

The Pharmaceutical Commons: Sharing and Exclusion in Global Health Drug Development

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Javier Lezaun¹ and Catherine M. Montgomery²

Abstract

In the last decade, the organization of pharmaceutical research on neglected tropical diseases has undergone transformative change. In a context of perceived “market failure,” the development of new medicines is increasingly handled by public-private partnerships. This shift toward hybrid organizational models depends on a particular form of exchange: the sharing of proprietary assets in general and of intellectual property rights in particular. This article explores the paradoxical role of private property in this new configuration of global health research and development. Rather than a tool to block potential competitors, proprietary assets function as a lever to attract others into risky collaborative ventures; instead of demarcating public and private domains, the sharing of property rights is used to increase

¹Institute for Science, Innovation and Society, School of Anthropology & Museum Ethnography, University of Oxford, Oxford, UK

²Amsterdam Institute for Social Science Research (AISSR), University of Amsterdam, Amsterdam, the Netherlands

Corresponding Author:

Catherine M. Montgomery, Amsterdam Institute for Social Science Research, University of Amsterdam, OZ Achterburgwal 185, 1012 DK Amsterdam, the Netherlands.

Email: C.M.Montgomery@uva.nl

the porosity of that boundary. This reimagination of the value of property is connected to the peculiar timescape of global health drug development, a promissory orientation to the future that takes its clearest form in the centrality of “virtual” business models and the proliferation of strategies of deferral. Drawing on the anthropological literature on inalienable possessions, we reconsider property’s traditional exclusionary role and discuss the possibility that the new pharmaceutical “commons” proclaimed by contemporary global health partnerships might be the precursor of future enclosures.

Keywords

neglected diseases, intellectual property, public-private partnerships, drug development

Introduction

Sharing is the new buzzword in pharmaceutical research and development (R&D). Confronted with the limits of a model that linked the capacity to innovate to the creation and protection of private monopolies, current calls for a revolution in drug discovery hinge on the need to loosen the constraints traditionally imposed by property rights in order to usher in a new era of “open innovation” (see Orti et al. 2009; Hunter and Stephens 2010; Kar 2010; Ardal and Røttingen 2012). Whether by sharing chemical libraries, establishing patent pools or placing clinical data in the public domain, improving research productivity seems to demand a greater willingness to abdicate full control over one’s own resources. “In the pharmaceutical industry,” write two experts in the economics of medical R&D, “sharing could be the key that allows companies to access the vast creative, intellectual, and technological resources required to tackle the formidable challenge of turning the riches of the genome into a treasure trove of new treatments” (Munos and Chin 2009, 1).

Nowhere is this imperative to share intellectual capital resources more evident than in the promotion of research to combat neglected tropical diseases (NTDs).¹ The discovery and development of new medicines for the “neglected diseases of the poor” requires, the argument goes, novel incentives and new organizational models. Greater R&D investment cannot be encouraged by further strengthening intellectual property rights (IPRs), for “a market monopoly incentive is irrelevant when market prospects are absent” (Trouiller et al. 2002, 2193). In a situation widely described as “market failure” (Backup 2008; Moran and Stevenson 2013; Mueller-

Langer 2013; Trouiller et al. 2001), and where the traditional profit incentive is seen as inoperative or too uncertain to warrant risky expenditures on research, the key is to create new communities of sharing, to trigger processes of reciprocal exchange that will reactivate the circulation of resources. Actors with the relevant expertise and capabilities—academic institutions, governments, philanthropic organizations and, critically, pharmaceutical companies—must join forces and launch new collaborative ventures.

The clearest instantiation of this new moral economy of R&D is the plethora of product development partnerships (PDPs) that currently occupy a central role in coordinating pharmaceutical research on NTDs. Designed to bridge traditional cleavages between the profit and not-for-profit sectors (and to make that distinction irrelevant), PDPs currently manage a substantial proportion of the international investment in new medicines. They have been the vehicle of choice for the global health R&D expenditures of the Bill and Melinda Gates Foundation, and are a significant recipient of grants from international aid agencies in the Global North.² PDPs use these philanthropic and state funds to support and subsidize drug discovery and development efforts, typically by commissioning research from pharmaceutical companies and academic institutions in Europe, Australia, and North America.

The label PDP covers a wide variety of organizations, with diverse business models and philosophies (Moran et al. 2010; Nwaka and Ridley 2003). The Medicines for Malaria Venture (MMV), the Drugs for Neglected Diseases Initiative (DNDi), and the Global Alliance for Tuberculosis Drug Development (TB Alliance), to name three prominent examples, have contrasting organizational agendas and *modus operandi*. MMV, founded in 1999, focuses on a single disease and manages a vast project portfolio, from lead generation through to clinical development and regulatory registration. It receives the majority of its funding from the Gates Foundation and plays a key coordinating role in the global pharmaceutical effort against malaria, partly by defining the target profiles of future pharmaceuticals (Burrows et al. 2013). DNDi originated in the Drugs for Neglected Diseases Working Group set up by Médecins Sans Frontières (MSF) in 2001, and it maintains a close relationship with the humanitarian nongovernmental organization (NGO)—a fact that accounts for its vocal stance on matters of IPRs and access to medicines (Chatelain and Ioset 2011; see also Redfield 2008). DNDi concentrates on the “most neglected diseases”—human African trypanosomiasis (sleeping sickness), visceral leishmaniasis and Chagas—and maintains a policy of not relying on any individual donor for more than 25 percent of its budget.³ The TB Alliance shares MMV’s focus on a single

disease, but has developed a more markedly entrepreneurial profile, adopting traits of a biotechnology start-up. It has, for instance, experimented with a different approach to Intellectual Property (IP), creating its own patent portfolio in order to attract partners and generate a funding stream independent of external donors. The field includes other organizations, such as the International AIDS Vaccine Initiative (IAVI), the Foundation for Innovative New Diagnostics (FIND), and the International Partnership for Microbicides (IPM), as well as various ad hoc initiatives by pharmaceutical companies, national governments, and international institutions.

