Collaborative Mechanisms for Intellectual Property Management in the Life Sciences

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EXECUTIVE SUMMARY

The OECD Working Party on Biotechnology (WPB) held a Workshop on "Collaborative Mechanisms for Intellectual Property in the Life Sciences" in Paris on 4-5 May 2009. Bringing together senior-level officials, academics and managers from a variety of backgrounds and experiences in the private, public and academic sectors, the workshop aimed to identify the manner in which collaborative mechanisms may increase efficiencies for the transaction of intellectual property, know-how and technology so as to stimulate innovation, foster R&D, facilitate value creation and promote access and commercialization of products and services.

By examining different mechanisms and the situations in which they have been employed, the workshop results were anticipated to enable policy-makers, industry, universities and others to assess the incentives to use these mechanism, the challenges that these mechanism present and the factors that need to be taken into consideration in their creation. Through the examination of different models and approaches, the workshop also explored the role of government policy and practices for achieving these objectives, as well as the manner in which the private and public sectors can useful employ collaborative mechanisms to improve their innovation and R&D cycles.

This workshop drew on an earlier Expert Roundtable of leading experts held by the Working Party on Biotechnology in Washington, DC, on 8-9 December 2005. The roundtable focused on identifying the different types of collaborative mechanisms and the manner in which they may be employed to facilitate access to and use of innovations for purposes of research, commercialisation and the provision of products/services, particularly in the life sciences. This forward-looking roundtable facilitated further discussion and has helped refine the issues surrounding such mechanisms, their utility and their application.

This report summarises the discussions and messages that emerged from the Collaborative Mechanisms for Intellectual Property in the Life Sciences Workshop, provides both a topology of mechanisms that contribute to knowledge networks and markets (KNM) and an initial assessment of how each contributes to research, commercialisation, access and the delivery of products and services in the life sciences.

This report was drafted by Iain Gillespie and Robert Wells. Special thanks go to Richard E. Gold of McGill University, Canada, who worked on drafting this report as a consultant.

CHAPTER 1
INTRODUCTION

In its *Guidelines on the Licensing of Genetic Inventions*, the OECD noted: "Research thrives on collaboration and getting the most out of the genetics revolution will rely increasingly on efficient and effective exchange between those researching and developing new innovations – as well as with those that would use these innovations."[1] As the OECD Innovation Strategy recognises: "The development of fully functioning knowledge networks and markets can have a significant impact on the efficiency and effectiveness of the innovation effort.... Their development is important for stimulating innovation and improving its efficiency by reducing transaction costs. Some good practice exists ... but significant scale-up is required."[2] These good practices include joint efforts through which to facilitate the circulation of knowledge and the rights to use knowledge among public- and private-sector actors. An OECD workshop was held in Paris in May 2009 to explore the nature of those mechanisms and to identify best practices to assist those creating, implementing and funding collaborations.

The OECD Innovation Strategy calls mechanisms that facilitate the circulation of knowledge "knowledge networks and markets" (KNM), which it defines as "arrangements which govern the transfer of various types of knowledge ... between independent parties".[3] KNM take many different forms and may be formal or informal in nature. "KNM are extremely varied: some are essentially based on prices and direct monetary transfers (*i.e.* markets); others are based on structural relations or networks; still others are a mix of the two."[4] An important subset of KNM includes collaborative mechanisms through which two or more actors co-operate to *i)* share knowledge, *ii)* share the legal rights to use knowledge or *iii)* create new knowledge through joint effort. These mechanisms are the subject of this report. They range from mechanisms that ease one-time transfers of intellectual property (IP) – chiefly patents, trademarks, copyright and database rights – to those that involve a continuous exchange and creation of knowledge among collaborators.

Collaborative KNM may originate in the private sector, in the public sector or through private-public sector partnerships. For example, the GRAVIT initiative in France brings together public-sector research entities in a manner that facilitates the use and exchange of knowledge subject to IP in a more efficient and effective manner. Among many examples in Japan, efforts are underway to create a patent pool and library for Japanese beef and to establish a patent pool for pluripotent stem cells. In the United Kingdom, the success of the Lambert Model Research Collaboration Agreements for collaboration between universities and industry has lead to the recent development of Model Consortium Agreements.

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1 OECD (2006), *Guidelines for the Licensing of Genetic Inventions*, Paris: OECD, pp 4-5.

2 OECD (2010), *The OECD Innovation Strategy: Getting a head start on tomorrow*, Paris: OECD, p. 158.

3 *Ibid* at p. 149.

4 *Ibid.*

The principal goal of the Workshop on Collaborative Mechanisms for Intellectual Property Management in the Life Sciences was to learn from the different types of KNM that have been established and to identify and extract best practices that others can incorporate in existing and future collaborations in the life sciences. Participants from various backgrounds such as technology transfer, business, IP law, competition and antitrust law, and research exchanged examples and ideas over the two-day workshop. Some of the broad themes addressed during the workshop included the following:

- Develop a better understanding of the types of KNM that can contribute to creating efficiencies in the life sciences;
- Analyse the objectives, characteristics and utility of each type of KNM;
- Examine the challenges and difficulties in establishing those mechanisms as well as possible approaches for overcoming the challenges; and
- Identify best practices for the establishment, governance, management, and operation of KNM.

Knowledge flows and innovation

Knowledge is far from homogeneous: it ranges from knowledge that can be packaged and exchanged without much additional effort ("explicit" knowledge) to knowledge that is so personal that nobody else can understand it ("tacit" knowledge).[5] In between these poles is "implicit" knowledge that may not be in written form but can be shared with little to moderate effort within expert groups (*e.g.* among cancer researchers, lawyers or businesspeople) or even with non-experts.

While all forms of knowledge are required in science and innovation – the research habits of scientists, the assumptions they bring to their research, the scientific language in which results are communicated, etc. – KNM deal principally with the circulation of implicit and explicit knowledge rather than with tacit knowledge. Through a combination of training, participation in communities of practice, personal interaction, and access to knowledge set out in publications, patents and other material, scientists and other actors use, combine, develop and improve knowledge. The role of KNM is to facilitate the use of these forms of knowledge in a way that takes into account the nature of the knowledge, incentives to invest in knowledge creation and dissemination, and the needs of national and international communities.

The effort required to share knowledge ranges from the cost of communicating it (e.g., access to the Internet or to published articles), to the costs of writing it down (e.g., detailed laboratory notes) to absorbing it by working alongside of someone who has this knowledge (e.g., by working in a laboratory, through an internship or from other hands-on experience). Fundamentally, the amount of effort varies in proportion to how implicit, as opposed to explicit, the knowledge is: knowledge that is more implicit requires more effort to record and pass along than does knowledge that is already in an easily digestible form. Von Hippel (1994) captures the idea of cost through the concept of "stickiness".[6] Stickiness refers to the incremental costs that one must expend in order to transfer a unit of knowledge in useable form to a person wishing to use it. The more explicit a unit of knowledge is, the lower these costs and thus the lower its stickiness. As

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5 Polanyi, M. (1958), *Personal Knowledge: Toward a Post-Critical Philosophy*, University of Chicago Press, Chicago; and Polanyi, M. (1967), *The Tacit Dimension*, Chicago: University of Chicago Press.

6 Von Hippel, E. (1994), "'Sticky Information' and the Locus of Problem Solving: Implications for Innovation" 40:4 *Management Science*, pp. 429-39.

KNM provide a set of mechanisms designed to facilitate the circulation of knowledge among independent parties, their form and structure will depend on the nature and stickiness of the knowledge in need of circulation. Thus, just as with the underlying knowledge they seek to circulate, KNM lie on a spectrum that depends on the stickiness of the underlying units of knowledge: from market or market-like structures that help circulate units of knowledge without much extra effort to collaborative research initiatives designed to circulate units of knowledge that move only when individuals and organisations are brought into close contact.

The level of stickiness of particular units of knowledge depends not only on the nature of the knowledge itself – whether it is explicit or implicit, reduced to writing or in the mind of a researcher, requires expert or simply lay knowledge – but in the ways in which actors deal with that knowledge, have established relationships with one another and are willing to share and exchange knowledge as opposed to hoarding and keeping secret that knowledge. KNM can reduce the stickiness of knowledge by reducing transaction costs in their exchange and of the exchange of the IP rights that control access to that knowledge.[7]

The Workshop on Collaborative Mechanisms for Intellectual Property Management in the Life Sciences dealt with the transfer and exchange of units of knowledge that are sticky for one of three reasons: *i)* the knowledge itself is explicit and easy to use but is subject to IP rights that render use of that knowledge costly in terms of identifying IP holders and negotiating licences with them; *ii)* the knowledge is explicit but costly to access for reasons other than the existence of IP rights; and/or *iii)* the knowledge is implicit and thus not amenable to being recorded, rendering it costly to acquire.

The context for the workshop

There has been a dramatic rise in international licensing activity over the past few decades. According to World Bank figures, the value of worldwide (cross-border) royalty and license receipts was nearly USD 120 billion in 2005, up from less than USD 30 billion in 1990 and approximately USD 80 billion in 2000. Although these figures also include copyright licensing figures, the overwhelming majority of licensing agreements are between private actors who have no obligation to disclose their transactions; thus, these figures most likely underestimate the total value of cross-border IP transfers through licensing agreements.

There is a need for better, more detailed information on licensing transactions. With a better understanding of technology markets, it may be possible to identify possible market failures and to fashion government policies or help entities develop more efficient strategies. To advance these efforts, the OECD co-ordinated a survey in 2007-2008 of patent applicants in the European and Japanese patent offices.[8] Participation in the survey was voluntary, thus the survey results may not provide a completely accurate picture of patent applicants and holders. Nevertheless, one can draw general conclusions. First, both small and large companies tend to engage in licensing – either as licensee or licensor – more than do medium-sized companies. Second, although many companies are willing to license their patents to unaffiliated third parties, they often face difficulties in doing so. The most oft-cited problem is their inability to identify potential licensees and partners. Other barriers to successful licensing include the complexity and

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[7] International Expert Group on Biotechnology, Innovation and Intellectual Property (2008), *Toward a New Era of Intellectual Property: From Confrontation to Negotiation*, Montreal: The Innovation Partnership. Available online at: http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP_Report_E.pdf

[8] Pluvia Zuniga, P.M., & D. Guellec (2009), "Who Licenses out Patents and Why?: Lessons from a Business Survey", *OECD Science, Technology and Industry Working Paper 2009/5*, *http://dx.doi.org/10.1787/224447241101.*

cost of negotiating and drafting licensing contracts, the technology not being ready for utilization or marketing, and the low price their invention commands in the market.

The survey identified several reasons why an IP holder would license its IP. The first is to leverage economic value from intellectual assets. Many companies have inventions that they do not exploit internally, for example, when the invention falls outside the company's core business. In such cases, licensing the technology to a third party can provide revenue without danger of undue competition. A licensor may also seek to establish its technology as the industry's *de facto* standard; generous licensing terms can be one method of ensuring that the technology is in such wide use that it becomes the standard. Others license their IP in exchange for licenses from others with complementary technology. In other instances, licensors may only conduct research and development (R&D) without the capabilities or business desire to commercialise a product. In such cases, licensing the technology they develop to a third party is a business necessity.

Likewise, there are several motivations for an actor to license in outside IP. Chief among these is that these licences enable the actor to gain access to complementary technology and know-how. Second, by licensing in technology, actors can reduce uncertainties, delays, and costs associated with performing R&D in house.

Intellectual-property rights

Within the life-sciences sector, different IP rights may be obtained, used and enforced. For example, trademarks may be obtained for the brand-name of a particular product or process. Copyrights may apply to the literature developed in relations to a product. Patents, know-how and trade secrets may be applicable to an invention or innovation being developed. The deployment of IP rights will depend on a number of factors, including an actor's area of specialisation, structure, anticipated activities, and whether it is engaged in commercial activity.

Within the life sciences, the most common IP rights include patents, trademarks, copyrights and related rights, and trade secrets/know-how. The following subsections provide a brief overview of these major forms of IP rights.

Patents

A patent is a right granted for an invention: a product or a process that provides a new way of doing something or offers a new technical solution to a problem. In order to be patentable, an invention must fulfil the patentability criteria of novelty, inventiveness (non-obviousness) and industrial use (utility). The application of the patentability criteria varies from country to country, and fulfilling other technical requirements may be required in order for a patent to be granted.

Subject to several important exceptions, a patent enables the patent holder to exclude unauthorised third parties from making, using, offering for sale, selling or importing for those purposes a product, a process, or a product obtained by a patented process. Generally this right is offered for a period of 20 years from the date of filing an application for a patent. In recognition of the lengthy period for the development and marketing approval process for bringing some products in the life sciences to market (chiefly, pharmaceutical products), certain jurisdictions offer Supplementary Protection Certificates or patent term extension/restoration, through which the term of patent protection may be extended for a period of time.

Trademarks

A trademark is a distinctive sign that identifies certain goods or services as those produced or provided by a specific person or enterprise. The objective of this system is to help consumers identify and purchase a product or service because its nature and quality, indicated by its unique trademark, meets their needs.

A trademark provides protection to the holder of the mark by ensuring the exclusive right to use that mark to identify goods or services, or to authorise another to use it in return for payment. The period of protection varies, but a trademark may be renewed indefinitely on payment of additional fees. Trademark protection is enforced by the courts, which in most systems have the authority to block trademark infringement.

Copyright and related rights

Copyright provides the right to exclude others from copying expressive works – including software – but does not cover ideas, procedures, methods of operation or mathematical concepts as such. The kinds of works that may be covered by copyright include: literary works such as novels, poems, plays, reference works, newspapers and computer programs; databases; films, musical compositions, and choreography; artistic works such as paintings, drawings, photographs and sculpture; architecture; and advertisements, maps and technical drawings. Unlike patents, copyright does not depend on official procedures and exists from the moment of creation of the literary and artistic work. Generally, these rights have a time limit, according to the relevant WIPO treaties, for example 50 years after the creator's death. As with other IP rights, authorisation from the rights holder or his or her authorised representative is required in order to copy, publish, distribute to the public or broadcast the protected work.

Trade secrets

A trade secret may be considered as any confidential business information that provides a business with a competitive edge. What is considered to be a trade secret is broad and can encompass manufacturing, industrial or commercial secrets. For example, a trade secret may include sales methods, distribution methods, advertising strategies, lists of suppliers and clients, and manufacturing processes. A trade secret can be protected for an unlimited period of time as long as it is actually kept secret.

Depending on the legal system, the legal source of protection of trade secrets may include legislation and case law on the protection of confidential information. While there are no procedural requirements for the protection of trade secrets, in practice, trade secrets are often protected through confidentiality or non-disclosure agreements and/or non-compete clauses.

Report structure

The following chapters will examine the three forms of knowledge that were the focus of the Workshop on Collaborative Mechanisms for Intellectual Property Management in the Life Sciences.

Chapters 2 through 4 examine KNM that facilitate the transfer and sharing of IP related to explicit knowledge. In the absence of KNM, transfers of this IP could be costly either in terms of identifying the relevant IP holders and negotiating licences with them or by the need to identify and bring together relevant units of knowledge. Chapter 2 discusses KNM that facilitate licensing

or transferring units of knowledge subject to IP between a limited number (usually two) actors. These include university licensing practices, model agreements and IP auctions. Chapter 3 focuses on patent pools and their application to the bio-pharmaceutical sector. Patent pools provide a mechanism through which to circulate packages of IP rights relevant to a particular technological need among a group of actors. Chapter 4 examines four forms of clearinghouses: for-profit, not-for-profit or philanthropic, open-source and open-access. Clearinghouses provide a means through which a large group of technology users can choose those IP rights needed to make use of particular units of knowledge. The fundamental difference between patent pools and clearinghouses is, then, that the former provide pre-packaged sets of IP while the latter leave it to the user to determine which among a set of IP rights the user needs. Both function by reducing transaction costs through eliminating the need to enter into individually negotiated licences between IP holder and IP user.

Chapter 5 examines KNM used to create new knowledge through research collaborations. The knowledge at the heart of these collaborations is a combination of explicit and sticky knowledge best transferred through face-to-face interactions.

Chapter 6 reviews barriers to the development of KNM and policy mechanisms available to overcome them. Chapter 7 concludes and highlights policy areas in which more work is required in order to understand the nature of KNM and how they fit into with the tapestry of innovation.

Annex 1 provides the agenda for the 2005 Expert Roundtable held in Washington. Annex 2 sets out the agenda for the 2009 Workshop on Collaborative Mechanisms for Intellectual Property Management in the Life Sciences.

