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### Drugs, Patents, and Well-Being

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## DRUGS, PATENTS, AND WELL-BEING

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### *Abstract*

The ultimate end of patent law must be to spur innovations that improve human welfare—innovations that make people better off. But firms will only invest resources in developing patentable inventions that will allow them to make money—that is, inventions that people will want to use and buy. This can gravely distort the types of incentives that firms face and the types of inventions they pursue. Nowhere is this truer than in the pharmaceutical field. There is by now substantial evidence that treatments for diseases that primarily afflict poorer people—including the citizens of developing nations—are dramatically under-produced, compared with drugs that treat diseases that afflict the wealthy. In addition, the pharmaceutical markets are rife with “me too” drugs—drugs that treat diseases or conditions for which successful medications already exist.

This state of affairs is not inevitable. In recent years, medical and psychological research on well-being has created the capacity for policymakers to draw direct links between patents and human welfare. Armed with this information, policymakers have, for the first time, the power to use the patent system to directly incentivize welfare-enhancing innovations. In this Article, we propose a system of extended patent terms for drug inventions that have a substantial impact on human welfare. We further propose that policymakers lift many of the legal protections for patents that have an *insubstantial* effect on human welfare—which we term “futility patents”—making those patents easier to challenge and invalidate. The result would be a reorientation of pharmaceutical firm incentives toward drugs that will have a significant impact on welfare, particularly for poorer and underserved populations, and away from drugs that are profitable but do little to improve human life.

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INTRODUCTION

What is the purpose of patent law? The conventional understanding of patents is that they exist to promote innovation—or, as it says in Article I, Section 8 of the US Constitution, to “promote the Progress of Science and useful Arts.”<sup>1</sup> But innovation is not good in and of itself. A society that innovated only more and better ways to torment itself<sup>2</sup> would not be doing well. Rather, the ultimate end of patent law must be to spur innovations that improve human welfare—innovations that make people better off. To accomplish this, patent law is parasitic on the marketplace. Patents entitle their owners to exclude competitors from making, using, or selling the patented invention for a limited time.<sup>3</sup> In effect, patents create legal quasi-monopolies: if only the patent owner can sell the patented invention, then the patent owner can charge (higher) monopoly prices and earn greater profits. It is this promise of greater profits that should spur innovation.<sup>4</sup>

Because patent law relies on the market—and the possibility of monopoly profits—it necessarily incorporates all of the strengths—but importantly, all of the many shortcomings—of market behavior.<sup>5</sup> Most notably, patent law relies on individual consumers to decide which inventions are valuable and which are not. Firms will only invest resources in developing inventions that will allow them to make money—that is, inventions that people will want to use and buy. The fact that people are excited to purchase an invention, even at monopoly prices, is usually taken to be a powerful signal that the invention is valuable and will increase human welfare. If not, why would people pay for it?<sup>6</sup>

But markets are hardly infallible. The fact that an innovation is beneficial for human welfare does not mean that it will be profitable, if the people whose welfare it will increase cannot afford it. This means that innovations that primarily serve poorer people will be underproduced.<sup>7</sup> In addition, sometimes it is possible to capture substantial market share with an invention that is only slightly better (or even no better) than the inventions that preceded it. This means that firms have significant incentives to play a version of follow-the-leader: if Firm A has created an invention that is selling well, Firm B can make money by creating a similar invention and siphoning off some of Firm A’s customers, even if Firm B’s

<sup>1</sup> U.S. Const. Art. I § 8, cl. 8.

<sup>2</sup> *See, e.g.*, Facebook, [www.facebook.com](http://www.facebook.com); Twitter, [www.twitter.com](http://www.twitter.com).

<sup>3</sup> 35 U.S.C. § 271 (“Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”).

<sup>4</sup> WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 20 (2003).

<sup>5</sup> Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 *YALE L.J.* 1900, 1927 (2013).

<sup>6</sup> For further discussion, see *infra* notes 41-45.

<sup>7</sup> Jean O. Lanjouw, *Intellectual Property and the Availability of Pharmaceuticals in Poor Countries*, 3 *INNOVATION POL’Y. & ECON.* 91 (2003).

invention represents, at most, a marginal improvement on Firm A's invention.<sup>8</sup> Patent law's reliance on markets can thus drive firms to invent products that they know will sell well, rather than products that might have a much greater impact on welfare.

These concerns are present across a wide range of technological areas, but perhaps nowhere more so than in the area of pharmaceuticals. There is by now substantial evidence that treatments for diseases that primarily afflict poorer people—including the citizens of developing nations—are dramatically underproduced, compared with drugs that treat diseases that afflict the wealthy.<sup>9</sup> In addition, the pharmaceutical markets are rife with “me too” drugs—drugs that treat diseases or conditions for which successful medications already exist.<sup>10</sup> A “me too” drug that taps into a large consumer market can be very profitable even if it offers small or zero (or negative) benefits compared with the drugs that preceded it. And these drugs, which contribute little or nothing to human welfare, can absorb scarce research and development funds from pharmaceutical firms and crowd out investment in drugs that might do much more good.

Policymakers have largely treated these shortfalls as if they are unavoidable, the necessary consequences of patent law's slavish devotion to the market. The problem has been thought to be one of measurement.<sup>11</sup> How could policymakers know which drugs are most valuable to welfare—and thus most deserving of encouragement and incentives—without a signal from the market? Put another way: if the entire point of patent law is to rely on the market to determine which inventions are valuable, it is no wonder that policymakers seem to be at a loss when the market turns unreliable.

But policymakers no longer need feel so constrained. In recent years, medical and psychological research on well-being has revealed new ways of understanding and measuring human welfare, to the point that policymakers can now estimate with substantial accuracy how much a given disease or condition diminishes welfare, and how much a particular drug treatment improves it. The most promising approach involves the science of hedonic psychology, through which researchers have been able to determine close proxies for welfare.<sup>12</sup> Hedonic

<sup>8</sup> See *infra* notes 69-71.

<sup>9</sup> Amy Kapczynski, Samantha Chaifetz, Zachary Katz & Yochai Benkler, *Addressing Global Health Inequalities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031 (2005).

<sup>10</sup> Brita Petarsky, *Should Financial Incentives be Used to Differentially Reward 'Me-Too' and Innovative Drugs?*, 28 PHARMACOECONOMICS 1 (2010).

<sup>11</sup> See *infra* notes 49-58.

<sup>12</sup> See DANIEL KAHNEMAN, EDWARD DIENER & NORBERT SCHWARZ, EDS., *WELL-BEING: FOUNDATIONS OF HEDONIC PSYCHOLOGY* (1999). Our work joins a growing cohort of legal scholars who are interested in applying the insights of hedonic psychology to legal problems. See e.g. JOHN BRONSTEEN, CHRISTOPHER BUCCAFUSCO & JONATHAN S. MASUR, *HAPPINESS AND THE LAW* (2014); ERIC A. POSNER & CASS R. SUNSTEIN, *LAW AND HAPPINESS* (2010); MATTHEW ADLER & MICHAEL FLEURBAY, *OXFORD HANDBOOK OF WELL-BEING AND PUBLIC POLICY* (2016); David Fagundes, *Buying Happiness: Property, Acquisition, and Subjective Well-Being*, 58 WM. & MARY L. REV. 1851 (2017); Irina D. Manta, *Hedonic Trademarks*, 74 OHIO ST. L.J. 241 (2013).

psychology is in its relative infancy, but there is an alternative as well: the medical concept of Quality-Adjusted Life Years (“QALYs”), which provide a reasonable measure of the length and quality of an individual’s life.<sup>13</sup>

These tools permit policymakers to draw direct links, for the first time, between patents and human welfare. These types of connections are generally impossible for many types of inventions, such as consumer electronics. It is difficult to determine the welfare impact of a new iPhone, and any given electronic device likely incorporates thousands of patents, which makes it hard to isolate the welfare effect of any given patent. But these sorts of connections are entirely possible for one class of invention: pharmaceuticals. First, the new research tools described in the preceding paragraph have made it possible to reliably measure the welfare impacts of diseases and their treatments. And second, each drug is typically linked to one central patent on the active molecule itself.<sup>14</sup>

Armed with this sort of information, policymakers have the power to use the patent system in ways heretofore unimaginable, to directly incentivize welfare-enhancing innovations without needing to rely upon the market to get those incentives right. In this Article, we design and describe precisely this type of system of patent-based incentives.<sup>15</sup> We propose that policymakers grant extended patent terms to drug inventions that have a substantial impact on human welfare, as measured using QALYs or hedonic psychology.<sup>16</sup> We further propose that policymakers lift many of the legal protections for patents that have an *insubstantial* effect on human welfare—which we term “futility patents”—making those patents easier to challenge and invalidate. The worst patents, those that offer zero or even negative contributions to social welfare, should be invalidated outright. The result would be a reorientation of pharmaceutical firm incentives: firms would have much greater incentives to pursue drugs that benefit poorer populations, because they could receive extended patent terms for those drugs. And they would have much weaker incentives to pursue “me too” drugs and other medications that might be profitable but have minimal effects on welfare. All told, our proposal offers the possibility of ameliorating the inadequacies and inefficiencies of the market for pharmaceutical drugs, a problem that has vexed policymakers for decades.

Our Article proceeds in four parts. Part I explains the manner in which patents are meant to promote welfare, and the ways in which systemic failures in the market for pharmaceutical drugs can cause them to fall short. Part II shows how policymakers can draw direct connections between drug patents and human welfare using hedonic psychology and QALYs. Part III describes and analyzes our proposal for heightened patent incentives for welfare-enhancing patents and

<sup>13</sup> Graham Loomes & Lynda McKenzie, *The Use of QALYs in Health Care Decision Making*, 28 SOC. SCI. & MED. 299 (1989),

<sup>14</sup> See *infra* notes 117-119.

<sup>15</sup> See *infra* Part III.

<sup>16</sup> Neel Sukhatme and Gregg Bloche independently published a similar proposal while our manuscript was in progress. See Neel U. Sukhatme & M. Gregg Bloche, *Health Care Costs and the Arc of Innovation*, 104 MINN. L. REV. 955 (2019). Although complementary, our proposal differs from their in a number of ways. See *infra* note 224 for further details.

diminished incentives for “futile” patents. In Part IV, we respond to some potential objections and demonstrate that our proposal is resilient to a variety of potential concerns.

Patent law has been tethered to the marketplace for too long, to deleterious effect. We propose to decouple it, to the benefit of patients, drug companies, and society as a whole.

## I. PATENTS, MARKETS, AND WELL-BEING

The U.S. Constitution gives Congress the power to grant patents to inventors in order “to promote the progress of...the useful arts.”<sup>17</sup> Most courts and scholars understand this language to create a consequentialist foundation for patent law that encourages Congress to enact laws to enhance human welfare.<sup>18</sup> Indeed, the Patent Act seems to require that patents only be granted to “useful” inventions.<sup>19</sup> Yet despite these commitments, patent law and scholarship have taken a decidedly *laissez faire* approach to the relationship between patents and welfare.<sup>20</sup> In this Part, we briefly introduce the standard theory for how patent law can enhance human well-being by solving a public goods problem in information.<sup>21</sup> We then show how courts and scholars have generally rejected the possibility of closely connecting patent doctrine—and especially particular patents—to well-being. Doing so, they argue, would involve insurmountable data and judgment challenges.<sup>22</sup> Moreover, many scholars believe that governmental attempts to connect patents to the well-

<sup>17</sup> Art. I, § 8, cl. 8. In full the clause grants Congress the power: “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.” For an account of the history of the clause and the relationship between its parts see Dotan Oliar, *Making Sense of the Intellectual Property Clause: Promotion of Progress as a Limitation on Congress's Intellectual Property Power*, 94 GEO. L. J. 1771 (2006)

<sup>18</sup> *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257 (1979); LANDES POSNER, *supra* note 4; RONALD A. CASS & KEITH N. HYLTON, *LAW OF CREATION: PROPERTY RIGHTS IN THE WORLD OF IDEAS* (2013); Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 129 (2004). *But see* ROBERT P. MERGES, *JUSTIFYING INTELLECTUAL PROPERTY* (2011).

<sup>19</sup> 35 U.S.C. § 101.

<sup>20</sup> Michael Risch, *Reinventing Usefulness*, 2010 BYU L. REV. 1195, 1205 (2010) (hereinafter *Reinventing Usefulness*); Christopher Buccafusco & Jonathan S. Masur, *Intellectual Property Law and the Promotion of Welfare*, 1 HANDBOOK ON THE ECONOMICS OF INTELLECTUAL PROPERTY 98 (Benjamin DePoorter & Peter Menell eds., 2019); Estelle Derclaye, *Eudemonic Intellectual Property: Patents and Related Rights as Engines of Happiness, Peace, and Sustainability*, 14 VAND. J. ENT. & TECH. L. 495 (2012).

<sup>21</sup> We use the terms “welfare” and “well-being” interchangeably throughout this Article.

<sup>22</sup> Risch, *Reinventing Usefulness*, *supra* note 20 at 1207 (“In practice, however, limiting patents to those that meet a pre-determined degree of utility would likely be too costly and unworkable.”); Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, 70 OHIO ST. L.J. 1361, 1374 (2009); Eric E. Johnson, *Calibrating Patent Lifetimes*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 269, 298 (2006); Clarisa Long, *Our Uniform Patent System*, FED. LAWYER, 44, 49 (Feb. 2008).

being they generate are unnecessary, because market forces are better determinants of value than legal institutions.<sup>23</sup> We conclude, though, by noting that many commentators are beginning to question the connection between patents and welfare, especially in the context of pharmaceuticals.<sup>24</sup> Although in some ways, pharmaceutical innovations are the shining lights of the patent regime, in many others, including runaway prices and neglect of rare diseases or those that primarily afflict the poor, pharma patents seem to do little to improve well-being.<sup>25</sup>

#### A. How Patent Law Tries to Improve the World

The standard economic justification for patent law is well known, and we will only briefly rehearse it here.<sup>26</sup> In many cases, inventions are extremely costly to create, but once they have been developed, they are often incredibly cheap to copy.<sup>27</sup> Most pharmaceuticals, for example, cost millions of dollars to develop and bring to market, but producing the actual medicine that people consume is typically inexpensive.<sup>28</sup> In a world without patent law, competitors could simply wait to see which drug innovations were effective and then produce these at substantially lower prices than the inventors, because the copyists don't bear any research and development (R&D) costs.<sup>29</sup> Anticipating this behavior, firms will never bother to invest resources in R&D, and society will forego the benefits of new inventions.<sup>30</sup>

This is where patent law steps in. Patent law gives inventors of “any new and useful process, machine, manufacture, or composition of matter”<sup>31</sup> a period of exclusive rights during which they are the only ones who can make or sell products that incorporate the patented invention.<sup>32</sup> During this period, patentees are effectively monopolists with respect to their products, which means that they are often able to charge prices for access to their inventions that substantially exceed the marginal costs of making those products.<sup>33</sup> Thus, patented pharmaceuticals typically sell for much higher prices than do identical generic drugs that enter the

<sup>23</sup> Risch, *Reinventing Usefulness*, *supra* note 20, at 1206 n. 42.