These ventures are all dedicated to creating new circuits of exchange among corporate, academic, and governmental organizations, and they share at least three key features: their focus on the development of new medical technologies (drugs, vaccines, and microbicides), their self-proclaimed “virtual” nature, and their emphasis on the pooling of proprietary resources as the key mechanism of enhanced collaboration. “Virtualism” refers here to the claim of being unencumbered by large investments in fixed capital resources or specific research trajectories, a freedom from costly legacies and sociotechnical lock-ins that allows PDPs to spawn diverse alliances and thereby multiply the number of projects under development. The sharing of proprietary assets, on the other hand, is the act that founds these public-private pharmaceutical projects, gives them concrete content, and demarcates their boundaries. Each project is constituted by the pooling of private goods, such as patents, compounds, data, facilities, or expertise.

These characteristics suggest a rearticulation of the relationship between property and value. Where traditional economic incentives are thought to be insufficient to activate existing intellectual capital resources, the ability to intensify investment depends on altering the way actors calculate the value of their assets. In particular, it depends on changing the valence of IPRs, from an instrument of exclusion—“a state-granted right to sue others,” as Mirowski (2011, 145) puts it—to a mechanism of attraction, a bait used to draw potential partners into collaborative research agendas. IP still functions as an instrument of control, but its mode of operation changes: it is used as a *funnel* to bind disparate actors in a joint effort, rather than as a *fence* “to ward off the activities of others in a particular domain” (cf. Rip 1986, 93).

This article explores this reimagining of the relationship between property and value by examining the discursive and organizational innovations established by global health PDPs. Our analysis draws from two parallel strands of fieldwork into collaborative networks developing new drugs and regimens against malaria and tuberculosis, as well as on two dozen

interviews with informants in PDPs, pharmaceutical companies, NGOs, and academic institutions.

The article is organized in three substantive sections. First, we consider the adoption within the field of global health of the model of the virtual research organization that characterized venture biotechnology in the 1990s. As with biotechnology start-ups, the self-attribution of virtualism serves to articulate a new promissory cycle, a temporal trajectory free of commitments to the past and fully oriented toward a future of opportunity (cf. Brown and Michael 2003; Borup et al. 2006; Pollock and Williams 2010; Hodges 2012).

We next consider how proprietary resources, and particularly IPRs, operate within these public-private research collaborations. Rather than a tool to protect a market monopoly and exclude others from the use of a particular innovation, IPRs are deployed as an attractor to bind diverse interests to a shared mission and give material reality to the new drug development enterprise. In other words, instead of demarcating public and private domains, property rights are used to increase the porosity of that boundary, allowing heterogeneous actors to come together around projects where that distinction is temporarily suspended.

This peculiar role of IP does not preclude property's traditional exclusionary function. Yet, in a world that touts partnering and sharing, exclusion operates in a different manner. Here we draw on the anthropological literature on gift giving and inalienable possessions (Weiner 1992) to explore how sharing creates its own "others," in two important senses. First, by identifying those actors who are not invited to participate in reciprocal exchange and are as a result excluded from the "partnership"—even if they perform work critical to the success of the enterprise. Second, by marking a set of valuables that lie outside the scope of formal exchange, possessions that actors strive to keep out of circulation amid the intensification of exchange.

We conclude by considering how these transformations in the nexus of value and property shape the "pharmaceutical commons" brought into being by global health PDPs. Cori Hayden has suggested that we consider "public" and "private" not so much as mutually impermeable spheres, but rather as "complex domaining effects" (Hayden 2010). Under some circumstances, she argues, calls for the expansion of the public or the communal "rhetorically and conceptually extend the normative work of the very property regimes they seek to contest" (Hayden 2010, 98; see also Hayden 2007). With this caution in mind, we question the simplistic assumption that sharing is good in and of itself. The exclusions and imbalances visible in the emerging regime of global health R&D suggest instead that the current emphasis

on “partnering” might in fact operate as the *precursor* of a future in which IP-centric and profit maximizing strategies will again take center stage.

Pharmaceutical Virtualism and the Catalysis of Expectations

The recognition of a “fatal imbalance” between the medical needs of the vast majority of the world’s population and the priorities of the pharmaceutical industry has led, since the start of the century, to a proliferation of initiatives that seek to harness public and private R&D infrastructures to accelerate the discovery of new medicines against neglected diseases. In a recent example of this trend, in January 2012 the UK and US governments, the Gates Foundation, the World Bank, thirteen pharmaceutical companies, and officials from disease-endemic countries signed the London Declaration on NTDs, pledging innovative, coordinated action to accelerate progress toward eliminating or controlling ten NTDs by the end of the decade. The London Declaration is just one instance of the growing trend to bring corporate and nonprofit actors together in the drug development process, a key recommendation of the World Health Organization’s strategy to combat NTDs (WHO 2012). The WHO-housed Special Programme for Research and Training in Tropical Diseases (TDR) is the key historical predecessor of the current wave of public-private partnerships. Established in 1975, TDR pioneered novel contractual arrangements and risk-sharing models between government agencies and pharmaceutical companies. It was, however, the arrival of the Gates Foundation in 2000, that changed the funding and organizational landscape “almost overnight” (WHO-TDR 2007, 63). A significant proportion of the Foundation’s philanthropy in global health R&D has been channeled through public-private PDPs, allowing these organizations to play an increasingly visible role in the coordination and management of drug development efforts (McCoy and McGoey 2011).

