False Hope and Fictitious Patents: Evaluating the Intellectual Property of OxyContin

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Abstract: This article evaluates the opioid epidemic through the lens of intellectual property law, focusing on OxyContin's trajectory from conception to market. Using interdisciplinary analysis and doctrinal legal examination, I theorise that the patent system relies on 'industrialised hope' in commodifying scientific outputs for overall societal benefit. OxyContin was one such output, though I contend it offered false hope. I show that OxyContin's key patents were granted based on unproven efficacy claims, while the FDA credulously approved the drug. OxyContin's originator, Purdue Pharma, mobilised patent protection, regulatory approval, and trademark-based marketing to create a blockbuster opioid that triggered the crisis. Rather than an aberration, I argue OxyContin exemplifies systemic flaws in the intellectual property system: misaligned incentives, inadequate patent examination, and insufficient regulation. When 'fictitious' patents are granted, this blurs the boundary between the patent and trademark regimes and undermines the patent system's foundational hope of advancing industrial progress.

Keywords: Patents, regulation, medicines, trademarks, commodification

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INTRODUCTION

No drug exists outside of, or prior to, the social relations through which it is produced and used. Medicines are not merely discovered once and for all time – they have an ongoing existence in laboratories, legal institutions, health sites, and daily life (Whyte et al., 2002; Hardon and Sanabria, 2017). With any new drug, although the chemical or biologic formula is fabricated by scientists, it is lawyers who create the governmental meanings of the substance, enabling its socialisation as a pharmaceutical product in the market (Jackson, 2012; Delaney, 2021). Indeed, the development of new medicines is shaped by a combination of the patent system, regulatory approval, and branded marketing. In this article I evaluate the process of transforming a scientific R&D output into a market commodity via the prism of a public health crisis, namely, the opioid epidemic in the United States (US). My jurisdictional concentration on the US is justified by its position at the epicentre of the opioid crisis, as well as being the most prominent patent and regulatory jurisdiction for the global pharmaceutical market. I focus on the opioid epidemic because it is acknowledged as a 'disease of design', distinguishing it from other forms of outbreak such as COVID-19 (Chow, 2019; Cuellar and Humphreys, 2019). In addition to design, another way of describing the opioid crisis is as a 'disease of the market'. After all, the birth of the crisis in the mid-to-late 1990s was not illegal drugs, but patients becoming addicted to government-regulated prescription opioids. The drug credited with triggering the epidemic – Purdue Pharma's OxyContin – was a patented market commodity advertised as a panacea for pain. Since OxyContin's launch in 1996, at least 247,000 people in the US have died from prescription opioid overdoses (*Harrington v Purdue,* 2024). The true figure of opioid-related deaths may be more than 500,000, with approximately 2m people still addicted (Williams et al., 2019; Bresler and Sinha, 2021).

Considering the nature of this predicament as a crisis of legally ordered human design, it is perhaps surprising that intellectual property (IP) scholars, with few exceptions (Dutfield, 2020; Hemel and Ouellette, 2020), have said little about the role of the patent system in incentivising opioid product development. In line with this article's focus on the pharmaceutical commodification process, I undertake the first substantive examination of OxyContin from an IP law perspective, exploring its trajectory from conception to market, assessing what lessons can be learned for IP theory and practice.

I make use of dual methods: I use interdisciplinary theoretical analysis (drawing on law and economic anthropology) to evaluate the role of IP within the pharmaceutical industry; and I undertake doctrinal legal assessment of the relevant OxyContin IP rights (the patent and trademark filings, associated litigation records, and regulatory documentation).

I begin my theoretical analysis by exploring the pluralistic foundations of patent theory.[i] I focus on two core themes: (i) the *a priori* rationale for *why* the patent system exists, which I describe as a form of 'industrialised hope' in the commodification of scientific outputs for societal benefit; and (ii) the theory of *ex ante* economic incentives that expresses *how* it is meant to operate, whereby the prospect of state-granted patent rights is said to encourage investment in R&D. I develop the idea of industrialised hope further by going beyond patenting, to two legal areas relevant to *ex post* drug development: first, the regulatory approval of medicines by the US Food and Drug Administration (FDA); and second, the use of trademarks in branding and marketing.

Moving to the OxyContin case study, I explore the key patents that Purdue filed in the early 1990s at the US Patent and Trademark Office (USPTO). I find that in its patent filings, regulatory submissions to the FDA, and marketing materials, Purdue used the hopeful language of the path-breaking invention – the wonder drug – to exaggerate OxyContin's supposed benefits and minimise its risks (Van Zee, 2009; Applbaum, 2009). My examination reveals that OxyContin's key early patents were granted based on suppositional, unproven efficacy claims. I find that these OxyContin patents should not have been granted by the USPTO, due to considerable doubts about their purported inventiveness. Yet, I note that weak patent examination is not uncommon. Inadequate resources of both time and expertise can lead to over-registration, meaning speculative, even fictitious, patent applications can get through the system (Tu and Lemley, 2021; Contreras, 2021). Further to this, I show that the FDA approved OxyContin as efficacious and safe in part due to a credulous approach to the efficacy claims of its patented formula.

Purdue mobilised the combination of patent protection, regulatory approval and trademark-based marketing for OxyContin, leveraging the legitimacy these legal regimes confer, triggering the opioid crisis. OxyContin proved to be the latest in a long line of commercial opiate and opioid products, including morphine and heroin, fabricated as panaceas by the pharmaceutical industry to offer the (false) hope of a low-risk drug to patients suffering pain. OxyContin stands as an egregious example of what happens when the idealised, hopeful language of invention combines with misaligned patent incentives in a market: a dystopian 'miracle drug' that causes mass addiction and deaths of despair (Meier, 2003; Cutler and Glaeser, 2021).

This brings me to my central argument. OxyContin's makers exploited industrialised hope - the foundational assumption that the patent system incentivises welfare-enhancing inventions - by securing fictitious patents based on unproven claims. Rather than being an aberration, the case of OxyContin highlights systemic flaws inherent in the current IP system, including misaligned incentives, inadequate patent examination, and insufficient regulation. Additionally, the case study reveals a troubling convergence between the patent and trademark systems. Despite their fundamentally different rationales – patents are designed to incentivise invention, while trademarks protect commercial reputation – the OxyContin case

demonstrates how the boundary between these supposedly distinct regimes can become permeable. If patents can be fictitious, granted based on an unproven argument rather than verified scientific results, then they operate less as incentives for advancing industrial progress, and more as aspirational fictions, barely distinguishable from trademark slogans promising benefits that may never be realised. Given these concerns, I consider whether the legal framework can be reformed.

INDUSTRIALISED HOPE

The patent system is unimaginable without hope – in progress, in markets, in societal welfare. How can we evaluate this type of hope? Here I take insights from Riles (2005; 2011; 2016) to argue that the practice of patenting relies on law's capacity to stabilise technological uncertainty via bureaucratic documentation. I describe this as embedding an industrialised form of hope in incentives, mass production and market ordering. I ground this in Riles's discussion (2016) of the 'intellectual, moral, or political crisis' of hope in a capitalist society, whereby human agency is instrumentalised, valorising a mode of production that rewards private interests. This idea of industrialised hope (market-based incentives and mass production) can be distinguished from the 'sense' of hope that legal adjudication offers via the right to hope (for a better life), as described by Trotter (2025). Industrialised hope can be historicised by acknowledging the modern patent system's emergence during the industrial revolution of the 18th and 19th centuries (Pottage, 2020). This chimes with the accompanying utilitarian belief that the progress of knowledge would create welfare-enhancing inventions such as pharmaceuticals (Bentham, 1843). Indeed, if we accept that the foundational assumption of the patent system is that new inventions will benefit the general public (Jefferson, 1813), then we can observe that the hopeful presumption of societal utility is a key rationale for *why* patent law should offer inventors the prospect of property rights (Machlup and Penrose, 1950; Mokyr, 2009; Ford, 2017). Hence, patent law encapsulates industrialised hope by offering a discursive prospect of exclusive, time-limited property rights to the inventor.

