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**A Cultural Commons Study of New Approaches to Drug Development:  
Case Studies from the Fight Against Malaria**

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**ABSTRACT:** The failure of the patent-driven, proprietary approach to drug development to provide treatments for diseases endemic in the developing world has led to a plethora of drug development initiatives involving public, philanthropic, and private entities (and every combination of these types) advertising themselves as “open”, “collaborative,” and so forth. While it is still too early to come to definitive conclusions about the effectiveness of the various efforts, we believe that it is possible and desirable at this point to begin to analyze the structure and governance of these projects. In particular, we suggest that the concept of “openness” in the context of drug discovery and development should be interrogated and refined, so that the institutions now being described as “open” can be distinguished and more clearly analyzed. To delineate a manageable cohort, we consider projects aimed at developing malaria drugs. In this initial paper, we focus on approaches aimed at involving private pharmaceutical companies in tackling neglected diseases. We compare three types of projects aimed at inducing private sector involvement: prizes and related approaches aimed at providing pecuniary incentives for developing drugs for neglected diseases, “public-private partnerships,” and arrangements for providing “open” access to intellectual property. In particular, we embark on a detailed case study, using the constructed cultural commons framework, of the Pool for Open Innovation for Neglected Tropical Diseases (POINTD), since it is the newest and least studied of these projects. The present draft is a work-in-progress based entirely on a literature review and study of publicly available documents. We plan to extend the case study with interviews of POINTD participants.

**NOTE TO READERS:** This is a very early work-in-progress and we welcome your comments, suggestions, and critiques. We also apologize for the paucity of references in this draft.

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I. Introduction

The patent-driven, proprietary approach to drug development has been under attack at least since the conjunction of the AIDS epidemic and the TRIPS Agreement in the 1990s, by those who are concerned about health problems in a global context. Many serious diseases, some rare and some endemic, go untreated in developing countries, at least in part for lack of financial incentives for pharmaceutical companies to invest in developing treatments for the diseases of the poor. Within the context of neglected tropical diseases, especially, there have been ongoing calls in the past ten years or so for various forms of “openness” in drug development. These proposals have spurred the launch of numerous projects aimed at solving the problems of drug development for neglected tropical diseases, along with advocacy and political movements aimed at limiting proprietary control, especially of upstream research and development and of research tools.

Incentives to search for new models and approaches to drug discovery have been heightened by the recent availability of substantial public (particularly from the United States) and charitable (particularly from the Bill & Melinda Gates Foundation) funds to address these issues. Meanwhile, the costs of drug discovery have risen more generally, while the pharmaceutical industry’s production of new drugs has stagnated. Concerns about the pharmaceutical industry’s “blockbuster” business model thus have spread beyond those focusing on neglected diseases of the developing world to a more general search for new approaches. Private pharmaceutical companies, driven by philanthropic and reputational concerns, by the availability of new funding sources, and by the need to explore ways to improve their approaches to drug discovery generally, have engaged in highly publicized efforts to cooperate on research and development activities and to engage in “public-private partnerships” focused on neglected tropical diseases and other diseases, such as AIDS, which pose particular problems for developing countries.

Alongside the calls for “openness” have been attempts to provide direct financial incentives for pharmaceutical companies to produce medicines for the developing world. Such initiatives include prizes, which may be disbursed when a specified goal is attained or when particular milestones are reached, advanced market commitments, aimed at producing low-cost vaccines, and Priority Review Vouchers, authorized by the U.S. Congress in 2007 to award priority in FDA review of a commercial drug in exchange for bringing a drug aimed at a neglected tropical disease through the review process. In some respects, these kinds of competitive incentives, like intellectual property rights, are in tension with more open approaches.

In sum, there are now a plethora of initiatives involving public, philanthropic, and private entities (and every combination of these types) advertising themselves as “open”, “collaborative,” and so forth. While much has been written about the promise of these new paradigms, there has been relatively little detailed comparative analysis of their operations and outcomes. It is too early to come to definitive conclusions about the effectiveness of the various efforts. However, we believe that it is possible and desirable at this point to begin to analyze the structure and governance of these projects. In particular, we suggest that the concept of “openness” in the context of drug discovery and development should be interrogated and refined, so that the institutions now being described as “open” can be distinguished and more clearly analyzed.

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Our approach to this question is to undertake case studies using the framework for study of “cultural commons” suggested by Madison, Frischmann, and Strandburg, which is in turn based on the path-breaking Institutional Analysis and Development (IAD) framework developed by Elinor Ostrom and others in the context of commons arrangements for governing natural resources. The framework is described elsewhere in this volume. We do not contend that all of the initiatives in our study meet any particular definition of “commons” (in fact, the extent to which resources are held in common by these entities is part of the inquiry). Nonetheless, we believe the “cultural commons” framework offers a meaningful way to begin to compare them.

To delineate a manageable cohort from the large number of recent initiatives characterized as “collaborative,” “open,” and so forth, we focus on projects aimed at developing malaria drugs for use in the developing world. Our reasons for this choice are several: Malaria is obviously a very important case, given its devastating effects in many developing countries. It has been the focus of a number of relatively well-funded efforts for a number of years. For this reason, malaria drug development is relatively further advanced than drug development for many other tropical diseases, and there are “open” initiatives at all stages of drug development, from upstream research through regulatory approval. There also are enough different entities working on malaria drug development to make it feasible to compare different approaches at each stage. Though most of these malaria drug efforts are still relatively new, some have been in operation long enough that it is now or soon will be possible to get an initial handle on the efficacy of these efforts.

In this initial paper, we focus on approaches that are being developed to involve private pharmaceutical companies in drug development for neglected diseases. A central issue in all of such projects is how to deal with intellectual property rights – including patents, trade secrecy, and data exclusivity and the various approaches for doing so are the primary focus of our analysis. We begin by briefly reviewing the role that intellectual property rights play in drug development, especially as related to neglected diseases, and outlining various approaches for dealing with IP in the context of medicines for the developing world, including government initiatives, including most notably the Priority Review Voucher program and Public-Private Partnerships (PPPs). We then focus the bulk of our analysis on a detailed case study of the recently-established Pool for Open Innovation for Neglected Tropical Diseases (POINTD), discussing how it relates to patent pools and voluntary licensing. All of these initiatives are new enough that it would be premature to draw conclusions as to their effectiveness. Nonetheless, we believe that an understanding of the ways in which these initiatives combine proprietary and open elements will illuminate the debate and assist in evaluating various approaches going forward.

## II. Drug Development for Neglected Diseases: Efforts to Engage the Private Sector

The drug development process is often described as a “pipeline” involving various stages from upstream basic research, through clinical trials and regulatory approval. There are various ways of mapping out this pipeline. One useful approach is provided by Maurer,<sup>1</sup> and includes the stages of basic research, finding and validating targets, finding and optimizing lead compounds,

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<sup>1</sup> UKMC article

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process development, pre-clinical testing, phases I, II and III clinical trials, FDA approval and post-approval phase IV testing. Traditionally, the more upstream stage of the pipeline has been the province of universities and other publicly-funded entities, while private pharmaceutical companies funded and conducted the later, more applied, stages of development. In this traditional model, upstream knowledge is shared by publication, while more downstream discoveries are protected by patents and trade secrecy so as to ensure a return on private investment. This traditional model, while never entirely accurate in light of the many overlaps and interactions between publicly-funded research and privately-funded drug development (including, for example, the role of academic medical centers in conducting clinical trials), has been complicated by the increasing trend of university patenting, but the general concept of a “hand-off” between publicly-funded, widely-shared upstream research and privately-funded proprietary development underlies the pharmaceutical business model. The assumption is that patents, data exclusivity (at the FDA), and trade secrecy, will provide market exclusivity, leading to profits that can be used to defray the high costs of downstream development and regulatory review.

There is a vast literature debating the trade-offs between access to medicines, particularly in developing countries, and the incentives for drug innovation purportedly provided by intellectual property rights (in which we include, for present purposes, patents, trade secrecy, and regulatory data exclusivity). Much of the debate has focused on the fight against HIV/AIDS, often (at least since the development of effective drug regimens) in the context of drug treatments that have been developed for use in wealthy countries. In this context, primary attention has focused on the end of the drug pipeline and the high drug prices justified, at least to some degree, by large investments by pharmaceutical companies. Partial solutions to this access to medicines problem now include tiered pricing by brand name drug companies, voluntary or compulsory licensing of generic companies, and public or private philanthropic purchases of needed medications. In late 2009, UNITAID established the Medicines Patent Pool (now operating independently, but with UNITAID funding) in an attempt to provide a “one-stop shop” for licensing of AIDS drugs for generic production to serve developing country needs. It is hoped that the availability of such licenses will also encourage the development of drug formulations “better adapted to resource-limited settings.”<sup>2</sup>

The situation with regard to diseases, such as malaria, which have small or negligible incidence in developed countries, is different from the situation with respect to HIV/AIDS. The problem is more than *access* to medicines – it is *existence* of medicines.<sup>3</sup> The traditional model is an abysmal failure in developing treatments for neglected diseases, for which pharmaceutical companies can anticipate no significant profit stream. Traditional publicly-funded institutions, on the other hand, even if they had enough money to undertake drug development, are ill-equipped to pursue downstream drug development. Thus, the development of drugs for neglected diseases faces two kinds of obstacles, in addition to the difficulties in disseminating treatments already discussed: 1) the need either to obtain large-scale funding or to reduce the costs of research and development and 2) the need either to recruit the participation of

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<sup>2</sup> [www.medicinespatentpool.org/WHO-WE-ARE2/Mission](http://www.medicinespatentpool.org/WHO-WE-ARE2/Mission).

<sup>3</sup> This does not mean that no treatments exist, since some treatments have been developed. See Hotez and Pecoul. But the development of new and effective treatments is strongly hampered by the absence of a potentially profitable market.

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pharmaceutical companies experienced in drug development or to develop other centers of such expertise.

Attempts to reduce the cost of research and development have focused primarily on the upstream end of the pipeline and include projects aimed at screening existing drugs for potential use in treating neglected diseases (thus drastically cutting the potential costs of regulatory approval) (e.g. Johns Hopkins initiative), projects aimed at making data or other resources more easily and broadly accessible (e.g. ChemBL or mr4), and projects aimed at coordinating the efforts of widely-dispersed researchers in an “open source” approach to a particular research task (e.g. OSDD). Progress at the upstream end of the pipeline need not necessarily involve pharmaceutical companies directly: the goal is to make sufficient progress to “de-risk” drug development enough to attract pharmaceutical company investment downstream, permitting a company either to make a sufficient profit to cover its costs or to be willing to commit resources at least partly as an exercise in philanthropy. Of course, an obvious response to the cost barrier grant funding provided either through private philanthropy or government agencies. Such funding clearly plays a critical role in drug development for neglected diseases, particularly with regard to upstream research.

Increasingly, however, governments and philanthropists are seeking to develop innovative institutions that will ensure that funding is effective in achieving the end goal of treatments actually delivered to those who need them. A few projects seek to replace profit-making pharmaceutical companies entirely, replacing them either with non-profit organizations or with government initiatives, but for the most part by finding ways to involve the private sector in drug development for neglected diseases. Of course, such attempts inevitably are complicated by the need to deal with issues of intellectual property. Three basic approaches are being pursued: (i) direct incentives, including publicly and philanthropically financed monetary prizes and, most relevant to our discussion here, government initiatives such as the US Priority Review Voucher; (ii) so-called public-private partnerships (PPPs), which are non-profit “virtual pharmaceutical company” ventures that manage drug development projects by funding and coordinating the efforts of private pharmaceutical companies, academics, and others; (iii) and patent pools, clearinghouses, and other projects aimed at collecting proprietary resources from more than one source and making them available for use in developing medicines for neglected diseases. In this Part, we briefly discuss the first two approaches, reserving a detailed discussion of the third for Part III.

