



PUBLIC-PRIVATE PARTNERSHIPS: SUSTAINABILITY THROUGH BETTER INTELLECTUAL ASSET MANAGEMENT

Prepared for
The Innovation Partnership

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Introduction

Public-private partnerships have achieved a great deal of visibility in recent years.² In the domain of health-related scientific research, the number of such partnerships has grown from a handful to the hundreds³ in response to the declining ability of more traditional models of R&D to generate new medicines generally⁴ and interventions for the world's poor in particular.⁵ Despite this newfound prominence, the sustainability of health-related public-private partnerships, as a model of scientific research and development, is in serious jeopardy. They face criticism from health activists due to the perception – perhaps legitimate in some cases – that they are beholden to corporate interests or overly dependent on the good will of a single sponsor. For their own part, most biotech and pharmaceutical corporations appear hesitant to enter public-private partnerships unless the initiative enhances corporate goodwill, is defined as “pre-competitive,” provides access to scarce resources, and/or the underlying contractual agreements can be gamed to their advantage. And while governments around the world frequently recite the merits of the public-private partnership model, very few countries have offered a consistent source

² To be clear, public-private partnerships operating in the health research domain are the sole focus of this paper. Further information about different types of public-private partnerships that fit within this broad family is provided below.

³ The number of such partnerships varies depending upon what definition of the term public-private partnership is employed. According to a database previously maintained by the Initiative on Public-Private Partnerships for Health (no longer operative), 52 of the 100 or so public-private partnerships engaged in actual product development that now exist were created between 1998 and 2003. No new “product development partnerships” (PDPs), as they are called, have been created since 2003. See Stefanie Meredith & Elizabeth Ziemba, “The new landscape of product development partnerships (PDPs),” in Global Forum for Health Research, *Health Partnerships Review: Focusing collaborative efforts on research and innovation for the health of the world's poor*, 2008, online:

http://www.globalforumhealth.org/filesupld/hpr/HealthPartnershipsReview_Full.pdf. [hereinafter Global Forum, *Health Partnerships Review*]

⁴ According to one source, in recent years an average of only three drugs that work upon novel “targets” (*i.e.* the DNA-based interface where human proteins are made) reach the market. See Brian P. Zambrowicz & Arthur T. Sands, “Knockouts Model the 100 Best-Selling Drugs – Will They Model the Next 100?” (2003) 2 *Nature Reviews Drug Discovery* 38. Similarly, a 2006 United States government report highlights the fact that FDA submissions for new chemical entities have decreased since 1995 notwithstanding substantial hikes in R&D expenditures between 1993 and 2004. See United States Government Accountability Office, *New Drug Development: Science, Business, Regulatory and Intellectual Property Issues Cited as Hampering Drug Development Efforts*, 2006, online: <http://www.gao.gov/new.items/d0749.pdf>.

⁵ Between 1975 and 2004, for example, only 1.3% of all new chemical entities reaching the market were designed to treat so-called “tropical diseases” and tuberculosis. See P. Chirac & E. Torreele, “Global framework on essential health R&D” (2006) *Lancet* 1560. For a good summary of the current crop of public-private partnerships engaged in “neglected disease” research and attendant policy problems, see Mary Moran, “A Breakthrough in R&D for Neglected Diseases: New Ways to Get the Drugs We Need” (2005) 2:9 *PLoS Medicine* 828.



of funding to support them.⁶ Philanthropic sources of funding have instead stepped in. Should donor fatigue occur, many public-private partnerships would be forced to cease operations.

To help ensure that public-private partnerships balance the interests of their various stakeholders and become more sustainable, improved intellectual asset management is necessary. An intellectual asset is any piece of knowledge, whether protected by law or simply useful, that has value to someone, whether the organization holding it or someone else. Although the phrase “intellectual asset management” is used widely by a variety of actors (policy-makers, academics, and business people), it has no commonly accepted definition.⁷ In this paper, the term will be used as follows:

Intellectual asset management refers to a broad range of decisions and actions – from deciding what knowledge has value to whom, whether intellectual property should be sought, through to how that knowledge or intellectual property can be utilized to facilitate further knowledge generation, development of a commercial product, and/or achieve other goals – that can be made by the creators and would-be users of that knowledge.

⁶ Only the United States and United Kingdom have offered consistent funding for product development partnerships. See Anna Wang, “Product Development Partnerships: Public-private partnerships among unequal partners?”, in Global Forum, *Health Partnerships Review*, *supra*.

⁷ Rather than a weakness, the absence of a commonly accepted definition is perhaps the term’s prime virtue: because intellectual asset management does *not* connote a particular view about intellectual property, it can be used without necessarily triggering reactions from opposing viewpoints – a situation that other organizations have, by continuing to centre the discussion around intellectual property, had to address quite delicately. The Centre for Management of Intellectual Property in Health Research and Development (MIHR), for example, offered the following disclaimer at the outset of its report:

Intellectual property is a tool to foster innovation. Intellectual property is here. And here to stay. Whether viewed as a legal concept, a social construct, a business asset, or an instrument to achieve humanitarian objectives, the value of intellectual property cannot be disputed. The notion that inventions can become *property* and can therefore be owned and sold, has encouraged scientists and researchers to invent, and entrepreneurs and companies to invest in innovation, by allowing them to profit from the resulting technologies. But by permitting entrepreneurs to exclude competitors and set higher prices, IP protection may also prevent some individuals, or populations, from being able to access products. There are many ways, however, that intellectual property can be utilized and distributed. Through the publishing of this *Handbook*, the companion *Executive Guide*, and the online version, we intend to help put intellectual property to work for the public sector and the public interest. We agree that intellectual property should be neither feared, nor blindly embraced; rather, it should be *managed* to maximize the benefits of innovation for *all* of society, *especially* the poor.

See MIHR, *Intellectual Property Management in Health and Agricultural Innovation: a handbook of best practices*, vol. 1, online:

http://www.iphandbook.org/handbook/resources_and_tools/Publications/links/ipHandbook%20Volume%201.pdf.



Given the breadth of this definition it is equally important to understand what intellectual asset management is *not* intended to encompass. It does *not* encompass or speak to the various legal standards or criteria embodied in national and international laws and regulations that are used to determine whether a particular technology, information/data, or thing is patentable, copyrightable, or subject to any other form of proprietary protection. Knowledge of these legal standards is highly relevant to intellectual asset management. But advocating for particular alterations to these standards is beyond its ambit.

Better intellectual asset management will not, of itself, resolve problems of access and innovation. Other factors, including legal rules, availability of finance, product regulation and the capacity of health systems, are in play and arguably should be subject to reform. However, improving intellectual asset management can have a significant impact because of the various transaction costs, detailed later, that poor decision-making will inevitably carry. This briefing note aims to demonstrate the value of sound intellectual asset management by a) canvassing different intellectual asset management strategies and tools that can be adapted to suit a public-private partnership's particular objectives and constraints; and, b) illustrating how informed decisions around the use or avoidance of intellectual property can significantly impact public-private partnership outcomes.

We begin with some further background about public-private partnerships (PPPs) and the context in which they are embedded, and then move to examine four individual PPPs and the intellectual property-related issues they have encountered to date in greater depth.

