Patents and fundamental rights in U.S. law: Excessive drug pricing as an instance of Unfair Competition

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Abstract

The United States suffers from a "resource curse" of essential medicines. It has great industrial and commercial capacity to meet the essential medicine needs of its citizens, yet by and large, *average* consumers struggle to obtain the drugs on which they depend to maintain a subsistence level of health due to the exorbitant drug pricing. As a result, they face a dilemma between paying the prices charged for access to the drugs or continued ill health. I believe that denying access to essential medicines on reasonable terms constitutes a form of injury to them. This thesis conceives of restrictive access's injurious effects on consumers as a legal harm and sees its lack of recognition in law as an explanation for the problem's continued existence. Traditional legal restrictions on patentee conduct, based on principles of patent misuse and antitrust, are unable to properly address this injury. While this might suggest a need for legal reform, there exists another solution almost entirely overlooked by commentators. This solution is the law of unfair competition, specifically its Unfairness Doctrine. In this thesis, I argue that the Unfairness Doctrine supports a tort-based cause of action against those who rely on patent rights to exclude consumers from access to essential medicines on reasonable terms. As such exclusion causes harm to consumers' autonomy and bodily integrity, I further argue that even if the Unfairness Doctrine does not apply, the nature of this harm, combined with the duty of the state to protect the fundamental rights of its citizens, supports legal intervention to prevent the excessive pricing of essential medicines.

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Introduction

The United States suffers from a "resource curse" of essential medicines. Essential medicines are pharmaceutical products that satisfy the primary health care needs of a given population. According to the World Health Organization, well-functioning health care systems are not only required to ensure that essential medicines are "available…at all times in adequate amounts," they are also to be "at a price the individual and the community can afford".[1] The U.S. has great industrial and commercial capacity to meet the needs of its citizens, yet by and large, *average* consumers struggle to obtain the drugs on which they depend to maintain a subsistence level of health due to exorbitant drug pricing. Brand name drugs have unusually high prices attached to them in the U.S.. Prices of these drugs can be anywhere from 80 to 150 percent higher in the U.S. than elsewhere.[2] The result is that a large number of consumers whose maintenance or improvement of health depends on access face a dilemma between paying the exorbitant prices charged for access to the drugs or continued ill health. I believe that denying access to essential medicines on reasonable terms constitutes a form of injury to consumers. Consumers are injured because their decision to buy or not buy the medicine is largely driven by their reliance on the essential medicine to subsist. These consumers therefore lack meaningful freedom to opt out of buying the highly-priced drug as that decision necessarily brings about health injuries.

[1] World Health Organization, 'Essential Medicines' (2020).

[2] Papanicolas, Irene; Woskie, Liana R.; Jha, Ashish K. 'Health Care Spending in the United States and Other High-Income Countries' (2018) 319 JAMA 1024.

The absence of price cap laws[3], the government's weak price negotiation mechanisms[4], and the absence of legal sanctions create an environment in which such high pricing has no legal repercussion. I believe that the lack of legal sanctions over high pricing of essential medicines is also largely a consequence of the stringent intellectual property protection afforded to patent rights in the pharmaceutical industry. As such, the rights to profit off of one's patented technology, irrespective of its costs on society, has practically been accepted as a corollary of the patent right itself. Industry representatives often argue that strong intellectual property protection is not only required as a matter of constitutional right but is also necessary to support long-term innovation. This argument relies on the assertion that the high prices are justified by the need to recuperate the costs of research and development. However, the essential medicines market can "bear" almost any price because private and public insurance programs generally absorb the costs of expensive pharmaceuticals. Others have argued that essential drugs markets are efficient on the basis of rising demand for prescriptions drugs[5] under the assumption that market failures generally arise when the market is no longer able to distribute the goods to those who value them the most (economically). However, the low price elasticity of demand for essential medicines stems directly from consumers' extreme reliance on the drugs to subsist[6], and is therefore rather ineffective as a measure of efficiency for the essential medicines market. Those who rely on public or private insurance will likewise continue to purchase the medicines because it is necessary for their

[3] 'Cost Control: Drug Pricing Policies around the World' (*Pharmaceutical Technology*, 2018).

[4] Juliette Cubanski and others, 'What's the Latest on Medicare Drug Price Negotiations?' (*KFF*, 2019).

[5] Ernst R Berndt, 'The U.S. Pharmaceutical Industry: Why Major Growth In Times Of Cost Containment?' (2001) 20 Health Affairs 100.

[6] Kai Yeung et al., 'Price Elasticities of Pharmaceuticals in a Value-Based-Formulary Setting' (2016) 27 Health Economics. (Price elasticity of demand is a measure of the responsiveness in the demand for a product with respect to its price under equality of conditions, such as constant income. A low elasticity of demand implies that the absolute value of the ratio between the proportional change in the quantity of the good demanded and the proportional change in the good's price is less than 1. Estimates from the economics literature confirm this characteristic of prescription drugs in a variety of settings.)

subsistence. The view that the pharmaceutical industry as a whole is efficient is inaccurate as excessive drug prices constitute the single biggest category of healthcare overspending in the U.S., well beyond high administrative costs or excessive use of CT and MRI scans. It also continues to rise over time.[7]

While monopoly pricing does not directly involve the use of patent rights, it is, loosely speaking, a consequence of those rights.[8] Patent rights create temporary monopolies over the patented technologies. The absence of competition not only emboldens patentees to charge a premium price for their product, it also creates the conditions that enable monopoly overcharges in the first place. In this context, high pricing of essential medicines can be understood as a function of patent rights. In addition, though patent-holding companies will often exploit the opportunities afforded to them by these rights for the better, many also use them to further restrict competition beyond the scope permitted by the patent rights, thereby creating an environment that is not only conducive to but also perpetuates the high pricing of essential medicines. This has been achieved through controversial patent practices like evergreening and the creation of patent thickets.[9] Reverse payment has also been linked to drug price increases.[10] [11] While many of those patent practices are not expressly authorized by any patent legislation, they also have not been outlawed.[12]

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[7] Ezekiel J Emanuel, 'Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up' [2019] *The Atlantic*.

[8] From here on out, the term "monopoly pricing" will be used interchangeably with "high pricing" of essential medicines.

[9] Stu Woolman, Elliot Fishman and Michael Fisher, 'Evidence of Patent Thickets in Complex Biopharmaceutical Technologies' (2013) 53 IDEA: The Intellectual Property Law Review.

[10] C Scott Hemphill, 'Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem' (2006) 81 New York University Law Review, 1553, 1583-86.

[11] Herbert Hovenkamp, Mark Janis and Mark Lemley, 'Anticompetitive Settlement of Intellectual Property Disputes' (2003) 87 Minnesota Law Review 1754–56.

[12] John R Schacht, Wendy H.; Thomas, 'The Hatch-Waxman Act: Legislative Changes in the 108th Congress Affecting Pharmaceutical Patents'.

These practices undoubtedly help create the competitive environment for high pricing, but they are not *the* culprit that directly restricts consumer access to essential medicines. The culprit, one might call it, is high pricing itself. With that said, while it is important that we do not confuse corporate conduct like high pricing with the explicit use of patent rights, scrutinizing how existing legal remedies deal with potentially injurious patent use nevertheless plays an important part in our understanding of the environment in which monopoly pricing of essential medicines takes place. Moving forward, I refer to high pricing of essential medicine as a form of patentee conduct or an exercise of patentee power. By patentee conduct, I mean any method of competition that is largely made possible in virtue of the actor's patent rights. Injurious patentee conduct can then be defined to include any method of business, which are backed by the power of patent rights, that causes significant negative externalities on its consumer base.

High pricing of essential medicines, as a form of injurious patentee conduct, negatively affects consumers' health by depriving consumers of reasonable access to medicines on which their subsistence depends and exploits their vulnerability by relying on their inability to refuse access to medicines on unreasonable terms owing to their health dependency. Traditionally, antitrust law and the judicially created doctrine of patent misuse have been used to regulate patentee conduct. Patent misuse is raised as a defense against infringement claims when the patentee's conduct allegedly exceeds its sanctioned scope. Antitrust law has been used to regulate patentee conduct where its exercise of patent rights causes harm to competition. Harm to consumer welfare as a result of increased pricing has been treated with antitrust analysis because monopoly pricing is generally seen as a rite of passage for patentees. Therefore, when a patent practice is said to cause harm to consumer welfare, the analysis has largely depended on showing of unlawful

expansion of the patent right or conduct that causes harm to competition as proxies for addressing price increases. We may aspire to eventually outlaw practices like evergreening and pay-for-delay settlements as antitrust violations or patent misuses. For the time being, however, antitrust law and the patent misuse doctrine's respective purpose and procedure present inherent obstacles to solving the restrictive access problem (Section 2). These two laws lack the concepts and principles to directly tackle the culprit of restrictive access of essential medicines – i.e. high pricing. I believe adjudication over the act of high pricing does not require showing that there is an undue expansion of patent monopoly or violation of antitrust laws. While anticompetitive patent practices can encourage and allow patentees to increase prices, the act of high pricing is independent of patent power and alone injures consumers, and therefore should be scrutinized in isolation. To address the restrictive access problem head on, we need to free the notion of consumer harm from the patent-antitrust nexus, which regards harm to consumer welfare as a consequence of harm to competition. Though many patent practices are anticompetitive and thereby harm consumer welfare, there are also many methods of competition that cause substantial social harm without amounting to any antitrust violation. This should serve as a clue that antitrust analysis is not the only tool when it comes to allegedly anticompetitive patent practices.

The pricing of most market goods, no matter how high, is not a crime. There is no legal reason for which restrictive access to market goods should suggest that the pricing conduct ought to be presumptively unlawful. This is because an expensive product, relative to average earning capacity, does not cause harm to those who cannot or choose not to purchase it in virtue of its price. The essential medicines market ought to be an exception because restricted access in that case *does* cause harm to consumers. The context of the market – which accounts for the purpose of the

product, the level of dependency on which the average consumer has of the product, and so on – must be considered in determining the law's degree of tolerance for certain pricing conduct. In order to target patentee behavior in the essential medicines market, the cause of action must be based on the injurious capacity and effects of their pricing conduct *alone*. Consumer harm must be linked to high pricing without mediation. Under the assumption that patent grants, as stimulants of innovation, are supposed to produce a net benefit in society, the scale at which the general public cannot access the benefits of innovation should raise serious concern regarding the lawfulness of the patentee conduct that put these barriers in place.

There are many co-dependent explanations for the drug access problem - e.g. regulatory failure due to lax patent enforcement practices, lack of direct pricing control mechanisms. My explanation conceives of restrictive access's injurious effects on consumers as a legal harm and sees its lack of recognition in law as an explanation for the problem's continued existence. I view patent practices that embolden high pricing of essential medicines (particularly those that have anticompetitive effects, such as reverse payments) not as direct causes of these pricing practices, but as structural roadblocks that have created an environment in which injurious patentee conduct can take place without legal sanctions. The background of my thesis is thus concerned with two sets of questions:

First, how can we show that patentee conduct that harms, specifically high pricing of essential medicine, is wrongful? There are two main ways: First, we can argue that (a) high pricing of essential goods violates patent law itself. Besides whether said high pricing directly contravenes the patent statutes, an important question here is whether high pricing of the patented technology

subverts the public function of the patent system as a whole (Section 1). Alternatively, we can (b) point to laws and principles outside of patent law (Section 2). Here, the question concerns whether the conduct, if not expressly authorized by the Patent Act, is an instance of patent misuse, violates antitrust law, or violates some other law to which patentee behavior may be subject. The exercise of all rights is subject to background laws. As such, no property right, however strong the protection afforded to it is, can be used to commit a tort. The controversy does not lie in the claim that all private conduct is subject to background laws aimed at harm prevention. Rather, the practical implications of that claim, as far as it can limit patentees' freedom to price at will, could be disputed if restrictive access to essential medicines is not a legal injury. *It is therefore the foremost task of this thesis to establish the injuries-in-fact that result from restrictive access to essential medicines as injuries in the law.*

Second, when the market routinely fails its consumer base, should the state intervene? On what basis can it do so? There are two main ways to trigger legal intervention: we can either (c) show that the conduct is unlawful (which relies on (a) or (b) above) or (d) point to the consumer harm as a standalone justification for state intervention. I explore these two options in turn in Sections 3 and 4 respectively. In this paper, I do not endorse or propose any pricing regulations, nor do I look into solutions for expanding the government's price negotiation powers. I also do not argue that any patent practice that has been linked to price increases should be outlawed as either a form of patent misuse or antitrust violation. Rather, I focus on how we might use existing law to regulate or prohibit the high pricing of essential medicines directly. Given our premise that private conduct is subject to background laws aimed at harm prevention, *the goal is to find a cause of action against patentees in virtue of their conduct's injurious effects on consumers.* In keeping

with my view that the high pricing of essential medicines constitutes a form of threat to the average consumer's health, the ideal law would hold the harmful effects of high pricing on consumers as its foci and accordingly outlaw patentee conduct that creates such harms.

Whether legal intervention is justified and on what basis it is justified when patentee conduct harms consumers must be answered, or qualified, within two frameworks: the first concerns the status of patent rights protection and the second concerns the rights or interests of those harmed. (1) Any legal intervention that could plausibly encroach upon constitutionally mandated intellectual property rights must provide a compelling state interest in doing so. This is necessary because even though monopoly pricing does not make direct use of patent rights, justification of high prices often rely on a property rights defense that concerns patent holder's freedom to exercise their right within lawful means.[13] (2) On the other hand, the government is arguably also beholden to the obligation to protect the public from harm. Thus, in situations where the presumptively lawful use of patentee power restricts access to essential medicine and injures consumers as a result, there is a very real tension between patentees' freedom to exploit their rights and the public interest to access medicines essential to their health. When those interests routinely conflict, this ought to demand government attention as it suggests that the business ethics of innovating pharmaceutical companies are contrary to the prosocial goals of the patent system. With that said, justifying state intervention in the pharmaceutical industry is particularly difficult as the legislative and judicial bodies have historically endorsed strong intellectual property protection in their effort to further the goals of the Intellectual Property Clause (IP Clause). [14] With that in mind,

[13] See Ejan Mackaay, 'Economic Incentives in Markets for Information and Innovation' (1990) 13 Harvard Journal of Law & Public Policy. (These defenses can also be based on the incentive-based argument that taking away a patent holder's freedom to charge high prices effectively erases the economic incentives provided for by the right to exclude.)

[14] U.S. Const. art. I, § 8, cl. 8.

the right to exclude, and the wide freedom granted to patentees in the exercise of their right, is not absolute.[15] Legal mechanisms like government march-in rights (through the Bayh-Dole Act) and the Takings Clause under the Fifth Amendment should serve as constant reminders of that fact. The existence and purpose of these triggers suggests that the state is readily available to intervene so long as we give it a reason to – e.g. that public interest calls for it. Antitrust law and the patent misuse doctrine also serve as legal expressions of the state's desire to regulate patentee conduct in the name of market fairness.

As we saw, patent misuse is raised when the use of patent rights unduly expanded its sanctioned limits. Antitrust law has been used to regulate patentee conduct where their exercise of patent rights caused harm to competition. However, they lack the concepts and principles that allow them to directly deal with the culprit of restrictive access of essential medicines – i.e. high pricing. The law of unfair competition (UC) is rarely talked about as a way to regulate patentee conduct. The legislature has taken a step to resolve UC issues by writing the Federal Trade Commission Act (FTC Act) into law and courts have constructed the Unfairness Doctrine to support that end. I believe these laws and principles can provide the public with a tort-based cause of action in virtue of the business conduct's injurious effects on the public. Alternatively, we can base the motive to intervene either on an overriding public interest (e.g. in fair and reasonable access to essential medicines) or on the state's interest in protecting a fundamental right (e.g. the right to secure one's autonomy and bodily integrity, which is necessarily obstructed when one cannot access essential medicines due to their high prices) (Section 4). If we accept that the injury incurred when one cannot afford an essential medicine harms one's autonomy and bodily integrity,

[15] David Lametti, 'Laying Bare an Ethical Thread: From IP to Property to Private Law?' in Shyam Balganesh (ed), *Intellectual Property and the Common Law* (Cambridge University Press 2012) 356.

then the basis for state intervention can be independent of UC. Whichever approach we choose, restrictive access to essential medicines cannot be properly addressed without some form of state intervention for the simple reason that any patent practice or business conduct, so long as they have not been expressly outlawed, is a presumptively lawful exercise of the patentee's right to exclude.

Covid-19 and the Resurgence of Compulsory Licensing?

Covid-19 has spotlighted corporate practices that have the ability to constrict public access to essential health supplies. Recent attention afforded to the impediments faced by patients in accessing coronavirus treatments has largely focused on blunt instruments such as compulsory licensing or regulatory takings approaches. In the following section, I use the ongoing pandemic to showcase why legislations meant to stimulate competition or commandeer patent rights are not ideal as long-term solutions for the access problem. The most direct way to curb high pricing of essential medicines is to outlaw high pricing itself.

During national health emergencies, the federal government has triggered various legislations in order to stimulate generic drug competition before the expiry of the patent in order to lower drug prices. There are several mechanisms that aim at price control. A commonly referred to mechanism is "compulsory licensing," which suspends the monopoly effect of a patent and allows competing drug developers to produce and supply the product in question. Legislations that compel licensing are controversial and have rarely been used successfully. One of the oldest legislations designed to stimulate production of national supplies is the Defense Production Act (DPA) of 1950. It authorizes the federal government to compel firms to produce essential health

care supplies to stem the expansion of the crisis. This opens up competition which, in turn, is supposed to lead to lower prices. The law, notably, also allows the executive branch to actively set a price ceiling for essential drugs and supplies.[16] Besides scaling up manufacturing of health care supplies through the DPA, profiteering can also be curbed by triggering the Bayh-Dole Act. This law makes public the patent covering an essential technology so long as the government had a contributory role in the drug's research and development. Importantly, the Act grants the government the power to take possession of the license and offer it to another company if the private sector licensor is not taking steps to "alleviate health or safety needs".[17] A similar outcome can also be achieved by invoking the Takings Clause under the Fifth Amendment.[18] This is a type of eminent domain statute for physical property and has been applied to intellectual property by extension. In the pharmaceutical world, this authority has been threatened twice, but ultimately was not invoked because drug manufacturers agreed to lower prices.[19] Government power under these acts are theoretically powerful. However, they have not been exercised once in the past five petitions made to the National Institutes of Health. The Institute's response in every case has been that the drug's price does not interfere with its availability.[20]

With the 2020 Democratic presidential candidates campaigning on lowering drug prices, march-in rights are now back in focus as a remedy for price gouging in pharmaceuticals.

