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Abstract

Recent debates in public health and social sciences have shown how biofinancialization has been fuelled by patents' transformation into 'patent-as-assets'. This paper traces the historical construction of one such patent-as-asset bundle: the multi-billion worth architecture of patents behind the hepatitis C blockbuster drug sofosbuvir. Following this process from the late 1980s to present times, we highlight the ontological entanglements of pharmaceutical patents and the scientific, legal, commercial and political contestations that result from the focal firms' assetization projects. By shining a light on these entanglements, our paper points to the extraordinary historical conditions required for the assetization of drug patents as well as to their vulnerability to contestations. In particular, we highlight new forms of patent activism that threaten the 'asset condition' of high-priced pharmaceuticals.

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Introduction

'The philosophy is very simple. Good drugs save lives and a major side effect is they can also make you rich'.[1] This statement was made by Dr Raymond Schinazi, one of the main scientists involved in the invention of the hepatitis C cure sofosbuvir and the owner of a company that held a string of crucial patents over the forthcoming drug, just after selling his company Pharmasset to Gilead Sciences for US$11 billion in 2011. This quote signals how pharmaceutical patents – initially designed to encourage inventors to disseminate their findings without fear of intellectual theft – have been increasingly turned into assets, allowing their holders to extract large quantities of wealth from them. However, this assetization dynamic is by no means an unavoidable or uncontested process. Following the history of the patents behind sofosbuvir, in this paper we highlight the socio-material resistances to the assetization of patents, demonstrating how this process involves numerous scientific, legal, commercial and political disputes. We outline how powerful pharmaceutical actors were able to appropriate an intricate patent architecture around sofosbuvir – and through this bundling stabilize a value regime that allowed them to turn the patents into assets. However, this assetization process has remained vulnerable to contestation by other actors including scientists involved in the invention, pharmaceutical competitors, and access to medicines activists. We demonstrate that the transformation of the patents underlying sofosbuvir into profitable assets passed through several phases between 1987 and 2020 that each entailed different forms of contestations. In the most recent period, these are mainly driven by civil society and are building a potential counterweight to the current 'assetized' pharmaceutical business model.

We build our conceptual argument on debates regarding biopharmaceutical assetization. Birch and Muniesa (2020) have recently called for detailed empirical investigations on how things are turned into assets, which they see as the conversion of scientific knowledge, legal and other practices into 'identifiable and alienable property' that 'can be owned … and capitalized as a revenue stream' (p. 14). Considering how patents are constructed, bundled and held together as assets helps to understand important facets of contemporary biopharmaceutical capitalism, particularly the value extraction mechanisms in the sector where the (bundled) patent-as-asset is the crucial cog in the appropriation of pharmaceutical value by 'technoscientific rentiers' (Birch, 2020). A move from the focus of earlier biocapital literature (for instance Sunder Rajan, 2006; Waldby, 2002) toward an examination of patents-as-assets thus allows to explain how the 'living things' that biopharmaceutical firms commodify are turned into future-oriented sources of rent through the construction of specific valuation and accumulation regimes (Geiger & Gross, 2021). In particular, we

highlight the construction and management of patent architectures as a vital lever in the profit-seeking activities of biopharmaceutical firms.

Tracing the multiple pre- and post-market patent oppositions threatening its 'asset form' through the case of sofosbuvir reminds us that patents-as-assets are never fully disentangled from their multiple positionalities in legal, scientific and social practices. Emphasizing the conflictual dimensions of patents-as-assets both supports and complicates existing calls to view pharmaceutical knowledge as communal (Boyle, 2003). In reality, as we will show, there is no straight line from open to enclosed knowledge (see also Kang, 2020). At the same time, a focus on the instability of patents-as-assets highlights the fact that the making of pharmaceutical assets and the many contestations they provoke open up to civil society new forms of activism against the financialized biopharmaceutical business model (Geiger & Gross, 2018; Parthasarathy, 2017). The story of sofosbuvir's patent contestations also includes a broader historical interest, as they contributed to major shifts in the biopharmaceutical political economy. This included the 1996 legal decision favourable to Emory University, which accentuated the rift between international and US patent law, an 18-month US Senate Committee on Finance Investigation into sofosbuvir's price and its impact on the US healthcare system, the activist oppositions against the sofosbuvir patents in 2015 and 2017, the first of their kind in high-income countries, and the advent of European state activism against pharmaceutical pricing strategies, culminating in the 2019 World Health Assembly Transparency Resolution. The contestations around this high-profile drug continue to reverberate in the political economy of pharmaceuticals, including in the fight for widespread access to COVID-19 technologies and vaccinations by access to medicines movements. Acknowledging patents' multiple origins and trajectories strengthens calls to infuse a public utility character into the industry, which have grown louder during the COVID-19 pandemic, and which may serve to reintroduce an explicitly moral economy that acknowledges the collective nature of the knowledge underlying an invention and a duty to make it useful to the public (Gaudillière, 2008). By putting its emphasis on the contested dimensions of assetization, this paper thus ultimately points to its potential reversibility.

The pharmaceutical patent as asset form

Patents have been playing a crucial role in pharmaceutical markets since the advent of the modern patent regime. The pharmaceutical patent builds on the patentability of 'living properties' (Gaudillière & Kevles, 2009) through what Parry (2004, p. 96) has called the 'enclosure of nature'. This long-term historical process resulted in patents being instruments to own and trade biological things, such as biochemical and genetic material (Gaudillière, 2008; Kevles, 2007). With the industry shifting from mass commodities to more targeted biopharmaceutical therapies, patents have arguably become even more

crucial. Contemporary biopharmaceutical companies often extract value from the identification of complex biological components typically designed to address small groups of patients, making the ownership of intellectual property over these components central.[2] Where the 'innovation' model of pharmaceutical capitalism derives power from the monopolistic control of market access through the patent regime, in the modern financialized model additional power is gained from controlling patents both as legal entitlements and as material manifestations of a future stream of earnings.