Typologies, Technology Transfer & The Evidence We Have

As a threshold matter, a partnership can be accurately described as “public-private” in our view provided each sector offers some form of support.⁸ Monetary support is, of course, crucial to getting a PPP off the ground but other forms of support are needed as well, such as the availability of laboratories, personnel or technology and know-how. That the contribution from one sector or the other is non-monetary should not therefore exclude an initiative from the PPP family. Moreover, philanthropic foundations can, from our perspective, fulfill the private sector component just as readily as for-profit corporations although the type of support they each bring to the table will typically differ.

⁸ Some question this label and suggest that re-ordering the terms to “private-public” would be more accurate because they see the private sector, not the public one, as the principal beneficiary of such partnerships. Others argue that the term partnership is itself misleading because neither sector contributes or benefits equally.



Having met this threshold condition of public and private support, PPPs can be subcategorized in various ways. There are those that are primarily advocacy organizations, those that aim to facilitate the R&D activities of others by procuring funds and coordinating tasks, as well as partnerships that are directly engaged in some, if not all, stages of the R&D process, from drug discovery, to clinical trials and manufacturing. None of these cadres of activity need be mutually exclusive, hence the difficulty in classifying PPPs along this dimension alone. Alternatively, PPPs may be distinguished based upon what type of scientific project they undertake: some focus upon developing treatments for conditions that disproportionately afflict the world's poor (so-called “neglected” or “tropical” diseases) whereas others tackle “big science” projects, particularly those that have arisen in the wake of the Human Genome Project. But it is woefully misleading to say that big science has less relevance in the developing world,⁹ especially as the disease burden of developing countries shifts with their ageing populations.¹⁰ Despite these shortcomings, both dimensions – type of activity and type of disease – are important to keep in mind when addressing the range of intellectual asset management issues that may arise.

No PPP, moreover, operates in isolation. Each is embedded within broader politico-regulatory, institutional contexts where norms, rules, and practices continuously evolve. And these norms, rules, and practices shape how new knowledge is disseminated and translated from basic discoveries into usable products, in other words, how innovation occurs.

Understanding context is thus critical to whatever successes PPPs ultimately enjoy. Unfortunately, however, technology managers often operate with a mistaken conception of how innovation actually occurs. According to this (mis)conception, innovation is essentially a linear process: publicly funded researchers at academic institutions make scientific discoveries and then disseminate them to the outside world, whether through traditional channels (*e.g.* conference presentations, published articles, graduating students) or more formal means (*e.g.* patent applications, licensing agreements, joint venture agreements, start-up companies). Private companies, in turn, whether acting alone or in concert with the academic researchers and/or other private entities, attempt to develop the initial technology into a product of some kind.¹¹ To complicate matters,

⁹ For example, the Structural Genomics Consortium – one of the four PPPs studied below – helped to generate information about proteins involved in malaria. See Structural Genomics Consortium, Unique Toronto Partnership Solves Structures Of Malaria Proteins: May Lead To New Drugs (25 May 2005), online: <http://www.sgc.utoronto.ca/SGC-WebPages/toronto-news-McLaughlin20050525.php>.

¹⁰ For a summary of disease burdens in the developed and developing worlds, see World Health Organization, The Commission on Intellectual Property Rights, Innovation and Public Health, *Public Health, Innovation and Intellectual Property Rights*, (2006), at 3ff, online: <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>.

¹¹ In conceptual terms, then, putting aside self-described PPPs, all scientific research and subsequent commercialization that is performed in developed countries today can be framed as a partnership between the public sector and the private sector.



transferring knowledge through patents and other formal agreements – a process commonly referred to as “technology transfer” – has become a highly prized activity in the United States,¹² and most other developed countries have sought to foster a similar state of affairs.¹³ Because many of the individuals tasked with managing PPPs have experience in formal technology transfer they may be predisposed to follow the norms and practices that are presently favoured in that culture.¹⁴

The trouble is that what we know about innovation should steer PPPs in a different direction. To begin, empirical data shows that the vast majority of academic research that is picked up by the outside world occurs through traditional channels,¹⁵ what we might term “knowledge transfer” generally (represented in black in Figure 1 below). Knowledge transferred through formalized “technology transfer” comprises the remainder (represented in grey in Figure 1 below).¹⁶ A second related point is that it is

¹² D.C. Mowery, R.R. Nelson, B.N. Sampat, & A.A. Ziedonis, “The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of Bayh-Dole Act of 1980” (2001) 30 Research Policy 99.

¹³ David C. Mowery Bhaven N. Sampat, “The Bayh-Dole Act of 1980 and University–Industry Technology Transfer: A Model for Other OECD Governments?” (2004) 30:1-2 The Journal of Technology Transfer 30 115.

¹⁴ Indeed, the results of an interview-based study conducted by Jon Merz for the World Health Organization indicated that executives of ND-PDPs show a great deal of respect for intellectual property (with only one of respondents admitting to knowingly infringing patents), which Merz attributed to the fact that many of those executives “have corporate biotechnology and pharmaceutical company backgrounds.” See Jon Merz, “Intellectual Property Issues: Public-private partnerships (PPPs)”, at 11ff, Study for the World Health Organization, Commission on Intellectual Property Rights, Innovation and Public Health, online: http://www.who.int/intellectualproperty/studies/intellectual_property/en/.

¹⁵ See *e.g.*, Ajay Agrawal & Rebecca Henderson, “Putting Patents in Context: Exploring Knowledge Transfer from MIT” (2002) 48:1 Management Science 44.

¹⁶ To be clear, this is not intended to be a literal representation of the data that we have. That the amount of information conveyed via formal technology transfer is dwarfed by the amount of information conveyed via other channels can, however, be safely assumed from a variety of sources. Consider the following summary of some of the literature:

Even at institutions such as the Massachusetts Institute of Technology (MIT), where entrepreneurialism and science were wed long before most other U.S. and probably all Canadian research institutions, only a small minority of faculty members in the departments of mechanical engineering and electrical engineering and computer science obtain patents. To be precise, “only about 10-20% patent in any given year, and nearly half of the faculty...sample[d] never filed a patent during the 15-year period under investigation.” Vastly greater numbers of the faculty surveyed publish their research. What is more, Agrawal and Henderson found that patents were estimated to account “for as little as 7% of the knowledge that was transferred from [MIT] labs to industry,” which is consistent with another finding “that only about 11% of the information obtained from university research was transferred through patents.” In fact, industry more often associates knowledge gained from the university by other means (*e.g.* publication; student mentoring; dissemination at conferences) with greater value. Private enterprises in Canada acquire new technologies “off-the-shelf” far more often than via licensing agreements. During a three-year period, from a target population of 675,000 private Canadian enterprises, only 4,120 (or 0.6%) had licensed technologies from universities, hospitals or federal government labs. And this percentage would be even smaller if firms that self-identified as spin-offs from Canadian universities (approximately one third of the 4,120 firms), which may have been incorporated for the very

not only research-oriented firms that innovate, but users as well.¹⁷ Users are particularly good at adapting technology to practical ends, redeploying existing technology in novel ways and in identifying gaps. Enlarging the total pool of potential users – finding creative ways to attract them to a project and allow them to contribute regardless of their institutional affiliations – is thus critically important to developing new and better targeted projects.

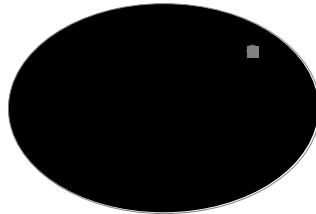


Figure 1. Representation of the ratio of formal academic-industry technology transfer (in grey) to knowledge transfer generally (in black).