[16] Sarah Karlin-Smith, 'How the Drug Industry Got Its Way on the Coronavirus' *Politico* (5 March 2020)

[17] 35 U.S. Code § 200

[18] Hannah Brennan et al., 'A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health' (2017) 18 Yale Journal of Law and Technology.

[19] The first case was during the anthrax terror case of 2001, when Health and Human Services Secretary threatened to use section 1498 rights to allow for importation of generic ciprofloxacin. In response, Cipro maker Bayer agreed to a lower price.

[20] Francis S Collins, 'National Institute of Health Office of the Director Determination in the Case of Norvir Manufactured by Abbvie' (2013)

Pharmaceutical companies are setting prohibitive prices for drugs discovered with taxpayer support, the argument goes, which ought to spur the government to take possession of the patents covering technology they helped develop. Though efforts to invoke march-in rights have largely failed in the past, we are witnessing a resurgence of calls for direct government intervention to make treatments widely accessible in the context of the Covid-19 Pandemic. In March, the Trump administration issued an executive order classifying "health and medical resources necessary to respond to the spread of Covid-19" as subject to the authority granted by the DPA to prohibit corporate price profiteering.[21] [22] Though this seems like a promising attempt to expand accessibility of essential health supplies, industry interests run deep.[23]

The Covid-19 Pandemic has sparked renewed scrutiny of corporate practices that effectively constrict public access to essential drugs. Vehement public criticism of multinational corporations like Gilead Sciences' conduct[24] reveals a social and moral dimension of patentee power that are routinely downplayed in the discussion of the use of patent rights. The fact that pharmaceutical companies have free reign to set prices of patented drugs is not unique to global pandemics. It is the reality of a free market system that readily accepts the argument that a high profit margin is necessary to recuperate the costs of R&D and stimulate future innovation.[25] The

[21] The White House, 'Executive Order on Preventing Hoarding of Health and Medical Resources to Respond to the Spread of COVID-19' (2020).

[22] Karlin-Smith (n 16).

[23] For example, there is a provision in the initial $8.3 billion coronavirus spending bill, which was intended to provide financial support for vaccine research and development, that prevents the government from delaying the introduction of any drug to address the crisis *over affordability concerns.* This effectively shot down the bill's initial stipulation that any products purchased must meet federal acquisition guidance on fair and reasonable pricing. Industry lobbyists also successfully *blocked provisions that would threaten revocation of patent rights* for any vaccines or treatments that the government decides are priced unfairly.

[24] Katie Thomas, 'Gilead Withdraws Request for Special Orphan Status on Experimental Virus Treatment' *New York Times* (2020).

[25] Amy Kapczynski, 'The Right to Medicines in an Age of Neoliberalism' [2019] Humanity Journal.

resurgence of march-in rights proposals invites us to rethink solutions for the burden consumers bear to access treatment for common diseases such as HIV, type-II diabetes, chronic inflammatory diseases, and so on. These are health emergencies that plague the nation on a daily basis. The harsh reality that the average consumer is unable to afford the medicine he needs to subsist is fundamentally at odds with the criteria for a "well-functioning" health care system, as defined by the WHO. According to a 2018/9 report published by the International Federation of Health Plans, a prefilled carton of Humira[26] costs $2,246 in the United States, compared with $1,102 in Britain, and $881 in Switzerland. Without insurance, it can cost up to $5,500 for a 30-day supply, and prices only continue to increase.[27] [28] [29] If compulsory licensing and government taking of patents are serious considerations for (inter)national health emergencies, then something much less interventionist – i.e. a statute or judicial doctrine that outlaws patentee conduct in virtue of its capacity to cause harm – ought to be considered for opening up access to these essential medicines. Laws that recognize injurious patentee conduct as the basis of a cause of action for consumers are arguably less interventionist than compulsory licensing or regulatory takings approaches, as they do not attempt to take away or restrict the scope of a patent right.

Use of these legislations (the DPA, the Bayh-Dole Act, the Takings Clause) would undoubtedly open up competition in the short run. The question remains whether they are *sustainable* methods to solve the access problem. The logic behind compulsory licensing and

[26] The top-selling anti-inflammatory drug by AbbVie. This is used to treat chronic diseases ranging from rheumatoid arthritis, Crohn's Disease, and multiple sclerosis.

[27] Christopher Rowland, 'Why Price of Humira Keeps Rising despite FDA Approval of Generic Competition' (*The Washington Post*, 2020).

[28] Danny Hakim, 'Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher.' (*The New York Times*, 2018).

[29] Ana Santos Rutschman, 'Regulatory Malfunctions in the Drug Patent Ecosystem Regulatory Malfunctions in the Drug Patent Ecosystem' [2020] Saint Louis University School of Law Scholarship Commons, 28.

government takings of patent rights assumes that it is the patent and its associated rights that *directly* lead to higher prices. As such, they assume that mitigating the patentee's monopoly power will lower prices through competition. While this might be true to a certain extent, we must accept that, in theory, while high pricing is often enabled by the right to exclude, its exercise does not strictly depend on patent power. Further, because these instruments do not require the further belief that any patentee conduct that creates considerable consumer harm ought to be outlawed (or be subject to scrutiny at minimum), interventions like compulsory licenses leave open the possibility that consumer harm will only be addressed in the short term – that is, so long as the compulsory license is in effect.

I believe the fundamental issue with the access problem is that there is no liability-based relation between the patentee and the consumers on the one hand, and between the patentee and the government on the other to curb conduct that prevents access. Currently, it is exceedingly difficult to create such a relationship in law. I believe this is primarily because there is no consumer welfare provision in patent law that creates an obligation incumbent upon patent holders to refrain from conduct that are or could substantially restrict access to essential technologies. The rules of patent law are limited and therefore unable to address the externalities that flow from its existence. As patent statutes primarily set forth the requirements to obtain a patent and what patent rights are – that is, what powers they grant the patent holder – they lack an important limiting mechanism for when the use or exploitation of that power causes harm to those without comparable powers. Remedies for wrongdoing within patent law only exist in the form of injunctions against patent infringements, standing to challenge patent validity, and the like. This model reveals that the types of actors that could potentially suffer harm resulting from patent use, non-use, or misuse are largely

limited to patentees and competitors who wish to work the technology. In other words, the logic of patent law serves to further the goal of society-wide innovation by determining the rightful worker of the patented technology. This calculus leaves out an important benefactor of the innovation – i.e. the consumer base, specifically those who *depend* on the enjoyment of the technology to survive or maintain their health.

Roadmap

The lack of consumer welfare provision suggests that patent law is limited and therefore unable to address the externalities flowing from its existence. Therefore, we must to look outside of patent law to reign in harmful patentee conduct. Many patent practices can be made subject to antitrust scrutiny and penalized if a threat to competition is shown. Antitrust law enforcement is theoretically geared towards the promotion of consumer welfare but, as we will come to see, consumer injury as a legal harm can only be established within this framework as an outgrowth of harm to competition. Furthermore, not all business conduct that causes consumer harm is or can be shown to be anticompetitive in the antitrust sense. This is especially true when the defendant's conduct is said to be within his patent right – i.e. that high pricing of essential medicine is a natural and lawful consequence of the patent monopoly. A liability-based relationship between the patentees and consumers must be more closely linked than what is currently stipulated by the rules of antitrust law. This can either be done by underwriting consumer interests (e.g. equitable access to the technology) into the concept of public interest in patent law or by calling upon another body of law.

Thus, an important reason why the conditions for wide(r) access to essential medicines are difficult to create is that the law has thus far not made it illegal, or at least sanctionable, to restrict access through high pricing (to the extent that it causes substantial harm). The core task of my thesis aims to find an existing law that recognizes high pricing for essential medicines as a legal wrong in virtue of its injurious effects on consumers. To do so:

(i) First, I explain why consumer injury resulting from high pricing of essential medicines does not give rise to a cause of action against patent holders in the current environment. What stands in the way of viewing patent uses that harm consumers as a legal wrong? Is this harm cognizable under patent law? If not, why? The key question here is whether the negative externalities from patent use or patentee conduct are justifiable under the patent system's public function. The answer to this question remains elusive.[30] (Section 1)

(ii) Second, I look to the available remedies outside of patent law (Section 2). Traditionally, antitrust law and the judicially created doctrine of patent misuse have been used to regulate patentee conduct. Patent misuse is raised when the use of patent rights unduly expanded its sanctioned limits. Antitrust law has been used to regulate patentee conduct where their exercise of patent rights undermined competition. Even though antitrust law enforcement is theoretically geared towards the promotion of consumer welfare, I argue that its procedural requirements ultimately thwart efforts to protect consumers.

[30] Srividhya Ragavan, 'Correlative Obligation in Patent Law: The Role of Public Good in Defining the Limits of Patent Exclusivity' (2016) 6 *NYU Journal of Intellectual Property & Entertainment Law*, 79.

(iii) Third, I discuss how we may fill this gap in the law by basing the cause of action against patentees on the law of UC (Section 3). The law of UC has been under-utilized as an alternate to antitrust law in regulating patentee conduct. I argue that the law of UC can more suitably regulate injurious use of patent power and remedy the corresponding injuries. Specifically, I believe the concepts of harm in the Unfairness Doctrine can capture consumer injury that result from restrictive access to essential medicines due to high pricing. In Section 3B, I supplement the concept of harm from the Unfairness Doctrine with the Razian idea of harm as injury to autonomy. This allows me to abstract away from tangible injuries and define the essence of the consequences of prohibitive pricing as a violation of consumers' autonomy and bodily integrity.

(iv) Lastly, I explore the possibility of harmed-based justifications for legal intervention that are not backed by statutory authority (Section 4). I argue that even if high pricing of essential medicines is not an unfair method of competition, the state can still find reason to intervene in patentees' decision to engage in prohibitive pricing because it has a duty to prevent harm when the conduct in question encroaches upon one's fundamental right – e.g. autonomy and bodily integrity. This follows from the point in Section 3B that even if one is not made worse off than before the purchase, a consumer can nevertheless be harmed due to the state failure to protect or improve its citizens' circumstances within its capacities – namely, by using its

powers to regulate patentee conduct when it infringes upon consumers' autonomy and bodily integrity.

Some might argue that attaching some form of tort liability to patentee conduct only targets the restrictive access problem axially, and that so long as reverse payments, evergreening, and patent thickets are permitted on the large, consumers will continue to suffer the consequences of these patent monopolies. This concern is present for any type of monopoly. Use of UC law to target patentee conduct – specifically high pricing of essential medicines – recognizes that pricing and patent practices are distinct issues. Currently, the right order in which the two issues should be addressed is far from clear. The thinking here is that targeting pricing first, independent of assessing the lawfulness of these enabling patent practices, makes the restrictive access problem much more manageable. In theory, firms in competition can continue to price highly (with or without overt collusion). This theoretical possibility suggests that insofar as restrictive access of essential medicines by way of pricing is not identified as a legal wrong, consumers will continue to receive the short end of the stick. Additionally, as showing of UC results in a cease-and-desist order, and not private damages recoveries as it is under antitrust law, the incentive for firms to settle with consumers should be mitigated. The largely regulatory nature of UC enforcement, I hope, will provide guidance toward a more humane pricing environment. The goal in establishing a liability-based relationship between patentee and consumers is to generate an obligation incumbent upon patentees to desist from the same pricing practices, as opposed to merely paying damages off. Moreover, by recognizing prohibitive pricing for essential medicines as a basis for cause of action in virtue of its injurious effects, the issue of consumer standing bears solely on proving harm in the manner as described by the law of UC. Then, harm resulting from the inability

to afford essential medicines can effectively rise to the level of a legal injury. As I mentioned earlier, a key reason why intervention methods like compulsory licensing and march-in rights claims might be ineffective in the long term is that their implementation is not geared towards harm prevention. Alternatively, should the relationship between patentee and its consumer base be tenuous, we shall find cause for state intervention on the basis of broader principles of harm that underly all areas of U.S. law. These two are independently viable, complementary solutions.

Chapter 1

Section 1. What Patent Rights Are & the Public Interest Justification

Even though monopoly pricing of essential medicines does not directly involve the use of patent rights, it is a consequence of the strength with which those rights have been protected. While it is important that we do not confuse corporate conduct like monopoly pricing with explicit use of patent rights, understanding the background in which patent rights function is important to seeing why consumers who are harmed by restrictive access to essential medicines might not find remedy in patent law itself. In the following discussion, I offer an explanation for why patentees are not liable for the consequences of high pricing by looking to patent use vis-à-vis the often narrowly interpreted public function of patents. The hope is that by seeing how the public interest justification of the patent system has been interpreted to mean public interest in increased innovation, and how most use of patent rights have been justified to that end, we begin to understand why the consumer interest in accessing the benefits of innovation might not be protected by patent law itself. If, however, the public function of patent rights is understood to include consumers' interest in accessing the benefits *of* innovation, then we might have a

foundation to claim that restrictive access due to high pricing, as an externality of certain patent practices, undermines the public function of the patent system.

For a patent use to violate patent law itself, it must at minimum undermine the purpose of the existence of the patent system – i.e. the public interest justification of the patent system. There are two gaps in the law and legal literature that prevents us from claiming that the general public's restricted access to the patented technology undermines the public interest of the patent system. First, without support that consumer interest is an important part of the public interest of the patent system, we cannot say why current enforcement of patent law seems to be undermining public interest in the first instance. Second and consequently, if consumer access to the patented technology is not part of what public benefit means for the patent system, then the negative externalities caused by certain patent uses cannot be meaningfully linked to patent conduct or the patentee in question. If this is the case, then we must to look outside of patent law to reign in harmful patentee conduct (discussed in sections 2 and 3). Below, I look to classical justifications provided for the existence of the patent system.

Though there is consensus that patent rights are the means to increased innovation, accounts generally differ in two ways. First, disagreement over what type of incentive the patent system provides split into those who think the system is primarily put in place to safeguard a property right to one's invention as a matter of *private* right as an end in itself, and those who think the grant of patent rights is a means to the public interest in technological advancement. [31] [32] While

[31] Lametti (n 15) 357.

[32] See generally Fritz Machlup, *The Production and Distribution of Knowledge in the United States* (Princeton University Press 1962).

the two views are not mutually-exclusive, they differ in their interpretation of the ultimate purpose of the patent grant. Second and relatedly, there is disagreement over what scholars think are the limits of patent rights.[33] These differences derive from a deeper disagreement over the appropriate interpretation of the "public interest" or "public benefit" of the patent system. For some, innovation and the dissemination of knowledge make up the public benefit itself. Under this conception, public interest may be served so long as patents continue to be granted, followed by open access to the technology after the patent's expiry. For others, public benefit requires diffuse populations aside from competitors to enjoy the technology. I believe that the intuition that certain patent practices can cause consumer injuries by restricting access to the technology is based on the latter belief that the patent system exists to serve a social function larger than cumulative innovation. In the following discussion, I unpack this intuition and offer a broader account of the public interest justification of the patent system that is able to account for the interests of the *general* public, which necessarily includes the consumer base of a patented essential technology.

Let us begin by looking at the source of the patent right. The IP Clause of the Constitution authorizes Congress to "promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[34] In creating the patent system, the government sought to advance two competing goals which, when balanced, aimed to promote scientific advancement for the benefit of society. Patent rights have generally been interpreted as property rights.[35] As an entitlement protected

[33] Edwin C Hettinger, 'Justifying Intellectual Property' (1989) 18 Philosophy & Public Affairs 31.

[34] U.S. Const. art. I, § 8, cl. 8.

[35] Robert P Merges, 'What Kind of Rights Are Intellectual Property Rights?' in Rochelle Dreyfuss and Justine Pila (eds), *Oxford Handbook of Intellectual Property Law* (Oxford University Press 2018).

under property rules, a patent primarily gives its owner "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States".[36] [37] The limitations set out in the patent statutes (e.g. scope, duration, form of exercise) are understood by some to "serve public policies that lawmakers consider more important than promoting innovation through rights exclusivity".[38] Even though the exclusive nature of patent rights gives the patentee wide freedom to exploit the patent as they wish, there are built-in limitations that are tailored to a publicly beneficial end. In general, patent rights can lawfully be used to restrict access to technologies on fair and reasonable terms. High pricing of the patented technology generally falls under lawful exploitation of patent rights. However, in some situations, the effect of such use can cause substantial harm to consumers as they severely restrict access to an essential technology on which the public depends. Whether this class of harm constitutes a subversion of the public interest of the patent system depends on how we define public interest. Below, I explore scholars' views on the purpose of the patent system (Tushnet, Lametti) and how that purpose has been undermined over time (Ragavan).

As we saw above, the patent system encourages innovation by granting inventors the exclusive right to prevent others from making use of the patented technology. Increased innovation and the dissemination of knowledge, the traditional argument goes, constitute the key public interests of the patent system.[39] Rebecca Tushnet has written that the patent system exists to promote public interest, rather than "benefiting private actors *or* [even] *balancing private interests*

[36] 35 U.S. Code §271.

[37] Richard Posner, 'Intellectual Property: The Law and Economics Approach' (2005) 19 Journal of Economic Perspective 57, 1..
[38] Lametti (n 15) 357.

