Chapter 3: Intellectual property

Intellectual property management in not-for-profit innovation:

The case of product development partnerships in neglected diseases

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Abstract

This study examines the management of intellectual property rights (IPRs) in the context of not-for-profit medical product R&D and innovation. The specific case of Product Development Partnerships (PDPs) in the area of neglected diseases is considered. A survey was conducted covering the whole population of PDPs. Consistent with previous literature this study finds that in the area of neglected diseases where commercial markets are low or non-existent, IPRs do not function as an incentive for innovation. Nevertheless, the management of IPRs is an important consideration for all PDPs. This is the case because PDPs can be both "users" of IPRs in seeking access to background technology and know how that can be protected by IPRs held by third parties, and also "producers" of IPRs related to the results of their R&D projects, alone or with partners. R&D collaboration is central to the PDP model. IPRs are one mechanism by which PDPs aim to attract private firm interest in R&D partnership, though R&D collaborations should work in line with the overall innovation and global access goals of the PDP. In this sense, the IP management approaches of PDP are conditioned by their non-profit nature and their mandate to bring about new medical products that are affordable and accessible to poor populations that need them. PDPs report use of IPR protection for strategic purposes that they consider further advance their not-for-profit goal.

Key words

Intellectual property rights, product development partnerships, medical products, R&D, innovation, collaboration, partnerships

I. Introduction

It is well known that the pharmaceutical industry actively seeks out patents and other forms of intellectual property rights (IPRs) and is opposed to weakening of intellectual property (IP) protection. In contrast, the IP practices and policies of not-for-profit R&D institutions

involved in medical product development are not well understood. In general, the role of IP in the context of not-for-profit innovation is an underexplored subject.

This study explores this question by examining a specific form of not-for-profit R&D organization: product development partnerships (PDPs) in the area of neglected diseases. The aim is to understand to what extent are IPRs are relevant for PDPs in working towards their objective of driving innovation in neglected diseases on a not-for profit basis, and in managing the R&D collaborations with a diversity of public and private actors.

The study analyzes the role of IPRs in the context of PDPs, from two perspectives. One the one hand, PDPs as potential users of IPRs, to obtaining access a technology or knowledge asset of a partner or a third party that is protected by IPRs. On the other hand, PDPs are considered as potential producers of IPRs, in deciding whether to protect through IPRs outputs developed as part of an R&D project and to license IPRs to third parties. A survey on was undertaken covering the whole populations of PDPs to understand the IP management policies and practices of PDPs. Overall, the study contributes to the understanding the role of IPRs under different institutional settings supporting R&D and innovation.

The remainder of the study is organized as follows. Section 2 reviews the literature on intellectual property as an incentive to innovation and other uses of IPRs by firms and universities alone and in R&D collaborations. Section 3 discusses the IP approaches of PDPs. Section 4 presents the survey data and discusses the results. Section 4 concludes

II. Intellectual property and incentives for innovation

II.1. IPRs and innovation

The understanding of incentives for R&D and innovation is a long-standing subject in economics of innovation. Economists have mainly given attention to intellectual property as an incentive mechanism and policy response to the problem of imperfect appropriability. Intellectual property is one among several incentive mechanisms used to promote R&D and innovation. Other mechanisms used include government and/or philanthropic sponsored prizes and procurement, i.e. direct subsidies, research grants or fellowships, or indirectly by employing scientists in public R&D labs or universities (David et al 1999, Gallini & Scotchmer 2002, Stephan 2010, Hall & Lerner 2010). The problem of appropriability refers to the situation where innovators may not be able to fully capture the profits associated with their innovation, given the potential for unintended spillover (i.e. transmission, imitation) of the information and knowledge created through their private investment in R&D (Arrow 1962, Levin et al 1987, Winter 2006). By limiting R&D spillovers, in theory intellectual property helps innovators to protect returns to innovation. On the other hand, R&D spillovers are an important source of technical progress (Levin 1988, Cohen 2010).

Intellectual property is a legal system that allows the exclusion of potential users of an innovation unless they meet the terms and conditions of the holder of intellectual property rights (IPRs) over it. IPRs are exclusive rights to commercialize a protected subject-matter (i.e. creative work, mark, design, product or process invention). The IPR holder can exercise the right to gain or maintain market advantage. IPRs can take various forms, including patents, copyrights, trademarks, and trade secrets. IPRs have limited durations (for trade

secrets protection lasts as long as the information is kept secret, trademarks can be renewed indefinitely, unlike patents and copyright). IPRs can be exercised, traded (sold or "rented" via a licensing contract, or otherwise transferred) or abandoned (Rockett 2010). Economics literature has given most attention to patents. A patent is granted by government with regards to an invention that may be a product or a process, when the application meets the patentability requirements and with the condition that the patent applicant publicly disclose information of the invention, sufficiently that it can be replicated and used by others once the term of protection is expired. Trade secrets, of a different nature, may also be used to protect innovations. The secret should not have been disclosed to the public and reasonable efforts must be done to keep the information secret.

Firms can use intellectual property in deciding whether and how to protect, use or transfer knowledge assets (including tacit and codified know how, technical and organizational) for their competitive advantage.[81] Nonetheless, knowledge generated through R&D is not perfectly appropriable, nor is easily transferable, often because the knowledge is tacit.

Empirical studies point to an increased propensity of firms to patent, particularly in the United States and Europe, but are inconclusive in explaining this trend. A review of empirical studies by W.M. Cohen casts doubt on the effectiveness of intellectual property as a mechanism for appropriability (i.e. patents that are invented around) and the impact of patents on innovation (Cohen 2010). Economists have also pointed to defects of intellectual property as an incentive mechanism, in particular the deadweight loss from monopoly pricing that reduces users (i.e. those not willing to pay the price of the license) and inefficiencies that are caused by "patent races". Inefficiencies are due, among other factors, to the difference that may exist between the private value of the intellectual property from the social value and imperfect sharing of information among R&D competitors (Menell & Scotchmer 2007). It has been suggested that joint ventures and other strategic alliances are a way to reduce such inefficiencies related to "patent races" (Schotchmer 2003), though empirical evidence is lacking.

II.2. The strategic use of IPRs by firms

A growing body of literature is showing that firms increasingly claim IPRs, particularly patents, to pursue a diversity of objectives, other than deriving profits from the commercialization, sale or licensing of a patented invention. In this regard, an empirical study finds that firms use patents to block rivals from patenting related inventions, to threat or protect against infringement suits, to strengthen bargaining position in negotiations with other firms for protected technology (i.e. cross-licensing), as a measure of internal performance, and the enhancement of the firm's reputation – with differences across firms and technologies (Cohen et al 2000). Similarly, a study on the patenting behavior in the semiconductor industry finds that by building larger portfolios of IPRs firms may reduce the holdup problem posed by external patent owners and enable firms to negotiate access to external technologies on more favorable terms (Hall et al 2001).

[81] Firms also rely on other means of appropriability to a greater extent that or in addition to IP, such as lead-time/first-mover advantage, secrecy and complementary capabilities. See for example Cohen et al 2000.

II.3. Use of IPRs in non-profit institutions

Historically, universities and public laboratories did not claim IPRs. Economists have also given attention to the increased patenting and licensing by public and private universities, a trend attributed in part to changes in IP regulations. While universities continue to receive significant public financing and play an important role in the dissemination of knowledge, legislations such as the United States Bayh-Dole Act of 1980 promote patenting by universities that restricts the dissemination of the research results and inventions from university to stimulate higher levels of university - industry interaction and technology transfer. Studies show that it is unclear what is the impact of increased university patenting and caution on negative effects of patents on inputs to future research that hinder downstream research and product development (Mowery and Sampat 2004, Geuna and Rossi 2011). As argued by Sampat with respect to the role of the United States' National Institute of Health in financing basic research, "if [publicly] funded institutions start to act too much like firms with respect to their patenting and licensing activities, this would seriously undercut the economic argument for public support, from either 'market failure' or a more heterodox perspective" (Sampat 2009).

