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OECD ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Intellectual property and competition policy in the biotechnology industry

Introduction

The science of biotechnology has been pushing the frontiers of human knowledge and intellectual property ("IP") for three decades. As scientists developed techniques for isolating and creating genetic material and began to apply them commercially, a new industry grew and so did its appetite for patent protection. Although the wisdom of granting patents on DNA is still debated, the policy of OECD countries to allow such patents has been fairly well settled for some time. The door was therefore open for biotechnological innovators to create a flood of IP, and they did.

The number of patent applications from the biotechnology industry has grown faster than the number of patent applications from other industries over the past several years. The thousands of biotechnology patents issued annually contribute to new products, services, and tools in agriculture, pharmaceuticals, and industrial products. The completion of the human genome and the use of human embryonic stem cells, for example, have raised the ambitions of biotechnology firms to lofty levels. Inventors who develop biotechnological innovations rely on IP rights to protect and validate their work. They also rely on IP licenses to gain access to needed tools and technologies.

In addition to spurring important inventions, however, the rising tide of biotechnology patents has brought concerns that they are being granted too freely and too broadly. Too many patents that cover too much ground will not only harm competition, but will also stifle innovation by making further research riskier, more difficult or more expensive. At the same time, certain licensing techniques that are used in the biotechnology industry can aggravate those problems. This *Policy Brief* addresses how government officials can cooperate to foster innovation without stifling competition, as well as some ways in which licensing behaviour that can fall foul of the competition laws. ■

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How do IP and competition policy affect each other?

Competition policy and IP policy are interdependent and affect each other in important ways. Overzealous enforcement of competition laws against IP owners can damage the incentives to innovate that IP systems are designed to foster. On the other hand, when IP is excessively easy to obtain, it may lead to market power to the detriment of competition and consumers. Therefore, in an environment where it is too easy to acquire patents, competition agencies and courts have a tendency to try to regain a balance by using competition laws to limit the undesirable effects of over-patenting. Because competition law is a relatively blunt instrument for that purpose, however, it would be preferable to fix the problems from within the patent system rather than from outside it.

That leads to the question whether competition agencies should become involved in the IP-granting process itself. For several reasons, including a lack of relevant technical and legal expertise, as well as limited resources, it would be imprudent for competition authorities to assume responsibilities related to reviewing IP applications. Furthermore, requiring approval from the competition agency would impose significant delays on the patent process. That, in turn, may dilute the incentive to innovate and retard the benefits that would flow from the patent, such as disseminating technological information and facilitating pro-competitive licensing agreements. In addition, it would be overkill for competition agencies to be involved in every patent application decision, since the vast majority of them do not raise any competition issues.

Nevertheless, competition agencies can undertake a variety of measures to promote a greater awareness of competition issues so that IP agencies can begin to take any necessary steps to improve the IP approval process themselves. Among the ideas that have already been successfully

Box 1.
IP BASICS.

A patent gives its holder the exclusive right to make, use, and sell an invention for a limited time (usually 20 years) within the country where its application was filed. In return, the applicant must disclose the invention in the text of the application. Patents are supposed to be granted only for inventions that are novel, non-obvious, and useful (having an industrial application). In addition, the patent application must include a specification of the invention with instructions that are adequate to enable a skilled person to produce or perform the invention. In other words, the specification must be "enabling". The invention itself is defined in the "claims", which are part of the specification. The patent's scope of protection can be determined by reading the claims.

There are other types of exclusive IPRs, *e.g.*, copyrights and trademarks, but patents provide a broader protection that goes beyond the specific expression of an invention to the concept of the invention itself. That is one of the reasons why patents are the IP of choice in the biotechnology field.

implemented in some jurisdictions are opening interdisciplinary dialogues with patent agencies to foster greater mutual understanding of each other's fields, commissioning expert reports that study a nation's patenting system to determine whether and how it is causing any undue competition problems, and holding seminars or hearings in which academics, public and private sector practitioners, and industry participants come together to discuss the overlap between IP and competition policies. Whatever IP-related initiatives competition agencies may take, they should strive to limit the anticompetitive aspects of IPR while respecting its necessity. ■

What can competition agencies do to facilitate compliance with competition laws?