[39] Ragavan (n 30) 51.

against the public interest".[40] If the patent system exists predominantly for the public interest, inventors and producers are "people to be rewarded instrumentally, in order to get them to generate the public benefit for their creations".[41] Under this conception, the state is not simply balancing private interests in the patent right against public interests in access and cumulative innovation. Rather, private interests of inventors are said to be "the means to the ends of the rights they hold".[42] The rights private actors hold are thought to "*mediate* the trade-off between incentives and access".[43] Though many legislators and scholars label patent rights as property rights in the sense that they "have economic value, have an *in rem*[44] and partly exclusive nature," these labels do not mean that the rights are absolute.[45] Absolute rights, as set out in the European Convention on Human Rights, are those that cannot be lawfully violated even in the presence of public interest justification.[46] The U.S. government's taking of private property (with just compensation) for public purposes under the eminent domain clause suggests that patent rights, as a form of property right, are not absolute. If patent rights are not absolute, their exercise must be limitable whenever its consequences harm a compelling state interest.

David Lametti critiques that while one might reduce the idea of "progress and incentives simply to economic terms," the view that patents confer a private right as an end in itself does not

[40] Rebecca Tushnet, 'Intellectual Property as a Public Interest Mechanism' in Rochelle Dreyfuss and Justine Pila (eds), *The Oxford Handbook of Intellectual Property Law* (Oxford University Press 2018) 1

[41] ibid 2.

[42] ibid 3.

[43] ibid.

[44] The Latin term "in rem" means "against a thing". Applied to property rights, property rights in rem means that the property owner has the right to not have his or her property interfered with. A right in rem is available against the world at large.

[45] Lametti (n 15) 356.

[46] Jonathan Law, *A Dictionary of Law* (9 ed.) Oxford University Press (Online Version 2018)

capture the full amplitude of the notion public interest that underlies intellectual property. The institution of patent law is not simply about according economic rights to the creator. As the notion of scientific progress is "tied… to the promotion of flourishing [and] *social benefits,"*[47] he argues that patent law is rather about "the balance of according rights limited scope in exchange for promoting the public's access to the [technology]… *all in service of the public good".*[48] Accordingly, patent rights are to be seen as "specific packages of rights tempered with duties and obligations".[49] While I share Lametti's view that the goal of patent law ultimately seeks to promote social benefits, I add to his view that the notion of social benefits is deficient so long as we understand it purely in innovation terms. That is, social or public benefit is not independently measurable by innovation output. This is echoed by Srividhya Ragavan's work, where he argued that the practical equivalence between the securing of patent rights and the fulfilment of public interest "dampens the presence of a duty of the patent owner to society. Instead, it has posited patent grants largely within a rights paradigm, [and therefore] dilute[es] the duty requirement of the patent holder".[50] I believe that the public interest of the patent system must be broader than simply cumulative innovation and the competitors' ability to work the invention after the expiry; it must include the enjoyment of the patented technology by the *general* public. This account should focus on the public benefit *of* innovation. "Public benefit *of* innovation" differs importantly from the idea of "public benefit *as* innovation" as it takes into account the ability of third parties besides competitors to access the benefits of the technology. This rings particularly true in the

[47] Lametti (n 15) 357.

[48] ibid 357.

[49] ibid 360.

[50] Ragavan (n 30) 52.

pharmaceutical industry, where innovation would lack social significance if the average consumer or the majority of the consumer base struggles to access it.

In response to the high pricing of essential medicines in the U.S., Ragavan has questioned the justifications for the exclusive rights conferred by the patent grant. He argues that the definition of patent rights as property rights has come to be a misfit as it fails to define the limits of the patent right as well as the public benefit goal of the patent system.[51] Even though property rights do not denote absolute ownership, patent law does not provide a clear answer as to whether or when public interest concerns may supersede the private rights of the patentee.[52] [53] [54] [55] This has meant that even during public health crises, essential medicine patentees do not have the duty to open up access to their technologies.[56] The lack of outer limits to patent rights not only causes an "imbalance in the rights versus duties construct within patent law," but also has "blurred the lines that define the public benefit goals of the system" as it has come to equate more patent grants with a net increase in public benefit.[57] This property-based conception of patents has led to a system in which more patents is "decoded" as more innovation. Overtime, disclosure, which is the sole condition for obtaining a patent (besides patentability issues), became treated as "the singular

[51] Ragavan (n 17) 46.

[52] See 35 U.S. Code §271

[53] See Thomas F Maffei, 'The Patent Misuse Doctrine: A Balance of Patent Rights and the Public Interest' (1970) 178 Journal of the Patent and Trademark Society.

[54] See John C Stedman, 'Invention and Public Policy' (1947) 12 Law and Contemporary Problems 649–79.

[55] See Jeanne Fromer, 'Should the Law Care Why Intellectual Property Rights Have Been Asserted?' (2015) 32 Houston Law Review
549.

[56] Ragavan (n 17) 49-50.

[57] Ibid 50

constituent element that delivers the [public interest] objectives of the [patent] system".[58] The resulting tendency is that the law treats the number of patents as a "proxy" for innovation that is presumptively beneficial to the public. The simple equation between patents and innovation has, as Ragavan argues, "encapsulated patent law with the appealing sheen of producing public benefit" when in reality the protection of private interests has dominated its objective.[59] What Ragavan points out here tells us that even if the public function accounts provided by Tushnet and Lametti are compelling, the goal of finding consumer interest in the patent public interest apparatus might be thwarted by the feedback loop between the securing of patent rights, increased innovation, and the fulfillment of public benefit. Below, I argue the public function of the patent system must encompass goals wider and more diverse than cumulative innovation alone. Specifically, it ought to take into account the general public's access to the benefits of innovation.

Ragavan's argument tracks the distinction I provided above, that there is a difference between the idea of benefit as innovation and benefits *of* innovation. The latter necessarily requires the public *at large* to enjoy the benefits of the patented technology. This public must go beyond licensees or potential competitors and include consumers. A defender of the "public benefit as innovation" view might maintain that the inclusion of consumers interests (1) misconstrues the purpose of the patent right, which is solely intended to spur innovation amongst those who have the capacity to work or improve upon the technology; (2) they might also object that inclusion of consumer interests in the public benefit apparatus is redundant, as cumulative innovation necessarily benefits the general public. The qualification there would be that consumer interest in

[58] Ibid 50-1.

[59] Ibid 48.

access is fulfilled as a byproduct of cumulative innovation, where cumulative innovation is the public benefit itself. Thus, they might conclude that in exercising their patent rights, patent holders are not obligated to *actively* ensure that consumer interest in access is fulfilled. While that interpretation is not strictly incorrect, I believe it offers a gravely deficient account of why we as a society desire some types of innovation in the first place. As a society, we desire innovation in essential medicines so the people in need, irrespective of their financial capabilities, can improve their health conditions. However, the barrier to access the benefits of innovation in essential medicines are often so high that even the average consumer cannot access them within reasonable means. As we saw, increased innovation, as a reflection for increased patent grants, have, can, and will take place when the private interests of patent holders alone are protected. Questions like "who should benefit?" and "who in fact benefits?" should invite us to think more critically about what the public benefit of private rights means. The scale at which the general public cannot access the benefits of innovation should raise serious concern regarding the way in which we define public interest in patent law.

While there is no equivalent provision in the Patent Act, invocation of public interest can enter by way of common law remedies.[60] In infringement suits, while only in rare instances were patentees denied injunctions in the name of "public interest," when injunctions were denied they were mostly for public health reasons.[61] More recently, the Supreme Court's decision in *eBay Inc. v. MercExchange, LLC* gave the law a fortified articulation of the public function of patent rights. In it, the Supreme Court implemented a "four-factor test" for issuing injunctions.[62] The last factor

[60] Scott A Allen, '"Justifying" the Public Interest in Patent Litigation' (2013) 88 Indiana Law Journal, 1052.

[61] *City of Milwaukee v. Activated Sludge, Inc.,* 69 F.2d 577 (7th Cir. 1934)

[62] *MercExchange, LLC v. eBay, Inc.,* 401 F.3d 1393-94 (Fed. Cir. 2005).

requires the patentee to show whether "the public interest would… be [served or] disserved by a permanent injunction".[63] Some scholars believe that *eBay* represented a turning point in the interpretation of the purpose of the patent system: now, cause for public interest can plausibly trump a patentee's ability to exclude others where the harm to public interest would be grave. This pronouncement is, at minimum, consistent with Tushnet's view that patent rights are put in place to facilitate a public function. However, as we saw from Ragavan's arguments, that the patent system is said to be public serving does not mean that the public at large benefits in fact. Whether or not a certain patent practice actually undermines patent law's public interest goal requires defining public interest in terms other than increased innovation and the dissemination of knowledge. The extent to which *eBay's* public interest prong proves to be helpful for consumer interest in access to essential medicines depends on how explicitly future courts spell out the terms of public interest. Until then, it remains unclear if mention of public interest is sufficient to deny a patentee its right to exclude. Nevertheless, *eBay* is sensitive to the idea that even constitutionally protected property rights are porous to public needs, even if those needs are not explicitly enshrined in law. The decision echoes Ragavan's core belief that the private interest in intellectual property right protection can be complementary but is distinct from the public interest of patent law. Public interest in patent law is, in Tushnet's words, "a thumb on the scales against [the] private control" of what makes good patent policy. It also gives us cause for just distribution beyond the goal of maximizing the utility of patent rights.[64] Moving forward, I hold constant the view that patent rights, which are fundamentally public incentives, serve a public function beyond maximizing the utility value of innovation amongst competitors. The public function, I argue, is better understood

[63] ibid 1391.

[64] Tushnet (n 40) 1.

as serving a broader base of benefactors, and this necessarily means the inclusion of the average consumer when it comes to essential medical technologies.

Section 2. Traditional Means of Patent Use Regulation

That no legislation explicitly places consumer interest in the apparatus of patent law does not foreclose the fight for fair and reasonable access in essential medicines. In this section, I look at how existing law regulates patent practices and patentee conduct and ask whether these rules can be applied to address the high pricing of essential medical technologies. There are three main areas of law that address and can regulate patentee conduct: (1) the doctrine of patent misuse; (2) antitrust law; and (3) the doctrine of inequitable conduct (not discussed in this thesis).[65] Over the years, courts have used these laws and judicially created doctrines to adjudicate whether certain conduct expanded the patentees' rights beyond the limited patent grant or additionally caused harm to competition. In the following discussion, I describe the doctrine of patent misuse and antitrust law's regulatory functions with respect to alleged abuse of patent rights and critique their shortcomings in addressing consumer harm. It must be made clear that the misuse doctrine and the antitrust analysis are not designed to scrutinize all types of patentee conduct. The patent misuse doctrine, as the name implies, is solely intended for scrutinizing explicit use of patents rights. The gambit of antitrust analysis is much broader. It can look at any patentee conduct that intends to or has the effect of restricting competition in a way that violates the antitrust laws. Intuition tells us that this still precludes it from scrutinizing the pricing of products, as pricing itself is not a competition restricting mechanism. We must accept that high pricing of essential medicines is a

[65] Glen P Belvis, 'Patent Antitrust, Misuse, and Inequitable Conduct '.

natural consequence of patent monopolies. With that said, we do not have to accept that it should be lawful. As monopoly pricing is generally a consequence of allegedly anticompetitive patent practices, the failure to curb these practices in antitrust law partially explains why prices of essential medicines continue to increase. The purpose of the discussions below is to identify a shared shortcoming when and if either the misuse doctrine or antitrust law is invoked to stop anticompetitive patent uses. The joint critique serves as a precursor to my positive proposal in Section 3.

2A. The Patent Misuse Doctrine

Anticompetitive patent practices are those that restrict competition beyond the scope of the patent monopoly. Patent practices like evergreening and reverse payment settlements are allegedly anticompetitive broadly for that reason. I suspect one reason it is so difficult to attach liability to these patent uses is because the project of defining improper patent uses itself has been unclear.[66] [67] So, what is patent misuse and how do we know when we see it? The short answer is that we do not know it when we see it. Defining the scope of patent rights – in particular what falls outside of it – is an inherently difficult task. It becomes most tricky when both statutory and common law are silent on whether a specific patent use is lawful or not – that is, when both statutory laws do not expressly authorize *X* use of patent right and common law has not found *X* to be unlawful. When there is no bright line between conduct expressly permitted by the patent laws and those prohibited by other areas of laws (principally antitrust), this creates an environment in which allegedly anticompetitive patent use can cause harm to consumers. Tracking the development of the patent

[66] Robert J Hoerner, 'The Decline (and Fall?) Of the Patent Misuse Doctrine in the Federal Circuit' (2002) 69 Antitrust Law Journal 669.

[67] Robin Feldman, 'The Insufficiency of Antitrust Analysis for Patent Misuse, 55 Hastings L' (2003) 55 UC Hastings Scholarship Repository 450, 428.

misuse doctrine is inherently valuable as it can provide us with a more concrete picture of what the common law has come to consider improper use of patent rights and why. In the following paragraphs, I take a cursory dive into the concept of patent misuse and track important moments in its development. I then discuss its doctrinal inadequacies for curbing anticompetitive patent practices that can cause substantial social harm in the pharmaceutical market. Even though high pricing and the anticompetitive patent practices that can drive it are distinct activities, the freedom to profit off of essential medicine has generally been seen as a corollary of the right to exclude. Understanding when the misuse doctrine applies and does not apply to explicit patent uses can tip us off as to why the misuse doctrine might not apply to the patent practices that encourage high pricing (e.g. reverse payments).

Patent misuse is a defense used by alleged infringers and arose in the context of increasing licensing and technology tying behavior.[68] The doctrine was developed by the courts to sanction patentees who improperly extend the patent rights to gain an unfair, anticompetitive advantage in the market. [69] As a categorical matter, patent misuse splits into those that violate the antitrust laws and those that unduly expand the scope of the patent monopoly. In assessing misuse that expands the scope of its sanctioned rights, the guiding question has been whether the patent practice increases the physical or temporal scope of itself. The assumption behind the scope analysis is that express authorizations from patent statutes immunizes a practice from scrutiny from other areas of law. As such, clarifying what a given patent legislation does and does not allow is integral in litigation against patent holders. [70] Other scholars have suggested that the patent scope analysis is

[68] Peter J Wied, 'Patently Unfair: State UC Laws and Patent Enforcement' (1998) 12 Harvard Journal of Law & Technology 477.

[69] Mark Lemley, 'The Economic Irrationality of the Patent Misuse Doctrine' (1990) 78 California Law Review 1599

[70] Feldman (n 58) 403.

often susceptible to regulatory capture by industry lobbying groups.[71] The interpretation of the scope of patent rights, they argue, therefore also increasingly reflect judicial overbreadth that favor patent holders.[72] To the degree that that is true, this might be a reality that we have to live with for the time being. A third view proffered by some practitioners sees the misuse as revolving around "the harm to the public interest created by the enforcement of patents tainted by loathsome conduct". The misuse inquiry, in their view, is aimed at "restrain[ing] practices that did not in themselves violate any law, but that drew anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy". [73] This path is only promising for creating patentee liability if the idea of public interest in patent law, as I argued in Section 1, includes the general public's access to the benefits *of* innovation within fair and reasonable means. Only under a broad construction of public interest can the patent misuse doctrine present us with a viable legal principle that can be used to support the claim that there is a relation of accountability between patentees and consumers that flows from patentees' obligations to refrain from unlawful expansions of their rights (usually with anticompetitive intent). If this interpretation is convincing, then the question as to whether business conduct like reverse payment settlements is unlawful therefore not only turns on the scope of the patent right, but also its cost and benefits for the public interest in reasonable access to essential medicine.

The contours of patent misuse gained clarity incrementally. *Motion Picture Patents Co. v. Universal Film Mfg. Co.* (1917), a case in which the patentee brought an infringement suit to

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[71] Herbert J Hovenkamp, 'Antitrust and the Patent System A Reexamination' [2015] Penn Law: Legal Scholarship Repository 482.

[72] Janice M Mueller, 'Patent Misuse through the Capture of Industry Standards' (2002) 17 Berkeley Technology Law Journal.

[73] Gene Quinn, 'Patent Misuse, Exploring the Basics ' (*IP Watchdog* , 2011)

enforce restrictions that were evidently anticompetitive, established patent misuse as an affirmative defense. The Appellate Court found that the conduct in question was tantamount to tying and therefore violated the Clayton Act. As such, the patentee's restrictive conduct should not be enforced through its patent infringement claim.[74] The Supreme Court ultimately rejected the antitrust approach, holding instead that patent law should be controlling in matters pertaining to the lawfulness of a patent practice.[75] While the outcome of its decision was effectively identical, the Supreme Court held that because "the exclusive right granted in every patent must be limited to the invention described in the claims of the patent*...",* any conduct that restricts the use of information outside the patent claims is unlawful.*[76]* Even though the logic of the ruling lies with the patent scope analysis, the reasoning is analogical to that of antitrust analysis. The Court reasons that "just as tying is bad in an antitrust context because it improperly extends a monopoly, so tying is bad in a patent context because it extends the scope of a patent".[77] *Motion Pictures* kickstarted the Supreme Court's use of the patent scope analysis in reconciling the overlapping concerns in patent and antitrust law.[78] From there on, the Court continued to develop the patent misuse doctrine alongside increasing concern over alleged patent abuses.

Over the years, the line between lawful patent conduct and patent misuse changed with statutes and judicial opinions. In 1988, Congress narrowed the scope of what constitutes patent misuse through the Patent Misuse Reform Act. The Act stated that a patentee may refuse to license

[74] See *Motion Pictures Patents Co. v. Universal Film Co.,* 243 U.S. at 517 (1917)

[75] ibid 514.

[76] ibid 516

[77] Feldman (n 68) 407.

