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Patent pooling: Uncorking a technology transfer bottleneck and creating value in the biomedical research field

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Date received (in revised form): 13th September, 2002

Abstract

Patent pools have long been used to collect intellectual property rights into a basket of rights that can facilitate the licensing thereof. By pooling relevant patent rights together, the out-licensing is streamlined and made more cost efficient. Many recent patent pools involved establishing and administering patents that meet an established industry standard and then granting non-exclusive licences to the patents that are considered essential to that standard, eg consumer electronics. While there are few, if any, established industry standards in biomedical research, there are opportunities to pool intellectual property rights that facilitate cost-efficient technology transfers and foster better research.

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Keywords: *pooling, patents, biomedical, antitrust, research, infringement*

INTRODUCTION

The following paper summarises opportunities for the use of patent pools in biomedical research and is based in part on a panel discussion held on this topic at a recent major biotechnology industry meeting.[1]

BACKGROUND

Much has been written and said about the history and use of patent pools in American industry. Before discussing the use of patent pools in the biomedical research field, we first provide some background information. In its basic form, a patent pool can be quite simple. In the broadest definition, a 'patent pool' is created by two or more patent owners who aggregate subject patents in order to cross-license to each other and out-license to third parties. A separate entity may be set up to administer the pool, which is typically independent of each patentee.

Benefits provided by pools

Patent pools are useful in a wide variety of industries and are a time-honored technique for technology transfer that can be pro-competitive.[2] In general, by establishing a central acquisition point for all of the technology in a pool, patent pools usually achieve at least the following four favourable outcomes:

- lower transaction costs of negotiating and administering licensing programmes;
- permitting and encouraging the wider use and adoption of the pooled technology, and permitting a better rate of return on research and development dollars;
- spreading the risks and benefits of technology implementation among the players in the field; and

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- removing blocking patents, and managing, reducing or eliminating litigation risks.

By obtaining a patent licence from a pool of basic or essential patents, multiple businesses can obtain all the necessary rights required to practise a particular technology. The patent pool does not lessen competition; rather, by allowing many players in a field to have access to technology on equal footing with one another, the players continue to compete in the marketplace for the downstream product that incorporates the technology.

Negotiation costs with a pool are simpler and more effective

The cost associated with negotiating one non-exclusive licence for a basket of rights, which is offered by a patent pool administer to all comers at the same (reasonable) price on the same terms, is much simpler and cost-effective than the alternative of having each player engage in separate negotiations with different patentees in order to collect the same basket of rights individually. In addition, obtaining a basket of rights through a well-formed patent pool removes the costs and manages the risks normally associated with freedom-to-operate studies, the uncertainty of patent litigation, and the time and effort required to negotiate with multiple licensers.

Pools lessen, the chance of killing off new initiatives

Another potential benefit to using the patent pool to out-license the available basket of rights is that it prohibits one patent owner from exerting sufficient power to kill new initiatives. That is, in the current marketplace, when each patent needed for a project must be separately in-licensed from the individual patent owner, it is not uncommon for the last essential in-licensed patent to be more expensive than its scope and technical merits would support. Thus, if a potential licensee has made its way through the patent thicket and has licensed all essential patents but one, the last patentee has a unique and controlling influence on the negotiations. This last patentee could attempt to hold out for an unreasonable royalty because he or she thinks they can get it from a licensee that they think will pay almost any price to obtain the last bit of freedom to operate. But by holding out for an unreasonable royalty, the last patentee also runs the risk of killing the whole initiative for the licensee. This last negotiation for the patent rights from the last patent holder of essential intellectual property (IP) can be a product killer and can ruin a business plan. People experienced in the field report that parties typically negotiate a reduced royalty provision, or a cap on royalties, to deal with anticipated patent royalty stacking problems encountered in dealing with multiple licensers. Unfortunately, even with a reduced royalty provision or a cap on royalties in most licences, it is possible for the separate royalties (eg arising from five or six patents) to turn a commercially viable initiative into one that is too risky for the licensee owing to the total cost of the stacked royalties.

Thus, there are very real, positive, economic consequences for achieving the above four favourable outcomes when patent pools are used successfully. Certainly not the least important is that if licences can be obtained affordably and easily, then any given licensee-company can spend more of its resources on its core competences and bring better products/services to market faster and cheaper. Research and development dollars are spent on technical innovation and not transactional costs.