Especially for PPPs primarily concerned with upstream knowledge generation (referred to here as “LSRC” or large-scale research consortia) as opposed to downstream product development, these realities should lead to a strong emphasis on broad data dissemination coupled with minimum restrictions on data use. In fact, we are already witnessing a variety of strategies to this effect in the field of genomics research (as shown in the case studies below), from outright dedication to the public domain, to patent pools, to click-wrap licensing. However, a whole set of secondary issues arise around the efficacy of those various strategies and how they can be fine-tuned to achieve a PPP’s stated objectives while coordinating resources made available by and balancing the (potentially conflicting) interests/expectations of the public and private partners involved. These issues will also be highlighted below.

purpose of technology transfer as opposed to independently choosing to do so, were excluded from the sample.

See Matthew Herder, *The Rhetoric of Innovation*, LL.M. thesis (2006, unpublished) at 78-80, citing *inter alia* Agrawal & Henderson, *supra*; W.M. Cohen, R.R. Nelson, & J.P. Walsh, “Links and Impacts: The Influence of Public Research on Industrial R&D” (2002) 48 *Management Science* 1; D.C. Mowery, R.R. Nelson, B.N. Sampat, & A.A. Ziedonis, *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act in the United States* (Stanford: Stanford University Press, 2004); and, N. Rosenberg & R.R. Nelson, “American Research Universities and Technical Advance in Industry” (1994) 23 *Research Policy* 323; and, Statistics Canada, *Public Sector Technology Transfer in Canada, 2003*, at 5, online: <http://www.statcan.ca/english/research/88F0006XIE/88F0006XIE2004018.pdf>.

¹⁷ Eric von Hippel, *Democratizing Innovation* (Cambridge, Mass: MIT Press, 2005).



PPPs undertaking actual product development, more specifically, those targeting neglected diseases (denoted in this paper as “ND-PDPs” or neglected disease product development partnerships) share these coordination-type challenges and likewise stand to benefit from user-driven data exchange and innovation. But because private partners perceive that such ND-PDPs may put their business interests at risk – notwithstanding that ND-PDPs are engaged in areas of R&D that those same private partners have, by definition, neglected to address – successfully negotiating access to and open use of data is an uphill battle. This additional layer of difficulty will be discussed below as well.

In the end, any typology or means of categorizing PPPs and the range of intellectual asset management decisions they face is likely to prove deficient. Within even one subset of PPPs, a wide variety of business models, resources, and approaches to questions of intellectual property can be found.¹⁸ And for that reason, more sophisticated intellectual asset management begins with the adoption of a case-by-case approach. We turn next to four brief PPP case studies (see Table 1 below for background details about each PPP to be examined) with that fundamental point in mind.

LSRC	ND-PDP
<p><i>Structural Genomics Consortium (SGC, 2004-)</i> “The Structural Genomics Consortium (SGC) is a not-for-profit organization that aims to determine the three dimensional structures of proteins of medical relevance, and place them in the public domain without restriction.”¹⁹ Funding for the consortium – \$30 million annually – is provided by the Canadian federal government, the Province of Ontario, the government of Sweden, three pharmaceutical companies (GlaxoSmithKline, Merck, and Novartis), and two foundations (the Knut and Alice Wallenberg Foundation and the Wellcome Trust).²⁰</p>	<p><i>International AIDS Vaccine Initiative (IAVI, 1996-)</i> “IAVI’s mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. IAVI is a global not-for-profit, public-private partnership working to accelerate the development of a vaccine to prevent HIV infection and AIDS. Founded in 1996, IAVI researches and develops vaccine candidates, conducts policy analyses, and serves as an advocate for the field with offices in Africa, India, and Europe. IAVI supports a comprehensive approach to HIV and AIDS that balances the expansion and strengthening of existing HIV prevention and treatment programs with targeted investments in new AIDS prevention technologies. As the world’s only organization focused solely on the development of an AIDS vaccine, IAVI also works to ensure a future vaccine will be accessible to all who need it.”²¹ In 2007, IAVI generated \$100</p>

¹⁸ *Ibid.*, at 6-7.

¹⁹ The Structural Genomics Consortium, online: <http://www.thesgconline.org/index.php>.

²⁰ The SGC’s website does not indicate the relative contribution made by each of the sponsors but roughly 20% of funding is provided by the pharmaceutical companies. The Structural Genomics Consortium, Organization and Funding, at 2, online: <http://www.sgc.utoronto.ca/about/SGC-overview.pdf>.

²¹ International AIDS Vaccine Initiative, About IAVI, online: <http://www.iavi.org/viewpage.cfm?aid=24>.

	million in gross revenue, 89% of which constituted government grants, 6% from private foundations, 4% from multilateral organizations, and 1% from private corporations and individuals. ²²
<p><i>Stem Cells for Safer Medicines (SC4SM, 2007-)</i> “Stem Cells for Safer Medicines is a public-private collaboration whose objective is: To enable the creation a bank of stem cells, open protocols and standardised systems in stem cell technology that will enable consistent differentiation of stem cells into stable homogenous populations of particular cell types, with physiologically relevant phenotypes suitable for toxicology testing in high throughput platforms.”²³ It was “founded via a consortium attracting both public and industry investment, including three major international pharmaceutical companies – GlaxoSmithKline, AstraZeneca and Roche.”²⁴ During the initial pilot phase of the project, a total of £ 1,050,000 will be available (with up to £ 100,000 being provided by each of the three pharmaceutical companies matched with a maximum of £ 150,000 from each of the five government bodies involved).²⁵</p>	<p><i>Drugs for Neglected Diseases Initiative (DNDi, 2003-)</i> Seven organizations, including five from the public sector (the Oswaldo Cruz Foundation in Brazil, the Indian Council for Medical Research, the Kenyan Medical Research Institute, the Ministry of Health of Malaysia, and France’s Pasteur Institute), one humanitarian organization (Medecins sans Frontieres), and one international body (the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) were responsible for the creation of this initiative. Using a virtual model of R&D, “DNDi is developing drugs for neglected diseases on a not-for-profit basis, initially focusing on sleeping sickness, Chagas disease and leishmaniasis.”²⁶ In 2006, DNDi reported receiving 48% of its income from public institutional funding (€ 4,902,153) and the remaining 52% (€ 5,398,048) from five private foundations.²⁷</p>

Table 1. Background information about four PPPs chosen for case study.

Four Case Studies & The Evidence (Cont’d.)

One of the few studies to date regarding PPPs and intellectual property was conducted by Jon Merz for the World Health Organization.²⁸ His study focused solely upon one subset of PPPs; namely, “product-development partnerships” (PDPs).²⁹ The author grouped various issues under two separate headings: contract and intellectual property. Under the

²² International AIDS Vaccine Initiative, 2007 Annual Progress Report, at 40, Figure 1, online: <https://www.iavi.org/viewfile.cfm?fid=49059>.

²³ Stem Cells for Safer Medicines, online: <http://www.sc4sm.org/>.

²⁴ Stem Cells for Safer Medicines, About, online: <http://www.sc4sm.org/about>.

²⁵ Stem Cells for Safer Medicines, Background Briefing, at 3, online: <http://www.sc4sm.org/downloads/SC4SM-QA.pdf>.