Within the pharmaceutical sector, industrialised hope provides a structuring grammar, shaping the directions of R&D. Essential to this is the progressive idea that inventors can achieve gains and abate risks that benighted prior generations of researchers and physicians. The structuring effect of industrialised hope is particularly visible in pharmaceutical development because hope can be linked both to patient acuities and to market perceptions of the value of the wonder drug (Geiger and Finch, 2016). Moreover, given that only a small fraction (10-15%) of new medicinal products will make it to market (Sun et al., 2022), the whole process of drug discovery involves hope in beating the odds. Inevitably, however, this

structuring hope contains two potential outputs: products of genuine hope and those offering false hope.

This brings up a crucial question: how can we distinguish between genuine hope and false hope? Making such a distinction may be difficult at the beginning of the product development process. In most cases, the hope behind early research into a new invention will be genuine. However, if an originator firm offers misleading or exaggerated findings to the patent office or the medicines regulator, it is reasonable to say that this crosses the line. In other words, when legitimate risks are minimised, and speculative claims to efficacy are made without solid evidence, even an initially genuine hope can become false (Fleck, 2021). This hazard is acute in the pharmaceutical industry because although one potentiality of industrialised hope is that new R&D will overcome existing risk doctrines, other negative potentialities remain. Thus, industrialised hope contains the seeds of both utopian and dystopian outcomes.

It is notable that achieving social benefit is not a technical requirement of patent law, even with respect to medicines. US law simply states that patents are granted over inventions that can show utility, novelty, and non-obviousness (inventiveness) (35 U.S.C. §§ 101-103). None of these criteria requires that a pharmaceutical invention should demonstrate a positive outcome or benefit to society. This leaves open the possibility that a person or firm may attempt to exploit, or even subvert, the hope at the heart of the patent system. As described below, the case of Purdue Pharma and OxyContin is one such scenario. Prior to examining this, it is worthwhile to put this opioid product in its historical and theoretical context, considering the relevance of prior opiate drugs developed for commercial use.

THE HISTORICAL CONTEXT OF OPIUM-RELATED PHARMACEUTICAL RESEARCH

Opium has been profoundly important to human development, including as the subject of global trade wars and military conflicts, such that Ghosh (2024) argues opium has a claim to be an 'agent' not only in the way it acts within the human body, but also in history itself. In ancient times, the Mesopotamians and the Greeks cultivated the poppy to relieve pain and to induce a state of sleepy, languid euphoria (Booth, 2013). Crucially, in the ancient world, opium's deadly qualities were never forgotten. Yet, in the more recent past we have sometimes succumbed to a modern temptation, if not to forget the dangers of opium, then of allowing ourselves to be blinded by industrialised hope – seduced by the idea that scientific R&D can create a product that transcends risks that are, or ought to be, evident.

This brings to mind the work of Berlant (2011), who defined the contemporary condition in which something we desire can also become an obstacle to our flourishing, that is, an attachment that promises satisfaction but delivers

disappointment, precarity, or harm. The term Berlant uses to describe this – 'cruel optimism' – has substantial affinity with false hope. On this, a relevant factor distinguishing the moderns from the ancients may be that, for example, the ancient Greeks were suspicious of hope. Hope was the final element left in 'Pandora's Box', with the ancient story ambiguous as to whether hope offered consolation or whether it was simply humanity's final curse. Potkay (2022) dates our modern tendency to view hope positively, rather than as a medium for subversion, to the aspirational period that followed the French and American revolutions.

This post-revolutionary era coincided with the growth of the patent system and the concurrent rise of the pharmaceutical industry. During the 19th century, even as opium wars raged in east Asia over trade, the poppy became the basis for a boom in medical innovation in Europe and the US, leading to the invention of new pain treatments. German scientist Friedrich Sertürner isolated opium's chemical alkaloid, naming the resulting substance 'Morphine' after *Morpheus*, Greek god of dreams (Courtwright, 2001). Sertürner claimed morphine possessed the positive pain-relieving qualities of opium without the harmful addictive effects. Although a bestselling pain treatment, its dangerously addictive nature soon became apparent (Zentner, 1983).

Then, at the end of the 19th century, scientists at the German company Bayer synthesised another opiate-derivative, branding it aspirationally as 'Heroin', after the German word *heroisch* (heroic), which was itself derived from another Greek word, *heros* (Dutfield, 2020). Bayer claimed, erroneously, that unlike morphine their new product would not lead to dependence harms (Sneader, 1998). In 1913, facing opposition from doctors concerned about the addictiveness of heroin, and its resulting harmfulness, Bayer stopped manufacturing the product; but the brand-name stuck, as the now generic heroin moved from being a legal sedative to a black-market drug.

The 19th century cases of morphine and heroin offer a cautionary tale about industrialised hope; namely, how the semantic power of scientific progress, as well as consumer branding, can manifest (false) hope in the form of a commercial pain product. To understand how this lesson was forgotten in the commodification process of a contemporary product such as OxyContin, we must first examine how the incentives created by the patent system operate in the modern pharmaceutical market.

THE PATENT SYSTEM, INCENTIVES AND THE MARKET

If industrialised hope underlies the purpose of the patent system, the incentive theory of patents offers an idealised operationalisation of this hope. The key tenets are: (i) inventions are knowledge goods that are non-rivalrous and non-excludable; (ii) this creates potential for free riding and the copying of technology by

competitors; (iii) this risk of free riding may disincentivise inventors from conducting R&D; and (iv) this justifies the state intervening to grant a time-limited patent to encourage investment in the development of such goods (Arrow, 1962; Stiglitz, 1999). Within this theory, harms to market competition or access to technology caused by the monopoly effect of a patent should be minimised because the right lasts for a limited period (e.g. 20 years).

It remains an idealised, abstract theory. At no point, from the 18th century to the present day, has there been consensus on the theory and practice of patent incentives in the economy (Machlup and Penrose, 1950; Biagioli, 2019). Prominent early thinkers including Smith (1776) and Jefferson (1813) advocated for a limited patent system, while also emphasising the risks of state-sanctioned monopolies (Swanson, 2020). Some 19th century economists argued that abolishing the patent system altogether could create incentives for local generic producers in rapidly industrialising societies who would make free use of foreign technologies (Van Gompel, 2019). Although by the mid-20th century the incentive theory of patent law had regained prominence, key economic thinkers of the period expressed concern about the difficulties of measuring whether the incentive effect of patents outweighed the costs (Plant, 1934; Keynes, 1936; Machlup and Penrose, 1950). Even the neoliberal economists of the mid-to-late 20th century found themselves divided, with Hayek particularly critical of the role of patents in hindering competition (Slobodian, 2020). Today, empirical evidence remains ambiguous on whether the costs of patents outweigh the benefits (Landes and Posner, 2003; Boldrin and Levine, 2008; Lemley, 2015; Purdy et al., 2020).

Rather than seeking to evaluate the entire patent system, my focus is on a micro-study: to investigate how a scientific R&D output such as OxyContin becomes commodified; and in so doing, to evaluate how the patent system interacts with the idiosyncrasies of the US pharmaceutical marketplace to incentivise the development of certain commodities rather than others. To prepare the groundwork for the case study, it is necessary to explain the context in which the industrialised hope of the patent system is actualised via incentives.

