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

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

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Abstract: In this article I evaluate the socio-legal 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 focus 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 undertake the first substantive examination of OxyContin from an IP law perspective, exploring its trajectory from conception to market, considering what lessons can be learned for IP theory and practice. Overall, I contribute a novel theoretical approach, examining patented pharmaceuticals as products of industrialised hope, while evaluating a practical case study of one such commodity, OxyContin. I conclude that the case of OxyContin highlights several problems inherent to the current system, including misaligned incentives, inadequate patent examination, and insufficient regulation.

Keywords: Patents, regulation, medicines, trademarks, commodification

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INTRODUCTION

There is no innate pharmaceutical object that precedes its socialisation. 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 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). Inceptive to the socio-legal ordering of new drugs is the patent system, with vital subsequent factors including regulatory approval and branded marketing. In this article I evaluate this 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 focus 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.

The opioid epidemic 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. Indeed, 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 Pharma L.P.* (2024)); and 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 this article I undertake the first substantive examination of OxyContin from an IP law perspective, exploring its trajectory from conception to market, and considering what lessons can be learned for IP theory and practice.

In undertaking this analysis, 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 analysis 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.[1] 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; 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.

On the first justificatory theme, I draw on the work of Riles (2005; 2011; 2016) to develop the concept of industrialised hope, focusing on the way legal frameworks stabilise technological uncertainty via bureaucratic documentation and market ordering. The hope embedded in the patent system can be described as 'industrialised' because it systematises the journey of an invention from aspirational idea to mass market commodity to financial asset. I historicise this by reference to the modern patent system's emergence in the 18th and 19th centuries as an instrument of the industrial revolution (Pottage, 2020). I take account of the accompanying utilitarian belief that the progress of knowledge would create welfare-enhancing inventions such as pharmaceuticals (Jefferson, 1803; Bentham, 1843). Taking this forward to the present day, I note that the industrialised hope of the patent system valorises an individualist mode of production that rewards private interests.

Focusing on the pharma sector, I evaluate the outputs of industrialised hope, sub-dividing them into two possibilities: products of genuine hope and of false hope. Genuine hope is the spur of many inventions. However, if legitimate risks are ignored or minimised, this hope can become essentially speculative, even false (Fleck, 2021). I position OxyContin as the latest in a long line of opiate and opioid products fabricated as panaceas by the pharmaceutical industry, offering the false hope of a low-risk drug to patients suffering pain, resulting instead in a dystopia of mass addiction.

Turning to the second theme, I evaluate patent incentives as a means to operationalise industrialised hope. I survey the literature on patents as market commodities and financial assets to demonstrate that the incentive effect of patents operates narrowly to encourage the development of certain commodities rather than others. I note that tenets of market economics, including incentives, should not be seen as 'naturally' occurring because to function they require non-market, governmental institutions (Polanyi, 1944). In this context, I evaluate how the market for new drugs relies on state regulation, including by patent offices.

I develop the idea of industrialised hope further by going beyond patenting, to two further legal arenas 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. On regulation, once a

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

medicine is approved the FDA label indicates what uses it can be marketed for, whether broad or narrow, as well as any risks or side effects. Approval enables marketing and branding, whereby the trademark system facilitates the projection of brand fictions – hopeful qualities, such as vigour and vitality – onto the drug (McDonagh, 2015). I note that this combination of regulatory approval and aspirational brand fictions is often key to consumer engagement in the modern pharmaceutical industry (Temin, 1979; Dutfield, 2020). It is the interplay, and overlap, of these three factors – patents, regulatory approval and trade marks – that enables market-ordered drug development.

Moving to the OxyContin case study, I investigate the extent to which this drug emerged as a product of industrialised hope. 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). I show that it is likely the key OxyContin patents should not have been granted by the PTO, due to doubts about OxyContin's 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). Meanwhile, I show that the FDA approved OxyContin in part due to a credulous approach to the efficacy claims of its patented formula (Vertinsky, 2021). In fact, OxyContin offered only false hope. Having undertaken theoretical and doctrinal analysis of the process of commodifying a pharmaceutical product (OxyContin) via IP, I argue that 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).

Ultimately, this article contributes a theoretical approach that examines patented pharmaceuticals as products of industrialised hope, while evaluating a practical case study of one such commodity, OxyContin. I conclude that rather than being an aberration, the case of OxyContin highlights systemic flaws and enduring problems inherent to the current system, including misaligned incentives, inadequate patent examination, and insufficient regulation. I consider whether the legal framework can be reformed via a Polanyian counter movement to enable industrialised hope to work more positively.

