many people have the right to exclude and no-one has an effective right to use, so that one impedes the other from using his technology but is also precluded from using the technology himself as he is impeded by the rights of exclusion of others. This concern is not the direct object of this paper.

The second eventuality postulated is that the grant of patents in fundamental upstream research may lead to a situation whereby patent owners stack licenses on top of future discoveries of downstream users, and/or impede the creation of downstream dependent inventions.

Heller & Eisenberg presented no scientific data to support their theory. The degree to which research is fragmented and dependent on too many other patents depends on many other factors including the breadth of the grant of the patent, the nature of the research and the extent to which it is cumulative or discrete, and the bargaining power of the players. Yet no evidence was given in that respect. Walsh & Cohen[6] attempted to test these hypotheses against more scientific data.

The conclusions of Walsh and Cohen on the issue of restricted access to upstream discoveries and its effects on innovation were ambiguous. They found that access to foundational discoveries can be restricted, and that patents over targets may limit access in certain cases.[7] Depending on the breadth of the interpretation and the capacity of a firm to market in timely fashion, lack of access might lead to less innovation. Particularly in the case of targets this might be a problem depending on the breadth and degree of restriction compared to the incentive necessary to invest in the first place. The effect of control upon such discoveries will depend on firstly, how essential it is for subsequent innovation, and secondly, the degree of rivalness in use of the first and subsequent products as that will in turn determine the motive to refuse access or not.[8]

The problem is that although such concerns have arisen, there is not much scientific evidence to support one finding or another. Does the existence of many patents hinder the development of products related to health care, and do upstream patents deter further innovation?

An empirical study of the German inventions and patent law concluded that there is a proliferation of DNA patents and unduly broad patents causing a situation of dependency of patents on earlier inventions, that may lead to a reluctance to enter fields in which genes have already been patented and that royalty stacking and higher transaction costs are present leading to an explosion of legal disputes and potential retardation of innovation.[9] Hence the existence of patents may lead to at least a

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5 Heller & Eisenberg, 'Can Patents Deter Innovation? Anti-commons in Biomedical Research', Science Vol. 280, 1 May 1998.

6 J Walsh & J Cohen, 'Research Tool Patenting and Licensing and Biomedical Innovation', Forthcoming in Cohen & S Merill (eds) *Patents in the Knowledge-Based Society,* Washington DC, National Academies Press.

7 *Ibid.*

8 *Ibid.*

9 J Straus, *Genetic Inventions and Patent Law*, OECD 2002.

redirection in other fields where it is thought that a dependency might be created. On the other hand, however, with regard to research tools a study showed that patents do not have a discernible effect on the cost or the pace of research as some are staple goods purchased without disclosure of intended use, and also as there are practical working solutions such as infringement that is hard to be detected behind closed doors.[10]

Whether the problem of access is real or not also depends on the interpretation of the breadth of the patent as regards infringement, amongst other. For example, in the US the *Scripps Clinic v Genetech* case the Federal Circuit found patent infringement by virtue of the production of the same protein by recombinant means, refusing to construe product claims to include inherent process limitations. It found that product by process claims are not limited to products prepared by the process set forth in the claims.

> The decision reflects two antagonistic results, creating possible process-related exceptions to infringement of a product claim that on its face makes no reference to any process parameters, while reading process limitations out of a claim that expressly recites them.[11]

Hence, the problem of patentability approval despite limited disclosure supporting their broad claims may be aggravated by the broad interpretation of infringement by the Courts.

In addition, the lax application of the patentability requirements may lead to unjustified extensions in scope. EU researchers in accord with US in a joint article of the President of the US National Academy of Sciences and the President of the Royal Society of London, admonish that:

> those who patent DNA sequences without real knowledge of their utility are stacking claims not only to what little they know at present but also to everything that might later be discovered about genes and protein associated with the sequence. They are in effect laying claim to a function that is not yet known or a use that does not yet exist. This may be in current shareholders' interests, but it does not always serve society well.[12]

Summing up, in view of the increased cumulative nature of innovation a concern has been raised that the proliferation of patents may lead to impeded access to essential technology and so impedance of innovation. Practical evidence confirms that patents have been extended both in subject matter and in scope and this is seen by the research community as often unjustified. As patents by definition involve a degree of exclusivity, their very grant is bound to affect access to the patented technology. Where their grant is unjustified or overbroad then lack of access is bound to be seen as unwarranted. While it is felt that this may in turn lead to an impedance of innovation, no evidence to date unambiguously establishes a clear negative effect on innovation.

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10 Nuffield Council on Bioethics, 'The Ethics of Patenting DNA', 2001

11 Y Ko, 'An Economic Analysis of Biotechnology Patent Protection' (1992) 102 Yale LJ 777.

12 D Gitter, 'International Conflicts over Patenting Human DNA Sequences in the US and the EU: An Argument for Compulsory Licensing and the Fair Use Exemption' (2001) 76 NYULRev 1623, p 19.

As regards specifically the issue of exclusion, so far practice evinces broad licensing patterns in most cases. Nonetheless there is still concern in the industry that access to essential upstream technology may be refused and it is felt that this may negatively impact on innovation. Whether this has to be seen as a systematic failure in the patent system or individual cases of blocked access is not clear. As the industry also attributes the lack of evidence of a discernible effect to the existence of working solutions, it is not clear what the status of each of those is and what the position would be in their absence.