ANALYSING THE COMMODIFICATION EFFECT OF PATENTS

In the system of industrialised hope, the state, via patent law, incentivises the commodification of technical activity by establishing property in a research output. As per Riles (2005; 2011), the system achieves this via technique, namely patenting, a specialised legal practice that draws boundaries around a scientific intangible: the invention. The construction of this invention relies on both scientific and legal language, transforming the technical artefact of the research output into the legal-textual artefact of the patent application (Pottage and Sherman, 2010).

On receiving this application at the USPTO, the patent examiner has the bureaucratic task of applying the patentability criteria. The examiner evaluates how

the 'person skilled in the art' – a legal fiction – would view the purported novelty and non-obviousness (inventiveness) of the claimed invention e.g. the new drug. The examiner achieves this by defining the claimed invention against all existing forms of prior art e.g. published scientific knowledge, existing patents, and public domain information. If the examiner is satisfied that the invention achieves its claimed advance in technology, the patent is granted. The patented invention becomes reified as an object of property, subject to legal adjudication, transactions, and licensing. Although the patent system encourages this commodification, this does not mean that every scientific output will be commodified, as some applications are rejected, and some scientists choose not to apply. Even patented pharmaceutical knowledge tends to be shared and learned; and eventually, upon expiry, it becomes part of the public domain, enabling generic manufacturing.

Public-private hybridity is built into this system. This is in line with the work of Karl Polanyi (1944), who showed that tenets of market economics, including incentives, should not be seen as 'naturally' occurring because to function they require non-market, governmental institutions. Hence, public patent offices are integral to creating the private market order. Peukert (2018) and Cohen (2020) take this perspective forward, using Polanyi to explore the fluidity between the IP system and non-market regimes. An insight that emerges is that the patented pharmaceutical reflects the hybridity of the Polanyian commodity: it can simultaneously possess aspects of a 'genuine commodity' (produced for the pharmaceutical market) and of a 'fictitious commodity' (reliant on non-commodified scientific discourse). This chimes with the work of non-legal scholars of Polanyi who concur that market commodities tend to be reliant on non-commodified forms of knowledge (Jessop, 2007; Grabher and König, 2020; Özveren and Gürpinar, 2024).

However, this hybridity may be a factor in exposing the system to misalignment and exploitation. As stated above, within the patent examination there is no requirement to demonstrate enhanced public welfare. Furthermore, once the patent is granted to the owner of the invention, public oversight by the USPTO recedes. As shown below, when the patent is leveraged in a financialised US system, the resulting unchecked market ordering drives predictable harms. These include incentives that direct R&D towards potential blockbusters and incremental patenting rather than meeting public health needs. Taking account of this hybridity and the risks of unchecked commodification, I return to Polanyi in the concluding part of this article, where I explore whether a key Polanyian concept – the counter-movement – could help to frame reform of the patent system.

PHARMACEUTICALS AS COMMODITIES – ADVERTISING AND PRICING

The market for healthcare products differs from country to country. When compared to its Organisation for Economic Co-operation and Development (OECD) peers, the US follows a strongly market-led, rather than a socialised or state-led, approach. A key differentiating factor is that in the US prescription medicines are marketed directly to doctors and to patients, with patient-centred advertisements presenting drugs as consumer commodities in ways that are illegal in all other OECD states except New Zealand (Feldman, 2022). US adverts often exclaim that consumers should 'Ask your doctor about' a particular drug. Yet, choosing which medicine to take is a fundamentally different sort of choice than choosing which video game to play or which holiday to take (Ju, Ohs and Park, 2019). The nature of the patient-doctor relationship creates risks. Patients are not ordinary consumers but are inherently vulnerable persons reliant on specialist advice on medications, particularly when the prescribed drug may be addictive, as with an opioid, since patients cannot switch easily to a less powerful alternative.

Price is another outlying marker of the US system, with prices much higher in the US than elsewhere (Anderson, Hussey and Petrosyan, 2019). One reason for this is that in the US patented medicines are largely paid for via market-based private insurance-based systems, with US public schemes less empowered to hold down costs than other OECD states. Unlike e.g. the UK National Health Service (NHS), the US government does not operate as a single payer and has limited its own powers to negotiate the price of medicines bought via the state-run Medicare and Medicaid (Rome, et al., 2023). This means that pharmaceutical companies have significant power to price their commodities as they see fit, making the US the highest-value global market.

PHARMACEUTICALS AS ASSETS – R&D, EVERGREENING AND PRODUCT-HOPPING

Undoubtedly, pharmaceutical research requires large amounts of upfront R&D investment (Sunder Rajan, 2017). For this reason, some scholars argue the incentive theory of patents has a particular resonance in the pharmaceutical industry (Bessen and Meurer, 2008). Moreover, as noted above, the success rate in drug development is estimated to be only 10-15% (Sun et al., 2022). Firms claim that these high R&D costs justify charging US patients elevated prices, e.g. over $1m per patient for some new products, to cover the costs of failures (Feldman, 2022). Nonetheless, the largest pharmaceutical companies, known as Big Pharma, tend to be highly profitable firms (Spitz and Wickham, 2012).

This brings up a significant question relevant to the OxyContin study below: how do patent incentives, operating in the pharma market, direct investment

towards commodifying certain R&D goals rather than others? On this, recently published legal and economic research indicates that firm decisions about which types of R&D to invest in are taken via forecast, not just of predicted revenues from product sales, but also of stock market perceptions about future IP asset value (Kang, 2015; Tulum and Lazonick, 2019; Dosi, Palagi, Roventini, and Russo, 2023; Roy, 2023). Hence, the US healthcare market is increasingly financialised.

Crucially, the combination of low success rate in drug discovery and the shareholder expectation of secure financial returns affects the directions of research. In this context, even if patents do create positive incentives for manifesting industrialised hope via R&D investment, the logic of the US pharma market pushes companies towards the promise of the largest financial return (Tulum, Andreoni and Lazonick, 2022; Barber, Sofides and Ramachandran, 2024). Thus, patent incentives push firms to direct R&D towards commodifying outputs with the potential to be blockbusters – defined as producing overall annual revenue of more than $1bn – to sell in high-income markets, especially the US (Bourgeron and Geiger, 2022). Prominent examples include Pfizer's Viagra, Abbvie's Humira, Novo Nordisk's Ozempic, and as I outline below, Purdue's OxyContin. A company with a patented blockbuster can benefit via direct revenue from sales; and, if publicly listed, it can benefit through the boosting of share price, including via 'buy backs', which can divert funds away from R&D investment (Schwartz, 2021). Even a private, family-controlled firm such as Purdue was highly influenced by perceptions of asset value (Keefe, 2021).

If firms have a greater incentive to invest in the patenting of drugs which cover diseases that affect high-income patients, this narrows the hopeful effect of the patent incentive to this sub-class of invention, meaning that 'diseases of the poor' tend to be under-researched, even left without hope of progress (Dutfield, 2020). This underlies the point that pharmaceutical companies are profit-focused enterprises, not public-focused institutions (Jackson, 2012). Indeed, it is often public investments that fill these gaps in unmet R&D, stimulating path-breaking research at public research centres and universities (and their spin-outs), as seen during the development of several COVID-19 vaccines (Thambisetty et al., 2022). This public-private R&D can be productive. Nonetheless, given that the industrialised hope underlying the patent system relies on an assumption that private investment in pharmaceutical inventions will enhance public health, it remains concerning that *ex ante* patent incentives are sometimes misaligned from public needs, a point I return to in the case study below.