Accordingly, the assetization of patents as a distinct 'modality of value' (Kang, 2020, p. 65) needs to be understood in the broader context of the financialization of the pharmaceutical industry (Lazonick & Tulum, 2011; Sunder Rajan, 2017). Biofinancialization has been defined by Glabau *et al.* (2017) as financial investments 'in domains where life is valued, manufactured, bought and sold'. Emphasizing the 'investment gaze' (Muniesa *et al.*, 2017) of biopharmaceutical firms, their financial backers and the broader market in which they are embedded, biofinancialization has been studied by two streams of research. A first stream has detailed the transformation of the financial policy of biopharmaceutical firms, which primarily affects the way firms allocate profit once it has been generated. Lazonick and Tulum (2011) for instance have shown how pharmaceutical profits have been increasingly invested in share buybacks, dividends and high executive pay, instead of R&D efforts. Here, biofinancialization is essentially understood as the extension of the shareholder value movement to the pharmaceutical sector.

A second stream of research, which is more central to this paper's argument, has focused on how biofinancialization affects the way profit is generated and extracted by pharmaceutical companies. Research has started to analyse the characteristics and consequences of speculation and rentiership strategies in the pharmaceutical sector, investigating the capital make-up of the industry (Birch, 2017; Sunder Rajan, 2017) and explaining critical issues related to the pricing and access to pharmaceuticals (e.g. Lazonick *et al.*, 2017; Quet, 2018; Roy & King, 2016). Where an 'innovation business model' would have large, vertically integrated firms investing in a research and development pipeline that culminates in monopolistic commodity markets, a 'financialized' model sees the advent of a 'relay race' (Roy, 2020) in the replacement of in-house R&D with acquisitions of smaller biotech firms, which are typically financed through venture capital. This lessens the larger firms' financial risks and fundamentally changes their investment strategies (Andersson *et al.*, 2010).

Recent research on biofinancialization thus both builds on and departs from previous literature on biovalue and biocapital (e.g. Helmreich, 2008; Mitchell & Waldby, 2010; Sunder Rajan, 2006), which played a vital role in explaining how lively material is turned into commodities, especially during the advent of the biotechnology industry. It highlights how financialized biopharmaceutical firms view patents not only as enabling the monopolistic capture of a large commodity market or as incentives for future innovation, but more importantly as portfolios of assets to be exploited through specific rent-seeking behaviours – to

be bought and sold, banked and speculated upon, strategized and pre-empted (Kang, 2020). By focusing on the new modes of profit extraction from biomedical patents, this research intersects with a broader interest in assetization across the social sciences, which has sought to understand how a wide variety of objects are turned into stores of wealth for financial markets (Birch, 2020; Birch & Muniesa, 2020; Langley, 2021). While the focus of this literature often lies on financial markets, assetization is not just financial speculation. As Langley (2021, p. 385) writes, 'the 'extraction' of value under financialized capitalism is increasingly held to operate in ways that turn less on asset price speculation, and more on rent relations enabled by the ownership of private property'. In fact, one of the most significant characteristics of a patent's 'asset condition' (Muniesa *et al.*, 2017, p. 34) is the ability to exclude others from any usage benefits arising, and to defend this ability through the courts of law. They represent, in Mirowski's (2012, p. 145) words, 'a state-granted right to sue others' over any actual and future benefits. Constructing the patent-as-asset requires considerable regulatory and legal work to separate out the narrowly technical patent from its social and moral context. When discussing the legal 'code' of intellectual property assets, Pistor (2019, p. 113) states that 'patents are creatures of law and the only battlefield therefore is a court of law'. Comparing historical decisions of the US and European Patent Offices (USPTO and EPO) with regard to life science patents, Parthasarathy (2017) traces how the EPO slowly opened itself up to the voices of patent activists and other affected publics. The USPTO on the other hand firmly upheld expertise barriers and retained a narrow definition of patents as techno-legal objects, delegating social, economic and moral decisions to the inventor. Parthasarathy's analysis demonstrates how the making and maintaining of patents continually threatens to overflow into multiple networks beyond the technical and legal spheres. Cutting these networks often displaces the controversies into other forums such as acts of civil disobedience.

Managing the legal and regulatory aspects of the patent-as-asset is part of a toolkit of asset management techniques that complements and, in some cases, replaces industrial production capabilities with intellectual property as the main source and focus of value creation and extraction (Geiger & Finch, 2016). The financialized biopharmaceutical business model rests on the ability to extract surplus value *primarily* through the maintenance and valorization of bundles of patents; value that is often unmoored from the development, production and use of the drugs themselves (Roy, 2020). Thus, the crucial form of control of the patent-as-asset is not the act of enclosure itself, but the ability to project future income through astute bundling and asset management. For this, the patent-as-asset relies on firms' ability to place patents within a valuation regime that ensures enforceable, stable high drug prices – a challenge that has arguably been considerably simplified through the spread of national health technology assessment procedures over the past 20 years (Sorenson & Chalkidou, 2012).

