Part I

Patent pools

1 Patent pooling for gene-based diagnostic testing

Conceptual framework*

Birgit Verbeure

1.1 Introduction

The presence of a patent thicket in a certain technology inevitably leads to a high number of licenses required to gain access to the patented technology. Consequently, this may result in the accumulation of royalties to be paid (royalty stacking). Such a situation may cause hindrance of access to and subsequent under-use of the technology, which is described in literature as the anticommons effect.[1] When access and use to a certain technology are hindered by the existence of multiple patents, held by multiple patent owners (a patent thicket),[2] a patent pool might be a useful model to facilitate access.

Patent thickets have arisen in technical fields other than the genetic area and patent pools have emerged to deal with overlapping patents for a long time.[3] One of the first patent pools was formed in 1856, by sewing machine manufacturers Grover, Baker, Singer, Wheeler and Wilson, all accusing the others of patent infringement. They met in Albany, New York to pursue their suits. Orlando B. Potter, a lawyer and president of the Grover and Baker Company, proposed that, rather than sue their profits out of existence, they pool their patents. In 1917, an aircraft pool

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[1] Heller, M.A. and Eisenberg, R.S., 'Can patents deter innovation? The anticommons in biomedical research', **280** *Science,* 1998, 698–701.

[2] Shapiro defined patent thicket as an overlapping set of patent rights requiring that those seeking to commercialize new technology need to obtain licenses from multiple patentees. Shapiro, C. (2001) 'Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard Setting', in Jaffe, E., Lerner, J. and Stern, S. (eds), *Innovation Policy and the Economy,* volume I, MIT Press, 119–150.

[3] Merges, R. (2001) 'Institutions for intellectual property transactions: the case of patent pools', in Dreyfuss, R., Leenheer Zimmerman, D. and First, H. (eds), *Expanding the Boundaries of Intellectual Property* Oxford University Press, 123–166.

was privately formed encompassing almost all aircraft manufacturers,[4] which was crucial to the US government entering World War I. In the late 1990s several patent pools were formed in the ICT branch starting with the MPEG-2 pool in 1997 for inventions relating to the MPEG-2 standard[5] with others to follow.[6, 7, 8]

According to a recent study under the auspices of NAS's Science, Technology and Economic Policy Board and Committee on Science, Technology and Law,[9] there is no real or substantial evidence for a patent thicket or a patent blocking problem in the field of genetics at present. However, it should be noted that the report is strongly focused on the influence of IP on research activities. At the same time, one is cautioned about the future: this lack of evidence is associated with a general lack of awareness or concern among the technology users on the one hand, and growing assertiveness of patent holders in asserting their rights on the other hand. Similar findings resulted from the European PATGEN project.[10] Nevertheless, cases of restrictive licensing or refusals to license practices have generated widespread controversy and disapproval because of the potential adverse effects on public health. Such studies were mainly reporting on problems relating to gene-based diagnostic testing, the reason why we further investigate to what extent a patent pool could alleviate the pains in this field.

Although there seems to be little evidence to suggest that there is an anticommons problem in the biotechnology industry in general, and in the genetics in particular, the biotech industry does have several characteristics that make it fertile ground for an anticommons. For example, a proliferation of patents held by a large number of market participants and an occasional tendency by companies to accumulate

[4] Dykman, H.T., 'Patent licensing within the Manufacturer's Aircraft Association', **46** *Journal of the Patent Office Society*, 1964, 646.
[5] Klein, J.I. 'Business review letter to Gerrard R. Beeney regarding MPEG-2', 1997, Department of Justice, Antitrust division.
[6] Klein, J.I. 'Business review letter to Gerrard R. Beeney regarding licensing of DVD technology', 1998, Department of Justice, Antitrust division.
[7] Klein, J.I. 'Business review letter to Carey R. Ramos regarding licensing of DVD technology', 1999, Department of Justice, Antitrust division.
[8] James, C.A. 'Business review letter to Ky P. Ewing regarding 3G platform' 2002, Department of Justice, Antitrust division.
[9] National Research Council of the National Academies, 'Reaping the benefits of genomic and proteomic research: intellectual property rights, innovation, and public health', 2005, National Academies Press.
[10] Hopkins, M.M., Mahdi, S., Thomas, S.M., Patel P. 'The patenting of human DNA: global trends in public and private sector activity (The PATGEN Project)', *Report on a European Commission's 6th Framework programme* 2006.