Another systemic aspect of industrialised hope relates to the continuing effect of patent incentives after initial invention. Recent empirical work indicates that pharmaceutical companies are increasingly engaging in risk-averse investment practices, directing their R&D away from potentially path-breaking discoveries and towards the incremental reformulating or repurposing of existing drugs as 'new

inventions' with the aim of extending market exclusivity (Feldman, 2018; Işık and Orhangazi, 2022; Angelis, Polyakov, Wouters, et al., 2023; Arāja, 2023). This type of re-commodification is known as patent 'evergreening'. It involves a patent holder filing a new patent application for e.g. a novel reformulation of the same invention, or a new method of use. Even if it may have minimal differential effect as a treatment, the new patent brings with it a fresh 20-year protection period. Why do such minimally inventive applications get granted? A contributing factor is that patent examination is known to be imperfect (Tu and Lemley, 2021). Examiners have limited time and resources to investigate patent applications, meaning dubious applications can pass through to grant, even when speculative (Dutfield, 2017). This problem was further highlighted during the recent Theranos scandal, where it emerged that the US blood testing firm had been granted dozens of patents for a technology that never worked as specified, and which is now viewed as fraudulent (Contreras, 2021).

Once the new version is patented, firms aim to 'hop' doctors and patients from the old formula onto the re-commodified one (product hopping), thus maintaining exclusivity and hampering generic price competition (Gurgula, 2020). This kind of patenting behaviour relies on only a minimal sense of hope in improving patient welfare, although it can create maximal short-term benefits for the firm.

A prominent example of this is Abbvie's Humira, which, due to evergreening, is projected to have more than 30 years of effective market exclusivity rather than 20 (Gibbons et al., 2023). Moreover, evergreening is a prevalent practice. Examining all drugs on the US market 2005-2015, Feldman shows that 78% of the drugs associated with newly granted patents were existing medicines receiving extended protection; and more than 70% of bestselling drugs had their protection extended on at least one occasion (Feldman, 2018). Evergreening tactics add an average of 6.5 years of exclusivity for formulation patents and an average of 7.4 years for method patents (Kapczynski, Park and Sampat, 2012).

A critical point is that if investment goes into re-commodification of existing products, rather than the creation of brand new commodities, the number of patents granted is no longer a reliable indicator of the rate of new medicines to market (Park, Leahey and Funk, 2023). The growth in incremental, rather than path-breaking, inventions means that despite a large increase in the annual rate of patenting in the past 30 years, the rate of drug discovery has stagnated (Işık and Orhangazi, 2022).

Returning to the key issue of how *ex ante* patent incentives interact with the US pharmaceutical market, the above analysis suggests that the incentives of the patent system are misaligned from the structuring hope at its foundation in two respects. First, in a financialised market patent incentives direct R&D investment away from diseases that affect low-income patients and towards potential blockbusters, narrowing the incentive effect. Second, in a context of inadequate patent examination, patent incentives encourage incremental inventing rather than path-breaking R&D, further limiting potential social benefits.

Before exploring how the above analysis relates to the birth of OxyContin, it is necessary to briefly consider two *ex post* factors relevant to the socio-legal journey of a pharmaceutical commodity from lab to market: regulatory approval and trademarks. These have become more significant since the mid-20th century, after the expense and time needed to obtain regulatory approval led to calls not only for patent protection, but for additional exclusivity rights (Temin, 1979).

PHARMACEUTICALS AS REGULATED PRODUCTS: THE ROLE OF THE FDA

The US FDA requires a New Drug Application (NDA) to be reviewed and approved before marketing can take place (21 U.S.C. § 355). This requires producers to provide data, including details on drug composition, manufacturing, pharmacology, and results of preclinical and clinical studies. Drugs cannot be put on the market without authorisation, but gaining FDA approval is also critical to pharmaceutical firms for two additional reasons. First, regulatory approval reassures doctors and patients, paving the way for mass marketing campaigns. Second, FDA approval comes with quasi-IP rights: a period of marketing exclusivity (usually five years) when only the original manufacturer can market the product, and data exclusivity regarding clinical data submitted to the FDA. Given their value, some scholars describe these regulatory property rights as 'new IP' (Feldman, 2016).

PHARMACEUTICALS AS BRANDS: THE ROLE OF TRADEMARKS

If the prospect of a patent offers the key *ex ante* IP incentive in the pharmaceutical industry, the trademark represents an important *ex post* marketing asset. In the pharma sector, this is known as the patent-trademark pairing (Thoma, 2020). The purpose of the mark differs from that of the patent – with the trademark the aim is not to encourage fabrication of the artefact itself (the invention) but to create a reputation good by relaying the artefact to a specific originating producer (Pottage and Sherman, 2010). Thus, trademarks apply to company names (Purdue), product names (OxyContin), and specific logos, colour schemes and slogans.

The use of trademarks in the pharmaceutical industry became widespread during the 19th century (Dutfield, 2020), including with Bayer's branding of 'Heroin', discussed above. An attractive trademark enhances a firm's ability to market the drug as being lifestyle-enhancing. Hence, pharmaceutical advertisements often combine the trademark with psychological messages, such as aspirations about self and society, normality and illness, happiness and unhappiness, with side effects listed only in small print (Nichter and Vuckovic, 1994). Firms also use trademarks

to reinforce the perception of innovative product quality above the competition (Gangjee, 2021). This multiplicity of meanings reflects the fact that while pharmaceuticals exist as stabilised medical substances, they have another life centred on brand image, which is constantly being made and re-made in the minds of consumers (McDonagh, 2015; Hardon and Sanabria, 2017).

In the study of OxyContin below, I explore how within the US market, use of patents can incentivise the commodification of an invention that may only offer false hope, while regulatory approval and trademarks can ease this invention's path to market success.

THE OXYCONTIN CASE STUDY: DID PATENT INCENTIVES SPUR THE DEVELOPMENT OF A BLOCKBUSTER OPIOID?

After the late 19th/early 20th century heroin prescription debacle, the FDA only authorised limited use opiate and opioid products for short periods. One such product was Purdue's MS Contin – a patented morphine drug aimed at end-of-life cancer patients launched in the early 1980s (Hagen et al., 2005). At the dawn of the 1990s, Purdue's MS Contin patents, covering its extended-release formula for morphine delivery, were due to expire. Since MS Contin was Purdue's most lucrative product, post-patent generic competition would mean a significant drop in revenues – unless, of course, a novel invention could be commodified.

Here we get to the crux of the *ex ante* incentive question: Purdue had to make a decision regarding what R&D activity to invest in. Given the success of MS Contin, Purdue's head of R&D (and later Chairman) Richard Sackler envisaged the possibility of opening the opioid market to a new drug based on their existing Contin technology (Keefe, 2021). Hence, the looming expiry of the patents on one drug – MS Contin – was the key incentive that prompted Purdue to pursue a new patentable opioid commodity along the same lines. Thus, Purdue's R&D investment followed the familiar pattern discussed above. The incentives of the patent system, operating in the US pharmaceutical market, pushed the company towards the most potentially profitable direction: the incremental repurposing of their opioid technology. In contrast, Purdue chose not to invest in R&D on new non-opioid pain medicines, nor on preventative pain therapies which could have been difficult to patent and commodify as an excludable product (Hemel and Ouellette, 2020).

Returning to the theme of industrialised hope as the structuring grammar of the system, if incremental patenting was Purdue's major motivation, can we assess whether, at the outset, the company also possessed the genuine hope of providing a welfare-enhancing drug? After all, chronic pain affects many people. Initially, it is possible that Purdue intended OxyContin to address this unmet health need. However, as I explore below, it appears that early in the patenting process Purdue's genuine hope transitioned to false hope. To demonstrate this, I turn to the relevant patents and related litigation, providing analysis which indicates that the core

technology of OxyContin was based on a speculative fiction – an unproven claim that the drug's novel formula would minimise addiction risks.