#### A. Prizes and the Priority Review Voucher System

Several proposals aim to address the neglected disease issue through direct financial incentives to pharmaceutical companies. These initiatives do not seek to change the traditional pharmaceutical proprietary business model, but rather to harness it for different ends. These include prizes, such as the X-Prize being developed to reward development of improved diagnostics for tuberculosis<sup>4</sup> and the Quotient Prize concept, based on the achievement of specified milestones, advocated by Bio Ventures for Global Health,<sup>5</sup> Advance Market

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<sup>4</sup> <http://www.xprize.org/prize-development/life-sciences#tb>

<sup>5</sup> <http://www.bvgh.org/What-We-Do/Incentives/IQ-Prize.aspx>

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Commitments for vaccine purchases,<sup>6</sup> and the Priority Review Voucher system, which provides a voucher for priority review of any drug to the developer of a drug targeting one of a list of neglected diseases.<sup>7</sup> The effectiveness of any of these approaches is a matter of debate and all are still at the experimental stage.<sup>8</sup>

The Priority Review Voucher system for neglected diseases was based on a proposal by Ridley et. al.<sup>9</sup> It was enacted into law as part of the 2007 FDA Amendments Act<sup>10</sup> and the program went into effect in 2008. The program takes advantage of a general program for priority review of “drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists.”<sup>11</sup> Priority review shortens the FDA’s target time for review of an application from 10 months to 6 months. Because it permits a drug to be marketed earlier (relative to patent expiration), priority review is considered valuable by pharmaceutical companies. (One estimate of the value of priority review is \$322M)<sup>12</sup> Because many lucrative drugs would not be otherwise entitled to priority review because they would be considered to offer “at most, only minor improvement over existing marketed therapies.”<sup>13</sup>

The Priority Review Voucher system is intended to exploit the fact that many lucrative drugs are ineligible for priority review to provide incentives for companies to develop drugs for sixteen specific tropical diseases (including malaria). A company that receives approval for a new drug for treating one of the specified diseases may be awarded a voucher that it may use to obtain priority review of any of its other (presumably more lucrative) drug applications. To obtain a voucher, the company need not commit to distributing the neglected disease treatment. A voucher may be sold once to another company for use in review of one of its drugs. In practice, it is not at all clear that the PRV system will be successful.<sup>14</sup> Since the program’s launch, only

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<sup>6</sup> <http://www.gavialliance.org/funding/pneumococcal-amc/>

<sup>7</sup> David B. Ridley et al., *Developing Drugs for Developing Countries*, 25 *Health Affairs* 313 (2006); <http://www.fda.gov/NewsEvents/Testimony/ucm219765.htm>

<sup>8</sup> For discussions and analysis of these and other proposed mechanisms for funding drug development for neglected diseases, see, e.g., Stephen M. Maurer, *Choosing the Right Incentive Strategy for Research and Development in Neglected Diseases*, *Bull. WHO* 376 (May 2006); James E. Lowell and Christopher D. Earl, *Leveraging Biotech’s Drug Discovery Expertise for Neglected Diseases*, *Commentary*, 27 *Nature Biotech.* 323 (2009); Robert Hecht, Paul Wilson, and Amrita Palriwala, *Improving Health R&D Financing for Developing Countries: A Menu of Innovative Policy Options*, 28 *Health Affairs* 974 (2009); Fernando Antonanzas et al., *Pharmaceutical Patents, R&D Incentives and Access to New Drugs: New Ways of Progress at the Crossroad*, 12 *Eur. J. Health Econ.* 393 (2011); Peter Hotez, *A Handful of “Antipoverty” Vaccines Exist for Neglected Diseases, but the World’s Poorest Billion People Need More*, 30 *Health Affairs* 1080 (2011). For a critique of Advanced Market Commitments see, e.g., Megan Scudellari, *Are Advance Market Commitments for Drugs a Real Advance?*, 17 *Nature Medicine* 139 (2011).

<sup>9</sup> *Supra* note \_\_

<sup>10</sup> 21 U.S.C. 360n.

<sup>11</sup> <http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm>

<sup>12</sup> Ridley, *supra*.

<sup>13</sup> <http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/speedingaccesstoimportantnewtherapies/ucm128291.htm>

<sup>14</sup> See, e.g., Emily Waltz, *FDA Launches Priority Vouchers for Neglected-Disease Drugs*, 26 *Nature Biotech.* 1315 (2008); Aaron S. Kesselheim, *Drug Development for Neglected Diseases – The Trouble with FDA Review Vouchers*, 359 *New Engl. J. Med.* 1981 (Nov. 6, 2008); Jeffrey Moe et al., *FDA Review Vouchers*, 360 *New Engl. J. Med.* 837 (Feb. 19, 2009).

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one company, Novartis, has obtained a PRV.<sup>15</sup> The voucher was obtained when Novartis obtained U.S. approval of the malaria drug, Coartem. Novartis’s move has been highly criticized, however,<sup>16</sup> in light of the fact that the drug had been available for nearly a decade and was registered in 85 countries. The PRV was awarded only because Novartis had not yet registered the drug in the U.S., though it had planned to do so because of “pressure from the US Government and army to supply travelling American citizens.” Perhaps with some poetic justice, Novartis’s recent attempt to use its PRV also appears likely to come to naught. Novartis used the voucher to obtain priority review of a new indication for its drug, Ilaris, in treating gouty arthritis. The FDA, however, did not approve the application, calling for additional clinical data in light of evidence of adverse side effects.<sup>17</sup> The effectiveness of the PRV system for inducing development of truly new treatments for neglected diseases thus remains in doubt.

## B. Public-Private Partnerships

By far the most widely discussed and implemented mechanism for inducing private pharmaceutical companies to play a role in developing drugs for neglected diseases is the so-called Public-Private Partnership (PPP). Though PPPs have various specific structures, their general objective is to enable the creation of new health-based technology and to ensure that it is available to as many patients as possible. As Taubman (2010) discusses, the World Health Organization has distinguished PPPs for product development for neglected diseases from PPPs focused on access to existing drugs (see also Merz, 1995). Product development PPPs are non-profit organizations that fund and manage the conduct of R&D—which may include discovery, preclinical, clinical, or manufacturing activities. Access PPPs, on the other hand, are non-profit organizations primarily concerned with expanding access to health-based technologies that are already in existence by collaborating with manufacturers and funding agencies, as well as development countries. Through such collaborations, access PPPs enable the purchase of existing drugs, vaccines and other medical technology and their distribution to patients in developing countries.<sup>18 19</sup>

Product development PPPs are intended both to provide incentives (often through funding) for private sector involvement in developing treatments for neglected diseases and to provide an institutional structure for bridging the gap between academic upstream research and downstream drug development. Because PPPs involve both public and private actors, they face complex questions about how to handle intellectual property, particular where either the knowledge brought to the table by private companies or the anticipated results have applicability to markets outside of the neglected disease that is the focus of the PPP. To succeed, then, PPPs must carefully craft out agreements pertaining both to the rights in and exercise of background

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<sup>15</sup> Andrew Jack, Novartis Hopes Success with Malaria Will Aid Second Drug, Companies – International, p. 23, Financial Times (London) (December 5, 2008)

<sup>16</sup> Tatum Anderson, Novartis under fire for accepting new reward for old drug, 373 Lancet 1414 (2009); Kesselheim, *supra*

<sup>17</sup> FDA Complete Response Letter Calls for More Clinical Data on Ilaris, Washington Drug Letter (Sept. 5, 2011).

<sup>18</sup> Taubman, A, A Typology of Intellectual Property Management for Public Health Innovation and Access: Design Considerations for Policymakers, The Open AIDS Journal, 4, 4-24 (2010).

<sup>19</sup> Merz FJ, Intellectual Property and Product Development Public/Private Partnerships Final Report. World Health Organization, Commission on Intellectual Property Rights, Innovation and Public Health (2005).

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intellectual property (IP) (that is, intellectual property that both or either parties bring to the partnership from the outset) and to research or project-based IP (that is, IP that is generated from funded research and development). PPPs thus must balance the need to encourage their private sector partners to engage in the necessary R&D and to commit resources to the project against the need to ensure broad access to the partnership’s final products for patients in neglected markets. PPP IP management may need to consider issues such as: IP exercise rights segregated by market—with the private sector partner maintaining ownership and/or exercise rights in developed markets while ceding rights for developing markets; conditions for access to proprietary general-use technology and know-how, such as background technology required for final product development; march-in-rights that ensure that IP developed by the partnership will be transferred to the non-profit organization in the event that the private sector partner fails to meet its commitments; and conditions for third party access to IP needed for dissemination of the new product in neglected markets (such as test data, background technology, and manufacturing know-how) parties in the event that the original private sector partner fails to meet agreed-upon dissemination goals.<sup>18, 20</sup>

To provide a flavor of how these partnerships are structured, we briefly discuss the strategies employed by three PPPs that are working on developing drugs to treat malaria: Medicines for Malaria Venture (MMV), the Malaria Vaccines Initiative (MVI), and the Drugs for Neglected Diseases Initiative (DNDi).

*Medicines for Malaria Venture* was launched in 1999, with seed funding of \$4M from a coalition of governments and foundations. In 2000, the organization received a donation of \$25M from the Gates Foundation. Since that initial donation, the Gates Foundation has ramped up its support to a total of about \$400M. Since its founding, MMV has received a total of \$480M in donations and pledges through 2015, which it has used to fund a targeted portfolio of projects ranging over the drug development pipeline from lead generation through drug approval and beyond into access and delivery.<sup>21</sup> MMV describes itself as a virtual R&D organization, which means that all of its R&D, access and delivery activities are undertaken in collaboration with partner organizations across the world (MMV, 2011). While MMV bears some resemblance to a granting agency or foundation, in that it provides funding in response to competitive proposals, its approach is tightly managed and focused on a well-defined portfolio of projects at every stage of the pipeline. As described in an independent evaluation of MMV on behalf of the World Bank: “The specific value added of MMV lies in its proactive management of the R&D pipeline. It functions as an efficient allocator of public and private resources to finance potential new malaria drugs. MMV’s relatively large portfolio permits it to enjoy internal efficiencies in resource allocation across candidate drugs that could not be realized with a small portfolio.”

Since its inception, MMV has worked in partnership with more than 130 research institutions and companies. Pharmaceutical and biotech company partners bring expertise and facilities in

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<sup>20</sup> Taubman, A, *Public-Private Management of Intellectual Property for Public Health Outcomes in the Developing World: The Lessons of Access Conditions in Research and Development Agreements*, Initiative on Public-Private Partnerships for Health Geneva (2004).