IP could indicate the emergence of a patent thicket and/or issues to gain access to the technology. Like in ICT, the biotech industry is characterized by rapid growth, a high level of complexity and a tendency to attach high importance and value to IP. But contrary to the IT industry, the attitude in biotech is much more protective. It is the aim of this chapter to review patent pooling as a concept (1.2) and to assess to what extent the concept could offer a facilitating effect on the licensing of IP for gene-based technology, in particular genetic testing (1.3).

1.2 Patent pools: the concept

Introduction

Definition

In order to overcome an anticommons effect, a patent pool provides for an agreement between two or more patent owners to license one or more of their patents to one another, and together as a package to third parties. As illustrated in Figure 1.1 two major licensing techniques are involved in the patent pool setup. On the one hand, a multiparty agreement is set up between the patent owners who license their patents as a package to one another and form a pool (lines within circle). On the other hand, a bilateral license agreement, usually in the form of a standard out-licensing agreement, provides for access of third parties to that package of patents (lines outside circle). As a consequence, a patent pool allows interested parties to gather in one instance all the necessary tools to practice a certain technology, i.e. "all-in-one license", rather than obtaining licenses from each patent owner individually.

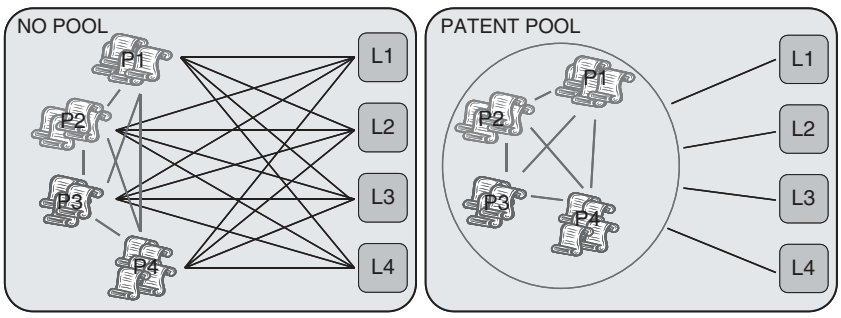

Figure 1.1 Comparative illustration of the different licenses needed in the absence or presence of a patent pool.

Motivation

Over the last hundred years, the reasons for setting up a patent pool have changed considerably. Roughly, two periods can be distinguished. From the introduction of the first patent pools in late nineteenth century and mainly during the first two decades of the twentieth century, patent pools were market based. They were set up to clear blocking patent positions and to cease patent hostilities, often after government intervention. Also the creation of a market division among horizontal competitors, naked price-fixing and other anti-competitive goals incensed some of the early patent pools. However, due to growing concern for and criticism of such uncompetitive behaviour, apart from some exceptions, no new patent pools were formed between approximately 1920 and the 1990s.[11]

Nevertheless, in the 1990s, the patent pool model was picked up again but the incentives for pool formation differed considerably. At this point in history, patent pools were typically designed to deal with substantial patent thickets for technologies that were essential to one and the same technical standard, which led to standard-based patent pools. Standards are technical specifications relating to a product or an operation, which are recognized by a large number of manufacturers and users.[12] Typically, such standards-driven patent pools are the ones we know from the ICT sector which set off with the MPEG-2 patent pool. This new approach to patent pooling shed a different light on the possible impact of patent pools on competition. By bringing together essential patents in a one-package license, the access to technologies essential to implement a standard was facilitated, bringing strong pro-competitive effects in the balance. As can be read in the Guidelines issued by the US Department of Justice and US Federal Trade Commission (FTC) in 1995,[13] it was recognized that cross-licensing arrangements and patent pooling "may provide pro-competitive benefits by integrating complementary technologies, reducing transaction

[11] This growing concern with regard to anticompetitive licensing conduct eventually led to a rigid approach of the US Department of Justice to licensing arrangements, identifying particular practices that it considered to be forbidden as the "Nine No-Nos" of intellectual property licensing. *See* Bruce B. Wilson, Deputy Assistant Attorney General, 'Remarks before the Fourth New England Antitrust Conference, Patent and Know-How License Agreements: Field of Use, Territorial, Price and Quantity Restrictions', 1970.