II.4 Use of IPRs in R&D collaborations

Existing studies on the use of IPRs in R&D collaborations examine collaborations that involve firms exclusively, or firms and universities in a single industry or across industries. One study finds that firms make strategic use of pre-existing IPRs as bargaining chips and also consider IPRs as important for protecting foreground knowledge created in the research partnership (Hertzfeld et al 2006). Another study finds that, in first instance firms prefer to divide ownership of patents that may result from research partnerships, as opposed to sharing (co-ownership of patents), given the co-patenting creates fewer opportunities for the firm to appropriate the full value of the patent, particularly where the firms have interest in exploiting the patent in the same domain of application (Belderbos et al 2014).

III. Review of PDP approaches to IP

III.1 The system integrator role of PDPs

PDPs are independent, not-for profit entities that drive R&D for new medical products in the area of neglected diseases, and function as "system integrators" that leverage the resources and capabilities of a diverse network of public, philanthropic and private sector actors (Munoz et al 2014). Understood in this way, PDPs are discernible from other forms of not-for-profit entities and public-private collaborations.[82] The particularity of a not-for-profit organization is that its objective is not to earn profit, but rather to serve the objectives of the organization.[83] A not-for-profit organization can be formally established as a legal entity in its own right, or

[82] Public – private partnerships are generally established to mobilize private sector resources to deliver essential public services or involvement in mayor projects by creating favorable market conditions that otherwise would not exist. Public – private partnerships in medical product development generally follows these same lines. In the area of neglected diseases there is generally a lack of commercial market opportunities for medical product development. There may be various forms of public-private partnerships in health, PDPs are a specific form with focused objectives on product development (see Galea and McKee 2014, Velasquez 2014).

[83] However, not-for-profit organizations can earn revenues to pursue their objective. They are legally exempted from income tax as profits are not distributed for personal gain of its owners/shareholders.

informally (i.e. unregistered association). The term "not-for-profit R&D organization" is used here to refer to a formally established organization that pursues a not-for-profit objective that requires substantial amount of R&D activity. The objective of the R&D is to amplify the social value of the innovation, in contrast to for-profit R&D by firms that aim to not capture as much profit as possible from their innovation.

The term "partnership" is used here to refer to collaboration among two or more parties to advance an R&D project, in a broad sense (not limited to joint R&D). R&D partnerships in a not-for-profit R&D organization may involve any number of not-for-profit entities (public universities and R&D labs, private foundations), for-profit entities (i.e. firms) and government agencies. The roles individual actors in the partnerships may vary, for example government or private charitable foundation may provide financing, a university or firm may provide technology, know-how and information, background IPR, infrastructure. A partnership is distinct from a regular business practice, such as the when a not-for-profit R&D organization purchases from any public or private entity a good or service against payment at market price. Moreover, for purposes of this study it is understood that a for-profit entity is in partnership when it is voluntarily engaged in an R&D project to support the objective of which underpins the not-for-profit R&D organization (as opposed to gain profits). The common objective of a R&D collaboration under a PDP-led R&D project is to advance the non-profit public health mission of the PDP, though partners may have other specific motivations for entering the collaboration.[84] Various types of entities opt to engage in different ways for the common purpose of advancing innovation for neglected diseases.

There is evidence that PDPs are playing an important role in driving new R&D and innovation in the area of neglected diseases in which medical products -medicines, vaccines, diagnostics - are lacking (Moral et al 2005, Chataway et al 2010, Troullier et al 2013, Munoz et al 2014).[85] A significant amount of collaborative R&D projects in the area of neglected diseases are taking place through Product Development Partnerships (PDPs).[86] These involve a diversity of public and private actors, including academic institutions, public research labs, hospitals, government health and regulatory authorities, contract research organizations, biotechnology firms and pharmaceutical companies, among others. Assuming a common mission of PDPs and partners engaged in R&D projects, one can expect that the approach to R&D collaboration under PDP-led R&D projects would differ from arrangements in the competitive, market-driven and profit-oriented environment of the pharmaceutical industry. Trends observed in the pharmaceutical industry highlight the competitive nature of medical product development. These include the consolidation of large firms, the decline in innovation

[84] Other studies have explored the specific motivations of entities involved in PDP R&D projects (Moral et al 2005, Munoz et al 2014).

[85] The term "neglected disease" is a used to denote diseases diseases that have a large burden in poor populations in developing countries, but no or little burden in the developed world, and that lack effective, affordable, or easy to use diagnostics and treatments. For the purposes of this study, and following Munoz et al 2014, in this study we consider neglected diseases to include Malaria, HIV/AIDS, Tuberculosis, and the group of 17 diseases classified as such by the World Health Organization. PDPs have successfully produced a number of new medical products that significantly improve prevention and treatment of selected neglected diseases, but they are yet to prove whether they can produce radical innovations, such as new chemical entities (See Munoz et al 2014).

[86] The emergence and growth of PDPs in the neglected disease R&D landscape can be associated both to growing concern of the public health problem and new opportunity for action in light of financial resources available, in particular from philanthropic sources (Gates Foundation). However, the financing landscape for PDPs shows scarcity and unpredictability of funds, concentration of few donors, which puts at risk the sustainability of PDPs in the long run. (See Global Health Technologies Coalition 2013).

as measured by the number of new medicines coming to the market despite strong use of IPRs, and increased use of defensive patenting strategies to extend the commercial life of their products and delay the entry of generic medicines to the market (EU Commission 2009, Comanor and Sherer 2013, Sternitzke 2013).[87] At the same time, contractual R&D partnerships and licensing is common among large pharmaceutical firms and small biotechnology firms. Empirical studies associate the growth in joint R&D agreements and licenses to the pursuit of various strategic motives, including to access financial resources, technology and know-how, to reduce cost and speed up R&D, and to reach new markets (Hagedoorn 2002, Arnold et al 2001, Roijjakers and Hagedoorn 2006).

Private firms are generally reluctant to invest alone in R&D in neglected diseases if there is low prospect of commercial returns (Matter & Keller 2008). On the other hand, academia and small firms lack the capacity to move basic research on to translational research. The PDP approach addresses both these problems, by taking the burden of financing R&D away from the partners involved in the R&D project, and by coordinating different actors in R&D and integrating the diverse set of capabilities into single R&D projects that are managed by expert staff in PDPs. In this manner, PDPs are able to de-link the cost of R&D from the price for medical products, provided there are no monopoly price distortions resulting from IPRs.

III.2 IP management by PDPs

There are a few studies that explore the question of how PDPs are affected by pre-existing IPRs and how they may use IPRs in pursuing their goals.[88] In this study we broadly refer to these questions as "IP management". Existing studies explore IP management policies, practices or strategies of a single or selected number PDPs, rather than the whole population of PDPs. In particular there is a lack of empirical study of the IP management policies by PDPs and the terms of IPRs in R&D deals and licenses with partners.[89]

This study aims to identify and understand the potential IP approaches of PDPs from within two distinct categories. The first is PDPs as "users" of IPRs. This category includes instances related to obtaining access to a technology or know-how that is protected by IPRs and ensuring that no partner in an R&D project infringes (in violation of) any pre-existing IPRs of third parties. The second is PDPs as "producers" of IPRs. This concerns the decision of a PDP whether to protect the know-how or innovations resulting from R&D projects with IPRs, and whether to allow partners in an R&D project to do so.