[78] ibid 409.

its patent without amounting to misuse.[79] [80] [81] More controversially, it also permitted patentees to condition the license or sale of the patented technology on a license to rights in another patented technology – otherwise known as tie-in.[82] Importantly, lawfulness of this conduct became contingent on whether the patent holder has "market power in the relevant market for the patent or the patented technology".[83] [84] This is perhaps the clearest articulation of the misuse doctrine's reliance on antitrust principles, despite the Court's insistence on the need to separate patent scope and antitrust analyses. Over time, the patent misuse analysis increasingly relied on antitrust principles. By *Mallinckrodt v. Medipart* (1992), the Federal Circuit required "a full-blown antitrust analysis in a patent misuse case that did not relate to tying".[85] [86] If the conduct is shown to reach beyond the patentee's exclusionary rights or has the effect of broadening the scope of the patent claims, *and does so with anticompetitive effect*, the court engages in the rule-of-reason analysis (a basic antitrust test). Under the rule of reason, the court must decide whether the practice imposes an unreasonable restraint on competition and take into account a variety of factors, including "its condition before and after the restraint was imposed, and the restraint's history, nature, and

[79] 35 U.S. Code §271 (d)(4)

[80] Richard Calkins, 'Patent Law: The Impact of the 1988 Patent Misuse Reform Act and Noerr-Pennington Doctrine on Misuse Defenses and Antitrust Counterclaims' (1988) 38 Drake Law Review 177..

[81] Arnold B Silverman, 'Patent Misuse: Limitations on a Patentee's Rights' (1992) 44 JOM.

[82] 35 U.S. Code §271 (d)(5)

[83] Brian D Hill, 'Princo Corp. v. Int'l Trade Comm'n: Patent Misuse No Longer a Deterrent to Anticompetitive Behavior in the Group Venture Context' (2012) 7 Journal of Business & Technology Law 361.

[84] 35 U.S. Code §271(d)(5)

[85] Feldman (n 68) 425.

[86] *United States v. Virginia.* United States Court of Appeals, Fourth Circuit. (**1992**) **976 F**.**2d** 700, 708-9

effect".[87] Lastly, the court must proof that the anticompetitive effects outweigh the procompetitive effects.

Proving a patent holder's market power can be particularly tricky. As patents do not automatically translate into market power, courts generally look to market share as the indicator of the patent holder's market power. In some cases, the market is "defined geographically and by product" and takes into account "the availability of substitutes".[88] Peter Wied has noted that depending on how widely or narrowly one defines a market, a patentee can have more or less market power *even though his patent right grants him the sole right to exclude.* For example, a narrow market might deny the existence of alternatives by limiting the market to the patented, brand name product. As such, the likelihood that patent uses will be labeled misuse, in virtue of the patentee's market power, is higher. Under a broader market definition, a patentee's market share is lower as the market accounts for generics and comparable biologics. The patent conduct in question can be exactly the same under these two market definitions, yet it will be much harder for the court to justify a finding of misuse in the latter scenario.

Given how burdensome it can be to establish an antitrust violation, Judge Posner, a critic of the rule of reason test in antitrust law, has said that the test is essentially a "euphemism for nonliability".[89] Applied to the patent space, imposition of the rule-of-reason analysis not only can make showing of misuse exceedingly difficult, in some cases it can conceal the improper conduct

[87] Glen P Belvis, 'Patent Antitrust, Misuse, and Inequitable Conduct'.

[88] Wied (n 69) 475.

[89] Richard A Posner, 'The Rule of Reason and the Economic Approach: Reflections on the Sylvania Decision' (1977) 45 University of Chicago Law School (Chicago Unbound) 1, 14

the misuse analysis seeks to outlaw. In his article, Robin Feldman has similarly critiqued that the courts' use of antitrust rules to identify improper expansions of patent monopolies due to its inadequacy in "identify[ing] the *types of harm* that patent misuse is designed to address".[90] The point that patents do not in themselves give rise to market monopolies provides us with the conceptual clarity needed in describing why it might sometimes be inapt to apply the patent misuse analysis to scrutinize particular patent uses or patentee conduct. When it concerns the anticompetitive effects of patent use, I believe it is the right to exclude, and not market share (regardless how high) directly, that influences how boldly the patent holder prices his products. Therefore, given the misuse analysis's reliance on showing of market power, many potentially anticompetitive patent uses might slip under the radar so long as we cannot show that the patent holder abused his dominant market position.

One potential way to avoid the dangers revealed through Judge Posner, Wied, and Feldman's collective critique is to require that misuse be assessed with respect to *how the patentee is using his right.* In certain circumstances, we might want to conceptualize potential patent misuse in terms of *unfair methods of competition* and business conduct in general. We can assess the effects of a patent practice on competition by, for example, focusing on the fairness or propriety of the patent use toward other competitors sans showing of market power. Any patent holder can behave anticompetitively toward other competitors in using its patent right, but not all of these indiscretions rise to antitrust violations. The importance of focusing on anticompetitive behavior (without proof of market power or abuse of a dominant market position*)* is crucial if we want to account for the injurious effects of those behavior on competitors, competition, and ultimately

[90] Feldman (n 68) 400.

consumers. From what we saw from the Patent Misuse Reform Act's exclusion of tie-in's as patent misuse, there seems to be some ambiguity between harm to competition and unfair methods of competition. While the two might be practically indistinguishable in the sense that unfair methods of competition almost always harms competition, they are distinct concepts. In other instances, unfair methods of competition might not lead to competition-reducing results that will trigger antitrust concerns. However, many of those patent practices are arguably unlawful uses of patent rights as they expand upon the patentee's statutory rights. By modeling the misuse test off of the rule of reason test in antitrust law, a party must either show that the patent use is *per se* anticompetitive or demonstrate that the net effect of the conduct tends to restrain, as opposed to promote, competition in a defined market. Given the less than consistent ways in which market power is defined, I fear that the misuse analysis, which relies on the rule of reason analysis to a great degree, may under-include improper patent uses that have potential to hurt consumers at scale. The worry is that if many anticompetitive patent practices can past the patent misuse test unscathed, then the high pricing of essential medicines, as a natural consequence of these practices, might likewise go unscrutinized. My critique here serves as a foreshadow to my positive argument in Section 3 that the law of UC is a more suitable body of law to address the type of foul play the patent misuse doctrine seeks to identify and the injurious behaviors these restrictive market conditions encourage – namely, the high pricing of essential medicines.

In sum, we saw that what has counted as patent misuse partially depended on judicial interpretation of what the patent right permits as a matter of right. This approach warranted the patent scope analysis, which some think ought to be assessed with reference to the public interest of the patent system. Secondly, we saw that while patent misuse is a standalone violation of patent

law, its analysis has also been deeply influenced by antitrust principles. Despite the Federal Circuit's reliance on antitrust rules, it continues to emphasize that condemnation of patent misuse need not depend upon showing of an antitrust violation in the first instance. In my discussion, I built on critiques of the misuse doctrine's reliance on antitrust rules as a way to expose its inadequacy in addressing the many patent uses that, perhaps not harmful to the market at first glance, may nevertheless cause injury to consumers. In any case, to the extent that the misuse doctrine can help us create a cause of action against patentees when consumers are harmed, it can only be used as a defense to an infringement action – e.g. when a competitor begins to manufacture a drug and allege that the patentee has unlawfully extended the terms of the initial patent grant. It is unlikely that this argument will be accepted in the courts. However, the fact that the misuse doctrine cannot be made to anticipate injurious patent uses or patentee conduct cannot be accurately termed as a shortcoming, as it is ultimately a defense to an infringement claim. The concept of patent misuse – the idea that there are impermissible uses of patent rights *because they run contrary to our conception of public interest* – is valuable and can guide our explanation in why use of patent rights that harm can warrant injunctive orders.

2B. Antitrust Analysis

In this section, I discuss the primary area of law that addresses patentee conduct due to its potentially anticompetitive effects – antitrust law. At the end of this discussion, I conclude that its provisions concerning consumer welfare is ultimately thwarted by (a) antitrust law's conceptions of harm and (b) antitrust litigation's procedural rules.

Antitrust law has a consumer welfare provision that in theory should provide consumers with a cause of action against patentees when their interests are harmed by the patentee conduct. Section 4(a) of the Clayton Act provides that "any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefore… and shall recover threefold the damages by him sustained".[91] An antitrust injury must be of a kind that results from conduct that is harmful to competition at large or is the result of the abuse of one's dominant market position. A finding of antitrust injury therefore has to be an "injury to the market or to competition in general" and "not merely to individuals or [sic] firms".[92] Further, to claim that one has suffered an antitrust injury, the plaintiff must show not only that there is an antitrust violation, but also that there is a causal connection between the violation and the alleged injury.[93] Typically, the antitrust injury analysis is limited to competitors and not the public at large as it is generally much more difficult for consumers to establish a connection between an alleged antitrust violation and the injury sustained. As is the case with the patent misuse doctrine, we can anticipate that in some cases, patent uses that have not been expressly outlawed *and* does not amount to abuse of market power, but nevertheless has the capacity to injure consumers, to pass antitrust scrutiny without much trouble.

In addition to showing antitrust injury, a plaintiff must also establish standing in an antitrust court.[94] *Associated General Contractors* set forth six prongs in determining whether a plaintiff has standing:

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[91] 15 U.S. Code §15(a)

[92] *McGlinchy v. Shell Chem. Co.* 845 F.2d 802, 812 (9th Cir. 1988).

[93] *Disenos Artisticos E Industriales, S.A. v. Work,* 676 F.Supp. 1254, 1276 (E.D.N.Y. 1987)

[94] William H Page, 'The Scope of Liability for Antitrust Violations' (1985) 37 Stanford Law Review 1512.

(a) whether there is a causal connection between the antitrust violation and the plaintiff's harm;
(b) whether the defendants intended to cause this harm;
(c) whether the injury is of the type intended to be prevented within the meaning of *Brunswick;*
(d) whether the injury is direct or indirect;
(e) whether the claim of damages is too speculative; and
(f) whether there is a risk of duplicative recoveries and a danger of complex apportionment.[95] [96]

The causal connection between an alleged antitrust violation and the plaintiff's injury-in-fact is difficult to establish for the same reasons that it is hard to show for misuse. The market definition problem described in the patent misuse analysis above tells us that the line between a patent and market monopoly is never entirely clear. If a patent does not automatically confer a market monopoly, then strictly speaking, the patent practice will not violate antitrust law even if it restricts competition beyond the patent right's permissible scope. Since only those with market power can injure in the way that antitrust law recognizes, the fact that patents do not automatically confer market power can make it burdensome or virtually impossible for consumers to establish a causal connection between the conduct and their injuries-in-fact. If (a) is difficult to establish for consumers, then standing might be perennially out of reach. Even if consumers successfully established standing, the complexity of producer-consumer relations and antitrust's compensatory mechanism can prevent consumers from actually receiving damages. In his critique of antitrust litigation, Daniel Crane notes that in the static injury framework, which "concern the effects on consumers from an increase in price," [97] [98] the clearest social cost of an antitrust violation falls

[95] Belvis (n 66).

[96] See *Associated General Contractors of California, Inc. v. California State Council of Carpenters et al.* 103 S. Ct. at 908-912 (1982).

[97] Daniel A Crane, *Institutional Structure of Antitrust Enforcement* (Oxford University Press 2011) 164.

[98] See generally Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice* (2005) 19–20.

upon "those who stopped purchasing from the defendant because the price increased too much" and those who "continue to purchase the product at the higher price". [99] For the latter group, the injury has been considered by some as a "wealth transfer from consumers to producers".[100] The complexity and variability of relevant economic relationships often stands in the way of compensation.[101] As Crane put it, a monopoly overcharge generally produces "endless ripples in the economy".[102] Given the diffuse nature of monopoly overcharges and the difficulty in "locating the real economic victims,"[103] Crane cautions that just because private damages recoveries are automatically trebled under the Clayton Act upon showing of an antitrust violation[104], this does not mean that consumer harm is meaningfully captured. In other words, even if antitrust enforcement deters certain harmful business conduct, the nature of static consumer injury combined with the difficulty in identifying them can often work against the protection of consumer welfare.

I believe a primary reason for which consumers have had trouble establishing antitrust standing is that the anticompetitive patent practices that enable high pricing of essential medicines, such as reverse payments and the creation of anticompetitive patent thickets, are not presumptively unlawful. Presumption of illegality is a high bar. To a lesser extreme then, we at least have reason to expect that certain practices, in virtue of their anticompetitive tendencies and close relation to

[99] Crane (n 98) 164.

[100] Herbert Hovenkamp, 'Antitrust's Protected Classes' (1989) 88 Michigan Law Review 48, 9–11.

[101] Crane (n 98).

[102] ibid 167.

[103] ibid 166.

[104] 15 USC §15(a) (2006)

increased pricing, to be made subject to antitrust scrutiny whenever they occur. The FTC is particularly vocal in its attack on reverse payments as a form of presumptively anticompetitive patent practice.[105] [106]According to an FTC study, these deals cost consumers and taxpayers $3.5 billion in higher drug costs every year.[107]

Let us explore reverse payments and the judicial attention they have received to illustrate the difficulty in applying antitrust analysis to cases involving the use of patent rights. It is uncontroversial that a payment by one competitor to another in return for the latter to stay out of the market is anticompetitive. Whether this principle applies in the context of patent disputes is a persistent debate. As a matter of doctrine, it is unclear if the principles of antitrust or patent law apply independently. The answer is far from clear because the subject matter – settlements of patent litigation that involve the patent holder paying consideration to the alleged infringer, resulting in delayed entry to the generic market – necessarily implicate competing principles from both areas of law. The tension arises where restricting reverse payments come into conflict with patentees' right to exclude others from competition. The disagreement amongst district courts tends to be over the appropriate type of analysis.[108] The ambiguity regarding its legality allowed the practice to go on unsanctioned since its rise in the 1990s. In 2013, the Supreme Court reversed the Eleventh Circuit's ruling that antitrust laws do not apply to the patent holders so long as the anticompetitive effects fall within the scope of their patent rights. The majority held that any large

[105] Hemphill (n 10) 1581.

[106] Carl Shapiro, 'Antitrust Limits to Patent Settlements' (2003) 34 The RAND Journal of Economics 411, 391, 408.

[107] 'Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2016 A Report by the Bureau of Competition' (2016).

[108] Robert A Pollock, Denise Main and Erin M Sommers, 'FTC Champions Inconsistent Positions on the Reverse Payment Settlement Debate' (*Finnegan*, 2012).

settlement payment that is "disproportionate to [the] litigation risk can be unlawful under antitrust's rule of reason… even if the settlement agreement does not go 'beyond the scope' of the patent's nominal coverage". Crucially, the plaintiff need not make a full-scale rule of reason argument, which traditionally requires one to define the relevant market, provide a detailed proof of market power, and its specific anticompetitive effects.[109] Given the particularities of each reverse payment (e.g. "its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification")[110], however, the Supreme Court held that reverse payments are neither presumptively illegal or legal. Though this ruling did not give the FTC the presumption of guilt against patentees they wanted, it established that reverse payments are at least subjectable to antitrust scrutiny. Since *Actavis,* reverse payments have decreased significantly. At the same time, there has been a parallel increase in a relatively new class of reverse payments involving "possible compensation". The FTC's 2016 Fiscal Year report categorized "possible compensation" settlements as those that are unclear whether "certain provisions act as [anticompetitive] compensation from the brand to the generic company".[111] This trend should signal that so long as reverse payments are not presumptively illegal, settlements that have hidden features of reverse payments will likely go under the radar.

[109] Herbert Hovenkamp, "Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision" 15 Minn. J. L. Sci. & Tech. 3 (2014) at 5-6.

[110] *FTC v. Actavis* 133 S. Ct. at 2238.

[111] Jamie Towey and Brad Albert, 'Then, Now, and down the Road: Trends in Pharmaceutical Patent Settlements after FTC v. Actavis' (*Federal Trade Commission*, 2019).

Another significant outcome of *Actavis* is the Court's decision that "consumer welfare," and not total welfare, should be the goal of antitrust enforcement.[112] Consumer welfare focuses entirely on output and low prices. If consumers are harmed as a result of increased prices, then the business conduct is said to be anticompetitive *in spite of offsetting producer gains*. Total or general welfare, on the other hand, takes into account producer benefits and sees them as offsetting efficiencies that can override costs to consumers.[113] The general welfare approach believes that this allows them to maximize aggregate wealth, and so benefit consumers in the long run.[114] [115] What this means is that the total welfare model ends up favoring producers, as it provides companies with wide latitude to adjust production costs in order to show that the total welfare is larger than costs on consumers.[116] Under this calculus, there would be no antitrust violation. The Court recognized the loophole in this approach in *Actavis* and foreclosed its use by equating harm to higher consumer prices and emphasized that the goal of antitrust enforcement should be to maximize consumer welfare.[117]

Nevertheless, outside of reverse payment cases, the procedural rules in antitrust litigation can still work against its compensatory goal. The central problem remains that though antitrust law aims to maximize consumer welfare, that goal is premised on economic efficiency. The reasoning that economic efficiency leads to the maximization of consumer welfare trickles down to the

[112] *FTC v. Actavis* 133 S. Ct. at 2234-35 (the majority opinion analyzing the consumer benefit provided by patent settlements)

[113] Herbert J Hovenkamp, 'Is Antitrust's Consumer Welfare Principle Imperiled?' [2019] Penn Law: Legal Scholarship Repository 102.

[114] Alan J Meese, 'Debunking the Purchaser Welfare Account of Section 2 of the Sherman Act: How Harvard Brought Us a Total Welfare Standard and Why We Should Keep It' (2010) 85 NYU Law Review 659.

[115] Barak Y Orbach, 'The Antitrust Consumer Welfare Paradox' (2011) 7 Journal of Competition Law & Economics 133, 148.

[116] Hovenkamp, 'Is Antitrust's Consumer Welfare Principle Imperiled?' (n 115) 104.

