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ORIGINAL ARTICLE

Value regimes and pricing in the pharmaceutical industry: financial capital inflation (hepatitis C) versus innovation and production capital savings for malaria medicines

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Abstract The idea of this paper is to draw a parallel between two diametrically opposed political economies of medicine that coexist today. The first is embodied in the invention, appropriation, and distribution of antivirals for hepatitis C, particularly sofosbuvir, which was commercialized at an initial price of $85,000 in the United States, €56,000 in France, and $8000 in Brazil. These prices destabilized payers in both the North and the South. The second economy encompasses the invention, industrialization and distribution of new therapeutic combinations for malaria that were commercialized by Sanofi from 2007 onwards at a price of $1 per treatment for public markets. This price was set by a contract negotiated with Médecins sans Frontières. In this paper, I examine the pricing of these 2 classes of drugs, and I argue that the prices synthesize these political economies: they summarize the policy of appropriation of these molecules, aimed at their monopolization or a model of common good; they are referred to economic value regimes designed to optimize the profitability of advanced capital or to increase the accessibility of drugs for public payers and patients; and they are justified or contested by moral economies.

Keywords Pricing · Value regimes · Financial capital · Humanitarian values

This paper draws a parallel between two diametrically opposed political economies of medicine that currently coexist.

The first one considered here is exemplified by the invention and use of direct-acting antivirals (DAAs) for hepatitis C, which present high therapeutic efficacy, and

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were put on the market in 2013 and 2014 by Gilead Sciences at an initial price of $85,000 in the United States, €56,000 in France, and $8000 in Brazil. The magnitude of these prices sparked strong controversy in countries both in the North and in the South, and the US Senate launched an investigation, published in December 2015, into Gilead Science's pricing of Sovaldi. In France, the national health fund stressed the shock wave that health systems had to face: "The arrival of new hepatitis C treatments has set off a shock wave in all health systems. For the first time, the question of access to innovative medicines has arisen, not for developing or emergent countries, but for the wealthiest ones" (June 2015). Around the same time, Brazilian HIV/AIDS patient organizations initiated opposition proceedings with the INPI to have Gilead's patents invalidated, and appealed to the Ministry of Health to get the production of a generic version of the molecule underway.

The second economy encompasses the invention, industrialization, and distribution of new therapeutic combinations for malaria that were put on the market by Sanofi in 2007, at a price of $1 per treatment for adults and $0.5 for children. The 'no loss, no gain' price formulation was contractually established between the owner of the innovation, the DNDi foundation (an offshoot of MSF), and the French multinational Sanofi, in charge of mass producing and distributing the medicine on the global donor market (Global Fund). While the price of sofosbuvir revived the global controversy around monopoly prices and profits in the pharmaceutical industry that was sparked in the early 2000s by the HIV/AIDS social movements, the pricing agreement on the artesunate and amodiaquine combination was mutually publicized by the DNDi and Sanofi in the *Malaria Journal* and received an award from a union of major global corporations in 2014: "Sanofi and DNDi, an independent not-for-profit foundation, receive the Corporate Social Responsibility Excellence award from the Association of Strategic Alliance Professionals (ASAP), in recognition of the 'profound, measurable, and positive social impact' that this decade-long public–private partnership has had in the fight against malaria".

The polarization of these two pharmaceutical economies appears to point to a twofold trend: the first is the financialization of the biotechnology and pharmaceuticals economy, analysed by many studies in the economics of finance (Malki 1997), of innovation (Cockburn 2003), and of institutions (Coriat and Orsi 2002), and in STS (Sundar Rajan 2006; Mirowski 2011; Birch and Tyfield 2012; Birch 2017). The extension of intellectual property rights to basic research tools, well upstream of any product, the new financial market regulations introduced in 1984, enabling companies without a net profit to be listed on the Nasdaq, and the growth of venture capital fuelled by pension funds, allowed for the emergence of a new capitalist economy of science, essentially built on its intellectual assets. The works of Malki (op.cit), Birch and Tyfield (op.cit), Kang (2019) have shown the transformation of intellectual property rights into assets that support the accumulation of financial capital and the expansion of an asset market. As these R&D companies provide pharmaceutical firms with research tools, or even products that they have developed up to the clinical stage, the question arises as to the impact of this economy on the costs of pharmaceutical innovation (Cockburn, op.cit.). The second trend is that of the new public/private partnership arrangements set up to develop affordable treatments for neglected diseases (Cradock 2017; Lezaun and Montgomery 2014; Lezaun 2018)

that have largely been deserted by industrial investment. These predominantly public and philanthropic pools of capital, in which private industry generally contributes one-fifth of the funds, practice no-profit pricing on humanitarian grounds (Andrew Lakoff (2010) calls this a "humanitarian biomedicine" regime). Finally, a third regime has emerged to challenge the pricing of the proprietary and financial regime: the generics economy, established in both the South (Cassier and Correa 2003; Chaudhuri 2005) and the North (Greene 2014; Nouguez 2017). This third regime often joins forces with the humanitarian regime: the DNDi cooperates with laboratories in Brazil, Egypt, and Argentina, either to develop new medicines for neglected diseases or to circumvent Gilead's monopoly on antiviral medication for hepatitis.

The pricing (Callon 2017)[1] of two categories of medicines discussed in this paper, for hepatitis C and for malaria, has been the subject of fierce debate or, on the contrary, consensual negotiations between inventors, industrial actors, payers, patients, governments, and parliaments. I analyse these price formulations to shed light on the highly polarized, and in these cases conflicting, "capital-value" regimes (Marx, Volume 3 of *Capital*)[2] at play in contemporary pharmaceutical capitalism. Moral values are put forward, either to justify and perpetuate the proprietary model and high profits, by supporting philanthropic initiatives (MacGoey 2012), or to offer an alternative based on the public good and the commons, so as to broaden access to treatment and optimize payers' purchasing power. While the biotechnological and pharmaceutical configuration surrounding the hepatitis C medicine has made intense use of patent rights, both to mobilize capital and to capture innovation rents, the one surrounding the malaria medicine deliberately opted for a common goods regime without patents or exclusive licenses. Gilead negotiated with the public and private health insurance funds in North America and Europe to extract maximum profit from sofosbuvir, whereas Sanofi sold its malaria drug on the Global Fund market.