Despite the ambivalence of evidence on the gravity of lack of access and its impact on innovation, industry participants still feel that this is a problem that needs to be addressed. Hence, for present purposes onwards, it is assumed that this theoretical possibility of exclusion may be a problem which in turn may lead to a deleterious effect on innovation. If so, tipping the balance too much in favour of patentees comes with an increased social cost in the biopharmaceutical industry in view of the vital nature of the goods and technology in question. The patent system has balancing instruments that permit for the limitation of breadth on a case by case basis, including claim interpretation, invalidation and compulsory licensing. Some of these balancing mechanisms are analyzed next, to assess their desirability and adequacy in easing these concerns.

PATENT LAW MEANS TO ENSURE ACCESS

Types of Inventions and Relations Amongst Them

The patent system is created to motivate several types of inventions. On the one hand there are pioneer inventions that involve a distinct step in the progress of art, as distinct from a mere improvement or amelioration of what had been done before. On the other hand are the technological improvements that may result from independent discoveries or intentional efforts to design around and therefore avoid infringing the patent.[13]

In view of the incremental nature of innovation there may be overlapping patent rights to technology that may have different relations amongst them. Patents may be blocking so that improvements are concerned; complementary, whereby different inventors independently patent different components of a larger invention, and where patents are useless without a license to the separate patented products; or competing, whereby patents compete with each other in the market whether because they are substitutes or involve inventing around the patents.[14] Yet the categorization amongst such patents is imperfect.[15]

In the case of improvements, the patent system treats them differently according to their significance and value as related to the pioneer invention.[16] At the bottom of the

[13] MJ Conigliaro, AC Greenberg and MA Lemley, 'Foreseeability in Patent Law' (2001) 16 Berkeley Tech LJ 1045.

[14] SC Carlson, 'Patent Pools & the Antitrust Dilemma' (1999) 6 Yale J on Reg 369.

[15] Hence, it is not clear where downstream dependent innovation/research fits in this demarcation.

[16] MA Lemley, 'The Economics of Improvement in Intellectual Property Law' (1997) 75 Tex LRev 989. This is also consistent with the inventive step determination in case of pharmaceuticals. The greater the structural

scale are minor improvers for which the law offers no protection and may appropriate their findings only by trade secrets or first mover advantages. The law, however, makes no allowance for them to infringe the pioneer invention. Higher up the scale are significant improvers that exceed the minimum social value threshold for patentability and are thus able to get an improvement patent. While they may not use the pioneer invention without the permission of the patent holder, they may prevent the patent holder (and any other unlicensed party), from using their improvement. This often leads to the case of blocking patents which, according to the transactional view of IPRs, is conducive to levelling the playing field and to minimizing the chances of a bargaining breakdown. In the EU there is also a provision for compulsory licensing in cases where the improvement patent involves an 'important technological advance of considerable economic interest.' Parallel to the rationale for blocking patents in the US, this is, *inter alia*, conceived to induce voluntary licensing between the parties. On the top of the scale of improvements, are radical improvers that are sufficiently radical to depart from all prior patents even though they may be in the literal language of the claim.

Patent law has embedded provisions to give account to improvement and follow-on innovation. These are balancing instruments of the patent system as an output and as an input for further innovation and development. Provisions to that end include most importantly the experimental use exemption and the compulsory licensing provisions. But, as will be seen, these patent provisions of themselves do not adequately address the issue of potential lack of access to essential upstream technology. They mostly address 'improvements' that do not necessarily cover downstream dependent innovation. The difference becomes clear in the case of research tools.

Research tools are sequences used in research with no immediate therapeutic or diagnostic value. They are a means to develop a commercial product such as a medicine or a vaccine and not an end product of themselves. For example the EST approach involving the rapid sequencing of the coding parts of genes was used as a means to locate entire genes. Research tools are licensed for particular sequences or applied to discover new drugs or other research, hence realizing a commercial value. They constitute the typical example of upstream innovation required to develop downstream innovation. It is in this instance that the balance the patent system of itself strikes, between inventions as an output and as in input for further innovation, is called into question. It is in this instance that the patent law safety nets of themselves may not be adequate to ease the concerns.

> There are various ways in which patents on DNA sequences which have a primary use as research tools may inhibit innovation and development: the cost of research may increase, as the grant of increasing numbers of patents will mean that ever more licenses are required before research can be conducted; research may as a matter of practice, be made more difficult if researchers are required first to negotiate the use of patented genes and sequences; *a patent owner may withhold a license*

distance and the better the technical effect of the invention as compared with the state of the art, the greater the likelihood that inventive step will be found. See B Domeij, *Pharmaceutical Patents in Europe*, The Hague, Kluwer Law International, 2000.

> *to gain maximum financial benefits, or license it exclusively to one or a limited number of licensees*… There is insufficient evidence to judge the extent to which the granting of patents over DNA sequences based on a primary use as research tools is producing the potentially deleterious effects set out above. However, we take the view that the exercise of a monopoly over what are now essentially discoveries of generic information accessible by routine methods is, in principle, highly undesirable.[17]

The adequacy of the most relevant for such purposes patent provisions is examined next.