PDPs as "users" of IPRs

The term "users of IPRs" should be understood in the context of this study as obtaining authorization from the patent holder to use IPR-protected technology or know how or any situations where the PDP can use the IPR-protected technology or know how lawfully. An assumption of this study is that the aim of the PDP is not to access IPR per se (i.e. to build their own IP portfolios through in-licensing), but to access technology and know-how that is relevant to initiate or advance an R&D project in the PDP portfolio. In following, the study

[87] Generic medicines refer to equivalent, unpatented versions of medicines that are usually cheaper than their patent-protected counterparts.

[88] Studies include Mahoney et al 2007, Eiss et al 2007, Taubman 2010, Global Coalition for Health Research 2013,

[89] This is partly due to the fact that the terms of research agreements and licenses are generally confidential. Some individual PDPs do report publicly their IP policies that guide their IPR practices. Munoz et al 2014 emphasize that greater transparency by PDPs and partners should be encouraged the donor and public health community.

assumes that gaining rights to use to pre-existing IP held by external sources is pursued when it is necessary to kick off or advance an R&D project, or where not doing so may lead to legal action.

Most PDPs do not have in-house capacity, or have limited capacity, to carry out the full range of R&D activities for medical product development. Most PDPs build their portfolio of R&D projects by defining a target product and then tapping into the various sources of knowledge for various public and private sector actors that may or may not be protected by IPR (from university, biotechnology firms, pharmaceutical firms), and coordinate and finance the participation of those actors and activities through the course of an R&D project. This means that PDPs often negotiate access (free or subject to payment) to IPR-protected technology or know-how as inputs for their R&D projects.

Where IPR is present, access to a technology/product embodying the IPR requires negotiating user rights, which normally take the form of licensing agreements.[90] One question that arises is to what extent can pre-existing IPRs (particularly granted patents and patent applications) inhibit the ability of PDPs to use the needed technology or know-how to allow new follow-on R&D and innovation.

Some studies indicate that patents can pose obstacles for new product development for PDPs. Two studies have noted that patents granted in disease-endemic developing countries and existing "patent thickets" on neglected diseases (i.e. Malaria) can hinder new R&D and innovation by PDPs (Mahoney et al 2007, Clark et al 2011).[91] These studies also note that some PDPs undertake mapping and analysis of existing patents (also known as patent landscaping or patent mining) in the early stage of the R&D project to determine the extent to which these are a hindrance and to also assist in defining the options available to PDPs.

PDPs as "producers" of IPRs

The term "producers" of IP is used in this study to refer to ownership of IPRs by PDPs. This study assumes that PDPs can choose between a number of different alternatives for the appropriation of results derived from R&D projects through IPRs, such as: Option 1: PDP does not claim IPRs; Option 2: PDP nor partners can claim IPRs; Option 3: PDP claim IPR; Option 4: PDP and partners can jointly claim IPRs; Option 5: Partner can claim IPRs. The study is interested in understanding whether and under which situations would PDPs seek to exercise these options.

PDPs are in essence aiming to bring about global public goods; medical products that respond to medical need regardless of the ability of the user to pay. In following, one can expect that

[90] R&D agreements are commonly done in the discovery phase. PDPs get access to the technology by the license to the IP, but not necessarily the know-how. Know-how may be added to the agreement and may be no less important than access to the technology. We may want to add some discussion on this here or elsewhere in the paper to clarify that the aim of the PDP is to access technology and know how and innovate, where IP is relevant only to the extent that it may be conducive or a barrier to this goal, but it certainly is only part of the whole picture.

[91] A patent thicket refers to a set of overlapping patent rights that require that those seeking to commercialize new technology obtain licenses from multiple patentees (Shapiro 2001).

PDPs would not seek to claim patents or other forms of IPRs over the results of R&D projects.

PDPs fund their activities from external sources, mainly by donations and grants by public and philanthropic institutions. Accordingly, one could expect that PDPs would not seek patents and restrain partners from seeking patents over the results of R&D projects to allow disclosure and dissemination. It would appear a sensible policy to allow public and philanthropic financed R&D to be made available widely to facilitate follow on research by anyone willing to do so. This is more so the case in the context of low level of private investment in R&D in neglected diseases. In a situation where PDPs are able to cover the costs of the activity of the partners in the R&D project, which engage on a voluntary basis in agreement with the common public health objective, it is questionable whether additional incentives in the form of IPRs for partners or staff of PDPs are necessary, rather than counterproductive, for their engagement in the R&D collaboration. One could also expect that donors, in support of the public health objective of PDPs, would oversee that the results of R&D projects are not privately appropriated and IPRs enforced in ways that can restrict further innovation and access to medical products. However, there is no clear evidence whether this is the case, as there are a diversity of donors which different formats and conditions for fund disbursements to PDPs.

The impact of patents on prices and affordability of medical products is an issue that one can expect PDPs to be concerned about and seek to address in their approach to IP issues within R&D projects. Patents are one of various factors that may affect prices, as it confers the patent holder monopoly rights over the marketing of the product for the period of the patent protection. Medical products in general, where available, are largely unaffordable for large populations in developing countries.[92] Private investment in R&D is recouped by pricing at a profitable level, which in turns excludes consumers that are not willing to purchase at the set price, or potential licensees of the patent right that are not willing to pay the set price. This deadweight loss is well acknowledged as a drawback of the patent system. One of the advantages of the PDP arrangement is that it can de-link the cost of R&D from the prices of medical products, by securing financing for R&D from sources other than the PDP and partners involved in an R&D project.

In cases where PDPs do claim patents and other forms of IPRs, one can expect that the motivation would be other than to derive profits from R&D and in line with their public health goal. It is widely acknowledged that patents are not an effective mechanism to stimulate R&D in neglected diseases given that opportunities to make profits do not exist to begin with (WHO 2006).[93] The historic low level of private investment in R&D in neglected diseases evidences this (Pedrique et al 2013).

[92] Medicines account for 20–60% of health spending in developing and transitional countries, and up to 90% of the population in developing countries purchase medicines through out-of-pocket payments, as both government and patients have low purchasing power (Cameron et al 2009).

[93] As discussed in the previous section, there are a number of mechanisms to promote R&D and innovation that may complement or substitute IPRs and private R&D investment. R&D and innovation can be carried out by private for-profit firms as well as by the public sector or as a hybrid combination, and funded by public or private for-profit or private non-profit entities, or a mix of these. PDPs are one model though there is significant diversity among PDPs. PDPs are institutional arrangements that manage partnerships involving various public and private actors in R&D projects that are financed by public and private non-profit entities, i.e. the Bill and Melinda Gates Foundation.

One motivation of a PDP to claim IPRs is to use it as a means to earn revenues to invest in their activities.[94] However, this would only be the case where there are buyers for the PDP licenses (i.e. for-profit firms interested in the patented technology with application for other diseases with commercial markets). In any case where the PDP holds an IPR, the PDP controls decision to offer the license and at what price. Parties that are not able or willing to pay the license price would be excluded, which could be in tension with the public health goal of PDPs. Thus, one can assume that PDPs generally would not trade off the exclusion effect of patents and impact on prices against expected low level of revenues to be made from patent licensing.

PDPs operate independently and are not subject to any international authority overseeing their activities or placing restrictions on their regulations or policies on use of IPRs.[95] It has been noted that PDPs have a high degree of autonomy and freedom in their work to make alliances and strike deals, through licensing or contracts, to pursue their objectives (WHO 2006). PDPs have the ability to manage IP in a flexible manner in pursuing their innovation goal but it should not come into tension with their global access mission. In this sense, it is useful to recall the warning of economists concerning trends in university patenting and licensing acting more as businesses than to advance public knowledge.