<sup>24</sup> *Infra* notes 64-75.

<sup>25</sup> Marlynn Wei, *Should Prizes Replace Patents – A Critique of the Medical Innovation Prize Act of 2005*, 13 B.U. J. SCI. & TECH. L. 25, 26 (2007).

<sup>26</sup> For lengthier treatments, see LANDES & POSNER, *supra* note 4; SUZANNE SCOTCHMER, *INNOVATION AND INCENTIVES* (2004).

<sup>27</sup> Eric Budish, Benjamin Roin & Heidi Williams, *Do Fixed Patent Terms Distort Innovation? Evidence from Cancer Clinical Trials*, 19 NBER, Sept. 5, 2013; Margaret K. Kyle, *Are Important Innovations Rewarded? Evidence from Pharmaceutical Markets*, 53 REV. INDUST. ORG. 211, 215 (2018).

<sup>28</sup> Kyle, *supra* note 27, at 213.

<sup>29</sup> Long, *supra* note 22, at 45.

<sup>30</sup> Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303, 310 (2013).

<sup>31</sup> 35 U.S.C. § 101 (2018).

<sup>32</sup> 35 U.S.C. § 283 (2018)

<sup>33</sup> Long, *supra* note 22, at 45.

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market once the patent has expired.<sup>34</sup> By giving inventors an opportunity to charge higher-than-marginal prices for access to inventions, patent law helps inventors recoup their R&D costs. It thereby provides an incentive for their innovative behavior.<sup>35</sup>

But patent law isn't all sunshine and rainbows. As we detail below,<sup>36</sup> patent law's incentive benefits come with significant costs. Higher prices for patented goods are borne by consumers or other payers (including insurance companies and the government). Moreover, many people are priced out of the market for patented goods, even though they would have been able and willing to pay prices based on the marginal cost of goods.<sup>37</sup> These people miss out on the benefits of the innovation, at least until the patent expires.<sup>38</sup> Furthermore, patent law imposes a number of other costs, including administrative costs of running the system and costs for competitors who must expend effort searching for existing patents and designing around them.<sup>39</sup> The law's goal is to develop a set of doctrines that optimizes this tradeoff between incentives for current inventors and access for consumers and competitors. Because granting patents produces both costs and benefits, an ideal patent law would figure out how to do so only when the existence of the patent incentive is worthwhile.<sup>40</sup>

Importantly, patent law does not directly subsidize invention.<sup>41</sup> Rather, it channels innovative activity through the market.<sup>42</sup> Patent law gives patent owners the exclusive right to sell products that embody their inventions, but those rights aren't worth much if no one wants to buy their products. Just as a copyright in a movie that no one wants to see is worthless, a patent that covers a product no one wants to buy conveys little value to the inventor. Accordingly, inventors will direct their efforts towards products that consumers want—which are generally products that will make their lives better off.<sup>43</sup>

<sup>34</sup> Kyle, *supra* note 27, at 213; Budish, Roin, & Williams, *supra* note 27, at 19.

<sup>35</sup> Heidi L. Williams, *How Do Patents Affect Research Investments?*, 9 ANN. REV. ECON. 441, 442 (2017).

<sup>36</sup> See *infra* Part I.C.

<sup>37</sup> Economists refer to this as deadweight loss. Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. REV. 672, 691 (2014).

<sup>38</sup> If they're still alive then.

<sup>39</sup> Stefan Bechtold, Christopher Buccafusco & Christopher Jon Sprigman, *The Nature of Sequential Innovation*, 59 WM & MARY LAW REVIEW 1 (2017).

<sup>40</sup> Roin, *supra* note 37, at 693 (“If the government could perfectly tailor patent awards, it could maximize the amount of socially valuable innovation incentivized without causing any unnecessary consumer deadweight loss.”).

<sup>41</sup> See Hemel & Ouellette *supra*, note 30, at 346.

<sup>42</sup> Sources cited in Christopher Buccafusco & Jonathan S. Masur, *Intellectual Property Law and the Promotion of Welfare*, 1 HANDBOOK ON THE ECONOMICS OF INTELLECTUAL PROPERTY 98, 102-03 (Benjamin DePoorter & Peter Menell eds., 2019).

<sup>43</sup> On the relationship between patents and preference satisfaction *see id.*

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In its current form, patent law permits the market to determine which inventions are valuable and worth pursuing.<sup>44</sup> But that is not a necessary or inevitable state of affairs. In the alternative, the law might try to drive inventors towards the kinds of inventions that are likely to have the biggest impact on social welfare. Thus, policymakers might try to determine whether different industries are more reliant on patent protection than others and then adjust the scope or duration of patents accordingly.<sup>45</sup> Going further, policymakers might try to fine-tune patent protection at the invention level—that is, with respect to each patent.<sup>46</sup> The law could try to weed out the inventions that do not increase social welfare and deny them patent protection.<sup>47</sup> Doing so could yield enormous welfare gains.<sup>48</sup>

### B. The Challenges of Connecting Patents to Well-Being

Patent law, however, has taken only limited steps to connect protection and social value at the industry level,<sup>49</sup> and it has almost entirely avoided doing so at the invention level.<sup>50</sup> This is despite the fact that the law has an obvious candidate in the Patent Act's first section: § 101's requirement that an invention be "useful."<sup>51</sup> The PTO and the courts could read this language to entail an affirmative requirement that patent applicants establish that their inventions are likely to improve social welfare relative to the status quo. Although at times they have flirted with this possibility, for the most part, "the requirement that an invention be useful has been nearly nonexistent."<sup>52</sup> Impossible inventions like perpetual motions machines might fall afoul of the standard, as could a chemical compound with no

<sup>44</sup> Amy Kapczynski, *Dangerous Times: The FDA's Role in Information Production, Past and Future*, 102 MINN. L. REV. 2357, 2363 (2018); Hollis, *supra* note 69, at 1; Kyle, *supra* note 27, at 214.

<sup>45</sup> Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1696 (2003).

<sup>46</sup> Kyle, *supra* note 27, at 212 ("Specifically, if more important innovations provide higher returns to society, then innovation policy should provide them with higher rewards.").

<sup>47</sup> Jonathan S. Masur, *Costly Screens and Patent Examination*, 2 J. LEGAL ANALYSIS 687 (2010).

<sup>48</sup> Carroll, *supra* note 22, at 1364 ("Uniformity cost is the social cost that arises when a particular use has been assigned to the party who is less able to make a socially productive use of the opportunity.").

<sup>49</sup> Roin, *supra* note 37, at 703 ("Patents almost always offer innovators the same set of legal entitlements to exclude others from making, using, or selling the claimed invention and run for a fixed twenty-year term beginning on the patent's filing date."). The relatively few situations of technology-specific patent law tend to relate to pharmaceuticals, including the term extensions provided by the Hatch-Waxman Act and the Orphan Drug Act. We discuss these doctrines at notes 115-119 *infra*.

<sup>50</sup> Patent law's nonobviousness doctrine is one effort to screen out inventions that would be socially costly. *KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (explaining patent law's obviousness doctrine); Masur, *Costly Screens*, *supra* note 47, at 690.

<sup>51</sup> 35 U.S.C. §101.

<sup>52</sup> Michael Risch, *A Surprisingly Useful Requirement*, 19 GEO. MASON L. REV. 57, 58 (2011) (hereinafter *Surprisingly Useful*).

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known use.<sup>53</sup> But otherwise, the PTO will not reject a patent application merely because it fails to provide therapeutic gains over alternatives.<sup>54</sup>

Scholars have defended patent law's uniformity and its unwillingness to consider a patent's utility on a number of fronts.<sup>55</sup> One obvious challenge is that many products are the result of dozens or even hundreds of patented technologies.<sup>56</sup> A smartphone incorporates hundreds of different patents, so assigning relative welfare values to any one of them would be impossible.<sup>57</sup> Even if it were possible to connect patents more or less directly to products, other data challenges loom on the horizon.<sup>58</sup> A policymaker would need to know about a product's sales and the sales of its competitors in order to gauge its contribution to well-being.<sup>59</sup> And, of course, manipulating patent rights in response to a patent's effect on well-being requires policymakers to articulate a valid and reliable measure thereof.<sup>60</sup>

Ultimately, then, most scholars have decided that the market is the most competent institution to determine and reward inventive value. Markets allow value to be measured *ex post* rather than *ex ante*, and they allow private individuals to make decisions about which products provide them with the most satisfaction.<sup>61</sup> Moreover, to the extent that inventors develop products that people do not desire, the standard theory suggests that only the inventors will bear the costs of their mistakes.<sup>62</sup> The firms and their investors will lose money if they fail to produce

<sup>53</sup> Sean B. Seymore, *Making Patents Useful*, 98 MINN. L. REV. 1046 (2014); Risch, *Surprisingly Useful*, *supra* note 52, at 65-66.

<sup>54</sup> Kyle, *supra* note 27, at 217. In fact, the PTO typically would not be in a position to make such a determination at the time of a patent application, because patents on drugs are often filed well before clinical testing for effectiveness has begun. "The first patent application is filed well before clinical trials have been completed, and little information on therapeutic value exists at that point."

<sup>55</sup> Long, *supra* note 22, at 49 ("The same might be said of a unitary patent system that Winston Churchill famously said about democracy: It's the worst form of patent system, except for all the others that have been tried.").

<sup>56</sup> See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998) (discussing the ways in which the holders of the many patents necessary for research can hold up innovation in a field).

<sup>57</sup> David S. Abrams & Bhaven N. Sampat, *Drug Patent Citations and Value*, draft on file with authors, at 3 ("Unlike many complex manufactured products that may involve hundreds or thousands of patents (e.g. mobile phones or routers) drugs tend to depend on one or two key patents.").

<sup>58</sup> Johnson, *supra* note 22, at 299 ("They depend upon inputs such as the importance of the invention, which is difficult or impossible to calculate *ex ante*, and which would likely involve expensive litigation or administrative costs if calculated *ex post*."); Carroll, *supra* note 22, at 1374.

<sup>59</sup> Roin, *supra* note 37, at 704 ("The lack of information about individual inventions also inhibits the development of sound technology-specific laws, since the government often does not know when to offer stronger or weaker patent rights and has difficulty administering the dividing lines between technologies.").

<sup>60</sup> Risch, *Surprisingly Useful*, *supra* note 52, at 64 ("Many issues cannot be resolved by simple appeal to the social good, because that goal is too general and progress toward it is too unmeasurable to provide any practical aid to decisionmakers.").

<sup>61</sup> Risch, *Reinventing Usefulness*, *supra* note 20, at 1206.

<sup>62</sup> *Id.*

products that the market demands, but, otherwise, society experiences little downside from their errors.<sup>63</sup>

### C. How Patents and Markets May Be Failing in Pharma

Despite criticism of patent law's effects on other areas of technology, commenters consistently hold up the pharmaceutical industry as the shining example of the success of the patent system.<sup>64</sup> Pharma patents are much clearer than software patents, so the contents of their disclosures are manifest.<sup>65</sup> And because pharmaceuticals rely less on sequential innovation, where one technology builds on another, they are less susceptible to trolls, thickets, and holdup.<sup>66</sup> Lastly, pharmaceuticals require enormous R&D investments that make it easier to justify long periods of exclusive rights compared to software.<sup>67</sup>

Yet while pharmaceuticals may demonstrate patent law at its most cost-justified, their shine has been seriously tarnished. There is now a compendious literature exploring the ways in which pharmaceutical innovations, although often touted as patent law's poster children, are, in fact, failing millions of people globally.<sup>68</sup> While pharmaceutical innovations are improving and saving lives around the world, pharma firms, lured by the extravagant returns associated with patented drugs, have largely failed to produce drugs that treat the needs of small populations and of the poor.<sup>69</sup> Very often, firms are producing "me too" drugs with limited therapeutic value but, thanks to patents and insurance markets, massive prices.<sup>70</sup> We explain these issues further below.

Although economists prefer to rely on markets as the best means to estimate the value of innovations, markets for pharmaceuticals are unusual in a number of important ways.<sup>71</sup> The demand side of the pharmaceutical market is especially peculiar. Unlike in standard markets for smartphones or automobiles, the ultimate consumers of pharmaceuticals—patients—are not primarily responsible either for selecting products or paying for them.<sup>72</sup> Doctors typically choose which drugs their patients take, and, because doctors do not pay for the drugs, they have little reason

<sup>63</sup> *Id.*

<sup>64</sup> Carroll, *supra* note 22, at 1390. *See also* Burk & Lemley, *supra* note 45, at 1578.

<sup>65</sup> JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 46 (2009).

<sup>66</sup> Long, *supra* note 22, at 45.

<sup>67</sup> Kyle, *supra* 27, at 215.

<sup>68</sup> Kapczynski, *supra* note 44, at 997; Buccafusco & Masur, *supra* note 42, at 7.

<sup>69</sup> Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation*, at 1, June 10, 2004, at <http://econ.ucalgary.ca/hollis.htm>; Kapczynski, *supra* note 44, at 997

<sup>70</sup> Kyle, *supra* note 27, at 211.

<sup>71</sup> *Id.* at 212 ("In most markets, economists measure the value of an innovation with estimates of demand. Markets aggregate information about a product's quality, and we expect the its price and market share to reflect this. In practice, this approach is difficult to apply in pharmaceutical markets, for reasons that will be outlined in the following section. As a result, the link between price (or profits) and social value—essential for innovation incentives—may be weak.")