In this paper, I draw on several studies on these medicines' price formulations and regimes of economic value. Although documents on price formation are classified—something currently challenged by NGOs, certain States, and the World Health Assembly's call for "price transparency"[3]—, tracking down the price formulations for sofosbuvir was facilitated by the intensity of the controversy that erupted in 2014 and 2015. The report produced by the US Senate, "The Price of Sovaldi", is a rare document that presents and comments on a range of instruments used by Gilead Science to set its price (Appendix E of the report includes 1500 pages of documents disclosed by the firm). I also recorded the many criticisms of this price by scientific and medical journals (*Nature*, the *JAMA*, etc.), humanitarian medical organizations (Pierre Chirac of MSF and the journal *Prescrire*), critical chemists advocating for

[1] Callon argues that "price formulation" combines operations of classification, ranking and product formatting, and price calculation formulae.

[2] "The capital value advanced", in Chapter 1, "Cost Price and profit", p 131, Volume 3 of Capital, "The Process of Capitalist Production as a Whole" Penguin.

[3] Improving the transparency of markets for medicines, vaccines, and other health products. Draft resolution proposed by Andorra, Brazil, Egypt, Eswatini, Greece, India, Italy, Kenya, Luxembourg, Malaysia, Malta, Portugal, Russian Federation, Serbia, Slovenia, South Africa, Spain, Sri Lanka, Uganda, May 2019.

the production of low-cost generic versions for countries of the South, and clinicians in France. I furthermore draw on research that I carried out with Marilena Correa of the Rio de Janeiro State University, on the Brazilian consortium which in 2015 challenged Gilead's patents and began copying sofosbuvir (Cassier and Correa 2019).

As for the pricing of malaria medicines, it has been publicized by multinational companies' eagerness to display their humanitarian commitment, and by global health organizations (WHO) and philanthropic organizations (DNDi) that governed the R&D processes and negotiated prices for the public pharmaceutical sector in developing countries. I draw on materials collected during two periods of research in 2008–2009 and 2016–2019, with MSF, the DNDi, the University of Bordeaux and the French start-up Ellipse Pharmaceuticals, which developed the artesunate–amodiaquine combination, and with Sanofi, both in its malaria department in Paris and at its plant in Morocco, which I visited in 2016. In the WHO archives, I also found a half a dozen R&D and pricing agreements on antimalarial medicines, between the WHO and industrial firms from the period 1988–2006.

Price formulations and economic value

I posit that 'price formulations'—to use the concept that Callon proposed in his book on "the grip of markets"—and the criticisms or alternative formulations in this respect shed light on the different regimes of economic value adopted or invented for the medicines studied, and on the conflicts around switching from one regime to another (from the proprietary regime to a generic medicine regime, for example). The price matrices developed by financial analysts to correlate the price of molecules with the price of shares on the stock market ("The Price of Sovaldi" 2015, p. 19) attest to how entangled sofosbuvir is in the financial capitalism of science and pharmaceuticals in the United States. The price agreements between the WHO and industry actors for the malaria medicines are hard evidence of the governance of innovations by global health organizations, for an economy with limited and controlled industrial profits. The critical chemists who formulated the price of the generic version of sofosbuvir advocated for an authorized copying economy, with the suspension of patents and a compulsory license. Debates on price formulations, as well as price transparency, have contributed to the invention of a health and industrial democracy, which challenges the "Pharmocracy" analysed by Rajan (2017).

I align with Callon, who posits that price formulations are a new "site of struggle" (p. 207). However, I do not think this holds as regard the relationship between price and value: focussing on the "power of formulas", Callon argues that price contributes to the constitution of value (p. 11), and that the existence of an economic value beyond the formulation of the price cannot be assumed. He even claims that Marx, in Volume 3 of *Capital*, cleverly releases himself from referring to value, speaking only of "production prices" (p. 332). This economic sociology, which prioritizes valuation processes over value, and capital as an "operation" over capital as a "thing in itself" that someone owns (Muniesa et al. 2017), tends to overlook the objectivity of capital, which the producer, the payer, the patient, the clinician, the Ministry of Health, and so on is faced with. Capital feeds on a particular type of appropriation

of value, controlled by those who hold it, and transfers of value between public and social payers and the firm that owns a molecule have a certain direction and scale (Roy 2017).

I posit that the price formulations as well as the disputes and alternative proposals considered in this paper reveal the interplay and interactions between price formulas and economic value. In their recent book *Enrichissement, une critique de la marchandise* (2017) (*Enrichment, a Critique of Commodities* (2020), Boltanski and Esquerre make the case that "the reference to value plays a central economic role as it allows payers to criticize prices" (p. 143, our translation from the original French version), even though it is "fictional in nature".[4] It is worth noting that the clinicians who in 2013 called into question the inflation of new cancer treatments in the journal *Blood*, themselves referred to the critical significance of value: "The doctrine of *Justum Pretium,* or just price, refers to the 'fair value' of commodities. In deciding the relationship between price and worth (or value), it advocates that, by moral necessity, price must reflect worth". But if we look further: the US Senate Finance Committee did in fact address the metrics of the value of capital when it wrote to Gilead's CEO, asking him about the discrepancy between prices and the costs of R&D and of production: "That price appears to be higher than expected given the costs of development and production, and the steep discounts offered in other countries" ("The Price of Sovaldi").