THE OXYCONTIN PATENT FILINGS AND LITIGATION

Purdue's plan to re-commodify their existing extended-release morphine technology centred on repurposing the Contin system to oxycodone, a semi-synthetic opioid one-and-a-half times more potent than morphine. Oxycodone had been invented in 1916, but for much of the 20th century, due to its potency, it had been used only in limited circumstances as a generic pain medicine (Sneader, 2005). However, by combining generic oxycodone with their Contin time-release formula, Purdue could make a legal-textual argument that their product was sufficiently novel and non-obvious (inventive) to be patentable under US law (35 U.S.C. §§ 103 (a), as applied in case law e.g. *KSR Int'l v. Teleflex* (2007)). Crucially, OxyContin's key inventive contribution – what marked it out from the existing state of art, thus making it patentable – was that its extended-release properties would be so efficient that there would be minimal addiction risks. Yet, a close examination of the patents Purdue filed at the USPTO reveals that this was an unsupported claim: a fiction at the centre of Purdue's technology.

Of the OxyContin patents, three – '912, '295 and '042 – are particularly important (as shown by their listing in the FDA 'Orange Book', the key resource for generic manufacturers who wish to replicate a drug). These three encompass assorted composition and method claims essential to OxyContin's formula. The '912, '295 and '042 patents each make the following assertion in identical form in the 'Detailed Description':

> It has now been surprisingly discovered that the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold [range] (10 to 40 mg every 12 hours — around-the-clock dosing) in approximately 90% of patients. This is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general.[ii]

Purdue's carefully chosen words – 'surprisingly discovered' – convey the kind of unexpected or unprecedented result that could be an indicator of non-obviousness, and thus, patentability. Indeed, according to Purdue's patent applications, OxyContin was inventive over existing products precisely because its formula would provide efficient pain relief by distributing the oxycodone to the patient over a much longer period (10-12 hours) than the generic form, which lasted only 4-5 hours. Taken at face value, the extended-release Contin technology would

enable patients with severe or irritating pain to enjoy a full night's sleep, while the slow distribution of oxycodone would prevent opioid addiction.

In 2004, the validity of these three core patents came under scrutiny during litigation between Purdue and Endo, a generic company (*Purdue v. Endo*, 2004). Endo applied for permission to sell a generic version of OxyContin under the Hatch-Waxman Act (1984), which facilitates such competition. Purdue's '912, '295, and '042 patents stood in Endo's way. In the United States District Court Endo argued that the three OxyContin patents should be held invalid and unenforceable because Purdue had misled the USPTO. It emerged that when Purdue filed for the patents in the early 1990s, the USPTO examiner had initially rejected the applications as obvious, holding that the mere application of the existing Contin formula to the generic oxycodone was not sufficiently inventive over the prior art (*Purdue v. Endo*, 2004) at 23-27). Notably, a retrospective investigation by Sarpatwari, Sinha and Kesselheim (2017) concurs with this, commenting that 'the combination of Contin and oxycodone would have been obvious to any pharmaceutical chemist', and thus, the patents should not have been granted.

Nonetheless, during patent prosecution correspondence in the early 1990s, Purdue managed to convince the USPTO examiner to reverse this decision by emphasising the firm's 'surprising discovery' of pain-relief efficiency (*Purdue v. Endo*, 2004) at 23-27). Yet, during the 2004 patent trial, Purdue scientist Dr. Robert Kaiko, an inventor named on the OxyContin patents, admitted that at the time of the patent process Purdue had conducted no clinical studies and had no evidence to support the claimed 'surprising discovery' on efficiency (*Purdue v. Endo*, 2004) at 23-27). In fact, Purdue's executives knew the patent claims were unproven and were merely 'Bob Kaiko's vision' (Keefe, 2021). In 2004 the District Court held the three patents were unenforceable due to the materiality of Purdue's misrepresentation, stating:

> Purdue made a deliberate decision to misrepresent to the PTO a 'theoretical argument' and an 'expectation' as a precisely quantified 'result' or 'discovery'.[iii]

An initial appeal at the United States Court of Appeals for the Federal Circuit in 2005 upheld this ruling (*Purdue v. Endo*, 2005). However, in a second appeal to the same court in 2006, the Court of Appeals overturned the first instance decision; but only on a narrow point, sending the case back to the lower court to examine precisely how material the misrepresentation had been to the question of validity (*Purdue v. Endo*, 2006). Before the point could be re-heard at the lower court, Purdue and Endo came to a settlement, which had the effect of keeping the patents alive.[iv] Notably, even though Purdue won the 2006 appeal on a technicality, that same appeal judgment contains a scathing indictment of Purdue's behaviour:

> Purdue repeatedly relied on that discovery to distinguish its invention from other prior art opioids while using language that suggested the existence of clinical results supporting the reduced dosage range. Presented with these unique facts, we cannot say the trial court erred in finding that Purdue failed to disclose material information to the PTO.[v]

ANALYSIS OF THE EX ANTE PATENT INCENTIVES

If we return to the theme of industrialised hope, we can observe how the ordering of the patent system incentivised OxyContin's materialisation as a commodity in the marketplace. The patent system provided *ex ante* incentives – the initial spur – for Purdue's efforts to commercialise an incremental R&D output as a market commodity. Moreover, given that OxyContin's core patent claims rested not on proven science but on a notional fiction, it is concerning that the USPTO granted the three patents. However, this is not entirely surprising given the longstanding problem of inadequate patent examination. The patent system envisages that post-grant litigation should offer a check on this weakness, because rivals can challenge the validity of granted patents in court. Nevertheless, the Purdue-Endo saga shows that litigation does not always resolve the conundrum of fictitious patents – in this case, the protracted litigation gave Purdue the time to negotiate a settlement with Endo that, in effect, preserved their validity.

This is not the end of the story. Purdue's initial patent activities were only one part of its efforts to turn OxyContin into a blockbuster. It is crucial to explore OxyContin's regulatory approval, its branding and marketing, and Purdue's subsequent patent filings.

THE FDA APPROVAL PROCESS

Due to widespread knowledge going back to the 19th century about the addictive nature of morphine, the FDA had only given a narrow approval to Purdue's MS Contin, restricting sales to a sub-set of patients e.g. cancer patients. This limited revenue growth. In contrast, OxyContin offered a greater opportunity – but only if a broad FDA approval could be secured.

As explained above, US law allows direct promotion and marketing of FDA-approved prescription medicines to both doctors and patients. Purdue's market research showed that many doctors (and patients) were unaware that the then-relatively obscure opioid oxycodone was more addictive than morphine (Dyer, 2019). Purdue reasoned that this lack of knowledge about oxycodone's potency would mean doctors would be open to prescribing it widely. Thus, if Purdue could convince the FDA that the patented extended-release formula of OxyContin would minimise addiction risk, this could justify marketing and prescribing the drug to a

broad tranche of patients, even to those suffering from only moderate or transitory pain (Lexchin and Kohler, 2011). Such a broad FDA marketing label would unleash OxyContin's potential to be a bestseller.

The question is: why did the FDA grant approval without solid evidence showing that OxyContin was safe i.e. non-addictive and non-harmful? The answer is multifaceted. One cause of the FDA's failures over OxyContin was the phenomenon of 'regulatory capture' – the blurring of the lines between the corporate and regulatory spheres, leading to a narrow product review. Notably, FDA officer Curtis Wright, who oversaw the approval process of OxyContin in 1995, took a highly paid job at Purdue in 1998 (Campbell and Rooney, 2018). It seems likely this conflict of interest was partially responsible for Purdue receiving a favourable outcome.

The other key cause is more pertinent to this article: Purdue argued that OxyContin was safe because its patented extended-release formula would drastically reduce the risk of addiction and abuse. In other words, Purdue's FDA filings for OxyContin rested on the same fiction contained in the patents.[vi] Although Purdue argued scientific research supported this assertion on safety, several of the papers Purdue cited were empirically flawed or based on anecdotal studies (Chakradhar and Ross, 2019).[vii] Purdue's own trials only studied short-term usage (Pappin et al., 2022).