<sup>72</sup> *Id.* at 212.

to consider their relative prices.<sup>73</sup> In some cases, drug companies may even be illegally paying doctors to prescribe their medications.<sup>74</sup> Ultimately, insurance companies and the government (through Medicaid, Medicare, and the Veterans Administration) are responsible for paying the majority pharmaceutical prices,<sup>75</sup> and so far, their efforts to rein in rising drug prices have largely failed.<sup>76</sup> In a recent study of prices of top-selling drugs between 2012 and 2017, the authors report a median price increase of 76%, with three quarters of drug prices increasing by more than 50% and almost half of prices more than doubling.<sup>77</sup>

Although the prices of patented drugs are rising at an astonishing pace, perhaps these high prices are justified in light of the enormous value they're providing with lifesaving and life-improving innovations. Again, many commentators are skeptical, and, again, they often blame the patent system.<sup>78</sup> One of the patent system's purported benefits is its reliance on markets to direct innovation towards the most socially valuable R&D.<sup>79</sup> As we've seen, this connection may break down when purchasers and payers are not the ultimate consumers of goods.<sup>80</sup> And it is further eroded when consumers' willingness or ability to pay for products is not a good proxy for their social value.<sup>81</sup> The market for pharmaceuticals exhibits exactly this disconnect.<sup>82</sup>

<sup>73</sup> Hollis, *supra* note 69, at 3 (“Second, pharmaceutical markets are extraordinary because the person choosing the medicine (the physician) is not the consumer, and often the consumer does not pay, at least directly. Thus similar but not identical medicines do not typically create strong price competition.”).

<sup>74</sup> Owen Dyer, *Firm Bribed Doctors to Prescribe Overpriced Drug, US Alleges in Suit*, 365 BRIT. MED. J. (2019).

<sup>75</sup> Mark A. Lemley, Lisa Larrimore Ouellette & Rachel E. Sachs, *The Medicare Innovation Subsidy*, NYU L. REV. 8 (forthcoming 2020) (“but here we note that most users don't directly pay the monopoly price for drugs. Rather, at least in developed countries, allocation of pharmaceuticals and other biomedical technologies is usually mediated through public or private health insurance.”).

<sup>76</sup> *Id.* at 3.

<sup>77</sup> Nathan E. Wineinger, Yunyue Zhang & Eric J. Topol, *Trends in Prices of Popular Brand-Name Prescription Drugs in the United States*, 2 JAMA NETWORK OPEN 1, 4 (2019) (“In total, 17 drugs (35%) more than doubled in costs, including Chantix, Cialis, Forteo, Lexapro, Lipitor, Lyrica, Onfi, Premarin, Renvela, Simponi, Viagra, and Zetia; tumor necrosis factor inhibitors Enbrel and Humira; and insulins Humalog, Humulin, and Novolog.”).

<sup>78</sup> Kapczynski, *supra* note 44, at 936; Neel U. Sukhatme & M. Gregg Bloche, *Health Care Costs and the Arc of Innovation*, 104 MINN. L. REV. 955 (2019); Hollis, *supra* note 69, at 3.

<sup>79</sup> LANDES & POSNER, *supra* note 4, at 25-28.

<sup>80</sup> See Christopher Buccafusco, *Disability and Design*, NYU L. REV. (forthcoming 2020).

<sup>81</sup> Carroll, *supra* note 22, at 1377 (“The information and product markets supported by intellectual property rights operate on the basis of users' ability to pay rather than willingness to pay to reflect the social value of innovation. As a result, the innovations or innovators selected for reward by "the market" will skew toward the interests of those with an ability to pay, who more often than not are the relatively rich.”).

<sup>82</sup> Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 153, 169 (2016) (“Consumers' willingness to pay for any particular product depends on its value to them. However, the social value of a drug is often poorly measured by the sum of its value to each individual consumer. There are often significant externalities associated with medical innovations that redound to the benefit of society, rather than the consumer, and are therefore not incorporated into individual willingness to pay.”).

## *Drugs, Patents, and Well-Being*

On the one hand, as we've described, the existence of insurance payments and guaranteed coverage makes treating certain diseases especially lucrative.<sup>83</sup> This is true even for drugs that produce little or no additional therapeutic value compared to their competitors.<sup>84</sup> Accordingly, firms are motivated to produce "me too" drugs to gain a share of the enormous markets for conditions covered by insurance.<sup>85</sup> Seeing the enormous markets available to first-in-class blockbuster drugs, other pharmaceutical firms rush to enter the market with similar compounds.<sup>86</sup> For example, the FDA approved the cholesterol-lowering drug pitavastatin in 2009, making it the *eighth* statin drug approved in the US.<sup>87</sup> By that point, the first-in-class drug had already been in the public domain and was available generically for eight years.<sup>88</sup> Although some of this behavior may be the result of efficient patent races or of drugs that respond to the heterogeneity of patients' needs,<sup>89</sup> many commentators view "me too" drugs as producing little overall value.<sup>90</sup> While they do not add much in the way of additional therapeutic gains, they simultaneously dissipate the rents (and thus the incentives) for the first-in-class drug.<sup>91</sup>

On the other hand, some diseases that primarily affect small or poor populations will not attract substantial investments, because the reward prospects are insufficient to justify R&D expenditures. When people are not covered by comprehensive insurance schemes like those in the developed world, their ability to pay for lifesaving medication is seriously diminished. Although better treatments for malaria and tuberculosis could have huge impacts on global well-being, pharmaceutical firms may underinvest in them because they will not make as much money as they can by treating rich people's diseases.<sup>92</sup> In addition, diseases that affect small populations, even if they are covered by insurance, will be undertreated by a pharmaceutical industry driven by market rewards.<sup>93</sup> If only a few thousand

<sup>83</sup> Lemley, Ouellette & Sachs, *supra* note 75 at 10 ("Part B covers all services and products which are "reasonable and necessary for the diagnosis or treatment of illness or injury," a phrase which is defined neither by the statute nor by regulations.").

<sup>84</sup> Hollis, *supra* note 69, at 5.

<sup>85</sup> *Id.*

<sup>86</sup> Joshua J. Gagne & Nitesh K. Choudhry, *How Many "Me-Too" Drugs is Too Many?*, 305 J. AM. MED. ASSOC. 711 (2011).

<sup>87</sup> *Id.* at 711.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> See e.g., Bishal Gyawali & Vinay Prasad, *Me-Too Drugs with Limited Benefits – The Tale of Regorafenib for HCC*, 14 Nature Rev. Clin. Oncology 653 (2017); A.S. Kesselheim et al., *Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease: A Systematic Review and Meta-Analysis.*, 300 J. AM. MED. ASSOC. 2514 (2008); Aidan Hollis, *Me-too drugs: is there a problem? Submission to the WHO Commission on Intellectual Property and Public Health* (13 December 2004) at [http://www.who.int/intellectualproperty/topics/ip/Me-tooDrugs\\_Hollis1.pdf](http://www.who.int/intellectualproperty/topics/ip/Me-tooDrugs_Hollis1.pdf).

<sup>91</sup> Hollis, *supra* note 69, at 5.

<sup>92</sup> See Michael Kremer, *Pharmaceuticals and the Developing World*, 16 J. ECON. PERSPECTIVES 67, 68-69 (2002).

<sup>93</sup> Bryan A. Liang & Tim Mackey, *Reforming Off-Label Promotion to Enhance Orphan Disease Treatment*, 327 SCIENCE 273 (2010).

people may need a treatment, firms will be less likely to invest in it, even if the treatment could produce much greater per-person benefits than other treatments that are used by millions of people. The 1983 Orphan Drug Act<sup>94</sup> has taken some steps to address this issue, but for reasons we discuss in Part III, we think it insufficiently aligns drugmakers' incentives with human welfare.

#### D. Can the FDA Help?

We might hope that the FDA, as the regulatory body that oversees the market for pharmaceuticals, could help solve some of these concerns. In many respects, however, the FDA is poorly positioned to respond. Unlike some of its European counterparts, the FDA does not condition marketability on cost-effectiveness.<sup>95</sup> If a drug is deemed safe and effective, it can be approved for marketing. In addition, the length of the FDA's clinical trials further distorts R&D spending.<sup>96</sup> And efforts to limit the duration and expense of clinical trials likely produce worse data on therapeutic value, allowing more low-quality pharmaceuticals on the market.<sup>97</sup> The substantial number of "reversals" of clinical trials, showing that drugs may be no better—or far worse—than existing alternatives indicates the scope of the problem.<sup>98</sup>

In the US, the FDA regulates the marketability of pharmaceuticals. The FDA will only approve the sale of a pharmaceutical drug to patients if the firm that owns the drug can prove that it is safe and effective.<sup>99</sup> Typically, this involves several rounds of clinical trials that initially determine whether the drug is toxic in non-human and human populations and then consider whether it effectively treats one or more diseases. But "effective" as used in the law and as interpreted by the FDA does not necessarily mean that the treatment is better than existing treatments, and it certainly does not mean that the new treatment is a cost-effective one. A drug's sponsor need only generate data demonstrating that the drug produces some improvement in outcomes for at least a subpopulation of those with the disease.<sup>100</sup>

<sup>94</sup> 21 U.S.C. § 360cc(a).

<sup>95</sup> Denis Roland, *Obscure Model Puts a Price on Good Health—and Drives Down Drug Costs*, WALL ST. J. (Nov. 4, 2019) <https://www.wsj.com/articles/obscure-model-puts-a-price-on-good-health-and-drives-down-drug-costs-11572885123>.

<sup>96</sup> Budish, Roin & Williams, *supra* note 27, at 1-2.

<sup>97</sup> Vinay Prasad, *Do Cancer Drugs Improve Survival or Quality of Life?*, 359 BRIT. MED. J. 1, 1 (Oct. 4, 2017); John Mandrola, Adam Cifu, Vinay Prasad & Andrew Foy, *The Case for Being a Medical Conservative*, AM. J. MED. 900 (2019); Diana Herrera-Perez, et al., *A Comprehensive Review of Randomized Clinical Trials in Three Medical Journals Reveals 396 Medical Reversals*, 8 ELIFE 1, 2 (2019), at <https://doi.org/10.7554/eLife.45183>; Margaret Kyle & Heidi L. Williams, *Is American Health Care Uniquely Inefficient?: Evidence from Prescription Drugs*, NBER Working Paper Series 23068, at 5, Jan. 2017.

<sup>98</sup> Herrera-Perez et al., *supra* note 97, at 1 ("Medical reversals are a subset of low-value medical practices and are defined as practices that have been found, through randomized controlled trials, to be no better than a prior or lesser standard of care.").

<sup>99</sup> See 21 U.S.C. § 355(d).

<sup>100</sup> Sukhatme & Bloche, *supra* note 78, at 982.

This data often comes from studies run by the patent owners,<sup>101</sup> and there are many commentators who are concerned about statistical manipulation of trial results.<sup>102</sup> A burgeoning medical literature has described numerous flaws in FDA clinical trials, including the use of non-clinical data,<sup>103</sup> the lack of randomly-controlled trials,<sup>104</sup> and non-representative study populations,<sup>105</sup> all of which tend to overstate a drug's efficacy.<sup>106</sup>

Further research by Eric Budish, Benjamin Roin, and Heidi Williams has shown how variations in the length of FDA clinical trials affect firm's R&D choices.<sup>107</sup> US patent law gives inventors a fixed 20-year term of protection, but the effective length of market exclusivity is shortened by the time it takes to conduct clinical trials.<sup>108</sup> Thus, the shorter the clinical trials, the longer the effective patent term. Generally, treatments for late-stage cancers involve shorter clinical trials than early-stage cancers, because it takes less time to demonstrate potential effectiveness.<sup>109</sup> With late-stage cancers, patients die much more quickly, so success or failure happens sooner. The authors demonstrate that firms have responded to this effective manipulation of patent duration by focusing significantly greater resources on late-stage cancer research than early-stage cancer research—even though treating early-stage cancers would likely produce much greater social value.

While reasonable minds could differ about the FDA's success at ensuring the quality of pharmaceutical available in the US, there is no doubt that it has failed to help with cost containment. This is because the FDA does not evaluate a drug's cost-effectiveness as a condition of its approval.<sup>110</sup> While many European administrative agencies consider whether to approve a drug according to the relative cost of treatment outcomes, neither the FDA nor Medicare make these sorts of decisions.<sup>111</sup> Thus, if a drug's sponsor can show that it will make even a modest improvement in treatment outcomes for some group of potential patients, the FDA will approve the drug even though its cost may be many times greater than

<sup>101</sup> Chi Heem Wong, Kien Wei Siah & Andrew Lo, *Estimation of Clinical Trial Success Rates and Related Parameters*, 20 *BIostatistics* 273, 273 (2019).

<sup>102</sup> See e.g. Vinay Prasad, *Do Cancer Drugs Improve Survival or Quality of Life?* 359 *BRIT. MED. J.* (Oct. 4, 2017); Kapczynski, *supra* note 44, at 2369.

<sup>103</sup> James D. Chambers, Teja Thorat, Colby L. Wilkinson & Peter J. Neumann, *Drugs Cleared Through the FDA's Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process*, 36 *HEALTH AFFAIRS* 1408 (2017) (hereinafter *Expedited Review*).

<sup>104</sup> Brett K. Beaulieu-Jones et al., *Examining the Use of Real-World Evidence in the Regulatory Process*, *CLINICAL PHARMACOLOGY & THERAPEUTICS* 1, 2 (Sept. 17, 2019).

<sup>105</sup> See Chadi Nabhan, Andrew Klink & Vinay Prasad, *Real-world Evidence: What Does It Really Mean?*, 5 *JAMA* 781 (2019). See also Beaulieu-Jones et al., *supra* note 104, at 2.

<sup>106</sup> See Mandrola, Cifu, Prasad and Foy, *supra* note 97, at 2.

<sup>107</sup> Budish, Roin, & Williams *supra* note 27, at 2.

<sup>108</sup> *Id.*

<sup>109</sup> *Id.* at 3.