Once can expect variance in the terms of the deals that PDPs may strike with partners, depending on numerous factors including the disease area under consideration (whether there is commercial potential in a segment of the market or application of the technology in other diseases with attractive markets), the bargaining position –power balance- of the PDP vis a vis the partner in the particular negotiation related to the "value" of the technology, the experience of PDPs in IP related negotiations, the inclination of the PDP to adopt business - like practices with respect to IPRs. As an example, a PDP may allow an industry partner to reserve the right to claim patents for the innovations derived from the results of the PDP-led R&D project for the same indication in markets of commercial interest to the partner, (i.e. in the case of HIV/AIDS or Malaria in developed countries) known as "market segmentation", or for other indications. Likewise, PDPs may request that partners make access commitments to ensure affordability of the product once developed, such as not claiming IPRs for the application of the R&D project. Limited information is available concerning these practices to allow for a detailed examination. Nonetheless, it provides a backdrop for the analysis of the question that concerns this study in assessing how PDPs manage IP related questions, in accessing technology or know-how for their R&D projects, in engaging partners into R&D projects, or in making use of IPRs on their own or with partners to pursue their public interest objective. The survey developed in this study examines in more detail the factors that

[94] The Infectious Disease Research Institute (IDRI) is an example of a PDP with a policy to license patented technologies it develops to third parties (i.e. biotechnology companies) for applications outside of the scope of neglected diseases (i.e. cancer) to reinvest royalties from licenses in its activities (Global Health Technologies Coalition 2013).

[95] A notable example of international regulation with regards to global public goods is the Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture. Member countries under the FAO Plant Treaty agreed that the system for access to resources under the treaty would be open to all without restrictions for subsequent innovation. In exchange, it was agreed that "recipients shall not claim any IP or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System" (article 12.3(d)).

influence terms for IPRs in PDP licensing, R&D or transfer of technology agreements with third parties.

IV. The Survey

IV.1. Data

The initial sample was list of 23 PDPs. The study aimed to cover the whole population of PDPs.[96] The survey questionnare was built from in January 2014 and integrated into an on-line platform to allow for the response to be done remotely. The final sample was a list of 21 PDPs.[97] The total response rate for each survey completed was 76%[98]. The target respondents for the survey were the individual(s) responsible for IP within the PDP. We communicated with the PDPs to allow self-identification of the appropriate survey respondent. Most of the respondents were legal counsels.

The survey was composed of multiple selection questions and open response questions. The questions concerned the importance of IP management for the PDP, the benefits or limitations of having IP policies, factors that influence the PDP approach to IP management, internal governance structure for IP management, activities in relation to IP management, the use of third-party IPRs by PDPs, the types of IPRs that PDPs produce and their motivations for doing so, the extent to which PDPs consider collaboration to be useful, policy on claiming results from collaborative R&D projects, factors that influence patent licensing agreements or R&D agreements, the extent to which patents held by the PDP or by partners can be obstacles for successful conclusion of partnership agreements, whether PDPs have had cases of patent litigation or infringement. The full survey results are available in the Annex.

IV.2. Results

Importance of IP management and policy

PDPs consider IP management to be an important activity. The majority (67%) of PDPs indicated that IP management is important for the PDP. No PDP considered IP management to be of low importance.

Most PDPs report having a defined IP management policy (87%), however most PDPs do not make the IP management policy publicly available (62%). Most PDPs consider that a defined IP management policy has the benefit of providing clarity internally (management team, board) and externally (donors, partners) and as guidelines for decision-making, negotiations and to execute agreements with third parties (i.e. contracts, material transfer agreements, sublicenses, business plans). The IP policy set the scope of what is permitted or not, and how the PDP operates on IP matters. Other benefits of IP management policies that were noted

[96] These PDPs were selected in accordance to the definition in Munoz et al 2014.

[97] The initial sample included iOWH that has now merged with PATH and is now named "medical product development program". The initial sample included PDVI and DVI. PDVI finalized its work and continued as DVI.

[98] The PDPs that responded the survey were DNDi, TBVI, DVI, TB Alliance, IVCC, IVI, MVI, FIND, Sabin Vaccine Institute PDP, IPM, MMV, MVP, Aeras, CONRAD, EVI and MDP.

included consistency and speed in decision-making and standardization between partners. It was also noted that an IP policy ensures that programs can be advanced without any potential or perceived barriers. Similarly, it was noted that an IP policy serves to ensure that products will be made available to the target populations in low income setting at affordable prices. One PDP noted that the IP policy serves to assure its private sector partners that it is aware of the IP situation and will respect and promote IP protection for the benefit of the companies and for the benefit of the public sector.

One PDP was of the view that not having a defined IP management policy is beneficial because it adds flexibility.

Characteristics of the PDP that influence the PDP approach to IP management

The characteristics of the PDP that influence the PDP approach to IP management

R&D plus access mission (88%), non-profit nature (81%), and that Work to large extent through R&D partnerships/collaborations (75%). Another characteristics considered important is that PDPs advance products that have no commercial return. One PDP noted that while its products will not command a dual market (at least not to a significant level), but if they did, then the PDP would "be diligent in attempting to establish and own a patent portfolio around it in order to use potential royalties from sales in industrialized countries to achieve the PDP global access objectives."

IP management governance

Some PDPs have staff explicitly dedicated to IP management (44%) while many do not (56%).

PDPs have diverse internal governance structures for IP management decision-making. In some PDPs, the responsibility lies with the head of legal (i.e. director or counsel). One PDP uses a consulting firm. In some PDPs the responsibility is shared or lies with business development, or with the head of R&D portfolio management. In some PDPs, IP decisions require approval of executive management (i.e. Director General). In some PDPs, IP decisions are brought to review bodies, such as an executive board committee or a portfolio management committee, a programme liaison group or programme management board. In some PDPs there are no committees or review bodies with such functions.

One PDP noted IP management is a contract management function and it also responds to "clear donor guidelines."

IP management activities

The diversity of activities reported by PDPs reflects the different approaches of PDPs in relation to IP management.

Many PDPs regulate IP issues in contracts and agreement with partners, for various purposes. These include ensuring access provisions (that products will be made available at affordable prices) and freedom to operate (operate without infringing IPRs). It may also serve the purpose of in-licensing IP-protected technology from third parties, or to license from one party to another.

Some PDPs report limited activities on IP management. These include PDPs that report they do not hold any IPRs, as a policy or practice, though they may include conditions on use of the technology in their agreements with partners, or allow partners to hold IPRs. Where partners are allowed to hold IPRs, the PDPs may not support patent filing and prosecution costs.

One PDP reported that its role is that of monitoring the IP situation, where all partners may hold IPR and have their own freedom to operate.

In contrast, other PDPs report as main activity filling of patents to protect inventions. Some PDPs note that this involves review of projects and publications and other disclosure for the timely filling of patent applications. The activities may also include protecting trade secrets and trade marks.

PDPs as users of IPRs

Most PDPs (75%) report they are a user of IPRs (have gained rights or obtained a license to use third party IP-protected technology). The main form of IPRs that PDPs seek access to is patents (87%), followed by copyright (40%) and trade secrets (40%), trademarks (33%). Data was also reported as an additional input that PDPs access which may be protected by IPRs.

The purpose of the use of patents includes for the transfer technology to third parties (62%) to obtain access to a technology or knowledge that is protected by a patent (54%), for freedom to operate (54%).

The majority of PDPs consider of high importance (80%) the access to the related know-how or capabilities of the patent holder, in addition to the right of use or license.

PDPs report that they never or rarely (76%) obtain an exclusive patent license (as opposed to non-exclusive). There is significant variance in the extent that PDPs may obtain royalty-free, as opposed to royalty-bearing patent licenses.