Patent Law Safety Nets

The experimental use exemption

The experimental use exemption doctrine is a very narrow exception that excuses the infringement of a patent. In Europe, acts done privately and for purposes that are not commercial and acts done for experimental purposes relating to the subject matter of the invention do not infringe the patent. The Community Patent Convention exempts from infringement acts done for experimental purposes relating to the subject matter of the patented invention.[18] These are aimed to understanding and/or improving the technology of the invention, or to experiments *on* the invention. It amounts to research in the technology field and the inventions are used for a different purpose than that for which they were originally created. This hence, represents only a small loss of revenue to the patentee as his main market resides in their non-experimental uses. The fact that such research may lead to improvements or new competing products that are patentable does not change the analysis.[19] Experimentation *with* a patented invention, however, does not advance the field of technology or contribute to innovation as it leaves the invention unchanged. This type of experimentation is not exempted and so in such cases a license is required. The problem of access to upstream innovation would come under this type of use of the invention. Hence, for example, a research tool that is used for conducting work will require permission from the patent holder, whereas people that study the research tools themselves will be considered exempted.

As articulated right now, the experimental use doctrine, in addition to being seldom used and of dubious nature and substance, does not and cannot cater for instances of access to essential technology. Its main weakness for present purposes lies in the fact that it does not provide a means to ensure that access is not precluded. Hence, in the case where access to research tools is essential to develop a downstream technology,

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[17] Nuffield Council on Bioethics, The Ethics of Patenting DNA, 2001, para 5.39-5.41.

[18] Art. 9 of the CPR provides the limitations of the effects of the Community patent. The rights shall not extend to:
(a) acts done privately for non-commercial purposes;
(b) acts done for experimental purposes relating to the subject-matter of the patented invention;
the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription nor acts concerning the medicine so prepared.

[19] P Ducor, 'Research Tool Patents and the Experimental Use Exemption - A no-win situation?' Nature Biotechnology, Vol. 17, Oct. 1999, p 1027. But is that desirable?

the exemption is inapplicable, and so it would not seem to be a viable means to ensure access to it.

Compulsory licensing

The Community Patent Regulation, in accordance with TRIPS, provides for three main cases of compulsory licensing (CL). These are in cases of:

- non-use for three years from the grant or four from the application;
- when necessary to use a second otherwise infringing patent that constitutes an important technical advance of considerable economic significance; and
- in cases of extreme urgency, crisis, or to remedy an anti-competitive behavior.[20]

The arguments in favour and against compulsory licensing will not be taken up here. But for present purposes it suffices to say that these provisions may have a utility both as a compeller inducing voluntary licensing but also as a safety net to address substantive concerns. From a patent perspective the provision relating to significant technological advances is the most significant to address the present concern.[21]

According to that provision, a license may be mandated in cases where there is a product or process that would otherwise be infringing a first patent, and which involve a significant technological improvement of considerable economic significance.[22] Industry–specific similar provisions have also been created such as the European Directive on Biotechnological Inventions that allows breeders to request a CL when he/she cannot acquire or exploit a plant variety without infringing a prior patent.[23] It also allows for CL where the patent holder cannot use a protected variety without infringing third parties' rights.[24]

While these provisions may be desirable, the extent to which they are sufficient is questionable as they have been narrowly interpreted and so only exceptionally applied. So, for example, the substantial improvement provision was applied by the German Federal Patent Court on June 7 1991, to find in favour of a grant of a CL.[25] In the case, Bioferon owned a patent for a pharmaceutical product polyferon for the treatment of chronic polyarthritis and also held dependent patents of specified uses of human immune interferon. The Court found that there was a public interest in the medical use of polyferon which was dependent on the dominant substance patent, but the Federal Supreme Court later, in December 1995 decided that a CL would not be granted if the public interest could be satisfied with other, more or less equivalent, alternative preparations. On the facts, it found that substantially improved therapeutic properties

[20] CPR, Art 21.

[21] The significance of the CL provision relating to anticompetitive behaviour is taken up later on, and the importance of the provision relating to extreme urgency and the implications it may have for the biopharmaceutical industry is not of direct relevance to the present concern and is analyzed in another paper.

[22] CPR, Art 21.

[23] Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, OJ 1998, L213/13, Art 12(1).

[24] Directive 98/44/EC, Art 12(2).

[25] See case analysis in Grounds for Granting Compulsory Licensing, at www.southecentre.org, p 4.

had not been established.[26] The decision reflects the hesitation of the courts to find the provision applicable on the facts.

It also bears noting that whether this provision can only be used for improvements or also for dependent or downstream technology is not clear. While the wording of the Community Patent Regulation only provides for a second infringing patent, and so on its face covers both cases, it would seem that this provision would be inadequate to cover cases raising issues similar to the research tools experience, as use is needed prior any *potential* patent. Hence, it would seem that this provision could not be used in cases of blocked access to an upstream innovation for downstream research, as opposed to already granted patents.