²⁶ Drugs for Neglected Diseases Initiative, Questions and Answers, online: http://www.dndi.org/cms/public_html/insidearticleListing.asp?CategoryId=160&ArticleId=309&TemplateId=2.

²⁷ Drugs for Neglected Diseases Initiative, DNDi Annual Report 2006, at 35, 37, online: <http://www.dndi.org/2008/100108/DNDi-AnnualReport-2006.pdf>.

²⁸ The findings of the study were based upon 24 interviews of representatives from 14 different PDPs.

²⁹ Thus his findings may not extend to PPPs generally.



former, Merz highlighted four contractual problems frequently encountered by PDPs: a) difficulties associated with in-licensing technologies from both academic technology transfer offices and private firms; b) inability to resolve manufacturing and distribution issues upfront (the issue of know-how transfer was a particular stumbling block in the case of vaccine manufacturers); c) determining in advance what constitutes a “reasonable” or “affordable” price for delivery of a health-related product in poor settings; and, d) how to segment the market for the end product(s) under development.³⁰ Under the heading of intellectual property issues, Merz noted that the PDPs he surveyed took diverse positions regarding intellectual property ownership, always conducted due diligence to avoid potential patent infringement (although seldom extensively), and encountered relatively few instances of outright patent blocking.³¹

However, it is important to underscore that all of these issues fit under the banner of intellectual asset management.³² Deciding at the outset who amongst the participants in a PPP will own any newly created intellectual property – the researchers? the companies? the PPP itself? or some mix of them all? – can be characterized as an issue of ‘governance.’ Negotiations with partners to allow access to necessary research inputs (*i.e.* in-licensing) or to translate new technologies into finished products to manufacture and sell (*i.e.* out-licensing) can be called an issue of ‘contracting.’ And due diligence to ensure that patents held are valid and that patent rights held by third parties are not infringed during the R&D process can be dubbed ‘good practice.’ But each of these issues of governance, contracting, and practice – to a greater or lesser extent – is connected to a technology or resource in respect of which intellectual property is held or could subsequently be sought and is therefore within the realm of intellectual asset management.

Stepping back for a moment, part of the challenge involved in intellectual asset management is to determine when it is inappropriate to seek intellectual property protection in respect of knowledge because it would run counter to the interests and overarching objectives of the PPP. This challenge is in fact manifold: first, the intellectual asset must be identified; then, the PPP must devise a way to record and monitor it; methods to share the asset amongst the PPP’s researchers and institutions must be devised; and decisions around who can best put the knowledge to use, how to facilitate their participation, and what rules, if any, to attach to the asset, whether for users inside the PPP or perhaps outside the initiative as well, must also be made.

Intellectual asset management is always ongoing (because no agreement can anticipate all future scenarios), and requires a great deal of expertise (because intellectual property, if poorly managed, can impose a range of significant transaction costs quite apart from

³⁰ Merz, *supra* at 8-10.

³¹ Merz, *supra* at 11-13.

³² To be fair, Merz was presumably not trying to classify some issues as intellectual property-related and others as outside that realm.



instances of outright blocking).³³ Table 2 below presents a non-exhaustive list of transaction costs that a PPP may endure depending upon one’s decision-making around intellectual property (note that the table was devised with one form of intellectual property, patents, foremost in mind).

Decision/Event	Transaction Costs
To pursue intellectual property	<ul style="list-style-type: none"> • Costs associated with patent filings (e.g. prior art searches, patent drafting, patent prosecution) • Post-grant costs (e.g. maintenance fees) • Enforcement costs (both out-of-pocket litigation costs and softer costs from being overly aggressive in enforcing rights on others) • Licensing costs (e.g. negotiating licences, monitoring, enforcement) • Costs to knowledge users because the knowledge is not freely available in the public domain³⁴
Decline to pursue intellectual property	<ul style="list-style-type: none"> • Costs of implementing an alternative strategy (e.g. dedication to the public domain; designing an open source policy and license) • Costs of policing that strategy, both amongst the various researchers and organizations involved with the PPP as well as against third parties who may wish to use the data/technology contrary to the terms and conditions of the license (see discussion of parasitic patenting below)
Encounter intellectual property held by a third party	<ul style="list-style-type: none"> • Costs of negotiating a license to utilize the patented data/technology • Inventing around the data/technology (i.e.

³³ For example, Merz notes that that “[f]ew [PDPs] reported cases in which they were unable to secure licences [from patent-holders].” In only two cases were requests for licenses refused, and in one of those two the PDP was able to invent around the technology. See Merz, *supra* at 13. Note, however, that the above statement is not meant to suggest that PPPs would, in every case, be better served by not pursuing intellectual property given the transaction costs they can potentially impose. Rather, the point is that focusing narrowly on instances of outright blocking by a patent-holder omits other decisions/activities (e.g. inventing around the technology; pursuing other avenues of research; implementing an open source type of approach to data sharing) that represent a cost for a PPP, which should inform its intellectual property management strategy going forward.

³⁴ This may not appear to be a cost to the PPP but rather potential outside users of the knowledge that the PPP generates. However, limiting the total pool of potential users to only those researchers and institutions that are formally involved with the PPP does represent an indirect cost to the PPP. The fundamental intellectual asset management question is whether enlarging the pool of potential users to include those outside the PPP would better serve its objectives without compromising the underlying partnership.



	changing the program of research) <ul style="list-style-type: none"> • Challenging the legal validity of the patents through litigation
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Table 2. Potential intellectual property-related transaction costs that a PPP may face.

Throughout the following brief case studies of two LSRC and two ND-PDPs these transactions costs should be kept in mind.

Structural Genomics Consortium

The race to sequence the human genome during the late 1990s and early twenty-first century is often described in black and white terms: as one approach (of releasing the data freely into the public domain) against another (of seeking patent protection over as much of the sequence as possible); as a battle between the noble public sector effort involving scientists from all over the world, particularly the United Kingdom and at the United States’ National Institutes of Health (NIH), and former NIH scientist-turned-profiteer Craig Venter and his company Celera Genomics. The eventual ‘victory’ of the public sector appears to have been deeply influential: several more recent LSRC claim to have endorsed a public domain approach to data release.³⁵ However, this account of the Human Genome Project (HGP) and the initiatives that have followed in its tradition mask other intellectual asset management decisions (and potential tradeoffs) that may be critical to achieving a particular initiative’s goals.³⁶ The Structural Genomics Consortium (SGC) represents a case in point.

The SGC’s decision to release information about the three-dimensional shape of human proteins (*i.e.* their structure) into the public domain is framed in both moral and instrumental terms:

The structures of human proteins in essence is part of the information that defines what it is to be human. Because of the fundamental nature and importance of the information, we place our results immediately and without restriction into the public domain. This not only provides the public with

³⁵ This approach may be traced back to the so-called “Bermuda Statement” in 1996 when publicly funded genomics researchers unanimously declared that “all human genomic sequence information, generated by centres for large scale human sequencing, should be freely available in the public domain in order to encourage research and development and to maximize its benefit to society.” See Human Genome Project Information, Summary of Principles Agreed at the First International Strategy Meeting on Human Genome Sequencing, online: http://www.ornl.gov/sci/techresources/Human_Genome/research/bermuda.shtml#1.