<sup>110</sup> Loren Lorenzetti, *Is it time for the FDA to consider cost when it comes to new drugs?*, *FORTUNE* (February 4, 2015).

<sup>111</sup> Sukhatme & Bloche, *supra* note 78, at 987-88.

alternative treatments.<sup>112</sup> It is not entirely surprising that the FDA does not consider a drug's cost in its approval decisions, considering where the agency sits in the product's lifecycle. At the time the FDA decides whether to approve a drug, it has not been on the market, and thus its price is not yet known. Accordingly, there may be little the FDA can do to connect patents with aggregate social utility.

\* \* \*

The pharmaceutical industry is thought to show the patent system at its best, incentivizing breakthrough innovations that would not have come about but for the promise of exclusive rights.<sup>113</sup> But patent law's one-size-fits-all, market-oriented approach has drawn attention to the ways in which it may fail to maximize social value. Is there an alternative? Could we figure out which innovations are, in fact, generating the most social value? And if so, could patent law do anything to incentivize research in those directions? We turn to these questions in the next two Parts.

## II. CONNECTING PHARMA PATENTS TO THEIR EFFECTS ON WELL-BEING

Although we may never know how much each of the hundreds of patents involved in smartphone technology affects human well-being, new data are able to estimate the relative effects of pharmaceutical patents on welfare. Recent research in hedonic psychology—the scientific study of well-being and happiness—is providing increasingly valid and reliable tools for measuring how various experiences, including taking pharmaceuticals, affects people's lives.<sup>114</sup> That data can be combined with data on the patents associated with pharmaceuticals to study whether and to what extent various patents are making people better off. First, we discuss the methodological strategies of connecting patents with well-being data, and then we report some results from recent studies of the efficacy of pharmaceutical innovations. Ultimately, the story is decidedly mixed: Although some new pharmaceuticals are dramatically improving patients' lives, many others are no better or worse than established alternatives.

### A. Patents, QALYs, and Well-Being

<sup>112</sup> See 21 U.S.C. § 355(d) (2012).

<sup>113</sup> Burk & Lemley, *supra* note 45, at 1578.

<sup>114</sup> See Daniel Kahneman, *Objective Happiness*, in WELL-BEING: THE FOUNDATIONS OF HEDONIC PSYCHOLOGY (Daniel Kahneman et al eds., 1999) [hereinafter *Objective Happiness*]; Ed Diener, Richard Lucas, Ulrich Schimmack & John Helliwell, *Defining Well-being*, in WELL-BEING FOR PUBLIC POLICY (2009); William Comanor, Stuart Schweitzer, Tanya Carter, *A Hedonic Model of Pricing of Innovative Pharmaceuticals*, in HEALTH POLICY AND HIGH-TECH INDUSTRIAL DEVELOPMENT (2005); John Bronsteen, Christopher Buccafusco, Jonathan S. Masur, *Well-Being Analysis vs. Cost-Benefit Analysis*, 62 DUKE L.J. 1603 (2013) (hereinafter *WBA*).

The first challenge in connecting patents with their effects on welfare is isolating the patents involved in pharmaceutical products. Recent research by Scott Hemphill and Bhaven Sampat has shown this to be possible.<sup>115</sup> The Hatch-Waxman Act requires drug companies to list the most pertinent patents covering a drug in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the Orange Book.<sup>116</sup> Hemphill and Sampat find that while each drug is associated with, on average, 2.7 total patents, almost all drugs are covered by a single “active ingredient” patent.<sup>117</sup> After this patent expires, generic versions of the drug tend to enter the market.<sup>118</sup> In separate analysis, David Abrams and Sampat have explored which of the multiple patents associated with a drug is chosen for extension under the Hatch-Waxman Act’s period of regulatory compensation.<sup>119</sup> Using this approach, they can assess which patent covers the active or main ingredient in the drug, and their findings strongly correlate with Hemphill and Sampat’s data.<sup>120</sup>

The bigger empirical challenge involves connecting pharmaceutical patents to their effects on patient welfare, but new research is now making this possible. Much of this research is inspired by the field of hedonic psychology, which attempts to scientifically measure how well individuals’ lives are going.<sup>121</sup> Over the last several decades, scientists have made considerable strides in developing valid and reliable tools for studying and comparing people’s experiences. This work reflects a turn from *decision utility*—judging people’s welfare based on the choices they make—toward *experience utility*—judging people’s welfare based on how they feel about their experiences.<sup>122</sup>

<sup>115</sup> C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEG. STUD. 613 (2011) [hereinafter *Drug Patents*]; C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327 (2012) [hereinafter *Evergreening*].

<sup>116</sup> Center for Drug Evaluation and Research, *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, FDA (40<sup>th</sup> ed. 2019).

<sup>117</sup> Hemphill & Sampat, *Evergreening*, *supra* note 115, at 330.

<sup>118</sup> Hemphill & Sampat, *Drug Patents*, *supra* note 115, at 615.

<sup>119</sup> David S. Abrams & Bhaven N. Sampat, *Drug Patent Citations & Value*, NBER 1, 8 (2018).

<sup>120</sup> *Id.* at 8. There is now substantial evidence that drug companies file additional patents related to their active ingredient patents in an attempt to extend periods of exclusivity. Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents*, 7 PLOS ONE, 1 (2012); Lisa L. Ouellette, *How Many Patents Does It Take to Make a Drug - Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299 (2010). These patents typically cover different formulations of the active ingredient or alternative dosage regimes and delivery mechanisms. This strategy, known as “evergreening,” raises a number of concerns about the length and breadth of pharmaceutical patents, but it does not affect researchers’ ability to isolate the principal active ingredient patent associated with each drug. Accordingly, we are confident that in the great majority of cases, it will be possible to determine the patent that supports the pharmaceutical.

<sup>121</sup> Kahneman, *Objective Happiness*, *supra* note 114, at 4-5.

<sup>122</sup> Daniel Kahneman, *Experienced Utility and Objective Happiness: A Moment-Based Approach*, in CHOICES, VALUES, AND FRAMES 673 (Daniel Kahneman & Amos Tversky eds., 2000).

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The shift toward experiences is especially appropriate in the context of pharmaceuticals for a number of reasons. First, as we have seen, people's choices about which drugs they take are not likely to be strong proxies for the welfare, due to the numerous distortions of the drug market.<sup>123</sup> Although we might trust people to choose whether they will get more happiness from a Ford or a Jaguar, we should be less confident that their choices between medications—if they even get to make any—are rational and well-informed.<sup>124</sup> Second, pharmaceuticals affect people's lives in a variety of different ways, and policymakers should have data that reflect those experiences. Measuring the success of a new drug in terms of patients' five-year survival rates ignores an enormous amount of information that we might care about.<sup>125</sup> Obviously, many drugs treat conditions that do not cause death. Knowing that the five-year survival rate of an acne medication is 99% tells us very little about the drug's effectiveness. In addition, many people are likely to care not just about their absolute survival but also the quality of their lives.<sup>126</sup> People might rationally believe that surviving for three years in fairly good health is better than surviving for five years in miserable health.<sup>127</sup> Accordingly, scientists need tools that will capture the nuances of patients' experiences.

We believe that the best way to measure a drug's effect on well-being is to survey people who are taking the drug and ask them how they are feeling.<sup>128</sup> As we have argued at length elsewhere, the best way to study people's welfare is to measure the range of positive and negative emotions that they experience during some period of time.<sup>129</sup> Research tools such as the experience sampling method (ESM), which uses smartphones to randomly query people about what they are doing and how happy or unhappy they are, can provide fine-grained data about individual well-being.<sup>130</sup> People's self-reports about their current experiences generate the most valid and reliable data on how they are doing.<sup>131</sup> For our

<sup>123</sup> See Bronsteen, Buccafusco & Masur, *supra* note 114, at 1607. See also Tara O'Neill Hayes, *Market Distortions Caused by the 340B Prescription Drug Program*, AMERICAN ACTION FORUM (Nov. 28, 2017), <https://www.americanactionforum.org/research/340bmarketdistortions/>.

<sup>124</sup> Wendy Netter Epstein, *Nudging Patient Decision-Making*, 92 WASH. L. REV. 1255 (2017); Hollis, *supra* note 69, at 3.

<sup>125</sup> Daniel Chisholm, Andrew Healy & Martin Knapp, *QALYs and Mental Health Care*, 32 SOC. PSYCHIATRY & PSYCHIATRIC EPIDEMIOLOGY 68, 68 (1997).

<sup>126</sup> Milton C. Weinstein, George Torrance & Alistair McGuire, *QALYs: The Basics*, 12 VALUE HEALTH S5, S5 (2009).

<sup>127</sup> Amiram Gafni, *Economic Evaluation of Health-Care Programmes: Is CEA Better Than CBA?*, 34 ENVTL. & RESOURCE ECON. 407, 408 (2006).

<sup>128</sup> Bronsteen, Buccafusco & Masur, *supra* note 114, at 1617.

<sup>129</sup> *Id.* at 1617-1620.

<sup>130</sup> See Iris H.L. Maes, et al., *Measuring Health-Related Quality of Life by Experiences: The Experience Sampling Method*, 18 VALUE HEALTH 44, 44 (2015); Alan B. Krueger, Daniel Kahneman, David Schkade, Norbert Schwarz & Arthur A. Stone, *National Time Accounting: The Currency of Life*, in MEASURING THE SUBJECTIVE WELL-BEING OF NATIONS: NATIONAL ACCOUNTS OF TIME AND WELL-BEING 9, 30 (Alan B. Krueger ed., 2009).

<sup>131</sup> See Diener et al., *supra* note 114, at 71-73; Dylan M. Smith, Ryan L. Sherriff, Laura Damschroder, George Loewenstein, & Peter A. Ubel, *Misremembering Colostomies? Former*

purposes, we could imagine studies that track people's responses to ESM questions during their treatment with a patented pharmaceutical and compare them to responses from people who are using an alternative treatment.<sup>132</sup> Studies like these would provide extraordinarily precise data about people's treatment, including information not only about their health states but also their emotions and moods.<sup>133</sup> Although such studies would provide the "gold standard" for well-being comparisons, they are expensive to run (especially for long periods of time) and would create substantial impositions on patients.<sup>134</sup>

For longer term effects, such as for treatments that last several years or more, scientists can use other means for measuring people's experiences. One of the most common forms of hedonic psychology research relies on questions about people's life satisfaction which are typically included in larger survey instruments such as the General Social Survey.<sup>135</sup> Life satisfaction surveys include one or more questions that ask respondents something like: "All things considered, how satisfied with your life are you these days?"<sup>136</sup> Although life satisfaction surveys do not provide the fine-grained data of ESM studies, they can be used to track people through treatments over a longer period of time.<sup>137</sup> For example, researchers have used life satisfaction data to explore patient's experiences with different treatments for breast cancer,<sup>138</sup> kidney transplants,<sup>139</sup> and ADHD.<sup>140</sup>

As we have explained in prior work, policymakers can use data from ESM and life satisfaction surveys to compute the number of "well-being units" ("WBUs") that people experience as a result of some change in an aspect of their lives.<sup>141</sup> The best hedonic surveys track individual well-being on a scale of -10 to 10, where 0 is equivalent to death or unconsciousness, and the ends of the scale represent the extremes of negative and positive experience. One WBU is equivalent

*Patients Give Lower Utility Ratings Than Do Current Patients*, 25 HEALTH PSYCHOL. 688, 691 (2006).

<sup>132</sup> See Inez Myin-Germeys et al., *Experience Sampling Methodology in Mental Health Research: New Insights and Technical Developments*, 17 WORLD PSYCHIATRY 123, 123 (2018).

<sup>133</sup> Ingrid Kramer et al., *A Therapeutic Application of the Experience Sampling Method in the Treatment of Depression: A Randomized Controlled Trial*, 13 WORLD PSYCHIATRY 68, 68 (2014).

<sup>134</sup> Alan B. Krueger et al., *supra* note 130, at 30.

<sup>135</sup> Diener et al., *supra* note 114, at 19.

<sup>136</sup> See William Pavot & Ed Diener, *Review of the Satisfaction with Life Scale*, 5 PSYCHOL. ASSESSMENT 164, 164 (1993) (discussing the strength of the Satisfaction with Life Scale and referring to the fact that it is a "judgmental process, in which individuals assess the quality of their lives on the basis of a unique set of criteria").

<sup>137</sup> Andrew E. Clark, Ed Diener, Yannis Georgellis & Richard E. Lucas, *Lags and Leads in Life Satisfaction: A Test of the Baseline Hypothesis*, 118 ECON. J. F222, F231 (2008).

<sup>138</sup> Marianne Carlsson, et al., *Evaluation of Quality of Life/Life Satisfaction in Women with Breast Cancer in Complementary and Conventional Care*, 43 ACTA ONCOLOGY 27 (2003).

<sup>139</sup> Arthur J. Matas, et al., *Life Satisfaction and Adverse Effects in Renal Transplant Recipients: A Longitudinal Analysis*, 16 CLINICAL TRANSPLANTATION 113 (2002).

<sup>140</sup> Aribert Rothenberger, Andreas Becker, Dieter Breurer & Manfred Dopfner, *An Observational Study of Once-Daily Modified-Release Methylphenidate in ADHD: Quality of Life, Satisfaction with Treatment, and Adherence*, 20 EUR. CHILD & ADOLESCENT PSYCHIATRY S257 (2011).

<sup>141</sup> Bronsteen, Buccafusco & Masur, *WBA*, *supra* note 114, at 1643.

to one point on the hedonic scale for one person for one year.<sup>142</sup> Thus, if an individual took a drug that raised her well-being from 7 to 8 for one year, that drug would have created one WBU of welfare. If 10 people each took a drug that raised their well-being from 5 to 8, and they took these drugs over a period of 10 years, this would yield an overall gain of 10 people  $\times$  3 points  $\times$  10 years = 300 WBUs. The use of WBUs thus offers a mechanism for rigorously measuring welfare changes over time, including those attributable to external factors such as new drugs.