CHAPTER 2
LICENSING AND AUCTIONS

The presence of IP rights over units of explicit knowledge has the potential to either facilitate or limit the exchange and transfer of that knowledge, depending on context, industry structure and business practices.[9] While, according to traditional economic theory, the creation of property rights in the form of IP should encourage both investment in R&D and the appropriate level of dissemination and sharing of knowledge subject to that IP, transaction costs can often become a significant barrier to that sharing:

> *Even where patent owners are amenable to licensing, the price demanded for use of a genetic invention might pose a barrier to researchers. Different research-performing institutions may have very* different *perspectives on the value of a research tool (Eisenberg, 1999). Moreover, negotiations over access to technologies and materials can be long and complicated, imposing delays and administrative burdens on research. Finally, the terms of licences or material transfer agreements – restricting publication and exchange of materials, demanding reach-through rights – can be such that they ultimately make collaboration and communication with other researchers more difficult.*[10]

Appropriate licensing practices, university and business strategies with respect to IP and new structures that reduce transaction costs for the allocation of IP rights all constitute KNM that have the potential to unlock the positive effect of IP on the exchange and sharing of explicit knowledge: "While there is no single model for the licensing or transferring of genetic innovations, the manner in which rights holders choose to carry out such activities has and will increasingly have implications for future R&D, especially involving fundamental or new technologies, as well as for access to the latest medical innovations."[11]

This chapter surveys KNM that reduce transaction costs in trading individual patents or bundles of related patents between individual actors, as opposed to between groups of actors or the community at large (which are examined in Chapters 3 and 4). The first KNM examined, model licensing agreements, reduce transaction costs by simplifying the licensing process. Model agreements eliminate the need to draft clauses that are standard in similar transactions and reduce negotiations to selecting the most appropriate of a limited set of clauses for the most contentious issues. The second KMN involves the creation of a governance structure through which IP can be bundled and licensed out by an entity in a series of transactions to different licensees. It illustrates an emerging model of universities as research and innovation hubs, being at the core of networks involving firms and communities of practice. The third KNM involves the creation of a marketplace through which to exchange patent rights. The marketplace reduces transaction costs both by lessening risks associated with the validity and business utility of patents traded and by identifying those actors most willing to acquire the IP.

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9 International Expert Group on Biotechnology, Innovation and Intellectual Property, *supra,* note 7.

10 OECD (2002), *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies*, Paris: OECD, p. 14.

11 OECD, *supra*, note 1, p. 5.

Creation of model agreements: The Lambert Toolkit

The Lambert Toolkit is a set of model agreements that were developed in the UK through negotiations between representatives from academia, government, large companies, and small companies. According to Malcolm Skingle of GlaxoSmithKline (GSK), the motivation for creating the Lambert Toolkit was to reduce the financial and time costs of negotiating IP agreements before commencing a research collaboration or sponsored research arrangement. The toolkit assists parties in allocating IP between them so as to clarify who is entitled to make use of which knowledge for which purposes. Prior to the development of the toolkit, actors found either their research delayed – as parties failed to communicate and to identify and resolve contentious issues – or that critical issues were left unresolved, leading to difficulty later in the relationship. Recognition of these problems led to the development of a set of agreements from which parties could choose how to govern their arrangements.

The model agreements are not mere models or frameworks but full-fledged legal agreements, guidance documents and a decision guide through which to select the most appropriate form of agreement. The Lambert Working Group concluded that simple models or frameworks were insufficient to reduce the transaction costs involved in initiating a relationship since they left too much to be negotiated. The group also recognised that permitting extensive modifications to the Lambert agreements would also defeat their cost-saving advantage. The agreements are designed to be fair to both parties, and thus represent an acceptable compromise rather than a "win" for either party at the expense of the other. This greatly reduces the time needed to arrive at a final agreement.

The model agreements address such basic issues as liability, state aid, tax credits, confidentiality and publication issues, ownership of and rights to foreground IP (*i.e.*, the new IP that is developed as a result of the collaboration), and contributions (financial or other research assets) of the parties to the arrangement. There are five model one-to-one research collaboration agreements and four multi-party model consortium agreements within the toolkit. For the most part, the agreements differ from one another largely on the basis of which party holds the foreground IP and on the level of access to knowledge subject to pre-existing IP.

Skingle reported that, as of 2009, GSK had entered into over 150 Lambert agreements with 26 universities in the UK, 19 institutions in the rest of Europe and 14 institutions in the rest of the world. The agreements have proved to be so successful in speeding up contract negotiation that GSK will not waste resources changing in any substantial way the terms set out in those agreements.

Creation of a governance structure: iPS technology development at Kyoto University, Japan

Induced pluripotent stem cell (iPS) technology – in which adult cells are reprogrammed into an embryonic stem cell-like state – was born in Kyoto University and reported in a murine (mouse) cell line as early as August 2006. As a result of its work in the area, Kyoto University is the holder of certain patents relating to these technologies. The research and commercial potential of iPS technology is significant. Yet, according to Yutaka Teranishi and Koji Murota of Kyoto University, Japanese universities are relatively inexperienced in commercializing and creating businesses from their IP portfolios. In particular, the Kyoto University office charged with negotiating licences and with collaborating with other institutions to consolidate IP related to iPS was ill-equipped to handle this task from either a business or a legal perspective. To address this shortcoming, the university created a governance structure that would provide a

university-controlled corporation with patent rights over the iPS technology, would license out that technology and obtain financing from private and banking partners to pay for international patent filing (which is not covered under grants given to the university). Through this structure, the university serves the role of a hub in an innovative collaboration system.

The principal objectives and activities of the governance mechanism are to seek alliances with foreign companies to develop the iPS technology and to negotiate with universities and research institutes around the world to collaborate in iPS cell-related research projects. In line with the OECD *Guidelines on the Licensing of Genetic Inventions*, all licences are non-exclusive and those to universities are on a royalty free-basis while those to industry are royalty-bearing. In addition, the corporation holding the IP has the mandate of consolidating IP in the field by licensing in technology from other universities and institutes in Japan. Finally, the mechanism provides support for the development and research on the standardization of iPS cells.

The use of a governance structure represents an evolution in licensing models away from one-off licensing transactions in which each deal is evaluated on its own merits – in terms of revenue generation and preservation of future rights – to a more holistic approach that takes a more coherent view of the long-term goals of the actors involved in facilitating future research while creating opportunities for private-sector investment.

Creation of a marketplace: Ocean Tomo

Ocean Tomo is an intellectual-capital merchant bank that seeks to create a more liquid market in patents through the creation of a patent-assessment and -auctioning system. According to Jonathan Barney of Ocean Tomo, the company facilitated the auction of over USD 100 million of intellectual property – principally patents – from 2006 to 2009. IP is typically auctioned in portfolios, so auctioned IP may include not only patents but patent applications and access to key personnel, such as the inventors. Patents are usually assigned although sellers typically retain a limited non-exclusive licence to continue using the invention.

In establishing the auctions, Ocean Tomo recognised two problems.

The first of these is that not all patents are equal in terms of either their validity or business value. Typically, Ocean Tomo receives requests to auction about 10 times the number of patents than it actually allows to go to market. To identify those patents to auction, Ocean Tomo conducts due diligence along three dimensions: *i)* the merits of the underlying invention, *ii)* the commercial value of the invention, and *iii)* the quality of the patent coverage. The company has developed a proprietary (and patented) rating system to assess patents, which it calls the "IPQ." According to Barney, the higher the IPQ, the higher the probability of patent maintenance (life expectancy of the patent) and commercialization of the patent. That is, the higher the IPQ, the higher the expected price for the IP at auction. Barney notes, however, that Ocean Tomo's due diligence focuses primarily on determining the economic value as an asset that others would likely seek to purchase and is not an opinion on the patent's underlying validity or utility. Buyers typically conduct their own, more detailed, due diligence of the IP that takes into account their own criteria and plans for exploiting the IP.

The second problem is that it is not always straightforward for potential buyers to know that a relevant patent is being auctioned. To counter this, Ocean Tomo undertakes a process of identifying potential bidders for the patents before the auction.

IP auctions represent a new form of IP trading that goes well beyond the more limited licensing strategies that actors currently employ. The auctions solve two problems that traditional licensing still encounters: *i)* its ad hoc nature; and *ii)* the difficulty of establishing a price. As licensing transactions leave it to individual actors to identify each other and negotiate an acceptable licence, they tend to be idiosyncratic in nature – reflecting the particularities of the parties and how they met – and provide little ability to compare price or reasonableness of the transaction. Model licensing agreements help overcome the first of these idiosyncrasies but not the second. Auctions, on the other hand, provide a set forum through which transactions take place on standard terms. Further, the large number of transactions provides a reasonable comparator through which to establish price.

A limitation of all of the KNM examined in this chapter is that they are based on individual transactions between two or only a few actors and deal only with trading IP rather than underlying units of knowledge. Chapters 3 and 4 describe KNM that facilitate one-to-many or many-to-many IP transactions while Chapter 5 examines KNM that enable the transfer, exchange and creation of units of knowledge rather than simply the IP applicable to that knowledge.

CHAPTER 3
PATENT POOLS

While the KNM described in Chapter 2 illustrate a trend to more sophisticated mechanisms through which to transfer IP between individual actors, other KNM enable multi-party IP transactions through the creation of both centralised and decentralised structures to which IP holders contribute rights and IP users extract rights. In centralised systems, an agent (which may be one of the IP holders or a third party) bundles IP and provides standard licences to that bundle to users, usually but not always for a fee. In a decentralised system, the agent provides a mechanism through which users and providers exchange IP and other rights, often using the Internet. This can be done for a fee or be free. This chapter will examine one form of centralised multi-party IP structure: the patent pool. Chapter 5 will examine a set of KNM called clearinghouses in which the agent facilitates the exchange of IP rights but the user is the one that selects the desired IP rights.

"There is no precise definition of a patent pool" according to recent report on patent pools in the life sciences.[12] "In general, a patent pool involves collecting a series of patents that relate to the use of a particular technology so that they can be efficiently licensed to those making, using or selling that technology. Once patents are brought into the pool, they are licensed out to others in pre-defined packages"[13] The distinguishing trait of a patent pool, among all KNM, is this bundling of IP rights. An agent – which can be one of the patent holders – packages IP rights around a central technological need. The number and content of the packages are usually determined by the patent holders establishing the pool or by a standards organisation that packages the IP around an accepted technological standard.

The report identified three types of pools. The first type, "particularly those created in the first half of the 20th century, arose from the need to overcome strategic behaviour from patent-holders that blocked the development and sale of a new product."[14] Many of these pools were nothing more than elaborate cross-licensing mechanisms and facilitated the control of a few actors to dominate the market. As a result of their anti-competitive effect, many of these pools were dismantled by mid-century. The second "[m]odern patent pools arise where companies wish to establish a common technological standard for an industry. These pools are pro-competitive in that they create the possibility of producing new technologies that, absent the pool, would have been difficult."[15] The third, more recent type of pool "aim[s] at overcoming transaction costs in order to serve public, rather than commercial, interest. This social-entrepreneurial approach is evident in the SARS patent pool that brought together public research agencies, a government department and industry so as to facilitate the development of a SARS virus vaccine."[16]

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12 Gold, E.R., T. Piper, J.-F. Morin, L.K. Durell, J. Carbone. and E. Henry (2007), *Preliminary Legal Review of Proposed Medicines Patent Pool,* Montreal: The Innovation Partnership, p. 8, *www.theinnovationpartnership.org/data/documents/00000003-1.pdf*

13 *Ibid.*

14 *Ibid.*

15 *Ibid.*

16 *Ibid.*

Patent pools are considered to be beneficial (that is, not anti-competitive) when they can provide the following: fair, reasonable, and non-discriminatory access to all who desire a license to the technology; one-stop licenses consisting of essential and complementary patents held by multiple patent holders; freedom to operate for licensees; an environment that facilitates technology research, implementation, and interoperability; and transparency for licensees.

Patent pools are common in the electronics sector, in which clear technological standards exist. As the discussion below illustrates, translating these types of pools to the life sciences field is far from obvious as little that could be considered to be a "standard" exists. On the other hand, pools of the social-entrepreneurial kind have shown themselves to be more applicable in the life sciences. Several such pools have been created, focusing on ensuring that particular products are made available – usually on a not-for-profit basis – to the research community or, more frequently, to those living in the world's poorest nations.

In its 2002 report, the OECD cast doubt on whether patent pools will work as well in the life sciences as in other industries: "While the concept is intriguing for biotechnology, it is questionable whether the technologies and markets for genetic inventions are amenable to pools."[17] Patent pools in the life sciences give rise to particular challenges. For instance, many life-science patent pools follow more of a patent aggregation model – trying to include as many of the related patents as possible – whereas patents considered as "essential" to a technological standard are included in patent pools for other technologies. This renders issues raised by the antitrust and anti-competition laws more complex when dealing with a life-sciences pool. Additionally, while life-science patent pools will likely face many of the same challenges faced by pools for other technologies, the former also face challenges discussed below.

Because of the dearth of examples of patent pools based around a technological standard in the life sciences, this chapter will begin by reviewing how standards-driven pools function in the electronics sectors, drawing on the examples of radio frequencies identification and digital compression technologies. It then turns to how lessons learned from these pools can be translated to the life sciences before turning to patent pools of the socio-entrepreneurial type aimed at addressing the needs of either the researcher community or those living in the poorest nations.

A patent pool at the heart of standard setting: the Radio-Frequency Identification Consortium

Radio-Frequency Identification (RFID) technology has a number of uses, including in inventory tracking, toll payments, public-transport payment, animal identification and so on. The technology involves the use of a tag (either passive or active) and a reader. In the simplest case, the reader emits a signal that a passive tag receives. The tag alters the signal – using the energy from the initial signal – to emit a unique identification. The reader receives this altered signal, which it uses to identify the tag. Because of its broad set of actual and potential uses and the importance of inter-operability between readers and tags, many members of the industry wished to establish clear standards for RFID technology. They developed these standards within EPCGlobal and ISO.

As William Dolan of Jones Day explained, however, there are more than 1 200 patents held by more than 20 different companies that directly relate to the standards adopted. If the standard was to be widely adopted and new entrants permitted to use it, a mechanism was needed to facilitate the right to use the knowledge underlying those patents. While broad licensing was an

[17] OECD, *supra,* note 10.

option, given the large number of patent holders and of potential licensees, a patent pool was preferred. In constructing the pool, however, the actors needed to answer a series of critical questions relating to the legal structure of the pool, who would manage it, how royalties would be allocated, and who would decide which patents to include in the pool using which criteria.

Until the mid-1990s, regulators would have considered creating a patent pool to assist in the creation of an industry standard to be anti-competitive. According to Dolan, regulators came to see patent pools as pro-competitive in the late 1990s – with the approval in 1997 of the MPEG LA patent pool – as long as the pools were careful to only contain valid patents relevant to a published industry standard, an independent expert evaluated patents within the pool, licensors could also issue licenses outside of the pool, and the pool was open to any actor.

Dolan stressed the importance of understanding the meaning of an "essential" patent. Essentiality can be defined in two ways: *i)* technical essentiality involves IP that would necessarily be infringed by anyone who practices the technology, and *ii)* economic essentiality arises when there is no viable economic alternative to the IP. For decades, only patents that met the technical essentiality standard qualified as an essential patent; however, that standard may be loosening, at least under U.S. law. One must tread carefully, as it is illegal to include non-standard or non-essential patents in a patent pool. For example, the LASIK patent pool was forced to break up when the government filed suit. In another example, Sony recently added patents related to digital MPEG-2, where the patent pool originally only included analogue MPEG-2 related patents. After several years of litigation and appeal, Sony was found not guilty of misusing the digital MPEG-2 patents. Nevertheless, the fact that Sony had to defend its actions illustrates the extreme care that must be taken in establishing and administering patent pools.

Digital Compression Technology: the experience of MPEG LA

MPEG-2 is a digital video compression standard adopted by the industry. In order to ensure that all manufacturers could participate in the standard, actors throughout the industry needed access to a core set of explicit knowledge that was subject to IP rights held by a diffuse set of companies. According to Bill Geary of MPEG LA – the independent agency set up to facilitate the creation of the pool – without broad access, there would have been the potential for confusion, conflict, and high negotiation costs due to patent bottlenecks. As had been noted by Dolan in his discussion of the RFID pool, the MPEG-2 pool was formed in 1997. Geary stated that, initially, the pool consisted of 8 patent holders with 25 patent families. It now contains 159 patent families from 25 licensors, including over 850 patents in 57 countries. MPEG LA manages all the patent families, licenses in all the patents and licences out pools of those patents, and collects and distributes royalties. A third-party expert evaluates patents submitted for participation in the pool to ensure that they are essential or blocking patents that read on essential functions of the MPEG technology or those practicing the technology.

According to Geary, the MPEG LA licensing model works because there are many licensors and many potential licensees to the MPEG-2 technology platform. It is thus a cost-effective way to deal with the otherwise thousands of separate licenses that would otherwise have to be negotiated between all of the different combinations of parties. The licensing model provides licensors with the opportunity for mass-market adoption of the technology while gaining a reasonable return on their investment in the R&D of their knowledge subject to their particular IP rights. It also provides licensees with convenience, access to the technology, freedom to operate, the opportunity to level the playing field against competitors, and the freedom to focus their efforts on product development and marketing rather than on licensing activities. In sum, the licensing model provides the right to use a marketable industry standard, includes as much of the essential IP as possible, licenses in a non-exclusive manner, assesses non-discriminatory

royalties, administers the pool in a transparent, independent manner, provides protections to both the licensee and licensor, passes legal muster (from the competition/antitrust laws), and provides freedom to all parties to develop competing products and standards.