[117] Ibid, at 7-8.

procedure of antitrust injury analysis. The proof of antitrust injury requires showing that the effect of the business conduct either intends to restrict competition or tends to create a monopoly. Under antitrust law, the court might stipulate that so long as the benefits of, for example, a particular reverse payment outweighs its costs on competition, it does not violation antitrust law even if it is shown to restrict competition beyond the scope permitted by the patent rights. As such, the resulting social externalities, irrespective of their severity or scale, are not injurious in the eye of antitrust law. Consumers not only have to overcome great burden to establish standing, the task of showing the injuries they suffered are those that antitrust law is designed to address also becomes doubly challenging. When courts miss the doctrinal distinction between harm to competition and harm to an individual in circumstances that demand it[118], it can undermine the protection of consumer welfare.

Chapter 2

Section 3. A Proposal: The Law of Unfair Competition

We have seen how the patent law route is foreclosed by the plain fact that there is no explicit consumer welfare provision in its laws. As an alternative way to read consumer protection out of patent law, I explored whether the public interest justification for the patent system can account for consumer interests in equitable access to the patented technologies. As the conception of public interest in patent law is generally understood as increased innovation in a particular technological area, patent law's remedies are available only to workers of the technology (and their challengers). This calculus leaves out an important benefactor of innovation – i.e. the consumer base, specifically those whose subsistence *depends* on access to the benefits of the

[118] Dan Butrymowicz, 'Antitrust Violation vs. Injury-in-Fact: A Distinction That Makes a Difference' (*The Federal Trade Commission*, 2016).

technology. The bottom-line is that so long as the public interest justification of the patent system does not include consumer interests in accessing the technology, patent practices that harm in the way described here cannot be deemed a violation of patent law. As such, the current state of patent law is not equipped to address the externalities that flow from its existence, particularly when it comes to restrictive access to essential medical technologies.

We also saw that the primary area of law that regulates patentee conduct – antitrust law – likewise cannot adequately address consumer harm that result from exploitations of patent power. Antitrust law is first and foremost concerned with harm to competition by unlawful market interventions. It sees consumer harm as a consequence of anticompetitive environments. As a result, for a consumer to show that his health has suffered or has been threatened due to high pricing, the consumer must show that the injury is causally related to harm to competition. Though *FTC v. Actavis* (2013) compels the courts to treat consumer welfare, as opposed to total welfare[119], as the goal of antitrust enforcement, the idiosyncrasies of antitrust litigation encloses consumers in a Catch-22 whereby they must first prove antitrust injury. When it comes to reasonable access to essential medicines, antitrust law's mode of consumer welfare protection is cumbersome and should, at the moment, suggest that injuries resulting from exploitations of patent power are also not neatly classifiable under antitrust law. Some might defend the apparent difficulty to establish consumer standing in these areas of law as an acceptable cost for judicial prudence (e.g. for reasons concerning judicial restraint and justiciability). Strict adherence to these judicial virtues in commercial contexts wherein consumer harm is pervasive yet largely undefined by law, however, can create resistance for utilizing existing areas of law that *are* well-equipped to regulate patentee,

[119] Herbert Hovenkamp, 'Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision Actavis Decision' (2014) 15 Science & Technology Minnesota Journal of Law 7.

or general corporate conduct on the basis of harm. Certain judicial principles must be scrutinized when its social consequences run up against our intuition that harm or threat to one's health as a result of industry-imposed barriers to access should never be tolerated.

Pharmaceuticals, like any other product, are put on the market under the presumption that they are safe and effective. However, because many people *depend* on essential medicines to subsist, there is also the expectation for those medicines to be accessible within reasonable means. Thus, in the health care context, the obligation to prevent harm should not simply mean refraining from actions that may cause unexpected, physical harm from, for example, deceitful clinical trials or marketing. I believe this duty of care must also extend to cover any foreseeable harms that could arise in virtue of consumers' *dependency* on essential medicines. Since consumers who choose to not buy a prescribed treatment are inevitably harmed by that choice, the imperative to refrain from exploitative patentee conduct must take into account harms that result from the decision to not purchase *in virtue of the treatment's price*. Injury from defects or faulty advertising results in strict liability partially because the law recognizes the coercive effect of misinformation on consumer's decision making. This liability standard does not apply to health injuries that can plausibly result from restrictive access to essential medicine due to high pricing. As patentees do not have a duty of care towards their consumers in ensuring the availability or accessibility of any drug, harms that result from restrictive access do not result in *any* form of liability. This has allowed the injury from restrictive access to be written off as an autonomy cost of patent rights. While harm resulting from defective products and that from restrictive access have different causes, the difference in their treatment in law are primarily due to the lack of duty to ensure reasonable accessibility for consumers of essential medicines. We need to recognize a rough commonality between injuries

that result from defects or false advertising and those that result from restrictive access to essential medicines to see that justifications for the lack of liability for the latter class of harm is under-substantiated, to say the least. Harms that arise from misinformation result from coercive purchasing conditions; consumers of exorbitantly-priced essential medicines are subject to comparable duress at the time of purchase when they are driven to purchase those medicines (discussed under the Unfairness Doctrine analysis).[120] This shared element of duress should make us question arguments that immediately write off injury from inability to access medicines as innovation costs. To approximate towards a patentee duty to refrain from exploiting consumers' health dependencies, we need a law that does not tolerate harms that result from restrictive access as innovation or autonomy costs.

The core problem remains that the injuries-in-fact – e.g. deterioration or threat of health due to essential medicine's prohibitive pricing – have yet to find a body of law with a definition of harm that can capture these injuries and in so doing make high pricing of essential medicines unlawful. We therefore need to find an alternative legal basis for the claim that certain exploitations of patent power should be subject to scrutiny in virtue of their capacity to injure. As we know, harm alone does not translate into legal culpability on part of the patentee. For these harms to rise to the level of legal injuries, we need to either (1) make a new law that prohibits patentee conduct that harms (either by legislation or court construction) or (2) find an existing law that can achieve the effects of (1). It is crucial that such a law take into account the factual injuries in determining the lawfulness of a business conduct. Subjecting injurious patentee conduct to the law of UC and its Unfairness Doctrine can fulfill this task as they can give form to a cause of action against

[120] I leave aside issues concerning the foreseeability of these harms for the time being.

patentees who use their rights in a harmful way. I believe the law of UC has a comparative advantage over antitrust law in regulating corporate conduct that involves, directly or indirectly, the use of patent rights. This is because it can account for a different type of injury – namely, the economic and physical harm that in fact or *may* result from purchasing (or not purchasing) an expensive essential medicine.

There are two important advantages to this approach. First, it could help us concretize the scope of fair and reasonable patentee conduct by laying down rules that govern what is disallowed in the exercise of private intellectual property rights with specific reference to its injurious capacities. Second, by basing the wrongfulness of an act on its actual and potential injurious capacities, we can begin to create a liability-based relation between patentees and consumers. For these reasons, UC law provides a more appropriate environment wherein a cause of action against patentees can be raised. In Section 3A, I provide a functional description of the law of UC to make apparent its suitability for curbing patentee conduct that harms. In Section 3B, I supplement the definition of harm in the unfairness test by using theories of harm from political theory to demonstrate that the consumer dilemma in obtaining necessary treatments is essentially one of restricted autonomy. The goal there is to use the Harm Principle's reasoning to more forcibly define the contours of restrictive access due to high pricing as a breach of fundamental rights. In Section 3C, I respond to potential objections to this approach concerning the federal preemption of patent law over state UC laws.

3A. Why the Law of Unfair Competition (UC)?

The law of UC, otherwise known as trade law, is a close relative of antitrust law. It oversees unfair *methods* of competition and deceptive or unfair business practices. Rules spelled out in the Federal Trade Commission Act (FTC Act) form most of the laws in the area of UC. The Wheeler-Lea Act (1938) amended Section 5 of the FTC Act and gave it authority to prohibit, among other business conduct, "unfair or deceptive acts or practices" as well as "unfair methods of competition" in commerce.[121] The amendment expanded the scope of Section 5 as it eliminated the need to show that the challenged conduct affects competition directly or negatively.[122] This means that even though Section 5(a) of the FTC Act authorizes the FTC to oversee conduct that could violate the Sherman and Clayton Acts, the Act can also cover conduct that is beyond the reach of antitrust laws.[123] Conduct beyond of the reach of antitrust laws are those that do not currently violate antitrust law but nevertheless has great potential to stifle competition and/or cause harm to consumers. This permits the Commission to "stop in their incipiency acts and practices which, when full blown, would violate [the Sherman and Clayton Acts]".[124] [125] Showing of UC results in a cease-and-desist order that can stop harmful conduct and outlaw similar conduct in the future. As showing of UC primarily results in a cease-and-desist order, and not private damages recoveries as it is under antitrust law, the incentive for firms to settle with consumers should be mitigated. The 1975 FTC Improvement Act gave the Commission further administrative and remedial powers

[121] 15 U.S. Code § 45(a)(1)

[122] Science, and Transportation Committee on Commerce, 'Unfairness: Views on Unfair Acts and Practices in Violation of the Federal Trade Commission Act' (1980) 103.

[123] Maureen K Ohlhausen, 'Section 5 of the FTC Act: Principles of Navigation' (2013) Journal of Antitrust Enforcement.

[124] *FTC v. Motion Picture Advertising Service Company, Inc*., 344 U.S. 392, 394-95 (1953)

[125] Debbie Feinstein, 'A Few Words about Section 5' (*Federal Trade Commission*, 2015).

to "establish civil penalties… seek restitution orders…" and so on.[126] It also allowed the Commission to "go *beyond case-by-case prohibitions* of unfair…practices by issuing trade regulation rules which proscribe such practices on an *industry-wide* basis".[127] [128] Effectively then, Section 5 gives the Commission the broad power to correct for market problems that are not per se anticompetitive (in the antitrust sense) but are nevertheless consumer unfriendly.[129]

FTC v. Sperry & Hutchinson Trading Stamp Co. affirmed the FTC's authority to proscribe unfair practices which are "neither directly nor traditionally deceptive, nor anticompetitive".[130] [131] This broad characterization allows plaintiffs to bypass the stringent requirements to show for market power in antitrust litigation. The *Sperry* Court summarized the FTC's adjudicating principle over unfair practices as one that "considers public values *beyond simply those enshrined in the letter or encompassed in the spirit of the antitrust laws*."[132] Although the consumer welfare principle – that which "encourages markets to produce output as high as is consistent with sustainable competition, and prices that are accordingly as low"[133] – is widely regarded as a foundational principle of antitrust law, I believe UC law has an edge over antitrust law in protecting consumer interests in access *when there is no clear violation of patentee conduct with respect to*

[126] Committee on Commerce (n 124) 105.

[127] Teresa M Schwartz, 'Regulating Unfair Practices Under the FTC Act: The Need for a Legal Standard of Unfairness' (1977) 11 Akron Law Review 1.

[128] FTC regulations concerning UC are found in Title 16 of the Code of Federal Regulations. When conflict between federal and state law arises, the federal law generally preempts state law.

[129] Committee on Commerce (n 124) 104.

[130] *FTC v. Sperry & Hutchinson Co*., 405 US 233 (1972)

[131] Schwartz (n 129) 7.

[132] *FTC v. Sperry & Hutchinson Co.,* 244 (1972).

[133] Hovenkamp, 'Is Antitrust's Consumer Welfare Principle Imperiled?' (n 115) 102.

patent or antitrust law. As the law of UC bases its cause of action on business conducts' capacity to harm consumers, its analysis is not tethered to showing of market power (and the abuse of that power), defining a market, and the conceptual overlaps between patent and market monopolies. However, even in cases where courts might forgo of the requirement to prove market power (as the Supreme Court did in *Actavis*) when considering the appropriate level of antitrust scrutiny a practice should be placed under, UC law's independent criterion of consumer injury circumvents the welfare tradeoff between producer gains and consumer losses. As I argued in Section 2, this can lead users of the analysis to under-include corporate conduct that do not raise antitrust concerns but nevertheless create substantial harm to consumers. The usual advantages of antitrust law are blunted when the conduct in question – high pricing of essential medicines - is inextricably linked to patent rights, which by law are granted with wide freedom to exclude. The independent criterion of consumer injury for outlawing business conduct is consistent with the intent of the FTC Act, which is to "[make] the consumer who may be injured by an unfair trade practice *of equal concern* before the law with the merchant injured by the unfair methods of a dishonest competitor".[134]

Before moving forward, let us clearly establish the connection between harm to consumer welfare and unfair practices. One might reasonably ask "yes, it seems unethical to list essential medicines at such a high price, but is it unfair? To whom is it unfair?" The Committee on Commerce has offered a rather elegant explanation to start with. Business conduct is unfair when they "cause artificial misallocations of consumers' economic resources, [and] thereby creat[es] a market d[y]sfunction". They are unfair "in the same sense that anticompetitive behavior [that

[134] 83 Cong. Rec. 3255 (1938) (remarks of Senator Wheeler)

create] similar market d[y]sfunctions [are] unfair".[135] According to this definition, abuse of patentee power, of which the high pricing of essential medicines is a kind, is unfair to consumers because those practices cause consumers economic harm. This claim gives us a cause of action only when economic harm can be identified. While evidence for such misallocation might not be difficult to produce, we can expect patentees to argue that consumers who buy the drug *choose* to do so, and as a result their health is improved. Therefore, there is no real harm, economic or otherwise. This is only superficially true. The commercial transaction alone and its health outcomes tell us very little about the fairness or efficiency of the market of essential drugs (in which demand is highly inelastic due to consumers' dependency on the drugs). The context of the purchase is needed to properly determine whether there was economic harm. The industry often attempts to justify soaring prices by claiming that high revenues are required to guarantee the development and production of future drugs.[136] Then, given the allocative inefficiencies[137] created by the need to shift economic resources away from other essential needs in order to cover the high prices set by the patent holder, the economic harm done to the average consumer becomes evident. The existence of this economic harm can have particularly devastating consequences to citizens in the lower socio-economic groups who, given their relative strenuous circumstances, might have especially narrow margins when it comes to re-allocating resources away from other essential needs.

In the context of essential medicines, the inability to redistribute large enough shares of one's income away from other needs also poses a threat to consumers' health. In particular, the

[135] Committee on Commerce (n 124) 103–4.

[136] Emanuel (n 7).

[137] Allocative inefficiency occurs when the consumer does not pay an efficient price.

higher the price of the medicine and the lower the socio-economic status of the consumer, the higher the likelihood that the consumer will have no choice but to opt out of the purchase. The level of dependency which one has on essential medicines, combined with the often time-sensitive nature of the treatments, make the purchasing condition coercive. To be clear, the element of duress is introduced not by one's relative dependency on the medicine, but by the high pricing alone. This should be clear as one's dependency on a particular essential medicine remains constant throughout time, all other conditions fixed. If the medicines were reasonably priced, the rational, average consumer would never feel *compelled* to opt out of the purchase. What compels one to do so is considerations of affordability. When pricing is beyond the purchasing power of average consumers, decisions to buy or not buy the medicine are never entirely autonomous as they are generally the outcome of a cost-benefit analysis no rational consumer would willingly engage in.

In brief, there are two types harm that could result from the purchasing condition describe above. Where prices could be lowered significantly, there is a misallocation of economic resources when consumers pay at a premium for essential medicines. This is a straightforward economic harm. The severity of the economic harm is magnified when we recognize that the decision to purchase is often not entirely autonomous. As the high prices introduce an element of duress into consumers' decision-making processes, those who ultimately opt out of the purchase are harmed physically. The presence of high prices means that there is always a potential for harm to one's bodily integrity. Both economic harm and harm to bodily integrity are injuries to autonomy as no rational consumer would ever choose to sacrifice his health unless compelled by external circumstances. In order to find a cause of action that captures the full range of harm that can result from the decision to purchase or not purchase essential medicines, we need a law that prohibits

conduct in virtue of its capacity to cause both economic harm and harm to one's health. The type and scope of this harm needs to be tailored in a way such that the consequences of restrictive access to essential medicine can be taken as explicit evidence for the injurious nature of high pricing. This source of authority, I argue, can be found in the FTC's Unfairness Doctrine. The goal of the Unfairness Doctrine differs from antitrust law's consumer welfare function as the law of the Doctrine concerns itself with *the economic and health injuries* that result from deceptive or wrongful business conduct. In general, there are two ways to create a cause of action. A cause of action can exist because there are damages that a law can provide remedy for. A cause of action can also exist because a law explicitly prohibits the conduct in question, regardless if the conduct caused any harm. The Unfairness Doctrine provides us with rules that support causes of action that arise from both damages and wrongful conduct. Importantly, it bases wrongful conduct on its relation to those damages *directly* – that is, the Doctrine can declare a business practice "unfair" simply because it causes harm to consumers. Together, the existence of harm and its connection to the conduct are sufficient proof that the conduct is unfair and therefore unlawful according to the Unfairness Doctrine.[138] I believe the fulfillment of the Doctrine's harm criteria can provide us with the missing causal link between monopoly pricing of essential technologies and consumer harm. This is primarily due to the fact that the Doctrine is designed, and therefore equipped, to distinguish between patent right *backed* conduct and explicit use of patent rights. As the Doctrine regards business conduct as actionable wrongs in virtue of their capacity to cause harm[139] – no less

[138] See Wied (n 69) 509. ("Furthermore, since state UC laws are designed to protect consumers, and have often been construed liberally to serve that end, most states' UC laws "do not require a showing of knowledge or intent for an act to be deceptive [or unfair]; this contrasts with federal claims for antitrust violations or inequitable conduct [under the patent misuse doctrine], which require a strong showing of intent on the part of the patent holder…given the Federal Circuit's requirement that a party show specific intent in an antitrust claim and the difficulty in producing such evidence, a claim under state law stands a greater chance of success".)