Created at the turn of the century, the public image projected by these PDPs borrowed heavily from the tropes that characterized the biotechnology sector in the late 1990s (the professional origin of many of the executives who came to manage these new global health R&D ventures). Like a typical biotechnology start-up, these presented themselves as virtual enterprises, with a minimal physical footprint, an emphasis on intellectual capital resources, and a willingness to outsource their research needs to contract research organizations. The presumed benefit of virtualism in global health R&D, as with venture biotechnology firms, is the cost savings implied by having little or no fixed infrastructure and the flexibility this affords to

initiate a myriad of different projects with multiple constellations of partners (Booth and Zemmel 2004; Lehmann 2001; Weisenfeld, Reeves, and Hunck-Meiswinkel 2001; Ledford 2013).

This language of flexibility and networked operations pervades the current global health R&D landscape. As a senior PDP executive proudly told us, “[Our PDP] is completely virtual, we have no labs, we have no manufacturing capabilities, it’s all through the virtual model.” As well as implying economic efficiency, virtualism carries here a connotation of versatility and unconstrained connectivity, as the following description of DNDi illustrates:

DNDi has adopted a pragmatic product-development partnership (PDP) approach based on a *virtual* model... DNDi has developed an innovative, *flexible* and *efficient* approach to conduct drug development. This is achieved through its *unique hybrid organizational culture* and *involves worldwide partnerships* that rely on state-of-the-art R&D expertise. DNDi plays a leading role in identifying partners and securing funding to initiate key projects, in line with its objectives *across scientific disciplines as well as cultural and organizational boundaries*. (Ioset and Chang 2011, 1361-62, emphasis added)

This characterization applies to the Gates Foundation itself. Trevor Mundel, President of the Foundation’s Global Health Division, puts it as follows: “It’s certainly not my intention to build up the Gates pharma company. What we have is more of a virtual construct” (Mullard 2012, 264). The implication is that the Foundation is relatively indifferent to which kind of organization hosts the research it funds:

I am pretty agnostic as to where the work is done though. Most of our work is executed through our partners, including the product development partners, who focus particularly on the development side of what we do. On the discovery side, a lot of the work is executed through grants to academic institutions, sometimes to biotech companies and even potentially to pharma. (Mundel, cited in Mullard 2012, 264)

The claim of these organizations to be virtual not only reflects a particular business model but also constructs the domain of NTD research and advocacy in a particular way. The discourse allows the imagination of new and positive futures, not tied to cumbersome technological or administrative legacies. These are futures that capitalize on the absence of a solid material identity. In the statement about DNDi mentioned earlier, the PDP appears as a placeless but highly networked organization, transcending the boundaries

of location, culture, organization, and scientific disciplines. It is virtual, hybrid, and flexible, not invested in any particular history of research and thus capable of projecting multiple futures. The function of the PDP is fundamentally to provoke change: “A catalytic role is played by DNDi in the day-to-day management, coordination and empowerment of the project stakeholders with a common defined objective” (Ioset and Chang 2011, 1362). As the etymology of the word “catalyst” suggests (from the Greek *katalysis*, meaning “dissolution, a dissolving”), the PDP is an actor dedicated to breaking down or loosening entrenched distinctions and separations, such as those demarcating “public” and “private,” “commercial” and “not-for-profit,” and “North” and “South,” in order to usher in a new kind of “open” science infused with promissory value.

A good instantiation of this spirit of catalysis is WIPO Re:Search, a recent initiative of the World Intellectual Property Organization (WIPO). It presents itself as a virtual “Partnership Hub,” offering a searchable database of proprietary resources to “qualified researchers” worldwide. The information in the database is sourced from a number of “providers,” including pharmaceutical companies, governmental organizations, academic institutions, and PDPs. In joining the network, these providers make a “commitment to devoting the time and resources required to transfer and share intellectual property, know-how and expertise to support development of drugs, vaccines and diagnostics for neglected tropical diseases, malaria or tuberculosis” (WIPO Re:Search website). Any resulting transfer between providers and users is then brokered through a not-for-profit third-party organization, BioVentures for Global Health.⁴

At the launch of WIPO Re:Search, Don Joseph, CEO of BioVentures for Global Health, outlined the sort of encounter the new “Partnership Hub” hoped to enable:

Consider a researcher in Tanzania. He’s working to find a new drug for tuberculosis, but has hit a roadblock. Drug development involves a great deal of trial and error, risk, and time. With WIPO Re:Search, this researcher in Tanzania can connect with a scientist at a pharmaceutical company to get the benefit, not only of additional resources, but also that company’s know-how about which experiments they’ve tried and which have succeeded or have failed. This can significantly reduce some of the error in trial and error and lead to neglected disease research, the Eureka moment, more quickly and effectively than might otherwise have been possible. (WIPO Re:Search press conference, Geneva, October 26, 2011)

The increased connectivity made possible by the willingness to share proprietary resources renews the promise requirement cycle of global health R&D—a promise that encompasses both the expectation of faster medical successes against tropical diseases, and, if less overtly, the “virtual reality” of the Global South as the location of both promising science and emerging markets.