Yet, upon closer scrutiny, pharmaceutical patents are characterized by an ontological instability that makes them uneasy candidates for the asset condition. Thambisetty (2007) for instance likens patents for innovative technologies to 'credence goods', referring to the significant intrinsic and extrinsic uncertainties attached to their claims. Patent stabilization and enforcement appear to be in a recursive relationship. Carolan (2010) argues that the enforcement of a property right through the courts is an important stabilizing feature for the patent, as enforcement requires specificity: 'without specificity there is no "it". And without an "it" there is *no-thing* to exchange, sell and/or protect from misuse' (p. 111). Where Carolan's focus lies on how the interpretative flexibility of the patent may threaten its stability, Lezaun and Montgomery (2015) question the boundaries between exclusion/inclusion and sharing/appropriating that the pharmaceutical patent claims to draw. Geiger and Gross (2018) present the case of the Geneva Medicines Patent Pool, a mechanism that at once corroborates the solidity of patents for essential medicines yet mobilizes for the necessity of sharing these assets for the common good. They also highlight the potential instability not just of the patent-asset itself but also of the valuation regimes that are associated with it.

Building on these combined insights, we examine in the sections below the contested journey towards the assetization of (a set of) pharmaceutical patents by tracing disputes about the delineations of the property rights given by patents and their roles in the assetization process across the realms of science and the law. This approach to patent assetization can fruitfully complement past debates on processes of (bio)commodification and the material resistances they provoked. The socio-material resistance occurring in the 'enclosure' (Parry, 2004, p. 96) of biochemical compounds detailed by Franklin (2001) and Salter and Salter (2007) for instance is one of the many facets of the contestation of the patent-as-asset. The processes through which patents are then bundled, traded, enforced internationally and turned into rents through high drug prices provoke resistances of similar (if not greater) amplitude as the ones described in the biocapital literature, as this paper aims to demonstrate.

Methodology

In the following sections, we trace the tumultuous legal, scientific, commercial, and political history of the patents behind sofosbuvir, a hepatitis C drug that has received as much public attention for its high price as for its therapeutic value (Roy & King, 2016). To piece sofosbuvir's evolution together, we had recourse to medical journals, reports, company accounts, annual reports, and secondary sources from periodicals, commentaries and interviews. To understand the history and medical background of this drug and the illness it is directed at, we used international and national health organization websites, reports and fact sheets, such as those produced by the World Health Organization (WHO) and US National Institute of Diabetes and Digestive and Kidney

Diseases. Reports produced by organizations such as *Médicins du Monde* and *Médicins Sans Frontières* (MSF) provided insight into the social impacts of the disease. Tracing the legal and commercial development of sofosbuvir required the collation of company accounts, annual reports and press releases, as well as utilizing the US Securities and Exchange Commission (SEC) database. Secondary sources from periodicals, commentaries and interviews further complemented the data collected. Research into the patents connected to sofosbuvir and their application history was conducted using the European Patent Office database (Espacenet) and the World Intellectual Property Organization (WIPO) Global Brand Database. Historical case studies (IPAdvocate), newspaper reports, and journals were used to investigate the history related to the development of HIV drugs and associated patents. Detail on activist contestations was sought through reports from WHO, I-MAK, and *Médicins du Monde,* and through nine interviews with European regulators and activists in the access to medicines movement involved in the opposition to Pharmasset and Gilead Sciences' hepatitis C drug patents.

Constructing a patent-as-asset: The case of sofosbuvir

In November 2011, Gilead Sciences acquired a biotech company called Pharmasset for US$11 billion, whose only significant asset was a molecule named PSI-7977. Gilead Sciences was a large US biopharmaceutical company founded in the late 1980s with a reputation for an acquisition-focused business strategy (Roy & King, 2016). Its main business was in small molecule antiviral treatments, and it became one of the first biotechnology companies (along with Amgen) to enter the top 15 for the largest pharmaceutical companies in the 2010s. What exactly this firm was purchasing for US$11 billion appeared nebulous to some analysts who stressed the risks associated with Gilead paying an 89 per cent premium on all outstanding shares for a biotech firm that had no products on the market and a pipeline consisting solely of 'three clinical-stage product candidates for the treatment of chronic hepatitis C virus (HCV)' (Business Wire, 2011). Gilead's share price fell 9.1 per cent on the announcement. Yet, according to Gilead, beyond any presently realized *pharmaceutical assets*, its acquisition of the aptly named Pharmasset represented 'an important and exciting opportunity to accelerate Gilead's efforts to change the treatment paradigm for HCV-infected patients' (Business Wire, 2011). To fully understand this statement, one needs to delve deep into the scientific, legal, institutional, commercial and political worlds that were entangled in the molecule PSI-7977, better known as the HCV drug sofosbuvir.

Isolating when sofosbuvir's history began is not a straightforward task, nor is it a straight road that started in one laboratory and culminated with a multi-billion-dollar financial asset. In the pharmaceutical industry, patents are usually filed during the early research phases to protect active ingredients that could potentially form the basis of a new drug. As the 'could' and

'potentially' suggest, this often leaves these early patents broadly structured, providing patentees with enough room to file amendments as the drug progresses. Such patents, referring to active ingredients, are typically designated as primary patents. As drug development advances into the later stages, additional patents are then filed pertaining to other aspects of the active ingredients, such as different dosages, formulations, or production methods. Such patents are referred to as secondary patents. To illustrate just how extensive patenting is within drug R&D, according to one WHO report, Gilead Science's patents pertaining to sofosbuvir comprise 14 different patent families, of which 12 are secondary patents claiming different combinations, methods of use and formulations of sofosbuvir, and two primary patents (WHO, 2016).[3] Inherited from its acquisition of Pharmasset, it is these two primary patents that have long been the focus of frequent opposition proceedings within patent regulatory bodies and national courts of law.[4]

Turning molecules into patents – 1987–2003

Ever since the virus responsible for the hepatitis C disease, once referred to as 'non-A, non-B', was discovered in 1989, HCV treatment was categorized as inaccessible and ineffectual. Patients fortunate enough to be treated for the disease were reliant on expensive and ineffective treatments, riddled with brutal side-effects. The pursuit of more effective drugs, which would also contribute to lessening patients' mental and physical distress, had long been a target for HCV researchers, a public health priority and a significant commercial opportunity.[5] This pursuit was based on a dramatic increase in antiviral research from the 1980s onwards in the study of HIV (Bryan-Marrugo *et al.*, 2015). Researchers agreed that combinations of several antiviral agents would be necessary to control the infection and achieve a 'major breakthrough' against HCV's high number of variants (De Francesco & Migliaccio, 2005, p. 959).