Challenges for creating patent pools in the life sciences

Geary pointed out, however, that there are broad challenges for life-science patent pools. Nevertheless, Richard Johnson of Arnold & Porter noted that several life-science pool initiatives exist, including in respect of Golden Rice, HIV/AIDS fixed-dose combination drugs, green fluorescent proteins, SARS and breast-cancer biomarkers, to name just a few. These examples illustrate both interest in and the difficulty of creating and maintaining pools in the life sciences. Johnson pointed to the heterogeneity of actors participating in the pool – including those from academia, industry, non-profit research labs, government, and trans-national organisations – as making it difficult to align interests. Second, he stated that finding a substitute for standards – which are critical to passing legal muster – may not always be easy in the life sciences. Some surrogates for standards may exist, such as consensus documents from the NIH or independent organizations, but it is uncertain whether these will always be legally acceptable. Third, the power and incentives surrounding IP rights in the life sciences tend to be less symmetrical than in other industries, again increasing the difficulty of gaining consensus. Fourth, as the same patents may be important for different platforms (*e.g.* gene testing, arrays, sensors, re-agents), the pool may have to deal with multiple platforms, again complicating arrangements. Finally, because there are so many interlinked technologies involved in the life sciences, freedom to operate analyses are more complex, especially when other factors such as material transfer agreements are considered, which may affect IP rights.

Given the above, Johnson cautions that a patent pool in the life sciences raises significant risks, such as over-inclusion of non-essential patents, including a sufficient core of essential patents to create a true "one-stop shop"; processes to remove patents overtaken by new standards or changing best practices, determinations of the validity, valuation, scope, and enforceability of many biotech patents (particularly those in the early stages); and the need to value the contributed patents to the pool to cover transaction costs associated with creating and administering the pool, and to achieve agreement on governance of the pool, especially when different entities with differing agendas participate in the pool. In a field that is developing so rapidly and is becoming increasingly complex, these uncertainties and limitations signal the need for caution in applying the idea of patent pools to the life sciences.

Johnson cautioned that universities and non-profits face their own special set of challenges in creating and maintaining a life-sciences patent pool. For example, these institutions may worry about diminishing levels of revenue from their patents or that royalties from patents may be hard to allocate to different contributing members of faculty. Some of the larger public institutions may have statutory limits on the amount of revenue they can gain from royalties, while others may have trouble reconciling their role as a "business" and/or "competitor" with their academic mission and might be subject to competition laws. There may also be issues with IP rights held by these institutions that may already be exclusively licensed to third parties or licensed as part of a litigation or dispute settlement. Finally, there are complications associated with industry-university collaborations, as some may perceive the academic mission to be compromised by them.

Industry actors may also find it difficult to participate in a pool. Johnson noted, for example, a dominant firm or player may not have an incentive to allow others to make use of its patents as this will diminish its power. Second, given the large variety of business models in use by life-sciences companies, aligning financial and IP interests within a single pool may prove very

difficult. This problem is exacerbated by the fact that biotech companies are not vertically integrated and that product pathways are such that it is difficult to extract royalties along a single value chain. These problems are particularly difficult for small to medium-sized enterprises for which IP is their only significant asset. Giving up control over that asset through a pool makes it difficult for them to gain a financial return and thus raise capital on the promise of a future return, at least using traditional business models.

These incentive problems, whether for universities or industry, depend, of course, on the status quo in terms of business models and industry structure. One could challenge these models on the basis that they are far from optimal from the perspective of universities, industry or even the public at large. Gary Pisano noted the underperformance of the biotechnology industry even before the crash of 2008: "While there have been a few very successful biotechnology firms (e.g., Amgen, Genentech, Genzyme), the economic performance of the sector overall has been disappointing by any objective standard."[18] He attributes much of this to the very proprietary model that makes participation in patent pools difficult:

> *Any strategies or policies at the university level (such as exclusive licensing) that discourage or inhibit the broad flow of basic scientific information are clearly problematic. … Even worse, in contexts like biotechnology, where basic scientific knowledge evolves with application of that knowledge to specific therapeutic problems, putting the science into the hands of more explorers is likely to accelerate the pace of scientific advance.*[19]

KNM, such as patent pools, provide a means through which to overcome the challenges that Johnson and others highlighted. While convincing actors to participate in them may often be difficult – given their entrenched ways of thinking and business models – KNM offer an important means through which to enable innovation in the life sciences.[20] The following examples of pools illustrate the potential of these KNM to facilitate research and the delivery of needed products. Most are, however, aimed at a philanthropic outcome. The challenge, as Dolan, Geary and Johnson enunciated, is to develop patent pools and similar KNM that aim at furthering research in areas of commercial, as well as social, interest.[21] Overcoming industry resistance to moving away from, even increasingly unproductive, business models is part of this challenge.

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18 Pisano, G. (2006), *Science Business: The Promise, The Reality, and The Future of Biotech,* Cambridge: Harvard Business School Press.

19 *Ibid.*

20 Baldwin, C.Y and E. von Hippel (2009), "Modeling a Paradigm Shift: From Producer Innovation to User and Open Collaborative Innovation" Harvard Business School Working Paper 10-048, available online at: http://ssrn.com/abstract=1502864

21 International Expert Group on Biotechnology, Innovation and Intellectual Property, *supra,* note 7.

Golden Rice

The patent pools in the life sciences with the greatest visibility were created to serve a public, usually philanthropic, purpose. These pools aim at the development and distribution of products – often agricultural – that suit the particular needs of developing countries. The Golden Rice patent pool is an early example.

The Golden Rice initiative aimed at developing a genetically-modified rice that produces pro-vitamin A in order to combat vitamin A deficiency.[22] According to the World Health Organisation (WHO), the most direct consequence of vitamin A deficiency is night blindness and overall blindness, but the deficiency also increases anaemia and risk from infection.[23] The WHO estimates that night blindness affects 5.2 million pre-school-age children and 9.8 million pregnant women. According to the WHO: "Approximately one third of the world's preschool-age population is estimated to be vitamin A deficient, with just less than 1% being night blind at a given time."[24] Vitamin A deficiency is worst in Africa and South-East Asia, in which between 44 and 50% of pre-school children are affected.

While adequate and appropriate nutrition would alleviate vitamin A deficiency in the long term, researchers around the world, supported by various UN agencies, aimed to find interim solutions to overcome the deficiency. Researchers examined food enrichment, micronutritional supplements and genetically modified staples as means to provide vitamin A to at-risk populations. Two researchers, Ingo Potrykus of the Swiss Federal Institute of Technology and Peter Beyer of the University of Freiburg, decided to address the problem of vitamin A deficiency by genetically modifying a food staple among at-risk populations – rice – to produce pro-vitamin A that, when consumed, would be converted into vitamin A. They published the results of their research – in which they announced the creation of Golden Rice – in 2000.

According to Potrykus, he and Beyer were committed to making Golden Rice freely available to those in need. They quickly ran into several barriers to doing so, including resistance from groups opposed to genetic modification, the lack of appropriate regulatory regimes in many developing countries and existing IP rights. An initial review revealed 70 patents that may have had some effect on limiting the use of the Golden Rice technology. This caused much concern about whether the project would be stopped in its tracks due to the existence of so many patents.

To address this concern, Potrykus and Beyer approached Syngenta, the holder of several patents in the area. Adrian Dubock of Syngenta took the lead by implementing an IP management plan. The first step in this plan was to evaluate which of the 70 patents initially identified were actually relevant to Golden Rice. The results were encouraging: only 12 of the patents were relevant and, of those, 6 were held by Syngenta. The second step involved a trade between Potrykus and Beyer on the one hand and Syngenta on the other. In return for an exclusive licence of their technology to Syngenta, Potrykus and Beyer received a licence back of not only their technology but to the six Syngenta patents. In addition, Syngenta made a financial

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[22] The use of Golden Rice is not without controversy. Both Greenpeace and activists, such as Vandana Shiva, argue that the rice has yet to be proven to actually deliver vitamin A in sufficient quantities, after being cooked, to address vitamin A deficiency. See, for example, Greenpeace (2005) "All that Glitters is not Gold: The False Hope of Golden Rice". Available online at: *www.greenpeace.org/international/Global/international/planet-2/report/2005/5/all-that-glitters-is-not-gold.pdf*; Shiva, V. The Golden Rice Hoax, *http://online.sfsu.edu/~rone/GEessays/goldenricehoax.html*

[23] WHO (2009) *Global prevalence of vitamin A deficiency in populations at risk 1995–2005. WHO Global Database on Vitamin A Deficiency*, Geneva: World Health Organization.

[24] *Ibid* at p. 16.

contribution to the project. Third, Syngenta obtained humanitarian licences from the holders of the remaining six patents and provided these to Potrykus and Beyer.

The result of this IP management strategy was the establishment of the Golden Rice Humanitarian Board that was given authority to licence out Golden Rice for free to farmers who gained not more than USD 10 000 per year from the rice. Virtually all subsistence farmers would qualify under this test. Larger productions would require a licence from Syngenta. With this strategy, the initial fears over IP fell away, to be replaced with an effective pool through which to licence farmers.

Nevertheless, Golden Rice has still not made it to market since it has encountered significant resistance from NGOs that are opposed to genetically modified food and argue that the technology is not effective in addressing vitamin A deficiency, as well as the lack of clear regulatory processes and delivery mechanisms in many countries.

One of the lessons to be learned from the Golden Rice pool is that clearing IP rights is not sufficient to render KNM effective: KNM must also enable the transfer of knowledge to regulators and provide a forum through which all those involved can discuss and prioritise how best to deploy that knowledge. These KNM will be discussed further in Chapter 5.

Conclusion

If life-science patent pools can achieve the type of efficiencies as attained in the information technology field, they can provide distinct advantages to both those contributing to the pool and using pooled patents. So far, there is relatively little experience in creating and maintaining a life-sciences pool. Further, the best-known life science pools have a clear philanthropic purpose. This confirms the conclusions of the 2002 OECD report casting doubt on whether pools really provide a useful KNM in the life sciences. It also raises the question of whether patent pools will ever come into generalised use or, as concluded by the OECD, they will only likely to be effective "[i]f a limited field of application and essential patents can be defined."[25] Alternatives to a pool, such as a patent clearinghouse, may offer more promise.

[25] *Ibid.*

CHAPTER 4
CLEARINGHOUSES

The absence of standards and the different potential uses of individual units of knowledge in the life sciences call for a search for KNM that provides more flexibility and less formality than do patent pools. One mechanism with promise is the clearinghouse. IP holders enter into a standard form licence with the clearinghouse (often an agent but, in its open-source version, an open licence to anyone) that they select. Those wishing to clear IP rights over particular units of knowledge falling within the clearinghouse enter into standard-form licences to cover those individual units. A practical example of a clearinghouse is that used to clear rights over the broadcast of music over radio in many countries.

The central distinction between patent pools and clearinghouses is that, in the former, the agent or patent holders determine which IP is to be licensed (through bundling) while in the latter it is the user who decides. Because of this and the fact that all licences are, by necessity, non-exclusive, clearinghouses raise far fewer antitrust or anti-competition concerns than do patent pools. They are thus easier and less costly to set up and generally require less – sometimes very little – administration.

This chapter will investigate four types of clearinghouses: industry-established clearinghouses operated on a for-profit basis, non-profit/philanthropic clearinghouses (whether established by industry or by a foundation), open-source clearinghouses and open-access clearinghouses.

A for-profit clearinghouse: MPEG LA's genetic testing supermarket

In his presentation on the MPEG-2 patent pool, Bill Geary warned that one cannot simply apply the MPEG LA or RFID models to the life sciences. He suggested, however, that in certain defined areas of the life sciences in which *de facto* standards have arisen, such as genetic diagnostic technologies, a patent clearinghouse (which he called a convenience store) may be appropriate. In particular, he highlighted the potential of constructing a clearinghouse around diagnostic genetic tests for Lynch Syndrome, hereditary hearing loss, and cardiovascular disease.

Geary's idea follows, in fact, the 2002 OECD finding that: "A patent clearinghouse would be a 'one-stop shop' offering clinical laboratories non-exclusive licences to a range of patented genetic tests on reasonable terms. It remains to be seen whether such an organisation could work in practice or who might instigate its establishment."[26] MPEG LA provided an answer to the latter question in April 2010, when it announced the creation of a diagnostic genetics patent licensing "supermarket" to "assist laboratories, testing companies and researchers in obtaining rights they need to design comprehensive diagnostic genetics tests that the market wants, thereby making these tests widely available through multiple channels at affordable prices."[27] The details of how the supermarket will function and which patents it will include have yet to be disclosed.

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[26] OECD, *supra,* note 10, p. 74.

[27] MPEG LA, Press Release, April 10, 2010, *www.mpegla.com/Lists/MPEG%20LA%20News%20List/Attachments/230/n-10-04-08.pdf*

Non-profit/philanthropic clearinghouses

Clearinghouses provide a particularly useful KNM for IP covering units of knowledge that are upstream from commercial or consumer products or services; that is, while being necessary to develop future products or services, they are not, in themselves, those products or services. In cases in which actors find that the IP rights covering those upstream units of knowledge are widely dispersed, they may find it in their mutual interest to allow others to use the knowledge controlled by their IP in exchange for access to the knowledge of those others. Much of the time, this service is paid for by fees that cover costs or is done for free on a philanthropic basis, particularly when users are in developing countries. This section explores several examples.

Eco-Patent Commons

One example of an industry-led clearinghouse is the Eco-Patent Commons. While not focusing primarily on the life sciences, patents contributed to the clearinghouse may include life-science patents. Four companies – IBM, Nokia, Pitney Bowes and Sony – created the commons in order to facilitate the development of environmentally beneficial technologies. None of the companies was in the environmental-technology business but they held patents that could be used to develop such technologies. These environmentally beneficial patents include those related to energy conservation or efficiency, materials reduction, or increased recycling ability. Rather than see these patents as a burden on further R&D, the four companies decided to combine those patents and license them out for free to those working on environmental technologies. Soon, other companies joined the clearinghouse, including Bosch, DuPont, Xerox, Ricoh, Taisei, Fuji Xerox and Dow Chemical. The pool currently holds more than 100 patents.

The structure and operation of the Eco-Patent Commons is governed by a "Structure and Governance" Framework, Ground Rules, a Non-Assert Pledge and a list of International Patent Classification (IPC) Codes. The Commons operates with a minimal structure sufficient to handle administrative work, manage the website, and provide point of contact for prospective members. The Commons currently has no membership fee but anticipates introducing one in the future. The membership fee would cover costs associated with the management of the Commons.

Patents included in the Commons are subject to a non-assert pledge that provides that the patent holder agrees not to assert the patent against implementers' environmentally beneficial use of the pledged patent(s). Those making use of the pledged patents are free to make, use, sell, and import inventions subject to the patents in the database without payment of any royalty if by doing so they achieve an environmentally beneficial result. The non-assert pledge can be withdrawn against particular users should those users assert a patent against the patent's contributor.

The European Mouse Mutant Archive

The European Mouse Mutant Archive (EMMA) is a researcher-led KNM that seeks to archive and distribute mouse mutant lines to the biomedical research community for non-commercial research and teaching purposes. Mouse mutant lines are important in biomedical research, as many human diseases can be expressed in mice, making them the perfect research tool. "When it comes to resource sharing, the two greatest impediments to fully exploiting global research using the mouse as a model organism are the barriers created by material transfer agreements and the underutilisation of public mouse repositories."[28]

[28] Schofield, P.N., T. Bubela, T. Weaver *et al.* (2009), "Post-publication sharing of data and tools" 461 *Nature* 171, p. 171.

EMMA is one of several institutions that facilitate the exchange of mouse lines by acting as a broker for those lines and associated IP. According to Martin Hrabé de Angelis, its director, although the main objectives of EMMA are to archive and distribute mouse lines, it also plays an important role as a resource database. In the future, de Angelis anticipates that the data inherent in the physical mouse model may become as important as the mouse line itself.

In order to become a member of the EMMA network, several conditions must be met, including the ability and capacity to archive mouse lines and involvement in the mouse research field. Most importantly, the member must be a signatory to a co-operation agreement, the primary purpose of which is to provide long-term, stable funding for EMMA. According to de Angelis, the total number of deposits have increased nearly eight-fold while the number of distributions has increased several-fold over a six-year period ending in 2009. Although EMMA does not initiate research or create its own mutant lines, when its staff recognise multiple different co-morbidities being deposited, it informs the depositing parties.

In order to encourage deposits into the archive, EMMA provides depositors with a grace period during which, at the request of the depositor, EMMA agrees not to distribute the deposited line for up to two years. This gives the depositor time to publish research results or to apply for IP rights associated with the deposited mouse strain. De Angelis noted that some consider this two-year period as insufficient as commercialization of mouse strains typically takes between three and five years. Nevertheless, the period represents a compromise between the interests of depositors and users and has proved effective in increasing the number of deposits. In any event, a two-year lead time is usually sufficient to protect against competitors.

Before EMMA distributes a mouse line to a user, the user must first enter into a material transfer agreement (MTA) with the line's provider. Typically, MTAs have a term of five years and contain either an agreement to acknowledge the source or co-authorship of the provider on any resulting publication. EMMA rarely intervenes in MTA negotiations except where the terms of the proposed MTA are too restrictive. EMMA requests that all depositors grant EMMA a licence covering all relevant IP held by them to allow EMMA to distribute the mouse lines and to permit users to use the mouse line for non-commercial and educational uses. Beyond this, EMMA does not get involved with clearing rights to the mice strains. That is, if a user wishes to either transfer a mouse line or use it for commercial purposes, the user will need to negotiate a licence with whomever holds IP rights over that line.