³⁶ It also downplays the importance of the simultaneity of the public and private genome sequencing efforts, which, economists argue may be the best strategy for maximizing social welfare benefits. See Carraro, Carlo, Pome, Alessandra and Siniscalco, Domenico, “Science vs. Profit in Research: Lessons from the Human Genome Project” (August 2001). CESifo Working Paper No. 541; FEEM Working Paper No. 60.2001, online: <http://ssrn.com/abstract=277668>.



this fundamental knowledge, but also allows commercial efforts and other academics to utilize the data freely and without any delay.

“What society wants,” says the SGC's CEO, Dr. Aled Edwards, “is for all this information to be out there, free of charge, no patents, no restrictions. And that's what we do.” The result is greater knowledge about the human body and about the mechanisms of disease. The information also promotes faster drug discovery, bringing potentially life-saving drugs to market sooner and more cheaply.³⁷

Even other collaborators and funders do not receive the data before it is placed online.³⁸

Not all information is open to the public, however. Specifically, the “Target List” – a list of proteins whose structures are unknown and of interest to participating academic and industrial researchers – is kept confidential, not only from the public, but also as between different researchers, companies, and funders involved in the SGC.³⁹ The SGC's Scientific Committee acts as steward of the list, determining which proteins will be studied. The Target List (and, to be precise, what proteins are nominated by whom) is kept confidential because it could reveal the research priorities and business strategies of collaborating private firms.⁴⁰

The *quid pro quo* is as follows: In return for making a financial contribution to the SGC, firms, like public sponsors, are given the right to nominate protein targets for inclusion on the Target List (*i.e.* potentially shape the research agenda), be represented on the Scientific Committee and Board of Directors of the SGC (*i.e.* actually shape the research agenda), as well as second researchers to one of three SGC laboratories (*i.e.* increase researcher know-how).⁴¹ From the perspective of participating firms, then, the confidentiality of the Target List helps to counterbalance any perceived losses associated with the SGC's decision to implement a public domain approach.

While this mechanism is indeed clever, it raises a prior concern around the efficacy of the SGC's strategy of placing protein structures into the public domain. As several commentators have pointed out, placing data into the public domain runs the risk of so-called “parasitic patenting” whereby a firm or individual combines publicly available data with their own privately-held data in pursuit of patented inventions.⁴² Some suggest that this is a *bona fide* risk even where data is made available under a “click-wrap”

³⁷ Structural Genomics Consortium, FAQs, online: http://www.thesgconline.org/about/faqs.php#faq_1.

³⁸ *Ibid.*

³⁹ Researchers (and the parent organizations) are, of course, aware of proteins which they themselves have nominated for inclusion on the Target List. However, they are not made aware of the list as a whole.

Ibid.

⁴¹ In exchange for 3 million GBP, organizations gain the following: “the right to nominate targets to the Target List; the right to nominate a member to the Scientific Committee and the Board of Directors; the right to place scientists to work within the SGC laboratories, under a confidentiality agreement.” *Ibid.*

⁴² See *e.g.*, Rebecca S. Eisenberg, “Genomics in the Public Domain: Strategy and Policy” (2000) 1 *Nature Review Genetics* 70.



license as was done for the International HapMap Project.⁴³ In either case, the goal of ensuring widespread, unencumbered use of the data is potentially compromised.

At present, the HGP provides preliminary evidence that such parasitic patenting can occur.⁴⁴ On the other hand, there is reason to believe that the risk of parasitic patenting is significantly less for protein structures than genes – there is no commercial use *per se* for protein structures whereas diagnostic technologies provide an immediate platform for genetic sequences.⁴⁵ In the end, though, we simply do not yet know how widespread the practice of parasitic patenting has become or, more importantly, whether it exerts a negative impact upon genomic or proteomic research and development.⁴⁶ Only time will tell whether a certain percentage of pending patent applications or issued patents have incorporated data from the SGC, the HapMap Project, or other HGP-styled initiatives, *and* whether those patent rights will be marshaled to the detriment of future research and development.

In the meantime, to the extent that ensuring unencumbered and timely access to data is framed as integral to an initiative's mandate and where the data/technology cannot be invented around – as in the case of the SGC – it is a risk that would seem critical to guard against. And there are several feasible ways to address this risk, including open source licensing, without imposing undue costs upon researchers engaged in upstream research.⁴⁷

⁴³ Donna M. Gitter, “Resolving the Open Source Paradox in Biotechnology: A Proposal for a Revised Open Source Policy for Publicly Funded Genomic Databases,” Social Science Research Network, online: <http://ssrn.com/abstract=901994>. The International HapMap Project is a:

multi-country effort to identify and catalog genetic similarities and differences in human beings. Using the information in the HapMap, researchers will be able to find genes that affect health, disease, and individual responses to medications and environmental factors. The Project is a collaboration among scientists and funding agencies from Japan, the United Kingdom, Canada, China, Nigeria, and the United States. [...] All of the information generated by the Project will be released into the public domain.

See The International HapMap Project, About the HapMap, online: <http://www.hapmap.org/thehapmap.html.en>.

⁴⁴ At the time that the public sector scientists and Celera published their respective findings, several observers alleged that Celera had copied the public sector's results. Celera denied doing so but by 1999 the company had filed patent applications in respect of 6,500 human gene sequences, and by 2000 it had been granted 300 patents. See Andres Guadamuz, “Open Science: Open Source Software Licenses and Scientific Research” (July 19, 2005), online: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=764064.

⁴⁵ Personal Communication with Aled Edwards, Director and CEO of the SGC.

⁴⁶ However, some commentators have speculated that about the harms of the HGP's release into the public domain approach. Rebecca Eisenberg, for instance, writes that “the public sector Human Genome Project has paid a price for this policy, which has advanced the competitive position of their private sector rivals in the race to complete the sequence of the human genome and may have enhanced their patent positions as well.” See Rebecca S. Eisenberg, “Correspondence: The Promise and Perils of Strategic Publication to Create Prior Art: A Response to Professor Parchomovsky” (2000) 98 Mich. L. Rev. 2368 at 2369.

⁴⁷ For example, Gitter, *supra* presents such an open source model in detail.



Box 1 – SGC

Strengths

- Adopts a clear position regarding whether to seek intellectual property rights in respect of newly identified protein structures.
- Offers a well-crafted mechanism (the Target List) to help address the legitimate business concerns of private sector partners while also precluding public sector participants from exerting undue control over the research agenda of the consortium.

Shortcomings

- Fails to incorporate safeguards against the prospect, however remote, of parasitic patenting.

Stem Cells for Safer Medicines

The United Kingdom's newly created Stem Cells for Safer Medicines (SC4SM) initiative, like the SGC, is intended to be “pre-competitive” and, in addition to government and philanthropic funding, is supported by a core group of large pharmaceutical companies.⁴⁸ The overarching goal is also to streamline drug discovery and development but by different biological means. Because stem cell-based therapies remain several years away, the SC4SM plans to utilize stem cells in the interim to test the safety of new drugs, in other words, as predictive toxicology tools.

However, the SC4SM has taken a decidedly different approach to intellectual property than the SGC. Specifically, the SC4SM does not require the prompt release of drug safety data into the public domain once it is generated. Instead, the SC4SM functions more or less like a club: Membership entitles entities participating in the initiative to utilize the intellectual property contributed by other participants as well as any new intellectual property generated as research projects unfold. Entities not participating in the SC4SM may get access to these resources but they are not entitled to them.