<sup>21</sup> <http://www.mmv.org/research-development/science-portfolio>; <http://www.mmv.org/access-delivery/access-portfolio>



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drug discovery and development, including access to cutting-edge technologies to speed up discovery by compound screening, as well as manufacturing capability. On the public side of the partnership, academic research institutions bring scientific research expertise and facilities in areas ranging from basic biology to clinical medicine and field expertise.<sup>22</sup>

MMV manages its portfolio of activities by entering into contractual relationships with the partners that it funds. The contracts are designed to ensure that the malaria drugs it develops and launches will be accessible to those most in need in malaria-endemic countries—thus maximizing the public health impact. To facilitate this goal, MMV negotiates intellectual property agreements with partner organizations relating to existing and newly generated intellectual property. While negotiated individually, MMV states that it follows an intellectual property policy that is geared toward ensuring that its goals are met. Specifically, MMV and its partners determine whether any newly generated IP should be the subject of a patent application or should be dedicated to the public domain based on “whether the IP has value as an incentive for the partners (or others in later-stage commercialization of the resulting products) to participate in the programme or has value in controlling how the product is distributed and used.”<sup>23</sup> While MMV does not necessarily take ownership of IP that is generated by the research it sponsors, it does insist on “appropriate license rights to any compound(s) being developed under its portfolio.” Particularly in the event that partners cannot follow through with their original commitments, agreement provisions “permit MMV to take ownership or appropriate licenses to both programme and background IPR to allow the project to be completed and the resultant drug to be launched in malaria-endemic countries.” These provisions address exclusivity, royalties and transferability rights.<sup>23</sup>

Specifically, MMV’s intellectual property policy requires that agreements follow the following three principles:

**Exclusivity:** If MMV does not own the necessary IPR outright, it would insist on being granted an exclusive license to use the ‘programme IPR’ and any necessary ‘background IPR’ to develop a drug for malaria and bring it to market. That license should be worldwide, to ensure maximum flexibility for later-stage activities such as manufacturing and distribution.

**Royalty-free:** Any such licenses are preferably royalty-free, at least in malaria endemic countries, to help keep costs to a minimum and ensure that the drug will be sold at the lowest price possible in these countries.

**Transferable:** Moreover, MMV does not conduct any R&D in-house or any manufacturing and, therefore, requires such rights to IP that can be transferred to other partners - especially manufacturing partners - if necessary.

With respect to final products, MMV will negotiate that delivery to the poor in developing countries be on a “no profit, no loss” basis.<sup>23</sup> MMV’s website indicates that two treatments, involving two different pharmaceutical companies have obtained regulatory approval under its

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<sup>22</sup> [www.mmv.org](http://www.mmv.org).

<sup>23</sup> [www.mmv.org/sites/default/files/uploads/docs/policy\\_documents/MMV\\_and\\_Intellectual\\_Property\\_Rights.pdf](http://www.mmv.org/sites/default/files/uploads/docs/policy_documents/MMV_and_Intellectual_Property_Rights.pdf)

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auspices: a pediatric formulation of the drug Coartem was developed in partnership with Novartis (which has produced Coartem since 2001); and WHO pre-approval was obtained for an IV form of a drug for severe malaria which had been available since 1987 but never taken through stringent regulatory approval. Other drugs, which are fixed-dose combinations of existing medicines are in the approval process.

*The PATH Malaria Vaccine Initiative (MVI)* is “a global program of the international non-profit organization PATH.” MVI was also established in 1999 and is substantially funded by the Gates Foundation. MVI seeks to accelerate vaccine development through multiple approaches including partnering and the funding of promising projects. Addressing challenges simultaneously on multiple fronts, MVI has several partners in ongoing vaccine projects worldwide.<sup>24</sup> The Initiative “establish[es] product development partnerships to develop promising malaria vaccine approaches” through the application of PATH’s Guiding Principles for Private-Sector Collaboration. In assessing a proposed private sector collaboration, PATH considers three issues:

**Availability:** Have PATH and the collaborators created a product-development program that is sufficiently rigorous, funded, and prioritized to provide a reasonable opportunity for success?

**Accessibility:** Have PATH and the collaborators envisioned a manufacturing and distribution plan that can lead to sufficient quantities of the product through appropriate channels to meet clearly defined public-sector demand in developing countries?

**Affordability:** Have PATH and the collaborators openly discussed and agreed upon a product pricing approach that can result in widespread adoption in public-sector programs of developing countries over a reasonable time through purchase by local governments or support of international donor agencies?

The initiative in parallel has outlined several rules-in-use for partner selection and management including assessment criteria, and the definition of roles, responsibilities and expectations respectively. Any agreement for example must include “a clearly defined management and decision-making structure for the collaboration” and “a clearly stated process for monitoring, evaluating, and terminating the collaboration”.<sup>25</sup>

According to PATH’s principles it “has a fundamental obligation to ensure dissemination of the results of its private-sector collaborations” and it uses “a variety of approaches, incentives, and mechanisms to reach a balanced relationship aimed at serving both public good and commercial objectives”.<sup>25</sup> The management of intellectual property appears to be defined within the guidelines principally in terms of types of collaborations: technology transfer, product development support, and product introduction. The first two collaboration types are particularly relevant to the discussion of technology and IP management. Transfer of a technology developed or owned by PATH to a private sector collaborator may include the transfer of intellectual property for further development, manufacturing, and distribution. Ultimately, then, PATH

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<sup>24</sup> Shotwell SL. 2007. Patent Consolidation and Equitable Access: PATH’s Malaria Vaccines, Chapter 17.21 in IP Handbook of Best Practices, Concept Foundation.

<sup>25</sup> PATH’s Guiding Principles for Private-Sector Collaboration, [http://www.path.org/files/ER\\_gp\\_collab.pdf](http://www.path.org/files/ER_gp_collab.pdf).

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supports collaborators by “providing significant resources or expertise (such as funding, management, co-development, and assistance with clinical studies) [] to support the collaborator’s development of a product.” Intellectual property rights (IPR) are utilized by PATH to ensure that a collaborator seeks to increase the availability, accessibility, and affordability of the technology in developing-country public health programs. Therefore, IPR appears to be linked to the recognition by PATH that commercial benefits are necessary in order to ensure a sustainable commitment to the collaboration.<sup>25</sup> Like MMV, MVI takes a highly managed approach to its funding of a specific portfolio of projects.

*The Drugs for Neglected Diseases Initiative (DNDi)*, established in 2003, is also a not-for-profit product development partnership, though it has a broader focus, working to research and develop new treatments for neglected diseases, in particular human African trypanosomiasis, leishmaniasis, Chagas disease, malaria, paediatric HIV, and specific helminth-related infections. DNDi was established in 2003 by a coalition of public sector institutions, the Medecins sans Frontieres, and the UNDP/World Bank/WHO’s Special Programme for Research and Training in Tropical Diseases. Since 2007, DNDi has delivered four products including two fixed-dose anti-malarials (ASAQ, developed with Sanofi-Aventis, and ASMQ, developed in collaboration with Brazil, South-East Asia and produced by a Brazilian public pharmaceutical company) (DNDi, 2011). In the development of ASAQ with DNDi, Sanofi-Aventis used differential pricing tailored to local conditions alongside discretionary IP enforcement. The company decided to forego its patent rights to the new formulation, while pricing and presentation are tailored to different distribution channels and affordability parameters. For example, in public sector markets, the new formulation is sold as ASAQ Winthrop at a no profit/no loss price, equivalent to less than \$0.5 per day for children under five years of age and less than \$1 per day for adults. A branded version, Coarsucam, is sold through private pharmacies at a regular price, and the combination product is also available under the Impact Malaria brand at a no profit/no loss price.<sup>26 27</sup> ASMQ is also being produced without patent protection.<sup>28</sup> Recently Sanofi and DNDi announced a three-year agreement for collaboration in researching new treatments for nine neglected tropical diseases (NTDs). The collaboration will involve Sanofi bringing molecules from its libraries into the partnership, while DNDi and Sanofi collaborate in research activities. Of interest for present purposes is the agreed-upon approach to intellectual property generated through the collaboration, which will be co-owned by Sanofi and DNDi.<sup>29</sup> The partners have apparently also agreed to “facilitate publication of the results to ensure access to the wider community of researchers focusing on NTDs.”<sup>29</sup>

DNDi’s intellectual property policy states that it will be “pragmatic” and guided by two principles: (1) “The need to ensure that drugs are affordable to and access is equitable for patients who need them; and (2) “The desire to develop drugs as public goods when possible.” Further, though reserving the possibility of patenting the results of its work, DNDi’s principles state that “[w]here 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

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<sup>26</sup> Sanofi and DNDi - Drugs for Neglected Diseases initiative - Sign an Innovative Agreement to Generate New Drugs for Neglected Tropical Diseases, May 30 2011.

<sup>27</sup> Mansell, P. Why patient access means market access, December 8 2010.

<sup>28</sup> <http://www.ip-watch.org/weblog/2008/04/17/innovative-partnership-to-create-another-patent-free-malaria-drug/>

<sup>29</sup> [www.dndi.org](http://www.dndi.org).

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public domain. . . . Given the costs involved, patenting is likely to be the exception rather than the rule.” Though DNDi’s general approach as a PPP and “virtual” pharmaceutical company is very similar to those of MMV and MVI, both its written IP policy and its activities thus far suggest that DNDi takes a more “open” approach, proactively avoiding IP protection when possible.

As these brief descriptions illustrate, PPPs are generally “open” only in particular limited senses. In structure, they are extreme exemplars of the concept of “open innovation” described by Henry W. Chesbrough.<sup>30</sup> “Open innovation,” in the Chesbrough sense, primarily connotes outsourcing, rather than sharing in a commons. The results generated by PPP research are also open only in limited ways. While some results are published in scientific journals, results may also be patented or kept secret by the companies involved. PPPs and their partners thus may choose to maintain significant control over research results, even while seeking to promote wide dissemination of the drugs in the developing world.

### III. Case Study: Pool for Open Innovation against Neglected Tropical Diseases

We now turn to a close analysis of the recently created Pool for Open Innovation against Neglected Tropical Diseases (hereinafter “POINTD”). POINTD began in February 2009 as an initiative of GlaxoSmithKline (GSK) CEO Andrew Witty. Witty pledged that GSK would make licenses to certain patents and know-how available for use in developing drugs to fight neglected diseases. This initiative eventually became POINTD. Since 2010, POINTD has been administered by Bio Ventures for Global Health (“BVGH”), which describes itself as “a non-profit organization whose mission is to save lives by accelerating the development of novel drugs, vaccines, and diagnostics coming from the biotechnology industry that address the unmet medical needs of the developing world.” BVGH is closely associated with the Biotechnology Industry Organization (BIO).

POINTD’s very name suggests that it is a “common pool” resource<sup>31</sup> that is available on an “open” basis. It also suggests a “patent pool,” which ordinarily brings to mind a collection of patents relevant to a particular enterprise that are available for licensing “in bulk” from a single entity.<sup>32</sup> Indeed, much of the news coverage of POINTD, as well as the website of Glaxo Smith Kline, where POINTD originated, refers to it as a “patent pool.” Here we use the cultural commons framework to unpack POINTD’s structure and to ask whether and to what extent it functions as a common pool resource or patent pool. The results so far are based on a literature review and thus subject to revision as we obtain more information through interviews. It seems clear from the analysis so far, however, that POINTD does not constitute a common pool resource, at least with respect to the patents and know-how which is its focus. Nor is it a “patent pool” in any ordinary sense of the term.<sup>33</sup> Rather, to the extent POINTD involves the pooling of

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<sup>30</sup> See, e.g., Henry W. Chesbrough, *The Era of Open Innovation*, MIT Sloan Management Review, Sloan Select Collection 35 (Winter 2011) (originally published Spring 2003).