While EMMA facilitates the archiving and transfer of mouse lines, it does not provide a total solution as it does not deal directly with overcoming transaction costs involved with negotiating individual MTAs. "Within the academic community, processing of MTAs has become a major impediment to the open and timely dissemination of mouse resources and associated data. Onerous terms and conditions in many MTAs have increased transactional costs for institutions and have become a major cause of delay in negotiations and the sharing of resources."[29] One example of good practice is the Jackson Laboratory in Bar Harbor, Maine. "The laboratory provides mice to academic and not-for-profit researchers with the simple notification that the mice are to be used solely for research purposes and are not to be sold or transferred to third parties without permission."[30]

[29] *Ibid.*, p. 172.

[30] *Ibid.*, p. 173.

A clearinghouse by another name: the pool for open innovation against neglected tropical diseases

Clearinghouses are also in use to achieve philanthropic goals. This is true of the – unfortunately named – Pool for Open Innovation against Neglected Tropical Diseases. This industry-led clearinghouse provides researchers with the ability to research, develop, and manufacture therapeutics aimed at one of a list of 16 neglected tropical diseases for sale into least developed countries.

Much progress has been made since the Commission on Health Research for Development noted in 1990 the great imbalance in research directed to diseases predominantly affecting the world's poor as opposed to diseases suffered in high-income countries. Dubbed the "10/90 gap" by the Global Forum for Health Research at its founding in 1998, global expenditures on health research have grown significantly through the first decade of the 21st century. According to David Rosenberg, Vice=President of GSK, 70% of these expenditures have been made by governments, 21% by philanthropy (the largest share of which is from the Gates Foundation) and 9% by industry.

Initial concern focused on infectious diseases primarily affecting the world's poor (the "neglected diseases"). According to Rosenberg, an estimated USD 2.5 billion was spent on R&D into 30 neglected diseases in 2008, but 77% of that money was spent on HIV/AIDS, malaria, and tuberculosis. Outside of these three diseases, there is little incentive for the private sector to invest in developing treatments for neglected diseases.

In response to the need to fund the larger set of neglected diseases, GSK announced in February 2009 that it would establish a patent clearinghouse (although it called it a pool at the time) for certain neglected diseases[31] for the development and manufacture of medicines for use in least-developed countries. While at the time of the workshop, only GSK had contributed patents to the pool, since the spring of 2009, Alnylam Pharmaceuticals and the Massachusetts Institute of Technology have joined the pool, bringing the total number of patents to over 2 300. GSK handed over management of the pool to BIO Ventures for Global Health (BVGH) in early 2010. BVGH, a non-profit funded by companies and foundations, will attempt to attract more companies to join the clearinghouse and will engage in education about it to encourage its use. Also in 2010, Emory University Institute for Drug Discovery, iThemba Pharmaceuticals in South Africa, and the South African Technology Innovation Agency all entered into agreements through which to licence the use of the IP in the clearinghouse.

The clearinghouse has been criticised for being too narrow in scope since it restricts sales to least-developed countries. Use in other developing countries requires the negotiation of a separate licence which each patent holder. Also, the clearinghouse does not include IP relating to HIV/AIDS. GSK has encountered particular criticism for not having joined the UNITAID patent pool, which aims to facilitate the development and delivery of fixed-dose combination and paediatric forms of HIV/AIDS drugs to the developing world. Instead, Viiv Healthcare, the GSK-Pfizer joint venture dealing with HIV/AIDS, has agreed to offer royalty-free licences to generic

[31] The list is as follows: tuberculosis, malaria, blinding trachoma, buruli ulcer, cholera, dengue/dengue haemorrhagic fever, dracunculiasis, fascioliasis, human African trypanosomiasis, leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, schistosomiasis, soil transmitted helmithiasis, and yaws.

companies of its HIV/AIDS portfolio for the manufacture of drugs (including combinations) in all least-developed, low-income and Sub-Saharan countries.[32]

While the interest of the South African Technology Innovation Agency in the clearinghouse is promising, it remains too early to assess its effectiveness. More patent holders need to participate to expand the scope of the clearinghouse and more scientists need to participate – particularly using the standard form licence rather than a negotiated licence – to determine whether this KNM effectively reduces transaction costs and speeds research. Developing and maintaining trust among relevant actors, including NGOs, will be critical.[33]

Open-source clearinghouses

Open source has surprised observers by its success. Based on the idea of ensuring royalty-free access to knowledge, the idea faced much scepticism by critics who claimed that innovation could not take place without the incentive provided by privately held rights. Given that open source relied on altruism and freedom from private rights, it was argued, it could not work. Over time, open source has proved to be a significant mechanism through which to innovate, with major industry actors adopting its precepts.

Open source, like the other KNM explored thus far, involves trading in IP rights. Rather than use IP rights to exclude others (except a limited set of authorised users), however, open source uses IP as a mechanism through which to keep knowledge free for use. In a pure open-source agreement, users not only promise not to burden the knowledge they access with exclusive rights but agree to contribute any knowledge they produce from that accessed knowledge to the clearinghouse on the same terms. Other, less stringent open-source mechanisms do not require the contribution of subsequent knowledge back to the clearinghouse. In the information technology field, the IP right is easy and inexpensive to obtain and maintain: copyright. As copyright arises automatically without the need to register and without following particular legal forms, it leaves a rich environment in which open source can act.

Given the success of open source in information technology, academics and academic institutions have explored the possibility of its use in the life sciences. This is not without difficulty. As Janet Hope, one of the main proponents of open source in the life sciences, explains: "The challenge, then, of modelling open source licensing in bio-technology is to create new licenses that can accommodate the complexity and variety of biotechnology transfer agreements, yet remain faithful to the underlying logic of open source."[34] One of the principal problems faced by life science open source is the heterogeneity of the IP involved: "This technological heterogeneity gives rise to heterogeneous patterns of ownership…. Each technology is thus covered – often incompletely – by a patchwork of different protections."[35] This problem of the complexity of IP rights does not exist with respect to all areas relevant to the life sciences. Software tools used in biotechnology, bioinformatics and databases of knowledge, which are governed by copyright or database protection, sufficiently resemble the IP environment for information technology as to be adaptable to an open-source environment. For the bulk of drug discovery, biofuel development and the creation of new agricultural products, however, the situation is much more complex. In these areas, a combination of patents, plant protection, trade secret and personal property render the proprietary environment confusing.

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32 Viiv Heathcare (2010), Press Release: Viiv Healthcare Announces further Initiatives to Improve Access to HIV Medications for People Living in the Least Developed Countries", *www.viivhealthcare.com/media-room/press-releases/2010-07-16.aspx*

33 OECD, *supra,* note 2; International Expert Group on Biotechnology, Innovation and Intellectual Property, *supra,* note 7, p. 67.

34 Hope, J. (2008) *Biobazaar: The Open Source Revolution and Biotechnology*, Cambridge: Harvard University Press, pp 144-45.

35 *Ibid*, p. 144.

How open source works: the example of the open innovation network

There are many examples of open source in the field of information technology. Linux – as well as the Apache Server and Mozilla's Firefox – is one of the better-known examples. Linux is an open-source operating system, particularly in respect of servers where it is second only to Microsoft. The copyright in the Linux software is freely available through a GNU General Public Licence that requires any improvement to be licensed on the same terms back to all others.

The Linux software community was concerned over the rise of software patenting and, in particular, of patents held by non-practising entities (known as patent trolls). According to Keith Bergelt, the CEO of the Open Innovation Network (OIN), these patents could be used to undermine the freedom on which the Linux community was based. To counter this threat, members of the community created the OIN as a defensive patent clearinghouse focused on ensuring freedom to operate for the Linux community. The OIN uses a multi-faceted approach in order to accomplish this, including the following: acquiring patents in the Linux technology field; performing directed inventions, with the goal of obtaining patents and/or authoring defensive publications to thwart others from seeking patent rights in an as yet undeveloped field; issuing royalty-free licenses to practitioners of and innovators in Linux; assisting those under threat of infringement litigation related to Linux; and identifying prior art relevant to pending patent applications and previously issued patents in order to have applications rejected or patents invalidated.

Bergelt explained that the OIN exists at the periphery of the open source community, solely acting to defend freedom of the community's participants. In particular, it does not play the role of an innovator for the sake of innovating: it innovates only if it deems this necessary in order to defend uncharted territory from others staking patent rights in the future.

The OIN thus represents a new form of KNM that aims less at distributing the right to use units of knowledge, as in traditional open source, than at providing a second layer of protection for an open source environment.

BioBricks Foundation

The BioBricks Foundation (BBF) is an organization that seeks to promote responsible synthetic biology, which it defines as the *de novo* design and fabrication of biological components and systems that do not already exist in the natural world through the redesign and fabrication of existing biological systems and components. As Andrew Torrance of the University of Kansas School of Law explained, the BBF manages a registry of genetic sequence data and physical incarnations of those sequences (embedded in plasmids) – called standard biological parts – that encode basic biological functions that users can mix and match.

The BBF makes standard biological parts available through a standard form open source licence. Under the current draft licence (January 2010), those contributing standard parts agree not to assert any IP rights in respect of both sequence data and physical material produced through the expression of that sequence data. Any user is welcome to use, design, and improve standard biological parts contained in the BBF clearinghouse but, unlike the GNU General Public Licence, is not obligated to contribute improvements or innovations made as a result of using those standard biological parts back to the clearinghouse. According to Torrance, as of 2009, the registry contained approximately 3 200 sequences and was rapidly growing.

Open access

The BBF is an example of an open source KNM that seems to function even in respect of areas related to patents. Nevertheless, the heart of the BBF is data, not physical material even though it crosses the boundary. The real test of the open source model, outside of bio-informatics and biological databases, will be its application in a field dominated by patents, such as in drug discovery. Some question whether open source will ever be a useful model in these fields as the cost of obtaining and maintaining the patents necessary on which to build licences may prove to be prohibitively expensive.

One of the more promising alternatives to open source is open access biotechnology. Unlike open source, which exploits the existence of IP to ensure free access, open access relies on a combination of contract and social norms to ensure access. By purposely not seeking IP rights, open access – also called free revealing[36] – mechanisms are significantly less expensive – there is no filing of patent applications nor any maintenance fees – and are flexible and easy to adapt to new environments. Given the absence of legal rights to enforce compliance, however, these mechanisms rely on the existence of social capital (mainly trust) and broad agreement by leaders on norms of use. While the workshop did not explore any open-access mechanisms, this chapter ends with a brief discussion of them.

The Structural Genomics Consortium (SGC) is an example of an open-access clearinghouse. The SGC is a public-private partnership with funding from governments, foundations and industry working in the area of drug discovery. Initially aimed at identifying the three-dimensional structure of proteins – in which it has had significant success as measured by the number of structures it has contributed to public databases and by the number and quality of the scientific publications it has generated[37] – the SGC has extended its research into the identification of probes to be used in epigenetics research. The SGC has adopted an open-access policy. Under this policy, the SGC will not seek, nor permit its affiliated scientists or collaborators (including from industry) to seek, patents that would grant exclusive rights over its research outputs. Further, it will work with its funders – including major pharmaceutical companies and foundations – to persuade others using the research outputs to similarly forgo patent rights.

Open access is based on two fundamental premises.

The first is that a proprietary attitude to all parts of drug discovery is extremely costly and inefficient:

> The fundamental problem is that industry collectively focuses too many resources on proof-of-concept studies for too few targets, and the studies are done in a proprietary way, with little collective learning. Further, because one 'secret' failure in proof of concept is never enough to dissuade others, these studies encumber the limited resources of industry for years, thereby limiting the ability of industry to pursue new and potentially relevant drug targets.[38]

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[36] Baldwin and Von Hippel, *supra*, note 20.

[37] Weigelt, J. (2009) "The case for open-access chemical biology" 10 EMBO Reports 941.

[38] Edwards, A.M., C. Bountra, D.J. Kerr and T.M. Wilson (2009) "Open access chemical and clinical probes to support drug discovery" 5, *Nature Chemical Biology* 436, p. 438.

The second premise is that obtaining patent protection in order to be able to support an open-source licence is far too expensive. The costs involved include not only the direct costs of patenting, but also of maintaining the secrecy of the unit of knowledge until a patent is filed (in order to meet patent-law requirements), establishing and updating open source licences and managing knowledge contributing under different open source licence terms which can quickly result in an ironic IP thicket.

The SGC has demonstrated that an open access clearinghouse can work, at least in early-stage drug discovery. The question is whether open access can work further downstream, such as in clinical trials39, and in other areas of the life sciences.

Conclusions

Clearinghouses constitute a family of KNM that address some of the difficulties with licensing, markets and patent pools: the costs of individual negotiations (even if based on a model agreement), the exclusion of many who could make use of the knowledge protected by the IP (even if a market for patents exists), and the need for standards in a field in which they do not exist. With their relatively low administrative cost, high flexibility, low antitrust and anti-competitive risk, and decentralised decision-making, clearinghouses have become an important component of the life sciences IP environment.

Much experimentation and improvement in the structuring and administration of clearinghouses is required. As the examples surveyed in this chapter illustrate, some clearinghouses are hampered by their limited scope (as has been claimed in respect of the Pool for Open Innovation against Neglected Tropical Diseases), the limited levels of participation by contributors or the limited nature of the rights cleared (as is the case with EMMA). New forms of clearinghouse continue to arise, however, whether led by industry, foundations or researchers, ensuring innovation in the design and operations of this promising KNM.

39 *Ibid.*

CHAPTER 5
RESEARCH COLLABORATIONS

So far, this report has focused on those elements of KNM that facilitate trade or access to IP rights rather than to the units of knowledge underlying that IP. While this has been the principal purpose of most of the KNM examined so far, many of them also provide mechanisms through which to exchange knowledge itself. For example, a model licence agreement would normally contemplate not only a licence to use IP but also some transfer of confidential information and know-how. The Ocean Tomo patent auction, on occasion, provides access to key personnel who hold knowledge as part of what is being auctioned. Clearinghouses vary in the degree to which they facilitate the exchange of knowledge as opposed to IP rights. The Eco-Commons and the Pool for Open Innovation against Neglected Tropical Diseases contain little in the way of knowledge exchange whereas EMMA, BioBricks and the SGC facilitate knowledge exchange to a larger or lesser degree.

The KNM at the centre of this chapter aim principally at facilitating the circulation of units of knowledge rather than IP rights. Much of this knowledge is sticky – that is, is contained in organisational structures, processes and networks as well as by individuals in carrying out their work – and is thus much less amenable to transfer through formal means such as licence, auction, pool or clearinghouse. Further, the main aim of these KNM is to create new units of knowledge through better use of existing knowledge. They thus engage participants in a longer-term relationship rather than in the *ad hoc* relationship of a typical IP transaction.

The legal forms of these KNM vary and evolve constantly. They include public-private partnerships (PPP), research consortia or collaborations, sponsorship programmes, alliances, and physical and virtual networks. What they all share is a constant exchange of units of knowledge through such means as the exchange of personnel, teams made up of individuals from different actors and networking efforts such as working groups, seminars, annual meetings and so on. Thus, unlike the more market-oriented transactions involved with the KNM in previous chapters, these KNM depend on developing and maintaining trust between participants that goes far beyond what any legal agreement could, by itself, provide.[40]

Collaborative research KNM vary along at least three dimensions: whether they are open or closed to outside actors and whether they are proprietary in the sense that they aim at creating knowledge that will become subject to IP or not. While the KNM surveyed in this chapter are proprietary, this may be more of function of the proprietary instincts of actors within the life sciences rather than a necessary component. A recent survey of Canadian university technology-transfer offices confirmed the emphasis that universities place on obtaining IP rights as a means of earning a profit: "The greatest challenge faced by the TTO is the general misconception of its role, that is, that TTOs are largely an engine of profit, within the broader mandate of a publicly

[40] International Expert Group on Biotechnology, Innovation and Intellectual Property, *supra,* note 7.

funded institution."[41] On the other hand, many of the most promising research KNM, such as the SGC, are non-proprietary. More work is required to elaborate on these KNM.

Industry-led collaborations

Vertex partnerships

Vertex Pharmaceuticals is a company that seeks to develop transformational small-molecule drugs for major diseases. It has four R&D centres in the U.S., Canada, and the United Kingdom that each has stand-alone discovery capabilities. Of interest to the workshop, Vertex has developed business partnerships with major pharmaceutical companies and partnerships with many universities around the world through which it collaborates on drug-discovery projects. Some of these partnerships take the form of technology-based research clusters through which the partners share cutting-edge equipment that would be too expensive for any of them to purchase alone.

John Thomson, Vice-President at Vertex, has highlighted the company's partnership with Harvard University. Under this collaboration, Harvard researchers propose research projects in the areas of oncology, infectious disease, immunology and inflammation, and neurodegenerative diseases, as well as in areas of basic technological enablement. Vertex reviews these proposals and determines which to fund based on the project's ability to provide medical insight and lead to translational possibilities. According to Thomson, the partnership emphasises freedom to explore rather than ownership. Tangible benefits are gained by both partners when knowledge is shared openly. Thomson stressed, however, that before entering into these types of industry-academia collaborations, the parties undertake a careful and candid assessment of each party's true goals.