Despite this weak evidence, the FDA took a credulous approach, relying on faith in OxyContin's patented, and apparently state-of-the-art, formula (Kolodny, 2020). Put simply, the FDA 'believed that this drug would be less susceptible to abuse than prior drugs because of its slow-release properties, but this proved not to be the case' (Vertinsky, 2021). Hence, OxyContin's apparently inventive qualities, expressed in the patents, obscured the decades of established data showing the addictive and harmful consequences of opioid use.

In December 1995 the FDA approved OxyContin, including its label and package insert, which indicated it was safe for wide usage, stating that "…'addiction' to opioids legitimately used in the management of pain is very rare" (Physicians' Desk Reference Staff, 1997). That the FDA acquiesced to this label was key to the marketing of OxyContin as a safe pain treatment for transitory ailments, leading to its over-prescription (Parker and Hansen, 2022). Despite offering false hope, Purdue's product could now enter the marketplace 'portrayed as a revolutionary wonder drug' (Cutler and Glaeser, 2021). The next step was a trademark and branding strategy.

HOPE AS THE 'PROMISE' OF REVITALISED HEALTH: OXYCONTIN'S BRAND FICTIONS

From OxyContin's launch in 1996 Purdue utilised a performative branding campaign, capturing the attention of patients and medical professionals alike.

Purdue's marketing of OxyContin benefited from the Sackler dynasty's vast experience of pharmaceutical advertising. During the 1960s Richard's uncle Arthur Sackler, a marketing guru for Roche, had pioneered an urbane branding campaign that transformed the image of the tranquiliser diazepam via the Valium brand, making it a bestselling drug (Hooten and Hooten, 2019). Just as Arthur Sackler had found a way to market a strong sedative as a treatment for minor anxieties, at Purdue Richard Sackler sought to represent a powerful opioid as a panacea for all kinds of pain (Ho, 2019).

The strategy centred on the distinctive trademark 'OxyContin', filed in 1992 and granted in 1996 by the USPTO, utilising slogans that highlighted the innovative qualities listed in the patents and stated on the FDA label. In its advertisements Purdue put the OxyContin trademark alongside statements that it would allow patients to 'get their lives back', making the unproven assertion that there was a 'less than 1%' chance of a patient becoming addicted (Keefe, 2021). Indeed, one OxyContin slogan was: 'The drug to start with and to stay with' (Van Zee, 2009). In this way, Purdue reassured doctors that patients could be prescribed OxyContin for the long-term, something which the medical community considered unthinkable about morphine. The combination of the recognisable commercial trademark, the (unproven) 'less than 1%' risk claim, and the broad FDA label, was vital to OxyContin's direct marketing to US doctors and patients (DeWeerdt, 2019).

In addition, Purdue engaged in indirect activities with an ambitious goal: to redefine the medical community's understanding of pain. Purdue sponsored medical conferences and set up seemingly independent pseudo-academic 'research groups' to advocate for opioid use. Inconspicuous Purdue funding was essential to the American Pain Society's 1996 campaign for pain to be treated as the 'fifth vital sign', leading to its official recognition as such in 2001 by the US Joint Commission on the Accreditation of Healthcare Organizations (McGreal, 2019). The combination of direct branding and indirect activities paved the way for OxyContin's extraordinary success. Between 1996 and 2019 OxyContin generated more than $30bn in revenue (Au-Yeung, 2020).

Although marketed as a product of hope, OxyContin led to despair. Tens of thousands of patients who used OxyContin as prescribed became opioid-dependent, many of whom suffered dire consequences, including spiralling addiction, overdose, and death (Van Zee, 2009). By the early 2000s opioid addiction had become a cascading tragedy, but Purdue continued to lobby members of US Congress to prevent a tightening of the FDA authorisation process, keeping OxyContin on the market even after paying a fine in 2007 for misleading marketing (Meier, 2007). In fact, in the 2000s Purdue even managed to pull off one final IP masterstroke: evergreening.

THE FINAL IP MASTERSTROKE – EVERGREENING AND PRODUCT-HOPPING

In line with the notion discussed above, that patents do not create a one-off incentive but a continuing process, during the 2000s Purdue utilised the re-commodification tactics of evergreening and product-hopping (Capati and Kesselheim, 2016). This coincided with two factors. The first was gradual public acceptance that OxyContin was contributing to mass opioid addiction, particularly when pills were crushed and snorted, producing an instant high (Meier, 2003). The second was the looming expiry of the initial OxyContin patents, and thus the threat of generic competition. Hence, this new project had the overlapping aims of combatting criticism of OxyContin's link to triggering addiction while extending market dominance. These factors prompted Purdue to direct its R&D investment towards reformulating OxyContin to be crush-resistant.

Consequently, in the 2000s Purdue applied for a series of new patents on reformulated, crush-resistant, OxyContin, and then launched the product in 2010. Purdue's aim was to hop doctors and patients from the old 1990s formula (soon to be generic) to the newly patented one (Noah, 2015). In line with this, in 2013 Purdue persuaded the FDA to withdraw the regulatory authorisation for original OxyContin. Remarkably, in its 2013 letter to the FDA, Purdue acknowledged that it was 'not possible to develop labelling…. that would create a positive risk/benefit ratio for the original formulation of OxyContin'.[viii] In effect, Purdue admitted that the original formula had never been a safe product. Rather than facing any negative consequences, Purdue stood to benefit from this admission, with the FDA label withdrawal preventing generic companies from selling opioid products equivalent to original OxyContin (Miller, 2013). This left reformulated OxyContin as a lucrative commodity: although crush-resistant, it still had addictive properties and it continued to possess existing brand penetration. Furthermore, Purdue held the new patents, which were not due to expire until the late 2020s (Ryan, Girion and Glover, 2016).

Crucially, the process of OxyContin's re-commodification appears to have hollowed out any remaining hopeful, knowledge-seeking aspects of Purdue's purpose. Purdue directed its R&D investment almost entirely towards evergreening rather than attempting new, path-breaking innovation. Keefe (2021) quotes one former Purdue executive who remarked that Purdue was so intent on extending the patent life of OxyContin that the company had acted like 'an intellectual property law firm that happened to have some R&D and a marketing arm'.[ix]

However, as with the original patents, there were significant doubts about whether Purdue's new reformulation patents should have been granted. During the 2010s, four of the new patents on reformulated OxyContin – Purdue's '799, '800, and '072 patents and the '383 patent licensed by Purdue from another firm, Gruenenthal – were challenged in court by generic companies, notably by Teva,

Epic, Mylan and Amneal. These firms sought to sell reformulated OxyContin as a generic. In response, Purdue sued the companies for patent infringement. The cases were consolidated, resulting in a 2014 US District Court ruling which invalidated Purdue's four new patents due to obviousness (*Purdue v. Teva (In re Oxycontin Antitrust Litig.),* 2014). In 2016 the US Federal Circuit upheld the lower court's invalidation of these patents on reformulated OxyContin (*Purdue v. Epic,* 2016). A contemporaneous case (*Purdue v. Ranbaxy,* 2013) involving multiple defendants ended in a dismissal.

These were not the only new patents of dubious quality. Another key patent on reformulated OxyContin (the '888 Patent) was invalidated after a challenge by Amneal, once again due to obviousness - and in relation to '383 the court found both obviousness and anticipation (lack of novelty) (*Purdue v. Amneal,* 2015). The invalidation was upheld on appeal (*Purdue v. Amneal*, 2016). Following a subsequent dispute, Purdue and Amneal eventually agreed an overarching settlement.[x] As recently as 2023, in *Purdue v. Accord* (2023), the US District Court for the District of Delaware held that five Purdue patents – 9,763,933, 9,775,808, 9,763,886, 9,073,933 and 9,522,919 – were invalid as obvious under 35 U.S.C. § 103. This decision was upheld on appeal (*Purdue v. Accord,* 2024).