<sup>31</sup> Ostrom; Madison et al.

<sup>32</sup> See Ed Levy et al., *Patent Pools and Genomics: Navigating a Course to Open Science?*, 16 B.U. J.Sci. & Tech. L. 75 (2010) for a discussion of the various usages of the term “patent pool.”

<sup>33</sup> Esther van Zimmeren et al., *Patent Pools and Clearinghouses in the Life Sciences*, Trends in Biotechnology (July 4 2011)

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any resource, that resource is information about patents that might be available for license for work on neglected diseases and patentees that might be willing to enter into such licenses. The cultural commons framework is very useful in teasing out the ways in which POINTD does and does not provide “open” resources for innovation in the treatment of neglected diseases.

A. Background Environment

To apply the cultural commons framework to POINTD, we begin by asking what kinds of property rights form the background “environment” in which the Pool is situated. Drug development takes place in a complex environment of public domain knowledge and knowledge that is protected by patent or trade secret law. The focus of POINTD is on the proprietary side, however, and its goal is to overcome barriers to drug development posed by patents and trade secrecy, while preserving the intellectual property rights and other proprietary interests of biopharmaceutical industry participants.

B. Basic Characteristics of POINTD

1. POINTD Actors

To understand POINTD, it is most helpful to begin with a description of its participants. As suggested by the IAD framework, we look at the actors involved in POINTD from two perspectives: What roles are available for actors to play? What types of entities participate and in what roles? POINTD clearly specifies three roles: *contributor*, *user*, and *administrator*.

a. *Contributor*

*Contributors* are entities that own patents or have know-how (which may include trade secrets) and wish to make it available for use in research into neglected tropical diseases on terms consistent with POINTD *principles*.<sup>34</sup> The responsibilities of *contributors* are described by POINTD as follows:

At a minimum, *contributors* must agree to a core set of *principles* around the Pool. They must identify those patents and applications they are making available to the Pool. Contribution of know-how is voluntary. Pool *contributors* have a choice as to whether, and on what terms, they will provide know-how to specific enquiries regarding possible use of technologies that might be of value to neglected tropical disease research or development project.<sup>35</sup>

Though we defer detailed discussion of the *principles* for now, a couple of points about the *contributor* role are worth making at this point. First, designation as a *contributor* entails identifying specific patents and applications that the *contributor* is willing to license on terms consistent with the *principles*.<sup>36</sup> Information about the patents and applications identified by

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<sup>34</sup> See section below on Rules for detailed discussion of the *principles*.

<sup>35</sup> <http://www.ntdpool.org/pages/for-contributors/faqs>

<sup>36</sup> We consider below the extent to which and in what way the principles constrain *contributors* in their licensing of the identified patents and applications.

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most contributors is available from a publicly searchable database on POINTD’s website. Second, *contributors* make no commitment to provide know-how associated with the patents and patent applications or more generally related to neglected tropical disease research, though they may do so.

POINTD has a small number of *contributors* so far. According to POINTD’s website, the current “*contributors*” of patents and know-how are GSK (the initial contributor, with about 175 listings in the database), Massachusetts Institute of Technology (May 2010, about 150 listings), the Medicines for Malaria Venture (August 2010, 4 listings), the University of California, Berkeley (August 2010, 4 listings), Caltech (August 2010, 7 listings), Alnylam Pharmaceuticals (July 2009, not listed), and Stanford University (November 2010, to be listed). Entries in the database often refer to a number of patents or applications filed in various countries on the same claimed invention. POINTD’s website reports that Alnylam has made available its “full portfolio of over 1500 issued and pending patents,<sup>37</sup>” but does not include the patents in the database. It is unclear from the publicly available information whether POINTD’s *administrator* maintains an itemized list of those patents and applications.<sup>38</sup> A LEXIS search reveals that Alnylam is the assignee of approximately 60 U.S. patents and about 200 published U.S. patent applications.

Though few in number, the current *contributors* are perhaps representative of the kinds of entities one might expect to participate in that role: pharmaceutical companies, biotechnology companies, universities, and non-profit organizations focusing on neglected tropical diseases. Not surprisingly, only patent-holding entities have joined (though it is not clear that POINTD’s structure would foreclose an entity from participating only so as to publicize an interest in licensing out know-how). It is notable, however, that since the announcement of the formation of POINTD by GlaxoSmithKline in 2009, the only for-profit entity to join as a *contributor* has been Alnylam.<sup>39</sup>

b. *User*

*Users* negotiate licenses with individual contributors (with negotiations potentially facilitated by the administrator, BVGH.) The publicly available materials<sup>40</sup> suggest that the role of *user* is not an ongoing status, but is tied to particular projects (and possibly to requests for access to particular patents, applications, and know-how). As discussed in greater detail below, the role of *user* seems to be similar to that of a grant recipient, rather than of an ongoing member of a *user* community.

Current POINTD *users* include Emory Institute for Drug Discovery, iThemba Pharmaceuticals, Technology Innovation Agency (TIA), Department of Science & Technology, Republic of South Africa, Stanford University, the Sandler Center for Drug Discovery at UC San Francisco, and the

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<sup>37</sup> <http://www.ntdpool.org/pages/potential-projects-rnai>

<sup>38</sup> POSSIBLE QUESTION TO ASK

<sup>39</sup> Note that Alnylam has been involved in a venture with GSK since 2008, which may or may not be related to its decision to participate in POINTD. [http://www.gsk.com/media/pressreleases/2008/2008\\_pressrelease\\_10027.htm](http://www.gsk.com/media/pressreleases/2008/2008_pressrelease_10027.htm).

<sup>40</sup> POSSIBLE QUESTION TO ASK

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University of Capetown.<sup>41</sup> (Stanford is thus the only entity so far to play both the *contributor* and *user* roles.) The *users* include four university organizations, one private company, and a governmental agency. However, most of the participation seems to be focused around a collaborative project between South African start-up company iThemba, which is partially funded by TIA, and the Emory Institute for Drug Discovery.<sup>42</sup> iThemba is a private company focusing on developing treatments for neglected infectious diseases. News reports indicate that, under licenses from GSK negotiated through POINTD, the collaboration screened small molecules and identified two targets for tuberculosis. The article also indicates that the licenses negotiated for the project included at least some exchange of know-how and that the arrangement involves give-and-take between GSK and the collaboration’s participants, including the use of GSK’s Tres Cantos laboratory facility, which is devoted to allowing outside scientists to research neglected diseases, rather than simply arms-length licenses.<sup>43</sup>

*c. Administrator*

The role of *administrator* is extremely important to POINTD’s operation. The *administrator* vets applications for *contributor* or *user* status, maintains POINTD’s website and the database of identified patents and patent applications, conducts outreach to potential *contributors* and *users*, and generally runs the operations of POINTD. POINTD itself has no employees, no staff, and no board of directors.

The *administrator* of POINTD is Bio Ventures for Global Health. Bio Ventures for Global Health is a non-profit 501(c)(3) organization closely affiliated with the Biotechnology Industry Organization (BIO). BVGH was started in 2004 with a grant from the Bill & Melinda Gates Foundation<sup>44</sup> and received an additional \$5.4 million grant in 2005. The Gates Foundation remains a major BVGH funder. BVGH’s primary activities are developing funding models for research and development for treatments for diseases of the developing world,<sup>45</sup> and producing reports about global health innovation.<sup>46</sup> BVGH is a major advocate for the FDA’s Priority

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<sup>41</sup> [www.ntdpool.org/news/partners](http://www.ntdpool.org/news/partners). The POINTD website does not list “*users*” explicitly. However, it lists “*partners*”, which seems to include both *users* and *contributors*. No other *users* were identified in a search of news reports, thus it is possible that there are other *users*, the identities of which have not been publicized. This seems unlikely, since POINTD has publicized these *users* very widely.

<sup>42</sup> Rianna Stefanakis and Don Joseph, 30 Gen. Eng’g & Bio. News, available at [www.genengnews.com/gen-articles/pooling-knowledge-for-neglected-diseases/3469](http://www.genengnews.com/gen-articles/pooling-knowledge-for-neglected-diseases/3469). (Note that the authors of this article are employees of POINTD’s administrator Bio Ventures for Global Health.)

<sup>43</sup> Rianna Stefanakis and Don Joseph, Pooling Knowledge for Neglected Diseases, Genetic Eng. & Biotech. News (Nov. 1 2010), available at <http://www.genengnews.com/keywordsandtools/print/1/20868/>. Note that this conclusion is contradicted by the very recent consultation draft of the Center for Global Health R&D Policy Assessment, Patent Pools: Assessing their Value-Added for Global Health Innovation and Access, which is based on a similar literature review and also on some interviews. That draft states that “[t]o date there have been no license agreements for any patent contributed to the pool.” The source of this contradiction may lie in the draft’s explanation that “while some interested parties considered licensing patents directly from the pool, they have instead decided to work with the Tres Cantos Campus facility [run by Glaxo Smith Klein as a laboratory for the use of outside researchers in investigating neglected diseases] directly. TIA and iThemba will use this campus for training while testing some of the pool compounds. <http://www.scidev.net/en/news/patent-pool-starts-to-attract-interest.html>. Interviews will be needed to clarify this situations.

<sup>44</sup> <http://www.bvgh.org/News/BVGH-News/Press-Releases/Article-June-7-2004.aspx>.

<sup>45</sup> <http://www.bvgh.org/What-We-Do/Incentives.aspx>

<sup>46</sup> <http://www.bvgh.org/What-We-Do/Information.aspx>

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Review Voucher program and for other projects aimed at providing financial incentives for industry efforts to combat neglected diseases. BVH’s Board of Directors is made up of the current and former presidents of BIO, the CEO and COO of BVGH, three biopharmaceutical industry executives, and two venture capitalists with backgrounds in the industry. Notably, universities and non-profit organizations (other than BIO) are not represented on the board. Bio Ventures for Global Health’s 2009 Form 990 indicated expenditures of around \$2 million, the bulk of which went to salaries, outside consultants, travel, and rent.

## 2. Resources Available Through POINTD

The next step in applying the cultural commons framework is to identify which (if any) resources are placed into a commons by POINTD. The answer to this question is considerably less obvious than one might anticipate. Though POINTD is called a “Pool,” its structure is not at all that of a traditional patent pool. As von Zimmeren et al recently have noted,<sup>47</sup> POINTD serves, instead, more as a clearinghouse of rights to patents and trade secrets.

In the usual case, a patent pool aggregates licenses to a number of patents needed for implementing a particular technology and then licenses the portfolio out to those seeking to practice the technology. Very often, the licensees and patentees are one and the same and the pool licenses are essentially cross-licenses. To avoid potential anti-competitive effects (and antitrust scrutiny) patent pools generally must aggregate complementary technologies and must offer licenses to all comers on non-discriminatory terms. Patent pools are in practice often formed around industry “standards.” More generally, a patent pool serves the purposes of negating the potential for hold-up and strategic behavior and lowering transaction costs with regard to technologies that form the basis upon which market competition stands (sometimes called “pre-competitive technologies”). In a traditional patent pool, the shared resources are patent rights (and sometimes associated trade secret know-how). Those who join the pool and/or buy licenses to the pool’s technology are permitted to exploit the technology represented by the group of patents and trade secrets in the pool.<sup>48</sup>

POINTD does not operate in this way. Despite the fact that GSK describes its involvement as “the donation of a number patents to a patent pool for neglected tropical diseases,”<sup>49</sup> POINTD is not a patent pool. *Contributors* to POINTD neither license nor assign any intellectual property to POINTD, nor do they authorize POINTD to grant licenses on their behalf. POINTD’s website states that it “facilitates access to the compounds, technologies, and expertise that will help organizations conduct research on treatments for neglected diseases more efficiently and effectively.” It does this, however, not by offering licenses to a pooled collection of patents and know-how related to neglected diseases, but by offering means to reduce the transaction costs of such licensing by providing a centralized source of information (the identities of patentees willing to enter into such licenses and some information about the patents and know-how to which licenses can be negotiated), setting up a framework for negotiations and some limitations

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<sup>47</sup> cite

<sup>48</sup> MINNA: Note that I think it will be a good idea to include a much more detailed inquiry into the competition issues raised by POINTD, especially in light of PRVs. That is one reason that I would like to include a comparison to the Medicine Patents Pool.