Although ESM and life satisfaction studies are increasingly popular, researchers and governments have come to rely on a metric called Quality Adjusted Life Years (QALYs) to determine the effectiveness of medical treatments across a wide variety of contexts.<sup>143</sup> While it is important to know how many lives a new drug saves or how many years it adds to patients' expected survival, these data paint an incomplete picture of the drug's effects on well-being. As we noted, the quality of a person's life is as important to her welfare as is its length, and the QALY provides a mechanism for studying the effects of different medical treatments.<sup>144</sup> Many European countries mandate QALY comparisons for health technology appraisals and cost-effectiveness studies, because they provide a single measure for evaluating alternatives.<sup>145</sup> Accordingly, pharmaceutical companies also have significant experience with them.<sup>146</sup>

To measure QALYs, researchers assess the number of years of life gained from a new treatment relative to the status quo treatment.<sup>147</sup> Then they discount (i.e., multiply) those additional life years by the health-related quality of life ("HRQoL") that patients experience during them.<sup>148</sup> HRQoL is assessed on a scale

<sup>142</sup> *Id.* at 1643-44.

<sup>143</sup> Chisholm et al., *supra* note 125, at 69-70; Sarah J. Whitehead & Shehzad Ali, *Health Outcomes in Economic Evaluation: The QALY and Utilities*, 96 BRIT. MED. BULL. 5, 13-14 (2010); Nancy J. Devlin & Paula K. Lorgelly, *QALYs as a Measure of Value in Cancer*, 11 J. OF CANCER POL'Y 19, 20-21 (2017).

<sup>144</sup> Chisolm et al., *supra* note 125, at 68 ("[T]he QALY transcends unidimensional measures such as life expectancy improvements or 5-year survival rates as indicators of the success or failure of medical intervention.").

<sup>145</sup> Hollis, *supra* note 69, at 16 ("There is very extensive experience with evaluating QALYs related to drug treatments, since a large number of governments and other insurers all over the world use such an approach..."); Whitehead & Ali, *supra* note 140, at 6 (2010) ("The use of QALYs is required by the National Institute for Health and Clinical Excellence (NICE) in the UK for health technology assessment"); Hollis, *supra* note 90, at 2 ("While imperfect, the use of QALYs enables a comparison to be made between the therapeutic benefits of different drugs in a standardized way and thus to find a meaningful measure of the social value of an innovation. The implementation of the QALY technique in deciding which pharmaceuticals to fund in a number of jurisdictions around the world has been highly successful, and it offers strong encouragement for a broader application of QALYs to determining how to reward pharmaceutical innovations.").

<sup>146</sup> Hollis, *supra* note 69, at 17 ("Drug companies have also used QALY-type analysis themselves in order to demonstrate economic effectiveness of treatments.").

<sup>147</sup> Devlin & Lorgelly, *supra* note 143, at 20.

<sup>148</sup> *Id.*

that runs from 0 to 1, where 1 indicates perfect health and 0 indicates death.<sup>149</sup> Negative numbers can represent states worse than death.<sup>150</sup> In most studies, researchers assess HRQoL along several different dimensions, including the severity of problems with mobility, self-care, performing usual activities, pain, and anxiety/depression.<sup>151</sup> The relative weights of each of these domains is judged by medical professions and members of public, rather than patients themselves (an issue we discuss further below).<sup>152</sup> For example, if a new cancer treatment extends patients' lives by four years relative to the status quo, and those four years are spent, on average, at a level of 0.65 HRQoL, then the drug is responsible for creating  $4 \times 0.65 = 2.6$  QALYs per patient. If one thousand patients receive the treatment, the drug would generate 2,600 QALYs. In some European countries, these data are combined with the cost of the treatment to determine whether it is cost effective. In the next Part, we argue that the PTO can use QALY data to manipulate the size of the incentives given to pharmaceutical companies.

We should note, however, that QALY data are not a perfect proxy for human welfare.<sup>153</sup> There is no such measure, so the important question for policymakers is whether QALYs are better than the alternative, which, in this case, means no data at all. It is also important to be aware of the limitations with using QALY data. First, QALYs are typically assessed with reference to the patient receiving treatment, but medical treatments can have many spillover effects.<sup>154</sup> Vaccines and treatments for communicable diseases don't just help people who receive them, but everyone in society. And a pharmaceutical that enables patients to return to work can improve the lives of their children, spouses, and caregivers.<sup>155</sup>

In addition, as we explained, HRQoL weights are assessed by asking medical professionals and members of the public how bad they think being in certain health states is.<sup>156</sup> There is substantial evidence, though, that healthy people are systematically bad at predicting how various health states would make them feel.<sup>157</sup> Because healthy people focus on *becoming* unhealthy rather than *being* unhealthy, and because they do not account sufficiently for the effects of hedonic

<sup>149</sup> Chisolm, *supra* note 125, at 68. *See also* Devlin & Lorgelly, *supra* note 143, at 20.

<sup>150</sup> Devlin & Lorgelly *supra* note 143, at 20 ("QALYs are estimated by multiplying the length of life in each health state by its HRQoL weight. The weights are on a scale anchored at 1 (full health) and 0 (a health state so bad it is as bad as being dead), with negative values indicating a health state considered to be worse than being dead.").

<sup>151</sup> *Id.*

<sup>152</sup> *Id.* at 19-20.

<sup>153</sup> *Id.* at 21.

<sup>154</sup> *Id.* at 21.

<sup>155</sup> *See* Whitehead & Ali, *supra* note 140, at 17 ("An improvement in the health of a woman/man with children may impact on the health of their children and may also help her/him return to work more quickly."); *see also* Devlin & Lorgelly, *supra* note 143, at 23 ("There may be wider benefits to society from treating cancer. For example, the reduced mortality and morbidity from cancer may enable cancer patients to return to work more quickly, or to contribute in other (non-income earning) ways to society, for example by caring for others or undertaking voluntary work.").

<sup>156</sup> *Id.* at 16.

<sup>157</sup> *Id.*

adaptation to new experiences, they tend to overestimate both the magnitude and duration of negative experiences.<sup>158</sup> In addition, QALY measurements focus primarily on physical health rather than mental health and well-being, so they may not fully capture the effects of a treatment on patients' feelings and emotions.<sup>159</sup> Accordingly, they may understate the value of treatments for mental health disorders or ones that increase pleasure. For these reasons, we encourage increased use of ESM studies for pharmaceuticals, but we believe that QALY-based measures represent a vast improvement over the alternatives. Until better well-being measures become widely available, QALYs are a worthwhile mechanism for assessing health outcomes from drugs and medical treatments.

## B. Which Patented Pharmaceuticals Improve Well-Being?

The past two decades have witnessed increased efforts by scholars and government agencies to assess the well-being impacts of new pharmaceuticals.<sup>160</sup> How often are they worth the enormous R&D investments and astronomical prices? The data are decidedly mixed. New treatments for some conditions have generated meaningful improvements over earlier options, but the story for many other patented pharmaceuticals is bleaker.<sup>161</sup> Below we report the findings of a number of recent studies to illustrate the broad variation in pharmaceutical effectiveness.

First, the good news. In a study of the relative effectiveness of new pharmaceuticals approved by the FDA between 1999 and 2011, James Chambers and colleagues report a number of drugs that produced meaningful improvements over previous options.<sup>162</sup> The two largest successes in terms of QALYs per person were deferasirox (Exjade), which treats hemosiderosis, an excess iron accumulation, and produces average gains of 4.2 QALYs per person, and imatinib mesylate (Gleevec), which treats leukemia and produces gains of 4.1 QALYs per person.<sup>163</sup> Although these drugs come with astronomical price tags (\$168,469 and

<sup>158</sup> Peter A. Ubel, George Loewenstein & Christopher Jepson, *Disability and Sunshine: Can Hedonic Predictions Be Improved by Drawing Attention to Focusing Illusions or Emotional Adaptation?*, 11 J. EXPERIMENTAL PSYCHOL.: APPLIED 111, 111 (2005); Peter A. Ubel et al., *Do Nonpatients Underestimate the Quality of Life Associated with Chronic Health Conditions Because of a Focusing Illusion?*, 21 MED. DECISION MAKING 190, 197 (2001).

<sup>159</sup> Rebecca Johnson, et al., *Where's WALY?: A Proof of Concept Study of the "Well-being Adjusted Life Year" Using Secondary Analysis of Cross-Sectional Survey Data*, 14 HEALTH & QUALITY OF LIFE OUTCOMES 126 (2016) ("[T]he fact that we found a ceiling effect in the EQ-5D-3L (as have others before us [51], with nearly three quarters of participants at the maximum score reinforces the likelihood that it does not capture relevant changes that matter to individuals or, therefore, to economic evaluations.").

<sup>160</sup> Nabhan, Klink & Prasad, *supra* note 105, at 781.

<sup>161</sup> Kyle, *supra* note 27, at 219.

<sup>162</sup> James D. Chambers et al., *Despite High Costs, Specialty Drugs May Offer Value For Money Comparable To That Of Traditional Drugs*, 33 HEALTH AFFAIRS 1751, 1752 (2014) [hereinafter *Specialty Drugs*]

<sup>163</sup> *Id.* at 1756.

\$151,746 incremental costs, respectively),<sup>164</sup> they are doing a great deal of good for the patients that receive them. Three additional drugs also produced at least one QALY improvement over the status quo, and one of them, bosentan (Tracleer), a treatment for pulmonary arterial hypertension, does so at a cost that is \$100,000 *less* than the alternative.<sup>165</sup> Sixteen out of the 102 drugs in the sample produced at least half of a quality adjusted life year on average.<sup>166</sup>

Because policymakers care about the total welfare produced by new pharmaceuticals and not just the welfare per patient, it is essential to know whether drugs are treating large or small populations. Adding four QALYs to one person's life is generally not as valuable as adding one QALY to one hundred people's lives.<sup>167</sup> While there certainly could be situations in which, for distributional equity reasons, policymakers might favor providing smaller benefits to one group over larger benefits to another, drugs that treat larger populations are, all else equal, more socially valuable.<sup>168</sup> Thus, from the perspective of a policymaker, what matters is overall welfare across the entire population (though of course the policymaker might want to focus on improving the welfare of those people who are least well off). Hundreds of QALYs will always outweigh just a few QALYs. Accordingly, in a subsequent study, Chambers and colleagues collected data on the U.S. incidence of diseases from the Centers for Disease Control and the National Cancer Institute.<sup>169</sup> They then calculated the aggregate number of QALYs per pharmaceutical if ten percent of the population with the condition received it.<sup>170</sup> Interestingly, the results differ meaningfully from the previous study. Although imatinib (Gleevec) produced more than four QALYs per person, only about 64,000 Americans suffer from leukemia.<sup>171</sup> Its estimated aggregate benefit, then, was only about 26,000 QALYs if ten percent of those people receive treatment.<sup>172</sup> By comparison, drugs that treated conditions with much higher incidence, such as high cholesterol, diabetes, hepatitis C, HIV, and smoking addiction generated significantly higher aggregate QALYs.<sup>173</sup> For example, 60 million Americans

<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

<sup>166</sup> *Id.*

<sup>167</sup> Bronsteen, Buccafusco & Masur, *supra* note 114, at 1632-33. *But see* JOHN RAWLS, A THEORY OF JUSTICE 140 (1971) (“[T]he principle of average utility directs society to maximize not the total but the average utility (per capita).”).

<sup>168</sup> On the distributional concerns of IP policy see e.g. Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821 (2006); Madhavi Sunder, *IP* 3, 59 STAN. L. REV. 257 (2006).

<sup>169</sup> James D. Chambers et al., *Estimating Population Health Benefits Associated with Specialty and Traditional Drugs in the Year Following Product Approval*, 15 APPL. HEALTH ECON. HEALTH POL'Y 227, 228-30 (2017) [hereinafter *Estimating Population*]

<sup>170</sup> *Id.* at 230. Ten percent was chosen to provide a conservative estimate. It is, of course, trivially easy to redo the math with different assumptions.

<sup>171</sup> *Id.* at app. table 1, online supplement, available at <https://link.springer.com/article/10.1007%2Fs40258-016-0291-9#Sec15>.

<sup>172</sup> *Id.*

<sup>173</sup> *Id.* at 231.

suffer from high cholesterol, and although ezetimibe only produced 0.172 QALYs per person compared to the standard treatment, if ten percent of those people get the drug, it would produce 1.1 million QALYs.<sup>174</sup> Pioglitazone, which was approved to treat type 2 diabetes in 1999, generates 0.170 QALYs per person, but if given to ten percent of the 18 million people with the disease, it would create an additional 696,680 QALYs.<sup>175</sup> According to Chambers and colleagues' data, fourteen drugs would generate at least 100,000 QALYs under their assumptions.<sup>176</sup>

Unfortunately, for many more pharmaceuticals, the story is not as promising. First, many molecular entities that receive patents do not enter into FDA clinical trials at all, presumably because their sponsors do not believe they are likely to produce promising results. Of the drugs that do enter clinical trials, the vast majority fail to win approval. In a new study, Wong, Siah, and Lo estimate that only 13.8% of drug development programs result in approval,<sup>177</sup> and their estimates are higher than some others.<sup>178</sup> In 2019, the FDA only approved forty-eight novel drugs, and nine of these were approved on the basis of surrogate endpoints rather than clinical ones.<sup>179</sup> This means that the drugs could gain approval without showing a direct treatment effect if they could at least show some positive effect on another "surrogate" outcome that is correlated with the treatment effect.<sup>180</sup> But relying on surrogate endpoints rather than clinical ones can dramatically overestimate a drug's total therapeutic effect.<sup>181</sup> Thus, most patented pharmaceuticals fail to meet the FDA's standards for safety and effectiveness, and those that meet it may do so on data of dubious reliability.<sup>182</sup>

In addition, the fact that the FDA has judged a drug to be effective does not mean that the drug represents an improvement over existing treatment options. In the studies by Chambers and colleagues, substantial percentages of drugs were estimated to be no more effective or less effective than existing options. That is, they produced zero or negative QALYs.<sup>183</sup> One of their studies found this to be true for 39% of the drugs studied,<sup>184</sup> and another estimated that 32% had zero or

<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

<sup>176</sup> *Id.*

<sup>177</sup> Wong, Siah & Lo, *supra* note 101, at 277.