Conclusion

Patent law provisions seem to predominantly cater for improvement considerations rather than the upstream/downstream relation of dependency found in the case of, for example, research tools.[27] This directs consideration to other means that may be used to address the latter concerns. The TRIPS Agreement legitimises compulsory licensing as remedy to anticompetitive practices. This raises the question of what anticompetitive practices are and how antitrust may be used to achieve the desired result in such cases. It effectively diverts the problem to the dynamics of the relation between competition and patent law. The issue of control of an upstream market by a company restricting access to the downstream competitors is not a new one to antitrust law. The leverage rationale lying behind it is as applicable to the biopharmaceutical industry as any other industry. The precise question then for our purposes becomes the following: can the EFD be applied to ensure that follow-on innovation is not impeded in the biotechnology industry by virtue of the control of an upstream technology, and would such application be desirable?

COMPETITION LAW TO COMPLEMENT THE PATENT SYSTEM

IP and Competition Law: a systems' interaction

Recent IP legislation conceives the possibility of abuse of IPRs and that IPRs are not unlimited rights, or deserving a different threshold from other property rights.

IP statutes allow for a consensual market to operate in four ways: they create property rights, lower transaction costs, provide valuable information, and contain a mechanism for enforcement.[28] Hence, IPRs are devised to create a market for information goods that would otherwise not be established, or at least not optimally: "IP is conceived to bring informational subject-matter into the realm of market rules to optimize their

[26] See Grounds for Granting Compulsory Licensing, at www.southecentre.org, p 4.

[27] As was earlier pointed out, this is aggravated by the fact that it is not clear where this type of information fits in the general categorization of patent law protection.

[28] H Ullrich, 'IP, Access to Information and Antitrust: Harmony, Disharmony and International Harmonization', in *Expanding the Boundaries of IP: Innovation Policy for the Knowledge Society*, Oxford, Oxford University Press, 2001; H Ullrich, 'Legal Protection of Innovative Technologies: Property or Policy?' 2001, in O Grandstrand, The Swedish Intellectual Property Symposium.

creation."[29] Private parties are left to internalize the decision of whether to create a type of knowledge whose value is not known before hand, and are given the opportunity to respond to the market created, that will in turn set the price of the created information. The rationale is similar to the one of real property:

> There appears then to be some truth in the conservative *dictum* that everybody's property is nobody's property. Wealth that is free for all is valued by no one because he that is fool enough to wait for its proper time of use will only find that it has been taken by another… The fish in the sea are valueless to the fisherman, because there is no assurance that they will be there for him tomorrow if they are left behind today.[30]

Efficient exploitation is attained by privatization.

Hence, IPRs are not exemptions from the competition provisions, but rather, the IP system depends on the well-functioning of competition, and is only devised to allow for the response to the opportunities and conditions of the market.[31] Hence, the system of IP is not conceived as protection *from* competition, but rather protection *for* competition in the market of intangibles, whose tangible embodiments are set against and valued according to the competitive market conditions which competition protects. IP does not guarantee a reward, but like any other property right, merely grants the opportunity for a reward on the market. Therefore, IP can only require equal treatment by the competition provisions. Like for any other property, the exclusivity allows for the autonomous determination of conduct and does not modify antitrust rules.[32]

IP sets out the regulatory framework, under which it provides for the grant of individual property. The exclusivity turns the public good into an economic good, for which competition alone can determine the value, providing the incentives and rewards according to demand.[33] In such cases, it depends on the well-functioning of competition on the market. As a piece of individual property, however it provides such autonomy of decisions and freedom of contracting, just as any other property, which competition must control just as any other case.[34] Here, IP does not constitute a justification for infringement of competition, nor does it grant the right to restrain or impair residual competition. "The exclusivity is granted to allow to respond to the opportunities in the market not to control it."[35] And, it is the competition provisions

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[29] *Ibid.*

[30] HS Gordon, The Economic Theory of a Common-Property Research: The Fishery, (1954) 62 Jnl of Political Economy 124.

[31] Indeed, as is later elaborated, the IP system is a constitutive element of the market.

[32] H Ullrich, 'Legal Protection of Innovative Technologies: Property or Policy?' 2001, in O Grandstrand, The Swedish Intellectual Property Symposium.

[33] The market sets the price, which was also the basic reason leading to the preference of property rights over the other schemes.

[34] Related to this issue is the question of whether IPRs are a right to do something suboptimal but useful or merely a basic right to optimize that can be overridden. The analysis of this issue is beyond the scope of the present inquiry.

[35] H Ullrich, 'Legal Protection of Innovative Technologies: Property or Policy?' 2001, in O Grandstrand, The Swedish Intellectual Property Symposium.

that determine when it controls the market, whether an IP or any other case is concerned, in the same way. There is no economic justification for treating IP differently.

The Transition from Separate to Unified Fields

The traditional confusion with regard to IP and its consideration as exempted or requiring a different threshold from competition, springs from the assumption that the exclusivity must be total and so the IP holder is allowed to charge at any price he wants, and so IP in the short term is allowed to exclude competition as it will enhance dynamic competition in the long-term.

> The problem with this approach is that, by an equation of the protected intangible subject-matter with its tangible embodiments, it creates a confusion between the reasons justifying the exclusivity (on the technology market) and an alleged right to restrain competition (on the product market). Therefore it assumes an antagonism where there is none. …The reason for protecting technologies … is that by their very nature, they cannot be exposed to competition, unless they are protected against imitation, in one way or the other.[36]

Hence, the traditional approach was to view antitrust and IP as two competing and separate fields, where IP granted a monopoly within which the property rights were absolute. Viewing the fields as separate spheres involving an inherent tension required the determination of what was in the scope of the property rights, so that anything within was lawful whereas anything beyond, constituted an antitrust violation. It is in this context that the European Courts and Commission resorted to the existence/exercise, the specific-subject matter and the essential function doctrine.