Competition agencies should consider publishing a set of guidelines describing how they will analyse licensing agreements and other IP-related conduct. Issuing guidelines will help businesses to structure their IP arrangements so that they are consistent with competition laws. In addition, competition agencies themselves will benefit from the exercise of defining their approach to various types of licensing conduct and other uses of IP. For example, the European Commission recently issued new guidelines on patents and licensing that explain the Commission's approach, create "safe harbours" in which businesses can be assured that they are acting within the law, and aim to create a good balance between protecting incentives to innovate and protecting competition. The United States has relied on guidelines that also include safe harbour provisions, since 1995. Similarly, the Korean Fair Trade Commission has enacted guidelines for reviewing the exercise of IP rights that include a "black list" of behaviour that can harm competition, as well as a "white list" of exempted practices that may be shown to have either a benign or a positive effect on competition.

It is advisable for competition authorities to incorporate in their guidelines a practice of distinguishing vertical relationships among licensing parties from horizontal ones. In other words, it is useful to identify whether agreements are between competitors or between non-competitors because that will inform the policy decision that needs to be made. Agreements between competitors are more likely to cause competitive problems and should therefore be subjected to greater scrutiny. Authorities in some jurisdictions expressly distinguish horizontal from vertical licensing agreements, as reflected in the European Commission's new guidelines, whereas other authorities, such as the Japan Fair Trade Commission, take the structural nature of the relationship into account as part of a broader rule of reason approach. ■

What types of licensing arrangements may cause competition problems?

Most licensing arrangements are beneficial to competition because they make it easier to transfer technology efficiently. Although a variety of IP licensing arrangements have the potential to harm competition, these arrangements may be structured so as to limit the potential for harm. Two types of arrangements are especially significant: grant-back obligations and patent pools. A grant-back obligation is a provision in a licensing agreement that requires the licensee to grant a license on any improvements it patents related to the original invention back to the licensor. On the positive side, grant-backs may encourage efficient licensing by providing a means for the licensee and the licensor to share risk and reward the licensor for making possible further innovation. Some grant-back arrangements, however, are more likely to damage incentives to innovate and cause competitive problems than others. Which side of the fence they fall on often depends on factors such as whether the grant-backs encompass distinct, severable improvements and whether the original licensor is given exclusive rights over those improvements.

Severable innovations can be used by licensees without infringing the original invention, whereas non-severable improvements cannot be used without infringing the original invention. Because licensors already have some control over non-severable improvements, even exclusive grant-backs of non-severable innovations are unlikely to cause competition concerns. In contrast, grant-backs of severable improvements may damage incentives for follow-on innovation because those improvements are not otherwise legally controlled by the licensor. They may also serve as a means of prolonging the licensor's market power by nullifying or reducing the threat of what would otherwise become rival products. Therefore, these types of grant-backs should be subjected to relatively more scrutiny, particularly if they are exclusive.

Patent pools, like most licensing arrangements, usually enhance competition. They may, however, occasionally reduce or eliminate it. Patent pools are formed when two or more parties get together and arrange to have their patents licensed as a package. They make it easier to exploit technology by removing IP barriers. They also promote the integration of complementary technologies and reduce the transaction costs of obtaining multiple licenses. In addition, they are often viewed as a cheaper and faster way to resolve some disputes than litigation is. Patent pools are uncommon in the biotechnology industry so far, but when they do arise, they bring some competition concerns with them. Patent pools that include only complementary and essential patents are much less likely to cause competitive problems than other kinds of patent pools. If, in contrast, a pool includes patents that are substitutes for each other, then there is a risk that the pool is actually a device for jointly selling what would otherwise be competing technologies. Thus, the pool could serve as a vehicle for sharing

markets and raising prices anti-competitively. Moreover, if a pool includes patents that are not essential (i.e., patents that have substitutes outside the pool), then it may foreclose third-party technologies because pool licensees will have already been granted access to the technology included in the pool. Therefore they would not need to buy access to any competing technology. As a result, when evaluating patent pools, competition authorities are advised to determine whether the pooled technologies are complementary and essential. ■

Are unilateral, unconditional refusals to license IP ever anti-competitive?