Some PDPs indicated that patent status of a technology does not influence the choice of that technology for an R&D project if it is considered the best technology for the project (47%). This would appear to indicate that PDPs are able to obtain a license from the patent holder. Other PDPs indicated that where there is alternative technology available to the patented technology, the PDP would choose alternative (27%). This may be explained because the PDP would rather avoid having to enter into negotiations a patent holder and avoid royalty payments from licenses. This is also supported by the fact that the majority of PDPs (87%) indicate that it is useful for third parties to share patents (allow the PDP uncompensated use of a patent) with the PDP. Most PDPs noted that sharing is equally useful in all R&D stages (64%), while others noted that in early development/discovery it is more useful, or in process/product development. Two PDPs indicated that the royalty-free sharing of patents to the PDP would not be useful at all, which may be the case for PDPs that would not make use of the patent information in any case, such as a PDP that is at the forefront of the research or a PDP whose central role is to disburse funds to support R&D done by third parties.

PDPs as producers of IPRs

Most PDPs reported to claim ownership of some form of IPR (69%). Others reported not to claim any IPRs (31%).

For PDPs that claim IPRs, the main form is patents (42%). Others include copyright, trade secret, trademarks and data. Some PDPs reported that technology and know-how is protected in agreements with partners. One PDP reported that it protects technology by requiring the partner to agree to transfer the technology if it is unwilling or unable to fulfil its obligations. Similarly, another PDP noted that it only reserves IPRs in case of a partners' non-compliance with contractual obligations.

There are several nuances in the patent strategies of PDPs. Some PDPs that do not seek ownership of patents nonetheless allow the partner to file patents. This may include allowing the patent holder to operate in the same area in which the PDP operated (in addition to allowing the partner to patent in relation to other areas of application of the invention, such as for other diseases with commercial markets). Conditions may nonetheless be placed by PDPs on the patent holder. One PDP described that allowing a partner to claim patents is conditioned to a grant-back, royalty-free, non-exclusive license to the PDP to continue to use the patent in its activities.

Some PDPs have a policy on who may seek patents on the results of R&D projects (60%), while others do not (40%). This is again explained by the divergence in IP approaches among PDPs.

For PDPs that allow patents on results of the R&D projects, there are a variety approaches and these may be taken on a case-by-case basis. These include decisions on whether to file a patent (i.e. whether the PDP alone decides, the partner alone decides, or the partner and PDP decide together), who files the patent (i.e. the inventor or the institution) and what happens after the patent is filled (i.e. whether the patent is then assigned on). Some PDPs report that the inventor (may be staff of the PDP or a partner) can apply for the patent, but the patent is assigned the PDP. Some PDPs report that a patent can be jointly held by a partner and by the PDP.

Among the PDPs that claim patents there a diverse of purposes reported, which the PDPs consider to fall within the scope of the broader objective of ensuring access to products at affordable prices to target populations. One of the purposes reported is to license-on the patent to industry, to raise their interest in partnering in manufacturing/distribution (50%). Another strategic use of patents reported was to cross-license to access technology owned by third parties (negotiate terms of use/license to third party patents in return for use/license to the patents held by the PDP). PDPs also reported that patents are used as part of a defensive strategy, to avoid third parties from unauthorized use of the technology or claiming ownership of patents over the technology (44%). Two PDPs reported to claim patents as a way to generate income via licensing to fund activities (13%). One PDP reported that a patent allows the PDP to exert control in the development and manufacturing of a product to ensure its proper use and quality. Another PDP reported it claims patents to fulfil pre-existing obligations to commercial partners or funders.

With regards to the results of R&D projects in the PDP portfolio, a variety of IP approaches may follow. A partner can hold a patent, with pre-agreed licensing terms to the PDP (67%) or other conditions placed in the contract that the products must be made available at affordable

prices in target populations. A PDP can hold a patent (60%). The PDP and partner or partners can jointly hold a patent (60%).

In the case of PDPs that claim patents, they are not generally allowing third parties uncompensated use of the patents, except for cases where the use is for non-profit goals (i.e. with academic partners) or non-commercial uses by partners. One PDP noted it licenses patents on an exclusive basis in developed countries and on a non-exclusive basis in least developed countries. Another PDP noted that it has cross-licensed or shared its patents in return for global access to the final product.

Open approaches to R&D collaboration

For most PDPs, open R&D collaboration (no patent claims for results of the R&D collaboration) is considered useful (67%), while others do not consider it to be useful (20%). Open collaboration was noted to be particularly useful in the discovery stage.

A variety of factors were reported as influencing patent licensing agreements or R&D agreements between the PDP and partners. Some of the factors more often recognized were the R&D stage (80%), the target profile of the product to be developed (73%), the specific disease targeted (67%), the regions/countries targeted (60%), the type of partner (60%), the target price of the medical product (53%). Other factors noted were the choice of sources to obtain the technology/knowledge/resources (47%), the markets that are targeted (private, public, purchasing entities) (47%), the source of funds of the PDP (40%), the estimated cost of production (40%), and commitment to providing access to the product to those most in need in developing countries.

Patents as barriers

PDPs reported that pre-existing patents held by partners were sometimes (43%) or rarely (36%) an obstacle for the successful conclusion of partnerships at any R&D stage. In contrast, PDPs considered that the patents held by the PDP are never (79%) or rarely (21%) an onstacle for the successful conclusion of partnerships at any R&D stage. Negotiations on the terms for ownership of future patents were considered as sometimes (47%) or rarely (40%) an obstacle for the successful conclusion of partnerships at any R&D stage.

IPR infringement and enforcement

All PDPs reported that they have never sought opposition or invalidation of any IPR held by a third party. Most PDPs also reported that they have not had any cases of patent litigation or infringement to deal with (81% as compared to 19%). One PDP noted that it has been cautious to proceed with a particular compound that is held by a biotech company because of the patents surrounding that compound and the inability of the PP to obtain a license to that compound.

V. Conclusion

Inventions in the area of public health can be developed as public goods, as opposed to private goods, to ensure dissemination and access to all populations. Models of innovation that de-link the costs of R&D and innovation from the prices of medical products can serve this purpose. In the case of not-for-profit PDPs, the costs of R&D and innovation are paid for mainly by public and philanthropic sources. Moreover, there is no economic incentive for private sector investment in R&D and innovation in the area of neglected diseases in which PDPs operate. The central mission of PDPs is to ensure access to medical products as public goods, which requires that these be affordable to all who need them. The R&D collaborations that take place within the framework of PDPs must be in line with this mission. Following these premises, one would expect that patents and other IPRs would play a very limited role in the framework of PDPs not-for-profit innovation.

This study finds that this is not the case. IPRs do not act as an incentive for the activities of PDPs in the sense that IPRs are expected to do so for private, profit-maximizing firms. However, IP management more broadly is an activity of relative importance for PDPs. This study finds that there is significant divergence between PDPs in their approaches to IP. The study was based on a survey covering the whole population of PDPs, with a response rate of 73%. The activities of PDPs can be divided into two broad categories. First, the "use" background IPRs held by third parties over technology, data or know-how that the PDP seeks to access. Second, the "production" of IPRs either by the PDP, by a partner, or jointly between the PDP and a partner. The survey conducted in this PDPs either do not claim any patents or other IPRs as a policy, or where PDPs do claim patents, they may do so alone, or jointly with partners. PDPs may also allow partners to claim patents alone over R&D projects with the conditions to allow use by the PDP. Consistent with previous studies on IPR use by firms and universities, this study finds that PDPs that claim IPRs or allow partners to claim IPRs do so for strategic purposes, under the assumption that it will ultimately advance the not-for-profit mission of PDPs of producing medical products that are affordable to poor populations. This requires significant skills from PDPs to manage the "IP laberynth" in aiming to ensure that IPRs do not become barriers to access to medical products and further innovation, though in any case IPRs can be barriers at least in developed countries where PDPs are granting exclusive licenses that enable the holder to charge monopoly pricing.

