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Agenda

Advancing economics in business

Patent pools in pharmaceuticals: a drop in the ocean?

UNITAID, an international drug-purchasing organisation, recently launched a patent pool to facilitate cheaper drugs for HIV-related illnesses. Rupert Booth, Oxera Senior Adviser, considers whether such patent pools have a wider role in making more productive use of intellectual property in the pharmaceutical sector, and identifies some of the problems that arise in their use

Background of declining productivity

The prime structural issue facing the research-based pharmaceutical industry is its declining productivity.[1] This is ultimately observed as a rising unit cost per drug, although its origins lie in the newer developments of biotechnology not filling the research and development (R&D) pipelines as rapidly as originally expected, despite their initial promise. This in turn leads to a shortfall in secure, patent-protected future revenue, which has implications for both societal health and the funding of future R&D. Recent research has also considered the organisational aspect of the problem, using data envelopment analysis (DEA, a comparative efficiency technique) to measure the declining returns to scale of R&D, and the association with merger history.[2] In particular, it appears that the successive acquisition of small biotechnology firms by larger pharmaceutical companies is a natural response to their sparse pipelines, but cannot be expected to provide a solution to that problem.

Given that the declining productivity issue appears to be deep-seated, it is vitally important (literally) to ameliorate its effects by making the best use of the intellectual property (IP) that does exist in the industry. One such initiative is the use of patent pools to remove some barriers to the exploitation of IP.

Patent pools

2010 saw the launch of a patent pool by UNITAID, which facilitates cheaper drugs for HIV-related illnesses. The pool was deemed necessary because the costs of drugs were unaffordable to many of those who required them (the high prices having previously been deemed necessary to support future research).

In 2008, UNITAID decided to create a voluntary patent pool for medicines, initially focusing on anti-retroviral drugs (ARVs) and stimulating the creation of new formulations. The aim was to encourage reductions in the price of existing ARVs, and to increase the number of generic manufacturers of these drugs, as well as to fill gaps in the product range, including fixed-dose combinations of newer products and special formulations for children. The creation of the pool involved not only the usual technical and legal expertise, but also grassroots political pressure in the form of petitioning and, in the UK, parliamentary pressure.

The response of the industry to patent pools has been slightly ambivalent. Pharmaceutical companies tend to be supportive of the concept and are setting up their own pools for diseases such as tuberculosis and malaria, and other diseases prevalent in the developing world—indeed, they are setting up their own schemes having observed the political pressures that can mount—but they are wary of any future compulsory arrangements.

In the past the pharmaceutical industry has been reluctant to move towards arrangements such as patent pools, in part because of the potential consequences under competition law (communication and information exchange between competitors is treated as suspicious under the competition rules). However, the UNITAID pool may prompt a re-examination of the relative merits of patent pools, and other arrangements such as cross-licensing—ie, an arrangement between parties to grant IP rights to each other.

A patent pool is a collection of IP rights into a single entity (necessary for administration) for the purposes

of cross-licensing to a third party.[3] Patent pools have a long history of unblocking obstacles to innovation.[4] Early examples include a pooling of sewing machine patents in 1865, a pooling of patents to enable aircraft manufacture in 1917, and a pooling of radio patents—and the establishment of an organisation that led to the creation of the Radio Corporation of America—in 1924. All of these predecessors could be deemed successful, although they were undertaken in a period before heightened concern about the implications for competition law compliance. More recently, patent pools have been created in the information and communication technology (ICT) sector—for example, to share the patents that form the MPEG_2 digital video standard in 1997, and for the patents relating to DVD-ROM and DVD-video specifications in 1998.

Legal guidelines

The most recent legal guidelines on patent pools were issued by the European Commission in 2010.[5] These guidelines cover the operation of standard-setting organisations, the prior disclosure of essential patents required for standards, and the principles for setting prices in patent pools or other 'horizontal agreements'.

In the USA there is also legal guidance, including clarification of the features of a pool that would make it pro- or anti-competitive. The US Department of Justice and the Federal Trade Commission issued the 'Antitrust Guidelines for the Licensing of Intellectual Property',[6] which indicate that pooling is more likely to be considered pro-competitive when it:

- integrates complementary technologies;
- reduces transaction costs;
- clears blocking positions;
- avoids costly infringement litigation; and
- promotes the dissemination of technology.