<sup>178</sup> Michael Hay, David W. Thomas, John L. Craighead, Celia Economides & Jesse Rosenthal, *Clinical Development Success Rates for Investigational Drugs*, 32 NATURE BIOTECH. 40 (2014) (estimating a 10.4% success rate); David W. Thomas, et al., *Clinical Development Success Rates 2006–2015*, BIOMEDTRACKER (2016) (estimating a 9.6% success rate).

<sup>179</sup> Asher Mullard, *2019 FDA Drug Approvals*, 19 NATURE REV.: DRUG DISCOVERY 79 (2020). The five-year rolling average is forty-four approvals per year. *Id.* at 79.

<sup>180</sup> Ross L. Prentice, *Surrogate Endpoints in Clinical Trials: Definition and Operational Criteria*, 8 STAT. MED. 431–440 (1989); Beaulieu-Jones et al., *supra* note 104, at 2.

<sup>181</sup> Beaulieu-Jones et al., *supra* note 104, at 2.

<sup>182</sup> In addition, many clinical trials are run by the drug's sponsoring firm rather than by independent organizations, and the trials involve ideal patient populations who are likely to respond better to the treatment than will real world populations. See Diana Herrera-Perez, *supra* note 97, at 2-3 (2019); Nabhan, Klink & Prasad, *supra* note 105, at 781–82.

<sup>183</sup> James D. Chambers et al., *Expedited Review*, *supra* note 103, at 1410.

<sup>184</sup> *Id.* at 1410.

negative QALY impact.<sup>185</sup> In the latter study of 102 new drugs, nineteen were “dominated” by the alternative. That is, they were both less effective and more expensive than the comparator treatment.<sup>186</sup> Moreover, another one-third of the drugs in this study generated fewer than 0.1 incremental QALYs.<sup>187</sup> Importantly, many of these poorly performing drugs would not treat especially large populations, so their aggregate therapeutic value is also low (or negative).

These disappointing results have been corroborated by other studies using different datasets. Abrams and Sampat studied new molecular entities approved in the US between 1987 and 2011.<sup>188</sup> The median incremental QALY improvement per drug was only 0.09 (approximately one additional month of life at perfect health), and 25% of the drugs in their sample have negative incremental QALYs.<sup>189</sup>

Margaret Kyle analyzed 352 new pharmaceuticals that reached the market between 2000 and 2016.<sup>190</sup> She compared these drugs’ prices to their assessments by France’s Haute Autorité de Santé, which scores drugs based on whether they represent improvements over existing standards.<sup>191</sup> Major improvements are scored 1, while those with no additional benefit are scored 5.<sup>192</sup> Perhaps unsurprisingly, imatinib (Gleevec) scored 1.<sup>193</sup> But almost half of the drugs in the sample (169) received a score of 5, while another quarter received a score of 4.<sup>194</sup> Despite their poor performance, however, these low scoring drugs were not significantly cheaper than their higher scoring counterparts.<sup>195</sup>

These sorts of relatively useless “me too” drugs nevertheless exist because the market for pharmaceuticals creates incentives for firms to develop them. Even if a drug represents at most a very incremental improvement on the status quo, it might succeed in winning substantial market share through effective marketing and outreach. The drug could become highly profitable even without contributing significantly to welfare, compared with treatments that preceded it. Thus, while pharmaceutical companies have produced some important breakthrough drugs that have benefitted thousands of patients, they have also produced many products that are outright failures from the standpoint of therapeutic outcomes (though not necessarily from the standpoint of profit). As we discuss in the next section, these failures have considerable social costs.

### C. Innovation Failures are Socially Costly

<sup>185</sup> Chambers et al., *Specialty Drugs*, *supra* note 162, at 1755.

<sup>186</sup> *Id.* at 1754.

<sup>187</sup> *Id.*

<sup>188</sup> Abrams & Sampat, *supra* note 119, at 11.

<sup>189</sup> Abrams & Sampat, *supra* note 119, at 11.

<sup>190</sup> Kyle, *supra* note 27, at 219.

<sup>191</sup> *Id.* at 218.

<sup>192</sup> *Id.*

<sup>193</sup> *Id.* at 219.

<sup>194</sup> *Id.* at 219–20.

<sup>195</sup> *Id.* at 224, 226.

## *Drugs, Patents, and Well-Being*

If the authors of this paper were to quit their jobs as professors to form a boy band, their decision would primarily generate private costs for themselves and their families. Having invested resources in a project with no possible audience, they would fail to recoup their costs. This is the disciplining power of the market. But the market for pharmaceuticals is different, for the reasons discussed in Part I. These differences mean that resources invested in drugs with negligible therapeutic benefits also produce substantial social costs.<sup>196</sup>

Of course, like all patents, pharmaceuticals that generate little therapeutic value still create administrative costs for an expensive regulatory system that approves and monitors them. Here, that includes both the costs of running the PTO and the costs of running the FDA.<sup>197</sup> In addition, because low value patents are still valid, competitors will have to search for them to determine whether their own inventions face litigation risk.<sup>198</sup> And having discovered the existence of previously granted patents, competitors will expend costs either licensing or designing around those patents.<sup>199</sup> These expenses increase the costs of R&D and, potentially, the costs to consumers.<sup>200</sup>

Yet there are further costs beyond these. When firms are incentivized to maximize private value rather than social value, they invest resources that could have been otherwise better spent.<sup>201</sup> As we have noted, pharmaceutical firms can obtain substantial profits by producing “me too” drugs that treat conditions that are treated just as well by existing options.<sup>202</sup> In a world of infinite R&D resources, we would not be worried about firms investing in pharmaceutical innovations that only produced modest improvements or that only treated tiny populations. But in reality, firms face capital constraints on their R&D,<sup>203</sup> so more money spent pursuing low social value drugs means that less money will be spent developing high social value drugs.

Although “me too” drugs ostensibly inject some degree of competition into the market and should decrease the prices of first in the market drugs, the evidence for price reductions is mixed.<sup>204</sup> Pharmaceutical companies determine the price of

<sup>196</sup> Paul Grootendorst, *How Should We Support Pharmaceutical Innovation?*, 9 EXPERT REV. PHARMACOECONOMICS OUTCOMES RES. 313, 315–16 (2009).

<sup>197</sup> The PTO’s annual appropriation is over \$2 billion. Deepak Hegde, *Funding and Performance at the US Patent and Trademark Office*, 30 NATURE BIOTECH. 148, 149 (2012). The FDA spends about \$2 billion of its annual budget on human drugs. Food & Drug Admin., *Justification of Estimates for Appropriations Committees, Fiscal Year 2021*, 73 (2020), <https://www.fda.gov/media/135078/download>

<sup>198</sup> Clarisa Long, *Costs in Patent and Copyright*, 90 VA. L. REV. 465, 469 (2004).

<sup>199</sup> Bechtold, Buccafusco & Sprigman, *supra* note 39, at 19.

<sup>200</sup> *Id.*

<sup>201</sup> Masur, *supra* note 47, at 687.

<sup>202</sup> Stephane Régnier, *What Is the Value Of ‘Me-Too’ Drugs?*, 16 HEALTH CARE MANAGEMENT SCIENCE 300, 312 (2013); Wineinger, Zhang & Topol, *supra* note 77, at 7.

<sup>203</sup> Carmelo Giaccotto, Rexford E. Santerre & John A. Vernon, *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J. L. & ECON. 195 (2005).

<sup>204</sup> Hollis, *supra* note 69, at 7 (“However, since me-too drugs do not typically result in large price reductions, it is likely that they attract more investment than is socially optimal.”); Wineinger, Zhang

their drug at market entrance according to when they anticipate branded competitors will enter the market, and they may lower prices over time to stay competitive.<sup>205</sup> Additionally, the entry of more branded competitors into the market seems to result in slowed price increases over time.<sup>206</sup> However, Wineinger and colleagues' recent analysis of trends in drug prices between 2012 and 2017 indicates that price increases are nearly universal, but the highest increases were between branded drugs and their “me too” variants.<sup>207</sup> Some evidence suggests that even the introduction of a generic competitor to a previously patented drug has little effect on the total consumption of the medication.<sup>208</sup> Although “me too” drugs may not substantially reduce the prices of blockbuster drugs, they do, nonetheless, take market share.<sup>209</sup> This means that the competition created by “me too” drugs may fail to benefit consumers through lower prices while simultaneously reducing returns to the pioneer drugs that made significant innovations.<sup>210</sup>

### III. CREATING INCENTIVES FOR WELFARE-ENHANCING DRUGS

The central objective of our paper is to bridge the divide we have described in the preceding Parts between market outcomes and welfare—that is, between drugs that will earn substantial amounts of money and drugs that will substantially improve welfare. In this Part, we propose a series of patent law mechanisms aimed at encouraging pharmaceutical firms to invest resources in developing drugs that enhance welfare. Simultaneously, we hope to discourage firms from investing in developing drugs that have only a limited effect on welfare, including “me too” drugs that largely duplicate existing drugs that are already on the market.<sup>211</sup>

#### A. Extending Patents for Beneficial Pharmaceuticals

& Topol, *supra* note 77, at 5 (“This finding suggests that prices of brand-name drugs are not largely affected by the presence of generic drugs or perhaps biosimilar products and others that may enter the market in the future.”).

<sup>205</sup> Régnier, *supra* note 202, at 307–308; Joseph A. DiMasi & Cherie Paquette, *The Economics of Follow-on Drug Research and Development*, 22 PHARMACOECONOMICS, Supp. 2, 1 (2004).

<sup>206</sup> Z. John Lu & William S. Comanor, *Strategic Pricing of New Pharmaceuticals*, 80 REV. ECON. STAT. 108, 116 (1998) (“More numerous rivals have the expected effect of slowing price increases.”).

<sup>207</sup> Wineinger, Zhang & Topol, *supra* note 77, at 6.

<sup>208</sup> Darius Lakdawalla & Tomas Philipson, *Does Intellectual Property Restrict Output? An Analysis of Pharmaceutical Markets*, 55 J. L. & ECON. 151, 153–54 (2012).

<sup>209</sup> Régnier, *supra* note 202, at 305 (“The ‘average’ me-too drug was launched 2.5 years (10 quarters) after the first entrant .... and captured 38.5% of market share.”).

<sup>210</sup> Hollis, *supra* note 69, at 6 (“Not only is the R&D investment into “me-too” drugs likely excessive, me-too products harm the returns available to pioneer drugs by capturing market share from them even before patent expiry. This harms the incentive to undertake research into pioneer drugs, to the extent that the innovator expects a reduction in its period of exclusivity.”).

<sup>211</sup> Gagne & Choudhry, *supra* note 86, at 711 (describing the relative uselessness of “me too” drugs).

## *Drugs, Patents, and Well-Being*

By way of example, consider a firm that is deciding whether to invest in two drugs, Drug A and Drug B. Drug A is a typical “me too” drug—it treats a condition (high cholesterol) for which there are already very good drugs on the market, and it does so only slightly more effectively than existing treatments.<sup>212</sup> But the market for drugs that treat this condition is enormous, and if Drug A can capture only part of that market it could be highly profitable. By contrast, Drug B treats a disease that disproportionately afflicts poorer people in the United States and Europe who face greater exposure to environmental toxins than do people living in wealthier communities.<sup>213</sup> Because the existing treatments are limited and produce serious side effects, the introduction of Drug B would have a significant effect on overall welfare. But the drug might not turn out to be especially profitable.<sup>214</sup> Most of the people who would want to take the drug are poor, and so their capacity to purchase the drug would depend on their access to health insurance and the reimbursement rates of Medicaid.<sup>215</sup> From a social welfare perspective, we would much prefer that the firm invest in developing Drug B. But the firm, thinking only of its own bottom line, is quite likely to select the more profitable Drug A instead. What is needed, then, is some legal mechanism that would create additional incentives for the firm to pursue Drug B (or dampen its incentives to pursue Drug A).

Our principal lever is the patent term. We propose extending the patent term for patents that are producing substantial welfare gains. Patents are valid for twenty years from the date on which an application is filed.<sup>216</sup> But pharmaceutical drugs typically do not reach the market until many years after the filing of a patent application because of the need to run clinical trials and secure FDA approval.<sup>217</sup> This means that the typical period of market exclusivity is only ten to fourteen years.<sup>218</sup>

<sup>212</sup> Cf. *Cholesterol Count: 4 Natural Statins*, <https://www.healthline.com/health/high-cholesterol/natural-statins> (describing the many statins available to treat high cholesterol).

<sup>213</sup> Beverly Wright, *Living and Dying in Louisiana's "Cancer Alley,"* in *THE QUEST FOR ENVIRONMENTAL JUSTICE: HUMAN RIGHTS AND THE POLITICS OF POLLUTION* 88-93 (Robert D. Bullard, ed., 2005) (explaining how pollution tends to be concentrated geographically, typically near poorer communities and communities of color, due to land use decisions by policymakers).

<sup>214</sup>

<sup>215</sup> Robert Capettini, David A. Dittman & Richard C. Morey, *Reimbursement Rate Setting for Medicaid Prescription Drugs Based on Relative Efficiencies*, 4 *J. ACCOUNTING & PUB. POL'Y* 83, 86-91 (1985).

<sup>216</sup> 35 U.S.C. § 154.

<sup>217</sup> Robin J. Strongin, *Hatch-Waxman, Generics, and Patents: Balancing Prescription Drug Innovation, Competition, and Affordability*, *National Health Policy Forum*, at [https://hsrc.himmelfarb.gwu.edu/sphhs\\_centers\\_nhpf/94](https://hsrc.himmelfarb.gwu.edu/sphhs_centers_nhpf/94) (2002).

<sup>218</sup> Roin, *supra* note 40, at 511; Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 *INT'L J. TECH. MGMT.* 98, 109-17 (2000) (suggesting that the typical effective patent term is ten to twelve years); Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 *MANAGERIAL & DECISION ECON.* 491, 492 (2007) (finding that the “maximum effective patent life” is typically fourteen years).