This scheme works by setting up two categories of intellectual property: “Background IPR” and “Foreground IPR.”⁴⁹ While ownership of Background IPR remains with each member of SC4SM, they are obligated to “grant to the [SC4SM] a royalty-free, non-exclusive, perpetual, worldwide and sub-licensable licence of its Background IPR solely for the purpose and to the extent necessary for each Project to be undertaken and completed.”⁵⁰ SC4SM is, in turn, responsible for sub-licensing such Background IPR to other “participants” in a research project to ensure its successful completion. If any new

⁴⁸ One company is the same: GlaxoSmithKline is involved with both the SGC and the SC4SM.

⁴⁹ Stem Cells for Safer Medicines, Intellectual Property Rights (IPR) Policy, online: <http://www.sc4sm.org/wp-content/uploads/2007/10/2007-09-sc4sm-ip-policy-final-draft.pdf>. Note that although this policy sets out a number of general principles, “Project Agreements” to be entered into as research projects get underway are to be considered the definitive statement regarding intellectual property and can deviate from this policy if approved by the SC4SM board. *Ibid.*, at 2.

⁵⁰ *Ibid.*, at 4, Article 5.1.1.



intellectual property results from the research project, that is, Foreground IPR, then the SC4SM must grant “a non-exclusive, perpetual, royalty-free, worldwide licence” in respect of same to each participant in that particular project as well as current members in the SC4SM more generally.⁵¹ Third parties that are external to the initiative may, subject to the SC4SM’s discretion, apply for and obtain a non-exclusive license to use such Foreground IPR. In all three cases Foreground IPR may only be utilized for “research purposes.”⁵²

Two sets of questions follow from the SC4SM’s intellectual property policy. The first set is definition-related. According to recent Court decisions, the distinction between ‘research use’ and ‘commercial use’ is increasingly difficult to draw. What exactly, then, does the term “research purposes” as used by the SC4SM encompass? Does it create ambiguity and thus set up future disputes? Moreover, is the distinction between Background IPR and Foreground IPR actually practicable? Or does it too suffer from ambiguity in the sense that some Foreground IPR will likely be unusable without access to related Background IPR as in the case of patented improvements?

A closer reading of the SC4SM’s intellectual property policy reveals that each definitional issue is carefully addressed. While the definitions that delineate the boundary between research use and commercial use are somewhat circular,⁵³ the distinction drawn is straightforward enough when read in light of the SC4SM’s overall objective of fostering more efficient drug development by using stem cells as predictive toxicology tools: The default rule is that members/participants/third parties holding a license to Foreground IPR cannot commercialize (*i.e.* sell, develop, dispose of, or authorize another party to do the same) stem cell technologies as predictive toxicology tools, but they can make full use of those technologies in their individual efforts to commercialize new diagnostics and drugs. If they wish to undertake “direct exploitation” of Foreground IPR, which presumably includes commercializing a stem cell technology as a predictive toxicology tool, they must apply for a license from the SC4SM to do so.⁵⁴ But, in order to ensure that any efficiency gains can be shared with other drug developers in the future, if granted such a license must be non-exclusive.⁵⁵ Similarly, in any situation where a party

⁵¹ *Ibid.*, at 5, Articles 5.3.1 and 5.4.1.

⁵² *Ibid.*, at 5, Articles 5.3.1, 5.4.1, and 5.5.5.

⁵³ This boundary is set by two terms (“research purposes” and “direct exploitation”) and their corresponding definitions:

“Direct Exploitation” means the right to, or authorise others to, develop, sell, dispose, or otherwise commercialise products or processes which are the subject of the Foreground IPR.

“Research Purposes” means the right to, or authorise others working on behalf of the party concerned, to apply (*i.e.* make and use, but not commercialise) IPR for all purposes relating to research, discovery, development, approval and commercialisation of diagnostic or pharmaceutical products.”

Ibid., at 3-4.

⁵⁴ *Ibid.*, at 5, Article 5.7.1.

⁵⁵ *Ibid.*, at 5, Article 5.7.1.



needs access to Background IPR in conjunction with Foreground IPR – whether in the course of an ongoing research project, to practice the Foreground IPR for research purposes, or for the purpose of directly exploiting the same – the terms of SC4SM’s intellectual property policy provide that such a license will be granted.⁵⁶

The more fundamental set of questions triggered by this policy stems from the SC4SM’s decision to capture new intellectual property as toxicology data is generated using stem cell technologies.⁵⁷ The decision to do so is probably attributable to the governmental report from which the SC4SM was born,⁵⁸ which repeatedly cast any failure to seize intellectual property rights as a major threat to the United Kingdom’s competitive interests. But is that actually the case? Given that venture capital interest in stem cell science is relatively low due to various uncertainties associated with the field,⁵⁹ the idea of using stem cell technologies to refine the process of drug discovery and development would seem quite smart. But is generating new intellectual property necessary to achieve that objective? Why not instead make the data available to all members/participants/third parties via a click-wrap license under terms and conditions similar to the HapMap Project’s license? Or, like the SGC, why not simply release the data into the public domain? Either mechanism would likely preclude the creation of new Foreground IPR putting aside the risk of parasitic patenting by third parties. In any event, making the data freely available would still appear to serve the objective of streamlining drug development, and perhaps prove more cost-efficient by shedding the costs of patent prosecution and litigation that the SC4SM has assumed⁶⁰ as well as negating the need to review license applications for use of Foreground IPR. The opportunity costs associated with having to constantly monitor the work for potential IP alone could significantly impede scientific gains that the SC4SM might otherwise make.

⁵⁶ *Ibid.*, at 5, Articles 5.2.2, 5.6.1, and 5.7.1, respectively.

⁵⁷ Beyond licensing any such Foreground IPR to members, participants or third parties in accordance with the terms of its policy, it is not clear what the SC4SM is expected to do with any new intellectual property that it owns.

⁵⁸ See Pattison Report, *UK Stem Cell Initiative, Report & Recommendations* (November 2005), at 63-67, online: <http://www.advisorybodies.doh.gov.uk/uksci/uksci-reportnov05.pdf>. It is tempting to suggest that the pharmaceutical companies that helped found SC4SM may have required the stance taken in the intellectual property policy. That the SC4SM, not individual pharmaceutical companies, retains ownership over any newly created intellectual property would seem to render this unlikely.

⁵⁹ These uncertainties include “an unknown timeframe for and level of return on investment, an unknown business model, and the potential for unravelling of public support upon any high-profile adverse reactions in clinical trials. In addition, the lack of regulatory clarity on the clinical application of stem cells makes the commercial sector even more wary of investing in this area.” *Ibid.*, at 50-51.

⁶⁰ Under Article 8.1, the SC4SM “will have the sole right (at its expense) to: (a) Prosecute and maintain any patents or obtain any other applicable protection covering the Foreground IPR; and (b) Take or defend any infringement or other actions or claims concerning the Foreground IPR.” *Ibid.*, at 6.



Box 2 – SC4SM

Strengths

- Promotes sharing of existing resources (Background IPR) amongst private sector partners.
- Takes into account the realities of R&D, for example, by guaranteeing access to precursor data/technologies (Background IPR) in order to ensure that new data/technologies or improvements can be practiced (which may become Foreground IPR).