The guidelines indicate that excluding firms from an IP pool can be anti-competitive if:

- in effect, the excluded firms cannot compete in the relevant market for the product incorporating the licensed technologies;
- the pool participants collectively possess market power in the relevant market; and
- the limitations on participation are not reasonably related to the efficient development and exploitation of the pooled technologies.

In summary, the degree of uncertainty surrounding the antitrust treatment of these arrangements declines as authorities publish specific guidance on their appropriate use.

Possible application to biopharmaceuticals

Patent pools and alternative approaches to cross-licensing are two means of dealing with the 'tragedy of the anti-commons' in biopharmaceuticals.[7] The tragedy of the commons arises where there is overuse of a common resource, leading to its depletion; the reverse applies where a series of gates with different key holders block access to the commons and thus prevent any exploitation at all. This has been an issue particularly in the ICT sector, especially when it has become necessary to develop an industry standard to allow the exploitation of a technology where multiple organisations hold key patents.

In these cases, a 'patent thicket' has arisen; the term was first coined in the 1970s, although it has become more widely known following a paper by Shapiro in 2001,[8] which offered the following definition: 'an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees'.[9]

The thicket prevents the exploitation of a technology because it depends on the cooperation of multiple holders of IP who might not have the incentive to cooperate, or, if they do, cannot agree terms or are deterred by the traction costs of formalising those terms. The paper also identified the problem of 'hold-up', which is not a delay but a case of large damages being extracted when new products inadvertently infringe patents after they were designed. The paper goes on to identify patent pools and cross-licences as two alternative solutions, and emphasises the need to show the complementarities of the patents involved, as opposed to their substitutability.

Regarding biopharmaceuticals, Heeler and Eisenberg highlight 'concurrent fragments' of DNA sequences, where a multiple patent problem might arise.[10] In a similar field—the pooling of IP—the SNP Consortium of Single Nucleotide Polymorphisms led to the creation of the SNP map, a map of the human genome that is of great assistance in drug discovery and is now available for common use in biomedical research.

Verbeure et al. highlight the reliance on patent pools in medical diagnosis, citing the diagnosis of non-polyposis colorectal cancer in particular.[11] To this could be added the field of medical devices for drug delivery, where the patent holders of a drug require the cooperation of patent holders of delivery mechanisms, or where design and manufacture patents are held separately.

Critics of pools, however, point to the costs of setting up pools and their appropriateness for the biopharmaceutical sector, as amplified below.

Objections to the use of patent pools

It is perhaps significant that patent pools have recently been most common in the ICT sector, where issues of interoperability and standardisation are paramount. In the absence of these requirements, more economical forms of avoiding anti-commons may be appropriate, such as cross-licensing. A report in *Innovation Strategy Today* analysed the attractiveness of the pool concept, and considered the following factors:[12]

- the number of pool participants;
- the number of patents held by each pool participant;
- the likelihood of a patent being useful;
- the number of patents required.

It then provided an example of the cost modelling of a patent pool, supposing that the cooperation of 25 IP rights holders was necessary for the commercialisation of vaccines. This highlighted some disadvantages, namely:

- difficulties in agreeing the value of patents in the pool;
- the complexity of setting up the pool;
- the possible inflation of costs by the inclusion of unnecessary patents;
- complications if litigation is already under way;
- the prevention of disclosure of technology into the public domain.

Below the focus is on the first of these objections—the relative worth of IP rights—which would have to be considered in any mutual IP agreement.

The economics of patent pools and cross-licensing

Some key economic concepts apply to setting prices or appropriate royalty rates for IP, recognising that patents are becoming a 'network industry'—ie, a system in which the whole cannot function without the contribution of its many parts. In setting returns for an individual patent holder, the concept of a fair, reasonable and non-discriminatory (FRAND) price emerges—however, the principles by which a figure is arrived at are far from clear. Indeed, as one response to the consultation on the EU guidelines noted:

> Having said we agree with the FRAND commitment, in view of past incidents, a FRAND commitment by itself would not be sufficient to warrant a license on reasonable terms in reality. We admit that it would be next to impossible to define what FRAND is in a concrete and universal manner.[13]

In order to advance this challenging field, two of the theoretical issues in setting a FRAND price were considered in an Oxera article in 2008[14]—namely, the Swanson–Baumol approach of considering the price that an IP holder might charge for the property prior to the creation of the pool; and the Shapely approach, where a cooperative game situation is considered in setting the price of each contribution.