The discovery of sofosbuvir as a therapy against HCV leads all the way back to the invention of what would eventually become two stalwarts of HIV antiviral therapies – two molecular compounds called 3TC and FTC. One of the many scientists and researchers dedicated to HIV drug development in the late 1980s was Dr Raymond Schinazi, a medical chemist at Emory University. In 1989, before HCV was even discovered, Schinazi learned of an interesting new compound, called 3TC, being developed by Canadian biotech firm, BioChem Pharmaceuticals. Enlisting a team of researchers at Emory to better understand the potential of this molecule, Schinazi led the synthesis of a closely related compound of 3TC, called FTC. The full commercial significance of this would only be realized years later, but glimpses of the two compounds' potential value became visible in subsequent research conducted by Emory in collaboration with the pharmaceutical company Burroughs Wellcome – the organization behind the first HIV antiviral AZT. This research revealed

that HIV viruses that developed a resilience to 3TC and FTC soon became more susceptible to AZT. This discovery not only provided evidence that combination therapies were an effective treatment option for HIV but also showed that the two compounds could potentially play a central role in the HIV antivirals market – a market, which, at the time, consisted of only one licensed drug able to directly treat the disease, namely AZT.

As patents began to be filed, the technoscientific journey behind the sofosbuvir drug took an early legal turn. Schinazi's team had lobbied for Emory University to file US patent applications for both 3TC and FTC in 1990 (Emory, 2019). But BioChem Pharmaceuticals itself had carried out early and extensive research on the 3TC compound. This work resulted in BioChem being awarded the first international patent for 3TC in 1989, having first filed an associated patent application – the determining factor in international property ownership.[6] Quickly enough, as they realized that they were both claiming rights over the invention of the FTC and 3TC molecules, Emory and BioChem entered a legal dispute. Within the US context, intellectual property operated on a 'first-to-invent' rule, whereas most international patent regulatory bodies, including the EPO and the Canadian patent office, operated on a 'first-to-file' patent system.[7] In 1996, after a protracted patent dispute, Emory University was awarded the US patent rights over 3TC (Emory, 1996). This decision accentuated a fundamental difference between international and US intellectual property law, triggering international institutional debates.

The Emory-BioChem dispute was only one layer of an increasingly complicated situation. A parallel lawsuit involving Emory's other star compound FTC had already sparked a legal battle between the university and Glaxo following the latter's US$3.8 billion merger with Burroughs Wellcome in 1995. Prior to the merger Emory and Burroughs Wellcome had collaborated on the development of FTC, however the newly formed Glaxo Wellcome decided to terminate its licensing agreement for the FTC patent in December 1995. Emory would later claim that this move was an attempt to 'stifle competition' to 3TC-based treatments, in which Glaxo Wellcome was a leader (Anason, 1996). In light of Glaxo Wellcome's decision, the further development of FTC was left to a small biopharma company called Triangle Pharmaceuticals, formed by former Burroughs Wellcome HIV researchers and previous collaborators from Emory and the University of Alabama. While the potential for the biopharmaceutical company to gain a significant slice of the buoyant HIV market aroused investors' interest, this early optimism slowly dissipated as parallel patent disputes around 3TC and FTC transformed into six years beset by counterclaims and lawsuits. The slow progress led researchers from Triangle to start two new pharmaceutical entities that would allow them to pursue the HCV research they felt had been side-tracked by the legal and commercial quagmire. Dr Schinazi would direct one, Pharmasset, while the second, Idenix, would be run by a scientist from the University of Alabama who had previously investigated AZT with Emory and Burroughs Wellcome. Building

on the knowledge gained from the development of the disputed HIV drugs, Pharmasset and Idenix's work concentrated on the development of nucleoside-type drugs[8] that could interrupt the lifecycle of HCV inside the liver. The work started to bear fruit when Pharmasset researcher Jeremy Clark discovered a nucleoside analogue (PSI-6130) that provided enough promise for Pharmasset to file a provisional application with the USPTO in May 2003 and several non-provisional applications for PSI-6130 in May 2004, with Clark as a named inventor.

Building exclusivity on a patent architecture – 2003–2014

After the transformation of HIV research into a string of disputed patents, the assetization process required a company to bundle all these patents and claim exclusive ownership over the future HCV patent architecture. Accordingly, with its newly patented PSI-6130 compound designed to treat HCV, Pharmasset started to attract the attention of larger pharma firms. The pharmaceutical firm Roche, interested in combining PSI-6130 with its own market leading HCV products, entered into a collaborative agreement with Pharmasset in October 2004. The basis of this agreement granted Roche the global rights to develop the compound and any associated prodrugs[9] for an upfront fee, R&D support, and milestone payments, as well as any royalties on product sales. Ultimately the collaboration failed to turn Pharmasset's promising compound into a HCV drug and the agreement regarding PSI-6130 ended in December 2006. However, the collaboration did lead to the development of several prodrugs, which signalled US$30 million in milestone payments to Pharmasset. This funding would allow Pharmasset to 'continue to develop and retain worldwide rights to ongoing and future hepatitis C programmes unrelated to the PSI-6130' as stated in the 2004 Roche-Pharmasset agreement. As collaborations with Roche attracted more external interest, Pharmasset's research on PSI-6130 began to yield similar molecules that displayed efficacy in clinical trial settings.