Shortcomings

- Neglects to consider the costs of seeking new intellectual property and whether such Foreground IPR is even necessary to achieve objective of streamlining drug development.

International AIDS Vaccine Initiative

Whereas the focus of LSRC insofar as ‘access’ is concerned tends to surround upstream research outputs (*i.e.* data, materials, and tools), ND-PDPs are by definition designed to produce or procure downstream medical interventions for those whom market-based models of R&D have failed. As such, dealing with pricing, market segmentation, manufacturing and distribution issues likely comprise a greater share of ND-PDP intellectual property-related activities relative to LSRC like the SGC or SC4SM.⁶¹ The core principles underlying each intellectual property agreement that the International AIDS Vaccine Initiative (IAVI) enters into reflect this:

IAVI’s intellectual property agreements are tailored for each partner and program, but all define “reasonable price” for developing countries as based on the income level of the country, among other factors. In IAVI’s current agreements, developing countries are those meeting World Bank criteria for lower and middle income countries. The pricing provision applies to the public sector in developing countries, which includes governments and nonprofit organizations.

Should a company funded by IAVI decline to produce a vaccine for developing countries in reasonable quantities at reasonable prices, IAVI will have certain rights to obtain licenses to contract with other manufacturers.⁶²

The adequacy of any provisions designed to achieve ‘reasonable pricing’ and thus equitable access for poorer populations is impossible to discern in the abstract.⁶³ Commentators often warn that incorporating reasonable pricing clauses into R&D agreements simply invites delay in the form of future negotiations. Whether such clauses have impeded IAVI’s efforts to date is not transparent.

⁶¹ For a quick summary of these issues, see Robert Eiss, “Managing intellectual property for global health outcomes: the example of product development partnerships”, in Global Forum, *Health Partnerships Review*, *supra*.

⁶² International AIDS Vaccine Initiative, IAVI’s Intellectual Property Agreements, online: <http://www.iavi.org/viewpage.cfm?aid=40>.

⁶³ Actual intellectual property agreements entered into by IAVI with private sector entities are not available on IAVI’s website.



However, it is clear that existing ND-PDPs, including IAVI, have struggled mightily to deliver meaningful capacity building in developing countries – a benefit that is part in parcel of the stated mission of virtually all ND-PDPs. And the reason, especially in the context of vaccine R&D, is intellectual property-driven.

Vaccine research, although not clotted by patented technologies for the time being,⁶⁴ is typically more complex than drug R&D and requires a significant amount of ‘tacit knowledge’ or ‘know-how.’⁶⁵ Companies engaged in vaccine research therefore effectively treat their employees’ cumulative knowledge and skill sets as trade secrets, and are accordingly reticent to partner with developing world organizations, especially at the manufacturing phase. There are some positive developments. There is one reported success story of a meningococcal conjugate vaccine being manufactured and produced by a group of public sector organizations, researchers, and companies outside the developed world. As well, a group of developing world vaccine suppliers appears to be emerging.⁶⁶ But concrete ways of offsetting potential losses in know-how, possibly inciting greater private sector participation in IAVI’s projects and, in turn, greater researcher capacity building in the developing world, are also worth exploring.

For example, building a non-compete clause (with certain territorial limitations) into a research agreement would – assuming it is enforceable – mitigate the impact of any know-how losses associated with capacity-building in a developing country.⁶⁷ Confidentiality agreements could be paired with non-compete clauses to serve essentially the same function.⁶⁸ Whether these and other contractual devices present acceptable tradeoffs to either private entities or ND-PDPs would presumably vary case-by-case. To date, however, ND-PDPs do not seem to have explored the full suite of management tools available to facilitate capacity building while appeasing intellectual property-related concerns.

⁶⁴ This appears destined to change in several sub-fields of vaccine research. Patenting activity in relation to the H5N1 avian influenza virus has, for instance, increased dramatically in recent years. See World Health Organization, *Working Paper: Patent issues related to influenza viruses and their genes*, at 11-12, online: http://www.who.int/csr/disease/avian_influenza/WIPO_IP_%20paper19_10_2007.pdf.

⁶⁵ For this reason the comment is often made that there is no such thing as a generic vaccine manufacturer.

⁶⁶ See F. Marc LaForce, Kader Konde, Simonetta Viviani, & Marie-Pierre Preziosi, “The Meningitis Vaccine Project” (2007) 25 Supp. Vaccine A97; and, Luis Jodar, F. Marc LaForce, Constante Ceccarini, Teresa Aguado, & Dan M. Granoff, “Meningococcal conjugate vaccine for Africa: a model for development of new vaccines for the poorest countries” (2003) 371 Lancet 1902.

⁶⁷ A non-compete clause is more likely to be enforceable if it is 1) clearly tied to a trade secret, 2) limited to a specific geographical area, and 3) otherwise drafted as narrowly as possible.

⁶⁸ Confidentiality agreements are generally more enforceable than non-compete clauses, but they should be drafted narrowly as well.



Box 3 - IAVI

Strengths

- Preserves the right to contract with third parties in the event that a manufacturing partner fails to meet reasonable pricing obligations (thus potentially lessening further delays).

Shortcomings

- Fails to provide a clear position regarding intellectual property.
- Fails to tackle directly the capacity building issue and utilize available contractual mechanisms to mitigate know-how/trade secret concerns of private partners.

Drugs for Neglected Diseases Initiative

The intellectual property policy put in place by the Drugs for Neglected Diseases initiative (DNDi) is worded as flexibly as possible, making it clear that DNDi will opt to do whatever appears best in each case in terms of ensuring that patients suffering from neglected diseases will have affordable and equitable access to any developed treatments, from disseminating its research outputs into the public domain, to acquiring and enforcing intellectual property rights in the service of public health:

DNDi will ensure that the results of the work carried out under its auspices are disseminated as widely as possible and its products made readily available and affordable in developing countries. Where the acquisition of IP is not necessary to promote its mission and goals, DNDi will make all possible efforts to ensure that the results of its work are placed and remain in the public domain. However, it is possible that promoting DNDi's mission and goals will sometimes require outputs to be protected by IP...Given the costs involved, patenting is likely to be the exception rather than the rule. Other non-patent types of IP such as confidential information ("trade secrets") and copyrights will also need to be considered.⁶⁹

The policy goes on to outline in considerable detail – especially in comparison to IAVI's intellectual property policy – why DNDi is open to acquiring intellectual property, under what circumstances, and various boundaries around how it will negotiate access to and use of intellectual property with potential partners. The bottom line is that "DNDi will not accept projects in which IP is obviously going to be an insurmountable barrier to follow-up research on behalf of DNDi and/or equitable and affordable access."⁷⁰

⁶⁹ Drugs for Neglected Diseases initiative, About DNDi, DNDi's Intellectual Property Policy, online: http://www.dndi.org/cms/public_html/insidearticleListing.asp?CategoryId=87&ArticleId=320&TemplateId=1.