Less theoretical and well-established approaches have been used for the valuation of intangible assets, including IP. In general, there are three alternative approaches: income (for example, relief from royalty); market price (requiring some form of benchmarking); and a cost-based approach. It is not possible to generalise on the application of different valuation approaches, and each case needs to be treated on its merits and the context of valuation. Where IP-related issues have been identified in advance of design and commercialisation, commercial bargaining can be relied on. However, if an infringement of IP has already occurred, the development of a strong case to support a particular valuation becomes essential.

Shapiro considers the negotiations over royalties that can occur both before and after the patent-infringing design has been produced.[15] The proposed model for patent negotiation takes into account:

- the strength of the patent and the fact that royalties are negotiated in the shadow of litigation;
- the threat of injunction (ie, where the downstream firm will have to withdraw its product);
- whether the downstream firm is aware that it is infringing a patent;
- the coverage of the patent with regard to the final product and the margin on the final product;
- the cost of the downstream firm redesigning its product to avoid using the patented technology.

Shapiro concludes that the negotiated royalties are dependent, in part, on the magnitude of damages that the courts would award if a licence could not be agreed and patent litigation ensued, which can lead to the elevation of royalties beyond what would be agreed if the threat of litigation were removed (hence the patent hold-up).

Conclusion

The pharmaceutical sector has made ample use of cross-licensing but has, until recently, tended to avoid

patent pools. The UNITAID initiative may lead to the examination of patent pools for other applications in the sector. Whatever the outcome, and even if the more traditional cross-licensing route remains the preferred one, in an era of declining R&D productivity, reducing transaction costs and maximising the use of existing IP are priorities.

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[1] See, for example, Cockburn, I.M. (2007), 'Is the Pharmaceutical Industry in a Productivity Crisis?', NBER Chapters, in *Innovation Policy and the Economy*, **7**, pp. 1–32, National Bureau of Economic Research, Inc.; and Pammolli, F., Riccaboni, M. and Magazzini, L. (2010), 'The Productivity Crisis in Pharmaceutical R&D', Working Papers 06/2010, Università di Verona, Dipartimento di Scienze economiche.
[2] Booth, R. (2010), 'A Multi-Dimensional Analysis of Post-Acquisition Performance: The Case of Research & Development in the Pharmaceutical Sector', PhD thesis submitted to Warwick Business School, December.
[3] Shapiro C. (2001), 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting', NBER Chapters, in: *Innovation Policy and the Economy*, **1**, pp. 119–50, National Bureau of Economic Research, Inc.
[4] See, for example, Clark, J., Piccolo, J., Stanton, J. and Tyson, K. (2000), 'Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?', United States Patent and Trademark Office, December 5th.
[5] European Commission (2010), 'Guidelines on the Applicability of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Co-operation Agreements'.
[6] US Department of Justice and the Federal Trade Commission (2005), April 6th.
[7] See Heeler, M. and Eisenberg, R. (1998), 'Can Patents Deter Innovation? The Anticommons in Biomedical Research', *Science*, **280**, pp. 698–701, May 1st.
[8] Shapiro (2001), op. cit.
[9] Ibid., p. 119.
[10] Heeler and Eisenberg (1998), op. cit.
[11] Verbeure, B., Matthijs, G. and Van Overwalle, G. (2006), 'Analysing DNA Patents in Relation with Diagnostic Genetic Testing', *European Journal of Human Genetics*, **14**, pp. 26–33.
[12] Krattiger, A., Kowalski, S., Eiss, R. and Taubman, A. (2006), 'Intellectual Property Management Strategies to Accelerate the Development and Access of Vaccines and Diagnostics: Case Studies of Pandemic Influenza, Malaria, and SARS', *Innovation Strategy Today*, **2**:2.
[13] Japan Electronics and Information Technology Industries Association (2010), 'The Comments of Economic Legislation Committee of Jeita to the Consultation on the Draft Guidelines on Horizontal Cooperation Agreement', June 25th, p. 4.
[14] Oxera (2008), 'Untangling FRAND: What Price Intellectual Property?', *Agenda*, February.
[15] Shapiro, C. (2010), 'Injunctions, Hold-Up, and Patent Royalties', *American Law and Economics Review*, **12**:2, pp. 509–57.