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Despite the relatively short patent term, the useful life of a pharmaceutical can extend for decades (or even centuries).<sup>219</sup> Contrast this with technologies such as electronics, which are often obsolete after a few years.<sup>220</sup> This means that when a drug patent expires, the underlying drug is often still selling quite well and would remain valuable to the firm producing it if the patent remained in force.<sup>221</sup> Extending the patent term would produce significant additional revenues to the firm that owns the drug. Of course, the point is not to reward firms that have invented drugs that are already in existence—once the drug has come into existence, no further reward is necessary.<sup>222</sup> Rather, the point is that the potential that a firm might obtain these additional patent rewards should figure into the firm's decision about which drugs to pursue *ex ante*.<sup>223</sup> The possibility of an extended patent term should place a thumb on the scale in favor of drugs that will substantially enhance welfare, thus increasing the number of such drugs that are produced and the rate at which firms undertake those projects.

Our mechanism for creating such incentives is straightforward. Once a drug patent reaches the sixteen-year mark, the patent's owner may apply for an extension of the patent term of up to five years. <sup>224</sup> We elected five years because it represents a meaningful proportion of the typical ten-to-fourteen year effective life of a drug patent.<sup>225</sup> The PTO will grant or deny the extension on the basis of how much the drug has improved welfare in the time it has been on the market. We propose scaling term extensions to the number of QALYs that drugs generate over alternative treatments. Drugs must increase overall welfare by at least 100,000 QALYs to qualify for any term extension. We selected this number because it represents a very

<sup>219</sup> John R. Allison et al., *Valuable Patents*, 92 GEO. L.J. 435, 452 (2003) (explaining that pharmaceutical drugs often have a valuable market life that extends for many years after patenting).

<sup>220</sup> *Id.* at 461 (contrasting drugs with electronic devices and other inventions, which often cease to be useful or valuable relatively soon after patenting).

<sup>221</sup> *Id.* at 455 (explaining the economics of the drug patent system).

<sup>222</sup> Jonathan S. Masur & Adam R. Mortara, *Patents, Property, and Prospectivity*, 71 STAN. L. REV. 963, 978 (2019) (describing, in the context of purely prospective changes in the law, how the *ex ante* perspective is what matters for creating patent incentives).

<sup>223</sup> *Id.* (explaining how *ex post* changes can affect *ex ante* incentives).

<sup>224</sup> The idea of increasing or decreasing the patent term in accordance with the welfare benefit of a patented drug was developed separately and roughly contemporaneously with Neel U. Sukhatme & M. Gregg Bloche, though that paper was published before the writing of this one was completed. Sukhatme & Bloche, *supra* note 78. However, our paper differs from theirs in a number of critical ways. Among them: we describe in detail how to measure the welfare effects of one drug as compared with another follow-on drug, which is a central issue that Sukhatme and Bloche do not address; we explain why policymakers should focus on a patent's aggregate welfare effects, while they seem to support per capita welfare effects; we advocate for the use of WBUs as the proper measure of welfare; we propose a corresponding system by which patents will be invalidated or weakened if they do not contribute substantially to welfare, making our mechanism two-sided, as compared with the one-sided mechanism in Sukhatme and Bloche's paper; and we describe in detail how a system of patent term extensions (and limitations) would function and address potential objections to it.

<sup>225</sup> Roin, *supra* note 40, at 511. Of course, we are not wedded to this time period; policymakers could certainly select a period of time that is shorter or longer.

substantial increase in overall welfare, one that only a few drugs achieve.<sup>226</sup> In the study by Chambers and colleagues that we described in the previous Part, only 14 of 102 drugs (13.7%) yielded predicted welfare gains of at least 100,000 QALYS.<sup>227</sup> If the drug increases overall welfare by at least 600,000 QALYS, it qualifies for a full five-year term extension. Again, this number is chosen to reward only the very highest-performing drugs. In Chambers' data, only a few drugs reach this threshold.<sup>228</sup> Welfare increases between 100,000 QALYS and 600,000 QALYS will warrant proportionate term extensions of between 0 and 5 years. Thus, for instance, if a drug increases welfare by 350,000 QALYS (halfway between 100,000 and 600,000 QALYS), it would qualify for a 2.5 year term extension. As we described above, ideally these welfare improvements would be measured in WBUs, which are the best proxy for actual changes in human welfare.<sup>229</sup> But until there is sufficient data to denominate drug effects in WBUs, we advocate using QALYS as a second-best option.<sup>230</sup>

When measuring the welfare increase attributable to any particular drug, our objective is to determine the counter-factual: How much has this drug increased welfare, above and beyond what would have occurred if this drug had never been invented or introduced? That is the proper baseline for determining how important this drug was to overall welfare, and thus the proper baseline for measuring whether this is the type of drug for which we wish to create additional incentives. As we describe in greater detail below, accurately measuring a drug's net effects requires a correct understanding of the treatment options that both preceded and followed it.<sup>231</sup>

We draw our inspiration for this mechanism in part from the Orphan Drug Act.<sup>232</sup> This law was designed to boost incentives for firms to develop pharmaceutical drugs that treated relatively rare diseases and conditions. The theory behind the Act is similar to the theory that underlies our paper: if a disease is relatively rare, the market for a drug that treats the disease may be too small to create the necessary incentives for a firm to develop that drug.<sup>233</sup> Under the Orphan Drug Act, a firm that patents a drug that treats a disease afflicting fewer than 200,000 people can apply for a seven-year extension of market exclusivity through the FDA.<sup>234</sup> In theory, this additional seven years of market exclusivity will provide the necessary incentive to develop the drug in the first place.<sup>235</sup>

<sup>226</sup> Chambers et al., *Estimating Population*, *supra* note 169, at 230.

<sup>227</sup> *Id.*

<sup>228</sup> *Id.*

<sup>229</sup> *See supra* notes 141-142.

<sup>230</sup> *See supra* Part II (explaining the reasons to prefer WBUs over QALYS).

<sup>231</sup> *Infra* Part III.B.

<sup>232</sup> Pub. Law 97-414 (1983).

<sup>233</sup> David Duffield Rohde, *The Orphan Drug Act: An Engine of Innovation? At What Cost?*, 55 FOOD & DRUG L.J. 125 (2000) (describing the intent and functioning of the Orphan Drug Act).

<sup>234</sup> 21 U.S.C. § 360cc(a).

<sup>235</sup> Rohde, *supra* note 233, at 129 (explaining the incentives the Orphan Drug Act was designed to create).

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But the Orphan Drug Act is an imperfect fit for the goal of increasing human welfare, and its mis-design highlights the advantages of our contrary approach.<sup>236</sup> The fact that a disease afflicts fewer than 200,000 people might be a reasonable proxy for whether additional incentives will be necessary to induce a firm to produce the drug.<sup>237</sup> But it is not a good proxy for whether the drug will increase welfare. If a disease afflicts fewer than 200,000 people, that is—if anything—an indication that a drug that treats that disease *may not* have a substantial aggregate effect on welfare. The very fact of the drug's narrowness is reason to worry that such a drug will not be as valuable as alternatives that the firm might pursue. Moreover, the Orphan Drug Act does nothing to address the principal problem with the market for pharmaceutical drugs, which we described above.<sup>238</sup> There are many widespread disease and conditions that predominantly afflict poorer people who cannot pay substantial amounts of money for expensive medications.<sup>239</sup> Drugs addressing these sorts of conditions will be undersupplied by the market. But there is no reason to believe that ability to pay for a drug will be correlated with whether the drug affects 200,000 people or fewer. Accordingly, it appears that the Orphan Drug Act is frequently used to extend the patent term of already-profitable drugs that have only relatively small effects on welfare.<sup>240</sup> Needless to say, this is not how a sensible law would be structured.<sup>241</sup>

We envision the PTO adjudicating whether a drug patent owner is entitled to a patent term extension in a trial-type proceeding before a board at the Patent and Trademark Office. The drug owner carries the burden of proof that the drug has in fact increased welfare and must present evidence demonstrating this fact. At the same time, other parties—competitors of the firm seeking the extension, the government, or nongovernmental organizations—should be afforded the opportunity to oppose the patent owner's claim and present evidence contradicting it. This proceeding will likely resemble Inter Partes Review, the administrative procedure by which competitors and other parties can challenge a patent before a panel of Patent Judges.<sup>242</sup> In addition, a losing party would have the option of appealing the PTO's decision to the Federal Circuit, just as the losing party in an Inter Partes Review can appeal.<sup>243</sup>

It is important for the question of a term extension to be resolved in advance of the point at which a patent expires, in order to avoid the inefficiency and

<sup>236</sup> *Id.* at

<sup>237</sup> *Id.* at 130.

<sup>238</sup> *See supra* Part II.

<sup>239</sup> TRACEY KIDDER, MOUNTAINS BEYOND MOUNTAINS, 126-27 (2004) (discussing the prominence of TB and HIV in Haiti and other poor nations).

<sup>240</sup> Jacquie Lee, *Rare Disease Drugs Turning Huge Profits Catch Congress' Eye*, BLOOMBERG LAW (Jan. 28, 2020) <https://news.bloomberglaw.com/pharma-and-life-sciences/rare-disease-drugs-turning-huge-profits-catch-congress-eye>.

<sup>241</sup> We take up this issue further in Part IV, *infra*.

<sup>242</sup> The obvious difference is that in an Inter Partes Review proceeding, the party challenging the patent bears the burden of persuasion, 37 C.F.R. § 42.20, whereas here the party seeking the patent term extension would bear the burden of persuasion.

<sup>243</sup> 35 U.S.C. § 141.

confusion that would result if a patent expired, generics entered the market, and then the patent was reinstated. In particular, the process would ideally be complete in time for a generic manufacturer to file for FDA approval in the event that the PTO denies the patent term extension.<sup>244</sup> Accordingly, we propose measuring a drug's impact on welfare at the sixteen-year mark in part because the process of application and decision regarding a term extension could be lengthy. The typical Inter Partes Review proceeding takes approximately 18 months.<sup>245</sup> Inter Partes Review cases that are appealed to the Federal Circuit usually take approximately 15 additional months to resolve.<sup>246</sup> Initiating the patent term extension decision at the sixteen-year marks should mean that the decision will be resolved at least one year in advance of the patent expiring. Meanwhile, the FDA has instituted plans to approve generic drugs within eight to ten months.<sup>247</sup> All told, then, it should be possible to complete the process for deciding whether to extend the patent term with enough time to spare for generic manufacturers to enter the marketplace by the time the patent expires.

## B. The Choice of Baseline

As we noted above, the proper choice of baseline for measuring a drug's impact on welfare is critical. The objective is to accurately construct the counterfactual question: How much did this particular drug increase human welfare, compared with a world in which it never came into existence? If the baseline is chosen incorrectly, it may lead the PTO to grant term extensions where they are unwarranted or deny them where they would be appropriate.

We begin with the simplest case. Imagine a disease that kills 1000 people annually. Firm A introduces a drug to treat this disease. Of the 1000 people who contract the disease each year, 500 of them take the drug, and 300 of them have their lives saved by the drug. The other 700 people do not experience any changes in their lives before they die from the disease. The drug is on the market for 10 years when its patent reaches the sixteen-year mark, meaning that it saves the lives of 3000 people. On average, the people whose lives are saved by the drug go on to live an additional 40 years at an average QALY of 0.7. The welfare benefit of the drug, measured against the baseline in which the drug does not exist, is given by the following equation:

<sup>244</sup> For a discussion of the approval process for generic drug entry, see Justina Molzon, *The Generic Drug Approval Process*, 5 J. PHARMACY & L. 275 (1995).

<sup>245</sup> Ryan Kenny, *Which Invalidity Avenue to Take: Inter Partes Review Verses Post-Grant Review*, IP WATCHDOG, <https://www.ipwatchdog.com/2018/07/31/which-invalidity-avenue-ipr-verses-post-grant-review/id=99460>. By way of comparison, it takes the PTO approximately two years to grant the average patent. Jonathan S. Masur, *CBA at the PTO*, 65 DUKE L. J. 1701, 1712 (2016).

<sup>246</sup> Kerry Taylor, Daniel Kamkar & Joel Broussard, *IPR Appeals In 2017: The Pendency and Success Rates*, LAW360, January 16, 2018.

<sup>247</sup> <https://www.raps.org/regulatory-focus%e2%84%a2/news-articles/2016/9/gdufa-ii-fda-looks-to-speed-up-generic-drug-approval-process>.

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Total welfare benefit = # people who benefit from having taken the drug × extra years of life

$$\begin{aligned} & \text{preserved} \times \text{welfare benefit per year of life} \\ & = 3000 \text{ people} \times 40 \text{ years/person} \times 0.7 \text{ QALYs} \\ & = 84,000 \text{ QALYs.} \end{aligned}$$

We would perform a similar calculation for a drug that improves lives rather than saving them. For instance, imagine that this disease is not fatal, but it reduces the well-being of any person afflicted with it by 0.25 QALYs for a period of five years. The drug prevents this reduction in 300 of the 500 people who take it each year (for each of ten years, meaning it successfully treats 3000 people). The overall welfare benefit of the drug is given by the equation:

Total welfare benefit = # people who benefit from having taken the drug × welfare loss avoided

$$\begin{aligned} & \text{per person per year} \times \# \text{ of years of the disease would have} \\ & \text{persisted} \\ & = 3000 \text{ people} \times 0.25 \text{ QALYs/person/year} \times 5 \text{ years} \\ & = 3750 \text{ QALYs.} \end{aligned}$$

If a drug combined both of these effects—preventing both mortality and morbidity—the welfare effects of the reductions in mortality and morbidity would obviously be combined.

Of course, it is rarely the case that a given disease can only be treated by one drug, the drug in question.<sup>248</sup> Much more commonly there are two or more drugs that can be used to treat a given disease, each of them with slightly varying effects.<sup>249</sup> Indeed, this issue of “me too” drugs—drugs that are introduced as slightly different versions of existing medications—is one of the central animating concerns of this Article.<sup>250</sup> In the typical “me too” drug scenario, a first drug is developed and released that treats a significant condition. This drug produces large revenues, which then induces subsequent drug manufacturers to produce similar drugs—perhaps slightly superior but perhaps not—in an attempt to win some of the market share away from the original producer.<sup>251</sup> In some cases, the second drug is able to capture only a relatively small fraction of the first drug’s market share; in other cases, it is able to capture almost all of the first drug’s market share. In addition, the introduction of a second drug could lower the prices that both firms charge for their various drugs; duopoly pricing is typically lower than monopoly

<sup>248</sup> Hollis *supra* note 69, at 5.