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 individualist 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 in individualist, market-based incentives can be distinguished from the 'sense' of hope that legal adjudication can offer via the right to hope (for a better life), as described by Trotter (2024).

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 inure to the benefit of the general public (Jefferson, 1803), 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, helping to shape the directions of path-breaking R&D and acts of 'creative destruction' (Schumpeter, 1939). Essential to this is the idea that inventors can achieve gains and abate risks that benighted prior generations of researchers and physicians. The structuring effect of industrialised hope is 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. The law simply states that patents are granted over inventions that can show utility, novelty, and non-obviousness (inventiveness) (35 U.S.C. §§ 101-103). Doctrinal issues are evaluated, such as whether isolated human DNA should be patentable, as in the famous US Supreme Court ruling in *Myriad* (2013), but not the question of overall social welfare. In other words, there is no methodical requirement that an invention ought to be shown to be inherently beneficial 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 may be one such scenario. Prior to examining the specific case of OxyContin, 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 R&D

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.

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 alkaloids, synthesising the resulting substance and naming it '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 a new 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 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 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 (1803) 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; Merges, 2011; 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 US pharmaceutical marketplace to incentivise the development of certain commodities rather than others. First, to prepare the groundwork for the case study, I must 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, 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.

THE HYBRIDITY OF THE PATENT COMMODITY

The above describes the patenting process, whereby the scientific output is transformed into a protected invention, laying the groundwork for its entry into the market. It is notable that public-private hybridity is built into this system. State patent offices help to create a private market order; yet, the legal recognition of the invention is reliant on iterative generations of public knowledge. IP scholars Peukert (2018) and Cohen (2020) take this forward, referring to the work of Polanyi (1944) to explore the fluidity between IP ordering and non-market regimes. A point 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 similarly explain that market commodities tend to be reliant on non-commodified institutions and forms of knowledge (Jessop, 2007; Grabher and König, 2020; Özveren and Gürpinar, 2024). Later on I return to Polanyi and explore whether a key Polanyian concept – the counter-movement – could help to frame reform of the patent system.

Prior to the OxyContin case study, it is necessary to go one step further – to explore how the *ex ante* incentives of the patent system interact with the idiosyncrasies of the US healthcare market to produce certain types of pharmaceutical commodity rather than others.

PHARMACEUTICALS AS COMMODITIES – ADVERTISING AND PRICING

The market for healthcare products differs from country to country. When compared to its OECD peers, the US follows a strongly market-led, rather than a socialised or state-led approach. A key outlying factor is that in the US medicines are marketed both 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 rights to negotiate the price of medicines bought via the state-run Medicare and Medicaid (Rome, et al., 2023). This means that that private pharmaceutical companies have near-untrammelled 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, investment in drug development is taken in hope of beating the odds – 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 (Tulum and Lazonick, 2019; Dosi, Palagi, Roventini, and Russo, 2023; Roy, 2023). Hence, the US healthcare market is increasingly financialised. This resonates with Riles' work (2011) on the derivatives market, noting how future possibilities are priced and exchanged. With financialisation the worth of an anticipated product of industrialised hope becomes quantifiable – its value shifting in line with market dynamics.

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 in 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 such a patented blockbuster can benefit via direct revenue from sales; and, if publicly listed, via the boosting of share price, including via 'buy backs', a controversial tactic that can divert funds away from R&D (Schwartz, 2021). Even a private, family-controlled firm such as Purdue was highly influenced by perceptions of asset value (Keefe, 2021).

Critically, 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 hybridity of public-private R&D can be productive. Nonetheless, given that the industrial 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 patented, firms aim to 'hop' doctors and patients from the

old formula onto the re-commodified version (product hopping), thus maintaining exclusivity and hampering generic price competition (Gurgula, 2020). This kind of patenting behaviour relies on 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 35 years of effective market exclusivity rather than 20 (Gibbons, 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 Sampar, 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). In this way, regulatory exclusivities and trademarks have become ever more crucial to the commodification of prescription drugs.

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. Code § 355). This requires producers to provide data, including details on drug chemistry, manufacturing, pharmacology, and results of preclinical and clinical studies. Drugs cannot be put on the market without authorisation, but gaining FDA approval also critical to pharmaceutical firms for two additional reasons: first, regulatory approval reassures doctors and patients, paving the way for mass marketing campaigns; and 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-trade mark 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 e.g. Purdue, product names e.g. OxyContin, and specific logos, colour schemes and slogans.