⁷⁰ *Ibid.*



Harnessing intellectual property to ensure affordable and equitable access is not without historical precedent.⁷¹ However, DNDi's policy evinces a rare degree of sophistication in intellectual asset management. And, contrary to general belief, the policy does not appear to be unacceptable to industry. Having steered the development of a fixed-dose formulation of artesunate amodiaquine (AS/AQ) for the treatment of malaria (and co-formulation in small, easy to swallow, water-soluble tablets for children), DNDi entered into an agreement with Sanofi-Aventis to produce and distribute the drug at a “target price of less than \$1 for an adult treatment and for \$0.5 for children to the public sector, international organisations, and NGOs.”⁷²

Despite this success, DNDi continues to encounter significant intellectual property-related barriers. One particular concern is tied to the libraries of chemical compounds held by pharmaceutical companies. Although select companies have made scores of data housed in these libraries – data that is typically unpatented but treated as proprietary because it holds tremendous value in terms of each company's ongoing R&D activities – available to DNDi, each company has stipulated that its body of data must be kept separate from the data of others.⁷³ This renders the process of identifying promising drug leads for neglected diseases from these compound libraries vastly less efficient than it might otherwise be. As one group recently explained in great depth, the degree of overlap between compound libraries of large pharmaceutical companies is not known but could be substantial. Thus, screening each company's compound library over and over again for new drug targets – a costly and time-intensive process – may, to a significant extent, constitute a redundant exercise.⁷⁴ The authors propose an elaborate mechanism to improve this process, to be implemented at a national level in order to foster systemic collaboration amongst academic scientists and ‘big pharma.’ Whether such a broad policy-based solution will be implemented in the foreseeable future is open to speculation. For DNDi, the ability to combine compound library data poses an immediate challenge, one of intellectual property-related negotiation and contracting.

⁷¹ For example, F.G. Banting, C.H. Best and the University of Toronto were lauded for the decision to patent a method for making insulin in order to monitor its safe production while making it freely available and entering several cooperative agreements to produce and distribute the new drug. See Charles Weiner, “Patenting and Academic Research: Historical Case Studies” (1987) 12 *Science, Technology, & Human Values* 50.

⁷² Sanofi-Aventis also agreed to “give 3% of private sector sales revenue to DNDi which DNDi will use to reduce the price of treatment to the public sector.” See *Drugs for Neglected Disease Initiative, Newsletter, DNDi-Sanofi Aventis sign agreement on AS/AQ*, online: <http://www.dndi.org/newsletters/10/partnership.htm>.

⁷³ Personal communication with Bernard Pecoul, Executive Director of DNDi.

⁷⁴ Arti K. Rai, Jerome H. Reichman, Paul F. Uhlir, Colin R. Crossman, “Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery” (2008) 8:1 *Yale Journal of Health Policy, Law, and Ethics*, Social Science Research Network, online: <http://ssrn.com/abstract=1085027>.



Box 4 - DNDi

Strengths

- Explains in detail DNDi's approach to intellectual property and openness to a variety of strategies provided its core objectives are not sacrificed.

Shortcomings

- Fails to secure interoperability of compound libraries held by private sector companies.

Conclusions

None of the foregoing case studies (and accompanying boxed summaries of each PPP's 'strengths' and 'shortcomings') does justice to the accomplishments of PPPs to date. There are many success stories. To name only two: In July 2007, the SGC surpassed its own goals by identifying 455 new protein structures of relevance to human health, and now has generated 20% of all the human protein structures ever solved. That same year, DNDi delivered its first product, AS/AQ, a fixed dose antimalarial suitable for poor rural populations and children.

In addition, the very fact of these PPPs and the alternative modes of doing science that they represent, are helping to reshape the way R&D is done. Industry is taking note. The Chief Medical Officer of Pfizer has, for instance, stated that the new business models that PPPs and other collaborative initiatives employ ought to be increasingly central to pharmaceutical companies' R&D strategies.⁷⁵

At the same time, the sustainability of PPPs remains in doubt. Government funding is inconsistent and concerns around transparency and accountability appear to be growing.⁷⁶ Improved intellectual asset management is not a panacea but it does promise to defray at least some of the costs PPPs endure. It can also help address transparency and accountability concerns by striking a balance between the interests and expectations of all parties involved and the stakeholders or constituencies that they serve.

All four of the PPPs studied above recognize intellectual property as an important element, typically, by devising a formal intellectual property policy or position and posting it online. These policies vary significantly in terms of content and level of detail. But there is a common thread. In each case, there is some kind of failure to translate the PPP's vision or position with respect to intellectual property into action or agreements that best serve the PPP's overarching goals. In some cases this may be attributable to a failure on the part of the architects of a PPP to anticipate the downstream costs of seeking intellectual property rights. Recall the SC4SM's decision to pursue the creation of so-

⁷⁵ Joseph Feczko, presentation at the Organisation for Economic Co-operation and Development High-Level Forum – Medicines for Neglected and Emerging Infectious Diseases: Policy Coherence to Enhance their Availability, Noordwijk-ann-Zee, The Netherlands, June 21, 2007.

⁷⁶ See generally Global Forum, *Health Partnerships Review*, *supra*.



called “Foreground IPR” or the SGC’s lack of protection against parasitic patenting. In others the ideal research agreement from the viewpoint of the PPP may simply be a ‘deal-breaker’ in the eyes of (private) partners. Perhaps providing for the creation of Foreground IPR was a stipulation of the pharmaceutical companies supporting the SC4SM. Think also of DNDi’s inability to secure interoperable access to private compound libraries.

Two types of services can help to remedy these diverse intellectual asset management failures. The first is predictable: greater capacity-building in the area of intellectual asset management. Unfortunately, most capacity-building teaches old models of technology transfer and does not develop the new models that the leading PPPs are experimenting with. Capacity-building aimed at creating a pro-active set of managers is instead called for – managers that have the expertise to inform and guide PPPs through the following sub-sets of intellectual asset management questions:

Asset Identification

- What intellectual assets does each partner contribute to the PPP?
- What intellectual assets are the PPP expected to generate?
- What strategies are available to monitor for any unexpected intellectual assets?
- How will diverse intellectual assets be measured?

Non-Proprietary/Proprietary Tradeoffs

- What are the costs and benefits of seeking intellectual property protection in relation to each genre of intellectual asset?
- How does intellectual property, or its absence, facilitate or impede contributions from knowledge users both inside and outside the PPP?
- Does seeking intellectual property rights serve the interests of one partner (or category of partner) more so than the others and/or compromise the PPP’s overall objectives? If so, is that partner’s position potentially misinformed by an incorrect understanding of intellectual property?

Asset Utilization

- What is the optimal method of disseminating and sharing intellectual assets, whether existing or to be developed?
- What formal or informal incentives, if any, should be associated with asset use?
- What rules or restrictions, if any, should be placed upon asset use?

The second remedy is less obvious but perhaps more critical: the development of mechanisms that overcome the tension between flexibility to address private interests and a commitment to open access – a tension that is at the heart of many of the foregoing questions. One of the most promising mechanisms is the introduction of a third party, trusted actor. That party can mediate concerns over the life of projects in a confidential setting. The parties to a PPP can therefore set out their objectives and concerns and then



establish a mediation procedure using this third party actor to develop solutions as the project matures and issues arise. At present, there are unfortunately very few organizations that are able to provide these services.⁷⁷ However, a newly created non-profit consultancy comprised of intellectual property experts – “The Innovation Partnership” (TIP) – hopes to offer these services to interested public-private partnerships going forward.

⁷⁷ This is especially true in the wake of the demise of “MIHR,” the Centre for Management of Intellectual Property in Health Research and Development, which previously undertook a considerable amount of capacity building activities. See MIHR, A Statement from the Board of Trustees, online: <http://www.mihr.org/>.