It seems to me that the price formulations discussed for hepatitis C antivirals or malaria medicines constantly refer to regimes of economic value, insofar as they assess the value of the various forms of capital invested to invent, develop, appropriate, market, or distribute those medicines. Price disputes highlight the disproportion between the different types of capital invested in innovation, production, market capitalization, the acquisition of inventions, and shareholder compensation. For the malaria medicines under the no-profit value regime, the price formulas were adjusted to the production costs, in some cases increased by a reduced margin controlled by the parties to the agreement.

I found both a variety of options and price constructions, and a range of capital-value regimes in operation. Value regimes built for the high-profit markets of hepatitis or cancer medicines utilize pools of industrial and financial capital that seek the excess profits from the sale of assets and goods protected by intellectual property rights. These excess profits are generated through value transfers and capture from public and social payers. The value regimes set up by the WHO or MSF to develop and disseminate medicines for neglected diseases and populations, pool public or philanthropic funds which do not operate on a capital-plus-profit basis, as well as devalued industrial capital from firms that do not claim profits either. In return they seek, in particular, moral redemption and a long-term market strategy in emerging countries.

[4] In order to have a reference scale, these authors invent a "meta-price", which is "an estimate of the value translated into numerical terms without being the result of an exchange". Some similarities could be found between these "meta-prices" and Marx's "market value" regulating commodity prices.

These highly differentiated 'capital-value' regimes, which support and justify very contrasting price formulations and scales, are inspired by Marx's *Capital*, which describes highly asymmetrical capital profitability indexes, sometimes in the same branch of activity. While some devalued capital does not earn the average profit, other capital is likely to reap extra profit from the exploitation of a natural or artificial monopoly or from surplus productivity (Volume 3, Chapter 10). The diversity of price options also appears in Volume 3 of *Capital*, where Marx describes "intermediate prices", which are set above or below the value. The following limit applies: price formulas below the production cost and especially the value, with a negative profit, can only destroy the capital.

The economic worth, as envisaged by Marx in the context of capitalism, results from a social relationship, based on the appropriation of the value created by total labour. This encompasses labour that is both living and dead, supported by variable and constant capital, and incorporated in turn into the commodity capital, the fixed capital of the private laboratory and the factory, and the stock exchange securities which claim their own share of the value created, beyond any fetishism of the commodity object or of a capitalistic substance. Marx thus described "the capital values" in Volume 3 (p. 362) as the different forms of value that constitute capital.

These capital-value regimes are just as constructed as the price formulations described by Michel Callon, and contribute to social and political relationships. The challenges to sofosbuvir's financialized value regime are likely to result in the implementation of a value regime based on local industrial capital to copy and multiply generic versions, in Egypt, Argentina, and Brazil, following the steps taken by generic manufacturers, local Ministries of Health and patient organizations to suspend or invalidate Gilead Science's patents. Here again, I adopt a different perspective to that of Michel Callon, who states that "the crux of the matter in relations of domination is not the appropriation of capital, but the calculation devices" (p. 206). Weakening the dominance of the patentee's monopoly power precisely entails undoing their property of the molecule, cancelling or reducing the flow of value they extract from it, and mobilizing new capital capable of reproducing and multiplying copies thanks to the intervention of local producers and to patients' demands, as in Brazil since 2014 to produce a generic sofosbuvir. If capital assumes the "capital account" (Weber), it consists of a relationship of appropriation of the value produced (Marx).

Financial capital inflation and the right to health: critics and conflicts over the price and value of sofosbuvir

I pointed out above that the introduction of sofosbuvir on the market generated a proliferation of studies, discussions, and contestations surrounding the pricing policy of the proprietary firm and, more broadly, the influence of the financialization of biopharmaceutical capital on the prices of therapeutic innovations. In this article, I examine the different pricing instruments used and discussed, to shed light on the capital-value regimes criticized or proposed.

The report published by the US Senate in December 2015[5] provides a detailed description of the process of Sofosbuvir's price formation, based on documents that Gilead agreed to disclose. The rapporteurs indicated that they were unable to obtain detailed information on Gilead's costs in getting the medicine to the market after buying out Pharmasset, the firm that had carried out the first scientific and clinical developments (p. 3). The senators revealed four types of instrument used by Gilead (Cassier 2016).

The first was a matrix devised by a financial analyst at Pharmasset in November 2011, two days before the firm was bought out by Gilead. The matrix combines Sovaldi price hypotheses with hypothetical prices of the firm's shares. The share price that the owners of Pharmasset were to agree to was combined with a price of $36,000 for this medicine. That price of the medicine was associated with the share price set for the buyout of Pharmasset. The actual transaction took place on 20 November, at $137 a share, with an acquisition of $11.2bn. This matrix linked the acquisition value of Sovaldi's assets on the Nasdaq to the pricing of the medicine on the market; in other words, it linked asset capitalism and commodity capitalism.[6] This puts into perspective the hypothesis of a substitution of commodity capitalism by asset capitalism (Birch and Tyfield 2012) and shows their interactions. The Sovaldi price hypothesis guarantees the price of the shares and, in return, the cost of the capital acquired must necessarily be recovered with the future price of the molecule. The US senators noted moreover that Pharmasset's price hypothesis in November 2011, $36,000, was way below that which was finally set by Gilead in 2013: $85,000. The market price ultimately set by Gilead covered the capital cost of the Pharmasset acquisition and the high profits that would allow for growing both the capitalization of Gilead (estimated at $142bn in 2014) and the firm's assets, valued at $34bn in the balance sheet. The optimization of net earnings per share and the net profit on the total asset led to a very high market price being set.[7] Roy (2017) has precisely documented Gilead's value extraction strategy through mass share buybacks, at the expense of the firm's new R&D programmes.

The US Senate Finance Committee also compiled a table of production costs for sofosbuvir, which showed their share to be very small, in the range of 0.9 to 3.9% of the price of the medicine. Putting these first two instruments side by side, the Senate shed light on the disconnect between the cost of productive capital and the cost of financial capital. It was clearly the latter that governed Sovaldi's price formation.