IP and competition policy through different means address the same dilemma, namely, the balance of the "monopoly privilege", and its dissemination- the vertical and horizontal dilemma. IP addresses these questions in the definition of exclusivity and its limits. Competition addresses these questions in maintaining competition in *the face of exclusivity as defined by IP*. This is also reflected in the fact that patent infringement claims and abuse of a dominant position claims based on refusal to grant access address the same problem: the definition of permissive exclusivity and patent breadth. And while both serve a series of social, economic and political considerations, and so may point to different conclusions depending on their different policies, IP and competition policy are interdependent and mutually determining.

Summarizing, IP and competition law are interdependent and inter-determining. IP changes a non-market to a market, sets out a regulatory framework embodying competition concerns, and by granting exclusive rights limits *competitors* in certain respects just as any other kind of property. But as a piece of individual property it may be abused, exploitatively or structurally as any other case, as competition law provides.

[36] *Ibid,* p 7.

It is in this sense that IP is a constitutive element of competition, constitutes protection *for* competition, but is not a restriction or exemption *from* competition law.[37]

How Antitrust Control Affects Incentives to Innovate

The typical and strongest argument against using antitrust law to control conduct that is condoned under intellectual property laws and in favor of immunizing it from liability, is that it will hamper incentives to innovate. While there is very little empirical evidence on the effects of such control in general, and compulsory licensing, in particular,[38] nonetheless it is argued that such a concern is based on a series of erroneous assumptions.[39] Firstly, it assumes that intellectual property laws grant holders an economic monopoly. Secondly, it assumes that the acquisition of monopoly power is the only way to appropriate revenues from inventions, and thirdly it assumes that antitrust liability would necessarily have overall adverse effects on incentives to innovate.

Intellectual property rights in general and patents in particular do not necessarily and automatically confer monopoly power on their owners.[40]

> The intellectual property laws do not purport to confer any monopoly, however, but only the right to exclude others from producing the good, expression or symbol covered by the intellectual property interest. This right is a property rights that is not different in principle from other property rights.[41]

The law encourages the creation of substitutes, of inventing around inventions and so substitutes may exist in the market. Hence, the legal monopoly granted by a patent does not in most cases coincide with an economic monopoly in the marketplace.

As regards the appropriation of revenues that provides the incentive to innovate, it is clear that intellectual property rights are not in most cases the most significant factor in ensuring returns in most industries. Factors such as lead time, reputational advantages and costly copying may present greater sources of excludability and profit.[42] While it is true that in the pharmaceutical industry specifically patents are the most significant of such factors in appropriating returns, here too, 'Economic analyses dispute the idea that the concentration of market power is the best way to ensure an optimal

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[37] See S Anderman, *EC Competition Law and IPRs: The Regulation of Innovation*, Oxford, OUP, 1998.

[38] FM Scherer, 'The Law and Economics of Compulsory Patent Licensing', New York University Graduate School of Business Administration 43-50, 1977.

[39] S Genevaz, 'Against Immunity for Unilateral Refusals to Deal in Intellectual Property: Why Antitrust Law should not Distinguish Between IP and Other Property Rights', to be published in Berkeley Law and Technology Journal

[40] *Ibid.*

[41] H Hovenkamp, MD Janis and MA Lemley, *IP and Antitrust: An Analysis of Antitrust Principles Applied to IP Law*, New York, Aspen Law & Business, 2002.

[42] See H Perritt, 'Property and Innovation in the Global Information Infrastructure' [1996] U Chi Legal Forum 261.

appropriation.'[43] Kenneth Arrow suggests that a monopolist has less incentive to innovate than a firm in a competitive industry as the latter has a higher incentive to reduce the cost for its product.[44] Hence, antitrust liability does not necessarily lead to overall decreased incentives to innovate in the relevant industry.

In addition, since antitrust control is limited and exceptional, it would only rarely impose a constraint on IP owners' courses of action.[45] In addition, Ayres and Klemperer suggest that the loss of incentive is negligible in comparison to the increase in social welfare stemming from limited restrictions on the patentees' market power.[46] But, the latter's suggestion applies only in cases where there is high price elasticity in the market so that every price reduction results in an increase in demand.[47] In industries like the biopharmaceutical where demand for the end product is not elastic as consumers *need* access to medicaments (as opposed to luxury products), the reduction in the monopoly price may have few consequences on deadweight loss and may greatly diminish incentives to innovate. Nonetheless, the same may not be the case in the pre-commercial stage of research where demand is for research tools by competing firms on different levels of the market, as distinct from end product situations. In addition, Scherer concluded that compulsory licensing had little effect on incentives to innovate in industries where parties had to maintain a high level of R&D to remain competitive or where the ability of competitors to invent around patents diminished the value of patent protection.[48] Even innovators' testimonies seem to take for granted that antitrust

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[43] S Genevaz, 'Against Immunity for Unilateral Refusals to Deal in Intellectual Property: Why Antitrust Law should not Distinguish Between IP and Other Property Rights', to be published in Berkeley Law and Technology Journal, p 9.

