Facilitating Assembly of and Access to Intellectual Property: Focus on Patent Pools and a Review of Other Mechanisms

ANATOLE KRATTIGER, *Research Professor, the Biodesign Institute at Arizona State University; Chair, bioDevelopments-International Institute, and Adjunct Professor, Cornell University, U.S.A.*

STANLEY P. KOWALSKI, *Franklin Pierce Law Center, U.S.A.*

ABSTRACT

This chapter reviews different forms of IP (intellectual property) "assembly" mechanisms (royalty-collection agencies, information clearinghouses, technology clearinghouses, open-source innovation clearinghouses, honest brokers, and other forms of facilitators, IP management services, IP commercialization agents, the services of merchant banks and venture capital enterprises, and patent pools). Emphasis is placed on patent pools, which are voluntary agreements between two or more patent owners to license one or more of their patents to one another or to third parties. Although there are many forms of patent pools, such arrangements fundamentally consist of the interchange (cross-licensing) of rights to essential patents by a number of entities, as well as an agreed framework for out-licensing the pooled intellectual property to each other and/or to third parties, including an agreed-pricing and royalty-sharing scheme.

There are both benefits and risks associated with patent pools. Benefits include greater ease with respect to resolving patent conflicts, making assembled patents in the pool available to others, and resolving disputes over blocking patents. Risks include antitrust liability. Under certain circumstances, patent pools have application in the area of humanitarian licensing as instruments of assembly of intellectual property.

1. INTRODUCTION

The importance of IP (intellectual property) "assembly" is becoming increasingly evident as the biotechnological components, both methods and materials, that are used in the R&D of agricultural and health innovations become more and more complex. The use of patent pools can be one way to achieve IP assembly. However, patent-pool formation is complex and often costly; it requires special economic, business, and legal considerations, and it is but one option to facilitate assembly and access.

One aspect of IP management is obtaining freedom to operate (FTO) for a given product in a given market.[1] Assembling intellectual property is therefore an essential step in innovation management. But having FTO alone does not bring a product to market, much less provide the product to the poor in developing countries. In this context, the value of patent pools must be carefully considered on a case-by-case basis, and, hence, the appropriateness of a patent pool for any given technological innovation will require careful analysis and consideration. This analysis will necessarily include legal, business, operational, and strategic considerations. Furthermore, it is important to remember that a patent pool simplifies the assembly of intellectual property, but does not in itself do much or necessarily lead to technology transfer or market access and distribution.

Before discussing patent pools in detail, the chapter will provide a brief overview of IP assembly options and mechanisms. This broader perspective will therefore place patent pools within

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a context of available IP assembly tactics and explain the advantages and disadvantages of each.

2. IP ASSEMBLY: MECHANISMS AND OPTIONS IN PERSPECTIVE

A complex mix of factors drives technological innovation, but they essentially boil down to national policies, international agreements, and market dynamics. Innovation is the starting point for making inventions commercially and socially useful, but innovation alone will not lead to technological products that can produce goods or services. An invention must be assembled by putting together the patents and other forms of intellectual property from third parties. In-licensing is the best-known mechanism for intellectual property assembly, and patent pools are a complex form of licensing. But other mechanisms are also standard corporate approaches, including:

- mergers and acquisitions (M&As)
- strategic alliances (collaborations, joint ventures, corporate partnerships)
- licensing (principally IP bundles comprising an entire range of inventions required to practice, also called freedom to operate)

By itself, however, the assembly of IP will not make an invention commercially useful; many other steps are required, ranging from regulatory to the access of know-how. From a broader perspective, assembly and licensing can be facilitated through a range of mechanisms. These are summarized in Table 1. In the context of this *Handbook*, the range of mechanisms listed also include capacity-building services that more broadly deal with technology transfer.

2.1 *Royalty collection agencies*

In its simplest form, a license collection agency is a mechanism whereby one entity collects royalties on behalf of its members for a small fee. In this situation, the members make deals and set royalty rates, either bilaterally or multilaterally. The multilateral system is best known in the music business. Many restaurants and bars, for example, have jukeboxes with hundreds of CDs where customers insert money and select songs from individual CDs. Each time a song is played, a percentage of the revenue goes to the publisher of the CD and to the artist. In the United States, the American Society of Composers, Authors, and Publishers (ASCAP), composed of over 170,000 artists and publishers of every kind of music, protects the rights of its members by licensing and distributing royalties for the nondramatic public performances of their copyrighted works.[3] ASCAP makes giving and obtaining permission to perform music simple for both creators and users of music, and its licensees encompass all who want to perform copyrighted music publicly.