[12] European Commission Communication COM (92) 445 final of 27 October 1992 on Intellectual Property Rights and Standardisation.

[13] US Department of Justice and Federal Trade Commission (1995) 'Antitrust Guidelines for the Licensing of Intellectual Property'.

costs, clearing blocking positions and avoiding costly infringement litigation."[14]

Set-up

The establishment of a patent pool is a long, complex, multi-step process. In view of the varied issues and interests at stake, expertise and joint collaboration of highly qualified patent attorneys, technical experts in the relevant field and legal advisors both in the field of patent law and competition law are required.

A patent pool may be and usually is formed upon the initiative of the patentees, acting as shareholders of the pool and as financiers of the licensing entity. Consequently, to a certain extent the patentees preserve authority over the licensing conditions. Third-party licensing may occur directly by patentees to licensees, e.g. by appointment of one of the partners of the pool. Alternatively, third-party licenses may be administered indirectly through a new entity specifically set up for the pool administration, a separate independent licensing authority.[15, 16, 17, 18]

The first situation will generally apply to patent pools with a relatively limited number of participating patent holders. In such organizations whereby one of the patent owners manages the patent pool, some safeguards with respect to its independence and confidentiality of business information should clearly be built in. The administration of larger pools puts a large burden on the administering body and will in general be transferred to an independent licensing authority.

Based on the nature of the patent pool initiators and the complexity of the pool's structural organization, three types of patent pools can be distinguished.[19] "Joint licensing schemes" are initiated by a group

[14] I*bid*. §5.5

[15] Shapiro, C., (2001) 'Navigating the patent thicket: cross licenses, patent pools and standard setting', in Jaffe, E., Lerner, J. and Stern, S. (eds), *Innovation Policy and the Economy,* volume I, MIT Press, 119–150.

[16] Clark, J. 'Patent Pools: a Solution to the Problem of Access in Biotechnology patents?' in a White Paper commissioned by Q. Todd Dickinson, the Under Secretary of Commerce for Intellectual Property and Director of the US Patent and Trademark Office, 2000.

[17] Klein, J.I., (1997) 'Cross licensing and antitrust law', *An Address to the American Intellectual Property Law Association* May 2, 1997.

[18] Merges, R. (2001) 'Institutions for intellectual property transactions: the case of patent pools', in Dreyfuss, R., Zimmerman, D.L. and First, H. (eds), *Expanding the Boundaries of Intellectual Property,* Oxford University Press, 123–166.

[19] Bekkers, R., Iversen, E., Blind, K. 'Patent pools and non-assertion agreements: coordination mechanisms for multi-party IPR holders in standardization', paper for the EASST 2006 Conference, Lausanne, Switzerland, 23–26 August 2006.

of (usually larger) licensors of a particular technology (or standard). One of them may act as an agent for the joint licensing contract. Most of these pools are eventually open to any holder of essential IPR to the standard in question. Nevertheless, they started as an activity of a small group.

"Patent pools with a licensing administrator" start off with an open call for essential patents for a certain standard by an independent body. Subsequently, the independent licensing administrator has a patent evaluation carried out (preferably by an independent third party) to determine essentiality to the standard in question. A priori, the licensors that decide to join such a pool do not know who the other licensors will be that will become a member of the pool. Well-known examples of such independent bodies acting as licensing authorities/administrators for several patent pools covering a diversity of technical standards at the same time are MPEG LA[20] or ViaLicensing.[21] The licensing administrator sets, in dialogue with the licensors, the royalty rate for the pool, and collects the royalties and redistributes them given a pre-agreed scheme.