Different OECD countries have different answers to this question. In several jurisdictions, it is possible for a unilateral refusal to license IP to violate competition laws, and there are procedures for using compulsory licensing as a remedy in such cases. Typically, in those jurisdictions, the first step is to determine whether the IP holder is in a dominant position. If it is, then the issue is whether that dominance is being used via an IP right to create conditions that reduce long run incentives to invest and compete dynamically. For example, the European Court of Justice has ruled that compulsory licensing remedies are allowed when unconditional, unilateral refusals to license copyrights prevent the emergence of a new product, are unjustified, and exclude any competition in a secondary market. In contrast, there are very few, if any, examples of liability stemming from unilateral, unconditional refusals to license IP in certain other countries, such as the United States.

Compulsory licensing can be a means of forcing competition into a market, but it has disadvantages and burdens that affect innovation, competition agencies and courts. Forcing an IP owner to grant licenses eliminates some of the control over the invention that served as an enticement to create it in the first place. Indeed, if competition law prevented IP owners from refusing to license, without more, it would proscribe exactly the same behaviour that IP laws permit and therefore damage the incentive to innovate. In addition, if a dominant firm is forced to license its technology to its competitors, then the competitors will no longer have the same incentive to invest in ways to invent around the original patent. Improvements that would otherwise have occurred may therefore be lost. Finally, a major drawback to compulsory licensing is that it requires competition authorities or courts – or both – to have at least some involvement in setting the terms of the license, and perhaps in monitoring its execution in practice, as well. Agencies and courts may find it cumbersome to have initial and ongoing involvement in licensing practices. ■

Should patent infringements ever be permitted?

It may come as a surprise that the answer is yes. While the research exemption for patents differs on a country-by-country basis, many OECD countries grant exemptions to the laws against patent infringement when a patented invention is used for purely experimental purposes. Some countries view the experimental use exemption as especially important in the biotechnology industry because research tools, upon which other inventions and potential inventions depend, make up a large proportion of the patents awarded. Furthermore, the exemption may ease the effects of overpatenting by clearing a path through patent thickets for at least some follow-on research. In addition, the experimental use exemption can increase competition in countries where it is interpreted liberally. For example, it can allow companies to work with patented technologies to determine whether they might have other useful applications. If applied too readily, however, the exemption may discourage innovation by depriving inventors of the full measure of reward from their inventions. Recent case-law in the United States seems to have narrowed the research exemption in that jurisdiction. ■

Is there an anticommons problem in the biotechnology industry?

An anticommons is a situation that is often mentioned in academic literature as a cause for concern for IP and competition policymakers. It arises when so many patents have been awarded that the difficulty of identifying which licenses are needed, and of negotiating and paying for those licenses, is so great that further innovation is discouraged or even halted. There is, however, little evidence to suggest that the biotechnology industry currently has an anticommons problem. Nevertheless, the biotech industry does have several characteristics that make it fertile ground for an anticommons, such as a proliferation of patents held by a large number of market participants and an occasional tendency by companies to accumulate IP for defensive purposes. ■

What special challenges does biotechnology present to IP and competition authorities?