2.2 *Information clearinghouses*

The term *clearinghouse* derives from banking institutions and refers to the mechanism by which checks and bills are exchanged among member banks so that only the net balances need to be transferred in cash. Today, the term has much broader meaning and includes any mechanism whereby providers of goods, services, or information are matched. The CBD (Convention on Biological Diversity) clearinghouse[4] for biodiversity aims to promote and facilitate technical and scientific cooperation, develop a global mechanism for exchanging and integrating information on biodiversity, and develop the necessary human and technological network. Information clearinghouses also provide entry to a country's biotechnology (for example, Finland[5]), as do training clearinghouses that offer training for biotechnology technicians (for example, BioLink[6]), and industry links, updates, news, and job markets (for example, BioPortfolio[7]).

2.3 *Technology clearinghouses*

A comprehensive Web-based clearinghouse can lower the transaction costs and increase participation. In practice, however, such gains have not been realized with IP exchanges. This is because the applications specified in patents are highly heterogeneous, often difficult to define, and can only be valued after considerable experimentation and refinement has taken place and then only within the technological application.[8] However, IP exchanges are not very common. Few of them are complete enough to allow a

Table 1: Summary of IP Assembly Mechanisms and Options

Type of Mechanism or Service	Characteristics	Examples
Royalty collection agencies: Collection of royalties for a small fee by one entity on behalf of its members	Useful if licensing industries are already established; can be created by industry itself	American Society of Composers, Authors, and Publishers; British Society of Plant Breeders
Information clearinghouses: Broad term denoting a mechanism matching providers of goods, services, or info.	Useful for the exchange of specific information related to an activity or industry; does not facilitate tech transfer per se	BioBin, BINAS; portals to countries or industries biotech, training programs
Technology clearinghouses: 1. Web-based IP auctions and licensing, including business-to-business	Appropriate for general purpose technologies, platform technologies, bundles; limited ability to spread tech transfer further	Virtual trading floors, patent auctions
2. Public-sector initiatives dealing with training, good practices, and the bundling of technologies	Appropriate for development; furthers tech transfer	Public Intellectual Property Resource for Agriculture (PIPRA)
Open-source innovation clearinghouses: Web sites on which anyone can post ideas or inventions, and anyone is allowed to turn the ideas into products	Potentially appropriate for open-source licensing and diffusion of tangible research materials	Barry Nalebuff and Ian Ayres "Why Not?" or HalfBakery
Brokers and other forms of facilitators: Typically focused on creating public–private partnerships, providing "managed" tech transfer	Appropriate for charting new territory and bringing public and private actors closer	African Agricultural Technology Foundation (AATF); Global Alliance for Vaccines and Immunization (GAVI)

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Table 1 (continued)

Type of Mechanism or Service	Characteristics	Examples
IP management services: Comprises a wide range of entities, both public and private, assisting institutions in managing their IP assets	Good for addressing systemic issues; establishes new modes of interaction	Law firms, management consultants, global nonprofit entities (for example, MIHR), and academic training
IP commercialization agents: 1. Commercial entities dedicated to commercialization of third-party intellectual property	Highly effective business model; useful to learn from their experiences and adapt to serve nascent private sectors.	BTG Ltd.; certain specialized law firms
2. Mixed commercial and public-good objectives	Useful to learn from their experiences and adapt the model to other biotech sectors	Concept Foundation, for example
Integrated commercial services: A range of services for M&As, spinouts, including IP audits, business valuation, due diligence	There could be a need for a nonprofit merchant-bank-type institution to provide services to small/medium size enterprises	Merchant Banks; venture capital investment services
Patent pools: A voluntary agreement between two or more patent owners to license one or more of their patents to one another or third parties	Pooling unlikely to change the underlying structural barriers to technology transfer; difficult to establish because industry players have divergent strategic interests; in partial/modified form, effective for tech transfer	Internal, company-specific pools; portfolio pooling, cooperative pooling, third-party aggregations, forced pooling
Other public technology transfer and financing mechanisms	Range from education and training institutions, to consortia in health, and to certain specialized UN programs (including South–South transfers)	
Company-to-company arrangements: collaborations, joint ventures, strategic partnerships, and corporate partnering	Some of the most ubiquitous and efficient systems of technology transfer, rarely requiring public sector assistance; different government policies either encourage or thwart them	

Source: Krattiger.[2]

prospective licensee to assemble all the needed licenses to obtain freedom to operate (FTO). In addition, actually negotiating with a company often not only allows for cross-licensing but also for the transfer of know-how or trade secrets. And finally, IP owners typically use their patent portfolios as a strategic tool, a practice not conducive to wide licensing. Merely clicking on a Web link, downloading a standard license, and wiring money is rarely sufficient for technology transfer to occur.