The third tool put forward to determine the medicine's price was based on cost/therapeutic benefit evaluations, compared to existing molecules and treatments for the same pathology. The use values of the various medicines or treatments were compared in terms of price and of the medical services provided. Gilead based its

[5] "The price of Sovaldi and its impact on the US Healthcare system", US Senate, Committee on Finance, 144 pages.

[6] Mathieu Quet (2018) clearly shows the deployment of the global sofosbuvir market with his notion of "logistical capitalism".

[7] Gilead's net margin for 2014, presented by Barclays in 2015, was 50% higher and kept rising in 2015. The return on equity was 76% in 2014, the year that Sofosbuvir was put on the market, compared to only 26% in the preceding years.

price, which consequently structured the market, on claims of a "major innovation" in terms of therapeutic efficacy, with vastly improved healing rates and shorter treatment times than those of available molecules.[8] "Company officials surmised that its medicine had a 'value premium' because of increased efficacy and tolerability, shorter treatment duration, and its potential to ultimately be part of an all-oral regimen (as it ultimately would be in combination with ledipasvir in Harvoni)". Gilead's price committee referred to the costs of treating hepatitis C with two antiviral molecules launched two years earlier by Merck (telaprevir) and by Vertex (boceprevir), used with ribavirin and interferon (molecules introduced in the late 1990s). This pricing model depended on the prices of preceding and competing molecules. Earlier prices and those of comparable products were regarded as "black boxes", and no information was provided to explain or regulate them. A letter to the editor of the *JAMA* noted: "However, overinflated prices of the alternative drugs are likely to make the cost-effectiveness of sofosbuvir appear more favourable" (Letters to the editor, *JAMA*, November 26, 2014 Volume 312, Number 20, p. 2128).[9]

The firm used a fourth instrument: a strategic analysis table, to assess the reactions to the various price hypotheses by the organizations that paid for healthcare, as well as those of doctors, patients, and activists (AIDS Health Foundation or Fair Pricing Coalition).[10] The payers' reluctance and the restrictions on access that they were likely to apply were considered to be possible from $60,000 and highly probable from $95,000, whereas doctors might delay the treatment for certain groups of patients or oppose the price from $60,000 and were very likely to do so from $95,000. Patients' and activists' negative reactions and their impact on public opinion were considered to be likely from $60,000 and very likely from $80,000.[11] Gilead had commissioned consultants to carry out a survey of 90 public- and private-sector payers, in which the clinical data of the new medicine were compared to existing treatments. The survey suggested that setting the price between $80,000 and $90,000 was 'acceptable' and did not limit access: "most payers are willing to accept at least $85 K for GT-1 before considering additional access restrictions" (p. 41). The firm calculated that, despite their budgetary restrictions, payers would prefer a

[8] An article published in the *JAMA* on 13 August 2014 defended the "value-driven" approach, which it contrasted with the "return on investment" approach to justify the high price of Sovaldi: "For instance, according to the average wholesale price from MediSpan, the cost of a 12-week course of sofosbuvir plus pegylated interferon and ribavirin is $116,910.72. This price is expensive, but the cost of a 24-week course of the first-generation protease inhibitor telaprevir plus pegylated interferon and ribavirin is $111,606.48, and the 48-week course that many patients need is $143,827.92" (T. Brennan, W. Schrank, "New Expensive Treatments for Hepatitis C infection", *JAMA*, vol 312, no. 6, pp. 593–594).

[9] Hence the limits of medicine price-setting committees' regulatory action, like that of the Comité Economique des Produits de Santé (health products economic council) in France. These committees focus on the therapeutic value of treatment, without opening the black box of the capitalistic value of therapeutic innovations, seen as taboo: "Faut-il changer le modèle financier de la recherche pharmaceutique?" (E. Fagon, vice-president of the CEPS, September 2014).

[10] "Aside from payer access and physician demand, there are a number of softer issues that could affect pricing decisions", Gilead document reproduced in the Senate report, page 30.

[11] Gilead noted that even at $50,000, activists would protest: "despite pricing at this level, activists are still likely to voice dissatisfaction with the strategy" (p. 47).

medicine that had a noteworthy therapeutic advantage.[12] In view of this preference, it saw an opportunity to set a high price and to capture the cost savings that payers would gain from the shorter treatment period afforded by Sovaldi:

> The new sofosbuvir regimen would only require 12 weeks—a potential savings of more than $27,000 at whole-sale costs. Instead of passing the potential savings onto payers, the consulting firm suggested an approach in which the savings would be added to sofosbuvir's topline revenue … Gilead was aware it was in a position to create clear savings for payers, but chose to pursue a 'regimen neutral' price justified by 'cost-per-cure' calculations that resulted in greater revenue per treatment than previous DAAs (p. 42).

The Senate could but conclude that the firm was clearly oriented towards the maximization of its financial returns: "it was always Gilead's plan to max out revenue, and […] accessibility and affordability were pretty much an afterthought".

Critics of Gilead's pricing policy pointed to the asymmetries between the different components of sofosbuvir's capital value, measuring R&D and industrial production costs in relation to financial capital inflation.[13] They cast doubt about the pricing instruments available to regulators and payers: while industrial actors highlighted the calculations of therapeutic value, which enabled them to make the capital value of the product invisible, clinicians and patient organizations put forward assessments of the value of the innovation and production capital to justify price reductions.