<sup>49</sup> <http://www.gsk.com/collaborations/patentpool.htm>



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on license terms (the *principles*),<sup>50</sup> and providing an *administrator* to serve as a liaison between potential parties to a license and “play a facilitating role in the process.”<sup>51</sup> In the end, though, “licenses will be granted directly by the company or organization that owns the IP.”<sup>52</sup>

The information provided to *users* by POINTD includes the identities of *contributors* and the searchable database of available patents and applications, both of which are available to the general public as well. Specific information about available know-how is not provided to the public by POINTD and presumably must be discussed in licensing negotiations, though *contributors* are expected to provide a “brief description” of available know-how to the administrator.<sup>53</sup> The “What’s in the Pool?” FAQ indicates that both GSK and Alnylam are willing to license know-how.<sup>54</sup> Interestingly, at least one organization indicated in interviews for the Consultation Draft study that “patents had initially attracted them to the pool, but access to know-how is what they were most interested in.”<sup>55</sup> The Draft also notes that “the focus of the pool has shifted towards improving access to know-how” because “patents themselves are currently not likely to impede drug R&D” for neglected tropical diseases.<sup>56</sup> Similarly, interviewees “suggested that the potential benefit of the pool would be less to do with access to the patents and more about access to compound data and know-how.”<sup>57</sup> The Consultation Draft also indicates that “because most of the IP that would help the PDPs to create NTD drugs has little commercial value, IP holders are generally willing to donate it or license it on a royalty-free basis.”<sup>58</sup> If this is the case, it reinforces the degree to which POINTD does not serve as a patent pool, but more as a matchmaker between *contributors* and *users*.

The usefulness of information and negotiation assistance available through POINTD is closely tied to the *principles*, which provide the framework for negotiating licenses and set norms and expectations about how the licensed technology will be used. The *principles* are discussed in detail in the section on Degree of Openness and Character of Control below.

### 3. POINTD Goals and Objectives

POINTD identifies its goals and objectives in its mission statement: “The Pool for Open Innovation against Neglected Tropical Diseases, administered by BIO Ventures for Global Health, motivates innovative and efficient drug discovery and development by opening access to intellectual property or know-how in neglected tropical disease research.” Though not stated explicitly, POINTD’s structure and *principles* also indicate that it seeks to motivate such drug development while maintaining the intellectual property positions of its *contributors* and their potential access to direct financial incentives such as Priority Review Vouchers.

### 4. Degrees of Openness and the Character of Control

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<sup>50</sup> Below we discuss to what extent the principles constrain *contributors* and *users* in negotiating licenses.

<sup>51</sup> Principles Para 5

<sup>52</sup> Principles, Para 5

<sup>53</sup> <http://www.ntdpool.org/pages/for-contributors/faqs>

<sup>54</sup> <http://www.ntdpool.org/pages/for-users/faqs>

<sup>55</sup> Consultation Draft at 47.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* at 50.

<sup>58</sup> *Id.* at 52.

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To what extent and in what specific respects can POINTD be described as an “open” organization? This inquiry has two related aspects: What limitations are there on participation in POINTD as a user or contributor? To whom and under what circumstances are POINTD’s resources available?

a. Openness to the Public

The information provided on POINTD’s website, which includes the searchable database of identified patents and patent applications, the list of *contributors* and *users*, the list of *principles* to which both *contributors* and *users* must commit, and FAQs for *contributors* and *users* providing a bit more information about POINTD’s operation, is open to the public. However, the subject matter or terms of specific licenses between particular *contributors* and *users* are not made publicly available, nor is information about available know-how (much of which may be trade secrets). Whatever services BVGH provides as a facilitator of licensing are also available only to those who have been accepted as *contributors* or *users*.

b. Openness with respect to *Contributors*

To list available intellectual property or to use POINTD as a route to negotiating a license to IP, an entity must apply to become a *contributor* or a *user*. The application process is handled by BVGH, as *administrator*.

The POINTD website describes the process of becoming a *contributor* as follows:

Entities wishing to contribute to the Pool may contact BIO Ventures for Global Health (BVGH). Pool *contributors* must then confirm that they will abide by the Core Principles and disclose to BVGH, in writing, those patents and patent applications that they are willing to contribute to the Pool. If know-how is part of the contribution a brief description should also be made available. Pool *contributors* understand and acknowledge that BVGH may publish the names, number, and brief description of the patents and patent applications for public inspection.

The *principles* give BVGH considerable discretion in the process of vetting *contributors*. It is unclear whether any entity that agrees to abide by the principles and make the necessary disclosures would be accepted in practice. The current list of *contributors* suggests that POINTD is open with respect to the *types* of *contributors* that may participate, though it may be notable that POINTD does not, at least thus far, have any *contributors* who are competitors of GSK, which started POINTD. Likely, this state of affairs reflects reluctance or delay on the part of other major pharmaceutical companies to join POINTD, rather than POINTD unwillingness to accept them, since both GSK and POINTD have attempted to recruit other pharmaceutical companies to participate.

POINTD is also open from the *contributor* perspective in the sense that *contributors* can remove their patents and patent applications from POINTD at any point:

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Owners retain complete discretion regarding ongoing access and licensing, including withdrawal from the Pool; subject only to any rights in the intellectual property previously granted by the *contributor* to a *user*.<sup>59</sup>

In sum, entry and exit into POINTD appears to be quite *open* for *contributors*, with minimal prerequisites for participation and relative ease of exit (though contractual obligations to licensees may well continue after a *contributor* withdraws).

c. Openness with respect to *Users*

To become a POINTD *user*, an entity must apply to the *administrator*. POINTD’s website emphasizes open access:

The Pool is accessible to anyone with a serious commitment to research and develop medicines for NTDs, including industry, academic researchers, funding agencies, and other third parties who can deliver real benefits for patients in least developed countries.<sup>60</sup>

However, in practice, the *administrator*, BVGH, has substantial discretion in deciding whether to accept a request to become a *user*:

In accordance with the core principles for the Pool, BIO Ventures for Global Health will undertake an inquiry of the potential licensee’s scope of work, the nature of its resources and capabilities, and other relevant factors in determining whether to grant access to a potential licensee. In appropriate cases, BIO Ventures for Global Health will consult with the Pool advisory committee, which includes representatives from the partners.<sup>61</sup>

Though there are no reports that POINTD has ever unreasonably denied an application to be a *user*, the process for vetting applications is certainly lacking in transparency. For example, BVGH seems to have complete discretion to determine what “other relevant factors” should be considered as long as these factors are “in accordance with the core *principles*.” The “Pool advisory committee,” with which BVGH promises to consult in undefined “appropriate cases,” is never described, or even mentioned except in this one connection. The list of “partners” on the POINTD website includes all current *contributors* and *users*. There is no list of members of the Pool advisory committee and thus it is unclear whether it includes all those listed as partners or (as one might suspect) only the *contributors*. In an ordinary patent pool (which this, of course, is not), granting the entities in the pool a veto over who can license the pool’s patents would raise questions about anti-competitiveness and collusion. In this context, there may be other concerns, which we will discuss later in this chapter.

Openness with respect to *users* is also limited by the fact that access to particular patents and patent applications appears to be granted for a pre-defined scope of work and confined by the considerable flexibility in licensing terms left to *contributors* by the *principles*. In summary,

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<sup>59</sup> Owners retain complete discretion regarding ongoing access and licensing, including withdrawal from the Pool; subject only to any rights in the intellectual property previously granted by the *contributor* to a *user*.

<sup>60</sup> <http://ntdpool.org/pages/for-users/faqs>

<sup>61</sup> <http://ntdpool.org/pages/for-users/faqs>

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while anyone can apply to be a *user*, BVGH, the Pool advisory committee, and the *contributors* retain essentially complete discretion over which applications are accepted and, as will be explored in the next section, extremely broad discretion over the terms of the resulting licenses. The analogy that comes to mind is the relationship between funding agency and grant applicant.

### C. Governance and “Rules-in-Use”

Having laid out in detail the characteristics of the actors and resources involved in POINTD, we can now explore how they fit together in action situations – in this case, the licensing of patents, patent applications and know-how by *contributors* to *users*. Ideally, we would explore what Ostrom denotes “rules-in-use,” the ways in which licensing transactions actually play out in practice. Unfortunately, various factors preclude a true analysis of “rules-in-use” at this juncture. First, POINTD is very new and there have as yet been few, if any,<sup>62</sup> licensing transactions carried to conclusion. The licenses to the Emory-iThemba-TIA collaboration are the only ones of which we are aware.<sup>63</sup> Second, much of the “action” in POINTD takes place in secret. Therefore, we confine our detailed analysis at this point primarily to the formal governance structure and rules, and then follow with some comments about the potential importance of informal norms and rules-in-use.

#### 1. History of POINTD

We begin with the history of POINTD, since its governance and rules grow directly out of its origins. POINTD began as an initiative of British pharmaceutical giant GlaxoSmithKline’s CEO Andrew Witty. Witty became CEO of GSK in May 2008 and almost immediately began a highly-publicized campaign of initiatives aimed at global health. Witty has developing country experience, having served as GSK’s Managing Director of Glaxo South Africa and Area Director of South and East Africa. His tenure as CEO coincides both with a difficult economic period in the pharmaceutical industry, which has spurred a variety of business model experiments, and a period in which pharmaceutical companies are being criticized for inadequate responses to global health needs. It also coincides with a period in which both governments and philanthropic organizations (most notably the Bill & Melinda Gates Foundation and the Wellcome Trust) are investing significant money in the neglected disease issue and exploring ways to provide incentives for private industry to produce therapeutics for those diseases. Notably, the United States Congress in 2007 passed legislation authorizing the FDA to issue transferable Priority Review Vouchers, which can be used to speed up review of potentially lucrative drugs, as rewards for the development of medicines for specified Neglected Tropical Diseases.

GSK’s initiatives are thus part of a wider industry context of experimentation with responses to both economic and reputational difficulties. Proposals to address neglected diseases using patent pools in particular have been around for some time, at least since a well-known proposal by James Love in 2002.<sup>64</sup> In 2006, a Commission on Intellectual Property Rights, Innovation, and Public Health convened by the World Health Assembly recommended that the WHO and WIPO

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<sup>62</sup> See Consultation Draft, *supra*

<sup>63</sup> POSSIBLE QUESTION TO ASK

<sup>64</sup> James Love, Commentary: Patents, Pools, and the AIDS Crisis, 23 *Multinational Monitor* 14 (June 1, 2002).