The Public Intellectual Property Resource for Agriculture (PIPRA),[9] on the other hand, as a *managed IP exchange* initiative involving universities, foundations, and nonprofit research institutions, seeks to make agricultural technologies more easily available so that subsistence crops for humanitarian purposes in the developing world and specialty crops in the developed world can be more rapidly developed and distributed. The rationale for PIPRA is that intellectual property is often unwillingly encumbered. Universities, for example, typically grant worldwide exclusive licenses. Changing these licensing policies and retaining the rights for humanitarian uses in the developing world would make it much easier to transfer intellectual property and tangible property (TP) from universities to the developing world.

PIPRA brings together public sector institutions to collaborate and bundle their licensed and unlicensed technologies, as "shared technology packages," making the technologies more readily available to member institutions for commercial licensing or for designated humanitarian or special use. As part of this effort, a database of patented agricultural technologies is being developed to inform researchers about FTO, allowing them to modify their research plan to include more licensable technologies (IP and TP) or public ones. PIPRA is also currently exploring the creation of a patent pool.

2.4 *Open-source innovation clearinghouses*

One special category of clearing houses is worth mentioning, the open-source innovation clearinghouse. Consider a Web site initiated by two Harvard Business School professors, economist Barry Nalebuff and law professor Ian Ayres, to prove that innovation is a skill that can be taught. One hotly debated idea at the site in recent months is the so-called "reverse 900 number"—where telemarketers pay people to accept calls. Their system of innovation is growing on the Web[10] and deploys economics, game theory, psychology, and contract law to argue that innovation can be routinized and institutionalized.

Another Web initiative, called HalfBakery,[11] allows anyone to post ideas for innovative products and services. Anyone can turn the ideas into marketable products if they wish, without the need for licenses. The service quickly gained international fame when what may have appeared as "half baked ideas" were turned into commercially successful products, though none, as yet, in the area of health and agriculture.

This mechanism should not be confused with open-source licensing.[12] With software, open-source licensing is essentially the licensing of inventions without patent protection—the only requirement is that any licensee must agree to make available to others any improvements in the invention or technology. Applying this established mechanism of open source from software to biotechnology, where *source code* has no real equivalent, has not worked as yet. New terminology might be appropriate, such as *distributed, internet-based collaboration* or "non-proprietary peer-production of information-embedding goods."[13] One attempt to implement open source is the Biological Innovation for Open Society (BiOS).[14] Essentially, BiOS is a specific form of a patent license. It is really another way to describe a patent license with some novel terms. To what extent BiOS will foster innovation remains to be seen.

2.5 *Honest brokers and other forms of facilitators*

Honest broker is a term often used in peace negotiations but it has also been used by nonprofit organizations engaged in public–private partnership building. One institution that had its foundation as an honest broker is the International Service for the Acquisition of Agri-biotech Applications (ISAAA).[15] During the 1990s, it operated primarily as a facilitator, matching available technologies

to meet identified needs, brokering technologies, and building capacity by transferring knowledge and know-how between companies in developed countries and the public sector in developing countries. ISAAA addressed other constraints in biotechnology transfer, such as regulatory issues. In the last few years, the organization has shifted its strategy toward knowledge sharing.

A similar, more-recent institutional mechanism is the African Agricultural Technology Foundation (AATF).[16] Like PIPRA, AATF is emerging from a Rockefeller Foundation initiative. AATF recognizes that new and unique public–private partnerships are needed to remove many of the barriers that have prevented smallholder farmers in Africa from gaining access to existing agricultural technologies. Focusing on the creation of these public–private partnerships, it seeks to dramatically improve access to agricultural technologies, materials, and know-how, at the same time promoting efforts to create sustainable markets.

A similar organization in human health biotechnology is the Global Alliance for Vaccines and Immunization (GAVI).[17] Created in 1999, it functions as a broker for private and public sector entities committed to expanding the use of vaccines in the developing world. International organizations, governments, vaccine industry, research institutions, and major philanthropists collectively form a dedicated partnership serving the shared GAVI objectives. It includes as a subsidiary, or financial arm, the Vaccine Fund, which sponsors GAVI's objectives in poorer countries. The alliance also has programs to stimulate the vaccine industry to develop and supply vaccines that are vital to low-income countries. GAVI acts more at the product transfer level, whereas ISAAA and AATF function somewhat further upstream. ISAAA initially also aimed at charting new territory and creating models (which are more time consuming) rather than transferring large quantities of technologies.