This second promise, the potential for profitable commercial opportunities in disease-endemic countries, is rarely mentioned by companies or PDPs when discussing their collaborations. Yet, the significance of developing countries as a potential source of future profit is widely recognized by actors in global health R&D. The following quotations offer a glimpse of those calculations:

If I'm making a wonderful new drug for dengue, say, and I know that my senior market for my anti-diabetic drugs is India, Brazil, Indonesia and Malaysia, etc. then maybe it's sort of part of, um . . . what do they call it in the supermarket—the loss leader—it's the loss leader thing in my package. (Academic scientist involved in PDP-sponsored collaborations with pharmaceutical companies)

One or two of our [commercial] partners are very clear about it—it is a way for them to enter into new markets which are still not well developed yet, but they think in ten, fifteen years' time they are going to be valuable markets and they would be already there having the good connections. So it's not completely philanthropic, but it serves our mission, so the public image is a way of getting into future markets. (PDP executive)

You begin to recognize that not only is it for humanitarian purposes, but the possibility of building markets and building new companies and building new opportunities in market places and countries and areas around the world that hold great promise. (Erik Iverson, former Associate General Counsel, Bill and Melinda Gates Foundation, quoted in Quinn 2012)

Thus, while the brochures of the PDPs are filled with images of poor patients, the pharmaceutical industry has its eye on the middle classes of emerging and developing countries, the future consumer of branded everyday medical products addressing increasingly prevalent noncommunicable diseases (IMS Health 2014). William Looney, former Senior Director at Pfizer, draws attention to this win-win scenario for PDPs and Big Pharma alike:

[A] PDP facilitates capacity building, especially across geographies and demographics. Specifically, it encourages the Big Pharma partner to consider a wider range of options in distributing medicines in unfamiliar but high-opportunity

emerging markets. . . . many Big Pharma companies . . . believe that investment in a PDP creates synergies with other, more profitable business segments through the technology transfers that seed the growth of a permanent local science and manufacturing infrastructure in markets where they want to expand their footprint. (Q Looney 2011)

In sum, the commitment of for-profit actors to join PDPs and combat NTDs is based on altering a short-term and narrow calculation of the value of their assets by drawing in less quantifiable considerations of social responsibility and network formation. Yet, the ultimate destination of their journey is still a conventional understanding of corporate opportunity, defined by their ability to position themselves successfully in “high opportunity emerging markets.” As the previous quotations imply, this vision of the future is one of profitable, IP-protected drugs sold to increasingly prosperous sections of the population in countries of the Global South. The PDP is the actor whose lack of attachment to any particular history enables it to span the chasms that separate current pharmaceutical predicaments from these future medical and economic promises. Present acts of seemingly disinterested giving are thus oriented toward a future in which the profit maximizing potential of pharmaceutical research will be restored. In other words, the commitment to NTD research and the establishment of public-private partnerships will eventually pay off by restoring a status quo *ante* of growing pharmaceutical profitability and strict focus on shareholder value—the status quo, however, that led to underinvestment and health inequalities in the first place.

IP: Attraction, Connection, and Transmission

The creative use of property sharing to anchor collaborative drug development was evident in the agreement that led to the first antimalarial brought to market by a PDP. In 2004, DNDi and Sanofi-Aventis agreed to consolidate their respective projects on new fixed-dose artesunate-amodiaquine combination therapies. The pharmaceutical company promised not to seek patent protection on the results of this collaboration and agreed to enjoy marketing exclusivity over any new drug only until the product was registered in a reference state or received WHO prequalification. DNDi took responsibility for developing the new bilayer coformulation (work that it commissioned from several academic laboratories and contract research organizations) and for coordinating the early clinical safety studies. The result of this partnership was a new artesunate-based combination therapy, known as ASAQ Winthrop. The drug was registered in Morocco

in 2007 and prequalified by WHO in 2008, at which point it became available for production by any generic manufacturer.⁵ Sanofi-Aventis agreed to supply the drug at cost to the public sector, but insisted on retaining the right to market a branded version (CoarsucamTM) and sell it for profit in the private markets of malaria-endemic countries. In exchange for DNDi's contributions, Sanofi-Aventis agreed to pay the PDP a royalty fee (3 percent of net private markets sales) for a period of seven years—money that DNDi has used to monitor the safety and efficacy of the treatment in the field and to lower the price of the drug for public sector actors (Banerji and Pecoul 2007; Bompert et al. 2011; Lacaze et al. 2011).

This early example of public-private collaboration heralded many of the features that would characterize product development agreements over the following decade, and shows the complexity and multifaceted nature of these arrangements. The sharing of proprietary resources—corporate research and manufacturing facilities, the new bilayer formulation, clinical trial data, and so on—and the forsaking of past and potential IPRs served to found and demarcate the collaborative effort. Publicly funded academic institutions conducted most of the initial (and riskier) research, but received no monetary returns or compensation beyond the contractual execution of the work. At the same time, the insistence of the pharmaceutical company on retaining a market presence through a branded product—thus deploying another tool in its IP arsenal—suggests a long-term strategy of market penetration in disease-endemic countries. Critically, the temporary alignment of interests depended on a policy of price discrimination that imposed a sharp dichotomy between “public” and “private” markets—a distinction bound to be problematic in malaria-endemic regions (Hayden 2007; Peterson 2014). In other words, while the collaboration enacted a project-specific merging of “public” and “private” interests, this integration was supported by the expectation of clearly segregated domains of action in the immediate future.