Faced with the new barriers to low- and medium-income populations' access to the medicines that was emerging, a collective of chemists in the UK and the US decided to go to war against Sovaldi prices by drawing up hypotheses on the production costs of the generic medicines that could cover the needs of these specific markets. These chemists proposed that the generic medicine policy followed since the 2000s to deal with the HIV/AIDS epidemic be copied, especially since the chemical structures of antivirals to treat hepatitis were similar to those of antiretrovirals. Learning costs would thus be reduced for generic manufacturers. Some of these chemists, for example Joseph Fortunak, had previously assisted chemists in Brazilian laboratories in duplicating certain ARVs, such as tenofovir, also active against hepatitis B, and in validating their production lines. This technical–economic work determined the production value of sofosbuvir, without integrating either the value of R&D work—since the aim was to produce generics that duplicated the invention—or the innovation rents derived from patents—since the idea was to cancel or suspend industrial property rights by means of compulsory licences. These production prices, which covered the entire new therapeutic class of direct-action antivirals for hepatitis C and B, were calculated for a production scale of at least 1 million

[12] A presentation in July 2013 to Gilead's Pricing Committee nevertheless "predicted that 24% of the payers it had surveyed would institute access restrictions of some sort for genotype 1 patients if Sovaldi were priced at $75,000, and that 47% would institute restrictions at $90,000" (p. 43).

[13] Pierre Chirac of MSF and *Prescrire*: "Gilead could have acquired Pharmasset for $300,000 in 2004. Instead, it acquired it for $11 billion" (September 2014).

annual treatments, which implied an increase in international funding to acquire the molecules. The production costs that these chemists managed to achieve were extremely low compared to the prices of the proprietary molecules[14]: "large-scale manufacture of 2 or 3 drug combinations of HCV DAAs is feasible, with minimum target prices of $100–$250 per 12-week treatment course. These low prices could make widespread access to HCV treatment in low- and middle-income countries a realistic goal".[15] This study on the production prices of antivirals for hepatitis, published shortly after Sovaldi was put on the market, served as an argument for all activists in the South and the North who were calling for a drastic reduction of the price of these molecules through changes to intellectual property rights, along with the production of generic medicines.

In Europe, MDM and then MSF filed an opposition at the EPO for the first time, requesting the invalidation of Gilead's patents. In parallel, nine generic producers also called for the Sovaldi patent's cancellation, on the grounds that it presented nothing new, and claimed that they were ready to produce generics. The EPO ultimately upheld the patents and the production of generics could not be launched.

In Brazil, several oppositions were filed by patient organizations, generic manufacturers, and the federal laboratory Farmanguinhos. From 2014, a consortium of three private companies began copying sofosbuvir. Brazil found itself in an original position regarding the production of Sovaldi, as one of its pharmaceutical firms had been involved in the Pharmasset innovation network at the turn of the 2000s. The founder of this Brazilian chemicals and pharmaceuticals firm had even sat on the Pharmasset Board in the late 1990s and had entered into a strategic partnership with the US firm. This Brazilian firm, the first to copy AZT in 1992 in Brazil, had all the technological knowledge and industrial capacities to produce sofosbuvir and that entire new therapeutic class in Brazil. The Brazilian INPI decided to invalidate the patent for a while, before reaffirming its validity. During this brief window of time, from July 2018 to January 2019, the Ministry of Health was able to purchase a few batches of generic sofosbuvir and lower the price significantly ($714 for the 12-week generic treatment versus $2,898 with Gilead). Faced with competition from generics, Gilead lowered its price to $1,344. As of 15 January 2019, freed of any generic competition, it increased its price by 1421% (to $19,098 per treatment).

The price formation of sofosbuvir reflects the emergence of a new biopharmaceutical value regime from the 1980s. The levels of sofosbuvir prices were directly related to the capital advanced and invested in the invention, appropriation, production, and commercialization of this medicine, by the two firms that had successfully developed it: Pharmasset and Gilead. This capitalistic story was at the same time about the unfolding of the new structure of the post-1980s and 1990s pharmaceutical

[14] These valuations are relatively close to, albeit lower than, the production costs calculated by Pharmasset and Gilead for Sovaldi: "The presentation shows that manufacturing costs for Pharmasset would be de minimis compared to the revenue each course of therapy would generate—ranging from 0.9% for a $50,000 course to 1.5% for a $30,000 course", p. 19, US Senate report.

[15] "Minimum Costs for Producing Hepatitis C Direct-Acting Antivirals for Use in Large-Scale Treatment Access Programs in Developing Countries", Andrew Hill, Saye Khoo, Joe Fortunak, Bryony Simmons, and Nathan Ford, CID, 2014, 58, pp. 928–936.

economy, with the disintegration between, on the one hand R&D firms fed by venture capital and the new financial markets, the Nasdaq, and on the other hand pharmaceutical firms specialized in buying out therapeutic innovations that had already been developed pre-industrially, that is, at a stage when the risks related to clinical research tend to decline. Pharmasset and Gilead exemplified this new scientific and capitalistic structure. Finally, a controversy published by the *JAMA* in 2014 pointed out that the capital spent by Pharmasset on developing sofosbuvir (at the most $350 m, according to the author, for Pharmasset's entire molecule portfolio) was completely disproportional to the capital accumulated by Gilead on that medicine: "Moreover, substantial ethical questions are raised when the market then bears a 600-to-1 overall return on investment for this drug" (*JAMA*, November 26, Volume 312, no. 20).[16] In this new model, the market price remunerates two cycles of capital increase, that of the inventor, Pharmasset, and that of the acquirer, Gilead, thus producing a cumulative effect. This stands out from the traditional model based on the free appropriation—or appropriation in exchange for the payment of royalties—of molecules invented by academic laboratories, which remunerates only the capital advanced by pharmaceutical companies (Gilead had used such a model for the previous molecule that supported its growth, tenofovir (Veras 2020)). In Brazil, the struggles to invalidate the patents and mobilize private and public capital to produce a generic sofosbuvir were freed from the cost of financial capital and the monopoly price for a short space of time, before Gilead was able to re-establish them.