In the case of "patent platforms", an organizational approach is adopted that deals flexible with multiple technologies (standards) and multiple product groups (employing one or more patents that are essential to a certain standard). It also aims to be more flexible towards the actual agreements between licensors and licensees. In the patent platform, there is one overall umbrella organization, as well as multiple entities which each develop licensing programmes for specific standards. The aim is to have a standard offer (bundle) available. However, within the context of the patent platform, licensors and licensees may also agree upon other arrangements, possibly involving cross licensing, licensing of non-essential patents, and so on. To date, the 3rd Generation Partnership Project (3GPP)[22] is the only example of such an approach. One could argue that there is little or no difference between the 3G platform model and an organization like MPEG LA or Vialicensing on the basis of organization or administration. We do however want to stress the importance of a particular feature of this third model. The platform deals with partly integrating technologies in a flexible approach tailored to the particular needs of different licensees. Licensing administrators dealing with multiple pools may adopt a more or less flexible approach within one patent pool, but will still treat these different pools independently. As will be discussed in more detail

[20] www.mpegla.com [21] www.vialicensing.com [22] www.3g.org

in part 1.3 of this chapter, it is exactly the flexibility within seemingly a single technology that justifies its separate classification, especially for the purpose of this paper.

Benefits and risks

From the experience in ICT, we learn that patent pools may have significant benefits which make for a pro-competitive counterweight for possible anti-competitive effects, which largely account for the critical opinions with respect to the patent pool model. A major beneficial effect to begin with is the elimination of stacking licenses. The licensing transaction costs are reduced by the introduction of a system of "all-in-one licensing" for non-member licensees instead of having to negotiate and acquire separate licenses directly from each of the patent owners individually (see Figure 1.1). At the darker/down side of this model, one has at the same time to take into account that the initial cost of setting up and negotiating a pool agreement will often be high. Another benefit is a decrease in patent litigation and its associated high cost. A patent pool also leads to the institutionalized exchange of technical information not covered by patents through a mechanism for sharing technical information relating to the patented technology, which would otherwise be kept as a trade secret. This is reflected by an exchange of know-how brought along by the set-up of a patent pool, thereby further facilitating innovation and efficient use of resources. However, from competition law point of view, such exchange should be limited to technical information only. The exchange should not extent to exchange of business information between competitors which risks resulting in cartel formation.

Patent pools may also offer an interesting instrument for government policy, in the sense that it is better to encourage companies to establish patent pools rather than for example to force them into a compulsory licensing scheme. However, one should not overlook that it was exactly those early patent pools created after government intervention that raised antitrust concerns. A major prerequisite for establishing patent pools is the voluntary participation of all patent holders, whereas the compulsory licensing mechanism is exactly intended for creating access in a situation where patent holders do not voluntarily wish to enter into (reasonable) licensing negotiations. In the past however, "non-voluntary patent pools" have been set up, i.e. patent pools initiated on the basis of government intervention. An early example of such non-voluntary patent pool was the airplane patent pool created by the US Government

in 1917.[23] More recently, attempts were made in the biomedical field to create access to HIV drugs for developing countries by setting up the "Essential Patent Pool for AIDS".[24]

One should be wary of some additional potential risks as well. Patent pools might shield invalid patents[25] and entail the risk of inequitable remunerations although expert valuation could settle disagreements on the value of the patents.[26] The major criticism is the danger of covering for a cartel and subsequent anti-competitive effects.[27, 28, 29]

Economics

As originally studied by Cournot back in 1838,[30] the creation of a patent pool is typically attractive when at least two entities hold blocking patents. Cournot's theory of the complements nicely illustrates that the inefficiency associated with multiple blocking positions can be eliminated by pooling patents and joint licensing. When individual patentees join forces and offer their IP in a single license as a package, the price of such package license is less then the cumulative price of the individual components when priced separately. Both the patentees and licensees fare better under such a regime. Because of the availability of a license