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promote patent pools for medicines relevant to developing countries.<sup>65</sup> In July 2008, UNITAID, an international organization formed in 2006 “to decrease the price of medicines for priority diseases and to increase the supply of drugs and diagnostics,” proposed the creation of a patent pool for medicines for developing countries and began to explore its feasibility. That proposal eventually resulted in the Medicine Patent Pool, which currently focuses on drugs for HIV/AIDS. The MPP was officially approved in June 2010<sup>66</sup> and announced its first licensing agreement for generic production of AIDS medicines in July 2011.

Though part of a larger context of increased attention to developing country health issue, GSK is considered a leader among biopharmaceutical companies, at least by some measures, such as the Access to Medicines Index,<sup>67</sup> which ranked GSK first among pharmaceutical companies in both 2008 and 2010.

Since Witty became CEO, GSK has inaugurated numerous global health initiatives. In February 2009, Witty announced four GSK initiatives aimed at bettering global health. First, Witty promised to cut drug prices in the Least Developed Countries (LDCs) to no more than 25% of US and UK levels. Second, he announced that GSK would reinvest 20% of any profits it made in LDCs in hospitals, clinics, and medical staff in those countries. Third, he announced that GSK would invite outside scientists to work on therapeutics for Neglected Tropical Diseases at its dedicated Tres Cantos laboratory in Spain. Fourth, and most relevant for present purposes, Witty announced at that time that GSK would contribute IP rights for drugs for the FDA’s Neglected Tropical Diseases into a “patent pool” to promote open innovation.

Other initiatives followed. In March 2009, GSK announced that it would cut the prices of more than a hundred of its patented medicines by an average of 45% in certain medium income countries. In July 2009 GSK announced a major investment in AIDS drugs for Africa and a royalty-free licensing agreement with South African generic Aspen Pharmacare (in which GSK has a 16% stake.)<sup>68</sup> In January 2010, Witty announced that GSK had devoted a year to screening its library of two million chemicals for potential activity against malaria. He promised to post data about the 13,500 “hits” online where the information would be freely available to researchers. GSK also announced that if clinical trials were successful for a malaria vaccine it was developing it would price the vaccine at only 5% over cost in certain countries and reinvest the 5% in malaria research.

GSK’s “patent pool” proposal was greeted with both praise and skepticism. Critics complained about the GSK proposal’s failure to encompass drugs for HIV/AIDS, though Witty countered that AIDS research did not need the same kind of boost as the NTDs since there was demand for AIDS treatments in the developed world. GSK may have blunted some of this criticism by its later AIDS initiatives.

In January 2010, GSK announced that it would turn operation of POINTD over to Bio Ventures for Global Health, which now serves as its *administrator*. BVGH, as described above, is a non-

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<sup>65</sup> BNA 79 PTCJ 77 (11/20/2009)

<sup>66</sup> Sarah Boseley, Triumph and Tribulations in Battle for Cheap AIDS Drugs, 6/9/10, guardian.co.uk

<sup>67</sup> <http://www.accessmedicineindex.org/>

<sup>68</sup> Reuters News, 7/14/09, Update 1- Glaxo investing \$97mln in AIDS drugs for Africa

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profit organization closely tied to the biopharmaceutical industry, with significant funding from the Gates Foundation. As already discussed, to this date only a few organizations (and no major pharmaceutical companies other than GSK) have become users or contributors to POINTD.

## 2. Governance

The governance of POINTD is almost entirely in the hands of the *administrator*, BVGH, subject to the *principles*, which are discussed in the next section. POINTD itself does not appear to have a separate institutional identity. It has no board and is not listed as a 501(c)(3) organization. The only other governance mechanism discussed in the public website is that BVGH may, at its discretion, consult with a “Pool advisory committee,” apparently made up of “representatives of the partners” during the process of vetting potential *users*.

In some sense, the *principles* may be seen as constitutional of POINTD, since they provide the framework for interactions between *users* and *contributors*. It is not clear what body, if any, would have the authority to revise the *principles* or to resolve any disputes as to their interpretation or as to whether a particular license term is consistent with the *principles*. Neither *contributors* nor *users* appear to have any formal voice in framing the principles, though nothing seems to constrain the *administrator* from changing them. With one exception, however, discussed in detail below, the *principles* do not create rights or obligations as between users and contributors, since all relationships are bilateral (with BVGH as a possible intermediary) and each relationship is formally defined by a license between a *user* and a *contributor*, which would be impervious to any change in the principles. Should BVGH change the principles at some point, disgruntled *contributors* and *users* could respond simply by ceasing to use POINTD as a clearinghouse for negotiations.

## 3. Formal Rules for POINTD’s Operation?

### a. The *Principles* and Formal Rules

Licenses negotiated through POINTD are based on an explicit set of *principles*, which are publicly available on the website.<sup>69</sup>

The so-called “core principles” are:

Licenses for patents and know-how will be:

1. Limited to therapeutics to treat the sixteen Neglected Tropical Diseases in humans (defined by the U.S. Food and Drug Administration).
2. Royalty free for sales in the world’s Least Developed Countries (“LDCs”) (defined by the United Nations).

Additional principles “govern the more detailed workings of The Pool”:

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<sup>69</sup> <http://www.ntdpool.org/pages/core-principles>

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1. Licensing policies and additional terms are expected to facilitate and encourage development, commercialization, and access of therapeutics to treat NTDs.
2. Pool *contributors* must be willing to grant to qualified participants with a concrete proposal at a minimum, a non-exclusive worldwide license to research, develop, manufacture, and export therapeutics for NTDs for sales into LDCs under the patents that pool *contributors* chose to contribute (subject to the other limitations of the Pool); provided that the therapeutic is not otherwise being developed (or actively being considered for development) or commercialized for the NTD by or through the Pool *contributor*. Licenses to patents to manufacture, import, use, offer for sale, and sell therapeutics on an exclusive or non-exclusive basis outside of the LDCs will be negotiated on a case-by-case basis with the IP holder.
3. Pool *contributors* may reserve the right to negotiate royalty rates beyond LDCs on a case-by-case basis. The royalty rates should take into account the contribution of the IP holder to the project and ensure rates that facilitate access of the therapeutic to the poor.
4. License agreements should, however, include a non-enforcement clause prohibiting the licensee from using any IP generated through use of licensed IP to inhibit any Pool *contributor's* use of its own IP placed in the Pool.
5. Pool *contributors* will retain the ownership rights to their original IP. Licenses will be granted directly by the company or organization that owns the IP, although BVGH may play a facilitating role in the process.
6. Ownership follows inventorship. Pool *contributors* may not deny a licensee the opportunity to seek patents on any product or technology developed using patents under the scope of the license granted. Licensees are encouraged; however, to share any newly created IP with the Pool where this would further the development of therapeutics for NTDs, provided the licensee is not actively developing (or considering developing) or commercializing the therapeutic for the NTD. Pool *contributors* may not expect any reach-through rights.
7. Reimbursement for the financial rewards that a U.S. FDA Priority Review Voucher or any other incentive would bring the licensee should also not be expected.
8. Contribution of know-how is voluntary. Pool *contributors* have a choice as to whether, and on what terms, they will provide know-how to specific enquiries regarding possible use of technologies that might be of value to an NTD research or development project. Consideration of such requests shall be based on:
  - The relevance of the know-how to the problem to be solved
  - The cost to the Pool *contributor* and the available resources of the Pool *contributor*
  - The plan and proposal of the requestor demonstrating that they can make use of the know-how
9. Where know-how is made available, Pool *contributors* may require licensees to respect the confidentiality of the know-how and limit its use to NTD-related projects.
10. Pool *contributors* shall disclose to BIO Ventures for Global Health (BVGH), in writing, those patents and patent applications that they are willing to contribute to the Pool. Pool *contributors* understand and acknowledge that BVGH may publish such patents and patent applications for public inspection.
11. The Pool will have de minimis standards, whereby any Pool *contributors* agree to all the principles in this paper.
12. Entities wishing to contribute to the Pool may contact BVGH.

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Many of the *principles* are hortatory in nature. For example the statement of Core Principles notes that “the main objective of the Pool is to incentivize research into NTDs by making patents and know-how (“IP”) more widely available, on terms that facilitate the development of new therapeutics, and to make the process efficient and effective.” Further, Paragraph #1 specifies that “licensing policies and additional terms are expected to facilitate and encourage development, commercialization, and access of therapeutics to treat NTDs.” Since reasonable minds may differ as to what license terms will facilitate development of therapeutics to treat NTDs and what might make the development of such therapeutics “efficient and effective,” these *principles* have little bite. The statement contains a “good faith” paragraph, which has even less substance, since the principles repeatedly emphasize the extent to which any licenses to know-how are entirely at the discretion of the *contributor*:

The Pool *contributors* are contributing to the Pool because they wish to use their assets to improve the health of the poor around the world through the development of new therapeutics for diseases with little or no commercial market. Therefore, requests for additional assistance from the *contributors* to the Pool will be considered in good faith by the Pool *contributors*.

Even among the more detailed *principles*, there are few specific and potentially enforceable commitments and many limitations favoring *contributors*. In particular (and not surprisingly), the principles contain limitations aimed at protecting both the intellectual property positions of contributors and the potential for commercial parties to obtain financial rewards from programs such as the Priority Review Vouchers. To see how this plays out, it is useful to analyze the *principles* separately as they apply to: i) licenses to patents listed by POINTD for use in the core areas of therapeutics for neglected tropical diseases for use in the least developed countries, ii) licenses to know-how for use in the core areas of therapeutics for neglected tropical diseases for use in the least developed countries, iii) licenses to patents or know-how for use in countries not included in the United Nations list of LDCs or diseases other than the FDA-defined Neglected Tropical Diseases, iv) IP (defined to include both patents and know-how) developed by licensees as a result of their work under the licenses.

*Patent Licenses for therapeutics for Neglected Tropical Diseases to be sold in Least Developed Countries.*

*Contributors* make one very clear commitment in signing on to the core principles: licenses negotiated through POINTD must be royalty free for sales in the LDCs. Paragraph #2 in the principles concerning more detailed workings sets out some further minimal requirements. Thus, *contributors* must be “willing to grant” licenses that are 1) worldwide and that 2) permit the licensee to “research, develop, manufacture, and export therapeutics for NTDs for sales into LDCs.” Further analysis highlights several explicit and implicit limitations to these commitments. Specifically:

- Licenses need only be granted to “qualified participants with a concrete proposal.” (Paragraph #2)



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- Licenses need not be available if the therapeutic is “otherwise being developed (or actively being considered for development) or commercialized for the NTD by or through” the *contributor*. (Paragraph #2)
- The principles do not set out any minimum time for the term of the license. Nor do they specify anything about termination provisions.

The phrase “qualified participants with a concrete proposal” is not defined. It is thus unclear whether contributors may determine that an entity is not a “qualified participant with a concrete proposal” independently from and over and above, the determination by BVGH whether to accept a particular application to become a *user*. In any event, given the process for vetting users, it is likely that *contributors* have more or less complete discretion as to whether to enter into a license with a particular entity.