While not a KNM, Vertex entered into novel funding arrangements with the Cystic Fibrosis Foundation (CFF) that, in the future, could be used to facilitate the exchange of knowledge. Under the arrangement, the non-profit CFF provided funding to the for-profit Vertex to pursue an innovative path to treating the disease: correcting the underlying mechanism of cystic fibrosis by restoring ion channel function. Vertex already had molecules in development that it agreed to accelerate with the CFF funding. The partnership has so far yielded two new drug candidates that have entered into Phase II clinical studies. Thomson stated that one of the key attributes of the partnership is the strength of both partners' commitment and dedication to innovation. To date, it is the largest financial commitment by a non-profit to a for-profit entity for biomedical research.

Vertex is also participating in a programme to investigate potential therapies for tuberculosis (TB) across a network of international research centres in the United States, India and China, with hubs in the U.S. and China. The result is a purpose-driven, integrated, multi-target drug-discovery programme that fosters asset- and knowledge-sharing among the various partners. One of the keys to the TB programme is to seek and obtain local participation through the centres in order to both target appropriate treatments and deliver them to those in need. The recognition of foreign research hubs acknowledges not only the shifting economic balance and the emerging market potential of China, but also its maturing technological prowess. By using the dual-hub approach, Vertex seeks to dissolve artificial knowledge boundaries between geographic borders.

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41 Bubela, T.M. and T. Caulfield (2010) "Role and reality: technology transfer at Canadian universities" 28, *Trends in Biotechnology* doi:*10.1016/j.tibtech.2010.06.002*

According to Thomson, one of the greatest challenges and obstacles faced by Vertex in initiating collaborations and partnerships is the IP protectionism that zealously defends chemical assets, particularly in the pharmaceutical industry. A singular focus on gaining and maintaining exclusive rights over these assets clouds a focus on the real drivers of innovation, such as the sharing of knowledge and skills. Thomson suggested that actors should design partnerships in such a way that the incentives and motivations of the individual parties converge on a shared vision for the project. Rather than focusing on maximising one's individual IP position, the partners should maximise the value of IP to the partnership as a whole vis-à-vis outside parties while maintaining a free flow of knowledge within the network. Thomson was adamant on this last point: freedom to operate should trump ownership in order to enable partners to develop their objectives and innovate new IP without being distracted by acquisitiveness.

Government-sponsored collaborations

Governments can support collaborations through direct participation, funding or providing an infrastructure through which collaborations can be maintained. This section will review some of these mechanisms.

Public-private collaborations for public health (NIH)

In addition to its main function of supporting basic and clinical health research in the United States – which is not infrequently conducted through collaborations – the U.S. National Institutes of Health (NIH) directly enters into research collaborations with industry and academic partners. According to Mark Rohrbaugh, Director of the NIH's Office of Technology Transfer, the NIH values its partnerships with academic and corporate partners and seeks to collaborate with these partners along the full spectrum of the development pipeline. As a government agency, the NIH has a unique role to play in public-private partnerships. First, it serves as a neutral and honest broker among private parties. In addition, it can help to identify and bring diverse parties to the table and to join the partnership. Furthermore, the NIH helps to ensure that the research addresses issues involving public health, open access to data, and fairness in the ways the various parties are treated. Through its participation, the NIH favours the widest public dissemination of IP and data resulting from the publicly-funded research.

The NIH can participate with third parties in a wide variety of collaborations ranging from informal research collaborations, research collaboration agreements, clinical trial agreements, and co-operative research and development agreements (CRADA). The CRADA is typically a collaboration between government and third-party laboratories, in which both parties provide expertise, equipment, materials, and possibly funding, while providing the third party with rights to elect an exclusive option to new inventions and IP generated by the collaboration. Rohrbaugh noted that several products have come to market as a result of CRADAs, including FluMist (influenza vaccine), Havrix (hepatitis A vaccine), Taxol (treatment for solid tumour cancers and Kaposi's sarcoma), Taxus Express (drug-eluting stent for coronary artery disease), Thyrogen (thyroid cancer treatment adjunct), and Velcade (treatment for multiple myeloma). Current examples of ongoing collaborations include a biomarkers consortium to develop promising biomarkers for research, clinical, and/or regulatory uses; an Alzheimer's disease neuroimaging initiative; and an osteoarthritis initiative.

TI Pharma public-private partnerships

Hans Schuitmaker of Top Institute Pharma (TI Pharma) reiterated the conclusion made earlier in this report: despite the enormous amount of money, time, and other resources being poured into drug discovery by the pharmaceutical industry, fewer drugs are entering the market. TI Pharma is one of a number of public-private partnerships created to reverse this trend. (The SGC, discussed earlier, is another.) It aims to improve the efficiency of the entire drug-development process and, in particular, to reduce the time and cost to develop new medicines. Focusing on priority medicines, as defined by the WHO,[42] TI Pharma provides funding, education and supervision to pre-competitive, translational research projects selected through a call for proposals. Its funds come from industry (25%), academia (25%), and the Dutch government (50%).

Schuitmaker explained that there are 44 research consortia funded through TI Pharma. To qualify for support, a consortium must include a minimum of three partners, at least one of which is from industry and another is academic. Most projects are much larger than this: they comprise six to nine participants, including large and small pharmaceutical companies, universities, and/or academic hospitals. The research conducted by the consortia is pre-competitive and is carried out by the consortia until proof of concept (the end of Clinical Phase IIa). Product development beyond this phase is beyond the scope of the consortia and must be conducted by a third party, typically one of the consortium members.

In order to simplify bargaining over IP issues, TI Pharma developed, in conjunction with its partners, what it calls "IP ground-rules" with which all funded consortia must comply. Once a consortium is funded, the consortium members must enter into detailed project agreements that provide specific IP rules as well as project plans, milestones and budgets. The IP ground-rules have several components. First, they state that all participants must not enforce their IP rights against other members of the consortium in carrying out the project. Second, they provide that any patentable knowledge produced through the consortium must be disclosed and evaluated to determine whether a patent ought to be sought. Third, if a new patent constitutes an improvement over an existing patent brought into the consortium from one of its members, that member will have the option of licensing it. Otherwise, the IP will be made available to any member that so desires through a negotiated licence. While this suggests that much of the IP will be licensed non-exclusively, in practice, the smaller companies negotiate with the other parties for areas of exclusivity.[43] Fourth, despite who ends up controlling the IP, all consortium members will continue to have the right to use the underlying knowledge for research purposes. Fifth, any revenues derived from the licensing of the patents will be split as follows: 10% to TI Pharma and the remaining 90% split according to the contributions made by the other partners. Sixth, publications are encouraged but will be reviewed – and possibly delayed – to ensure that they do not disclose any information that would undermine a patent application. Each consortium has one IP co-ordinator assigned to it who is responsible for co-ordinating and managing the entire process from disclosure to licensing.

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42 WHO (2004), *Priority Medicines for Europe and the World*, Geneva: World Health Organization. Priority medicines are defined as those that treat autoimmune diseases (osteoarthritis, chronic obstructive pulmonary disease (COPD)), cardiovascular diseases (cardiovascular, acute stroke), cancer (lung, breast, intestinal cancers), infectious diseases (bacterial resistance, influenza, tuberculosis, HIV/AIDS, malaria), and brain diseases (Alzheimer's, depression – elderly).

43 Van Giessel, J.-F., I. Meijer, and B. Mostert (2008), *Baseline study Innovation Programme Life Sciences & Health*, Technolopolis Group, Amsterdam, *www.technopolis-group.com/resources/downloads/life_sciences/991_LSG_small.pdf*

Schuitmaker observed that, based on TI Pharma's experience to date, several issues recur. First, smaller companies are typically unwilling to share or give up their exclusive IP rights, as they typically have only one or a couple of IP rights. Second, consortium members – even larger universities and companies – do not necessarily know or understand whether they have IP that is of marketable value. Third, to encourage participation in a consortium, members need to have confidence in the other potential participants. One method of accomplishing this is to invite potential members to examine how other successful, projects have been conducted. Fourth, consortia must be flexible and adapt to change, such as those caused by mergers and acquisitions or other corporate reorganisations that could lead to a participant's change in research focus. Fifth, a project is not driven by an organisation, but the individuals who work within it. Thus, there may be instances where the personal interests of the researchers may not correspond to the goals of the project and/or of the participating company. Sixth, there is an inherent tension between the stated goals of the consortium and the interest of the researchers to move beyond those goals. In order to ensure a successful collaboration, partners must be aware of and be prepared to address these issues.

TI Pharma is similar in structure and ambition to other public-private funding organisations, such as Genome Canada. These structures have a complex mandate that is sometimes hard to manage as they are expected to simultaneously support ground-breaking research, training and education, economic development and engagement with both industry and academia. How well these structures compare to other funding and co-ordination mechanisms is not known and would be a useful area for further study.

While the primary ambition of TI Pharma is to create and exchange new units of knowledge, its IP policy is fairly standard and proprietary, at least outside the consortium. The IP ground-rules set up two levels of access to knowledge subject to IP: one for those inside the consortium and another for those outside. Inside the consortium, knowledge can be freely used for the purposes of achieving the goals of the consortium without payment or restriction. That is, those who are inside the "club" have free access to that knowledge. Actors outside the consortium are subject to exclusive IP rights and thus cannot use that knowledge in any privileged way. This division between those inside the club and outside renders the knowledge contributed to and produced by the consortium as a "club good". It represents an expansion of the more traditional IP model in which a single actor – rather than a larger, more diverse group of actors – controls the IP and thus constitutes an important form of KNM with respect to IP.

Treating knowledge produced by a consortium as a club good is not the only alternative. As discussed in the last chapter, this knowledge can also be subject to either an open-source or open-access regime. For example, the Structural Genomics Consortium, discussed in Chapter 4, provides that all knowledge produced by the consortium – with a membership very similar to that of TI Pharma – will be freely available to all. Because the knowledge it produces is not subject to IP, the SGC does not need a dedicated IP co-ordinator, does not need an elaborate IP evaluation process and does not need a significant budget to obtain, licence and enforce IP rights. Its conclusion is that these extra costs far surpass any benefit that it or its consortium members will ever likely derive from seeking IP rights. Whether the TI Pharma or the SGC model is superior – or, more exactly, in which circumstances one or the other model is superior – remains an open question.

MAGNET

Working from the same philosophy as TI Pharma, the Israeli MAGNET program aims at enhancing the long-term and international competitive edge of the country's industrial and research actors through greater co-operation between private and public actors in pre-competitive research in a variety of technological fields. As was the case with TI Pharma, consortia must include a minimum of three industry actors and academic institutions that collaborate on developing marketable high-technology products and services.

Ilan Peled, the Executive Director of the MAGNET program, stated that the program is based on the principle that the synergy between actors will result in products and services with a greater value than if the actors worked independently. The partners work together from gap identification, to action plan development to implementation. As with TI Pharma, projects are created from the bottom up, with groups of actors identifying both gaps and ways to address them. Once their proposal is selected, industrial members of the consortium receive a grant worth 66% of approved research and development costs while academic members receive a grant worth 80% of those costs. Typically, the life span of a consortium is about five years. For industry participants, the real incentive to participate in a MAGNET collaboration is acquiring access to high-quality, cutting-edge technology without expending resources, especially human resources, to do so.

The MAGNET program differs from the TI Pharma's model in two respects.

First, those partners who develop IP get to keep it, rather than the IP being pooled in the case of TI Pharma and allocated later to those partners who desire to have it (except in the case of an improvement patent which is allocated to the party with the original invention). Despite this rule, however, all MAGNET partners are entitled to use the knowledge underlying that patent for their own research and development:

> *A unique feature of the cluster norms in the MAGNET Programme is the intellectual property rights regime. The rights to technology developed within a cluster programme, belong to the developer, but each member of the consortium is granted a free license to use the new technology to develop their own products.*[44]

Second, according to Peled, each MAGNET consortium houses a knowledge centre and organises conferences and working groups. In the two consortia that Peled described – the Bio Tov Consortium, aimed at enhancing the health and taste of foods, and Bereshith, with the goal of developing both stem cells and enabling technology – the consortia created centralised knowledge bases, consisting of data, stem cells and other commonly developed knowledge unit. These structures constituted their own KNM within the larger consortia.

While TI Pharma and MAGNET aim to foster consortia (or clusters, both physical and virtual), each takes a slightly different approach to the knowledge sharing and production. While the legal differences on IP rights allocation are significant, the end result is usually the same: one entity holds title to IP but all partners are entitled to use it. However, in the case of TI Pharma there is the possibility that an actor, often a SME, negotiates for exclusive rights to certain knowledge for defined purposes. Both KNM also engage in the sharing of both sticky and sub-patentable explicit knowledge through training, joint databases and so on.

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44 Cluster Competitiveness Group (2008), *The MAGNET cluster programmes in Israel: a case study for the Commission of the European Communities Enterprise and Industry Directorate-General*, p. 3, *www.clusterobservatory.eu/library/100117.pdf*. See also D. Goktepe (2003), "The Triple Helix as a model to analyze Israeli Magnet Program and lessons for late-developing countries like Turkey" 58 *Scientometrics*, 219-39.

Canada-California Strategic Innovation Partnership

The Canada-California Strategic Innovation Partnership (CCSIP) is a funding co-ordination mechanism aimed at supporting collaborative research, development and delivery projects between research institutions and companies in California and Canada in five focal areas: infectious diseases, high-speed networks, stem cells, alternative energy, and nanotechnology. While CCSIP does not provide funding directly, each partner puts aside limited pools of money to fund its own researchers' participation in joint research endeavours, and additional partners may also provide funding. CCSIP works with those actors and government agencies in Canada and California to identify areas of interest, co-ordinate policies and select projects for support. In selecting projects, CCSIP emphasises a project's capacity to train researchers, attract capital and deal with IP.

According to Angus Livingstone, Managing Director of the University of British Columbia's University-Industry Liaison Office, it was clear from the inception of CCSIP that it would not be feasible to develop universal template agreements or protocols for IP exchange that would be appropriate for all projects developed through CCSIP. Instead, the partners developed a general framework that addresses several broad themes and issues relating to IP, including cross-border issues. For example, the U.S. Bayh-Dole Act requires that products developed as a result of federally funded research be manufactured within the U.S. and also requires the government to maintain march-in rights to the IP associated with those products. The framework includes an inter-institutional protocol for exchanging newly developed IP, a mechanism for transferring newly developed IP to a third party and good practices for the management of newly developed IP.

Cancer stem cell consortium/stem cells for safer medicines

Matthew Herder of the University of Dalhousie explicitly contrasted the IP policies of two consortia that conduct stem cell research. The Cancer Stem Cell Consortium (CSCC) brings together funding agencies in Canada and California interested in furthering stem cell research. In particular, it aims to assemble a large-scale repository of tumour samples from various populations for research purposes, including identifying, validating and commercialising biomarkers. The CSCC funds research and does not conduct it or commercialise it. Thus, all IP belongs to the institutions that conducted the relevant research. The Stem Cells for Safer Medicines (SC4SM) is a public-private consortium that seeks to build stem-cell banks, open protocols and standardised systems in stem cell technology. Unlike CSCC, the SC4SM holds all IP generated by the research it supports and licenses this out to members and third parties on a non-exclusive basis. The SC4SM also licenses in from its members IP needed to conduct research and to allow users of the SC4SM IP to practice it.

While the goal of both consortia is to further stem cell research and, in particular, to develop stem cell banks, their structures differ significantly. Unlike other government-led consortia such as MAGNET or TI Pharma, CSCC does not establish any overarching IP policy to ensure the free flow of knowledge and the ability to use that knowledge within the consortium. On the other hand, the SC4SM goes beyond both MAGNET and TI Pharma in having created a centralised mechanism through which to ensure ease of licensing to third parties in order to maximise knowledge flow and use.

University-led collaborations

GRAVIT

The Grenoble-Alpes Valorisation-Innovation-Technologies consortium (GRAVIT) is a KNM that crosses the border between facilitating the circulation of IP and facilitating the creation and circulation of units of knowledge. It performs the former task by seeking and then licensing IP; it accomplishes the latter by investing in the maturation of a technology through grants and expert assistance.

GRAVIT was founded by four universities and three national research institutes based in the Grenoble in the Rhône-Alpes region of France.[45] According to Jeanne Jordinov, President of GRAVIT, the consortium aims to identify and nurture promising technology from public universities and laboratories until they are ready to transfer to industry. Overall, GRAVIT's objective is to homogenise and simplify practices and tools to accelerate and reduce costs throughout the decision-making process in the R&D process. It does so by conducting technical, economic and IP risk assessments; marketing of IP rights; and developing laboratory prototypes that industry can use as a model for commercialisation. The consortium focuses on both the health and energy fields, especially where the two overlap, such as in medical imaging. GRAVIT receives it funding from both the regional and national government as well as from the European Union.

GRAVIT complements the activities of each public institution's technology transfer office by commissioning market surveys, providing financial assistance and bundling knowledge produced at the different institutions. One of the advantages of the consortium, according to Jordinov, is that it provides a mechanism through which to overcome the different sets of rules and policies at the different institutions by formulating common processes and policies around IP and licensing. Without this co-ordination, IP may be subject to a fractured holding and thus be difficult to license.