The impact of IPRs on the results of PDP R&D porfolios, whether held by PDPs or by partners, is not readily observable. PDPs reported generally that they are offering non-exclusive licenses (PDP can grant the license to various third parties, not necessarily royalty free) to the use of their patent-protected technology or know-how for developing countries and least developed countries, while offering exclusive licenses for developed countries (subject to royalty payments). This study was unable to observe the details of the IPR licensing, contracts, technology transfer, R&D and other agreements between PDPs, R&D partners and third parties (i.e. donors), which often define the conditions of use of IPRs.

PDPs are playing an important role in advancing R&D in areas where private sector will not invest. However, the evidence of the strategic use of IPRs by PDPs as not-for-profits that are funded through public moneys should send off alarm bells to policy makers. Greater transparency and oversight is required from the public health community, such as the World Health Organization, to ensure that PDPs and their partners respond in all their activities, including IP management, to the principle of global access.

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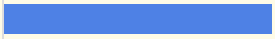
Annex: Survey questionnaire

1. Indicate the name of the PDP

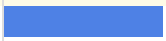
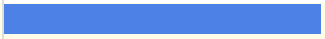
Text Response
Drugs for Neglected Diseases Initiative (DNDi)
TBVI Tuberculosis Vaccine Initiative (TBVI)
Dengue Vaccine Initiative (DVI)
Global Alliance for TB Drug Development (TB Alliance)
IVCC
International Vaccine Institute (IVI)
PATH Malaria Vaccine Initiative (MVI)
Foundation for Innovative New Diagnostics (FIND)
Sabin Vaccine Institute PDP
International Partnership for Microbicides (IPM)
Medicines for Malaria Venture (MMV)
PATH/WHO Meningitis Vaccine Project (MVP)
AERAS
CONRAD
European Vaccine Initiative (EVI)
Microbicides Development Programme (MDP)

2. Indicate the name of the survey respondent and whether you authorize us to disclose the name in our research report.

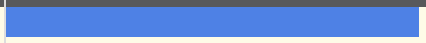
#	Answer		Response	%
1	Name		15	94%
2	I authorize disclosure of my name in any EPFL research		6	38%

❑ 3	❑ I do not authorize disclosure of my name in any EPFL research		❑ 9	❑ 56%

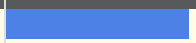
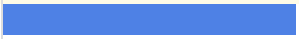
3. How important is IP management for the PDP?

❑ #	❑ Answer	❑	❑ Response	❑ %
❑ 1	❑ low		❑ 0	❑ 0%
❑ 2	❑ medium		❑ 5	❑ 33%
❑ 3	❑ high		❑ 10	❑ 67%
❑	❑ Total	❑	❑ 15	❑ 100%

4. Does the PDP have a defined IP management policy?

❑ #	❑ Answer	❑	❑ Response	❑ %
❑ 1	❑ yes		❑ 13	❑ 87%
❑ 2	❑ No		❑ 2	❑ 13%
❑	❑ Total	❑	❑ 15	❑ 100%

5. Is the IP management policy publicly available and/or published?

❑ #	❑ Answer	❑	❑ Response	❑ %
❑ 1	❑ Yes		❑ 5	❑ 38%
❑ 2	❑ No		❑ 8	❑ 62%
❑	❑ Total	❑	❑ 13	❑ 100%

6. What are the benefits of having a defined IP management policy?

Text Response
Clear guidelines internally and externally. Reference to the policy during negotiations
Clear view on the position of the PDP
There are many as have been laid out in the IP Handbook. In particular, DVI needs to assure its private sector partners that is is aware of the IP situation and will respect and promote IP protection for the benefit of the companies and for the benefit of the public sector.
To ensure that our management team, our board, donors and key strategic partners have a clear understanding of what our IP policy is.
Clarity and standardisation between partners
While it is necessary to consider each case on its own merits, a policy establishes the guidelines enabling rapid and consistent decision-making. By the way, I assume that you refer to patent filing policy when you talk about "IP management policy".
Sets scope of what is permitted and not, clear to partners how we operate
To ensure we can advance the PDP Programs without any potential or perceived barriers
MMV needs to address IP management in all of its research programmes as all programmes generate Foregraound IP. Decisions need to be made on ownership of IP, protection of IP, rights to the IP, etc.
Policy is available upon request. A defined policy provides clarity for employees and guides our negotiations with other organizations with whom Aeras has collaborative relationships.
clear guidelines to execute third party agreements, eg, contracts, MTAs, sublicenses, etc., and business plans
To ensure that products will be made available to the target populations in low income settings at affordable prices
Sets out the agreed position as to how IP generated under the MDP programme will be managed.

Statistic	Value
Total Responses	13

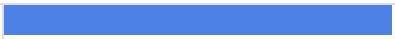
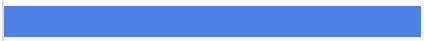
7. What are the benefits of not having a defined IP management policy?

Text Response
Flexibility

Statistic	Value
Total Responses	1

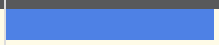
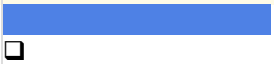
8. Do any of the following characteristics of the PDP influence the PDP approach to IP management?

#	Answer		Response	%

❑ 1	❑ Non-profit nature		❑ 13	❑ 81%
❑ 2	❑ Work to large extent through R&D partnerships/collaborations		❑ 12	❑ 75%
❑ 3	❑ R&D plus access mission		❑ 14	❑ 88%
❑ 4	❑ Any other		❑ 2	❑ 13%

❑ Any other
❑ Our product will not command a dual market (at least not to a significant level). If it did, we would probably be diligent in attempting to establish and own a patent portfolio around it in order to use potential royalties from sales industrialized countries to achieve our Global Access objectives.
❑ Advancing products that have no commercial return

9. Is there any staff in the PDP explicitly dedicated to IP management?

❑ #	❑ Answer	❑	❑ Response	❑ %
❑ 1	❑ Yes		❑ 7	❑ 44%
❑ 2	❑ No		❑ 9	❑ 56%
❑	❑ Total	❑	❑ 16	❑ 100%

10. What is the internal governance structure in the PDP for decision-making on IP management?

❑ Text Response
❑ Responsibility of the Director of BD and Legal, some issues brought to the Executive committee when necessary
❑ Legal counsel
❑ Any IP agreement has to be approved by the Director General. There are no other committees or review bodies.
❑ We have established an IP committee to oversee key IP decisions and to recommend any changes to our IP strategy
❑ Portfolio manager recommends to the management team
❑ We use a Consulting firm for IP. The Dir Portfolio Management is the point of contact. Decision are taken by Dir Portfolio and CSO, submitted to Director general for approval.
❑ Any decision needed will be made by MVI's Portfolio Management Committee.