2.6 *IP management services*

The best-known IP management services are law firms that specialize in patenting and licensing and management consultants, such as KPMG, the Boston Consulting Group, and Ernst & Young. These commercially oriented entities are discussed in the next section, but let us first focus on the nonprofit players in this field. A new organization headquartered in the United Kingdom, the Centre for the Management of IP in Health R&D (MIHR),[18] essentially acts as a service to public sector organizations in developing countries (and some private ones) to manage their intellectual property (in-house–generated, in-licensed, and to-be in-licensed) more authoritatively. It assumes that health programs that manage intellectual property well are more effective at mobilizing resources, technologies, and partners to deliver improved health care to the poor.

2.7 *IP commercialization agents*

Many types of "consulting" services fall broadly within this category, but only one institution is solely dedicated to the profitable commercialization of third-party intellectual property in the fields of health, medicine, and other biotechnologies: BTG Ltd.,[19] formerly known as the British Technology Group. Perhaps the world leader in commercializing novel technologies, BTG operates globally with a focus on Europe, North America, and Japan. The firm combines a strong commercial focus with a deep understanding of how to develop innovation, enhance intellectual property, and achieve critical development milestones. Clients include public research centers and global technology companies, from startups to multinational companies. It functions as a retainer for technology innovators, charging fees and sharing in revenues generated from its services.

In addition to services in several areas, the company seeks licenses for the technologies they manage. This includes assistance in seeking venture capital, the management of startups around platform technologies, and R&D funding to ensure that the technologies in BTG's portfolio become commercially viable. To accomplish this, BTG acquires or in-licenses promising technologies, assists in patent protection of inventions, forms alliances to advance inventions through an R&D phase, and develops technology marketing strategies. In effect, BTG pools

necessary technologies centered on the core innovations it manages, in order to increase the value of its portfolio. On the development side, the most prominent enterprise is the Concept Foundation,[20] headquartered in Thailand, which provides a mechanism to turn intellectual property, developed or owned by international organizations, into competitive and cost-effective products to be distributed at the lowest possible cost, especially into the public sector healthcare channels of developing countries. This intellectual property is typically owned in the form of data from medical research and clinical trials, data from pharmacological studies, manufacturing instructions, and so on. In some cases, the intellectual property owned by international organizations such as the World Health Organization (WHO) is enhanced through IP donations from pharmaceutical manufacturers earmarked for public sector healthcare services in the developing world. The licenses are negotiated by highly experienced foundation staff led by a former senior executive in pharmaceuticals.

2.8 *Merchant banks*

The term *merchant bank* was developed hundreds of years ago to describe well-financed organizations that sought high returns on their investments in return for predictable risk (which was also the original idea of a limited-liability company). Today's investment bank services include IP audits, business valuation, due diligence, and fairness opinions,[21] acting as a confidential advisor in preparing divestiture, managing the entire process of initial public offerings (IPOs), marketing divestitures, finding acquisition targets, structuring transactions, providing financing, facilitating financing, and refinancing existing debt.

Merchant Banks are essentially full-service centers for M&As, financial management, agreements, required government filings, antitrust issues, valuations, due diligence, and so on. Their services are crucial for any type of business, large or small.

2.9 *Other technology transfer mechanisms*

It would be negligent to fail to mention other types of technology transfer facilitators, ranging from education and training institutions (for example, universities across the world), to international agricultural research centers (for example, the CGIAR), to health consortia (for example, the Program for Appropriate Technology in Health [PATH]), or the many specialized UN programs. Company-to-company arrangements (including collaborations, joint ventures, strategic partnerships, and corporate partnering) are some of the most ubiquitous and efficient systems of technology transfer.