Nonetheless, by 2019, as more and more US states took legal action against Purdue, the company was forced into a reckoning. After several investigations, Purdue pled guilty as a corporate body to federal crimes related to the marketing, branding and distribution of OxyContin, and filed for bankruptcy (*In Re Nat'l Opiate Litig.*, 2017)). After the bankruptcy filing, a number of pending patent disputes were terminated before trial, such as *Purdue v. Intellipharmaceutics* (filed in 2017, terminated in 2020). At time of writing the legal matters of liability arising from Purdue's bankruptcy have yet to be finalised (*Harrington v Purdue*, 2024)).

The consequences of this reckoning have gone beyond a single firm. Other opioid producers who followed Purdue into the market, such as Endo, have also faced legal proceedings (Frieden and Houry, 2016). The FDA has taken stock of its credulous approach to prescription of opioids (Ryan, Girion and Glover, 2016). Even the World Health Organization has reconsidered the way it evaluates and recommends opioids, due to the risk of corporate influence and corruption (Dyer, 2019).

Arguably, IP scholarship has yet to reckon with how we should respond to the fact that this avoidable public health tragedy was created by a regulated market commodity, developed via IP incentives. I now turn to evaluating this.

WHAT LESSONS CAN BE LEARNED?

One could argue we should be cautious about drawing lessons from such an egregious example of 'innovation gone wrong'. Yet, there is much about the OxyContin case that should provoke wider concern. In the case of OxyContin the IP system provided not only the initial spur, but also the continuing incentive to engage in evergreening to extend market exclusivity. Rather than an aberration, Purdue's actions highlight systemic flaws, including the misaligned incentives provided by the patent system, the problem of weak patent examination, and the use of incremental patenting tactics. These problems are far from unique to the case of OxyContin. The case study adds to a body of evidence that attempts by rightsholders in the US pharma market to 'game' the patent system via exploitative market behaviour can lead to harmful results (Feldman, 2018; Barber, Sofides and Ramachandran, 2024).

This raises the prospect that reform is needed. It is here that Polanyi's notion of a 'counter-movement' is relevant. In the IP context, Suthersanen (2023) argues that the social costs of IP could stir up a counter-movement to moderate IP protections, with a key aspect being a shift away from market incentives towards public goals. Framing this as a counter-movement is particularly apt for pharmaceutical patenting, which transforms cumulative scientific knowledge into a hybrid commodity that can be monopolised and traded. Unchecked market ordering generates predictable harms: gaming behaviour, such as evergreening, and the prioritisation of profitable blockbusters over public health needs. The below reform proposals can be understood as Polanyian counter-movements because they are institutional mechanisms designed to re-embed the patent system within broader social purposes, such as public health imperatives. This could modulate the incentive system and subordinate the market logic that created the conditions for the opioid crisis.

What specific reforms might this consist of? Although an all-encompassing approach to reform is beyond the scope of this paper, it is possible to map out several plausible directions. I begin with the structuring hope inherent to the system and then turn to practical reforms. Given my focus on the US, these possible reforms are directed to that jurisdiction, though these suggestions may open up space for research on reforms in other jurisdictions.

RETHINKING INDUSTRIALISED HOPE

Does the commodification of OxyContin represent a subversion of patent theory's hope that incentivising R&D will invariably benefit the public? Is there something inherent in industrialised hope – its potential for not just genuine, but also false, hope – that opened it up to this exploitation? How should we respond when market ordering causes public harm?

With these questions in mind, it is notable that the OxyContin study reveals a self-justifying circularity in the system, whereby hope and optimism for a miracle drug can be harnessed by actors who may not have societal welfare in mind. The combination of patent examination and FDA approval is supposed to ensure the scientific integrity of health commodities and protect the public. Yet, the OxyContin case demonstrates how market forces can overwhelm these safeguards. Due to the utilitarian assumptions of industrialised hope, when a patent is granted it is all too easy to assume that the patented invention itself must be useful. Thus, patent law contributes to mythmaking: a reifying process which venerates 'the invention' even where, as with OxyContin, the utility versus risk calculus is far from clear. This reification masked Purdue Pharma's behaviour – in putting forward the fictitious patent claim that their product was efficacious and safe, the firm exploited the hope inherent in the system.

Is the belief in the inevitability of innovation bringing improved outcomes an example of systemic false hope? Relevant here is the widespread assumption among patients, and perhaps among some healthcare professionals, that anything that is new and inventive must necessarily be better than older, tried and tested medicines (Miola, 2015). While OxyContin is a notorious example, any new medicine that has not gone through full trials and testing can possess risks that outweigh the benefits for patients. This is pertinent given the growing use of early access schemes, which enable medicines to be marketed with limited trial evidence, in what has been described as a turn towards hope-based, rather than evidence-based, medicine (Sandman and Liliemark, 2017). There is a parallel between this hope-based medicine and the 'faith-based' IP discussed above.

Furthermore, the case study indicates a problematic convergence between the patent and trademark systems that warrants careful examination. Despite their fundamentally different rationales – patents are designed to incentivise innovation by granting exclusive rights in exchange for the disclosed invention, while trademarks protect commercial reputation and brand identity – the OxyContin case demonstrates how the boundary between these supposedly distinct regimes can become porous under certain conditions. The above analysis of the 2004 Purdue litigation reveals that the '912, '295 and '042 patents were granted despite being based on nothing more than an executive's hopeful 'vision' of pain-relief efficacy and safety – scarcely different from the wishful thinking of Elizabeth Holmes in the Theranos fraud case. If patents can be fictitious, granted based on an unproven argument, then they operate less as incentives for genuine innovation, and more as pure aspirational fictions, barely distinguishable from trademark slogans promising benefits that may never materialise.

This raises the need for reform of all aspects of the system of industrial hope – not just patenting, but also the process of gaining regulatory approval, and the rules on marketing of branded prescription medicines.

PRACTICAL REFORMS

Perhaps the most pressing practical issue is the problem of inadequate patent examination. Even though OxyContin's key patent claim was, in all likelihood, obvious, its path through the USPTO shows that examiners can struggle to deal with the volume and complexity of applications, leading to the award of patents on fictitious inventions (Contreras, 2021). Although post-grant litigation is intended as a check on this problem, it can work very slowly at invalidating such patents. On a positive note, since the OxyContin patents were granted, the US has taken a step to address this problem via the 2011 America Invents Act, which created an inter-partes post-grant patent review forum – the Patent Trial and Appeal Board (PTAB) – offering a speedy and less costly opportunity to challenge weak patents (Helmers and Love, 2023). Challenges to Purdue's 'evergreen' patents have been made at PTAB, such as in *Collegium v. Purdue* (2021) which invalidated the '961 patent, a decision which was upheld on appeal (*Purdue v. Collegium*, 2023). Nevertheless, even the PTAB system allows parties to settle, which can keep weak patents on the register, indicating that persistent power dynamics may undercut this existing reform. In addition, the sheer volume of granted patents means post-grant review cannot eliminate all problems of weak examination. Evergreening remains an issue because current novelty and non-obviousness standards are insufficiently rigorous to prevent pharmaceutical companies from obtaining multiple patents on minor modifications to existing drugs.

From a Polanyian perspective, could a counter-movement be imagined that would impose regulatory constraints on this commodification process? One possible option to counter abusive practices would be to require patent examiners to apply more stringent patentability tests for novelty and non-obviousness, as this would assert a public interest threshold that market actors must meet. In this vein, substantive reforms have been mooted – such as raising the novelty standard (Dutfield, 2017; Sinha, 2024) or limiting drugs to a single 20-year exclusivity period (Feldman, 2018).