The frugality of capital devoted to medicines for neglected diseases: price formulations and capital-value regimes for antimalarial medicines

Whereas sofosbuvir supported an inflation of financial capital to capture the monopoly price of a new, therapeutically highly effective molecule on the global market, the invention, development and distribution of the artesunate–amodiaquine combination to treat malaria mobilized a combination of public, philanthropic and industrial capital that was not profit-seeking. The accumulation of capital, particularly financial capital, was very high for Gilead, while in the ASAQ economy it was, by contrast, very sparse. Likewise, the financial capital inflation of sofosbuvir put pressure on public and social payers to the point of destabilizing them, while the very low capital cost of ASAQ increased the purchasing power of global donors, such as the Global Fund.

What are the driving forces behind this economic value regime requiring little profit and thus little capital? This frugal capitalistic regime is explained by the history and economics of its invention, and especially the types of capital involved, the appropriation regime adopted, the low-income populations targeted, and the governance of this economy by a humanitarian organization: MSF/DNDi.

[16] Marx defined the financial capital of proprietors by its disconnection from the operations of industrial capital.

The first source of frugality stems from the fact that all the basic molecules in this new therapeutic class, artemisinin-based medicines, were invented, developed, and clinically tested in the People's Republic of China from the late 1970s onwards. These basic molecules, including artesunate used in the artesunate and amodiaquine combination, were developed at a time of public property in China and are free of patent rights. When MSF and the DNDi decided to develop ASAQ in 2002, they were able to use the molecule freely. This was a first source of capital saving.

Second, the investments required to develop the formulation of the artesunate–amodiaquine combination were initially supported by public and philanthropic funds. ASAQ's R&D programme was set up by MSF in the early 2000s with a view to rapidly developing fixed-dose artemisinin-based combinations to control malaria resistant to existing treatments. It was an innovation project run by a humanitarian organization that had experience with resistance to malaria treatments in Africa from the 1990s, and that undertook to introduce artemisinin-based medicines from south-east Asia in East Africa. This R&D programme benefited from the guidance of the WHO and Tropical Diseases Research (TDR), which recommended developing artemisinin-based co-formulations through the organization of public/private partnerships.[17]

The DNDi Foundation is a public/private partnership bringing together humanitarian medicine (Redfield 2008), global health (TDR/WHO), medical research institutions in the South (the Oswaldo Cruz Foundation, the Indian Council for Medical Research, the Kenya Medical Research Institute, the Malaysian Ministry of Health), and the Pasteur Institute. Its ambition is to develop an alternative therapeutic innovation model for the so-called neglected diseases based on a non-exclusive appropriation model and 'cost-plus' or no-profit pricing formulas. In 2002, the DNDi established the Fixed-Dose Artesunate Combination Therapy (FACT) consortium to develop two pharmaceutical technologies at two sites: the artesunate–amodiaquine combination was to be developed around Bordeaux University in France, and the artesunate–mefloquinine combination was to be developed at the Fiocruz Farmanguinhos Institute in Rio de Janeiro.

The funds allocated to the FACT consortium were public subsidies from the European Union, the *Agence Française de Développement,* the Swiss government, and philanthropic organizations, primarily MSF and the DNDi, which accounted for half of the total and expected no returns on their investments. The amounts involved remained modest, given that some of the work was directly funded by Bordeaux University, at no charge. The development costs of ASAQ borne by the DNDi totalled $12.5 million (clinical trials and industrialization costs borne by Sanofi were not included). The majority of costs carried by the consortium were devoted to development and registration. The distribution of these funds corresponded to a large degree to R&D expenditures for malaria, as evaluated by UNITAID economists for the period 2007–2011: 51% of these expenditures were covered by government grants, 32% by philanthropic organizations, and only 17% by industry.[18] The

[17] Antimalarial Drug Combination Therapy, Report of a WHO Technical Consultation, 4–5 April 2001.
[18] Malaria Medicines Landscape 2015, UNITAID, 117 pages.

share of industrial R&D tends to increase when molecules reach the clinical trial and registration phase. These innovation projects, initiated and partially funded by humanitarian organizations, were intended to break down the barrier of ownership and accessibility for low-income populations.

The artesunate–amodiaquine combination technology was developed by a network of academic research laboratories and R&D start-ups in France and, to some extent, in Brazil and Germany.[19] Although it was not patented, at the insistence of MSF/DNDI, the formulation of this fixed-dose combination with two molecules that were difficult to combine in the same pill was based on inventive technology designed by researchers at Bordeaux University. The university provided its technology free of charge, while the pharmaceutical development start-up, Ellipse Pharmaceuticals, supported by a large French engineering group, Bertin, derived some profits from its work that was funded by the DNDi research contract. However, Ellipse Pharmaceuticals, which contributed significantly to the invention of the co-formulation, did not receive any intellectual property rights, in accordance with the non-patenting policy imposed by DNDi. An original feature of the design of this medicine lies in the humanitarian organization's strong involvement in the definition of the therapeutic use value of the medicine, and in that of its value in terms of production costs. The head of the Bordeaux start-up set out the constraints involved: "Finding a somewhat sophisticated technical solution to separate these products was possible, but we quickly encountered problems of cost-price incompatibility with the spirit of a tropical medicine" (Ellipse).[20]

The R&D was thus essentially taken care of by public-sector laboratories and university spin-offs. In no instances did the latter own the technology; they worked as sub-contractors on specific development tasks with which the consortium had entrusted them. The FACT consortium also partially funded clinical trials and the registration of the medicine, before Sanofi stepped in to take care of its industrialization, to complete the clinical trials and to make the necessary investments for the pre-qualification of its production unit in Morocco. Here the pharmaceutical multinational entered the scene only after the development stage had begun, under the DNDi's authority. The agreement signed in 2004 between the DNDi and Sanofi—with temporary exclusivity granted to the firm until the registration of the medicine by the WHO in 2008—was based on a common good regime for the new medicine. The latter was therefore not patented, even though the Bordeaux academic researchers would have preferred to have some form of control over the invention (Lacaze 2011). The agreement specified a regime of "no-profit" or "minimum-profit" prices to ensure the medicine's accessibility to the public sector" (Partnership agreement between the DNDi and Sanofi to jointly develop ASAQ Winthrop®, a non-patented ASAQ FDC to be sold at cost plus a small margin" (DNDI 2015, p. 12)). This

[19] The toxicological studies were carried out at two Brazilian start-ups; the analytical methods were entrusted to Sains University in Malaysia; and the first scale-up was subcontracted to Rottendorf Pharma in Germany.