The generative dimension of property sharing has only become more central, as collaborative networks in global health R&D have proliferated over the last decade. Sharing can take multiple forms, from standardized Material Transfer Agreements (MTAs) with a clearly circumscribed object of exchange and limited duration, to open-ended research framework agreements that integrate the R&D activities of the partners over a longer period and can be extended on multiple occasions.⁶ Sharing also includes, as in the case of the DNDi-Sanofi agreement, a commitment *not* to deploy existing IPRs or seek new IP protection over the results of collaborative research efforts. As will become apparent, the differential use of these forms of

exchange says much about the contours and stratification of these “partnerships.”⁷

WIPO Re:Search, introduced earlier, offers perhaps the best example of the role that IP sharing is expected to play as a partnering mechanism. In the discourse of this initiative, property is less a form of ownership or an instrument of exclusion, and more a means of creating connections and social lubrication. In the words of David Brennan, then CEO of Astra Zeneca:

I think collectively sharing the IP that we have, along with the other assets that were mentioned, the resources and the expertise, we hope that the contributions that we make will lead to new partnerships and new opportunities for researchers to speed the discovery and the development of solutions for neglected tropical diseases. (WIPO Re:Search press conference, Geneva, October 26, 2011)

Holding IP, and offering to share it, serves to attract potential new partners. In an interview with senior PDP executives, we were told: “we see this [their own IP] as a tool, a necessary tool to help us engage with the partners we need”:

... when we form partnerships—you know, [our PDP] is virtual, we need a partner to work with us on certain drug candidates—one critical element for this partnership ... is intellectual property.

The willingness to share IP materializes connections that would otherwise remain mere potentialities. As a senior academic involved in the R&D process indicates:

One of the things that I thought was really important about IP is going down each stage from discovery to development to clinical trials into, you know manufacture, distribution, and then working with ministries for access, etc. Each stage is very much like a relay race in the Olympic Games. At each stage, the baton has to be passed smoothly from one person to the next. If you think of a relay race, the person who you're passing to is already running at the same speed as you. So ... as you go into development, you should already be thinking about both regulatory issues—to get it qualified—but also the partnership down the line. Who's going to be your partner?

The image of the baton in the relay race points to the fundamental question at the heart of this world of virtual drug development: who will be my next partner? Who will be waiting at the next milestone to carry the baton further

down the “critical path” that leads to a new medicine? IP is the tangible asset that structures this process of relaying. Its sharing creates a situation in which both parties to the transaction appear to one another with a degree of certainty, in which the transaction itself acquires a material form, allowing a set of expectations about the future to be inscribed into the ongoing progress of the project.

These uses of proprietary resources are overlooked by mainstream economic and legal literatures exclusively focused on the role of IP as a technology of enclosure. The discourses of PDPs point instead to the use of IP as a “ticket of admission,” a resource that allows the holder to gain access to relevant networks (cf. Rosenberg 1990). The dynamic of appropriation thus has a peculiar temporal trajectory: property rights referring to a past invention are shared (or given up) in exchange for the ability to pursue future-oriented collaborations that will yield not yet fully identified goods.

Temporalities of Sharing: Promise, Precaution, Deferral

Despite the generalized imperative to share, IP is not used uniformly by the actors that make up the global health R&D landscape. For instance, academic institutions and their technology transfer offices are often chastised by their partners as unduly attached to singular pieces of IP. “It’s IP that they believe that they can make money on,” notes one PDP executive disapprovingly. That is, they hope to exploit their proprietary assets in a direct and immediate way, rather than using them to attract and entangle others in longer-term and more open-ended collaborations. Universities, this argument goes, often insist unreasonably on defining the scope of transactions from the outset, instead of using the initial act of sharing to open up a virtual space of greater but as yet indefinable potential.⁸

Indeed, as one academic involved in multiple PDP-sponsored collaborations with pharmaceutical companies put it, the IP agreement should be used to formalize the downstream roles and responsibilities of each partner and thus “capture” Big Pharma at the start of the partnership. This is linked, in his view, to a desire to secure good quality drugs further in the development process, but is also related to the need to guarantee a revenue stream in a sector, like academia, that relies primarily on soft funding via research grants. As he puts it, “you can never be sure as an academic what’s going to happen next year.”

Such a defensive attitude toward the future leads to a cautious approach to sharing and contrasts with the more cavalier attitude advocated by PDP managers. An executive who joined a prominent PDP after a career in biotech start-ups and pharmaceutical companies describes this shift in perspective as follows:

Whilst I was a biotech executive I would never enter into a relationship with a large pharmaceutical company that had anything in the future undecided, because if I were going to get into an R&D collaboration and demonstrate that we've just got the best new drug for whatever disease, I never wanted to be in a position where I'm negotiating with Big Pharma where we have undecided economic benefits at the start. At the same [time], as a large pharmaceutical company, I would never want to leave unsaid the economic terms of a collaboration with a biotech company because if it's the greatest thing since sliced bread I didn't want to be held up by the biotech company to get the deal done, so I would always insist on getting the deal done.

Transitioning into the field of global health R&D required a new mentality:

It took a couple of months being on the job before I got very comfortable with the position of "Let's defer the tough issues, because if we're going to enter in a drug-discovery collaboration why do we really need to determine what percentage of the priority review voucher we need to capture when we're five to ten years ((laughing)) away from actually getting a priority review voucher? Why do we need to determine what royalty rate we need to capture in the U.S. when we're ten years again from that?" It took me a little bit of time to recognize the value of just deferring that kind of stuff and why that's actually a good thing for us and why we don't need to worry about it.

An appreciation for "the value of just deferring" is important in a field where the promise of a financial return can be tenuous at best. PDPs have to capitalize on the opportunities this uncertainty affords. In the present, this involves generating further collaborations and establishing a new pipeline of projects. In the future, the value of a product will only be realized when the viability of that drug is confirmed. Thus, PDPs establish a domain of sharing and exchange with a particular temporal structure: a new pharmaceutical "commons" is posited as a holding bay for inventions of questionable value prior to their enclosure at an unspecified point in the future. The partnership functions as a "placeholder" for ideas, resources, and technologies whose true economic significance requires for its actualization an intensification of effort in the present (cf. Riles 2011, 175). In the words

of that same executive: “By putting it into the public domain we’re essentially deferring what the rights and obligations of each of the parties will be until we find a combination [therapy] that’s really worth developing.”