In 2007, following numerous lesser candidates, a promising successor to PSI-6130 was discovered in the form of PSI-7977 – the molecule that would finally become sofosbuvir. As with its predecessor, Pharmasset quickly moved to file provisional applications with the USPTO for PSI-7977, including a novel synthesis method. A month later, with no market-ready product but three clinical trial stage compounds in the pipeline and a novel method of synthesis patented, Pharmasset began to trade publicly on the NASDAQ. The provisional application for PSI-7977 turned into an official application in March 2008. However, like the patent disputes in the development of 3TC and FTC, it was the provisional patent application that granted Pharmasset with 'first filing' dates of 2003 and 2007 that would become an important anchor for the commercial future of PSI-7977. Moreover, similar to 3TC and FTC's many ownership claimants, Pharmasset was not alone in its pursuit of

anti-HCV drugs. In one of its numerous subsequent patent defences, Gilead listed 25 companies that held a HCV drug candidate in pre-clinical trials in 2007, many of them spawned by HIV antivirals research (Gilead Sciences, 2015). Given the similarities between the central 'prodrug', PSI-7977, and its predecessor molecules, such as PSI-6130, FTC and 3TC, the ability of a pharmaceutical company to own an uncontested exclusivity over the sale of sofosbuvir thus centrally relied on its ability to own the full architecture of patents behind this drug.

Pharmasset's aims thus quickly turned to building 'a growing portfolio of issued patents covering PSI-7977' (Pharmasset, 2011); that is, transforming PSI-7977 into a commercial blockbuster by claiming control over several related patents. The effort required to achieve this was hinted at in reports by Gilead Sciences after its Pharmasset acquisition indicating that provisions had been made surrounding the legal battles that would be required for its US$11 billion gamble to become a worthwhile commercial bet:[10]

> Pharmasset owns patents that claim [PSI-7977] as a chemical entity and its metabolites. However, the existence of issued patents does not guarantee our right to practice the patented technology or commercialize the patented product. Third parties may have or obtain rights to patents which they may claim could be used to prevent or attempt to prevent the company from commercializing the patented product candidates …

The acquisition of Pharmasset by Gilead Sciences was finalized after a bidding war in January 2012, and the pharmaceutical company quickly moved to realize the potential of this HCV treatment. Clinical trials yielded more promising data, buoying what had initially been muted stock market expectations.[11] Designated as a 'breakthrough therapy' by the US Food and Drug Administration (FDA), sofosbuvir was fast-tracked by almost a year in an expedited approval process that ended in December 2013 with approval for sofosbuvir to be used as a component of an HCV treatment regimen. Approval from the European Medicines Agency swiftly followed in January 2014.

Yet, despite these successes, the solidity of the architecture of patents that Gilead was building around sofosbuvir was threatened by its molecular predecessors. In its 2012 annual report, Gilead declared that before acquiring Pharmasset it had been made aware that 'Roche asked Pharmasset to consider whether Roche may have contributed to the inventorship' of PSI-7977 in light of its previous collaborative agreement pertaining to the development of PSI-6130. Gilead pointed out that future revenues from the sale could be adversely affected if Roche were to successfully prove that it contributed to the inventorship. In March 2013, Roche initiated an arbitration case regarding its collaboration agreement with Pharmasset, claiming that it had an exclusive license for sofosbuvir because Gilead's new blockbuster was connected to PSI-6130. Roche asserted that in selling products connected to sofosbuvir, Gilead was infringing on the patent to which it had an exclusive licence.[12] Roche

was not the only potential obstacle to claiming full ownership over PSI-7977. Several contract and litigation claims around PSI-6130 had also been initiated by its named inventor, Jeremy Clark. In February 2008, Clark had filed a lawsuit against Pharmasset seeking to void an assignment provision in his employment agreement and claim ownership of another of the US Patents associated with sofosbuvir, according to an SEC file. Two further lawsuits were filed by Clark in September 2009 and June 2010. Although all lawsuits were eventually dismissed, the solidity of the sofosbuvir patents had been questioned.

The institutional differences between the US and European patent laws in a globalized pharmaceutical market also came back to haunt sofosbuvir's current owners. In February 2012, the USPTO declared interference[13] between one of Gilead's primary patents and a patent granted to the other company formed in the shadow of the 1990s HIV patent disputes, Idenix, to determine which party was first to invent the compounds claimed in the subject matter of both parties' patents. The situation was further complicated when the European Patent Office granted Idenix a European patent corresponding to one of Gilead's sofosbuvir patents. Idenix, along with several European universities, filed a lawsuit against Gilead in 2013.

At the cusp of sofosbuvir's global market launch, yet another large pharmaceutical firm, Merck, contacted Gilead in 2013 requesting a payment of royalties relating to the sales of sofosbuvir and the need for Gilead to obtain a license to patents assigned to a Merck subsidiary. Gilead countered this request by seeking a declaratory judgement that Merck's patents were invalid and therefore not infringed upon by Gilead's own patents. The separate lawsuits would soon converge when Merck acquired Idenix for US$3.85 billion in June 2014. By that time, sofosbuvir had just been launched under the brand name of Sovaldi on the US, European and other international markets – at a heretofore unprecedented list price of US$84,000 per treatment (Roy & King, 2016). Despite all the twists and turns in its development and the many disputes to its ownership, it appeared that Gilead had succeeded in creating a valuable asset out of a stock of knowledge that had its roots deep in the frantic search for HIV treatments in the 1980s. Gilead proceeded to earn US $62 billion in combined product sales of its sofosbuvir based medications over a five-year period and saw its stock price shoot up from around US$21 in early 2011 to a high of US$120 in 2015.[14] Yet, sofosbuvir's market launch provided a third window of opportunity to contest sofosbuvir's asset condition – this time round, it would be civil society that would lead the charge, as the drug's patent architecture turned into a political object.