The GRAVIT process is as follows. First, GRAVIT issues calls for proposals in certain technological fields. Those individuals within a member institution with a promising technology subject to the call submits it for evaluation. Second, GRAVIT's Selection and Monitoring Committee assesses the proposed technology for its innovative character, market potential, IP position, management vision and transversal character, meaning that it involves more than one discipline or more than one research group within the consortium. Those that the committee accepts move on to the third stage. Third, a GRAVIT officer will spend between 2 and 15 days on an accepted technology in order to develop an action plan with respect to its IP position and market potential, identify the needs of potential users of the technology and develop a budget for implementation of the action plan. At this point, no direct funding is provided to the laboratory that proposed the technology. Fourth, the technology is again presented to the Selection and Monitoring Committee to determine whether to fund the maturation of the technology. If the committee decides to take on the technology, GRAVIT will provide funding to implement the action plan, including the acquisition of IP, the development of a prototype, the conducting of feasibility tests, and the marketing analysis, among other items. Following completion of this stage, the now-matured technology is handed back over to the institutions involved for licensing or spin-off.

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45 The member institutions are: Grenoble Institute of Technology, Joseph Fourier University, Pierre-Mendès-France University, University of the Savoie, Commissariat à l'Energie Atomique, Centre National de la Recherche Scientifique, and Institut National de Recherche en Informatique et en Automatique.

To assist in the above process, GRAVIT created an Intellectual Property Committee. This Committee established a baseline IP policy for all technologies taken on by GRAVIT, evaluates the IP potential of new technologies, and identifies complementary sets of IP.

Jordinov stated that one of the most important lessons learned thus far from the collaboration is that its participants must be willing to continually adapt and learn, even if by trial and error. Flexibility is critical: each partner must adjust to the needs and motivations of the others, leading to greater cohesion and increased benefits for all. Jordinov suggested that, to enable the construction of this type of environment, the organisation needs to be managed by an independent and professional staff whose role is not to make decisions, but to facilitate decision making by the partners.

GRAVIT follows a traditional technology-transfer process with an important twist: it provides funding and expertise at a critical stage in a technology's development between proof of principle and prototype. It also provides an infrastructure through which to combine knowledge units residing in different institutions in order to create a more coherent and valuable proposition to eventual industry partners.

West Coast Licensing Partnership

The West Coast Licensing Partnership (WCLP) is a consortium of seven smaller and like-minded research institutions on the Canadian and U.S. west coast[46] to aggregate technologies in select fields: animal models and biomarkers. According to Angus Livingstone of UBC and leading member of the WCLP, the group purposely excluded larger universities – notably the University of California – and restricted the technologies to those of relatively low or moderate economic value in order to test the idea of a partnership in a low-risk manner. Once proven, the partners may expand both the scope of the partnership to additional fields and to additional partners.

Livingstone explained that the WCLP is an experiment in progress aimed at lessening transaction costs, developing technical expertise, and better fulfilling the social benefits of technology transfer. So far, the WCLP works as follows. First, it licenses not simply IP but also tangible assets containing the expression of knowledge, such as mouse lines. Second, the WCLP licences its technology only on a non-exclusive basis. Third, the consortium bundles technology from different members within it. For example, it has mouse line bundles relevant to oncology, neurology, cardiovascular and obesity as well as biomarker bundles in oncology and neurology.

The WCLP is at an early stage. Livingstone stated that the seven partners have signed a non-binding memorandum of understanding (MOU) that sets the framework for administration, revenue and cost sharing, and IP management. The MOU also contains an inter-institutional agreement (IIA) that all participants have agreed to use with respect to each bundle of technology. Finally, a third party has been selected for processing and fulfilling orders for materials. In the case of mouse lines, this is the Jackson Laboratory. As of 2009, no licences had been issued.

According to Livingstone, the WCLP offers benefits to both member institutions and potential licensees. The consortium permits member institutions to leverage technologies that may be of limited use individually, but may draw greater market pull when aggregated with other similar technology. In addition, it secures greater access to research assets and tools while strengthening

[46] The members are as follows: the University of British Columbia, the British Columbia Cancer Agency, the University of Washington, Fred Hutchinson Cancer Research Center, the Oregon Health & Science University, Scripps Research Institute, and the Salk Institute for Biological Studies.

relationships among the relatively smaller research institutions located on the Canadian and U.S. west coast. For the licensees, the WCLP reduces transaction costs by providing a one-stop, single licence source for animal models and biomarkers from multiple institutions. The licensees obtain not only information and access to the technology they seek, but also added value from related technologies.

One of the main challenges faced by the WCLP was winning the attention of the potential participants to the partnership. By design, the WCLP was formed to bring lesser-known, "low-priority" technologies in the lower third of value in the biological IP spectrum. As a result, it was difficult to gain the time, attention, and resources of key individuals at the various institutions that play a role in licensing IP, entering into collaborations and resource sharing. In addition to identifying and gaining the attention of the potential participants, it is important that any partnership identify and consider practical issues such as logistics of order fulfilment, marketing strategies, and formulas for pricing components of the licensed IP.

While GRAVIT represents an important evolution in technology transfer from a single institution to group of institutions working under common policies and practices, the WCLP opens the opportunity of novel licensing strategies, including broader use of non-exclusive licensing. Both KNM offer lower transaction costs and the potential to turn what otherwise would have been uninteresting knowledge and associated IP when taken on their own into marketable bundles of knowledge and IP.

Conclusions

Knowledge-creating KNM vary in structure, scope, membership and the form of access they provide within the collaboration and to third parties. Some of the KNM are organised through industry, others through government and still others through research institutions. Some are profit-seeking while most are non-profit, at least in terms of the direct outputs of the collaboration. Some seek to facilitate general access to knowledge while others are designed to more efficiently produce a proprietary product. What is noteworthy is that there is no necessary correlation between the type of actor sponsoring the KNM and the proprietary nature of the research outcomes. In fact, some of the most open KNM are those sponsored by industry including SC4SM and the SGC.

CHAPTER 6: POLICY CHALLENGES

Following discussion of the various KNM described in this report, workshop participants discussed the roles of government and the private sector in facilitating the formation of KNM. While much experimentation is taking place, many if not most companies and research institutions lack the knowledge, skill and resources to put together a KNM. In light of this, governments and industry actors can play an important role in advocating for KNM and in supporting their creation.

The role of governments in KNM formation

The policy community has become particularly engaged in discussions over the importance and construction of KNM in the life sciences in the aftermath of the Myriad Genetics case.[47] Two outcomes of that discussion were the 2002 OECD Report on Genetic Inventions and Intellectual Property Rights[48] and the 2006 OECD Guidelines on the Licensing of Genetic Inventions.[49] Various efforts have been made within OECD Member Countries to implement the Guidelines. For example, the Canadian government held various workshops and meetings with technology-transfer agencies. The NIH adopted, at about the same time as the OECD, guidelines of a similar vein. Other countries have similarly held workshops or used more passive means – such as website postings – to implement the guidelines. All candidate countries for accession to the OECD had to demonstrate compliance with the guidelines, and a review of member-country implementation is underway.

In the Canadian example, it was soon realised that, while directed specifically at genetic inventions, the guidelines were of more general application. Further, many if not most of the institutions for which the guidelines were intended did not have policy or guidelines of their own and did not know how to incorporate the OECD guidelines into their own practices. One of the conclusions that Canada was able to draw from its experience is that there is a wide variation in the sophistication and preparedness of institutions to address IP and collaborations. To overcome this heterogeneity, the various government agencies and ministries involved in health, agriculture and science policy will have to co-ordinate their efforts in order to effect change in this sector. It is also critical that each of these entities have a clear direction and mandate for what they wish to implement and achieve.

Policy makers at the workshop noted that there is a need for greater clarity of the drivers for collaboration. In particular, it would be helpful to understand how KNM can be used to leverage public-sector investments in research and to increase knowledge and IP flows between universities and industry. An analysis of gaps in technology transfer and the role that KNM can play in bridging these would similarly assist governments in designing programmes. For example, many technology-transfer offices, particularly in smaller universities and public

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47 For an extensive discussion of the case and the policy response to it, see Gold, E.R. and J. Carbone (2010) "Myriad Genetics: In the eye of a policy storm" *Genetics in Medicine* 12: S39-S70, doi: 10.1097/GIM.0b013e3181d72661; and Drouillard, L, Gold, ER (2009). in *The OECD and Transnational Governance,* Mahon, R., McBride, S., eds, Vancouver: UBC Press, pp. 205-25.

48 OECD, *supra* note 10.

49 OECD, *supra*, note 1.

research organisations, lack the human and financial resources to develop novel KNM.[50] If government can play a role in removing some of the barriers and weights from those smaller technology transfer offices in order to free them to participate in collaborative efforts, this could have important positive consequences on innovation. The government can also play a role in collecting and disseminating information on the innovation environment, such as funding the creation of patent landscapes and data on the social and economic impact of innovation that it funds through its agencies.

Governments have increasingly promoted technology transfer through IP licensing, particularly through the universities.[51] While considerable emphasis has been placed on generating income for universities or economic growth, studies show that most technology-transfer offices do not generate net profits for the institutions involved[52] and that economic growth depends much more on structural and cultural factors than on the existence of IP and university licensing.[53] That is, these studies are making it increasingly apparent that technology transfer needs to be understood as far broader than simply obtaining and transferring IP. One study concluded that is the historic working relationship and training of graduate students who then work in industry that has been responsible for industrial innovation in the U.S. rather than IP policies. As Mowery and Sampat observe: "Indeed, there is some question as to the necessity of a 'patent-oriented' policy to encourage stronger research collaboration and technology transfer."[54]

The OECD Innovation Strategy recognises this shift in understanding of the role of technology transfer away from narrow visions of income generation to knowledge circulation: "However, it has become clear that there are complex trade-offs between stronger public-sector IPRs and increasing knowledge transfer from the public sector to industry."[55] It is within the larger vision of technology transfer, that KNM can play such an essential role. While able to transfer IP rights, as discussed in chapters 2 to 4, KNM are also able to facilitate the circulation of implicit knowledge among actors working on common problems.

Government can play an important role in facilitating the creation of KNM and expanding the role of university and research-institute technology practice to focus more on collaboration and knowledge circulation rather than narrowly on patenting and *ad hoc* licensing. As several of the examples surveyed, particularly in Chapter 5, illustrate, governments can and do establish KNM or act as neutral brokers to bring public and private sector actors together to develop collaborations.

The Dutch experience with TI Pharma is illustrative of how governments can facilitate the creation of KNM. The Netherlands funded a report, prepared through the WHO, that identified medicines that required development for the benefit of both Europe and global health. Based on this report, the government created an agenda, guidelines and policy framework through which develop those medicines. Hence was born TI Pharma, which aimed at accelerating drug development of those medicines through a public-private partnership. This effort elicited

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50 Carbone, J, E.R. Gold, B. Sampat, S. Chandrasekharan, L. Knowles, M. Angrist, and R. Cook-Deegan (2010), "DNA patents and diagnostics: Not a Pretty Picture", 28 *Nature Biotechnology* 784-91.

51 Baldwin and Von Hippel, *supra*, note 20.

52 See, for example, Edwards, Bountra Kerr & Wilson, *supra*, note 41.

53 Mowery, D.C. and B.N. Sampat (2005). "The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?" in *Essays in Honor of Edwin Mansfield, The Economics of R&D, Innovation, and Technological Change*, Link, AN, Scherer, FM, eds., New York: Springer, pp. 233-45.

54 *Ibid* at p. 243.

55 OECD, *supra,* note 2, p. 130.

tremendous interest and participation from the private sector. The idea behind the programme was so successful that approximately one-third of the private actors who had sought, but did not receive, government funding nevertheless went ahead and built a collaboration with partners to whom they had been introduced through the program.

Government can directly facilitate KNM creation by assisting technology-transfer offices at universities and public research organisations – particularly the smaller among these – by encouraging and supporting them in becoming innovation hubs and knowledge brokers. As the examples of GRAVIT and the WCLP illustrate, there is much to be gained by bringing together knowledge and IP held by a dispersed set of institutions in order to facilitate further development. Governments can also sponsor the collection of information – relating to technology and patent landscapes, valuation of knowledge, etc. – that may help technology-transfer offices better identify partners for both collaboration and licensing. Government can also facilitate collaborations by funding shared resources, such as cell or mouse line banks, that are costly to maintain. Finally, governments can assist in resolving disputes either by helping partners resolve disagreements over price or scope of rights or by directly intervening, such as through march-in rights, if the results of publicly-funded research are not used in a manner that serves the public good.

Government can also facilitate collaborations and drive behaviours through indirect policy initiatives. Government can take steps to increase the entrepreneurial spirit amongst academics and researchers. For example, governments can help fund programs that assist academic researchers in developing entrepreneurial skills.

The role of the private sector in KNM formation

Industry has also embraced KNM. In fact, due to the speed of innovation and experimentation of business models, it has almost become imperative for business to do so. Nevertheless, developing and implementing KNM takes time, money and a spirit of openness. Since the onset of the global financial crisis in 2008, some governments and companies have become more conservative in approach and retreated to protectionism. Such approaches pose an obvious challenge to KNM, one that can be overcome by reiterating the importance of these mechanisms to ongoing innovation.

Industry representatives at the workshop noted that KNM, while not the only way to drive innovation, are increasingly important in reducing transaction costs, increasing knowledge circulation and increasing innovation. The goal should be, however, not simply to increase the number of KNM, but also to design them better to meet the needs of all parties. KNM should not, in particular, be seen as an alternative to IP but as a way to better use IP to attain innovation that not only produces profit for the private sector, but meets the real health, food and environmental needs of the community. This is particularly true in an era in which IP has undergone much scrutiny and been subject to much criticism. While much criticism fails to account for the positive role that IP plays in society, some of it is well deserved. KNM go a long way toward addressing those legitimate concerns and advances the social contract between society, IP holders and knowledge users that aims at encouraging innovation for the social good. Participants noted that there is a real risk that if we do not demonstrate the value and use of IP rights, the public may lose understanding of and/or support for IP rights.

The life-sciences field, in particular, is undergoing an extraordinary period of flux and change in business models.[56] To help industry and research institutions adjust to these changes, government support is necessary both in terms of policy development and in respect of funding. Industry participants have called on governments to better allocate and distribute funds that support KNM in a manner that minimises risk to participants. Government could play a greater role in linking together IP, KNM, and capital formation. Finally, more attention needs to be placed on the industrial partners participating in KNM. Most of the discussion at the workshop focused on the perspective of research institutions. More awareness is needed, however, of the needs of industry and the institutions that will develop and/or commercialise knowledge as well.

Participants also noted the growing importance of markets outside of the U.S., Europe and Japan and, in particular, the growth of collaborations with institutions in those markets. KNM must address not only the laws and practices in these major markets, but also the developing laws and policies in emerging markets. For example, China has developed new guidelines for applying its antitrust laws to collaborations. These need to be explored and incorporated into KNM. There is also a critical need to assist companies to establish and familiarise themselves in new, growing, and untapped markets.

Outreach and education are the key to reaching companies that may not yet be aware of the value of KNM. Industry participants noted the need of making policies that make KNM user-friendly and cost-effective so as to encourage participation. Transactional complexities should not be permitted to overwhelm the attempts to create collaborations. Participants noted that, as the examples discussed in previous chapters illustrate, there is no one model of KNM that will suit all needs. It would therefore be helpful to develop tools to enable parties to construct KNM based on a discussion of pros and cons of different structures. The OECD could take a lead in developing these.

Industry participants noted that one of the lessons to be extracted from the examples studied at the workshop was that freedom to operate within KNM needs to be addressed before considering whether the KNM should produce IP and, if so, how that IP is to be allocated. That is, the primary objective of the collaboration should be to maximise the freedom for all partners to explore within their respective priority areas. For example, different parties can be provided with freedom to operate based on diseases of interest. This would permit the parties to avoid distractions outside of their disease area and thus help them to overcome deep-rooted protectionism, especially when it comes to chemical compounds, and can promote sharing of knowledge between the partners.

Participants called for greater efforts in addressing research and development into neglected diseases. Most programs promise very little financial reward for innovating in this area; often, the reward comes to little more than a hope of breaking even after years of investment and effort. When one considers the cost of bringing a small molecule drug to the marketplace from discovery through to research, clinical trials and regulatory processes, cost recovery does not supply a sufficient incentive for even the largest companies to take on the risk of delving into developing a drug for neglected diseases. Innovative funding mechanisms, such as the NIH's priority voucher program, could be studied and explored. Under that program, a company that develops a drug for a neglected disease obtains a voucher that can be used to cut six months off the review period for a subsequent drug approval. While this provides an incentive to large pharmaceutical companies with cash on hand and other products that it is putting through the regulatory approval process, it may not provide much of an incentive to smaller companies with little cash and few products. Other mechanisms to encourage such research are also required.

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[56] Baldwin and Von Hippel, *supra*, note 20; International Expert Group on Biotechnology, Innovation and Intellectual Property, *supra* note 7.

CHAPTER 7
CONCLUSIONS AND FURTHER WORK

Over the last decade, KNM have expanded in number and in ambition as public- and private-sector actors cope with a quickly changing innovation environment. There are several drivers behind these changes.