❑ Contract management function, clear donor guidelines
❑ Decisions are managed by and through an Executive Board Committee
❑
❑ Executive Team
❑ Head of Legal is responsible for IP management
❑ When an invention disclosure made by an employee it is reviewed by Head of R&D (including other relevant research team members), CEO and General Counsel and a decision is made whether or not to file a patent
❑ Initial decision by contracts and program teams. Final decision by Executive Director
❑ IP issues are regulated in the contracts signed with organisations that are supported by EVI
❑ Publication/dissemination of data and results was managed by the Programme Liaison Group (specified membership, set quorum & set majority), Responsible for overall management of MDP (including monitoring achievement of programme objectives) was the Programme Management Board (all partners, set quorum & set majority)

❑ Statistic	❑ Value
❑ Total Responses	❑ 15

11. What are the main activities undertaken in the PDP in relation to IP management?

❑ Text Response
❑ Insuring access provisions and freedom to operate within all contracts and partnerships
❑ In principle no IP is owned by the PDP
❑ Mainly DVI monitors the situation. All the developers have their own IP and FTO. We do not feel the field is impeded by competing or overlapping IP claims.
❑ Filing patents, protecting inventions, trade secrets and trademarks and licensing IP
❑ Ensuring access through licensing if necessary.
❑ Follow up of our patents, search for patentability by consulting firm.
❑ Very few - we typically do not support patent filing and prosecution costs incurred by our partners.
❑ We do not hold any IPR, its covered under our agreements with our partners
❑ Patent protection, publications
❑ Licensing agreements, patents
❑ Protection of IP, in and out-licensing of IP
❑ Review of projects, manuscripts for publications and other disclosure to ensure timely filing of patent applications.
❑ Establishment and implementation of policy through contracts and agreements with partners. Protecting inventions by filing patents. Licensing drugs from othwer organizations.

❑ Ensure via contractual clauses that products will be made available at affordable prices
❑ Granting of licences/rights in respect of IP brought into/tested as part of MDP. Patentable results were not expected to be generated in the course of MDP activities.

❑ Statistic	❑ Value
❑ Total Responses	❑ 15

12. Is your PDP a user of IP (has gained rights or obtained a license to use third party IP-protected products/processes/services)?

❑ #	❑ Answer	❑	❑ Response	❑ %
❑ 1	❑ Yes	❑	❑ 12	❑ 75%
❑ 2	❑ No	❑	❑ 4	❑ 25%
❑	❑ Total	❑	❑ 16	❑ 100%

13. Does the PDP use this form of IP?

❑ #	❑ Answer	❑	❑ Response	❑ %
❑ 1	❑ Patents	❑	❑ 13	❑ 87%
❑ 2	❑ Trademarks	❑	❑ 5	❑ 33%
❑ 3	❑ Copyright	❑	❑ 6	❑ 40%
❑ 4	❑ Trade secrets	❑	❑ 6	❑ 40%
❑ 5	❑ Other	❑	❑ 3	❑ 20%

❑ Other
❑ Technology, as in requiring agreement to technology transfer if partner is unwilling or unable to fulfill its oblgations.
❑ data
❑ we only reserve IP rights in case of non-compliance with contractual obligations

Statistic	Value
Total Responses	15

14. What is the purpose of the use of patents?

#	Answer		Response	%
1	To obtain access to a technology or knowledge that is protected by a patent		7	54%
2	To ensure freedom to operate (without infringing patents held by third parties)		7	54%
3	To transfer technology to third parties		8	62%
4	Any other		3	23%

Any other
all of the above!
All of the above
Comment: access to a patent never ensures freedom to operate.

Statistic	Value
Total Responses	13

15. How important is it for the PDP to access related know-how or capabilities of the patent holder, in addition to the right of use or license?

#	Answer		Response	%

❑	❑	❑	❑	❑
❑ 1	❑ low	❑	❑ 0	❑ 0%
❑ 2	❑ medium	❑	❑ 3	❑ 20%
❑ 3	❑ high	❑	❑ 12	❑ 80%
❑	❑ Total	❑	❑ 15	❑ 100%

❑ Statistic	❑ Value
❑ Total Responses	❑ 15

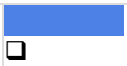
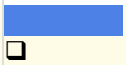
16. How often does the PDP obtain a patent license that is exclusive as opposed to non-exclusive?

❑ #	❑ Answer	❑	❑ Response	❑ %
❑ 1	❑ Never	❑	❑ 6	❑ 38%
❑ 2	❑ Rarely	❑	❑ 6	❑ 38%
❑ 3	❑ Sometimes	❑	❑ 2	❑ 13%
❑ 4	❑ Often	❑	❑ 2	❑ 13%
❑ 5	❑ All of the time	❑	❑ 0	❑ 0%
❑	❑ Total	❑	❑ 16	❑ 100%

❑ Statistic	❑ Value
❑ Total Responses	❑ 16

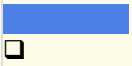
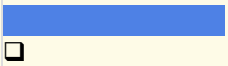
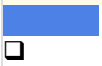
17. How often does the PDP obtain a patent license that is royalty-free as opposed to royalty-bearing?

❑ #	❑ Answer	❑	❑ Response	❑ %
❑ 1	❑ Never	❑	❑ 4	❑ 25%
❑ 2	❑ Rarely	❑	❑ 1	❑ 6%
❑ 3	❑ Sometimes	❑	❑ 3	❑ 19%

❑ 4	❑ Often		❑ 4	❑ 25%
❑ 5	❑ All of the time		❑ 4	❑ 25%
❑	❑ Total	❑	❑ 16	❑ 100%

❑ Statistic	❑ Value
❑ Total Responses	❑ 16

18. Does the patent status of a technology influence the PDP selection of that technology for an R&D project?

❑ #	❑ Answer	❑	❑ Response	❑ %
❑ 1	❑ Yes, if there is alternative technology available the PDP will choose alternative		❑ 4	❑ 27%
❑ 2	❑ No, if good terms can be reached for the use of the patent		❑ 1	❑ 7%
❑ 3	❑ No, if the technology is considered the best choice for the project		❑ 7	❑ 47%
❑ 4	❑ Other		❑ 3	❑ 20%
❑	❑ Total	❑	❑ 15	❑ 100%

❑ Other
❑ n/a
❑ Obviously, we want to avoid royalty obligations whenever possible. As stated above, existence of a patent around a partnered technology is otherwise a minor factor contributing to our decision-making.
❑ we only ensure that IP situation will allow making products available at affordable prices in developing

countries

❑ Statistic	❑ Value
❑ Total Responses	❑ 15

19. Is it useful for third parties to share patents with the PDP (allowing the PDP uncompensated use of a patent)?

❑ #	❑ Answer	❑	❑ Response	❑ %
❑ 1	❑ Yes	❑	❑ 13	❑ 87%
❑ 2	❑ No	❑	❑ 2	❑ 13%
❑	❑ Total	❑	❑ 15	❑ 100%

❑ Statistic	❑ Value
❑ Total Responses	❑ 15

20. Is there a particular R&D stage in which sharing of patents is more useful?

❑ #	❑ Answer	❑	❑ Response	❑ %
❑ 1	❑ Yes	❑	❑ 4	❑ 36%
❑ 2	❑ No, all are equally useful	❑	❑ 7	❑ 64%
❑	❑ Total	❑	❑ 11	❑ 100%

❑ Yes
❑ Discovery
❑ Early in development
❑ R&D and Process development
❑ Early development

❑ Statistic	❑ Value

Total Responses	11

21. Is the PDP a producer of IP (claim ownership of any form of IP)?

#	Answer		Response	%
1	Yes		11	69%
2	No		5	31%
	Total		16	100%

Statistic	Value
Total Responses	16

22. Does the PDP produce this form of IP?

#	Answer		Response	%
1	Patents		5	42%
2	Trademarks		0	0%
3	Copyright		3	25%
4	Trade Secrets		0	0%
5	Any other		4	33%
	Total		12	100%

Any other
n/a
All of the above except copyright
We rarely prosecute our "own" patents, but we do refer to MVI's Background Technology in our agreements (in effect, that would be mostly know-how and trade secret-type of IP).
data

Statistic	Value
Total Responses	12

23. Does the PDP have a policy on who may seek patents on the results of R&D projects in the PDP portfolio (i.e. whether by the PDP, individual PDP staff, the PDP with partners, or partners alone)?