Elements of successful pools

Successful pools have several elements

There are several elements of successful patent pools, but pools additionally need to be crafted so as to avoid running foul of the US antitrust laws.[3] Successful patent pools typically have the following features:

- A protocol to objectively define those patents that may be in the pool, as opposed to those that should not be in the pool, with the goal being to aggregate the correct patents that meet the objective of the pool.[4]

- Terms and conditions that ensure access

to the assembled patents at a reasonable royalty and on a non-discriminatory basis.

- Terms and conditions that preserve the opportunity for potential licensees to license individual patents directly from the patent owners.

- Procedures and auditing features that do not disseminate competitively sensitive proprietary information among owners of pooled patents.

- Terms and conditions that avoid licensing conditions that discourage future innovations.[5]

Careful planning is needed to prevent violation of US antitrust laws

Meeting the needs of a well-functioning patent pool that does not run foul of US antitrust laws requires careful planning in establishing the pool and crafting the terms of the licence to be offered. US antitrust enforcers[6] look at a variety of things when evaluating the lawfulness of a patent pool and typically look to whether the proposed licensing programme is likely to integrate complementary patent rights, and if so, whether the resulting benefits are likely outweighed by the competitive harm posed by other aspects of the programme. In particular, pools must permit a means to determine the validity of the patents in the pools; there must be little or no aggregation of competitive technology – that is, the patents should be complements of one another;[7] the pool agreement must not disadvantage competitors in downstream product markets; and the pool participants must not collude on prices outside the scope of the pool, eg on downstream products.

Valuable lessons can be taken from the model of the SNP Consortium

A recent patent pool that failed to pass the scrutiny of the US antitrust enforcers is the VISX/Summit excimer laser patent pool. In challenging the patent pool, the Federal Trade Commission (FTC) stated that instead of competing with one another, the two firms that made up the pool were discouraging competition and agreeing not to license their patents independently. Furthermore, each had veto power over any licences granted to another manufacturer of the laser. Indeed, no competing laser manufacturer was ever licensed, and competition was stifled. The two companies involved in the pool argued that their patents were not mutually blocking and thus complements, not substitutes. Nevertheless, the two companies involved in this FTC investigation settled the dispute, lifted restrictions on each other regarding the licensing of their respective patents, and the pool ended up dissolving. In short, do not collude to benefit the members of pools at the consumer's expense.

THE SNP CONSORTIUM: A SUCCESSFUL POOL OF TECHNICAL EFFORT

The SNP Consortium,[8,9] while not involving a collection of pooled patents, is an example where pooled intellectual property and pooled technical effort by over a dozen pharmaceutical companies and research institutions achieved both a cost-efficient and very pro-competitive outcome. The underlying problem behind the SNP Consortium was a need for a so-called SNP Map. A standardised SNP Map was predicted to be of great value in drug discovery to enable a better understanding of the relative positioning of genes along the human genome. Unfortunately it was cost prohibitive for one company to fund the creation of a SNP Map, since it was estimated by some that the project would cost over US$48m. Consequently, a number of pharmaceutical companies agreed to form a consortium, each of whose members would contribute several million dollars.Working with several academic institutions, including the Whitehead Center and the Wellcome Trust, the Consortium set out to create this very valuable research tool.

The Consortium agreed to make the SNPs and a SNP Map of their relative position on the genome available to the public to be used by anyone – even those that did not contribute any funds. The

Patent pools have the potential for application in biomedical research

SNPs and the SNP Map were made available to non-members: (1) since none of the Consortium members was in the business of selling gene sequences; (2) since the real reason for seeking to produce the Map was to enable drug discovery; and (3) if the funds for the project were not collected quickly at the formation of the Consortium, then the project would not even get started, let alone get completed. To minimise the chances that control over any intellectual property in the SNPs would end up in the control of non-members that might try to extract licence fees from the Consortium or its members, provisional patent applications were filed as discoveries were made, and the provisional applications were later converted into US utility patent applications. Instead of prosecuting these applications to allowance, the applications were converted into Statutory Invention Registrations and their contents donated to the public, with no proprietary rights being retained by the members of the Consortium. The Consortium members could patent any downstream inventions made using the SNPs and the SNP Map without any additional payment to or licence from the consortium. Thus, any non-naturally occurring genetic sequence synthesised by a drug maker, biotechnology firm or academic by using the SNP Map as a gene-hunting tool could still be patented by that inventor.