3. FOCUS ON PATENT POOLS

A patent pool is "*an interchange of patent rights by several companies. Either one or more of the patent owners, or some separate entity, has the right to license others under the pooled patents.*"[22] In essence, a patent pool is a voluntary agreement between two or more patent owners to license one or more of their patents to one another or to third parties. In other words, they are "*the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool.*"[23] And further, "*The rationale for patent pools is simple: by reducing the number of necessary transactions and by simplifying patent landscapes, they can reduce transaction costs and facilitate technology transfers. Patent pools have the obvious but important advantage of considerably reducing the number of licences that need to be negotiated.*"[24]

Although there are many forms of patent pools, such an arrangement fundamentally consists of the interchange (cross-licensing) of rights to essential patents by a number of companies, as well as an agreed framework for out-licensing the pooled intellectual property to third parties, including an agreed-pricing and royalty-sharing scheme. Patentees can provide licenses directly to licensees, or licenses can be provided indirectly via a licensing entity that is specifically authorized to administer the patent pool.[25] "*A key difference between a patent pool and a cross-licensing agreement is that, in the former, the patent owners agree to license to third parties that do not themselves contribute patents to the pool.*"[26]

3.1 *The main pros and cons*

Patent pools are "*competitively beneficial in that they may help resolve patent conflicts, make assembled patents in the pool available to others, or resolve disputes over blocking patents. On the other hand, a patent pool is a horizontal agreement among competitors and carries the potential for abuse and as a cover for an anticompetitive cartel.*"[27] Hence, a patent pool, depending on how it is organized and implemented, represents a potential double-edged legal sword: able to cut through patent-thicket blockages to facilitate access to critical technological innovations, yet also potentially honed in such a way that antitrust issues arise. In other words, patent pools can facilitate access by overcoming IP obstacles via assembly of patents or can inhibit access via monopolization of intellectual property (complete with inequitable remunerations) and shielding of invalid patents.[28]

In addition, from a practical perspective, it is important to know what patent pools can, and cannot, facilitate. For example, patent pools serve the assembly of intellectual property, not the transfer of technologies per se. Although the U.S. Department of Justice (DOJ) along with the U.S. Federal Trade Commission (FTC) have observed that "*by promoting the dissemination of technology, cross-licensing and pooling arrangement are often procompetitive,*" it is critical to understand that, in the context of technology transfer and collaboration with developing country partners, patent pools would *mainly assist with licensing intellectual property*. That is, such developing countries would not necessarily benefit equally from sharing know-how, show-how, and trade secrets. Hence, patent pools can serve certain purposes and confer benefits, but they are not an IP management panacea.

Still, a patent pool can have advantages: intellectual property can be licensed through an efficient one-stop shop, stacking licenses can be eliminated, patent litigation can be averted, and institutionalized exchanges of otherwise proprietary know-how (trade secrets) can be facilitated.[29] Significant research and administrative costs would decrease dramatically. Speed and efficiency would be greatly increased. A patent pool is an IP management tactic that can have a significant positive affect on facilitating access to innovations, yet, it is important to recognize that a pool may not be the only way to achieve these objectives, and that, in the overall context of best practices in IP management, there may be other equally effective approaches.

Patent pooling has been more focused in the realm of DVD technologies, where it makes sense to generate revenue through sales and not licensing. Such patent pools help to clear blocking positions. But with regard to patent pools for public-health initiatives, it appears that there is less likelihood that companies will give up their exclusive IP rights, depending, of course, on the technologies under consideration. This is because pools tend to arise organically because the owners of intellectual property are mutually stymied; this, for example, has not yet happened for vaccines. The technology is not at the same level of maturity as in the DVD industry. Patent pools are especially useful for developing industry standards. Hence, although patent pools have been successfully implemented in various industries (notably electronics), their application to health and agriculture may still be, relatively speaking, premature. The pros and cons are summarized in Table 2.

3.2 *Organization and establishment*

Organizing and establishing a patent pool is not a simple matter.[30] It is a long, complex, multistep process, with many technical, legal, and business challenges. It therefore requires the interdisciplinary coordination of efforts by attorneys, scientists, business professionals, and other experts. Setting up a successful patent pool therefore requires organization and planning, based on sound information and solid analysis. These conditions having been met, the operational, business and legal aspects of the pool can be effectively managed and successfully executed.

A ten-step checklist for setting up a patent pool would include the following considerations:

1. Determining the validity of the patents to be pooled
2. Determining the essentiality of the patents being considered for inclusion in the pool
3. Patent analysis by an independent expert

4. Nonexclusive licenses to the pool
5. Licensees must be free to develop and use alternative technologies
6. Grant-back licensing provisions, from licensees to licensors, on improvements to essential patents and with reasonable terms, should be available on a nonexclusive basis
7. Royalties should be distributed among the licensors according to a formula set forth in the patent pool agreement
8. Royalties paid to the pool by licensees should be fair, reasonable, and nondiscriminatory
9. Sensitive business information must be safeguarded
10. Appropriate dispute resolutions, preferably, independent and neutral, should be part of the patent-pool agreement