#	Answer		Response	%
1	Yes		9	60%
2	No		6	40%
	Total		15	100%

Statistic	Value
Total Responses	15

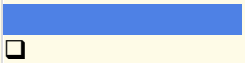
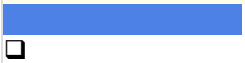
24. What is the policy on who may seek patents on the results of R&D projects in the PDP portfolio?

Text Response
We do no seek ownership of patents, we let the partner file if interested against full non-exclusive licence rights to use the patent inour activities.
The inventor applies for the patent but assigns it to IVI.
All patents are assigned to TB Alliance
Partners seek patents
Institution and joined inventors
EIther the partner decides on its own (pharma company) or MMV and partners decide together. MMV may decide on its own if all the IP rights were assigned to MMV.
By PDP If solely developed by PDP employees; Jointly with collaborators if jointly developed; By collaborator if it is sosly developed by collaborator
owner(s) of the patentable results may seek the patents

Statistic	Value
Total Responses	8

25. For the PDP, what is the purpose of producing patents?

#	Answer		Response	%

❑ 1	❑ To generate income via licensing to fund activities		❑ 2	❑ 13%
❑ 2	❑ As a defensive strategy to avoid third parties from unauthorized use of the technology or claiming ownership of patents over the technology		❑ 7	❑ 44%
❑ 3	❑ To license patents to industry to raise their interest in partnering in manufacturing - distribution		❑ 8	❑ 50%
❑ 4	❑ Any other		❑ 8	❑ 50%

❑ Any other
❑ none
❑ n/a
❑ Control the development and manufacturing of a compound to ensure proper use, quality and access
❑ As stated, this is not a major driver in our strategy, as our product is not a typical dual market product.
❑ NA
❑ For cross licensing so that Aeras can access technology owned by others
❑ To ensure access to products at affordable prices in the target populations
❑ to fulfil pre-existing obligations to commercial partner & funders

❑ Statistic	❑ Value
❑ Min Value	❑ 1

Max Value	4
Total Responses	16

26. Which of these situations apply to the results of R&D projects in the PDP portfolio? (in relation to who can be an assignee of the patent, not inventor)

#	Answer		Response	%
1	The PDP can hold a patent		9	60%
2	The PDP and partner(s) can jointly hold a patent		9	60%
3	PDP staff or member(s) can can hold a patent in their own name		1	7%
4	A partner can hold a patent, with pre-agreed licensing terms to the PDP		10	67%
5	Any other		2	13%

Any other
n/a
A partner can hold a patent under the condition to make the products available at affordable prices in target populations

Statistic	Value
Total Responses	15

27. To what extent does the PDP share patents or is considering sharing patents (allow a third party uncompensated use)?

Text Response
If applicable, unlimited use without compensation of IP for non-profit goals
N/A
Not at all because it has no patents.
We are comfortable licensing our patents on an exclusive basis in the developed world and on a non-exclusive basis in the least developed countries
Not
Not sharing
We will consider sharing whenever it furthers achievement of our Global Access objectives.
N/A
with academic partners
it may happen (hasn't happened yet)
Have cross-licensed or shared our patents in return for global access to the final product.
Frequently
All partners have right to use for non-commercial activities

Statistic	Value
Total Responses	13

28. For the PDP, is open R&D collaboration useful (no patent claims for results of the R&D collaboration)?

#	Answer		Response	%
1	Yes		10	67%
2	No		3	20%
3	In a particular research stage		2	13%
	Total		15	100%

In a particular research stage

❑ Yes, when encouraging companies to work with us in identifying optimal combination drug regimens
❑ Discovery

❑ Statistic	❑ Value
❑ Total Responses	❑ 15

29. Which of the following factors influence patent licensing agreements or R&D agreements between the PDP and partners?

❑ #	❑ Answer	❑	❑ Response	❑ %
❑ 1	❑ R&D stage	❑	❑ 12	❑ 80 %
❑ 2	❑ Target profile of the product to be developed	❑	❑ 11	❑ 73 %
❑ 3	❑ Target price of medical product	❑	❑ 8	❑ 53 %
❑ 4	❑ Type of partner	❑	❑ 9	❑ 60 %
❑ 5	❑ Choice of sources to obtain the technology/knowledge/resources	❑	❑ 7	❑ 47 %
❑ 6	❑ Specific disease that is targeted	❑	❑ 10	❑ 67 %
❑ 7	❑ Regions / countries that are targeted	❑	❑ 9	❑ 60 %
❑ 8	❑ Markets that are targeted (private, public, purchasing entities)	❑	❑ 7	❑ 47 %
❑ 9	❑ Source of funds of the PDP (public, philanthropic, industry)	❑	❑ 6	❑ 40 %
❑ 10	❑ Estimated cost of production	❑	❑ 6	❑ 40 %
❑ 11	❑ Any other	❑	❑ 2	❑ 13 %

❑ Any other
❑ n/a
❑ Commitment to providing access to the product to those most in need in developing countries.

Statistic	Value
Total Responses	15

30. Are pre-existing patents held by partners ever an obstacle for the successful conclusion of partnerships at any R&D stage?

#	Answer		Response	%
1	Never		3	21%
2	Rarely		5	36%
3	Sometimes		6	43%
4	Often		0	0%
5	All of the time		0	0%
	Total		14	100%

Statistic	Value
Total Responses	14

31. Are pre-existing patents held by the PDP ever an obstacle for the successful conclusion of partnerships at any R&D stage?

#	Answer		Response	%
1	Never		11	79%
2	Rarely		3	21%
3	Sometimes		0	0%
4	Often		0	0%
5	All of the Time		0	0%
	Total		14	100%

Statistic	Value
Total Responses	14

32. Are negotiations on terms for ownership of future patents ever an obstacle for the successful conclusion of partnerships at any R&D stage?

#	Answer		Response	%
1	Never		1	7%
2	Rarely		6	40%
3	Sometimes		7	47%
4	Often		1	7%
5	All of the Time		0	0%
	Total		15	100%

Statistic	Value
Total Responses	15

33. Has the PDPs done any opposition/invalidity of any IP held by third party?

#	Answer		Response	%
1	Yes		0	0%
2	No		16	100%
	Total		16	100%

Statistic	Value
Total Responses	16

34. Can you describe a case/cases?

Text Response

Statistic	Value
Total Responses	0

35. Has the PDP had any case of patent litigation/infringement to deal with?

#	Answer		Response	%
1	Yes		3	19%
2	No		13	81%
	Total		16	100%

Statistic	Value
Total Responses	16

36. Can you describe a case/cases?

Text Response
Never any litigation/nfringement issues
We have been cautious about proceeding with a particular compound held by a biotech company because of the patents surrounding that compound and our inability to obtain a license to that compound
We had dealings with an R&D partner which was in patent litigation with a third party (I am not sure if this was your question).
n/a

Statistic	Value
Total Responses	4

37. Can you share any case studies, best practice or examples of IP management / licensing deals by the PDP?

Text Response
We are currently in discussions regarding the licensing of a Phase 3-ready regimen to a global partner where we are offering a non-exclusive license to all countries of the world except the High Income Countries where we are offering an exclusive license. Our partner will pay us royalties on sales where they have an exclusive license.
Licensing deals: it is good to "stage" your agreements according to the stage of the project. E.g., if you fund an early-stage feasibility study where you are mostly interested in the resulting data, it doesn't make any sense to negotiate complete terms relating to, say, the commercialization of a product resulting from the use

of the technology applied in the study.
❑ IPM has several non-exclusive licenses for ARV technologies
❑ n/a

❑ Statistic	❑ Value
❑ Total Responses	❑ 4