First, our understanding of innovation has deepened significantly over the past decade. Older models in which innovation is developed within a single firm and protected by exclusive IP rights are waning as newer models based on innovation produced through networks of globally dispersed public and private actors come to the fore.[57] We better understand the nature of knowledge and how its circulation leads to innovation. Explicit knowledge ranges from that which anyone can know, to sticky knowledge that, while written down, can only be fully appreciated by those who have studied and worked in a field. Implicit knowledge is unwritten and is transmitted by working side by side, through training and joint research. Knowledge moves back and forth between actors, opening up the potential for innovation by anyone through whom it passes, including researchers, users or communities.

Second, far from being an esoteric subject, the mechanisms used to drive innovation are now the subject of intense public scrutiny. From the 1999 protests at the meeting of the World Trade Organisation in Seattle onward, civil society has focussed on the ways in which innovation systems in general, and IP in particular, address the health needs of the world's poorest. Governments and industry have listened to concerns over access to medicines, devising new funding mechanisms, more philanthropic efforts and new models of sharing. That HIV/AIDS and neglected diseases continue to go untreated in many parts of the world demonstrates that the challenge of arriving at solutions is ongoing. KNM can help by organising research differently and allowing the rapid dissemination and use of knowledge to combat disease.

Third, innovation has become much more democratic in its functioning.[58] As noted earlier, ever more countries are developing innovation infrastructures and are participating in global research and development networks. In addition, a greater variety of actors create innovation well beyond so-called innovating companies. Further, technological innovation alone is often not sufficient to address important health, food and environmental needs: innovation in policies, institutions and practices are required through public engagement, data collection and analysis and discussion.

KNM have emerged as one of the tools available to address these and other drivers. None of the KNM studied constitutes ideal models of how to form collaborations; each was designed to address a particular set of interests based on existing knowledge, level of aspiration and levels of trust. The trend points to KNM becoming more ambitious in the scope of activities covered, the heterogeneity of the partners and the level of access given to actors outside the KNM. This is a positive progression led by participants themselves as they gain confidence and experience with

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57 Baldwin and Von Hippel, *supra*, note20; International Expert Group on Biotechnology, Innovation and Intellectual Property, *supra* note 7.

58 Von Hippel, E. (2005), *Democratizing Innovation*, Cambridge: MIT Press.

less ambitious KNM. Given the fact of this evolution, governments and foundations should be hesitant before imposing any one model of KNM on actors.

The emergence of KNM

Model agreements and frameworks provide a useful KNM in respect of the transfer of IP within a fairly homogeneous set of transactions and actors. The discussion at the workshop highlighted the point that there is an inverse relationship between the flexibility and malleability of model agreements and their utility. The great value of these agreements is that they can significantly cut transaction costs in negotiating and managing them. The more flexible they are, the fewer these savings are. Other arrangements, such as auctions or the adoption of internal policies and practices, can also help reduce transaction costs involved in identifying partners and negotiating agreements. By bringing some standards to negotiations, all of these KNM make one-to-one contracting more efficient.

Once one enters the realm of multi-party transactions, the KNM landscape becomes more complicated. While model agreements and frameworks may continue to be useful, their costs saving will be reduced as projects increase in complexity and ambition. In these cases, KNM must address a multiplicity of issues, including the availability of financial and human resources, the nature and types of knowledge and best modes of having that knowledge circulate, differing levels of technical expertise, cross-border legal issues and differences in the expectations of the partners. With so many challenges, it is crucial that parties trust each other or the collaboration will fail. It is thus important that potential parties openly discuss their expectations for the collaboration and investigate different ways of constructing the KNM to best meet their goals. Government can play a role by reducing the information and knowledge barrier by bringing together potential partners, by providing environments in which they can get to know each other in order to foster trust, by providing incentives to collaborative efforts and by removing disincentives to partnership.[59]

Two forms of multi-party KNM distinguish themselves: those that aim at circulating IP in explicit knowledge and those the primary purpose of which is to facilitate knowledge creation and circulation. In the first category are patent pools and clearinghouses; in the latter, various forms of public-private partnerships, regional networks, and large-scale, multi-national research consortia. Some of these have, as one of their aims, the production and commercialisation of IP; others aim to create knowledge and have it circulate as widely as possible whether with or without IP. The diversity of KNM highlights not only the differing interests and purposes that bring collaborating parties together, but also innovation by governments, industry and research organisations in designing solutions to meet innovation challenges.

The Workshop identified several overarching themes in respect of KNM. First, KNM are driven as much by a social imperative as an economic one. Challenging existing business models, emphasising the importance of trust, sharing knowledge, and exchanging insights are not easy. Government, university and business leaders need to both emphasise the importance of collaborations to their institutions' success and create an environment in which collaboration is not only not penalised – through restrictions on knowledge sharing, failure to fully count co-authored papers for tenure and promotion, failure to provide resources to administer collaborations and so on – but is actually rewarded. Second, bringing together individuals from different disciplines and different sectors gives rise to problems over communication. Individuals working within a KNM must overcome the different concepts and assumptions that exist in their

[59] Baldwin and Von Hippel, *supra*, note 20.

home discipline so as to communicate together.[60] Government can play an important role in overcoming these barriers by identifying the issues that need to be addressed in designing a KNM, tools through which to address those issues and frameworks and guidelines for the actual design of KNM. The government has an essential role in facilitating the creation of KNM by making more vigorous and robust linkages of innovation, IP strategies and capital development.

Further work

While it is now clear that KNM have become important tools within the innovation landscape, much about how best to construct, implement and assess the performance of them remains unclear. This report contributes to the effort to resolve some of these uncertainties by providing clearer descriptions of KNM currently in use relating to the circulation of IP and to the circulation and creation of knowledge. The examples studied provide a better understanding of the context in which these KNM were created, the motivations of the actors involved and successes to date. What it does not do – and the data needed to do so does not yet exist in a useable form – is provide evaluative tools that would better enable those creating, regulating, investing in or participating in a KNM to ensure that they have selected one of the more appropriate forms of KNM for the problem they are trying to address. Further work is therefore needed with respect to KNM in order to address these needs.

In the short to medium term, four sets of activities would assist policy-makers, industry, funders and research organisations to create better KNM to address their particular concerns. These are discussed in the paragraphs that follow.

First, as noted by several of the participants at the workshop, a guide on how to design a KNM would be very useful. The examples surveyed in this report suggest that, while KNM can vary in size and scope, they contain different sub-mechanisms that comprise the whole. Consider, for example, TI Pharma and the SGC. Both of these consist of one KNM that deals with the circulation of knowledge within the partnership and a different KNM to circulate IP rights inside and outside the partnership. In both, explicit as well as implicit knowledge flows freely within the partnership through an internal IP and knowledge pool. Each differs, however, in the way they deal with third parties. In the case of TI Pharma, licences to non-exclusive IP are provided; in the case of the SGC, all knowledge produced is open access.

A guide to designing KNM would enable those constructing a KNM to identify the types of knowledge that will be used as inputs into the KNM, the knowledge that will be produced within the KNM and the knowledge that the KNM will make available to third parties. The guide will then assist KNM designers to identify how each type of knowledge and IP should ideally circulate among members of the KNM and how they should circulate with third parties. Based on this, the guide would provide possible sub-mechanisms to address the circulation of each form of knowledge and IP within the KNM.

Second, there is a need to conduct qualitative and quantitative comparisons between different KNM operating in the same field. At present, however, there is no agreement on the metrics to be used on conducting these comparisons. Different groups and organisations around the world have begun designing such metrics, but there is little co-ordination or coherence between them. If no attempt is made to harmonise these efforts, governments, funders, industry and research organisations will find it hard to compare different KNM through a standard set of metrics. It would therefore be helpful to all actors if some standard set of measures could be adopted to

[60] Gold E.R. *et al.* (2004) "The Unexamined Assumptions of Intellectual Property: Adopting an Evaluative Approach to Patenting Biotechnological Innovation" 18, *Public Affairs Quarterly* 299.

assess KNM performance. These measures would need to be designed so as not to skew results *a priori* in favour of certain forms of KNM rather than others. For example, if the number of patents or licences obtained were counted as a measure, this would discriminate against KNM based on open-source or open-access methods. Rather than measure such intermediate – and misleading by themselves – factors, metrics should focus on obtaining a reasonable understanding of the effect of KNM on knowledge production (*e.g.* number and impact of peer-reviewed articles), knowledge circulation (*e.g.* number of doctoral students and post-doctoral fellows trained and working in industry) and economic development (*e.g.* number of local or regional companies that co-supervise doctoral students with a partner, engage in personnel exchanges or are located close to a hub).

Third, greater efforts to collect and analyse data are required to identify and support the use of selected metrics. These data collection efforts should aim both at a better understanding of the baseline innovation eco-system in which a KNM operates and at the impact of the KNM on that environment. Patent-landscaping methodologies, databases of licences issues by public research organisations, and data on the number and nature of actors in a given field all help to provide a baseline that will assist in KNM design and implementation as well as in assessing KNM performance. Data on graduate students trained and where they end up working, number and nature of personnel exchanges, number and terms of licence agreements and so on will help measure the difference that a KNM has made on a particular innovation eco-system.

Fourth, there is a need to design KNM that address gaps in the KNM landscape surveyed in this report. For example, there is a dearth of KNM that involve the use of markets to circulate non-patentable explicit knowledge. This knowledge, such as molecular libraries, codified do-how and know-how and so on, is not easily circulated through market mechanisms. Such markets would make knowledge that is currently subject to trade secret available to a broader set of actors. While other KNM, such as research collaborations, help in circulating this knowledge, they do so only between participants in the particular KNM. Further, as noted earlier, smaller companies often do not wish to circulate such knowledge within a partnership as they fear that they will not be able to extract value for the knowledge that they contribute. If this knowledge could be made the subject of a market transaction in which the knowledge provider were able to obtain fair value for its transfer, not only would more knowledge be circulated, but more smaller industrial actors would likely participate in a KNM.

The OECD could play an important role in the work suggested above. Given its Innovation Strategy and its leadership on the study of KNM, the OECD is well-positioned to develop a guide for KNM creation. Further, the OECD could take a leadership role in defining metrics for evaluating KNM. Given its convening power, the OECD could invite industry, government and research groups working on KNM metrics to a workshop, the goal of which would be to establish a set of agreed-upon basic metrics. The OECD can contribute significantly to data collection given its strength in economic and social analysis. Last, developing mechanisms through which to circulate sub-patentable explicit knowledge through the market could be greatly assisted by the analytical strengths of the OECD.

Conclusion

Governments, industry, funders and public research organisations have, over the last decade, become engaged in a growing number of KNM. Given the experience to date, one can now begin to identify common structures, problems and trends with respect to KNM and their operation. This report has provided a survey of a sample of KNM, the motivations that led to their construction, how they operate and how they deal with, respectively, IP and knowledge circulation.

Based on this survey, one can conclude that not only are KNM here to stay, they are quickly evolving. Industry has embraced KNM as a way to overcome increasing cost and risk involved in life sciences research, to obtain access to often diffused knowledge and to engage highly trained personnel. Governments look to KNM as a means of addressing fundamental health, food and environmental concerns through faster, more efficient research. Research organisations increasingly realise that they will ask better questions and obtain better answers to fundamental questions in the life sciences by working with others. Patients, farmers, consumers and the public all wish to obtain the benefits of new technologies, to better understand the consequences of the use of that technology and to have their tax contributions spent on research used more efficiently. KNM provide a set of mechanisms that address each of these concerns.

While the development of KNM has been rapid, it has hardly been systematic. This report, along with other work by the OECD, has attempted to bring some structure to their study and to suggest practical next steps designed to make it easier for actors to create and participate in KNM and to measure the success of those KNM.

ANNEX 1

WORKSHOP ON COLLABORATIVE MECHANISMS: ENSURING ACCESS

Woodrow Wilson Center for Scholars
One Woodrow Wilson Plaza, 1300 Pennsylvania Avenue NW,
Washington, DC 20004-3027

8-9 December 2005

PROGRAMME

BACKGROUND INFORMATION

While the discussion of the use of collaborative mechanisms within the life sciences, and especially in the field of biotechnology is fairly recent, certain organisations have recommended their consideration. Some of the recommendations include:

AUSTRALIA:
Australian Law Reform Commission 99: *Genes and Ingenuity: Gene Patenting and Human Health* (2004)

Recommendation 24–2: The Australian Competition and Consumer Commission (ACCC) should develop guidelines to clarify the relationship between Part IV of the *Trade Practices Act* and intellectual property rights. The guidelines should address:

(a) when the licensing or assignment of intellectual property might be exempted under s 51(3) or might breach Part IV; and

(b) when conduct that would otherwise breach Part IV might be authorised under Part VII of the *Trade Practices Act*.

The guidelines should extend to the exploitation of intellectual property rights in genetic materials and technologies, including patent pools and cross-licensing.

CANADA:
Expert Working Party on Human Genetic Materials, Intellectual Property and the Health Sector to the Canadian Biotechnology Advisory Committee - *Human Genetic Materials: Making Canada's Intellectual Property Regime Work for the Health of Canadians* (October 2005)

• Enhanced voluntary mechanisms to limit unduly restrictive practices and remove barriers to diffusion of HGM-based innovations, for example through development, of licensing guidelines and encouragement of industry initiatives to create patent pools and other mechanisms to remove barriers to diffusion of HGM-based innovations. With respect to HGM-based inventions developed using public funds obtained through federal grants, the granting bodies should develop licensing guidelines adherence to which would be a condition of funding;

Recommendation 10
The federal government, in consultation with industry, should encourage and facilitate the development of patent pools and other mechanisms to remove barriers to diffusion of HGM-based innovations.

UNITED STATES:
National Academies of Science Report: *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (November 2005)

Recommendation 11
NIH should undertake a study of potential university, government, and industry arrangements for the pooling and cross-licensing of genomic and proteomic patents, as well as research tools.

DAY 1 – THURSDAY, 8 DECEMBER 2005

MEETING CHAIR – Joseph Straus

MEETING RAPPORTEUR – Christina Sampogna

INTRODUCTION AND CONTEXT SETTING

This session will provide an overview of the problems that have arisen or that potentially may arise. The Chair will set the context for the discussion of the next two days by outlining the purpose of the Workshop and the desired outcomes.

Chair: **Joseph Straus**, Max Planck Institute

Speakers: **Wayne Grody,** UCLA School of Medicine, *Perspective on Gene Patents from the Academic Medical Center*

Philippe Gorry, Institut BERGONIE, *Effect of Gene Patenting in the Daily Practice of Diagnostic Testing: Past & Future*

Stephen Hansen, American Association for the Advancement of Science (AAAS), *Survey Results of the Impact of Intellectual Property on Scientific Research*

SESSION 1: PATENT POOLS OVERVIEW

As past experiences with regards to patent pools have been in fields other than the life sciences, the purpose of this session will be to draw on the first-hand experiences of individuals involved in these other pools. This session will look at the factors and conditions that favoured the creation of the DVD and the MPEG pools, the challenges that arose in establishing these patent pools, the infrastructure chosen for the establishment of each pool, as well as an overview of how each pool has functioned since its creation.

Chair: **Kenneth Dam**, University of Chicago

Speakers: **Richard Johnson**, Arnold & Porter, *Patent Pools: Overview & The DVD Experience*

Larry Horn, MPEG LA, *The MPEG Experience*

SESSION 2: PATENT POOLS – APPLICATION IN GENOMICS AND GENETICS

The establishment of patent pools is currently generating considerable interest in the field of biotechnology and particularly for genomics and genetics applications. Research on the feasibility of establishing patent pools particularly within the genetics field will be discussed during this session. In addition, the issues and challenges of creating a patent pool in the life sciences will be discussed based on a recently initiated undertaking.

Chair: **Joseph Straus,** Max Planck Institute

Speakers: **Jorge A. Goldstein,** Sterne, Kessler, Goldstein & Fox, *Patent Pools and Standard Setting in the Biotechnology Industry*

Birgit Verbeure, Catholic University of Leuven, *Patent Pools and Genomics*

James Simon, ViroNovative BV, *Patent Pools in Biotechnology - Setting Precedent with SARS*

Discussant: **Barbara A. Caulfield,** Affymetrix Inc.

SESSION 3: FEASIBILITY OF PATENT POOLS – TECHNICAL, BUSINESS AND LEGAL CHALLENGES

This session will focus on the different technical, business and legal challenges that parties interested in establishing a pool could face. Points for consideration and discussion include: what are the important factors/hurdles for establishing a standard in the biotechnology industry; what are the business and economic conditions for establishing a pool; what are the incentives for financiers to invest in or support the establishment of a pool; what are the incentives and disincentives for intellectual property owners' to form a pool.

Chair: **James Simon,** ViroNovative BV

Speakers: **Susan DeSanti,** Federal Trade Commission, *Anti-Trust, Standards and Patent Pools*

Reiko Aoki, University of Auckland, *Lessons from Standard Consortiums*

Richard Johnson, Arnold & Porter, *Business Perspective*

Robert Wells, Affymetrix Inc., *Fostering Innovation through Patent Pools: A Private Sector Perspective*

Discussant: **James Simon,** ViroNovative BV

SESSION 4 FEASIBILITY OF PATENT POOLS – ANTI TRUST/COMPETITION CHALLENGES

Anti-trust concerns are a significant consideration for the establishment of patent pools. This session will include diverse competition authorities' guidelines pertaining to patent pools. Some questions for consideration include what criteria could be employed for determining which patents may, ought to or should not be included in a pool; what incentives are there for members of a pool to invent around or challenge the validity of each other's patents.