A ten-step procedure for setting up a patent pool would include the following activities:

1. Observation of a potential patent thicket that could be overcome by an appropriately structured patent pool
2. Patent and scientific experts identify essential technologies
3. Patent experts identify patents and patentees
4. Working group set up by counsel
5. Initial agreement among patentees to move forward with pool development
6. Further evaluation of patents by both scientists and patent experts
7. Agreement on patent-pool conditions
8. Signing of patent-pool consortium agreement
9. Antitrust analysis and evaluation as per the jurisdictions under consideration (for example, the United States, Europe, and Japan)
10. Execution of patent-pool agreement

Patent pools are set up by the patent holders, who function both as shareholders of the pool and also as financiers of the designated licensing authority (if the patentees themselves do not function as the actual licensors). The patent holders,

Table 2: Summary and the Pros and Cons of Patent Pools

Pros	Cons
Integrates complementary technologies	Difficult to agree on the value of individual patents contributed to a pool
Reduces transaction costs	Complex to set up and avoid antitrust problems (collusion and price fixing)
Clears blocking positions	May inflate licensing costs through nonblocking or unnecessary patents
Avoids costly infringement litigation	Complex when many patents are under litigation, as is the case with biotechnology
Promotes the dissemination of technology	May shield invalid patents and thus prevent much technology from entering the public domain
Levels the playing field	

therefore, establish and retain authority over the licensing provisions.[31]

3.3 *Examples of pools*

One of the first such patent pools was created for the manufacturing of sewing machines in the mid-19th century.[32] Other examples of early patent pools include aircraft manufacturing, glass manufacturing, and radio technology. In each case, the pool contributed significantly to industry standards (for example, radio waves). More recently, patent pools were created to enable standard settings in DVDs, video games, and MPEG2 video-compression technology. Interestingly, private and public sector participants formed the latter in 1997: Columbia University, Fujitsu, General Instrument, Lucent, Matshushita, Mitsubishi, Philips, and Sony.

Typically, however, patent pools are constituted by members who each contribute patents in their respective fields. Whether or not developing country institutions will qualify to become members of patent pools will, naturally, depend on their respective potential contributions.

The following types of patent pools exist today:

- **internal, company specific.** For example, DuPont combining technologies through internal development or Syngenta complementing its internal portfolio with outside technology through licensing and M&As; critical challenge is to keep internal innovation ongoing and tightly managed
- **portfolio pooling**. Internal technology supplemented with third-party technologies, for example, Microsoft; critical challenge is to have a dynamic team handling in-licensing and aligning strategies closely with the overall corporate strategy
- **cooperative pooling.** Companies agree to combine their technologies and allow them to be managed by a separate entity, typically for standard-setting purposes; critical challenge is to avoid antitrust issues
- **third-party aggregations.** For example, strategy practiced by BTG Ltd.; critical challenge is to work around antistacking provisions that are very common in biotechnology licenses
- **forced pooling.** For example, rarely enforced compulsory licensing and the pooling forced by the U.S. government shortly after the radio was invented

3.4 *Patent pools in biotechnology*

In biotechnology, unlike in much of the electronics industry, standard setting is not really an issue, which may explain why patent pools have not been necessary for the biotechnology industry to commercialize products (for example, in the development of drugs and vaccines). Nonetheless, as the biotechnology industry continues to grow and mature, and with specific sectors becoming commercially focused, there may be fundamental challenges that can be effectively addressed via patent pooling.

For example, the issue of "research tools" in the life sciences has led to a call for patent pooling in the U.S. companies, and institutions involved in biotechnology research are encountering widespread delays due to the near-universal patenting of research techniques that were traditionally available in the public domain. Uncertainty over the prospective costs of licenses, royalty stacking that creates uncompetitive costs, delays in obtaining licenses, and the differing definitions of *pure research* versus *product development* across different territories are all inhibiting biotechnology R&D in many areas.

Similarly, one of the biggest public concerns voiced against the PTO for its practice of granting of patents for inventions in biotechnology, particularly in genomics, is the difficulty of accessing patented inventions for basic biological research and R&D. One solution to this constraint is to form patent pools, a mechanism successfully implemented by other industries.

In a rapidly changing field such as biotechnology, patent pools can have significant procompetitive effects and may improve an industry's ability to survive. For developing countries, patent pools may eventually become even more important because companies can easily obtain the licenses required to practice a particular technology, which reduces transaction costs and facilitates the rapid deployment of new applications in health and agriculture. Hence, there is no reason

that a novel type of patent pool, centered on preferential licensing terms to developing countries, could not be established.