[44] *Ibid*; see also KJ Arrow, *Economic Welfare and the Allocation of Resources for Invention, in Essays in the Theory of Risk-Bearing*, Markham Publishing Co, 1971.

[45] *Ibid*, p 10.

[46] I Ayres & P Klemperer, 'Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies' (1999) 97 Mich LRev 985, p 990: 'Because the last bit of monopoly overcharging is so disproportionately damaging, restricting the patentee's monopoly power a small amount is likely to increase social welfare. The benefit of reducing the deadweight loss of supra-competitive pricing is likely to outweigh the costs of a slightly lower incentive to innovate.'

See also S Semerano, 'The Efficiency and Fairness of Enforced Sharing: An Examination of the Essence of Antitrust' (2003) 52 Kansas LRev 57, p 25: 'All things being equal, forced sharing may discourage both the innovator and the sharer from investing in improvements. But all things are not equal. Shared property may enable more vigorous competition than would otherwise occur, and that competition may stimulate investment to a greater extent than forced sharing may reduce it. A firm not faced with competition will only consider innovation's demand-expanding and entry-delaying effects. A firm faced with competition, however, will have an incentive to innovate not only to expand the existing market and deter entry, but also because of the fear of losing market share to, and the desire to gain it from, a competitor.'

[47] S Genevaz, 'Against Immunity for Unilateral Refusals to Deal in Intellectual Property: Why Antitrust Law should not Distinguish Between IP and Other Property Rights', to be published in Berkeley Law and Technology Journal, p 11.

[48] FM Scherer, The Economic Effects of Compulsory Patent Licensing, NY, NY University, 1977; FM Scherer & D Ross, Industrial Market Structure and Economic Performance, Abingdon, Houghton Mifflin, 2nd ed, 1980: 'all in all the substantial amount of evidence now available suggest that compulsory patent licensing, judiciously confined to cases in which patent-based monopoly power has been abused… would have little or no adverse impact on the rate of technological progress … ' p 456-7.

liability might arise just as in any other case, and that is not perceived to affect incentives.[49]

Recent Recognition

Article 8 of TRIPS provides that '*appropriate measures… may be needed to prevent the abuses of intellectual property rights* … '. This reflects the fact that intellectual property rights are *not* immune from the competition provisions and that it is possible for patent holders to abuse their position. The Database Directive 96/9/EC also contemplates the possibility of abuse by a copyright holder:

> protection by the sui generis right must not be afforded in such a way as to facilitate abuses of a dominant position … . Whereas the provision of this Directive are without prejudice to the application of Community or national competition rules.

The Directive reflects the notion that IP is not exempted and that it is subject to the application of competition rules, *just as any other case* of property rights.

In addition, the Draft Legislation on a Community Patent[50] provided for a system of compulsory licensing 'to provide guarantees against abuses of the rights conferred by the patents'.[51] The Commission may grant such licensing of a Community patent where inter alia:

i) licensing is needed to use a second patent involving an important technical advance of considerable economic significance in relation to the invention claimed in the first patent, subject to an obligation to cross-license;

ii) in times of crisis or extreme urgency, or to *remedy a practice determined after judicial or administrative process to be anticompetitive*.

Hence, the patent system contemplates the possibility of compulsory licensing of patents where there is anticompetitive action as determined by competition law and not IP. This might be a reflection of the fact that in accordance with economic theory the patent is just as any other property right for the purposes of competition law, and that the incentives and need for innovation do not qualify for an immunity firstly because it is not known how much incentive is necessary and so it may not be sensitive to these limited instances of control, and secondly because there might be static distortions outweighing dynamic benefits or other concerns about follow-on inventions. Patents grant a legal monopoly that is not necessarily to be equated with an economic monopoly. For example, in the pharmaceutical industry patents do not award a legal monopoly over the treatment of a specific disease, but only over a specific product or process. Hence there is often potential for strong competition between products in a therapeutic class. The lack of equation of a legal with an economic monopoly however,

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[49] FTC/DOJ Proceedings on Competition and IPRS; March 19 2002: A. Diverse perspectives on patents. B. Business perspectives on patents. Biotechnology and Pharmaceuticals.

[50] Proposal for a Council Regulation on the Community Patent, COM(2000) 412 final, August 1, 2000, OJ C 337 E/278, Nov 28 2000

[51] In Explanatory Memorandum of Proposal

works two ways. It requires that no presumption be instituted that patents create market power,[52] but it also requires that when it coincides with an economic monopoly it is not exempt. Where the legal and the economic monopolies coincide, the antitrust provisions will apply as they control according to the market conditions, something that the patent system would be unable to do in view of the fact that it operates ex ante.

These are significant developments as it is not only competition law that controls IPRs, but IPR statutes also envisage and recognize the legitimacy and necessity of such control. IP statutes may be seen to reflect an understanding that IP and competition are no longer assumed to have separate spheres, so that the metes and bounds must be sought within which IP is absolute, but IP remains subject to competition law scrutiny as provided for by the latter for any case according to its effects. Hence, the compulsory patent licensing provision may be read as directing the question of what constitutes an anticompetitive act to antitrust law according to its established rules.