[139] Shyamkrishna Balganesh and Gideon Parchomovsky, 'The Role of UC in the Common Law' in Shyamkrishna Balgaensh (ed), *Intellectual Property and the Common Law* (Cambridge University Press 2012) 498.

and no more - its analysis does not have to accept arguments that defend pricing conduct as a matter of property right and its associated autonomies. In the following discussion, I explore how the Unfairness Doctrine can help us concretize the harms that result from restrictive access to essential medicine as legal injuries and, consequently, how that can curb excessive pricing of essential medicines as an unfair method of business.

On December 17, 1980, the FTC declared in its Unfairness Policy Statement that remedying "[un]justified consumer injury is the primary focus of the FTC Act, and [is] the most important of the three criteria" in assessing unfair methods of competition.[140] [141] According to the Unfairness Doctrine, in order to claim that patent practices like reverse payment settlements is an unfair business conduct, we must show that (1) the resulting consumer injury is substantial, (2) the benefits of the competition method to consumers does not outweigh its costs on society, and lastly, (3) the injury is of a kind that could not have been reasonably avoided by the average consumer. The concept of consumer injury it offers differs from antitrust injury in two respects. First, it differs in type. Unlike antitrust injuries, injuries from unfair methods of competition are measured by their severity, scale, and reasonable avoidability i*rrespective of the patentee's supposed market power*. Second, it differs in scope. As the range of plaintiffs who can suffer the legal injury resulting from UC is undefined, it is arguably much simpler to establish consumer standing through UC claims. In the following analysis, I hold high pricing of essential medicines as the unfair method of competition and argue that the consumer harm suffered thereafter fits the type and scope of injuries the Doctrine is designed to address. The overarching goal here is to show that the Unfairness

[140] Unfairness Policy Statement, 104 F.T.C. at 1073.

[141] J Howard Beales, 'The FTC's Use of Unfairness Authority: Its Rise, Fall, and Resurrection ' (*Federal Trade Commission*, 2003).

Doctrine can provide consumers with a cause of action against patentees in virtue of their injurious pricing (where injurious pricing is indicated by its capacity to create unavoidable, substantial harm at scale). Additionally, I believe by subjecting high pricing of essential medicines to the principles of UC law, we will begin to see a clearer divide between monopoly pricing that harm and those that do not.

To show that the high pricing of essential medicines constitutes an unfair method of competition, the injury:

(1) must be "substantial"[142]

In this stage, the unfairness analysis asks the FTC to objectively determine whether there has been substantial consumer injury. Substantial consumer injury can take the form of "economic harm" or "*threat* to health and safety*"*. In other words, that a business practice affects a consumers' health negatively, or otherwise simply *poses a threat* to their health and safety is itself evidence that the business practice is potentially unfair. By dictating that a practice is unfair if it has the capacity to *threaten* to health and safety, the substantial injury test cuts through the complications that often come with antitrust claim constructions (discussed extensively in Section 2).[143] In the following discussion, I sidestep the argument that consumers who purchase the medicines suffer economic harm. Instead, I focus on showing that high pricing of essential medicines harms consumers as it threatens their health. I believe the substantial injury criterion can help us carve out a space for the health consequences that result from the inability to afford highly priced

[142] 15 U.S. Code § 45(n)

[143] See generally Committee on Commerce (n 124).

medicines to be assessed as a legal injury. Without the provision that threat to health constitutes a substantial injury for which the relevant conduct can be penalized, it might seem arbitrary as to how, at least in the eye of the law, negative health effects that result from the consumer's decision to not purchase an essential medicine could be linked to the patentee's pricing conduct. This is because barring circumstances where there is a product defect or faulty advertising, consumers are presumed to assume all the negative health consequences should they choose not to buy the medicine, even if price is the only deterrent to purchasing the drug.

As the *threat* to health is a constant state of potentiality, it arguably is present at the moment in which the consumer is effectively forced out of the purchase due to a limit in his financial capacity to overcome the barrier to access. If injury exists where the threat to health arises, we need not necessarily show that any physical injury has materialized (although it is generally the case that such physical injuries already exist). The threat to health arises from an interaction of the consumer's inability to afford the medicine and his particular dependency on the medicine. With that said, the reason that these consumers' health is threatened is not because of their financial circumstances. Presuming the vast majority of those consumers is representative of the *average* consumer who has an *average* earning capacity, the threat to their health should instead be attributed to the medicine's pricing. It would be non-sense to argue otherwise that the *average* consumer's inability to afford essential medicine is because he is too poor or that he has been financially irresponsible. The inability to afford and high pricing are two sides of the same coin in the sense that high prices necessarily means that the majority of the consumer base will not be able to afford the medicine; however, it would be fallacious to say that the inability to afford is what threatens one's health and therefore the business conduct in question should be exempt from

liability. High pricing of essential medicines exploits the vulnerability of people who depend on essential medicines to subsist. From this we should be able to conclude that the average consumer's inability to afford essential medicines is the *consequence* of high pricing and not a result of their individual financial capacities.

Consumers whose health depends on a given essential medicine but nevertheless opt out of the purchase often do not exercise free decision making. Rather, their decision hinges on the degree of their dependency on the medicine vis-à-vis their ability to pay for it. The potentiality of threat becomes more likely when the negative health consequences of not purchasing the drug outweighs the its "benefits" (e.g. saving some money). Depending on the level of dependency one has on an essential medicine, as well as the urgency with which one needs the treatment, the threat to one's health can be greater and more imminent. The outcome of this cost-benefit analysis can go either way and does not depend on one's health needs or financial means independently. A consumer can choose to buy the drug when he can and is willing to stretch his wallet. However, it is generally a matter of time before this willingness turns into inability. On the other hand, a consumer can also choose to not buy the drug when he can and is willing to do without. In like manner, there is a durational limit to which one can endure a severe illness if untreated. In short, if the decision-making process is guided by avoiding the worse alternative given one's ability or willingness to stretch his financial means or otherwise endure the illness, the ultimate decision is hardly a free choice. As high pricing will always place the average consumer in one of these two situations, the threat to health is perennially present.

Additionally, under the circumstance that one suffers a physical injury due to restrictive access to essential medicines, the substantial injury criterion accounts for both small, uniform harm across a large number of consumers as well as significant, diverse types of harm to individuals. The FTC's reasoning is that even though "…in the aggregate, total injury may not be large, as in cases when the company is small, or the practice is one that creates unnecessary transaction costs… but relative to the benefits, the injury may [nevertheless] be substantial".[144] Under this framework, it seems that neither can inability to pay across a group nor an individual consumer's inability to pay for a drug be easily dismissed as non-injuries. This suggests that not only is "substantial-ness" independent of the severity of the injury, it is also indiscriminate towards the heterogeneity of injury claims across consumers. We might also have reason to believe that since threat to health is a potentiality that consumers with different financial capabilities can all suffer at one point or another, "substantial injury" is not limited to those who are unable to afford the essential medicine out of pocket. This could open up the possibility for consumers under comprehensive insurance plans to also claim that high pricing is an unfair method of competition towards them. For this class of consumers, the injury might exist more in the form of economic harm than threat to physical health.

In short, the effects of monopoly overcharges in essential medicines always result in threat to health, as it is always possible that consumers with different financial capabilities will not be able to afford it at one time or another. For those who can, whether out of pocket or by insurance coverage, the injury will take the form of economic harm provided that the pricing of the medicine is in fact an overcharge. The harmful potential of high pricing means that individual consumers do

[144] Unfairness Policy Statement, 104 F.T.C. at 1073.

not need to show that they cannot afford the medicine in order to prove that they have been injured, nor do they have to show for a materialized, physical injury. So long as the threat to health is present, the conduct that posed the threat can be deemed an unfair method of competition. As the FTC's enforcement of the unfairness doctrine allows it to seek penalties as opposed to damages (as in antitrust law), the Commission is not required to "establish standing to sue or make their case on behalf of any particular class of purchasers". Rather, they can "focus on the overall social harm of the conduct and pursue remedies designed to deter and prevent such conduct in the future".[145] The through line in UC claims has an ethical undertone that aims to outlaw conduct not only on the basis of individual injury claims, but also on the injurious effects of high pricing at a society wide level.

(2) Second, once it is determined that there is substantial consumer injury, it must be determined that the injury is "not outweighed by countervailing benefits to consumers or competition that the practice produces". [146]

While this prong is facially similar to the antitrust principle that determination of whether a practice harms consumers should be based on its injurious net effects, its purpose is to ensure that market outcomes where the benefits and costs are balanced is not undermined by *unsubstantiated* injury claims.[147] The FTC explains, for example, that high prices are not presumptively unfair in part "because they provide important signals to other market participants to reallocate resources in ways that ultimately benefit consumers, such as entering the market or

[145] Crane (n 98) 166.

[146] 15 U.S. Code § 45(n)

[147] Beales (n 142).

increasing production if they are already in the market".[148] I believe this statement is only applicable *if the high pricing of a product does not produce substantial injury and, crucially, is not a function of the producer's patent power.* If the analysis finds that high pricing of essential medicines indeed threatens consumer's state of health, it is unthinkable why it would, on the other hand, counterbalance those costs with the benefits of the conduct in question. In any case, it seems that the task of proving the benefits of one's conduct outweighs its costs should belong to patentees. The burden would be on the patentee to justify the *necessity* of those prices and show that the injuries suffered are outweighed by the benefits of those prices *to consumers.* As the Unfairness Doctrine focuses on consumer injury as indicators of unfair practice, the costs and benefits associated to a particular practice should strictly pertain to consumers. From here, we can reasonably expect that the analysis, so long as it finds threat to health and economic harm are present, would reject any defense of high pricing as a justification for recuperating R&D costs or incentivizing future innovation. Arguably, pharmaceutical companies would still profit liberally from their patent-backed market power so as to sustain future R&D and benefit consumers in turn if they lowered the price of essential medicines. As a final thought, I believe the Unfairness Doctrine will not under-include harmful conduct so long as we hold true the basic assumption of UC law, which is that the means never justify the ends of a competitive market when those means result in considerable harm, economic or health-wise.[149] As the FTC Act's means-centric approach is tailored to protect consumer interests, we can interpret the goal of this criterion as outlawing conduct that undermines public interest, where public interest revolves around consumer welfare with specific attention to protection from harm. If the benefits to high pricing outweighs its costs

[148] ibid.

[149] Balganesh and Parchomovsky (n 140) 497.

on consumers, then the logic of this criterion implores us to accept that high pricing should be permissible under the law of UC. However, as I argued above, it seems unlikely that such a conclusion could follow if the courts accept that the high pricing of essential medicines in fact causes substantial injury in the form of economic harm and threats to health.

(3) Third, a practice is only unfair if the injury is one that "consumers themselves could not reasonably have avoided".[150]

Litigation history shows that most of the FTC's unfairness suits are brought under circumstances in which consumer choice is hindered. Cases are generally brought to put a stop to seller behavior that "unreasonably creates or takes advantage of an obstacle to the free exercise of consumer decision making".[151] In recognizing that there are some injuries that consumers cannot reasonably avoid, this test assumes that there is something else responsible for the injury other than the consumer's use of the product. This requirement recognizes that even though a market relies on the ability of individual consumers to make private purchasing decisions without intervention, there are certain types of business conduct that can prevent consumers from exercising their decision-making autonomously. Consequences of autonomous decisions on the other hand, even if harmful, are generally assumed by consumers. We can all see why there is no legal recourse to suing a manufacturer if the consumer injury results from using the product incorrectly, and not from misguiding user instruction or a product defect. The reason is simply that if the decision to purchase occurs without deceptive marketing, misguiding instructions, or an

[150] Unfairness Policy Statement, 104 F.T.C. at 1073.

[151] This emphasis on informed consumer choice has commonly been adopted in other statutes as well. *See, e.g.,* Declaration of Policy, Fair Packaging and Labeling Act, 15 U.S.C. 1451 ("Informed consumers are essential to the fair and efficient functioning of a free market economy".)

existing product defect, then any ensuing injury from use of the product cannot be said to be a consequence of deception, misguidance, or defect. Injuries that result from using a product incorrectly or recklessly are avoidable by the average consumer. To the contrary, when a company falsely advertises the benefits of a drug (with or without knowing that the drug can cause various side effects across diverse individuals), then the consumer decision to purchase is necessarily clouded by misinformation. Any resulting injury is then the consequence of that misinformed decision.

If my analysis under the substantial injury criterion is convincing, then it should be apparent that consumers of exorbitantly-priced essential medicines are subject to comparable duress at the time of purchase when they are driven to purchase those medicines. There, I argued that depending on the level of dependency one has on an essential medicine, as well as the urgency with which one needs the treatment, the threat to one's health can be greater or smaller, more or less imminent. A consumer can choose to buy the drug when he can and is willing to stretch his wallet. However, it is generally a matter of time before this willingness turns into inability. On the other hand, a consumer can also choose to not buy the drug when he can and is willing to do without. In like manner, there is a limit to which one can endure a severe illness if untreated. The outcome of both scenarios is plausibly harm – one that the consumer could not have reasonably avoided because the decision-making process was forcibly driven by damage avoidance. The two scenarios illustrated here should steer us away from the belief that one's financial capabilities is the cause of the injury suffered. Anyone can face threat to his or her health at one time or another. The uncertainty of this, as I argued, also interacts with the growing urgency with which one needs a treatment. In short, if the decision-making process is guided by avoiding the worse alternative

given one's ability or willingness to stretch his financial means or otherwise endure the illness, the ultimate decision is not a free one. If the decision to purchase (or not purchase) is made when the consumer is at a severe disadvantage, not unlike that of product defects or faulty advertising, then the resulting injuries could not have been avoided. One might object that the consumer, in opting out of the treatment, should have foreseen that his health would deteriorate. Therefore, the injury is entirely avoidable. In response to this objection, I would simply flag that we must distinguish between foreseeability and avoidability. In cases of product defect or faulty advertising, the consumers could not have avoided their injuries because the misinformation prevented them from foreseeing potential dangers. However, this does mean that foreseeability entails avoidability. In theory, one could always foresee danger in using a product. Therefore, the person who buys a chainsaw can reasonably foresee the inherent dangers of using a chainsaw, but still be unable to prevent any injuries that result from defects. Likewise, I believe the consumer who opts out of his drug treatments foresees that his health will deteriorate as a result. But this does not mean that he could have avoided the consequences of his choice. To say so would mean that the consumer's alternative to avoiding the injury is just to buy the drug, but that would be an unhelpful suggestion. Just as no one expects a defect and its associated risks, the health consequences, while foreseeable, are inevitable as no sick person (should) expects to have to bear the consequences of a "choice" they did not want in the first place.

In sum, if we can agree that (1) the inability to afford essential medicine due to their high prices is a substantial injury, that (2) the costs of the injurious practice is not outweighed by its benefits to consumers, and lastly, that (3) consumers could not have reasonably avoided the injury, the conclusion should be that high pricing is an unfair method of business as far as it concerns its

effects on consumers. There exists at least two significant rulings that are consistent with the goals of the Unfairness Doctrine (one prior to and the other after the adoption of the Doctrine). In 1968, it was found that "just as a person can be damaged without legal injury, so also can a person be legally injured without actual [or physical] damage". [152] Three decades later, the principle of harm without legal injury was established in *Steel Co. v. Citizens for a Better Env't*. Under this framework, some scholars argued that consumers ought to be included in the assessment of unfair business conduct.[153] Daniel Crane notes that "under the current U.S. system of standing, a private plaintiff who is a direct purchaser from an overcharging monopolist[154] has a right of action *to* recover the full extent of the overcharge, *even if the plaintiff passes on the entire overcharge downstream and therefore suffers no economic damage*."[155] Relinquishing the requirement of showing "actual damage" could mean two things. First, it could mean that consumers do not have to show for a physical injury. Proof of threat to health would be sufficient. Second, it could mean that consumers whose health improved from accessing the medicine can likewise be injured by the overcharge even if they did not *directly* incur an economic harm. Under the latter idea of legal injury (i.e. without actual damage), both consumers who opted in and out of buying the drug have a right of action to recover from the overcharging monopolist as a matter of UC. I believe this distinction between legal injury from actual damage and legal injury *sans* actual damage was representative of a gradual separation between antirust and UC claims on the one hand, and a reckoning with the harmful potential of patent power on the other.

[152] *Hanover Shoe, Inc. v. United States Mach. Corp.,* 392 U.S. 481 (1968)

[153] Crane (n 98) 167.

[154] Here monopolist is used in the sense of patent holder, not a market monopolist.

[155] Crane (n 98) 167.

3B. Restrictive Access as Harm to Autonomy

The Unfairness Doctrine does not spell out particular conditions under which injuries resulting either from the purchase or use of products can be deemed "not reasonably avoidable". The question therefore naturally arises - what impairs consumers' decisions to purchase a drug such that resulting injuries are those that consumers "could not reasonably have avoided?" Earlier, I noted that the degree of free exercise or control in a consumer's decision-making process is a crucial determinant for assessing whether or not the consumer could have avoided the injury. To support this proposition, we need a substantive argument for why restrictive access to essential medicine, and the conditions that create restrictive access, in fact creates consequences that we can call unavoidable harm. The following discussion is thus occupied with two complementary questions. First, what exactly is being harmed when pharmaceutical companies leverage their patent rights to price essential medicine at will? Second, are these injuries reasonably avoidable? I ground the answer to the first question in what I think is an implied fundamental right of consumers. Specifically, I define the essence of this fundamental right as the liberty against external encroachment in securing one' autonomy and bodily integrity. I believe the notion of unavoidable harm from unfair business practice and harm to autonomy is inextricably linked when the object in question concerns access to essential medicines. By arguing that it is one's autonomy that is being harmed when essential medicines are unfairly priced, I hope to show that the injurious effects of high pricing cannot be reasonably avoided by the average consumer. I believe identifying the essence of an unavoidable injury is inherently valuable as it can provide us with a stronger cause of action against patentees that is based on a violation of fundamental rights. The goal here is not to argue that the access to reasonably priced essential medicine should amount to a constitutional right. Rather, it is to simply to identify a deeper basis of the threat to health. I believe

this can pave the way for the state to intervene when prices of essential medicines hurt consumers *even in the absence of the Unfairness Doctrine* (discussed in Section 4).