POTENTIAL USE OF PATENT POOLS IN THE BIOMEDICAL FIELD

The question on the minds of many is: How can patent pools be used in an industry lacking an industry standard that sets the definition of 'essential patents'? To answer this question, one needs to remember that patent rights do not include the right to make anything, but only the rights to exclude others from making, using, offering for sale or selling, or importing the patented article or method. Thus, the intuitive answer to the above question is that any patent whose power to exclude provides strong market advantages would be inappropriate for placing in a pool. Simply put, there is no economic motivation for any patent rights holder to out-license any rights that are used to protect its revenue stream and profit margins. Thus, patents with claims directed to the actual diagnostics product or therapeutic product are not likely to be in a patent pool. However, many technologies that are needed to evaluate and develop the final diagnostic and/or therapy may be more appropriate for a patent pool. That is, let the researchers have a cost-effective means to obtain the best technologies with which to perform their research; and permit the ultimate therapy and diagnostic to compete on its own merits (with respect to therapeutic result, patient cost, ease of use, ease of distribution and patient administration).[10]

There is no industry standard

Industry standards might not always be needed to establish a pool

While having an agreed-upon industry standard certainly makes the case for the need for a patent pool easier, an industry standard is not required for a successful pool. As seen from the large variety of industries that have used patent pools over the last hundred years,[2] many positive results for the industry as well as the consumer have been achieved. Many of these historical pools have been 'non-standard setting' environments. While there is no economic incentive for patent rights owners to offer non-exclusive licences to all-comers under patents whose power to exclude protects a valuable market advantage, there are many patents out there that do not fit this description of power.

A quick review of the database of US patents in five relevant biomedical patent classes reveals that over 30,000 patents have been issued in the last six years. It is hard to imagine that each of those patents provides a distinct market advantage for the patent owner. For the vast majority of innovations, out-licensing provides a revenue stream without sacrificing the corporation's profit margin on the corporate crown jewels. Out-licensing

revenue would be incremental, but would permit a greater return on investment in research and patent prosecution costs.

It is in those areas where the potential technology is far more valuable when pooled with other complementary technologies that the use of patent pools in biomedicine can begin.

Potential areas for consideration: Libraries of targets

Copyright pools may offer a model for patent pools

Like the SNPs discovered by the SNP Consortium, many research materials used in drug discovery can in a small way be likened to the library of musical works offered for licence by the American Society of Composers, Authors and Publishers (ASCAP) and the Broadcast Music Inc. (BMI)[11] to all those interested in their respective library of copyright works. Having easy and affordable access to a wide variety of materials permits a more rationale drug design process – much in the same way having an easy and affordable way to obtain rights in copyrighted music permits other musicians to make their own renditions of previous songs.

Pools are a potential way to obtain licences in target libraries

In drug design, researchers need as much information about how, when and where in the body a particular compound reacts. Thus, for example, to the extent researchers are engaged in high-throughput screening to evaluate the reactivity or interaction of a particular compound, the more data points one has access to, the better one's research would be. In high-throughput screening, many, if not all, of a company's library of medicinal compounds (a number that can run into millions) are screened for signs of interaction with a biological receptor of interest. If a positive interaction is observed, the compound is said to be a hit and it is evaluated for further development as a drug. Much more useful would be a knowledge of how that particular compound performed against a battery of all known biological receptors of a given classification, for example all known kinases. Then the researcher can get a much better picture of the biological properties of a compound. Thus, a researcher having access via a licence to the patents that claim each of the multiple receptors in a class will have the better high-throughput analysis at the end of day.

Unfortunately, because of the fragmentation of the biomedical research industry, there is virtually no overlap in patent ownership of patents that claim the individual members of a given class of receptors. Researchers face a gauntlet of individual licence negotiations and fees, and the patent owners similarly face a great number of time-consuming licence negotiations that may or may not yield a fee or royalty. In this situation, the pooling solution would be to create a pool defined as the collection of the particular class of targets and only those targets would be welcomed into the pool. Centralised acquisition is achieved and better asset administration and better research is the result.

Why would every relevant patent holder want to contribute to the pool?