Defending patent monopoly against civil society – 2014 to today

Sofosbuvir's market launch in 2014 as the most expensive pill ever came as a shock, and it triggered extensive political and societal reactions (Chabrol

et al., 2017). When Gilead took the decision to set a US$1,000 per-pill (or $84,000-per-treatment) list price for sofosbuvir, it charged a higher price than had been intended by Pharmasset[15] and one that would allow it to profit far beyond the US$11 billion price tag it had paid to acquire Pharmasset. In fact the drug's list price was so high that it would singlehandedly deal a blow to health insurance systems even in the wealthiest countries. In the United Kingdom for instance, with its 160,000 hepatitis C patients, the NHS had to budget £8 billion for its access to sofosbuvir, threatening its financial equilibrium (Boseley, 2015); the US Medicaid programmes spent US$1 billion in 2014 alone on treating less than 2.4 per cent of hepatis C patients with Sovaldi (US Senate, 2015). As the sofosbuvir patents resulted in access to medicines issues for a broad patient base, they also became political questions. The US Senate Committee on Finance launched an inquiry on the price of sofosbuvir, which found the pricing strategy 'designed to maximize revenue with little concern for access or affordability' (US Senate, 2015). The blatant assetization of pharmaceutical patents for an essential medicine was also quickly seized on by patent activists both in high-income and low-to-middle income countries (HICs and LMICs) who militated against Gilead's pricing strategy and its effects on health systems (Chabrol *et al.*, 2017).

Civil society action against patents can come in three overlapping forms: calls for voluntary licensing, for compulsory licensing, or courtroom patent opposition (Baker, 2021). Legal action against patents by NGOs were common in LMICs, particularly in the area of HIV/AIDS, but exceptional in HICs. The sofosbuvir case was the first in which these three modes of action against a patent monopoly were strategically enacted by activists in HICs. As it became clear that the cost of the drug charged by Gilead would affect the balance of national health insurance systems, activists lobbied their governments to pursue compulsory licenses. TRIPS, the international Trade Agreement on Intellectual Property, allows for exceptions or so-called flexibilities where governments can label drugs as essential and license their production to local companies at a lower cost, paying a royalty to the holder of the patent. However, as our research participants explained, governments from high-income countries rejected demands from activists to utilize these flexibilities for fear that this might single them out negatively with respect to future negotiations with large pharmaceutical firms and within the international trade community:

> Interviewee (A04): When we asked the [French] Ministry of Health [to use compulsory licensing], they answered that it was way too strong as a political action against Gilead and the pharmaceuticals firms in general and that the patent was too solid and that trying to organize against a patent, to ask for compulsory licensing, they would lose on a legal level.
>
> Interviewee (A02): We have been indeed advising governments to look at this option and to use the option because our concern is actually that is it is not used

> enough. There is a tendency to be so reluctant with using it that it creates a kind of stigma around using compulsory licence like you will be an outcast if you use that.

Turning from state-directed to legal action, and aware of sofosbuvir's history, activists thus pivoted to patent oppositions. The patent opposition is a legal challenge aimed at contesting the validity of a patent where it does not fulfil the patentability criteria defined by law, which postulates that a patentable invention must be novel, involve an inventive step, and be capable of industrial application.[16] Between 2015 and 2018, several activist and patient groups tried to redefine the boundaries of Gilead's sofosbuvir patents through two patent oppositions (Nightingale, 2016). These legal procedures primarily attacked the criterion of the novelty of the inventions held by Gilead and described the main sofosbuvir patents as abusive, including the fact that the science behind it was too old to be patented.[17] In February 2015, a consortium of access to medicines NGOs led by *Médecins du Monde* filed a patent opposition on several of the most critical patents behind sofosbuvir at the European Patent Office (EPO). This patent opposition led to the partial revocation by the EPO of one crucial patent behind sofosbuvir in October 2016. In March 2017, the NGOs MSF and MDM led a second opposition against another central compound of the patent architecture behind sofosbuvir at the EPO. This opposition was joined by 30 organizations from 17 European countries. A final EPO decision is still pending at the time of writing, but Gilead Sciences has already reacted to the arguments put forth by this opposition by modifying the patent claims in favour or more restrictive wording.

While these challenges did not manage to break the patent architecture of Gilead's monopoly, they were nonetheless considered a success by activists. As outlined, sofosbuvir's patent architecture was based on three main elements: patents protecting the so-called base compound or active ingredient (such as 3TC and FTC), the prodrug (or marketed compound, PSI-7977), and those protecting intermediate compounds and processes for making the drug. The ownership that Gilead had acquired in the 2000s over this patent architecture gave it strong exclusive rights that needed to be challenged at several levels in order to 'de-assetize' the patents behind sofosbuvir. The first patent opposition was targeted against the prodrug patents, whereas the second patent opposition was targeted at the base compounds. Despite the partial success of the first patent opposition, the revocation was not enough to break Gilead's monopoly over the drug and allow for the production of generic sofosbuvir by other companies. Nonetheless, they represented a milestone in activist challenges to patents in HICs as the first highly publicized instance in which a coalition of activist groups set up a legal challenge in HICs against a patent using the patent opposition procedure. It also signalled a discursive and moral victory over Gilead's pricing regime, as this research participant explains:

> Q: So was the patent opposition seen as a success, even though strictly technically speaking it wasn't really?