The nature of the biotechnology industry creates unusual challenges for IP agencies, which have been criticised for issuing biotechnology patents too freely. Too many patents may lead to the unnecessary creation of market power and a slowdown in innovation. The biotechnology industry is characterised by rapid growth, complexity, comparative youth, and a tendency for its participants to attach a high degree of importance to IP. In combination, these characteristics have created an industry that collectively submits a large and quickly growing number of difficult, highly technical patent applications, which makes it harder for patent examiners to pare

down broad claims and weed out all of the applications that do not meet statutory patentability criteria. Approving patent applications that should have been limited or rejected could, in some cases, reduce competition by providing patent protection to undeserving technologies. It could also retard innovation by making it more difficult for inventors to do their work without infringing or paying for someone else's technology.

The nature of the biotechnology industry also presents competition agencies with substantial challenges and implies that an extra measure of caution may be warranted when they contemplate intervention. Presently, many competition agencies around the world consider themselves under-equipped to analyse this technologically advanced and quickly changing industry. While some agencies have begun to take steps to recruit personnel with expertise geared toward IP and/or biotechnology, others do not have sufficient funding to do so. In view of the level of their expertise at this relatively early stage, and in light of the small number of competition cases that have involved the biotechnology industry to date, competition authorities are advised to proceed quite carefully in this field so as to ensure that their actions do not have the unintended effect of discouraging innovation. The industry's rapid development has also led to situations in which enforcement officials have found that by the time they are ready to take action, the relevant companies have changed their behaviour or their ownership. ■

For Further Information

More information about this Policy Brief and the OECD Competition Division can be obtained from Jeremy West.

Email: jeremy.west@oecd.org

Tel.: [+33 1] 45 24 17 51

Website: *www.oecd.org/competition*

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For Further Reading

OECD, **Intellectual Property Rights**, (Best Practices Roundtable) (2004).
Available on the Internet: *www.oecd.org/dataoecd/61/48/34306055.pdf*.

OECD Ministerial Report, Patents and Innovation: Trends and Policy Challenges (2004).
Available on the Internet: *www.oecd.org/dataoecd/48/12/24508541.pdf*.

OECD, **Merger Review in Emerging High Innovation Markets**, (Best Practices Roundtable) (2003).
Available on the Internet: *www.oecd.org/dataoecd/40/0/2492253.pdf*.

OECD, **Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies** (2002).
Available on the Internet: *www.oecd.org/dataoecd/42/21/2491084.pdf*.

Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy (2003).
Available on the Internet: *www.ftc.gov/reports/index.htm*.

Where to contact us?

OECD HEADQUARTERS
2, rue André-Pascal
75775 PARIS Cedex 16
Tel.: (33) 01 45 24 81 67
Fax: (33) 01 45 24 19 50
E-mail: sales@oecd.org
Internet: *www.oecd.org*

GERMANY
OECD Berlin Centre
Schumannstrasse 10
D-10117 BERLIN
Tel.: (49-30) 288 8353
Fax: (49-30) 288 83545
E-mail:
berlin.contact@oecd.org
Internet:
www.oecd.org/deutschland

JAPAN
OECD Tokyo Centre
Nippon Press Center Bldg
2-2-1 Uchisaiwaicho,
Chiyoda-ku
TOKYO 100-0011
Tel.: (81-3) 5532 0021
Fax: (81-3) 5532 0035
E-mail: center@oecdtokyo.org
Internet: *www.oecdtokyo.org*

MEXICO
OECD Mexico Centre
Av. Presidente Mazaryk 526
Colonia: Polanco
C.P. 11560 MEXICO, D.F.
Tel.: (00.52.55) 9138 6233
Fax: (00.52.55) 5280 0480
E-mail:
mexico.contact@oecd.org
Internet:
www.rtn.net.mx/ocde

UNITED STATES
OECD Washington Center
2001 L Street N.W., Suite 650
WASHINGTON DC. 20036-4922
Tel.: (1-202) 785 6323
Fax: (1-202) 785 0350
E-mail:
washington.contact@oecd.org
Internet: *www.oecdwash.org*
Toll free: (1-800) 456 6323

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