Still, when considered from the perspective of the overall biotechnology industry, while patent pools may be very useful for assembling IP related to platform technologies that need to establish industry-wide standards (for example, DVD, MP3), the value of patent pooling is much less when industry interests are not aligned (still maturing industries), which, indeed, is the general case with biotechnology. Hence, in the context of R&D in many biotechnological applications, for example, with respect to vaccines—an evolving field with no platform and with no technology clearly in the lead—industry interests can hardly be considered aligned. Indeed, if a technology has not matured to the stage where industry standards can even be contemplated, then a patent pool would likely not be the favored option. At these earlier stages in the R&D of innovative technologies, few companies will have an interest in giving their rivals preferential access to their technologies. Companies also typically become cautious about antitrust issues when a patent pool is suggested, which might also hinder participation.

As an illustrative example of the current situation with (at least most of) the biotechnology industry and the potential for using patent pools, Gaulé draws our attention to the recent SARS outbreak:

Shortly after the severe acute respiratory syndrome (SARS) outbreak in February 2003, patent applications covering sequences of the genome of the SARS coronavirus were filed by several research teams around the globe. Some have argued that this may result in a complex, uncertain IP situation that could delay the development of SARS vaccines and diagnostic tools. As a result, the four parties known to own key patent applications (CDC) have expressed their willingness to form a patent pool and enable wide access to the SARS genome. But consider the differences between the SARS patent pool and the consumer electronics pools. The SARS patent pool will not be in an industry characterized by all-important network effects or be closely linked to a standard. For the moment, the licensors are not vertically integrated firms but universities and public institutions, and so there will be far fewer licensees. Most importantly, however, the commercial products in which the licensed technology will be embedded do not yet exist and will be developed by the licensees after extensive R&D efforts. Therefore, the licensing policy of the SARS patent pool might be quite different from other modern patent pools.[33]

However, the use of patent pools in biotechnology will likely increase as sectors of the industry mature into focused, identifiable technologies and products/services (as has been the case in the electronics industry). One area where this appears to be the case is diagnostic genetics, that is, disease-specific (for example, breast cancer and cystic fibrosis) diagnostics. This indeed appears to be an example of a rapidly emerging area of the biotechnology industry where patent pools might be applicable and advantageous. Unlike the general area of genomics, which is broadly diverse, diagnostic genetics is commercially focused on identified diseases with clear industry standards (mutations for analysis), and the players in the field share common goals. Hence, patent pools, narrowly constructed to address the diagnosis of specific polymutational diseases (for example, cystic fibrosis), could have great utility in overcoming IP thickets that inhibit access to advances in genetic diagnostics.[34]

Those who advocate patent pools as a solution to a general problem with assembling intellectual property related to biotechnological advances in health and agriculture should keep in mind that they embody many challenges; for example, in addition to the presence, or lack thereof, of industry standards, patent pools are expensive to establish and maintain. Hence, unless a given technology reaches a certain economic threshold, there is no financial incentive to establish a patent pool. The economic feasibility of a pool is determined by:

- number of pool participants
- number of patents held by each pool participant
- likelihood of a patent being useful for a given platform
- number of patents required to assemble a viable platform
- market value of the assembled platform

- cost to assemble and maintain the pool

As the biotechnology industry continues to grow and mature, the applicability of patent pools will also likely increase.

3.5 *Legal concerns*

One reason why patent pools are often approached with caution is because U.S. antitrust law has the reputation for precariously situating patent pools on the borderline between allowed monopolies and antitrust violations. Although the legalities of forming patent pools exceed the scope of this chapter, it is worth noting that the U.S. Department of Justice (DOJ) along with the U.S. Federal Trade Commission (FTC) have published guidelines for patent pool applications and require an opportunity to review applications for them.[35]

The PTO has summarized the DOJ/FTC patent pooling antitrust guidelines, and this serves as a concise template for understanding the potential antitrust implications of patent pools.[36] When making antitrust determinations, courts consider these guidelines as part of a multifactor weighing "rule of reason" analysis.[37] What follows is a brief excerpt from the PTO paper.

Since 1979, the FTC has had a similar procedure, in which businesses may seek FTC advisory opinions concerning proposed business practices. These procedures led to Justice Department and FTC policies in the IP licensing area, and in 1995, these agencies issued Antitrust Guidelines for the Licensing of Intellectual Property, *"IP Guidelines," which sets forth their enforcement policies in this area. The IP Guidelines specifically address pooling arrangements involving IP owners and their rights.*

In particular, the IP Guidelines state that IP pooling is procompetitive when it:

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

The IP Guidelines also discuss that excluding firms from an IP pool may be anticompetitive in these circumstances:

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

Anticompetitive effects may also occur if the pooling arrangement deters or discourages participants from engaging in research and development that is more likely when the arrangement includes a large fraction of the potential research and development in an innovation market.