(1) What exactly is being harmed when pharmaceutical companies leverage their patent rights to price essential medicine at will?

When asked what is being harmed or violated when consumers cannot afford the medicines they need, the answer is often something like a human right to health or a constitutional right to health care. In the following discussion, I explore these ideas together and discuss why entitlements to health care is aspirational but at last (currently) unfeasible in the American legal system. I propose instead for harm resulting from restrictive access to essential medicine to be couched under the liberty against government encroachment upon autonomy.

The U.S. Constitution does not contain the words "medicine," "medical care," health care," or even "health". Many constitutional scholars argue that a web of constitutional protection of health-related interests is nevertheless present.[156] The Supreme Court has been conservative in its efforts to construct entitlements to health care. In *Maher v. Roe* (1977), for example, the majority opinion held that "the Constitution imposes no obligation on the States to pay the pregnancy-related expenses…" and ruled that abortion rights were not a positive health entitlement. The legal distinction between a health-related right (which can be constructed in the form of negative liberty) and positive entitlement to funding to support those negative liberties has enabled the courts to

[156] Jennifer Prah Ruger, Theodore W Ruger and George J Annas, 'The Elusive Right to Health Care under U.S. Law' (2015) 372 New England Journal of Medicine 2558.

rule that there can be a negative liberty without a complementary positive entitlement to realize it. This leaves open a space for state discretion that puts the less well-off at a severe disadvantage. Justice Blackmun's dissent criticized *Maher* for what he saw as a "specious distinction" between negative liberty and positive entitlement, stating in *Beal v. Doe* that "the Court concedes the existence of a constitutional right but denies the realization and enjoyment of that right on the ground that existence and realization are separate and distinct.'"[157] *Youngberg v. Romeo* (1982) handed down a broader pronouncement on the limitations of federal obligations. In it, the Court ruled that "a State is under no constitutional duty to provide substantive services for those within its border". The effect is that it is exceedingly difficult, or near impossible, to "generate a positive entitlement to funding or access to effectuate these negative liberties as they relate to health and bodily autonomy".[158]

The question as to whether an entitlement to health care is plausible in the U.S. deserves a treatise unto itself. For the purpose of my task here, I believe something more domain-indiscriminate is sufficient. That is to say, access to essential medicine need not necessarily be protected under a right to health (care). As we saw, one line of reasoning shared by these cases is that while the Constitution does not (yet) stipulate any obligation for the states to provide health care, what it can guarantee is *the negative right against government interreference with the interest in question.* As opposed to a right to health care, I therefore broadly define the essence of the public interest in fair and reasonable access to essential medicines as the liberty against government

[157] Ruger (n 140) 2560.

[158] Ibid 2560.

and/or patentee encroachment in securing one's autonomy and bodily integrity.[159] Even though we might not yet be able to label the substance of this public interest as a constitutional right, characterizing it as a liberty against external interference should move it closer to a substantive right. Substantive rights are those that individuals are said to possess and those which the government may not infringe in its lawmaking capacities. The Supreme Court has ruled that the interests in securing one's "personal autonomy, bodily integrity, self-dignity, and self-determination" are protected under the Due Process Clauses.[160] Over the decades, the Supreme Court has found rights to bodily integrity as encompassing the right to refuse lifesaving treatment, to refuse medical care within the vague right to due process contained in the Constitution, and to reproductive freedom. Taken together, these cases have been interpreted to reflect increasing judicial recognition and willingness to protect claims grounded in individual autonomy and bodily integrity when it comes to health care.[161]

My proposal to conceptualize restricted access to essential medicines as harm to bodily integrity is beneficial in two regards. The logic here is similar to that of "burying" the right to abortions under the general right to privacy. As with the reproductive rights cases above, one might object that drawing a clear line between the negative liberty against state interference and the positive entitlement to healthcare provision leaves a chasm through which a great majority of citizens will be uncared for. Undeniably, these concerns flow through my proposal – i.e. conceptualizing public interest in drug access as a negative liberty against patentee or government

[159] Though it is patent practice that directly causes the harm, I make little distinction between government and patentee encroachment because the patent practices, insofar as they are permitted by the state, they represent government-sanctioned powers.

[160] *Griswold v. Connecticut*, 381 U.S. 479 (1965)

[161] Ruger, Ruger and Annas (n 157) 2559.

interference. I address this concern in Section 4 where I explore the possibility of state duty to outlaw patentee conduct *on the basis of harm alone* – that is, without statutory prohibition. The goal is not to require public provision of essential medicines. The goal is simply to find a cause to sanction patentee practice that places unreasonable barriers to access essential medicines.

(2) Are harms that result from restrictive access unavoidable?

In the following discussion, I explain how the various positions consumers are put in in order to purchase the medicine they require limit their autonomy. I propose that the Harm Principle, as articulated by Joseph Raz, can provide us with an account of harm that underpins the Unfairness Doctrine's third criterion. Raz bases the idea of harm off of limitation to personal autonomy.

Innovating pharmaceutical companies often "evergreen" their patents, create patent thickets around the primary patent, or partake in pay-for-delay settlements that restrict competition (arguably) beyond the scope permitted by the initial patent grant. The absence of competition not only emboldens patentees to continue charging a premium price for their product, it creates the conditions that enable monopoly pricing in the first place. The consequence is that consumers not only cannot afford the drug prescribed to them, *they have no freedom to opt for a cheaper alternative*. For Raz, to be autonomous a person "must not only be given a choice," but "he must be given an adequate range of choices". He writes that "a person whose every decision is extracted from him by coercion is not an autonomous person…".[162] As a consequence of these injurious patent practices, consumers are effectively coerced into purchasing the only available brand name

[162] Joseph Raz, 'Autonomy, Toleration, and the Harm Principle' in Susan Mendus (ed), *Justifying toleration: conceptual and historical perspectives* (Cambridge University Press 1988) 314.

drug or else suffer a continued state of ill health. Under these circumstances, it seems that one is not only harmed because the injury is one which the consumer could not have reasonably avoided, but is harmed because one's autonomy is severely limited by the monopoly overcharge. The notions of unavoidable injury and limited autonomy go hand in hand. If one cannot subsist due to circumstances out of one's control, then one does not have control over the maintenance or improvement of one's health. One's decision to buy or not buy an essential medicine is always motivated by the relative dependency and urgency with which one needs the medicine. This much is uncontroversial. However, this motivation becomes *coerced* when the terms to access are so prohibitive that the decision to purchase (or not purchase) a drug is *not only* driven by need but is also largely determined by one's ability to overcome the financial barriers. In these circumstances, there is always a stark trade-off between health and financial capability. Whatever the consumer's decision is, the health consequences suffered thereafter will always be a product of coercive purchasing conditions, and therefore are arguably unavoidable. If one cannot reasonably be expected to avoid the injury from a market decision made under duress, then one does not have sufficient control over one's body. This should suggest to us that harm to autonomy is conceptually prior to the notions of threat to health and unavoidable harm.

In Raz's critique, he writes that autonomy is "not a choice between good and evil". [163] Our context requires a modification of the "good and evil" dichotomy. If health is our subject matter, then it seems like a rather insignificant comparison to say that buying the drug is "good" in that it improves our condition, and the consequences of not buying is "evil" in that it can worsen our condition. Under this framework, does it not mean that regardless how high the price tag is, buying

[163] ibid.

is always better than not buying the drug? If we make financial health as our sole subject matter, *not* buying the drug is "good" and buying the drug is "evil" (in that it decreases one's capacity to afford future prescriptions or requires one to make sacrifices in other areas of life). Under this framework, does it not mean that *not* buying is always better than buying, irrespective the price? Raz's response might be that regardless if the consumer ultimately obtains the drug, the consumer has to go through extensive cost-benefit analysis to determine if either decision will lead to less suffering, whether in physical health or financial terms. To say that the consumer's autonomy is harmed because his range of choices is limited to a "good" and "evil" one does not fully capture the core dilemma consumers of highly priced essential medicines are in. Their dilemma is *not simply* that the "good" option– i.e. buying the drug – is paired with an "evil" one – i.e. not buying the drug. Arguably, this dichotomy will always hold even if these drugs are offered for a low price. The central dilemma is rather that the only viable choice to improve one's health is priced so high that it is often not a real choice for many consumers. The more appropriate dichotomy is thus between a "bad" – i.e. buying the highly-priced drug and having to sacrifice other essential needs - and "worse" one – i.e. not buying the drug and suffering the health consequences. For a person to choose autonomously, the set of choices must either offer *at least* two ways to improve his situation (e.g. a brand name and generic at two price points), or set the terms of access for the only available option at a reasonable rate such that the choice to purchase is not, as I argued, a decision between a bad and a worse one. If we are convinced by the conception of harm as restrictions to autonomy, and the duress it places on one's capacity to make an unencumbered decision, then we can see how high pricing of essential medicines can *potentially* be a violation of the fundamental right in protecting oneself against external intrusion on one's autonomy and bodily integrity. In any case, conceptualizing the injurious effects of restrictive access along the lines of harm to

autonomy and bodily integrity can get us closer to proving that high pricing of essential medicines, *at minimum,* is unfair practice.

3C. Tensions from Federal Preemption of State Unfair Competition Laws

The IP Clause is the sole authority under which U.S. intellectual property laws have been enacted. Thus federal patent legislation passed with the authority of the IP Clause, combined with the Supremacy Clause, which establishes the Constitution and federal laws as supreme, has created a strong tradition of federal preemption in intellectual property cases.[164] As we saw, courts have used antitrust law and judicially created doctrines like the patent misuse doctrine as a check on patent rights when their use reached beyond the scope of their statutorily granted power. These approaches have not spared controversy due to the tension between federal intellectual property law and state enforcement of antitrust laws. When state laws are said to conflict with the rights granted by federal patent statutes, they are often preempted by federal law. With that said, many scholars think that federal law's preemptive power over state laws in the intellectual property space remains unclear.[165] As this raises legitimacy questions for the UC law proposal, I respond to this concern and address whether UC law is usable in cases where federal intellectual property law is potentially controlling.

The Supreme Court has classified three types of preemption doctrines. The grounds for preemption are summarized by the Federal Circuit in *Cover v. Hydramatic Packing* (1996):

[164] Wied (n 69) 479.

[165] Jeanne Fromer, 'The Intellectual Property Clause's Preemptive Effect' in Shyamkrishna Balganesh (ed), *Intellectual Property and the Common Law* (Cambridge University Press 2013).

(1) **Explicit preemption** occurs when Congress explicitly provided for preemption of state law in the federal statute;
(2) **Field preemption** occurs when "the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it, either because the federal interest [in the field] is so dominant or because the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose";
(3) **Conflict preemption** can occur when "compliance with both federal and state regulations is a physical impossibility," …or where state law "stands as an obstacle to the accomplishments and execution of the full purposes and objectives of Congress.[166]

Peter Wied notes that given the absence of an explicit preemption clause in the patent statute, state laws ought to be assessed under the latter two forms of preemption. The Federal Circuit has also held that "there is no field preemption of state UC claims that rely on a substantial question of federal patent law" due to the "lack of such congressional intent, in conjunction with the underlying presumption disfavoring preemption".[167] This means that we are left with conflict preemption as the only plausible obstacle in subjecting patentee conduct to UC law.

The issue of state UC law's encroachment on federal patent law was addressed in *Sears, Roebuck & Co. v. Stiffe.* Citing conflict of objectives, the Supreme Court ruled that "just as a State cannot encroach upon the federal patent laws directly, it cannot, under some other law, such as that forbidding UC, give protection of a kind that clashes with the objectives of the federal patent laws".[168] In *Kewanee Oil,* the Supreme Court noted the three functions of the patent statutes, namely that they are enacted to provide (1)"an incentive to inventors," (2) "[t]o insure adequate

[166] *Cover v. Hydramatic Packing Co.,* 83 F.3d 1390, 1393 (Fed. Cir. 1996)

[167] *Hunter Douglas, Inc. v. Harmonic Design, Inc.,* 153 F.3d 1318, 1333 (fed. Cir. 1998), *cert. denied,* 119 S. Ct. 1037 (1999); see also Wied (n 61) 483.

[168] *Sears, Roebuck & Co. v. Stiffel Co*. 376 US at 231 (1964).

and full disclosure," and to ensure (3) "that which is in the public domain cannot be removed therefrom by action of the States".[169] The rule therefore is that so long as the use of the state law does not conflict these objectives, it will generally be permitted.

Additionally, it seems that the courts are optimistically open to the use of state laws as a means to curb negative externalities on consumers in the normal course of intellectual property use. Wied points to a constancy across these preemption cases that use of UC laws are permissible if they are aimed at preventing consumer confusion in commercial activities rather than regulating the contents or activities as they relate to intellectual property. This is consonant with the Court statement in *Kewanee* that "instead of being aimed strictly at the act of copying, the protection of trade secrets [through UC law] promoted '[t]he maintenance of standards of commercial ethics'".[170] The relevance of commercial ethics in preemption cases is particularly telling of the court's understanding of the distinct purpose of UC law. Shyamkrishna Balganesh and Gideon Parchomovsky have described UC law as having a key role in "shaping commercial morality and ethics" .[171] Balganesh has emphasized what he calls the "broadening function" of UC law. Use of UC concept, he argues, "enables equity and common law courts to expand the relatively rigid rules of property and torts". [172] The broadening function of UC law can provide courts and policymakers with a "limiting mechanism to scale back existing intellectual property and exclusionary protection in areas where the law seems to be expanding at the cost of social welfare".[173]

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[169] *Kewanee Oil Co. v. Bicron Corp*., 416 US 480-81 (1974)

[170] ibid 481.

[171] Balganesh and Parchomovsky (n 139) 484.

[172] ibid 484.

[173] ibid 502.

Applied to the context of monopoly overcharge of essential medicines, so long as we are not using the Unfairness Doctrine to take away something from the public domain by invalidating the patent, or otherwise claiming that the patent was obtained through fraud, the invocation of UC law should not come in conflict with the objective of federal patent law. I believe my use of UC law, specifically Section 5(a) of the FTC Act and its Unfairness Doctrine, lies outside the preemptive scope of the IP Clause. Since patent law contains no provision concerning consumer welfare, the use of the Unfairness Doctrine to target the social externalities that result from patent use or injurious patentee conduct should not ring alarms for preemption. In essence, what the Unfairness Doctrine does is that it provides consumers with a legal recourse in the form of an injunction if the plaintiff can show that the consumers' injury matches those described in the Doctrine. FTC enforcement of the Unfairness Doctrine should not stand in the way of the full execution of the IP clause and other federal patent legislations. Using consumer injury as a basis to outlaw business conduct arguably does not undermine the patent incentive, does not impede disclosure of inventions, and does not forcibly or without warrant remove knowledge from the public domain. At most, if a case under the Unfairness Doctrine were to succeed, this would lead to a cease-and-desist order upon which the patentee must either stop its conduct in the manner as contested by the plaintiff, regardless if the conduct makes explicit use of patent rights. No patent invalidation will occur as a result of this injunction. If the means and ends of UC and patent law do not conflict, then the worry of federal preemption should be attenuated.

Section 4. A World without the FTC ACT: The Duty to Prevent Harm

In Section 3, I explored how the law of UC, specifically the Unfairness Doctrine, can provide a basis for a cause of action against patentees in virtue of high pricing of essential medicines' injurious effects on consumers. There, we saw that while one's decision to buy or not buy an essential medicine is always motivated by the relative dependency and urgency with which one needs the medicine, this motivation becomes *coerced* when the barriers to access are so high that the decision to purchase (or not purchase) a drug is *not only* driven by need but is also largely determined by one's capacity to overcome the financial burdens. In these circumstances, there is always a trade-off between health and financial capability. Whatever the consumer's decision is, the health or financial consequences suffered thereafter will always be a product of coercive purchasing conditions, and therefore have been argued to be unavoidable. As substantial and unavoidable injuries are the results of encumbered consumer choice, any conduct that is coercive in the manner described is unfair.

If, however, the Unfairness Doctrine, or UC law at large, fails to curb patentee conduct that cause substantial and unavoidable harm, does it end there? To explore this possibility, let us partake in a thought experiment wherein there is no statute that outlaws injurious patentee conduct. In this world, the justification for legal intervention would differ from that of the Unfairness Doctrine as wrongdoing would not be found on the basis of a statute or doctrine. A cause of action against patentees might find its basis on the plain fact that harm has occurred. Patentee conduct could be wrongful because they violate a fundamental right of consumers. Though the right to health (care) route was foreclosed in Section 3B, I noted there that consumers' interest in fair and reasonable access to essential medicine can be secured in the liberty against encroachment upon

one's autonomy and bodily integrity. The idea that corporate practice that directly restricts people's access to essential medicines effectively harms their autonomy is echoed throughout my analysis of consumer harm under the Unfairness Doctrine. Consumers not only would never wish to sacrifice their health out of destitution, they would never do so if the circumstances effectively bring about that outcome. Consumers might therefore reasonably view the barriers to subsistence as an undue infringement upon their efforts to maintain or improve their health. Efforts to maintain and improve one's health, arguably, is a matter of bodily integrity. In section 3B, I prefaced that, should the law of UC fail to curb injurious patentee conduct, defining the essence of the interest in fair and reasonable access as a liberty right against encroachment upon one's autonomy and bodily integrity can provide us with a stronger cause of action against patentees that is based on a violation of fundamental rights.