The use of trademarks in the pharmaceutical industry goes back to the 19th century, including the case of Bayer's Heroin, discussed above (Dutfield, 2020). The use of 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; Applebaum, 2009). 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 (i) patents can incentivise the commodification of an invention that may only offer false hope, while (ii) regulatory approval and (iii) 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 early 20th century heroin prescription debacle, the FDA only authorised limited use 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 patent 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. It is possible that Purdue had an initial intention that Oxycontin could 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. I now turn to my examination of the relevant patents, FDA filings, and related litigation, which indicate 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, FDA FILINGS AND PATENT 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 Co. v. Teleflex Inc.*, 550 U.S. 398 (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 US PTO reveals that this was an unsupported, suppositional 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.[2]

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 Pharma L.P. v. Endo* (2004)). Endo filed an Abbreviated New Drug Application (ANDA) to allow it to sell a bioequivalent version of OxyContin under the Hatch-Watchman Act (1984), the primary US law which facilitates generic competition in pharmaceuticals.

[2] '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.

Purdue's '912, '295, and '042 patents stood in Endo's way. In the United States District Court for the Southern District of New York 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 Pharma L.P. 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 PTO examiner to reverse this decision by emphasising the firm's 'surprising discovery' of pain-relief efficiency (*Purdue Pharma L.P. 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 Pharma L.P. 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.'[3]

An initial appeal at the United States Court of Appeals for the Federal Circuit in 2005 upheld this ruling (*Purdue Pharma L.P. 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 Pharma L.P. 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.[4] Notably, even though Purdue won the 2006 appeal on a technicality, that same appeal judgment contains a scathing indictment of Purdue's behaviour:

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[3] *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, No. 00-CV-8029, 2004 WL 26523 (S.D.N.Y. Jan. 5, 2004) (unreported) at 24. Quote reported in G. Harris, 'Judge Says Maker of OxyContin Misled Officials To Win Patents' NY Times (Jan. 6, 2004).

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

> 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.[5]

ANALYSIS OF THE EX ANTE PATENT INCENTIVES

If we return to the theme of industrialised hope, we can observe how the governmental 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 troubling that the US PTO granted the three dubious patents. However, this is not entirely surprising given the longstanding problem of inadequate patent examination (Dutfield, 2017). 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 case shows that litigation does not always resolve the conundrum of speculative or 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 LABEL, THE OXYCONTIN TRADEMARK AND MISLEADING MARKETING MATERIALS

Due to widespread knowledge about the addictive nature of morphine, the FDA had only given a narrow approval to Purdue's MS Contin, restricting sales to a subset 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,

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

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.[6] 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).[7] Purdue's own trials only studied short-term usage (Herder et al., 2022).

Despite this, 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, which indicated it was safe for wide usage, stating that "…'addiction' to opioids legitimately used in the management of pain is very rare" (OxyContin Package Insert, 1997). That the FDA acquiesced to this label was key to the marketing of OxyContin as a safe pain treatment for transitory ailments (Parker and Hansen, 2022). Despite only offering false hope, Purdue's product could now enter the

[6] 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

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

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 branding. 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 US PTO, and utilised 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 to direct marketing, 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 by the US Joint Commission on the Accreditation of Healthcare Organizations in 2001 (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. Hundreds 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 (Keefe, 2021). 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 controversial 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'.[8] 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

[8] 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).

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 attempt 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'.[9]

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 – '799, '800, '072 and '383 – 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 Pharma L.P. v. Teva Pharma., USA, Inc. (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 Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1345 (Fed. Cir. 2016)). A contemporaneous case (*Purdue Pharma L.P. v. Ranbaxy Inc.*, (2013)) ended in a settlement.