[20] Sandra Mignot: "Le consortium FACT et le traitement du paludisme: Exploration d'un nouveau modèle d'innovation thérapeutique", Paris, Master's thesis, EHESS, (2010), 86 pages.

agreement also provided for the payment of royalties on sales of the ASAQ version that was to be commercialized by Sanofi on private markets under the trade name Coarsucam. These royalties covered 4% of the consortium's funding, particularly for surveillance studies on the medicine's side-effects in several African countries, and were reinvested to improve the medicine's use conditions. Yet the amount of royalties paid to the DNDi, which was already very small, declined with the reduction of ASAQ Coarsucam production for the private-sector market. Sanofi-produced ASAQ is now intended primarily for the donor market, especially the Global Fund, for low- and medium-income countries.

Sanofi's industrial investment is based on several strategic objectives: (1) maintaining the firm's presence in the malaria field, in which Poulenc was already present at the beginning of the twentieth century; (2) counteracting the negative repercussions of the Pretoria Trial in 2001, by creating an Access to Medicines Department for neglected tropical diseases; and (3) increasing its industrial and logistics presence in Morocco and on African markets, classified by the multinational as "emerging markets" (interview with Sanofi-Maphar's Casablanca plant manager in 2016). Establishing production in the Casablanca plant necessitated the creation of local expertise and industrial knowledge. The industrial teams in Casablanca had to overcome a real production crisis in 2011–2012, at the same time as the Global Fund sets up a new subsidized market system, the AMFm, which resulted in strong growth in demand for ASAQ. At that time, Sanofi was the sole provider of fixed-dose ASAQ. Obtaining ASAQ's pre-qualification from the WHO also required investments to improve the plant's system for documenting production operations and quality control. However, the economy of this local production has limitations: (1) the Casablanca plant imported the active ingredients for amodiaquine from India and for artesunate from Italy; and (2) the ASAQ boxes produced in Casablanca returned to France before being shipped back to African markets, for reasons of financial consolidation within the multinational (WHO inspection, November 2016).

The value regime devised for the invention, production, and marketing of ASAQ is particularly capital-efficient: while it is based on an innovation system distributed across academic laboratories and spin-offs from the university, transactions with the start-ups are services financed by research contracts that offer no exclusive intellectual property rights over the pharmaceutical technology. Therefore, this technology cannot be converted into an asset whose value could be increased on financial markets. The invention was put in the public domain and could be legally copied by the Indian generic manufacturers who are dominant in the market today. Sanofi's involvement in the production of ASAQ, "a no profit no loss model for the public sector" (Sanofi Morocco), covered a segment of Sanofi's global capital that was 'devalorized' compared to the firm's capital invested in high-profit markets such as cancer or diabetes.

The price formulation adopted by the DNDi and Sanofi, adjusted to industrial production costs and not to remunerating R&D costs, was invented by the WHO and its Tropical Diseases Research department in the late 1980s. To promote the accessibility of innovative malaria drugs, the TDR imposed a price formula on its industrial partners that was adjusted to the production price. A limited margin was applied to the medicines that would be sold to the public pharmaceutical sector, while the

firm could freely set its price for the private market. The WHO justified this price formula to industrial actors based on the R&D investment costs that it had supported for the development of these molecules, mainly by covering most of the costs of clinical trials. This pricing model was applied in several agreements, including those with Rhône Poulenc in 1994 and Novartis in 2001. Through an agreement signed in 1988 with Artecef, a Dutch firm, the WHO had even acquired an additional means of power: it held a patent on the molecule's manufacturing process.

Intertwined and conflicting economic and moral value regimes

In *Pharmocracy* (2017), Rajan highlights the tensions between ethical values based on social justice advocating for access to treatment, and the accumulation of value through capital. He shows how ethical values are likely to support alternatives to capital, unless they are appropriated by capital itself to perpetuate or expand its markets: "Ethics can be potentially opposed to surplus value but also deeply tangled within its logics". Lezaun and Montgomery (2014) have studied the new moral economy of PPPs in the field of neglected diseases, which are likely to pave the way for new closing and profit strategies. Susan Cradock (2017) stresses the alternative dimension of the non-profit PDPs and the "humanitarian pharmaceutical production model" that she has studied in the field of tuberculosis medicines, compared to the standard pharmaceutical model based on shareholder demands. Redfield (2008) has shown how MSF, by creating a virtual laboratory to invent new therapeutic solutions, the DNDi, combined a moral economy of medicines as public goods with research investments.

The value and price regimes studied here show a close entanglement of economic and moral values, as well as dynamics that result in defending or extending control over capital or controlling and reducing its power. These opposing dynamics pervade the two pharmaceutical economies studied: that of antivirals for hepatitis and that of antimalarial medicines.