My basic belief is that restricting consumers' access to essential medicines constitutes a sanctionable wrong *irrespective if a law can be interpreted to outlaw said conduct.* This is because no property right, however strong the protection afforded to it is, can be used to commit a tort. I hold central the legal principle that if there is a right or involved, then there ought to be a corresponding duty on part of a relevant party to protect that right or interest. Thus, even in the absence of statutes that outlaw harmful conduct, there ought to remain a viable cause of action for consumers when their autonomy is harmed by the exercise of patentee power. I explore this position with two brief, related suggestions. First, I argue that it is the state who has the duty to prevent harm even if no statute requires it to. Accordingly, existence of harm alone should be sufficient to create a cause of action against the state to use its coercive powers to regulate the harmful practices. Second, I propose that if showing of undue burden has led courts to prohibit

policies and practices that created those burdens in the past, then the principle behind the undue burden standard should be expanded to cover harms that result from restrictive access to essential medicine. I argue there that the principle that guides the undue burden test is just an iteration of the goal of harm prevention. This principle of harm prevention is what can give the state a formal duty to exercise its powers to ensure that the broader social purpose of the patent system – i.e. public access to the benefits *of* innovation[174] – is not undermined by private interests.

4A. The Duty to Prevent Harm

In Section 1, I argued that a broader conception of the public benefit of patent law requires an expansive understanding of the purpose of the patent system. The public interest of the patent system must be broader than cumulative innovation itself; it must include the enjoyment of the patented technology by the *general* public. As I noted there, promotion of the public interest in accessing the benefits of the technology cannot be meaningfully carried out lest it be buttressed with the legal duty to protect it. We learned a similar lesson from the history of our health care case law that without federal or state obligation to protect certain liberties, patients are not entitled to the provision of those services (at least through state funding). Private entities' decision to not provide, say, abortion procedures can align with and so be supported by state interests if there is no overriding federal legislation that strictly requires its provision. With that said, the argument I wish to advance is *not* that there ought to be a federal legislation that requires some form of government subsidization of essential medicines. Although this would undoubtedly mitigate the

[174] I distinguish "benefits of innovation" from "benefits as innovation" in Section 1 and endorse the former as the correct interpretation of the public interest of the patent system.

access crisis, I believe it cannot adequately help us transform injuries-in-fact into legal injuries (for reasons explained in the introduction).

I believe a cause of action can be created on the existence of harm alone when supplied with a satisfactory justification for state intervention. To do so, we need a political framework that regards the rule of law as existing to maintain a social order that cannot sustain itself when any person's autonomy is privileged over that of others. Currently, the law's broad construction of the right to exclude and the lack of consumer welfare provision in patent law tell us that we do not live in a legal world that values patentee and consumers' liberty from interference equally. When those interests collide, there is simply no legal concept that adequately captures the consumer harm suffered. While antitrust law provides litigants with the antitrust injury claim, we saw how its procedural requirements can ultimately thwart efforts to protect consumers. If even the Unfairness Doctrine fails to curb injurious monopoly overcharges, then perhaps a formal duty to prevent harm independent of statutory law is the structural change needed.

In my discussion of harm in Section 3B, we saw that for some political theorists, failure to live up to one's duty to improve another's situation can also constitute a form of harm. Immanent in that notion of harm is the assumption that there exists a duty to prevent harm. According to this broader conception of harm then, the question arises to whom the duty to prevent harm belongs. Since patentees are not bound by patent law to minimize foreseeable consumer harm, is their conduct liable to some broader principle of harm prevention? Alternatively, is it the government who has the duty to ensure that all forms of patentee power do not harm? As patents and their associated rights are sanctioned by the state, the state is a principal enabler of the legal environment

in which monopoly overcharges of essential medicines is permitted. It should therefore be incumbent upon the state, as a protector of fundamental rights, to impose injunctions on patentee conduct when they cause harm to consumers' autonomy and bodily integrity. The Harm Principle regards the prevention of harm to anyone as the *only* justifiable ground for coercive interference by the state. According to these theories about the limits of the law then, it is clear that matters pertaining to the prevention of harm is not only within the purview of the state, it is *the reason for which the rule of law exists*. If the government is obliged to prevent harm when it occurs, then the means used to carry out that duty is justified *even if it supposedly limits the harmer's autonomy.* This limitation of patentee autonomy is supposed as the exercise of any property right is always subject to background laws. Therefore, any exercise of patent rights, or patentee conduct generally, that effectively commits a tort against another person is not an entitlement of patent rights. With this understanding, any use of patent power justifies legal intervention by the state if it causes harm to others, particularly when it infringes upon another's ability to determine for themselves the maintenance and improvement of their bodily integrity and autonomy.

We should note that Raz does not assume that respect for autonomy requires the government to refrain from pursuing any conception of morality through legislation.[175] The Harm Principle not only allows the government to use its coercive powers to stop acts that diminish people's autonomy, it also encourages the state "take actions which are required to improve people's options and opportunities".[176] Because any intervention premised on an autonomy-based value, where this value is not only personal autonomy but also entails "the dut[y] on people to

[175] Raz (n 163) 313.

[176] Ibid 328.

secure for *all* the conditions of autonomy,"[177] ordering patentees to desist from pricing essential medicines exorbitantly would not amount to an unjustified limitation of their autonomy. What the rule of law exists to maintain is an order in which *everyone's* autonomy can be maximally lived out. If the blanket protection of patentee autonomy takes away from consumers their opportunities to improve their situation, then the state, as an agent of harm prevention, can be justified in intervening to restore the consumer's lost autonomy. In short, the duty to secure conditions necessary for everyone to enjoy maximal autonomy precedes that for the autonomy to exercise the right to exclude. In a world where there is no such duty, the mightier can legitimately justify his limitation of another's autonomy as an exercise of his *individual* autonomy. Yet we believe that in a world where individual autonomy is a function of one's economic or political might, the rule of law would cease to function as it can be expected to discriminately privilege certain autonomies on the basis of economic or political might. Over time, such a system would fail to ensure autonomy as a baseline condition for all. If we can accept that the state's duty to prevent harm allows it to limit patentee autonomy whenever its consequences severely limits consumers' autonomy, then a cause of action based on the existence of harm alone is not entirely implausible.

4B. A Tradition for Harm Prevention

Above, I discussed how the state's duty to prevent harm can serve as a standalone justification for intervention in cases where their conduct clearly causes harm to consumer's autonomy. Specifically, I argued that this duty to protect the public interest in reasonable access to essential medicines can be formalized if it bases itself off of principles of harm prevention. Here, I support that proposition with concepts and legal reasoning from the undue burden standard and

[177] ibid 328.

substantive due process to show that harm prevention is already a recognized principle courts use in judging whether a given legislation is injurious to people's fundamental rights.[178] From there, I attempt to show how harm to consumer interest in reasonable essential medicine access, if conceived of as a fundamental right, can plausibly be put under these two tests to justify state intervention on the basis of harm.

Fundamental rights are a group of rights that encompass those that appear in the Constitution (specifically the Bill of Rights) and substantive rights carved out under the Due Process Clauses, which prohibit federal and state governments from depriving any person of "life, liberty, or property, without due process of law".[179] [180]As laws that allegedly encroach upon a fundamental right must be strictly scrutinized to be upheld as constitutional, the Undue Burden test stipulates that legislation that restricts one's fundamental rights shall be outlawed. The goal that the undue burden test actively tries to achieve, I argue, is essentially harm prevention. Presumably, when the court is assessing which burdens are undue, the line between undue and tolerable burdens is governed by the perceived and actual capacity of the legislation to cause injury to the affected people's fundamental rights. Redescribed as harm prevention, the reason that burden is undue for purchasers of essential medicine would be that the high prices prohibit consumers to make a meaningful choice (i.e. buy or not buy) because either decision can lead to unwanted health consequences in the short and long run. As I argued in Section 3B, depending on

[178] Jennifer Prah Ruger, 'Toward a Theory of a Right to Health: Capability and Incompletely Theorized Agreements' (2006) 18 Yale Journal of Law & the Humanities (See for an overview of the health-related interests state courts, legislatures, and Congress have carved out protection for throughout the years.)

[179] U.S. Const. amend. XIV, § 1.; U.S. Const. amend. V.

[180] Legal Information Institute, 'Fundamental Right ' (*Cornell Law School*).

whether the individual consumer places a higher value on health or other essential needs, the decision to buy at market price (or even with public insurance) is either a bad or worse one.

If we are convinced that the undue burden test is essentially an injunctive mechanism for fundamental rights harm prevention, and showing of undue burden has led courts to prohibit policies that created those burdens in the past, then it should not be far-fetched to claim that the undue burden standard can be expanded to cover harms that result from restrictive access to essential medicine these overcharges, as I argued, harms one's autonomy and bodily integrity. To the extent that these prices should be permitted, the state or defendant would have to provide a legitimate, rational justification for their existence.[181] To motivate this discussion, we must at least make a convincing argument on two fronts:

First, we must argue that the consumer interest in unencumbered opportunities to improve one's situation through essential medicine, *which is necessary to the maintenance of one's life and health,* should be protected as a substantive right under the Due Process Clauses. This will help us move the consumer interest in question from a public interest to a fundamental right (in the form of a negative liberty). Only when restrictions to reasonable access to essential medicine is viewed as a breach of fundamental rights does the undue burden test apply. As substantive due process demarcates the line between acts that are subjectable to regulation and those that lie beyond the reach of state interference, it is important that we demonstrate why exactly legislation or business conduct that restrict consumer autonomy does so in a way that deprives consumers of their life and

[181] *Planned Parenthood v. Casey,* 505 U.S. 833, 920. (Justice Stevens' partial concurrence in *Planned Parenthood v. Casey* (1992) defined undue burden as policies that are "too severe [in its execution of the intended goal] or… lacks a legitimate, rational justification".)

liberty without due process of law. I believe my discussion on how high pricing harms consumers' autonomy and bodily integrity in Section 3B provides an adequate start to this task. As I argued there, the notion of restrictions to consumer choice and harm to autonomy is closely intertwined when it comes to access to essential medicine because the high price points (combined with the fact that there are often no generic alternatives) structures consumers' decision-making process in such a way that, depending on whether the individual consumer places a higher value on short term physical health or long term financial capacity to continue purchasing the drug, the decision to buy at market price (or even with public / private insurance) is either one that limits their autonomy or *severely* limits their autonomy.

Second, we must show how doctrines designed for assessing the constitutionality of legislations can be applied to business conduct. While the standard primarily applies to legislation, we should recognize that all patent use and conduct that have not been outlawed are presumptively lawful manifestations of federal patent law. Many of these (arguably anticompetitive) patent practices and patentee conduct exist in the grey area of presumptive legality precisely because they are neither expressly authorized by patent statutes nor have they been outlawed. To clarify, in applying the undue burden test to corporate conduct, the Court would not be ruling on the constitutionality of the patent statutes when adjudicating whether, say, reverse payments are lawful exercises of patent rights. In this sense, the undue burden standard and substantive due process do not match our needs in exact terms. With that said, I believe by using the abstract principle of harm prevention that underly the undue burden test, the state would be justified to determine if high pricing of essential medicines restricts the consumer's autonomy and bodily integrity in a fashion that violates one's fundamental right to autonomy. I began this (thesis) by noting that restrictive

access to essential medicines cannot be properly addressed without some form of state intervention for the simple reason that any patent practice or business conduct, so long as they have not been expressly outlawed, is a presumptively lawful exercise of the patentee's right to exclude. Therefore, at the least, the law's impulse of harm prevention and the existence of consumer harm should be sufficient to stimulate discussion around the need for state intervention even if these harms are not conceptualized as interferences with one's autonomy and bodily integrity.

Conclusion

We began this discussion by identifying the controversial and persistent problem of restrictive access to essential medicines in the U.S.. In the essential drugs market, broad protection of patent rights often give rise to monopoly overcharges as companies pursue high profits. The egregious manifestations of this industry behavior can partially be explained by the absence of price cap laws, the government's weak price negotiation mechanisms, and the absence of legal sanctions – all of which create an environment in which market pricing at will has no legal repercussions.

The Covid-19 Pandemic has sparked renewed scrutiny of corporate practices that effectively constrict public access to essential drugs. Recent attention afforded to the impediments to accessing coronavirus treatments has largely focused on blunt instruments such as compulsory licensing or government takings approaches. The logic behind compulsory licensing and regulatory takings of patent rights assumes that it is the patent (and its associated rights) that *directly* lead to higher prices. As such, they assume that mitigating the patentee's monopoly power will lower prices through competition. While this might be true to a certain extent, we must accept

that, in theory, while high pricing is often enabled by the right to exclude, its exercise does not depend on patent power. I believe the fundamental issue with the access problem is that there is no liability-based relation between the patentee and the consumers on the one hand, and between the patentee and the government on the other to curb conduct that prevents access. Currently, it is exceedingly difficult to create such a relationship in law. I believe this is primarily because there is no consumer welfare provision in patent law that creates an obligation incumbent upon patent holders to refrain from conduct that are or could be injurious to the public. The rules of patent law are thus limited and therefore unable to address the externalities that flow from its existence.

Many patent practices can be made subject to antitrust scrutiny and condemned if a threat to competition is shown. As we saw, patent misuse is raised as a defense against infringement claims when the patentee's conduct allegedly exceeds its sanctioned scope. Antitrust law has been used to regulate patentee conduct where their exercise of patent rights caused harm to competition. Even though antitrust law enforcement is theoretically geared towards the promotion of consumer welfare as it is primarily designed to address harm to competition, consumer injury as a legal harm can only be established as an outgrowth of harm to competition. This is difficult as the line between a patent and market monopoly is never entirely clear. Additionally, consumers have to overcome great burden to establish standing, as the task of showing that the injuries they suffered are those that antitrust law is designed to address is challenging to begin with. While antitrust law provides litigants with an antitrust injury claim, its procedural requirements ultimately thwarts efforts to protect consumers.

In order to target patentee behavior in the essential medicines market, the cause of action against patentees must be based on the injurious capacity and effects of their pricing conduct alone. The legislature has taken a step to resolve unfair competition issues by writing the Federal Trade Commission Act (FTC Act) into law and courts have constructed the Unfairness Doctrine to support that end. The law of unfair competition, specifically its Unfairness Doctrine, has been under-discussed as an alternate to antitrust law in regulating patentee conduct. As it can outlaw methods of competition on the basis of consumer injury *alone,* the law of unfair competition can provide the public with a tort-based cause of action in virtue of the business conduct's injurious effects on the public. The Unfairness Doctrine offers us three conceptions of injury that can capture the harm that results from restrictive access to essential medicines. Upon showing that the injury is "substantial," is "not outweighed by countervailing benefits to consumers… that the practice produces," and is not of a kind that "consumers themselves could…reasonably have avoided," the pricing conduct can be outlawed as an unfair method of competition. In my analysis, I argued that threat to health occurs at the moment in which the consumer is forced to weigh their health dependency against their willingness and ability to stretch their financial means. Depending on the level of dependency one has on an essential medicine as well as the urgency with which one needs the treatment, the threat to one's health can be greater and more imminent. If high pricing of essential medicines causes economic harm and poses a threat to health, the resulting injury is at least substantial. From here, we can reasonably expect that the analysis, so long as it finds threat to health and economic harm are present, would reject any defense of high pricing as a justification for recuperating R&D costs or as a matter of patent right. In any case, I believe the Unfairness Doctrine will not under-include harmful conduct so long as we hold true the basic assumption of unfair competition law, which is that the means never justify the ends of a competitive market

when those means result in considerable harm, economic or health-wise. Lastly, I argued that the injury is of a kind that consumers could not have reasonably avoided because the purchasing conditions are coercive. If the decision-making process is guided by avoiding the worse alternative given one's ability or willingness to stretch his financial means or otherwise endure the illness, the ultimate decision is not an autonomous choice. If the decision to purchase (or not purchase) is made when the consumer is at a severe disadvantage, not unlike that of product defects or faulty advertising, then any resulting injuries likewise could not have been avoided.

Should the law of unfair competition fail to curb injurious patentee conduct, having defined the essence of the interest in fair and reasonable access as a liberty against encroachment upon one's autonomy and bodily integrity can provide us with a stronger cause of action against patentees that is based on a violation of fundamental rights. I believe that even in the absence of statutes that outlaw harmful conduct, there ought to remain a viable cause of action for consumers when their autonomy and bodily integrity are harmed by patentees. I supported that proposition with legal reasoning from the undue burden standard and substantive due process to show that harm prevention is already a recognized principle courts use in judging whether a given legislation (in this case state sanctioned use of property rights) is injurious to people's fundamental rights. From there, I provided a brief discussion over how harm to consumer interest in reasonable essential medicine access, if conceived of as a fundamental right, can plausibly be put under these two tests to justify state intervention on the basis of harm.

One might object that drawing a clear line between the negative liberty against state interference and the positive entitlement to healthcare provision leaves a chasm through which a

great majority of citizens have been and will be uncared for. For reproductive rights cases, this shortcoming meant that even if one has the right to abortions through the liberty against government interference, one has no right to demand the provision of abortions through state funding. Undeniably, these concerns flow through my proposal: conceptualizing public interest in drug access as a negative liberty against harm from patentee conduct does not translate into the ability of federal and state governments to require that pharmaceutical companies lower drug prices. Nevertheless, I believe that, by appealing to broader notions of autonomy and undue burden, the controlling tendency of patent law can be attenuated. At the minimum, consumers will be given a fairer chance at establishing standing without having to prove that they suffered an antitrust injury. Equally important is the implication that high pricing would not be viewed as a corollary right of the patent right. As monopoly pricing is merely a consequence of market power, it would be wrong to compare consumers' autonomy against the autonomy of patentees. In principle, this would mean that when a court is deciding between the consumers' autonomy and that of the patentee, it becomes much less clear why the right to exclude should enjoy near unconditional protection at the expense of consumer's autonomy from harm. While the state might not be obligated to subsidize the purchase directly, what it can do is use its duty to prevent harm to autonomy as an injunction against the use of rights that create prohibitive barriers to access essential medicine. In sum, I believe the abstract principles of harm prevention that underpins the undue burden test and substantive due process not only provides us with a final line of defense when all statute-based causes of actions are exhausted, it can also serve as a standalone justification for state intervention. This thought provides me with tremendous comfort and hope that the scale between producer and consumer interests will be rebalanced.

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