Multiple incentives exist to bring patent holders into a pool

There are a variety of commercial and legal practices that could act as incentives to encourage the contribution of patents to a properly defined pool. For example, if a pool were defined to be directed to platform-type technologies – ones that relatively large numbers of research entities could benefit from using – then with the proper pricing structure, it is likely that the combined factors of the price, the volume of licensees, and the low cost of out-licensing for the contributing members would be enough encouragement for sufficient numbers of patentees to participate in the pool. In the example of high-throughput screening, it is likely that a patentee will have more users of his patent if the sum of the pooled technology is far more useful than any individual patent by itself. While any given patentee could license the receptor separately and hold out for a very high royalty, there is also an increased risk that

the licensee would simply walk away and be happy with 60 data points instead of 62 data points that they might have had if they had continued to negotiate with the hold-out patentee. To put it into economic terms, the marginal value of the last increment of knowledge about a compound can be outweighed by the marginal cost of the last increment of freedom to operate in this field of drug research. It is ever more unlikely that one patent can dominate the entire field of a well-defined target pool. This is so because there are no standards in the biomedical research area and because, as the authors found as they reviewed recent US cases, of the US courts' increasingly narrow claim construction of many biology-based patents.

Pools may tend to drive down industry standard royalty rates

Another factor that should tend to encourage all relevant patent owners to contribute to the pool and discourage the non-pool member from holding pool licensees to ransom, is the fact that negotiated royalties on technology similar to the patented technology and 'industry standard royalty rates' are factors considered by US courts when evaluating patent damages for infringement.[12] If the pool is of a sufficient and significant number of relevant patents, the 'industry standard royalty rate' is *de facto* set by the pool and could put downward pressure on damage calculations that would negatively affect a patentee's claim of 'inflated' damages awards if they should some day sue for patent infringement.

Pools may act as a disincentive to fragment research programmes among multiple countries

In other areas where there is a dominating patent, if the improvement patents are of sufficient interest to the owner of the dominating patent[13] (such that they would desire access to their own in-licence) or if the dominating patent rights of exclusion do not provide strong market differentiation to the dominating patent owner's product, the dominating patent owner would be well served to license their patent broadly through the pool and enjoy a higher rate of return of research dollars then would otherwise be possible, while also obtaining an in-licence through the pool to the improvement patents of the pool's licensees.

Pools may help those patentees who lack market differentiation

Another motivating factor to contributing certain technology to the pool is the way in which the patent laws around the world work together to encourage the movement of certain stages of research from one country to another. For example, commercial entities do not enjoy an exemption from patent infringement for basic research in the USA, while they do enjoy such an exemption in much of Europe. However, in the USA, many companies plan to, or do presently, rely on 35 USC s. 271(e)(1) as a defence to patent infringement for later stages of research (as they collect data for submission to the Food and Drug Administration) – a defence not available in Europe.[14] Consequently, some basic research is performed in Europe and other data are created in the USA to take advantage of these differences in the various patent laws.

If the cost of a licence can be negotiated to the point of an acceptable research cost, potential licensees who have moved their basic research away from the USA to countries with liberal 'basic research exemptions' for commercial entities may be more willing to perform such research in the USA. Also, those companies planning to rely on 35 USC s. 271(e)(1) as a defence to patent infringement may be much more willing to take a licence just to control and manage litigation risks and all of its associated costs and disruptions. Thus, for the right price, the universe of potential licensees could expand and the patentees' incremental revenue would increase.

Thus, there are inherent incentives for the creation of pools of certain research technologies at the proper price.

How can bogus patents be kept out of the pool?

Like the patent pools relating to standards, an independent technical expert could be used to evaluate all potential patents to ensure that the pool is properly maintained. Moreover, the royalty-

Pools have to guard against inclusion of bogus patents

sharing mechanism can be structured to discourage patentees from loading non-essential or bogus patents in the pool. Moreover, the risks that antitrust enforcers may determine that non-essential patents are in the pool and cause the pool to be declared illegal should also encourage proper pool membership.

CONCLUSION

There are sufficient numbers of non-critical patents held by a wide variety of patent owners that, when evaluated in view of the economic incentives to out-license, create a ripe environment for patent pools – especially for complementary patent rights. The lower administrative costs, greater utilisation of technology, and differences in research exemptions under patent infringement laws are just a few of the incentives for patent owners to out-license and create centralised acquisition for licensees of valuable research technology.