The ability to defer, understood here as the power to postpone an exclusionary use of property rights to a later point in the development process, is obviously a very good indicator of the differentials of power that structure this field. Those with the most power are happy to move forward with relatively unspecified agreements, in the expectation that the current power balance will still be to their advantage further down the line. Not least because they will retain the legal and infrastructural resources—existing patents but also, crucially, technical expertise, research facilities, and access to capital—that will make them an obligatory point of passage for any downstream development.⁹

The unequal distribution of the power to defer and “not worry about it” also reflects the existence of diverse accounting frameworks among the actors that make up this field. The metrics by which university technology transfer offices are evaluated, for instance, rely heavily on the number of invention disclosures, patents, transfer agreements, and license income (Sorensen and Chambers 2008; Mirowski 2011), whereas PDP performance is typically measured by a less straightforward mixture of quantitative and qualitative indicators.¹⁰ And just as PDPs are held to a more expansive and less IP-centric set of performance metrics, so the NTD arms of pharmaceutical companies are (in some cases) accounted for as part of these organizations’ corporate social responsibility activities, rather than through the strict measures of productivity characteristic of their for-profit core. Deferral is here possible because evaluations are less closely linked to monetary returns on individual investments.

We can thus describe these intersecting temporalities of sharing as configuring a peculiar *timescape* of global health drug development (Adam 1998). PDPs posit a trajectory of pharmaceutical innovation characterized by a certain temporal modality (rectifying a history of neglect), timing (capitalizing on current philanthropic interest in NTDs), and tempo (accelerating the discovery of new products).¹¹ This timescape not only encompasses the past and the present but also critically extends into the future. Here, as Adam suggests, we should be concerned with the latent, immanent characteristics of ongoing deeds that are material at the level of process but not as yet as the products of action. In the case of PDPs for neglected diseases, these futures-in-the-making are triggered by the sharing of proprietary assets—that is by the performative, sociolegal, and scientific practices of “partnering for global health.” A key question remains, however: which

actors possess the power and authority to define these global pharmaceutical futures—or, inversely, how does exclusion operate in a system predicated on the intensification of sharing and the extension of networks?

The Outsides of Partnership

Each product which is created needs a patent. It's not a question of 'to whom does this patent belong' and it's not a question of 'patent, yes or no'. But it is 'where does it belong to?' Who takes responsibility for it? Not just who owns it. You know, I think the concept of IP is not only a concept of who has the right to own and to exploit; in our field, it's the right to what we should define as the responsibility that goes with having an IP. (Senior academic scientist)

The discourse of responsibility permeates the PDP world: the responsibility of caring for “neglected lives,” the responsibility of developing public health goods, even the responsibility, as the previous quote suggests, to put one's property to a socially productive use. Questions about the motivations that drive pharmaceutical companies and other for-profit actors to share IP are frequently answered by reference to corporate social responsibility (CSR). Anthropological analyses of CSR in public-private alliances characterize it as a ritual of corporate virtue (Dolan and Rajak 2011; Rajak 2011). Such a ritual is meant to endow corporations with moral capital, and also serves to obscure, under the mantle of “partnership,” severe differentials of power and influence among those who participate in the joint venture. What we need to elucidate are the forms of exclusion brought into being by the imperative to share that characterizes global health partnerships.

The most evident form of exclusion occurs through the demarcation of the boundary between the inside and the outside of these communities of sharing. IP sharing agreements play a critical role in drawing this boundary, not only by defining under which circumstances (and with which actors) resources cannot be shared but also, if less explicitly, by identifying the actors who are unwilling or unable to share. The most interesting example concerns contract research organizations (CROs). In a landscape of avowedly “virtual” actors they carry out much of the laboratory and clinical work, yet they are rarely considered “partners” in the drug development process. As one PDP executive put it:

We don't have that kind of relationship [partnership] with a CRO or with many different fee-for-service organizations. So I think the best way to think

about it is, fee for service, where we mandate what's done, we own all rights that come out of it, and we can fire them tomorrow if we want to and we control everything; versus a partnership, which is much more collaborative, there's usually joint licenses back and forth.

This seemingly unambiguous distinction between those who perform R&D under contract and those with whom IP is shared becomes more nuanced upon closer inspection. For instance, when a CRO is the holder of IP and makes it available—often through a contract for services—to a PDP, it is often presented as a member of the “partnership.” This is particularly true of CROs involved in early stage research activities. Companies such as Scynexis or Collaborative Drug Discovery (CDD), which license their proprietary drug discovery software to PDPs, are often mentioned in annual reports and press releases as partners of equal footing to academic institutions or pharmaceutical companies. In contrast, CROs that perform critical work but do not contribute IP to the collaboration are generally not included in public presentations of the partnership.

Mirowski and van Horn (2005) have analyzed the rise of the CRO and the way pharmaceutical companies deploy IP differently between these “data mules” and more “thoroughbred” academic institutions. In the particular case of global health R&D, the exclusion of those who perform “fee-for-service” work from membership in the partnership buttresses the identity of the collaboration as a form of “public” or “open” science. CROs have come to epitomize privatized, commercial science. Declaring them external to the partnership thus preserves the not-for-profit identity of the enterprise. It is interesting to note that those IP-owning CROs that are most active in global health R&D and collaborate routinely with PDPs often try to develop “public” or not-for-profit lines of work. CDD, for instance, which provides organizations like MMV or DNDi with drug discovery and data management software, has launched CDD Public, a free access repository of data presented “as a service to the community.”¹²

A second critical form of exclusion concerns not what kind of actor is declared external to the partnership, but which assets are kept out of circulation in spite of the pressure to share. Following Annette Weiner's classic formulation, an act of sharing can be seen as an attempt to gain access to certain “inalienable possessions,” valuables that their owners attempt to keep out of circulation despite the pressure to join in a process of reciprocal exchange (Weiner 1992). The role of IP in marking out this domain of “not sharing” is ambiguous. It is not necessarily the case that IP-protected assets

are by definition the most precious, or that IP is consistently used as the mechanism that confers inalienability. Quite the contrary, as we have noted IP is often the bait used to attract others into the partnership; it is in fact *the giving up* of IP-protected assets that triggers the process of mutual exchange.