Moreover, on patentability standards, it is worth reiterating that despite it being an *a priori* assumption in the theory of patents that inventions should be useful to society, in patent law there is no methodical requirement that societal benefit should be demonstrated before grant. Is there a way to change the system to reward social benefit? Here, a Polanyian counter-movement to the unchecked market order would seek to re-embed the patent grant within the social purpose of public health policy, whereby governmental institutions would no longer merely facilitate market exchange through granting patents, but would actively differentiate based on public health criteria. Specifically, some scholars argue that extensions for market exclusivity linked to pharmaceutical patents should differentiate between levels of term depending on the drug's potential societal benefit (Buccafusco and Masur,

2021). This could include patent-term extensions for welfare-enhancing drugs and, by contrast, refusal of extensions for inventions that do not create public benefit. A full analysis of this proposal is beyond this article, but it is worth further investigation.

A more radical Polanyian counter-movement would involve shifting away from the patent-based model in key areas of health. This could involve increasing public funding, via grants or prizes, for pharmaceutical R&D directed at specified public health outcomes, and requiring the resulting outputs to be patent-free. Rather than merely reforming the terms of commodification, this would de-commodify certain types of pharmaceutical innovation. While such a transformation faces significant political and economic obstacles, elements of this counter-movement already exist. A recent example of this is the creation of the patent-free COVID-19 vaccine, Corbevax, developed at Texas Children's Hospital and Baylor College (Hotez et al., 2023). This idea also accords with recent attempts, sponsored by the US Senate, to deal with the misaligned incentives of the patent system by boosting incentive options other than patents.[xi]

On regulatory reforms, the OxyContin study shows the risks of deficient governmental assessment, as occurred in the Purdue-FDA scenario. There are obvious ways to mitigate this risk, not least by having a more definitive boundary between the corporate and regulatory spheres, and by taking a more critical view of potentially overblown or specious efficacy claims, even when patented. A clear path to a better approach is shown by the example of regulators in Europe, who were much less credulous than the FDA in accepting Purdue's claims, with e.g. German authorities recognising how dangerous it would be to allow broad prescription of an opioid (Häuser, 2021). This differential outcome shows the advantage of having tight regulation of health products where addiction is a risk (Arnold, Amato, Troyer and Stewart, 2022).

Finally, the OxyContin study shows that the US approach to mass marketing of drugs as typical consumer commodities, whereby trademarks are utilised in sometimes misleading ways, creates hazards. Rather than making changes to the trademark system, a straightforward method of mitigating risks would be for the US to follow most of its OECD peers in banning mass consumer advertising of prescription medications.

CONCLUSION

Fictions abound in the intellectual property of OxyContin. By putting forward the fictitious patent claim that a more powerful opioid than morphine would be less addictive due to its extended-release technology, Purdue relied upon, and exploited, the structuring hope at the heart of the IP system. Within this system of industrialised hope, patent law enabled commodification of Purdue Pharma's

invention, while FDA approval and the use of distinctive trademarks eased its path to market. Amid false hope and profuse fictitiousness, key institutions missed the central truth: OxyContin was nothing other than a highly addictive narcotic.

In light of the above, OxyContin ought to stand as a cautionary tale that demonstrates certain flaws of the incentive theory of patents. In the absence of rigorous scrutiny at key institutions, reasoned belief in the patent system can morph into blind faith, incentivising behaviour that offers false hope, or even causes considerable harm. Although we must be careful about drawing lessons from such an egregious example, the study reveals useful insights that could allow us to bolster safeguards within the system. Efforts such as boosting public funding and offering prizes aimed directly at public needs, as alternatives to patents, as well as undertaking reforms to improve patent examination and tighten FDA processes, could help to prevent another legally ordered product from creating a similar crisis in the future. To stop dystopian harms recurring we require an IP and regulatory system better capable of distinguishing between genuine hope and false hope, and between scientific fact and speculative fiction.

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Purdue Pharma L.P. v. Ranbaxy Inc., No. 1:2010cv03734, 10 Civ. 3734 (SHS), 2013 U.S. Dist. LEXIS 102308 (S.D.N.Y July 18, 2013) (Stein, J.).

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US PATENTS ON ORIGINAL OXYCONTIN

The 1996-2010 editions of the FDA Approved Drug Products with Therapeutic Equivalence Evaluations (a.k.a. the Orange Book) listed 6 OxyContin patents:

4,861,598
4,970,075
5,266,331
5,508,042
5,549,912
5,656,295

US PATENTS ON REFORMULATED OXYCONTIN

The 2011-2025 editions of the Orange bookand its supplements listed a cumulative total of 33 patents (including 4 patents not owned by Purdue, as indicated):

5508042
6488963
7674799
7674800
7683072
7776314 (Gruenenthal)
8114383 (Gruenenthal)
8309060 (Gruenenthal)
8337888
8808741
8894987
8894988
9060976
9073933
9492389
9492391
9492392
9492393
9522919
9675610
9763933
9770416
9775808
10130591 (Gruenenthal)
10369109
10407434
10675278
10696684
11,304,908
11,304,909
11,964,056
12,060,361
12,246,094
12,280,152

Additional Purdue-owned patents relevant to opioids, but not in the Orange Book:

7,129,248
8,821,929
9,693,961
9,763,886

TABLE OF TRADEMARKS

US 'OXYCONTIN' TRADEMARKS (WORD MARKS)

74339006
75069553

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ENDNOTES

[i] Other justifications include invoking a natural right to (intellectual) property, but this is less accepted within juridical discussions of patents (Machlup and Penrose, 1950).

[ii] '912 patent, col. 3, ll. 34-41. Claim 1 of the '912 patent shows the composition claims, covering a controlled release oxycodone formulation for oral administration. Claim 1 of the '042 patent shows the method claims for reducing the range in daily doses required to control pain.

[iii] *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, No. 00-CV-8029, 2004 WL 26523 (S.D.N.Y. Jan. 5, 2004) (unreported). Quote reported in Harris (2004).

[iv] 'Endo Pharmaceuticals Announces Settlement of Oxycontin Patent Case' (Aug 28 2006) - https://www.sec.gov/Archives/edgar/data/1100962/000134100406002398/exhibit99_2.htm

[v] *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, 438 F.3d 1123, 1131 (Fed. Cir. 2006).

[vi] Purdue Pharma, FDA Application summary: Oxycodone hydrochloride controlled release tablets (OxyContin tablets). (December 6, 1995) - https://www.accessdata.fda.gov/drugsatfda_docs/nda/96/020553s002.pdf

[vii] See e.g. a notorious paper by Portenoy and Foley (1986).

[viii] FDA, 'Purdue Pharma L.P.; Withdrawal of Approval of a New Drug Application for Oxycontin - A Notice by the Food and Drug Administration 08/07/2013' 78 FR 48177 - https://www.federalregister.gov/documents/2013/08/07/2013-18694/purdue-pharma-lp-withdrawal-of-approval-of-a-new-drug-application-for-oxycontin#:~:text=On%20April%2018%2C%202013%2C%20FDA,effectiveness%20(78%20FR%2023273).

[ix] Extract from Keefe (2021) at 749 (e-book edition).

[x] 'Purdue and Amneal OxyContin clash ends' *Life Sciences Review* (15 August 2018) - https://www.lifesciencesipreview.com/news/purdue-and-amneal-oxycontin-clash-ends-3057

[xi] United States Senate Health, Education, Labor and Pensions Committee, Bernard Sanders, Chair Majority Staff Report, 'Public Investment, Private Greed' (June 12, 2023) - https://www.sanders.senate.gov/wp-content/uploads/Public-Medicines-Report-updated.pdf