References and notes

1. A panel discussion regarding the use of patent pools in biotechnology was held on 12th June, 2002, in Toronto, Canada, during the BIO 2002 Conference. The panel was moderated by Mary Ann Capria, and included panelists: Frank Grassler; Mary A. Woodford, an economist with Cornerstone Research; David Entin, Director, Intellectual Property Licensing, EntreMed, Inc.; Ken Heyer, Economic Director, Enforcement, US Department of Justice; and Alden Abbott, Head of Policy Evaluations, US Federal Trade Commission.
2. That patent pools have long been used in nearly all industries cannot be denied. See the transcripts from the 1935 Congressional Hearings dealing with the Pooling of Patents, HR 4523, before the House Comm. on Patents, 74th Cong. 1140, 1144–1145 (1935):

   > some form of patent consolidation [is] in use in the existence of patent deadlocks and overlapping inventions [in the fields of]: Automobile[s], agricultural machinery, aviation, building equipment and supplies, chemicals, communications, electrical-equipment industries, food industries, glass, machinery and machine equipment, mining, munitions, oil, office equipment and machinery, paper, radio, railroad equipment, rubber, steel, scientific instruments, utilities. . . (Charles A. Welsh, Jr, economist)

   More recently, in the latter part of the twentieth century, patent pools have been used for MPEG-2 compression technology, DVD video and DVD-Rom, photorefractive keratectomy eye surgery, and the IEEE 1394 data bus. Examples of non-patented intellectual property that is pooled for purposes of facilitating licensing include the ASCAP and the BMI, which administer the licensing of copyrighted subject matter in the music industry.
3. *See* US Department of Justice (DoJ) and Federal Trade Commission (FTC) (1995), 'Antitrust Guidelines for the Licensing of Intellectual Property' (URL: www.usdoj.gov/atr/public/guidelines/ipguide.htm).
4. In industries such as computers and consumer electronics, where interoperability is essential, an industry standard has been the gatekeeper to the patent pools. Typically the pool of patents is defined as the 'Essential Patents', which include any patent claiming an apparatus or method necessary for compliance with the relevant standard under the laws of the country which issued or published the patent. The administrator of the pool typically uses an independent technical evaluator to determine whether any patent is necessary for compliance with the particular standard.
5. For example, conditions of patent pools that are considered to have positive effects on innovation include the requirement for all participants in the pool to license to each other all 'essential' patents that they obtain in the future, so that future 'blocking' patents are less likely to occur and larger royalties are thus paid on newer patents.
6. Both the DoJ and the FTC have a business review process that offers an opportunity for organisers of pools to discuss their proposals with the relevant agency and receive guidance concerning likely enforcement intentions. If a patent pool in the biomedical research field were to be established, it is believed that only one agency, either the Antitrust Division of the DoJ or the FTC, would review the terms and conditions of the pool. At this point, there is no way to predict which one. The Antitrust Division of the DoJ performs its business practice review pursuant to 28 CFR s. 50.6 and the FTC provides an advisory opinion pursuant to 16 CFR ss. 1.1–1.4.
7. A broad definition of complement patents are patents that are used together to build value in a downstream product or system. A complement may also be understood by its antonym – 'substitutes' – which are competitive technologies that can be used to replace each other. As expected, technologies are not so easily categorised and many patented technologies may be complements from one point of view and substitutes from another point of view. Moreover, a patent pool with some substitute patents as part of the pool is

not inherently bad – it just depends on whether there are several other substitutes outside the pool.

8. Single nucleotide polymorphisms (SNPs). An SNP is a type of genetic mutation in which the mutant allele, or alternative form of the gene, differs from the native type of allele by a single nucleotide mutation.
9. URL: http://snp.cshl.org/
10. As seen in the computer and consumer electronics industries, patent pools have not lessened innovation, but rather have increased the wide range of consumer end-products on the market, and each licensee is free to patent and not grant back non-essential patented technology. Participants in these patent pools are fierce competitors.
11. The ASCAP and the BMI act as non-exclusive licensing agents for composers.
12. *See* Skenyon, J., Marchese, C. and Land, J. (2000), 'Patent Damages Law & Practice', West Group, ss. 3.8–3.20.
13. A broad patent is said to dominate a narrower patent (often directed at an improved embodiment within the claims of the broad patent) if the narrower patent owner cannot practice their technology without a licence from the dominating patent. At the same time, the dominating patent owner is blocked from practising the improvement claimed by the narrow patent.
14. 35 USC s. 271(e)(1) provides: 'It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.'