What this suggests is that the sharing of IP is means a to gain access to other goods not explicitly encompassed by the transaction. Discussing their motivations to engage in PDP-brokered collaborations, actors describe the range of goods they hope to obtain from the collaboration, valuables that are not the object of formal exchange between the parties but are expected to flow through the partnership. A pharmaceutical industry executive, for instance, lists the following items to describe the assets and capacities he hopes to gain access to: “regulatory expertise,” “expertise in access” (to future markets in developing countries), “a better sense of what the world needs,” “defined target product profiles,” “a perspective on the value” of products in the corporate pipeline, “a wide network of contacts and collaborators,” and, finally, “the big picture” on global health, an assessment of trends and expectations in the field that would allow the company to measure the value of its own R&D portfolio. These might seem rather intangible returns—none of them will be the subject of an MTA or collaborative research agreement—but they are the benefits he hopes to reap in return for sharing or giving up IP and other private resources. By the same token, one can surmise that these are the possessions that his partners will want to keep out of circulation, if only to protect their appeal to the pharmaceutical industry as potential future collaborators.¹³

The situation thus echoes Weiner’s (1992, 42) analysis of gift giving, where “The seemingly linear aspects of reciprocal give and take are merely overt attempts to become part of, to participate in, or conversely, to snare, what is not part of that exchange.”¹⁴ In other words, gifts trigger a complex pattern of holding and releasing. As in the examples described by Weiner, the desirability of an organization as a potential partner depends on its ability, amid the seeming frenzy of reciprocity, to keep to itself and *not* exchange those possessions that make it attractive. This triggers a peculiar temporal dynamic, where the desire to reach through to the partner’s inalienable possessions motivates new acts of sharing. As Weiner (1992, 42) suggests, the “paradox of keeping-while-giving” is the engine of future exchange, as the “radiating presence” of inalienable possessions attracts others to further rounds of collaboration.

Conclusion: The Pharmaceutical Commons as a Precursor to Future Privatizations

In the new world of “open innovation” for neglected diseases, we have argued, proprietary assets in general and IP in particular function as a tool to attract and connect the diverse actors and interests that must join forces to facilitate effective drug development. Property rights are not used to produce an immediate return or rent, or to demarcate a space of monopolistic use, but to trigger and materialize new partnerships. Yet the new pharmaceutical “commons” crafted by the PDPs rests on the expectation of future enclosures, whether they are in the guise of property rights and marketing opportunities attached to new medicines against NTDs, or result from an expanded ability to extract profit from drugs for unrelated diseases in “emerging markets.”

As legal historians have long argued, the public domain is sustained through a temporal surrendering of private property, but this suspension is often oriented toward future acts of privatization (Rose 2003; Chander and Sunder 2004). Carol Rose’s (2003) analysis of intellectual space broadly, and of the Internet specifically, as *res publicae* is telling in this regard. The Roman law category of *res publicae* was used to categorize aspects of tangible space belonging to, and open to, the public. Such things included roads, harbors, ports, and bridges—the channels of trade and commerce. Yet, Rose (2003, 100) observes, “the idea of *res publicae* works hand in glove with a regime in which most resources are the subject of private property. . . . The openness of trade routes presumes that the users of these routes have their own incentives to trade, and that those incentives come in large part from private ownership.” Whereas in physical space the channels of *res publicae* have a geographic character, in intellectual space the key parameter of publicness is temporal. This, Rose suggests, is because under intellectual property law, all once proprietary intellectual achievements are turned into *res publicae*. Insisting on the co-dependent nature of the public and private domains, she concludes that “private property and *res publicae* are separated only temporally” (Rose 2003, 104).

The role of PDPs, and the moral economy of “sharing” they embody, can be interpreted in this light. A re-imagining of the value of property is implicit in the discourse and organization of this field, and this new valence of property is intimately connected to the establishment of a peculiar *timescape* of global health R&D. Value, as we have illustrated previously, is linked to the deferral of enclosures, because only through deferral can the channels of collaboration be kept open *in the present*. The network extends itself through the promise of revisiting property rights at a

specified point in the future. In the meantime, the stronger the network, the more valuable it becomes for all involved: “The greater the network of trade, the larger the market, the greater the opportunities for specialization, and the better for all participants” (Rose 2003, 98). So it is that public and private become hyphenated. As Cori Hayden (2010, 88) has proposed, “the pharmaceutical public domain is not just an undifferentiated space of enhanced access and flow; it comes into force not against restrictive pharmaceutical patent regimes, but bundled neatly with them.”

Public and private, we have pointed out, are not just *spatial* domaining effects, but *temporal* ones as well. The question is not simply the coexistence in the present of diverse modes of appropriation and sharing, the sort of “diverse ecology of the open and the proprietary” that Jane Calvert identifies in other areas of life sciences innovation (Calvert 2012; see also Hilgartner 2012a, 2012b). The problem is also how to characterize evolutionary cycles in the ownership structures that shape the field of NTD drug development, how to identify the sorts of power differentials that are projected into the future by present acts of reciprocity. The imperative to share, we have argued, carries with it multiple forms of exclusion: exclusion in the present by not being the bearer of property (having nothing to share) and exclusion in the future by not having shared in the past and therefore having no claims to the fruits of collaboration. Furthermore, this economy of “open innovation” is one in which the most desirable valuables, those that confer true advantage over the long-term, often remain external to the sphere of formal sharing, inalienable possessions carefully kept out of circulation.