Chair: **Joseph Straus,** Max Planck Institute

Speakers: **Frances Marshall,** Anti-Trust Division – DOJ, *Mitigating Competitive Concerns About Patent Pools*

Hiroko Yamane, National Graduate Institute for Policy Studies, *Japanese Guidelines on Standardization and Patent Pool Arrangements*

Alan Gunderson, Competition Bureau of Canada, *Intellectual Property Enforcement Guidelines*

Willard Tom, Morgan, Lewis & Bockius, *Experience of the SARS Pool*

Discussant: **Jorge A. Goldstein,** Sterne, Kessler, Goldstein & Fox

DAY 2 – FRIDAY, 9 DECEMBER 2005

SESSION 1: PATENT CLEARING HOUSES OVERVIEW

Clearing houses have been more prevalent in the entertainment fields, especially for the distribution of music, software and similar products. This session will examine the nature of clearing houses, the manner in which they have been employed, as well as the challenges that may arise in their establishment.

Chair: **Willard Tom,** Morgan, Lewis & Bockius

Speakers: **Jeff Kushan,** Sidley, Austin, Brown & Wood, *Practical Considerations for Clearing Houses for Patent Licensing*

Koichi Sumikura, National Graduate Institute for Policy Studies, *Intellectual Property, Genetic Inventions and Research Tools Consortium*

Discussant: **Brian Stanton**, National Institutes of Health

SESSION 2: PATENT CLEARING HOUSES - APPLICATION IN GENOMICS AND GENETICS

More recently, there has been consideration of whether clearing houses-type mechanisms may be applied to the life sciences field. This session will examine the feasibility and challenges of such an undertaking.

Chair: **Joseph Straus**, Max Planck Institute

Speakers: **Dianne Nicol,** University of Tasmania, *Why Australian Biotech Would Benefit from a Clearing House*

Samuel Abraham, British Columbia Cancer Agency, The BC Cancer Agency's Approach

Geertrui Van Overwalle, Catholic University of Leuven, *Clearing Houses and Genomics*

Discussant: **Richard Johnson**, Arnold & Porter

SESSION 3: ALTERNATIVE APPROACHES

In addition to pools and clearing houses, diverse approaches have been employed to address some of the challenges arising in the biotechnology community. This session will aim to identify the factors that underpin each approach, the challenges, the manner in which each initiative operates, and the lessons learned.

Chair: **Sean O'Connor,** University of Washington, Faculty of Law

Speakers: **John G. Stewart**, Wellcome Trust, *Pre-competitive Collaborations in Genomics: SNP Consortium and HapMap Project*

Janet Hope, Australian National University, *Open Source Biotechnology*

Sara Boettinger, PIPRA, *PIPRA Experience*

Discussant: **Larry Horn,** MPEG LA

ROUND TABLE ON THE "WAY FORWARD"

The aim of this session is to provide an overview of the previous two-day discussions, a summary of the different perspectives, to draw out conclusions and to gather perspectives of options for taking this work forward. All participants will be invited to provide their perspectives.

Chair: **Joseph Straus**, Max Planck Institute

Concluding Remarks

ANNEX 2

Financial contribution from
Avec le financement de

Health Canada Santé Canada

Workshop

Collaborative Mechanisms
For
Intellectual Property Management
in the Life Sciences

PROGRAMME

4 -5 May 2009

OECD Headquarters
2, Rue Andre-Pascal, 75016 Paris

Workshop Objectives

The Department of Health Canada has provided financial contributions for the organisation of this *Workshop on Collaborative Mechanisms for the Management of Intellectual Property in the Life Sciences*. This Workshop will contribute to policy analysis and guidance instruments for collaborative mechanisms for the management of intellectual property. It will also contribute to the OECD Innovation Strategy.

The Workshop aims to:

- Develop a better understanding of the types of collaborative mechanisms for the management of intellectual property that can contribute to creating efficiencies in the life sciences;
- Analyse the objectives, characteristics and utility of each type of collaborative mechanism;
- Examine the challenges and difficulties in establishing such types of mechanisms as well as possible approaches for overcoming such challenges;
- Identify best practices for the establishment, governance, management, and operation of collaborative mechanisms for the management of intellectual property.

Organisation

Each day of the Workshop will open with a keynote speech. On May 4th, the Keynote speech shall be given by OECD Deputy Secretary General Pier Carl Padoan. On May 5th, the Keynote speech shall be given by Commissioner Ian Fletcher, of the United Kingdom Intellectual Property Office. On Day 1 (May 4th), the OECD secretariat will present briefly on overarching challenges facing governments, the public sector and industry in the life sciences and emerging findings. It will also set out the Workshop objectives.

Sessions 1-4 will be moderated sessions organised by category of collaborative mechanisms for intellectual property management. Each Session will consist of speakers presenting on different initiatives. At the end of each Session, time has been allocated for moderated discussions involving the speakers and all workshop participants. A paper has been developed providing background information and questions for discussions.

A moderated Roundtable Policy Discussion (Session 5) will be held on the afternoon of Day 2 of the Workshop (May 5th). This Roundtable Policy Discussion will be organised into three sequential mini-sessions according to type of actor. The mini-sessions will take place in the following order *1)* governments, *2)* public sector and *3)* private sector. For each mini-session, discussion leaders will begin by making an intervention of 5-10 minutes and then will lead the discussion with workshop participants. The focus of the interventions will be on promising approaches; good practices/lessons learned; challenges identified; knowledge gaps; future outlook and key messages; and potential areas/subjects of work for the OECD.

Programme

Monday, May 4, 2009

KEYNOTE ADDRESS

- **Pier Carlo PADOAN**, Deputy Secretary-General, OECD

INTRODUCTION: CHALLENGES AHEAD - FOSTERING INNOVATION AND R&D

Chair: **Iain GILLESPIE**, Head, Science and Technology Policy Division, OECD

This session will describe current and upcoming challenges for governments, industry, universities, research organisations, patient groups, technology transfer offices, and the global community in view of fostering R&D and stimulating innovation as well as set out the workshop objectives.

- *Collaborative Mechanisms for IP: Challenges and Opportunities*
  Christina SAMPOGNA, Science & Technology Policy, OECD
- *Mapping the Market for Licenses*
  Dominique GUELLEC, Economic Analysis & Statistics, OECD

SESSION 1: INTELLECTUAL PROPERTY SHARING: MODEL AGREEMENTS & FRAMEWORKS

Chair: **Margaret MCKAY**, Lead, IP Policy and IP Management Guidelines Project, National Research Council of Canada

- *Collaborative Management of IP in Academia: an Innovative Framework for Networking*

  Jeanne JORDANOV, President, GRAVIT
- *Cross Border Collaborations for Research and IP Exploitation*
  Angus LIVINGSTONE, Managing Director, University-Industry Liaison Office, University of British Columbia

  Matthew HERDER, Visiting Professor of Law, Loyola University Chicago
- *Public-Private Collaborations to Advance Public Health*
  Mark ROHRBAUGH, Director, Office of Technology Transfer, National Institutes of Health, United States
- *The Lambert Toolkit: From Concept to Practice*
  Malcolm SKINGLE, Director of External Science & Technology, GlaxoSmithKline

SESSION 2: COLLABORATIVE INNOVATION

Chair: **Samuel ABRAHAM**, Vice President, Strategic Relationships, British Columbia Cancer Agency, Canada

- *Pharmaceutical Discovery Alliances for the 21st Century: Innovation Alliance Structures for New Discovery Research, Cystic Fibrosis and Tuberculosis*
  John A. THOMSON, Senior Vice President, Strategic Research Alliances, Vertex Pharmaceuticals Inc.

- *Synthesizing Law For Synthetic Biology*
  Andrew TORRENCE, Associate Professor, University of Kansas School of Law

- *Managing Intellectual Property via Public-Private Partnership: TI Pharma*
  Hans SCHUITMAKER, Programme Manager, TI Pharma

- *The Israeli Experience in Sharing Knowledge via MAGNET Consortium*
  Ilan PELED, Director, MAGNET

SESSION 3: CLEARINGHOUSES, EXCHANGES/AUCTIONS, BROKERAGES

Chair: **Richard JOHNSON**, Senior Counsel, Arnold & Porter

- *Open Invention Network and the Rise of Defensive Patent Pools*
  Keith BERGELT, CEO, Open Invention Network

- *Eco-Patent Commons: Companies Pledging Patents to Promote Ecologically-Friendly Innovation*
  Nicolas GROLLIER, Director, IBM Corporation

- *Auctioning of Intellectual Property Rights: Does it Work?*
  Jonathan BARNEY, Managing Director, Ocean Tomo

- *Brokering for Research: European Mouse Mutant Archive*
  Martin Hrabé de ANGELIS, Director, European Mouse Mutant Archive

Tuesday, May 5, 2009

KEYNOTE ADDRESS

Ian FLETCHER, Chief Executive and Comptroller General, Intellectual Property Office of the United Kingdom

SESSION 4: PATENT POOLING

Chair: **Richard JOHNSON**, Senior Counsel, Arnold & Porter

- *Golden Rice and the Importance of Public-Private Partnerships*
  Ingo POTRYKUS, Emeritus Professor, Swiss Federal Institute of Technology
- *Patent Pooling: Innovative Collaboration System in Induced Pluripotent Stem Cell Technology*
  Yutaka TERANISHI, Professor, Kyoto University; Vice Director, Innovation Centre
- *Patent Pool for Research: Neglected Tropical Diseases*
  David ROSENBERG, Vice President, Corporate Intellectual Property Policy, GlaxoSmithKline
- *Addressing Diagnostic Biomarker Patent Thickets*
  William L. GEARY, Jr., Vice President, MPEG LA
- *Patent Pooling & Standards: UHF RFID*
  William DOLAN, Counsel, RFID Consortium
- *Challenges in Establishing Patent Pools*
  Richard JOHNSON, Senior Counsel, Arnold & Porter

SESSION 5: POLICY ROUND TABLE DISCUSSION

Chair: **James SIMON**, CEO, ViroClinics

This session will be a Roundtable discussion involving government delegates, session chairs, speakers, and experts.

- *Characteristics of promising approaches and good practices/lessons learned*
- *Challenges identified and knowledge gaps*
- *Future outlook and key messages*

- *Challenges and Outlook: Government Action & Policy Making*

  Discussion Leaders:

  - **Lisa DROUILLARD**, Department of Industry Canada
  - **Jim HOULIHAN**, Intellectual Property Office/ Department of Innovation, Universities and Skills, United Kingdom
  - **Maurizio TOMASI**, Istituto Superiore di Sanità, Italy
  - **Bart WIJNBERG**, Ministry of Health, Welfare and Sport, The Netherlands

- *Challenges and Outlook: Public Sector*

  Discussion Leaders:

  - **Margaret MCKAY**, National Research Council of Canada
  - **Mark ROHRBAUGH**, National Institutes of Health, United States
  - **Zelina BEN-GERSHON**, National Council for Research and Development, Israel

- *Challenges and Outlook: Private Sector*

  Discussion Leaders:

  - **Richard JOHNSON**, Arnold & Porter
  - **David ROSENBERG**, GlaxoSmithKline
  - **John A. THOMSON**, Vertex Pharmaceuticals Inc.

OECD SUMMARY & CLOSING REMARKS

- **Iain GILLESPIE**, Head, Science and Technology Policy Division, OECD

BIBLIOGRAPHY

Baldwin, C.Y. and E. von Hippel (2009), "Modeling a Paradigm Shift: From Producer Innovation to User and Open Collaborative Innovation" Harvard Business School Working Paper 10-048, available online at: *http://ssrn.com/abstract=1502864*

Bubela, T.M. and T. Caulfield (2010) "Role and reality: technology transfer at Canadian universities" 28 Trends in Biotechnology doi:10.1016/j.tibtech.2010.06.002

Carbone, J, E.R. Gold, B. Sampat, S. Chandrasekharan, L. Knowles, M. Angrist, and R. Cook-Deegan (2010), "DNA patents and diagnostics: Not a Pretty Picture", 28 *Nature Biotechnology* 784-91.

Cluster Competitiveness Group (2008), *The MAGNET cluster programmes in Israel*: *A case study for the Commission of the European Communities Enterprise and Industry Directorate-General.*

Drouillard, L, and E.R. Gold (2009), in *The OECD and Transnational Governance,* Mahon, R. and S. McBride, eds, Vancouver: UBC Press, pp. 205-25.

Edwards, A.M., C. Bountra, D.J. Kerr, and T.M. Wilson (2009), "Open access chemical and clinical probes to support drug discovery" 5 Nature Chemical Biology 436.

Goktepe D. (2003), "The Triple Helix as a model to analyze Israeli Magnet Program and lessons for late-developing countries like Turkey" 58 Scientometrics, 219-39.

Gold E.R. *et al.* (2004) "The Unexamined Assumptions of Intellectual Property: Adopting an Evaluative Approach to Patenting Biotechnological Innovation" 18 *Public Affairs Quarterly* 299.

Gold, E.R., and J. Carbone (2010), "Myriad Genetics: In the eye of a policy storm" *Genetics in Medicine* 12: S39-S70, doi: 10.1097/GIM.0b013e3181d72661

Gold, E.R., T. Piper, J.-F. Morin, L.K. Durell, J. Carboneand E. Henry (2007), *Preliminary Legal Review of Proposed Medicines Patent Pool,* Montreal: The Innovation Partnership, p. 8., *www.theinnovationpartnership.org/data/documents/00000003-1.pdf*

Greenpeace (2005) "All that Glitters is not Gold: The False Hope of Golden Rice". Available online: *www.greenpeace.org/international/Global/international/planet-2/report/2005/5/all-that-glitters-is-not-gold.pdf*

Hope, J. (2008) *Biobazaar: The Open Source Revolution and Biotechnology*, Cambridge: Harvard University Press.

International Expert Group on Biotechnology, Innovation and Intellectual Property (2008), *Toward a New Era of Intellectual Property: From Confrontation to Negotiation*, Montreal: The Innovation Partnership. Available online at: *www.theinnovationpartnership.org/data/ieg/documents/report/TIP_Report_E.pdf*

Mowery, D.C. and B.N. Sampat (2005), "The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?" in *Essays in Honor of Edwin Mansfield. The Economics of R&D, Innovation, and Technological Change*, Link, A.N., and F.M. Scherer, eds., New York: Springer, pp. 233-45.

MPEG LA, Press Release, April 10, 2010. Available online at: http://www.mpegla.com/Lists/MPEG%20LA%20News%20List/Attachments/230/n-10-04-08.pdf

OECD (2002), *Genetic Inventions, Licensing Practices and Intellectual Property Rights: Evidence and Policies,* Paris: OECD.

OECD (2006), *Guidelines for the Licensing of Genetic Inventions*, Paris: OECD.

OECD (2010), *The OECD Innovation Strategy: Getting a head start on tomorrow*, Paris: OECD.

Pisano, G. (2006), *Science Business: The Promise, The Reality, and The Future of Biotech,* Cambridge: Harvard Business School Press.

Pluvia Zuniga, P.M., and P. Guellec (2009), "Who Licenses out Patents and Why?: Lessons from a Business Survey", *OECD Science, Technology and Industry Working Papers*. doi: 10.1787/224447241101

Polanyi, M. (1958), *Personal Knowledge: Toward a Post-Critical Philosophy*, University of Chicago Press, Chicago; and Polanyi, M. (1967), *The Tacit Dimension*, Chicago: University of Chicago Press.

Schofield, P.N., T. Bubela, T. Weaver *et al.* (2009), "Post-publication sharing of data and tools" 461 Nature 171.

Shiva, V., *The Golden Rice Hoax*. Available online at: *http://online.sfsu.edu/~rone/GEessays/goldenricehoax.html*

van Giessel, J-F, I. Meijer, and B. Mostert, (2008), *Baseline study Innovation Programme Life Sciences & Health*, Technolopolis Group, Amsterdam. Available online: *www.technopolis-group.com/resources/downloads/life_sciences/991_LSG_small.pdf*

Viiv Heathcare (2010), Press Release: Viiv Healthcare Announces further Initiatives to Improve Access to HIV Medications for People Living in the Least Developed Countries". Available online at: *www.viivhealthcare.com/media-room/press-releases/2010-07-16.aspx*

von Hippel, E. (1994), "'Sticky Information' and the Locus of Problem Solving: Implications for Innovation" 40:4 *Management Science*, pp. 429-39.

von Hippel, E. (2005), *Democratizing Innovation*, Cambridge: MIT Press.

Weigelt, J. (2009), "The case for open-access chemical biology" 10 EMBO Reports 941.

WHO (2004), *Priority Medicines for Europe and the World,* Geneva: WHO.

WHO (2009), *Global prevalence of vitamin A deficiency in populations at risk 1995–2005. WHO Global Database on Vitamin A Deficiency*, Geneva: World Health Organization.