The DOJ has applied these guidelines in considering and approving three proposed patent pools. Its first review set forth the following additional guidelines:

- The patents in the pool must be valid and not expired.
- These can be no aggregation of competitive technologies and setting a single price for them.
- An independent expert should be used to determine whether a patent is essential to complement technologies in the pool.
- The pool agreement must not disadvantage competitors in downstream product markets.
- The pool participants must not collude on prices outside the scope of the pool, for example, on downstream products.

Currently, the guidelines have been "collapsed" into the following two overarching questions:

1. Whether the proposed licensing program is likely to integrate complementary patent rights

And if so:

2. Whether the resulting competitive benefits are likely to be outweighed by competitive harm posed by other aspects of the program

4. CONCLUSIONS

Patent pools have received much attention in recent years as a possible solution to the patent

thicket. This review shows that patent pools are indeed one possible option, but others should also be considered. Organizing and establishing a patent pool is not a simple matter. It is a long, complex, multistep process, with many technical, legal, and business challenges involving the interdisciplinary coordination of efforts by attorneys, scientists, business professionals, and other experts. Setting up a successful patent pool therefore requires organization and planning, based on sound information and solid analysis.

As procompetitive arrangements, patent pools are aimed at IP assembly. They seek to resolve patent conflicts (reducing litigation), to settle disputes over blocking patents (accelerating product development and FTO), and to facilitate arrangements for licensing patents in the pool to outside members (accelerating the setting of standards and reducing licensing transaction costs). They exploit economies of scale by integrating the technical complementarities of the pool members.

From a legal perspective, pools require careful antitrust considerations to avoid potential, perceived, or real anticompetitive behavior by pool members or, more importantly, by the pool itself. From an operational perspective, only essential patents can be included in a pool. And finally, from a business perspective, the interests of the various IP holders need to be aligned in order to bring them to the table (pools are invariably voluntary arrangements). ■

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ANATOLE KRATTIGER, *Research Professor, the Biodesign Institute at Arizona State University; Chair, bioDevelopments-International Institute, and Adjunct Professor, Cornell University, PO Box 26, Interlaken, NY, 14847, U.S.A. afk3@cornell.edu*

STANLEY P. KOWALSKI, *Franklin Pierce Law Center, 2 White Street, Concord, New Hampshire, 03301. U.S.A. spk3@cornell.edu and skowalski@piercelaw.edu*

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9 See also the brief note titled About MIHR and About PIPRA in the first pages of this *Handbook*.

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17 www.vaccinealliance.org.

18 www.mihr.org.

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21 A fairness opinion provides an independent, objective analysis of a proposed deal's financial aspects from the point of view of one or more of the parties to the transaction. Any number of factors in deals involving both public and private companies can trigger the need for a fairness opinion. These documents are frequently used to protect the interests of company directors, stockholders, investors, and involved parties with any kind of fiduciary responsibility. Fairness opinions are often requested in deals involving public offerings, leveraged buyouts, or major refinancing/restructuring.

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26 See *supra* note 23.

27 See *supra* note 21.

28 See *supra* note 24.

29 Ibid.

30 The information used in this section is adapted from the article of Verbeure B, E Van Zimmeren, G Matthijs and G Van Overwalle. 2006. Patent Pools and Diagnostic *Testing. Trends in Biotechnology* 24(3): 115–20.

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34 Ebersole, TJ, MC Guthrie and JA Goldstein. 2005. Patent Pools and Standard Setting in Diagnostic Genetics. *Nature Biotechnology* 23(8): 937–38.

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36 Clark J, J Piccolo, B Stanton and K Tyson. Patent Pools: A Solution to the Problem of Access in Biotechnology Patents? U.S. Patent and Trademark Office. 5 December 2000. www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf

37 See *supra* note 21.

38 Krattiger A, S Kowalski, R Eiss and A Taubman. 2006. Intellectual Property Management Strategies to Accelerate the Development and Access of Vaccines and Diagnostics: Case Studies on Pandemic Influenza, Malaria and SARS. *Innovation Strategy Today* 2(2):67-122. www.biodevelopments.org/innovation/index.htm. See also *supra* note 2.