On the competition law side, it is clear that IP is subject to competition control as Commission and Courts practice attest. While the Courts and Commission, in their latest decisions have abandoned the insistence on defining the scope of IP protection under the existence/exercise, and specific subject-matter doctrines, nonetheless they still reflect a *theoretical* understanding that IP warrants a different threshold of general immunity except for the 'exceptional circumstances'.[53] As has been seen, this not warranted. The circumstances should be no more exceptional than they are for other cases. The Commission's recent *Microsoft* decision reflects a move to that direction, insofar as it reads *Magill* as suggesting that 'intellectual property rights are not in a different category to property rights as such.'[54]

THE ESSENTIAL FACILITIES DOCTRINE AS APPLIED IN THE BIOTECH FIELD

Viewing the dynamics of the relation between patent and competition law this way is significant, as this way a solution to the concern with regard to patents in the biopharmaceutical industry may be sought in competition law. In the case of a controlling upstream innovation that impairs the progress of the downstream innovation by virtue of limited licensing practices or in many cases a refusal to deal, it would seem that antitrust is the most effective mechanism to judge when access to such upstream innovation should be granted, and to compel such access.

As was seen, such concerns are not new to antitrust law, and indeed doctrines have developed outside the pharmaceutical industry, such as the essential facilities doctrine, which are also applicable to the present industry. The essential facilities doctrine contemplates the imposition of a compulsory license in cases where access to the facility is necessary to compete. Such an antitrust remedy should be seen as a complement to the IP remedies only requiring a different threshold- that of a dominant

[52] See for example the IP Licensing Guidelines 1995 in the US that recognize that.

[53] I insist on theoretical understanding, as in practice it would seem that the circumstances are in no way different than they were in other cases.

[54] Commission Decision of 24 March 2004, C(2004) 900 final, para 550.

position as opposed to the existence of a significant technological advance of significant economic interest found in the patent statutes.

What is suggested is that the essential facilities doctrine *can* be interpreted and used in such a way as to address the potential problem in the biopharmaceutical industry. Its application involves two questions: firstly whether the essential facilities can be applied to intellectual products. It is argued that substantively the issue is the same whether a physical or intellectual input is at stake. In addition there is no policy reason to apply antitrust principles differently and so the creation of a new doctrine to address the same concern may just add greater confusion.

The application of the EFD to address concerns of access to essential upstream innovation reflects a concern regarding follow on innovation and a policy decision to give priority in such cases to such concerns. It has been argued that especially since initial research is usually supported by academic incentives or public funds, in such cases patents may be more a barrier to applied research than an incentive for the basic research.[55] The application of antitrust control as proposed would be limited to cases where the monopoly is effectively over a variety of product lines and so there is a series of dependent inventions. There is no evidence that such antitrust control would hamper incentives to innovate, and so it is assumed that subject to contrary evidence the normal antitrust principles should be adhered to, and considerations of potential technology impedance should be given priority.

The second question that needs addressing is how one applies the EFD to the biopharmaceutical industry and how that addresses the concerns. The main problems to be encountered would be whether there need to be two markets in an antitrust sense and whether there needs to be a new product. The *IMS* decision left a lot of discretion in this respect.

As regards the two markets requirements the Court adopted a liberal interpretation:

> it is sufficient that a potential market or even hypothetical market can be identified. Such is the case where the products or services are indispensable in order to carry on a particular activity … [56]

Hence, it would seem that this case can be used for precedent in not requiring two markets in an antitrust sense but rather applying the EFD according to the essentiality of an input for the operation of a market. Hence, in the research tool example where access is needed to potentially develop some downstream product the doctrine remains applicable and the research tools if truly indispensable *could* be an essential facility.

The second requirement relates to the requirement of a new product. Again, the Court in *IMS* adopted a more broad interpretation as it refers to '*intention* to produce new goods or services':

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[55] JH Barton, 'Patents and Antitrust: A rethinking in light of patent breadth and sequential innovation' (1997) 65 Antitrust LJ 44.

[56] Case C-418/01 [2004] 4 CMLR 28, para 44.

> may be regarded as abusive only where the undertaking which requested the license does not intend to limit itself essentially to duplicating the goods or services already offered on the secondary market by the owner of the copyright, but intends to produce new goods or services not offered by the owner of the right and for which there is a potential consumer demand.[57]

This is of significance in the biopharmaceutical industry as it takes into account the case of research tools. It refers to intention to produce as distinct from actual production of new products. This would allow for a CL to be granted relating to a certain indispensable research tool while taking into account that a more extensive use of it is *likely* to lead to more products but will not necessarily do so. Hence this will allow access to research tools to be used for further research irrespective of what that later leads to. It effectively involves endorsing a wider definition of 'new product' to include *potential* innovation.

Effectively the essential facilities doctrine can be used to grant access where this is otherwise refused, to an indispensable input for further research. It hence can address problems associated with potential technology impedance and potential restricted access to necessary inputs. It involves recognition that inputs to innovation *can* be an essential facility, and bases it on treating IP just as any other case, adopting a broader definition of a new product while addressing the same substantive issues. This of course rests on the assumption that the more research paths undertaken the better. While the economics of innovation and whether concentration or competition is more conducive to innovation are far from clear, it is assumed in this scenario that in some cases where access may be refused, access would be more desirable. The essential facilities doctrine addresses this and fine tunes the balance according to its determination of 'essentiality' and 'indispensability' on the facts of the case. As a practical matter, the delineation of these concepts would need to be addressed. As a matter of law, however, its application can be contemplated.