Under Paragraph #2, *contributors* also need not award licenses if they themselves are developing, commercializing, or actively considering developing a therapeutic for a neglected tropical disease. The purpose of this limitation may seem obscure at first glance, given that these are, after all, neglected diseases. Why would a *contributor* be concerned about competition in the development of therapeutics for neglected diseases? Here it is worth recalling the availability of Priority Review Vouchers to those who obtain approval for a new drug for one of the specified Neglected Tropical Diseases. Priority Review Vouchers may be used to obtain priority review for *any* new drug and are alienable. They thus may be extremely valuable to pharmaceutical companies that have commercially viable drugs needing FDA approval.<sup>70</sup> Companies may, therefore, have incentives to compete with one another to try to obtain PRVs (indeed, stimulating development of such drugs by commercial pharmaceutical companies is the very purpose of the PRV provision). (It is difficult to say how popular the PRV program will turn out to be. So far, only one voucher has been awarded and used, but the PRV program, like POINTD, is very new on the timescale of drug development.) Other financial incentives, such as prizes, may be used to incentivize development of therapeutics for NTDs. Of course, an entity that is pursuing a proprietary reward could simply refrain from listing patents with POINTD that are relevant. However, a company that is pursuing such rewards by developing a particular type of NTD therapeutic might nonetheless wish to offer licenses for use beyond the scope of its current or anticipated development efforts. The limitation allows for that possibility.

There is a further wrinkle in the story about Priority Review Vouchers and similar financial incentives for developing drugs for NTDs. The principles say nothing about either the term of a license negotiated through POINTD or acceptable termination provisions. Moreover, Paragraph #2 is less than clear as to whether a *contributor's* interest in the disease must precede the license in order for the patentee development-commercialization limitation to apply. The *principles* specify only that licensees need not financially reimburse *contributors* for any Priority Review Vouchers the licensees themselves obtain as a result of the licenses. It would seem, therefore, that a POINTD license could contain a provision permitting the *contributor* to terminate the license once it begins to “actively consider” development of a therapeutic for a neglected tropical disease using the licensed technology. Such a termination provision would permit a *contributor* to use the POINTD process strategically, waiting for a licensee to make progress toward a

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<sup>70</sup> BVGH reports that estimates of the value of a PRV range between \$50 million and \$500 million.

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successful drug, and then taking over development, using the results of the licensee’s efforts as a springboard toward a Priority Review Voucher.<sup>71</sup> Of course, one might take a sanguine view of such a strategy. If biopharmaceutical companies are motivated to make royalty-free licenses available that eventually facilitate the development of drugs for neglected diseases, perhaps Priority Review Vouchers are simply doing their job. But if much of the work is done by others (particularly if they are government-funded or non-profit entities), that would certainly add to the acknowledged costs of the PRV system. At the moment, of course, this is all speculation since neither the POINTD nor the PRV system has seen much action to date.<sup>72</sup>

*Licenses to know-how for use in the core areas of therapeutics for neglected tropical diseases for use in the least developed countries*

The *principles* separate the treatment of patents and patent applications identified to POINTD and “know-how” (presumably including trade secrets). Paragraph #8 specifies that “contribution of know-how is voluntary” and that *contributors* “have a choice as to whether, and on what terms, they will provide know-how to specific enquiries . . .” Paragraph #8 does, however, specify three factors upon which “consideration of such requests shall be based:” “the relevance of the know-how to the problem to be solved;” “the cost to the Pool *contributor* and the available resources of the Pool *contributor*;” and “the plan and proposal of the requestor demonstrating that they can make use of the know-how.” Licenses to know-how under POINTD may require confidentiality.<sup>73</sup>

Evidently, the intent of the *principles* is to make know-how licenses more discretionary than patent licenses. But in what regard? All licenses (whether for patents or know-how) are subject to the Core Principles, meaning that they must be royalty-free for sales in the LDCs and can be limited to therapeutics for the specified NTDs. Paragraph #8 suggests that *contributors* have greater discretion in determining who may become a *user* of know-how, but the practical implications of this distinction are likely to be minor, given the great influence that *contributors* already would seem to have on the process of vetting potential *users*. The most operative distinctions between the treatment of patents and the treatment of know-how are probably: 1) the complete freedom to set the terms of know-how licenses<sup>74</sup> and 2) the fact that no publicly available list or description of available know-how is maintained.<sup>75</sup> The *principles* do not require advance disclosure of the availability of know-how for license, even to the administrator, though the *Contributor* FAQs state that “[i]f know-how is part of the contribution a brief description should also be made available.”<sup>76</sup>

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<sup>71</sup> Of course, a licensee could keep some of its progress secret, but there are many ways that contributors could learn about licensee progress. Some licensees will publish or publicize their results. Moreover, the license itself could provide for progress reports.

<sup>72</sup> The implicit attention to the potential for PRVs in the principles may also be an artifact of BVGH’s interest in the program. BVGH, besides administering POINTD, is policy organization with close ties to the biotech industry. IT heavily promotes the PRV program. <http://www.bvgh.org/What-We-Do/Incentives/Priority-Review-Vouchers.aspx>.

<sup>73</sup> Paragraph #9.

<sup>74</sup> Compare Paragraph #2 (licenses should be “non-exclusive worldwide license[s] to research, develop, manufacture, and export therapeutics for NTDs for sales into LDCs”) with Paragraph #8 (*contributors* choose “on what terms” they will provide know-how).

<sup>75</sup> Compare to Paragraph #10.

<sup>76</sup> <http://www.ntdpool.org/pages/for-contributors/faqs>

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Though the *principles* emphasize the discretionary nature of any transfer of know-how, the hortatory paragraph at the end provides that “requests for additional assistance from the *contributors* to the Pool will be considered in good faith by the Pool *contributors*.” More specifically, the *Contributor* FAQs attempt to encourage that licensees be given access to more than the bare patented technology. In response to a question about whether *contributors* have “obligations to provide technology, assistance, interpretation or know-how,” the FAQ reaffirms that “[e]ach *contributor* may determine the extent of any further assistance it is willing to provide to potential licensees.”<sup>77</sup> Yet, the FAQ continues to say that “[i]t is presumed that *contributors* will provide some facilitating introduction and technology transfer consistent with the asset, and will be reasonably available to address questions about the assets.”

*Licenses to patents or know-how for use in countries not included in the United Nations list of LDCs or diseases other than the FDA-defined Neglected Tropical Diseases*

Like licenses to know-how, any licensing to patents or know-how for use outside of POINTD’s core area of concern (NTDs in LDCs) are entirely discretionary. For example, Paragraph #2 provides that any patent licenses for use or sale outside of the LDCs “will be negotiated on a case-by-case basis with the IP holder.” Paragraph #3 spells out explicitly the right to charge royalties for any such licenses, though “the royalty rates should take into account the contribution of the IP holder to the project and ensure rates that facilitate access of the therapeutic to the poor.”

While licenses for use or sales in countries outside of the LDCs are addressed in the *principles* and FAQs, there are no provisions regarding licenses for use in addressing diseases other than the FDA Neglected Tropical Diseases. It would appear that such diseases are simply beyond the scope of POINTD. The restriction of POINTD’s scope to the Neglected Tropical Diseases on the FDA’s list for Priority Review Vouchers is no accident. For example, AIDS, which has been the focus of much of the advocacy to medicines in developing countries, is not included in the list even though POINTD has been criticized for its failure to address AIDS. The omission has been explained by Witty as relating to the fact that AIDS is not a neglected disease because its effects in the developed world provide incentives for research and development.<sup>78</sup> Critics suggest that the omission has more to do with GSK’s commercial interests in marketing its AIDS medications.<sup>79</sup>

*IP developed by licensees as a result of their work under the licenses*

The *principles* deal to some extent with questions about intellectual property created by licensees as a result of their work under POINTD licenses (hereinafter “Licensee IP”). In the *principles*, “IP” is defined to include both patents and know-how (presumably meaning trade secret know-how). The provisions of the *principles* and FAQs dealing with licensee IP have received very little attention in discussions of POINTD in the press or elsewhere, but they are important to understanding the formal commitments embodied in the *principles*.

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<sup>77</sup> <http://www.ntdpool.org/pages/for-contributors/faqs>

<sup>78</sup> Cite.

<sup>79</sup> Cite. Maybe some more about this?

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First, Paragraph #6 of the principles provides that licensees must be permitted to obtain patents on their own inventions made through POINTD licenses and that “pool *contributors* may not expect any reach-through rights.” More specifically, Paragraph #7 provides that *contributors* do not receive reimbursement for PRVs or other financial rewards that licensees obtain as a result of their work based on the licenses. There is some ambiguity (because of Paragraph #8’s grant of discretion with respect to license terms), but these limitations on *contributors*’ reach-through rights probably apply to POINTD know-how licenses as well as to patent licenses.

Second, though licensees may obtain patents on the results of their work under POINTD licenses, they are “encouraged,” though not required, by Paragraph #6 to “share any newly created IP with the Pool where this would further the development of therapeutics for NTDs.”

The simple story is thus that *contributors* do not retain reach-through rights with respect to any Licensee IP, while licensees are encouraged to replenish POINTD’s offerings with such IP. To the extent POINTD plays out this story in reality, it is consistent with POINTD’s transaction-cost-reducing role and potentially makes POINTD self-sustaining. If reach-through rights are prohibited and licensees contribute their IP back to POINTD, the result should be an expanding list of available IP at the forefront of research and development for any therapeutic directions for which initial *contributors* and *users* are found.

Several things complicate this story. First, as already discussed, *contributors* can withdraw their IP from POINTD at any time, may provide for license termination if they themselves become interested in developing or commercializing an NTD therapeutic, and may have incentives to do so to obtain Priority Review Vouchers or other financial rewards for developing therapeutics for NTDs. Licensees are similarly “exempted” from the “encouragement” to put Licensee IP into POINTD if they are developing, commercializing or considering developing an NTD therapeutic. This exemption makes sense only if *users* anticipate some pay-off from exclusive development of such therapeutics and seems most likely aimed at preserving the incentives for *users* provided by PRVs and other financial rewards, such as prizes. Like the similar exemption in Paragraph #2, this exemption reflects the tension between the goal of openness, so as to facilitate the use of complementary knowledge held by different parties, and the goal of incentivizing investment in NTD research using competition for exclusive rewards.

Second, though Paragraph #6 provides that *contributors* do not get reach-through rights to licensees’ IP, Paragraph #4 may undermine that principle. Paragraph #4 states that licenses should “include a non-enforcement clause prohibiting the licensee from using any IP generated through use of licensed IP to inhibit any Pool *contributor*’s use of its own IP placed in the Pool.” Importantly, this Paragraph constrains the licensing discretion of *contributors* as well as *users* because it requires inclusion of a provision that protects all *contributors* – not just the particular *contributor* negotiating the license.

What exactly must such a non-enforcement provision cover? It is not at all clear what is subsumed in the scope of “inhibiting” a *contributor*’s “use” of its intellectual property by “using” a licensee’s IP. We may assume that “IP generated through use of licensed IP” means IP generated while exercising rights granted under the license (which we have been calling “Licensee IP”). Even so, the meaning of “use” of IP, which occurs two more times in Paragraph

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#4, remains ill-defined. Intellectual property rights are legally defined as “negative rights,” which empower the IP owner to keep others from doing things that would infringe on those rights. A natural interpretation of “use” of IP is thus “enforcement.” However, this interpretation clearly will not work in Paragraph #4. It makes no sense to speak of a licensee inhibiting a contributor’s enforcement of its IP by enforcing Licensee IP. Other similar interpretations of “use” (such as “license”) are equally nonsensical if applied throughout the sentence. Alternatively, “use” of IP might mean (somewhat colloquially) “using” the underlying invention or know-how, what is called “practicing the invention” (for example, by making, using, or selling it) in patent lingo. Incorporating this meaning of “use” consistently into Paragraph #4 is also unsatisfactory. What would it mean for a licensee to inhibit a contributor’s practice of its own invention by practicing Licensee IP?