[23] As the US contemplated the needs of entering and fighting in World War I, the problems associated with the development, manufacture, supply availability, innovation and cost of airplanes were brought to the forefront. In the early days of aviation, the Wright brothers and Curtiss company, whilst also litigating each other on their patents, retarded innovation in the aircraft industry. The National advisory committee for aeronautics was created which recommended "the formation of the Aircraft Manufacturers Association among all aircraft manufacturers to manage a patent pool". The US Congress passed a law to enable the Secretary of War and the Secretary of the Navy to secure by purchase, condemnation, donation or otherwise essential patents as they may consid er necessary to the development and manufacture of aircraft in the US for governmental and civil purposes. Eventually, the AMA's patent pool was created. The level of allocation of royalties was forced upon the patent owners under threat of the government to take over the patents.

[24] See www.essentialinventions.org/docs/eppa.

[25] Aoki, R. 'The Consortium Standard and Patent Pools' 55(4) *The Economic Review*, 2004, 345–356.

[26] Bekkers et al. 'Patent pools and non-assertion agreements'.

[27] Aoki, R. 'The Consortium Standard and Patent Pools' 55(4) *The Economic Review*, 2004, 345–356.

[28] Versaevel, B., Dequiedt, V. 'Patent Pools and the Dynamic Incentives to R&D' *Cahiers de Recherche, Working Papers No 2009/6*, available at www.em-lyon.com/ressources/ge/documents/publications/wp/2006-09.pdf

[29] See note 23, above.

[30] For a brief description of Cournot's original work on complements, and modern extensions, *see* Shapiro, C. (1989), 'Theories of Oligopoly Behavior', in Schmalensee R. and Willig, R. (eds.), *Handbook of Industrial Organization*, Elsevier Science Publishers, 330–414, at 339.

that covers all, there is a higher chance on effective marketing of market products which in turn results in higher revenue for the patentees on their IP. At the other side, since the package license is available at a more reasonable price, the public fares better by having a market product available with a lower royalty burden. More recent economic modelling studies on the patent pool concept, confirm Cournot's early findings.[31]

More recently, more complex studies have been conducted to evaluate the effect of the formation of a patent pool on welfare, thereby aiming at better understanding which characteristics of patent pool arrangements lead to pro-competitive effects, and therefore indicating which patent pools should be authorized by the regulator. A clear outcome of these studies highlights the importance of the essentiality of the patents included in the pool. The foregoing analyses evaluate the impact of a pool on welfare after the formation of that pool, i.e. *ex post* perspective.[32]

A new approach to the economic study of the patent pool model looks at the perspective before the formation of a patent pool and reveals additional interesting observations. This *ex ante* approach[33] led to the conclusion that the perspective of joining a patent pool would have a positive impact on R&D activity, i.e. higher R&D investment and enhanced speed of R&D. In other words, the prospect of patent pooling has an innovation stimulating effect. More in particular, it is perceived as crucial to be part of the pool initiators. However, this phenomenon gives rise to the observation of two distortions. On the one hand there is the risk for pre-pool overinvestment in order to be participant in the pool formation. But on the other hand, there may well be a risk for underinvestment after pool formation. Hence there might be a negative effect on further innovation once the pool has been set up.

This theoretical determination of the incentives effect of the prospect of a patent pool is also reflected in the setup of patent pools in a context of cooperative standard setting. Ironically, exactly the role of standard setting bodies in the set-up of patent pools as such may raise anti-trust concerns. Standard setting bodies almost always coordinate standard setting by competitive or potentially competitive business

[31] Lerner, Josh and Tirole, Jean, 'Efficient Patent Pools' (5 August 2002). Available at SSRN: http://ssrn.com/abstract-322000.

[32] Aoki, R. 'The consortium standard and patent pools' **55**(4) *The Economic Review*, 2004, 345–356.

[33] Versaevel, B., Dequiedt, V. 'Patent Pools and the Dynamic Incentives to R&D', *Cahiers de Recherche, Working Papers No 2009/6*, available at www.em-lyon.com/ressources/ge/documents/publications/wp/2006-09.pdf.