This way the antitrust duty to deal remedy may be seen as interchangeable with or at least complementary to the patent CL provisions, only with a difference in threshold; one requiring a patent of significant technological advance of considerable economic interest, and the other requiring the existence and abuse of a dominant position by virtue of a refusal to grant access to an *essential* input as set against the market conditions, respectively.

While the effect may be similar to that envisaged with the creation of the compulsory licensing provisions for dependent patents, it appeals to a wider and potentially different line of cases, in that it is not restricted to dependent *patents* but may be applied to downstream innovation as distinct from improvements.

Of course such a provision would only be applied in the most exceptional of cases, yet it would have an effect also indirectly in encouraging voluntary licensing. It offers more flexibility as a rule than the dependency provision, as it relies on a rule of reason approach of assessing the effects of a refusal to grant access. The advantage of the

[57] *Ibid,* para 49.

antitrust application of a duty to deal is that it is set against the market conditions so as to see to what extent access to the input is indeed necessary in view of the other alternatives and substitutes, to what extent a benefit will accrue to the consumers by virtue of access and to what extent indeed the market has proven the patent to control not only a specific product or process but indeed a whole area of endeavour.

The approach effectively advocates a more explicit consideration of follow on innovation in the application of antitrust analysis and that may not only be true for the application of the duty to deal provisions, but also for investigations of cross-licenses and patent pools, and potentially mergers.[58] Indeed in the EU unilateral restraints on innovation have on several occasions been condemned,[59] whether because they involved the gaining of control over potentially competitive innovations, preventing downstream innovation, and foreclosing innovation by raising barriers to entry.

The recent endorsement of the innovation markets approach in the *Genzyme/Novazyme*[60] merger in the US can be seen as another instance where competition law is used to control, mitigate or counter-balance what are deemed to be undesirable patent effects as set against the market conditions. The innovation markets approach is aimed at assessing the effects of a merger on the incentives for R&D and innovation. It assesses the extent to which output in the upstream R&D market may be restrained and whether the latter may lead to adverse competitive effects on the downstream product market at some time in the future. The concern is similar to that of the present case in that it aims at encouraging multiple research paths by keeping essential innovation tools de-concentrated even if only to protect innovation on a research/pipeline level as distinct from commercialisable products. Merger control in this instance is used as means to ensure that R&D is not too concentrated so that downstream potential markets *may* develop, and uses remedies such as divestiture and compulsory licensing to achieve that result. Similarly to such an approach, the essential facilities doctrine could be used to ensure that R&D is not suppressed by the control of essential inputs in the R&D process by a few dominant firms with the discretion and possible motive to deny or reduce access to such inputs.

While it would seem that much uncertainty surrounds most fundamental questions and so many assumptions have to be made, the importance of CL as a means of addressing follow-on innovation consideration should not be underestimated.

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[58] See for example innovation markets approach in merger review, and consideration being paid to potential competition. See also for example JH Barton, 'Patents and Antitrust: A rethinking in light of patent breadth and sequential innovation' (1997) 65 Antitrust LJ 44, that proposes that attention also be paid to technology lines and not only product market or technology or innovation markets. 'Clearly there are antitrust issues when a license or merger concentrates control over product lines or combines into one management several patents covering complementary ways of manufacturing a specific product.'

[59] See M Dolmans, 'Antitrust and the Suppression of Technology in the US and Europe: Is there a Remedy? Restrictions on Innovation: An EU Antitrust Approach' (1998) 66 Antitrust LJ 455.

[60] See FTC Jan 13, 2004 closing the investigation of Genzyme Corp.'s 2001 acquisition of Novazyme Pharmaceuticals.

> To the extent that neither statutory nor case law establishes clearly the legal scope of an IP grant, one should also look to policy concerns in determining whether a unilateral refusal to license should ever be considered an antirust violation.[61]

In addition, recognizing the existence of CL under antitrust law to remedy a situation of blocked follow-on innovation as a *last resort safety net* (whether this wants to be seen as remedying a perceived patent failure or simply balancing the system as initially contemplated) would seem to be a feasible and indeed desirable option. While competition law and the essential facilities doctrine is not the only measure to improve the balance, it is a means of enhancing the innovation/access balance. It requires no change in the current state of the law, and only involves an interpretation of the antitrust laws as applicable to patents and cases of a refusal to grant access, albeit with a more explicit recognition and articulation of what those laws are, to account for the potential technology impedance problems in the biopharmaceutical industry.

Effectively the approach advocates using dynamics of the competition and patent law balance to address innovation concerns as a system's interaction.

[61] '… (*Continued*) … There is no definitive test for dividing the optimal level of protection for IP. Logically the law should not place antitrust constraints on a monopolist's right to refuse to license if such constraints would undermine the IP laws. Conversely, the law should not give IP holders the carte blanche to refuse to license if that would result in frustrating the very objectives that IP laws seek to achieve.' M Lao, 'Unilateral Refusals to Sell of License IP and the Antitrust Duty to Deal' (1999) 9 Cornell JL & Pub Policy 193.