Of course, a layperson will undoubtedly lose patience with this lawyerly pedantry. The most natural reading of Paragraph #4 takes the term “use” to have two different meanings. In other words, Paragraph #4 should probably be interpreted to say: “Licenses should include a non-enforcement clause prohibiting the licensee from enforcing any of its own IP generated through practicing inventions or know-how licensed through POINTD in such a way as to inhibit any Pool contributor’s practice of its own inventions or know-how that is available through POINTD.”

Accepting this interpretation for the moment, we are still left with several puzzles. First, under what circumstances might a licensee’s enforcement of its IP rights “inhibit” a *contributor* from practicing the *contributor*’s own inventions or know-how? The implication is that when the *contributor* practices its own inventions it is simultaneously infringing Licensee IP. This might happen, for example, if *contributor* and licensee each own one of a pair of so-called “blocking patents” covering an invention and an improvement to that invention. (For example, a patent claiming a particular chemical and a patent claiming a new use of the chemical.) If the *contributor* practices the improved invention, it will infringe the licensee’s patent. A contributor might alternatively want to practice its own patent simultaneously with a piece of Licensee IP if the two patents cover complementary inventions, which are of greater use when practiced together. (For example, patents each claiming one of two chemicals which are used together as a therapeutic). The bottom line is that the only way enforcement of one party’s patent can “inhibit” another party’s practice of its own patent is where the second party seeks to practice *both* patents. By precluding a licensee from “inhibiting” a *contributor*’s use of its IP, Paragraph #4 would thus seem effectively to require a licensee to grant every *contributor* a royalty-free license to use Licensee IP in conjunction with the contributor’s own listed IP. For example, suppose User A licenses a tool or method from Contributor B through POINTD and uses that tool or method to develop Chemical A. Suppose also that Contributor C has listed as available through POINTD a patent on a different Chemical C. If Contributor C combines Chemicals A and C into a drug, Paragraph #4 seems to say that the license between User A and Contributor B should preclude User A from suing Contributor C for infringement.

Within the neglected tropical disease context, one might well applaud Paragraph #4 as removing one more potential transaction cost barrier to the availability of NTD therapeutics. With Paragraph #4 in place, if *any* invention available to be licensed through POINTD and *any* invention developed through a POINTD license are best used jointly to produce a therapeutic,

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the *contributor* of the first invention will be authorized to do so. Indeed, a license to a more traditional patent pool might well contain a similar provision requiring that improvement patents be included in the pool. Note, however, that in a traditional patent pool, both the licensee and the contributors to the pool would then be able to practice the combined invention. In the POINTD situation, however, since *users* negotiate individual licenses with individual *contributors*, the *user* who developed one invention (Chemical A in our example) under a license from one *contributor* (Contributor B) may or may not be authorized to combine the two inventions (Chemicals A and C), depending on whether that *user* has (and retains) a license from the *contributor* who developed the other invention to be practiced simultaneously (Contributor C).

The bilateral nature of POINTD licensing leads to this seemingly strange result. Thus, Paragraph #4 provides additional opportunities for *contributors* to “make off with” PRVs and other rewards for commercializing therapeutics for NTDS, despite the fact that development of the therapeutic depended on the work of a *user*.

Moreover, the non-enforcement provision required by Paragraph #4 does not seem to be limited to the context of NTDs for LDCs. Patent rights often extend beyond particular applications. It is certainly possible that a POINTD licensee might use licensed IP to develop and patent an invention that, when used in conjunction with some claim in some patent available for license through POINTD, would have applications beyond neglected tropical diseases. While the *user*’s license would extend only to specific patents and apply only in the NTD context, the non-enforcement provision would appear to cover such combinations. Thus, for example, if User A licenses a method or tool from Contributor B and, in the process of using that method or tool to investigate a therapeutic for an NTD, develops and patents an improved or different method or tool, it would appear that User A would be precluded from enforcing the patent on the new method against any of Contributors A through Z, even if Contributors A through Z were using the method to work on a commercial application of one of their POINTD-listed patents.

Even more questions remain. Does a contributor’s “use” of its own IP encompass the licensing out of that IP? If so, does the ban on enforcement extend to enforcement against those who may have licensed the contributor’s IP? The potential for such a lawsuit might certainly be understood to “inhibit” in some sense a contributor’s ability to license out its own IP.

Of course, Paragraph #4 contemplates that its prohibitions would be concretized in a non-enforcement clause in a license. The terms of a specific license would undoubtedly remove some of the ambiguities left by Paragraph #4’s formulation. But that raises another issue. Paragraph #4, unlike the rest of the principles relating to licensing terms, requires licenses to provide rights to third parties (the other *contributors*). Thus, there is potential for conflict between *contributors* if different licenses instantiate Paragraph #4 in inconsistent ways. It is not clear whether the *administrator* is empowered to police licenses negotiated through POINTD for compliance with this (or any other) provision, to mandate inclusion of a standard non-enforcement provision, or to resolve disputes about the proper implementation of Paragraph #4.

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*Summary*

Stepping back from the minutiae of this attempt to understand the extent to which the *principles* might function as enforceable rules, a few points are in order. First, the *principles* reflect their origins in a pharmaceutical company and POINTD’s continued close ties to the biopharmaceutical industry. Their detailed provisions are designed to leave flexibility and require minimal commitments (particularly for *contributors*), to permit participants to take advantage of financial and other incentives, such as Priority Review Vouchers, and to protect the potential for commercial markets. Second, the *principles* leave many ambiguities and provide no evident way to resolve them. Partly, this results in the afore-mentioned flexibility, but there is also clearly room for conflict and dispute. Third, the *principles* are largely just that – unenforceable, hortatory statements of goals and intentions backed up by “good faith.” It is unclear from our research so far<sup>80</sup> to what extent more formal contractual obligations underlie the published *principles* and *user* and *contributor* FAQs. *Users* and *contributors* are required to “agree” to the *principles*. The form of this agreement is under investigation, but at most it is likely to comprise a contractual relationship with BVGH, rather than any contractual obligations to other *contributors* or *users* beyond what is contained in bilateral licenses. Much thus depends on the specifics of the licenses negotiated on a bilateral basis. Importantly, and with the exception of Paragraph #4, the *principles* do nothing to obligate or connect users and contributors with one another, except in the context of specific bilateral licenses.

#### 4. Informal Rules and Rules-in-Use

POINTD is a very young institution and has yet to move far beyond its origins with GSK’s Andrew Witty. It has few *contributors* or *users* and few of those are for-profit companies.<sup>81</sup> For our part, we have not yet obtained copies of any licenses or other agreements negotiated using the POINTD framework (if they exist). At this point, it is not meaningful to discuss the specifics of POINTD “rules-in-use.” However, the above analysis permits a few observations. POINTD has such a non-constraining structure that its success in moving beyond facilitating a few bilateral licenses will depend on developing norms and Rules-in-Use to flesh out the *principles*. Such informal rules are necessary in at least three respects. First, the *principles* leave many gaps and ambiguities that will have to be filled somehow. BVGH, in its role as facilitator of negotiations, could play a significant role in determining how the *principles* are instantiated in licensing agreements. To the extent the details of such agreements are kept secret, BVGH may be an important intermediary in setting norms across agreements. If common practices do not evolve, POINTD will end up as little more than a “community billboard” advertising contributors’ willingness to negotiate licenses for NTD research. Second, the *principles* are grounded in a promise of “good faith” and many largely hortatory commitments. Because there are few formal and concrete commitments (and many loopholes) in the *principles*, the way in which these promises are interpreted and the extent to which they become norms that may be enforced by reputational penalties will determine the nature and stability of POINTD. Third, and relatedly, the *principles* walk an uneasy line between the stated goal of therapeutics for neglected

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<sup>80</sup> POSSIBLE QUESTION TO ANSWER

<sup>81</sup> Note that Alnylam has been involved in a venture with GSK since 2008.

[http://www.gsk.com/media/pressreleases/2008/2008\\_pressrelease\\_10027.htm](http://www.gsk.com/media/pressreleases/2008/2008_pressrelease_10027.htm). I don’t know whether this relationship has anything to do with Alnylam’s participation in POINTD.

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diseases and concessions to commercial interests. This is particularly apparent in the IP provisions and the various provisions that touch on the possibility of Priority Review Vouchers. Norms and, relatedly, reputational penalties for actions inconsistent with POINTD’s purported socially-motivated goals will largely determine whether POINTD participants engage in strategic exploitation of the *principles* and to what extent it is acceptable to compromise commitment to POINTD’s stated goal of providing open access to relevant IP in order to respond to more proprietary incentives for developing NTD therapeutics.

Of course, POINTD’s eventual success will depend on whether it can attract more *contributors* and *users*. This in itself will likely depend on whether and in what way norms of social responsibility evolve in the biopharmaceutical industry more broadly and which of the various approaches to the NTD issue that are presently being explored catch on. One might speculate that POINTD’s *principles* and FAQs are intentionally full of gaps, ambiguities, and loopholes (one can hardly believe that GSK and the industry-funded BVGH were unable to obtain the services of lawyers adept at drafting clear and enforceable agreements) so as to place a low bar to industry participation and then permit norms to evolve based on the reputational rewards of acting in accordance with the stated values and reputational risks of strategic behavior inconsistent with those values. More cynically, one might speculate that the *principles* were drafted so as to allow industry actors to gain reputational rewards without making serious commitments to treating Neglected Tropical Diseases. In any event, the formal structure leaves significant room for the evolution of informal “rules-in-use.” Time will tell whether there is enough “buy-in” to this particular approach to make it sustainable and effective.

#### IV. Conclusion

Though it would be premature to draw conclusions from this preliminary analysis, we can make a few observations at this point. First, the Pool for Open Innovation for Neglected Tropical Diseases is, by its structure, neither of patent pool nor particularly open. Instead, it provides a database of patents that are available for license for work on neglected tropical diseases, a mechanism by which private firms can signal an interest in collaborating on such efforts, and, potentially, some standard practices and boilerplate terms for licensing such collaborations. At close inspection POINTD is closely tied to the public-private partnership model and could be described as a facilitator of public-private partnerships, though on a smaller scale than PPPs like MMV, MVI, and DNDi. Second, it seems that it may be particularly difficult to construct commons-like arrangements in the “middle” of the drug discovery pipeline. True patent pools, such as the UNITAID-founded Medicines Patent Pool for AIDS drug, may be most useful in situations similar to those in which they are ordinarily used – either for pre-competitive platforms or standards or for products covered by patents owned by more than one company. Other commons-type arrangements, such as data sharing, seem workable at the upstream end of the pipeline. In the middle the public-private partnership seems to predominate. That may be because pipeline management in the intermediate range requires a top-down approach, or because the need for access to proprietary know-how that is not specific to the neglected disease context makes companies unwilling to participate in commons-type approaches. Or perhaps it is just that no one has yet devised quite the right “open source” approach.



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Continued research is however necessary to determine and understand openness across the pharmaceutical value chain. Here, the efforts of the Open Source Drug Discovery Project (OSDD)—a global platform for collaborative discovery work into novel therapies for neglected tropical diseases including malaria, tuberculosis, and leishmaniasis could provide insight not only into global models of open collaboration, but openness with respect to intellectual property during translational research.