> Interviewee (A04): The first patent opposition was considered a success because at the EPO in the first proceedings, the patent was maintained in the amended form, but it also said that the patent was not strong enough and had to be amended so that it could still be considered as valuable or valid. What happened is that just right after the EPO decision there has been a press race to interpret the EPO decision and Médecins du Monde was very quick to say that they won because the patent had to be transformed, even though it couldn't allow States to produce generics, it was clear [that it was an] example of patent abuse … The EPO considered that the [patent] application didn't describe sofosbuvir efficiently and clearly enough and it was really weakened.

Thus, beyond adding an important tool to the access to medicines toolkit and skillset in HICs, the true victory lay in the opposition's symbolic power, as patents had become political objects at the boundary of patent holders' property rights and the rights of society to benefit from pharmaceutical inventions, thereby directly questioning the drug's valuation regime.

It is noteworthy that although civil society understands patents as political objects that should be examined for the collective benefit they provide, political and commercial patent contestations need not be separate from each other. In the course of the second patent opposition against Gilead's architecture of patents, for instance, EPO documents show that generic companies joined the procedure launched by political activists. Activists used the same patentability criteria as Gilead's pharmaceutical competitors to prove the abusive dimension of the sofosbuvir patents and contest the underlying monopoly over the molecules' production. Furthermore, contrary to the push for compulsory licensing, the two patent oppositions did not make appeal to the drug's ethical and moral entanglements but referred to potential scientific weaknesses in its patentability – chiefly its lack of novelty – by highlighting its traces in extant HIV research. The echoes of the HIV/AIDS access to medicines struggles in LMICs in the early 2000s were clearly audible both in the form that civil society contestations around sofosbuvir took and in the legal arguments used to fight its patent-as-asset condition:

> Interviewee (A06): Yeah, [the first opposition] is showing that there is an issue, that they are abusive and that it can be done differently. Patents are supposed to reward an innovation and at the moment everybody is saying, what's an innovation and then you have a discussion at very high level meetings, at the European level setting, what is innovation, and we know that they are trying to develop a new framework to direct future monopolies, and then I think just showing that there are abuses and making sure that people know that they are abusive; it's already … it is part of our role.

In summary, the gaps left open in the circuitous route of enclosure in the history of sofosbuvir can be seized not only by rival companies wishing to gain a piece of the asset pie, but they can also help other actors – for instance

states or civil society – contest the asset condition of the biopharmaceutical enterprise. Since the launch of sofosbuvir in 2014 and the public outrage its inflated price point caused, legal contestations against the patent-as-asset have become an important extension of the toolkit wielded by access to medicines movements globally. And they are becoming an increasingly important part of civic resistance against biopharmaceutical financialization – not least in the current global debates around COVID-19 technologies and vaccination know-how.

Concluding discussion: Deconstructing a patent-as-asset

This paper traced the journey through which scientific knowledge dispersed across many organizations involved in HIV and HCV research was accumulated into an asset bundle – though a fiercely contested one, as illustrated. Our retelling of this story was guided by a central question in the context of assetization research: How are pharmaceutical entities turned into and maintained as assets? Tracing the scientific developments and legal patent disputes around sofosbuvir demonstrates that the chemical compound and its patented alter ego leave multiple traces in multiple places. Firms such a Pharmasset – with a name that leaves no doubt over the business model pursued – are conceived as 'financial artefacts' (Mirowski, 2012, p. 296) or assets themselves, designed to be turned into acquisition targets by larger pharmaceutical manufacturers. Yet, in order for these companies to create their own 'asset condition', work has to be invested in a double-move of isolating and assembling numerous entities: patents foremost, but also scientific expertise and methods, personnel, chemical compounds, results from clinical trials, and the viruses themselves. As these entities move from one context to the next, they leave traces in the world from whence they came: sofosbuvir, for instance, has deep ontological shadows in early HIV and HCV research, public universities, various biopharma start-ups and multinationals, bodies of clinical trial participants and patients, global patent offices, national healthcare budgets, and several courts of law. Barry (2005) speaks of pharmaceutical chemicals as 'informed' by their contexts, associations and histories. Our case provided a brief window into just how tall an order is to tie up all of these loose 'informational' ends and aggregate these entities sufficiently to claim a singular patent-as-asset. We also showed how vulnerable to contestation this bundling is, including firms claiming an ownership stake from other private entities over what transpires to become a valuable pharmaceutical asset, politicians seeking to contain healthcare costs, and access to medicines activists fighting the abusive nature of patenting claims.

Recent research has highlighted the contested dimension of assetization in other areas, including the controversies surrounding the transformation of high-carbon projects (Langley *et al.*, 2021), high-speed railway infrastructures (Buier, 2020), or natural resources (Levidow, 2020) into financial assets. This research underlines the various clashes between moral, social and market

qualifications that assetization processes entail; it also highlights the various material resistances companies encounter in their assetization efforts. Extrapolating from our case and this extant research, we suggest there is no such thing as an asset unless one manages to narrow the 'investor's gaze' to a highly limited set of metrological, spatial and temporal parameters. Metrologically, the pharmaceutical patent becomes an asset through court decisions demarcating clear boundaries to the pharmaceutical's chemical alter egos and through upholding rentiership valuation regimes. Yet, as we demonstrated, these metrological boundaries are forever questioned – legally, scientifically and morally. From a spatial perspective, assetization relies on a demarcation of legal and economic jurisdictions – for instance in the different interpretations of US and European 'first to file' patent law, or in the price arbitraging between different national health systems (Christophers, 2014; Quet, 2018). Yet again, despite global patent governance rules, these boundaries are blurred where differences in national patent regimes clash, when national governments start sharing pricing data, or when NGOs in HICs learn from their colleagues in LMICs how to fight abusive patents. Temporally, assets are by their very nature forward-looking, as the idea of future earnings sits at the very core of rent-seeking. Yet, casting this gaze into the past, as the NGOs' patent oppositions did, or too far forward into the future, and the asset condition is jeopardized – in sofosbuvir's case, Gilead was eventually penalized by stock market investors for having sold a 'cure' rather than a treatment for chronic illness, thus likely running out of patients at some point in the future (Roy, 2020).