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 (*Purdue Pharma L.P. v. Amneal Pharms.* (2015)). Purdue appealed and prior to the appeal hearing, it agreed a settlement with Amneal.[10] As recently as 2023, in *Purdue Pharma L.P. v. Accord Healthcare* (2023), the US District Court for the District of Delaware held five Purdue patents were invalid as obvious under 35 U.S.C. § 103 (9,763,933, 9,775,808, 9,763,886, 9,073,933 and 9,522,919). This was upheld on appeal (*Purdue Pharma L.P. v. Accord Healthcare* (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, in 2020 Purdue eventually 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'y Opiate Litig.*, 290 F.Supp.3d 1375 (J.P.M.L. 2017)). After the bankruptcy filing, a number of pending patent disputes were terminated before trial, such as *Purdue Pharma L.P. v. Intellipharmaceutics* (filed in 2017, terminated in 2020). At time

[9] Extract from Keefe (2021) at 749 (e-book edition).
[10] 'Purdue and Amneal OxyContin clash ends' *Life Sciences Review* (15 August 2018) - https://www.lifesciencesipreview.com/news/purdue-and-amneal-oxycontin-clash-ends-3057

of writing the legal matters of liability arising from Purdue's bankruptcy have yet to be finalised (*Harrington v Purdue Pharma L.P.* (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. 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). Rather than an aberration, Purdue's actions appear to be in line with the logic of the market, 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.

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 aimed at moderating IP protections, with a key aspect being a shift away from market incentives towards public goals. What specific reforms might this consist of? Although an all-encompassing approach to reform is beyond the scope of this paper, by taking forward the idea of a shift towards the public, 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 it is possible these suggestions may open up a space for reflections, and future research, 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 to industrialised hope – its potential for not just genuine, but also false, hope – that opened it up to this exploitation? This brings to mind the work of Lauren Berlant, who defined the curious condition in which something we desire can become an obstacle to our flourishing i.e. an attachment that promises satisfaction but delivers disappointment, precarity, or harm (Berlant, 2011). The term Berlant used to describe this – 'cruel optimism' – has substantial affinity with false hope. On this, 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. A key point is that when a patent is granted, it all too easy to assume that the patented invention itself must be useful. Thus, patent law contributes to myth-making: 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 to the system.

More critically, is a 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.

At a deep level the case study also shows that, despite their differing rationales, there can be very little daylight between the patent and trademark systems. The combination of the patent examination and FDA approval process is supposed to ensure the scientific integrity of health commodities and protect the public. Yet, the case demonstrates a convergence between the regimes – with patents (driven by hope) ultimately functioning more like trademarks, in that the patent system incentivises game-changing 'miracle drugs' but lacks the resources to ensure the pursued science is more than fictitious. Analysis of the 2004 Purdue litigation shows that the patents were granted 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 – i.e. a vision ultimately as empty as a company's trademark slogan. Put simply, in the OxyContin case the

market drivers of industrialised hope rendered the patents as 'fictitious' as brands. If the line between hopeful patents and constructed brands can be so thin and porous, it begs the question: in the end, is the patent system really all that different from the trademark system?

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 medicines. This gives urgency to ongoing attempts, sponsored by the US Senate, to deal with the misaligned incentives of the patent system by boosting incentive options other than patents, such as enhanced government funding and prizes aimed at stimulating path-breaking R&D directed towards public needs.[11]

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 eventual 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 patents have been made at PTAB, such as in *Collegium Pharm., Inc. v. Purdue Pharma* (2021) which invalidated the '961 patent. Yet, even the post-2012 system allows parties to settle, which can keep weak patents on the register, indicating that persistent power dynamics may undercut reform efforts.

Moreover, the sheer volume of granted patents means post-grant review cannot eliminate all problems of weak examination. Evergreening remains an issue. Here, one proposal for reform is the idea that a drug should receive only one period of 20-year patent exclusivity, disallowing the extension of incremental monopolies on existing drugs (Feldman, 2018). Other scholars argue for raising patentability standards to discourage this tactic (Dutfield, 2017; Sinha, 2024).

On patentability standards, it is worth reiterating that despite it being an *a priori* assumption in the utilitarian theory of patents that inventions should be useful or

[11] 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

beneficial to society, in patent law there is no methodical requirement that this should be demonstrated before grant. This raises the question: should substantive patentability standards be raised? For example, should the law be reformed in this respect to examine not just utility, novelty, and non-obviousness, but also social benefit? On this, some scholars argue that the patent application process should differentiate between levels of protection, scope, and term depending on the pharmaceutical's potential societal benefit (Buccafusco and Masur, 2021). This could include patent-term extensions for welfare-enhancing patents and, by contrast, invalidation of patents, or shortening of patent term, for inventions that do not create public benefit. A full analysis of these reform suggestions is beyond this article, but they are worth further investigation, even with the caveat that is may not always be possible to predict welfare effects at the patent application stage.

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 give broad approval to an opioid (Häuser, 2021). This 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, the legal fictions of 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 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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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 book listed a total of 32 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

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

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

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74339006
75069553

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