This is clearly a vicious circle for the poor in general, and for researchers in resource-limited countries in particular. According to this analysis, then, the exclusions enacted by “sharing” might well be coterminous with the exclusions associated with acts of privatization, throwing into doubt the assumption that sharing and partnering will, by themselves, create a qualitatively different distribution of power in global health R&D.

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Notes

1. In this article, we use the category “neglected tropical disease” (NTD) or “neglected diseases” to encompass malaria and tuberculosis, in addition to the seventeen diseases affecting populations in low-income countries identified by the World Health Organization in its official list of NTDs: http://www.who.int/neglected_diseases/diseases/en/ (accessed December 15, 2013).
2. In the United Kingdom, for instance, product development partnerships received 91.8 percent of the funds allocated by the Department for International Development to neglected diseases research in 2009 (see Policy Cures 2011).
3. In 2012, for instance, the Drugs for Neglected Diseases Initiative received 22 percent of its funding from Médecins Sans Frontières and 20 percent from the Gates Foundation.
4. BioVentures for Global Health incarnates the transposition of organizational models and rhetorics from the world of biotechnology to the field of global health R&D. The organization is a spin-off of the Biotechnology Industry Organization (BIO), and, although itself a nonprofit organization, it “maintains close ties to industry partners through BIO and the International Federation of Pharmaceutical Manufacturers and Associations” (Dent et al. 2013, 593).
5. Generic versions of ASAQ Winthrop are manufactured by Indian companies. DNDi is currently trying to find an additional manufacturer in sub-Saharan Africa.
6. In a recent review of PDP relationships with pharmaceutical companies, the PDP Funders Group categorized about 25 percent of agreements as Material Transfer Agreements, the rest being collaborative research/development agreements, and others such as Memoranda of Understanding (Rowley 2012b). To the best of our knowledge, no work has yet systematically categorized the type of relationships PDPs have with contract research organizations (CROs). We return to CROs and their invisibility later in the article.

7. A noticeable feature of conducting fieldwork on this issue is the difficulty, due to confidentiality clauses, in gaining access to the contracts through which the parties to an IP sharing agreement articulate the specific conditions of exchange. In other words, there is a general reluctance to share the agreements through which the actors agree to share (a lack of transparency noted in official reviews of this field, see Rowley 2012a). We take this to be an indicator of the central thread of our argument, namely, that IP sharing is used strategically to project specific forms of control into the promissory futures of global health—forms of control that are not well described by conventional understandings of IP as a protective fence, but are neither synonymous (or compatible) with a generalized notion of “openness.”
8. The argument that university technology transfer offices display a certain “myopia of protectiveness” (Laursen and Salter 2005), that they “misconstrue patents as ends, rather than means” (Mirowski 2011, 143), is often mentioned by the actors that make up the global health R&D landscape (outside university technology transfer offices, that is). This suggests an interesting degree of ambivalence toward the “entrepreneurial university” and its IP-centric ways (cf. Russell and Nathan 2013). For a nuanced account of the strategic calculations that drive university licensing practices, see Owen-Smith (2005).
9. This dynamic is similar to that identified by economists in relation to the commitment of for-profit organizations to basic research. As Rosenberg (1990, 173) put it in a classic paper: “a greater confidence in the strength of one’s downstream commercialization capabilities should increase the willingness to perform basic research, by strengthening the prospect that the firm will capture a larger share of the potential downstream benefits that may be generated by such research.” If we replace “perform basic research” with “share IP,” we arrive at a perfect formulation of the expectations of differential return that justify the willingness to share one’s own proprietary resources.
10. As a 2007 report sponsored by the Gates Foundation states, “Based on our analysis, what is needed is *not a new checklist* for donor evaluation but rather a *more accurate representation* of the work PDPs are conducting now and *in the future*” (FSG Social Impact Advisors 2007, 9, emphasis added).
11. There might be a further temporal dimension to these partnerships: the competitive advantage in being the first one to strike a collaboration or establish a network. In other words, the pressure to “defer the tough issues” could also be explained by the desire to be the “first mover” in a field, such as “open source” pharmaceutical R&D, with its own internal competitive dynamics.
12. See https://www.collaboratedrug.com/pages/public_access (accessed May 25, 2014).

13. Inversely, the partners of pharmaceutical companies typically identify a range of possessions they hope to gain access to through the collaboration: high-throughput screening technologies, state of the art medicinal chemistry, the logistical and financial muscle necessary to bring a clinical trial to fruition, and high technology manufacturing capacities, for instance. These possessions hardly become alienated by the willingness of those companies to share IP.
14. Weiner (1992, 43, emphasis added) describes, for instance, how “when a Trobriander keeps a famous kula shell, other players seek him out, bestowing upon him other bounty in an attempt *to make him into a partner*.”

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Author Biographies

Javier Lezaun is James Martin Lecturer in Science and Technology Governance at the Institute for Science, Innovation and Society, University of Oxford. His current research focuses on practices of exchange and appropriation in the contemporary life sciences.

Catherine M. Montgomery is a research fellow in the Department of Sociology and Anthropology at the University of Amsterdam. Her work focuses on the social and political dimensions of techno-scientific change relating to biomedicine in transnational contexts. Her current research explores adaptation through experimentation in pharmaceutical clinical trials.