Thus, patent contestations work by redrawing the connections that the asset bundle has so carefully been disentangled from. The crucial moment we have captured in this paper – the market launch of a '$1,000 per day pill' – has been decisive for access to medicines movements because they were able to not only draw material connections between the chemical compound under dispute and its many predecessors, but in doing so they also succeeded in raising questions over its biofinancialized valuation regime. While these contestations may not have fundamentally shaken the business model prevalent in the pharmaceutical industry and the increasingly exorbitant prices through which they become manifest to the public, they have left traces themselves. Similar to the geopolitical shifts arising from the commodification movement described by Polanyi (1945), which began with ontological resistance and local contestations, the further-reaching consequences of the political backlash around sofosbuvir and other patents-as-assets have begun to translate into broader institutional shifts. These include the so-called Transparency Resolution on pharmaceutical pricing passed in May 2019 at the World Health Assembly, thanks to an alliance of LMICs and HICs including Italy, Spain, Japan and Norway (World Health Assembly, 2019). In Europe, smaller states have formed two transnational alliances, Beneluxa and Valletta, to share heretofore opaque pricing information (Natsis, 2017). And models of knowledge 'sharing' have become at least a topic of conversation in a notoriously secretive industry (Lezaun, 2018).

In fact, while the global COVID-19 pandemic tragically highlights the continuing global inequalities in access to medicines, the ensuing vaccine equity debate and calls for COVID-19 medicines and vaccines to be 'global public goods' (Love, 2020) demonstrate the shifts in the political economy of pharmaceuticals that recent patent disputes have helped facilitate. By arguably giving civil society a greater voice and a clearer institutional backing, questioning the pharmaceutical 'asset condition' during the pandemic crisis was an issue that gained a broad societal platform. For instance, the (usually undisclosed) amounts of public funding of the different COVID-19 vaccine candidates were made public early on in the pandemic (Cornish, 2020). This disclosure bolstered calls by civil society organizations for a 'People's Vaccine' – a vaccine without any patent strings attached.[18] A coalition of the WHO and donor foundations supported a proposal for a voluntary sharing mechanism modelled on the Geneva Medicines Patent Pool only weeks after the pandemic reached its early peaks in April 2020 (Geiger & McMahon, 2021). Finally, in what may be the strongest signal yet that the political economy of pharmaceutical patenting may be shifting, after initial reticence many HICs including the United States joined South Africa and India in support of a global temporary waiver on intellectual property rights for Covid-19 vaccines and treatments (Thambisetty *et al.*, 2021). Despite the horrific loss of life, perhaps now is the time when the 'techno-scientific singularity' (Kang, 2015, p. 34) that is the pharmaceutical patent will be asked to account for its multiple ontologies – and thereby become somewhat more resistant to its assetization.

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Notes

1 As reported by Berkrot (2011).
2 The recent transformations of the biopharmaceutical sector are described by Robbins-Roth (2000) and Pisano (2006), and the shift between the historical chemical pharmaceutical industry and the contemporary biopharmaceutical sector is detailed by Sunder Rajan (2006).
3 According to the EPO a patent family is a collection of patent applications covering the same or similar technical content, which are related to each other through priority claims.
4 Within the EPO opposition proceedings to any granted European patent may be filed by any member of the public except for the proprietor themselves. There are three possible outcomes to patent oppositions; (i) the opposition is rejected and the patent is maintained as granted; (ii) the patent is maintained in an amended form, and (iii) the patent is revoked.
5 Globally about 71 million people are chronically infected with HCV (WHO, 2019).
6 According to this rule, the right to grant a patent lies with the first person to file a patent application for the corresponding invention, regardless of the date of the actual invention.
7 Prior to 2013, US patent law operated a first-to-invent patent system, in which the date of invention would surpass the date of filing a patent application as a determining factor in the award of patent rights.
8 Nucleosides are basic building blocks of nucleic acids.
9 A prodrug works by masking the components of a parent drug that might inhibit the drugs' ability to work in the body.
10 See SEC file 333-173006.
11 From a base price of US$20 in mid-2011, Gilead's share price had doubled by January 2013 and more than quadrupled by the time of sofosbuvir's market launch.
12 In August 2014, the arbitration panel ruled in favour of Gilead Sciences following Roche's failure to establish its claims to sofosbuvir.
13 Declaration of 'interference' in the US patent system is an administrative procedure designed to determine who was the first to invent the subject matter claimed in different patents.
14 Product sales taken from Gilead full year financial results 2014–2019.
15 As Roy and King (2016) explain, Pharmasset had initially planned for a price between $36,000 and $72,000 per therapy.
16 See the European Patent Office's legal guidelines, part G, chapter VI, article 7, 1. Retrieve from https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vi_7_1.htm
17 Notice of Opposition to a European Patent (EP2203462) recorded on 10 February 2015 and notice of Opposition to a European Patent (EP2604620) recorded on 27 March 2017.
18 See the People's Vaccine (https://peoplesvaccine.org/).

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