Informed by past struggles over IP relating to HIV/AIDS medicines, and having lost a great deal in 2006 in India, and in 2008 in Brazil, two countries in which its tenofovir patent had been cancelled, Gilead endeavoured to save the day in two ways: first, by applying a policy of differentiated prices for low-income countries; and second, from September 2014, by offering voluntary licences to 11 Indian manufacturers[21]—which also had the benefit of pulling the rug from under patent opponents' feet (an Indian firm actually withdrew its opposition). This strategy of voluntary licences followed the same model as a patent pool system created by UNITAID in 2010 at the insistent request of MSF, to reduce the barrier of access for populations

[21] "Gilead is committed to increasing access to its medicines for all people who can benefit from them, regardless of where they live or their ability to pay", "Chronic hepatitis C treatment expansion Generic Manufacturing for Developing Countries", Gilead, February 2015.

of the South.[22] Gilead authorized its Indian licensees to sell their medicines to a list of 91 low- and medium-income countries that it had drawn up. NGOs' reactions to this strategy were divided: some celebrated the use of voluntary licenses, which they had been demanding for years, while criticizing restrictions on intermediate countries (J. Love's Knowledge Ecology International)[23]; others, such as MSF, were highly critical when medium-income countries (such as Brazil and Thailand) were excluded from this system, since they accounted for half of the world's population affected by hepatitis C. MSF appealed to Indian producers to refuse these licenses.[24] The DNDi, adopted a strategy of circumventing Gilead's system by partnering with an Egyptian producer and a biotechnology firm in the US, Presidio Pharmaceuticals, to offer sofosbuvir in combination with ravidasvir at $300 (the Sovaldi patent had previously been refused by the Egyptian patent office). The moral values of justice advocating for access to medicines gave rise to intense struggles. Gilead's particularly acute form of financial capitalism thus integrated humanitarian preoccupations and used mechanisms recommended by MSF in the late 2000s, in the form of the Medicines Patent Pool and voluntary licences to cover poor countries. Meanwhile, DNDi teamed up with generic producers in the South—Egypt, Argentina—to curb the multinational's control of the global market.

Sanofi entering into an alliance with the DNDi to produce ASAQ was part of a strategy to justify the proprietary model, perpetuate its influence on the malaria medicine market, and assert its presence in emerging markets. At the same time, the pharmaceutical economy supported by the DNDi had an alternative reach based on public good regimes or non-exclusive licensing of the knowledge it held, on no-profit or cost-plus pricing formulas, on a model of innovation guided by health needs, and on independent governance concerned with preserving the predominance of public contributions over the private contributions it received.[25] As a result, Sanofi had to adopt the DNDI's mandatory non-patentability policy for ASAQ, such that the de facto commercial monopoly it enjoyed between 2008 and 2012 was undone by the spread of the local production of copies in India and China. The DNDi implemented its policy of local production of ASAQ in Africa through a technology transfer, which it financed in Tanzania to the tune of $2.5 million, independently of Sanofi. In 2017, Sanofi sold the majority of Maphar's share capital in Casablanca to a long-standing pharmaceutical retail group in Africa, Eurapharma. This can be seen as a withdrawal of Sanofi from lower margins, as opposed to the multinational's high-profit areas. Ultimately, the multinational benefited both from the productivity of

[22] The Medicines Patent Pool signed agreements with patent holders and then sub-licensed generic manufacturers. MSF legal expert Ellen T'Hoen was to be administrator of the MPP, along with Jorge Bermudez of the Oswaldo Cruz Foundation.

[23] "KEI welcomes the Gilead HCV licenses, as a step to expand access to treatments. Notes challenges that remain", 15 September 2014.

[24] "Indian generic companies should reject Gilead's controversial hepatitis C 'Anti-Diversion' programme", MSF, 19 March 2015.

[25] Between 2003 and 2018, public contributions were greater than those of the private sector. DNDi also endeavoured to balance contributions within the private sector between Gates and other donors: MSF, the Wellcome Trust, Mundo Sano, etc.

this commons-based innovation model and from a kind of "humanitarian redemption".[26] The creation of Sanofi's Access to Medicines department, which supports projects offering little or no profit, in order to better preserve the multinational's high profits on other markets, is a form of philanthropic capitalism as understood by MacGoey (2012) and Birn (2014). It diverges from the moral economy of the humanitarian organization, based on communal and social justice values as defined by Thompson (1971).

The ASAQ project was part of a series of proposals to establish public and common goods, with new formulations and a new price government running counter to the foundations of Sanofi's and Gilead's proprietary and financial economy. The price formulations of such public goods generally provide for a price adjustment to production costs, with a limited and controlled profits, as well as a neutralization of R&D costs borne mainly by public and philanthropic funds. The non-exclusive distribution of technologies negates any monopoly profits. Additionally, these price formulas exclude the inflation of capital and financial profits, the share of which is, by contrast, excessively large in the price formulations of today's proprietary economy. The urgency of experimenting with alternatives to market exclusivity was stressed in January 2020 in the *British Medical Journal* in an article titled: "New business model for research and development with affordability requirements is needed to achieve fair pricing of medicines" (Suleman et al.), which cites several experiments and proposals, including those of the DNDi. Very recently, the WHO proposed a mechanism to ensure that anti-Covid technologies are shared and universally accessible (WHO, Covid-19 response, 18 May 2020). Some associative or political players are calling for the mandatory sharing of these technologies or their public purchase and management by the WHO. The governance of these global public goods is linked to demands for "price transparency" put forward by the WHO, MSF, patient organizations, and several States (cf. "Improving the transparency of markets for medicines, vaccines, and other health products", World Health Assembly, May 2019).

Through the joint analysis of price formulations, capital-value regimes and moral justifications, this paper has compared two political economies of pharmaceuticals at two ends of the spectrum, with very high profits, on the one hand, versus with limited or no profits, on the other. In so doing, it has simultaneously illuminated the critique of the new imbalances of financial capitalism and the construction of alternatives to reduce exclusive markets and capital accumulation, with a view to maximizing public and social surpluses in health care.

Compliance with ethical standards

Conflict of interest The author do not have any competing interests—intellectual or financial—in the research detailed in the manuscript.

[26] This enabled Sanofi to reconcile "money and life"—the title of a book by the medievalist Jacques le Goff in (1986).

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