<sup>249</sup> *Id.*

<sup>250</sup> Gagne & Niteesh, *supra* note 86, at 711.

<sup>251</sup> Hollis, *supra* note 69, at 5; Gagne and Niteesh, *supra* note 86, at 711.

pricing,<sup>252</sup> although as we showed in Part II, the evidence for this effect is mixed.<sup>253</sup> Nonetheless, competition can have the salutary effect of increasing the number of people who are able to afford one of the two drugs.<sup>254</sup>

The question is how to judge the welfare impacts of Drugs 1 and 2, given the fact that both of them exist and compete for the same market. First, consider Drug 2. The proper baseline for judging Drug 2 is not a hypothetical world in which Drug 1 does not exist. After all, Drug 1 *did exist* when Drug 2 was developed and first hit the market. Drug 2 only deserves credit for the marginal welfare gains produced by its introduction into the market, above and beyond the welfare gains that Drug 1 was already producing.<sup>255</sup> Drug 2 might generate some welfare gains simply because it is better than Drug 1. In addition, Drug 2 might also generate welfare gains because its introduction lowers the cost of both drugs and enables more people to afford them. Put another way, if the introduction of Drug 2 causes an additional person to be able to take either Drug 1 or Drug 2, then Drug 2 deserves credit for that gain in welfare. But if the introduction of Drug 2 induces someone to switch from Drug 1 to Drug 2, Drug 2 only deserves credit for the marginal gain in welfare that the person receives from taking Drug 2 instead of Drug 1. This can be expressed with the following equation:

$$\begin{aligned} & \text{welfare gain from Drug 2} = \text{marginal welfare gain from patients who switched from} \\ & \text{Drug 1} \\ & \qquad \qquad \qquad + \text{total welfare gain from new patients who start taking} \\ & \text{Drug 2} \\ & \qquad \qquad \qquad + \text{total welfare gain from new patients who start taking} \\ & \text{Drug 1} \\ & \qquad \qquad \qquad = (\text{welfare gain from Drug 2} - \text{welfare gain from Drug 1}) \\ & \times \# \text{ patients} \\ & \qquad \qquad \qquad \text{who switched from Drug 1 to Drug 2} \\ & \qquad \qquad \qquad + \text{welfare gain from Drug 2} \times \# \text{ new patients taking Drug} \\ & \qquad \qquad \qquad 2 \\ & \qquad \qquad \qquad + \text{welfare gain from Drug 1} \times \# \text{ new patients taking Drug} \\ & \qquad \qquad \qquad 1 \end{aligned}$$

<sup>252</sup> Jean-Pierre Benoit & Vijay Krishna, *Dynamic Duopoly: Prices and Quantities*, 54 REV. ECON. STUD. 23, 26 (1987) (showing that pricing will generally be lower and quantity will be greater under a duopoly than a monopoly).

<sup>253</sup> See *supra* notes 204-210 and accompanying text.

<sup>254</sup> Gagne and Niteesh, *supra* note 86, at 711.

<sup>255</sup> This is one of the limitations of the data produced by Chambers and colleagues that was discussed in Part II. They had to rely on existing studies that compared pharmaceuticals to alternative treatments. Often, several drugs that came out over a period of years were compared to the same baseline treatment rather than to the drugs that had reestablished the new baseline. Chambers et al., *Estimating Population*, *supra* note 169, at 230.

We anticipate that the patent extension trials conducted by the PTO can improve this process. The added time period may help with baseline comparisons, and firms and other organizations should be incentivized to both produce and challenge data.

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$$\begin{aligned} &= \text{welfare gain for each patient taking Drug 2} \times \# \text{ patients} \\ &\text{taking Drug 2} \\ &\quad - (\# \text{ patients taking Drug 1 before Drug 2 is introduced} - \\ &\quad \# \text{ patients} \\ &\quad \text{taking Drug 1 after Drug 2 is introduced}) \times \text{welfare gain} \\ &\quad \text{for each} \\ &\quad \text{patient taking Drug 1} \end{aligned}$$

The first term on the right hand side of this equation is the total welfare gain of all people taking Drug 2. The second term represents all of the people who have switched away from Drug 1 as a result of the introduction of Drug 2. This second term is subtracted from the first to represent the fact that Drug 2 deserves credit only for the marginal gains to these individuals from the switch.

Consider a numerical example to illustrate our approach. Suppose that a disease afflicts 1000 people and causes them to lose 0.2 QALYs annually. Drug 1 is introduced, 500 people begin taking Drug 1, and each of those people see an increase in their welfare of 0.1 QALY each year. Subsequently, Drug 2 is introduced. Drug 2 improves the welfare of someone afflicted with Disease by 0.2 QALYs, which is slightly better than Drug 1. Three hundred of the 500 people taking Drug 1 switch to Drug 2. In addition, this forces both Drug 1 and Drug 2 to lower their prices, such that 50 additional people start taking Drug 1 and 100 additional people start taking Drug 2. Now there are 400 people taking Drug 2 and 250 people taking Drug 1. In total, after the introduction of Drug 2, Drug 2 is producing 80 QALYs in yearly welfare gains and Drug 1 is producing 25 QALYs in welfare gains for a total of 105 QALYs in yearly welfare gains. However, the welfare gain attributable to Drug 2 is only:

$$\begin{aligned} \text{Drug 2 welfare gain} &= 400 \text{ people} \times 0.2 \text{ QALYs/person} - (500 \text{ people} - 250 \text{ people}) \\ &\times 0.1 \\ &\text{QALY/person} \\ &= 80 \text{ QALYs} - 25 \text{ QALYs} \\ &= 55 \text{ QALYs.} \end{aligned}$$

Or, put another way, Drug 2 gets credit for 0.1 WBUs for each of the 300 people who switched over (30 QALYs total), plus 0.2 WBUs for each of the 100 new people who started taking Drug 2 (20 QALYs), plus 0.1 QALY for each of the 50 new people who started taking Drug 1 because of the introduction of Drug 2 (5 QALYs) for a total of 55 QALYs. Drug 1 is credited with the remaining 105 QALYs – 55 QALYs = 50 QALYs of welfare gain, which is the equivalent welfare gain it was producing before Drug 2 was introduced.

The upshot is that with the appropriate choice of baseline, truly groundbreaking drugs that yield substantial welfare gains are awarded greater credit

toward patent extensions, while “me too” drugs that yield only marginal gains are awarded less credit. Here, Drug 2—the better drug—is able to capture much of the market and is thus producing greater welfare gains than Drug 1. But the fact remains that Drug 2 is only a minor improvement on Drug 1, and it was the original introduction of Drug 1 that generated the greatest welfare gains. Accordingly, Drug 1 receives greater credit toward a patent term extension. It is socially beneficial for pharmaceutical firms to spend more resources pursuing drugs like Drug 1 and fewer resources pursuing drugs like Drug 2.

This type of calculation can be repeated recursively for any number of drugs that treat the same condition. The principle underlying it remains consistent: the greatest rewards should go to the patented drugs that make the greatest impact on welfare, measured against the status quo ante before the drug was developed. Following a successful drug with a slightly more effective treatment for the same condition is precisely the sort of behavior, exploiting the market structure of pharmaceutical drugs, that we hope to disincentivize.

### C. Futility Patents

We have thus far been describing the incentive mechanisms we envision being deployed to spur creation of welfare enhancing drugs and medical treatments. But there is no reason that this mechanism need be one-sided. That is, we can do more to spur welfare enhancing drugs than increasing patent incentives for successful drugs. We can also create disincentives for firms to produce and patent drugs or treatments that have small or negative effects on overall welfare—“me too” drugs and the other sorts of treatments we described in Part II. Here, too, a drug’s effect on welfare would be measured against the baseline that would have existed if the drug had never been created. Thus, follow-on innovations that represent only mild improvements over pre-existing drugs and treatments (but subsume significant market share) would be understood to have produced only meager welfare gains.<sup>256</sup>

In parallel to the process we described for extending a patent term, we propose that any party be permitted to initiate a proceeding in the PTO to have a patent adjudged as a “futility patent” as early as the patent’s twelfth year of existence. At this proceeding, all interested parties—competitors, insurance companies, or public interest organizations—could present evidence as to the patent’s negative or relatively small impact on overall welfare, and the patent owner could present contrary evidence. We expect that this process and any accompanying appeal to the Federal Circuit would take no more than three years to complete. If the patent were challenged in its twelfth year and classified as “futile,” whatever disadvantages might apply to it would begin no later than the patent’s fifteenth year. The reason for beginning the process this early is that penalties for futile patents will only be successful and only worth pursuing if they arise substantially before the end of the effective patent term.

<sup>256</sup> Chambers et al., *Specialty Drugs*, *supra* note 162, at 1755.

The penalty for a futility patent should vary depending on whether the patent has a small beneficial effect on overall welfare or whether it creates zero or negative welfare. With regard to patents that generate zero or negative welfare effects—patents that are no better, or even worse, than what preceded them—we recommend putting teeth in the patent law’s utility requirement.<sup>257</sup> As we explained in Part I, the requirement that a patent be “useful” has heretofore been interpreted to impose only a very minimal barrier to patenting.<sup>258</sup> It weeds out inventions for which there is no known use, but little more than that.<sup>259</sup> But there is no reason that it should be so limited, and there are (as we have explained) good reasons to eliminate and discourage patents that make no meaningful welfare contribution. Accordingly, we propose that Congress enact a law instructing the PTO to invalidate any patent that has produced zero or negative social welfare by the time it is challenged in a “futility” hearing. This would give real meaning to the patent law’s ostensible requirement that patents be useful. And it would dramatically diminish the incentives for firms to invent drugs that merely duplicate, or are even inferior to, the drugs that preceded them. Where the market for pharmaceuticals creates distortions, patent law can help to smooth them out.

For patents on drugs that are creating only small gains to welfare, we would not recommend as drastic a remedy as cancellation. Instead, we would ideally apply a penalty that is symmetric to the enhanced rewards described above for welfare-enhancing drugs: the patent terms of those drugs should be reduced when the drug falls short of a pre-determined welfare threshold. Unfortunately, however, there is a complication that makes administering a penalty of that type effectively impossible. Congress can increase patent terms by statute, and it has already done so a number of times,<sup>260</sup> but it cannot reduce patent terms below twenty years without running afoul of the United States’ commitments under The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>261</sup> TRIPS establishes various floors for intellectual property rights among signatory countries, and one of those floors is a minimum term of twenty years for utility patents.<sup>262</sup> A mechanism to disincentivize the creation of these types of drugs must therefore rely on other policy levers.<sup>263</sup>

<sup>257</sup> 35 U.S.C. § 101.

<sup>258</sup> Risch, *Surprisingly Useful*, *supra* note 52, at 156.

<sup>259</sup> See *supra* Part I.

<sup>260</sup> Orphan Drug Act, Pub. Law 97-414 (1983); Hatch-Waxman Act, Drug Price Competition and Patent Term Restoration Act, Pub. Law 98-417 (1984).

<sup>261</sup> Trade Related Aspects of Intellectual Property, Article 33 (“The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”).

<sup>262</sup> *Id.* Mark D. Janis, *Second Tier Patent Protection*, 40 HARV. INT’L. L.J. 151, 152 n. 6 (1999) (discussing the TRIPS requirement of twenty years of patent protection).

<sup>263</sup> In addition, although patent owners will generally have sufficient incentives to generate data about the effectiveness of their products, other parties may not. Kapczynski, *supra* note 44, at 2365. The costs of obtaining well-being data are higher for other parties than they are for patent owners, and the benefits that can be obtained from those data will be spread among many parties, undermining their potential value to any particular party. Kapczynski & Syed, *supra* note 5, at 1927. This may reduce the rate at which competitors decide to challenge existing patents as futile, because

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Despite this hurdle, there are a wide variety of penalty options for policymakers to choose from. Even without directly invalidating less worthwhile patents or reducing their terms, Congress or the PTO could, by statute or rule, weaken these types of patents and encourage challenges to them—thus reducing their overall value—in a number of ways. Perhaps most obviously, the fact that a patent produces negligible or negative welfare benefits should make it ineligible for a term extension under the Hatch-Waxman Act<sup>264</sup> or the Orphan Drug Act.<sup>265</sup> Hatch-Waxman extensions compensate patent holders for the time that their drugs spend in FDA clinical trials, lengthening their formal patent terms in order to produce effective exclusivity periods that are closer to twenty years.<sup>266</sup> Although FDA review can help establish whether the pharmaceutical is minimally safe and effective, as we explained above, FDA approval is poorly correlated with actual welfare benefits.<sup>267</sup> By the time the patent holder applies for a Hatch-Waxman extension, however, it is possible to know how well the drug actually works. If the answer is “not very well,” there is no reason to provide an extension. The same is true for drugs that receive extensions under the Orphan Drug Act. By definition, drugs that are eligible for this extension treat small populations, so they are less likely, all else equal, to generate significant aggregate welfare benefits.<sup>268</sup> And as scholars have shown, pharmaceutical companies may be manipulating the law to receive added protection for blockbuster high-profit drugs.<sup>269</sup> Term extensions in such cases are unwarranted.

Additional policy levers abound. Congress could pass a law removing the presumption of validity from futility patents.<sup>270</sup> This would allow any party challenging the patent in court to prove that the patent is invalid only by a preponderance of the evidence, rather than by the higher “clear and convincing evidence” standard.<sup>271</sup> The PTO could waive the Inter Partes Review filing fee, which currently stands at \$15,500, for challenges to futility patents.<sup>272</sup> This would make it less expensive for any third party to challenge the patent before the PTO

to do so would mean that a firm would effectively be producing a public good. It is for this reason that we suggest that the government and public interest groups be permitted to bring similar challenges.

<sup>264</sup> Drug Price Competition and Patent Term Restoration Act, Pub. Law 98-417 (1984). This law, colloquially known as the Hatch-Waxman Act, permits patent owners to apply for patent term extensions when the FDA took a longer time to approve the underlying drug.

<sup>265</sup> Orphan Drug Act, Pub. Law 97-414 (1983).

<sup>266</sup> See Brian P. Wallenfelt, *Hatch-Waxman and Medical Devices*, 40 WM. MITCHELL L. REV. 1407, 1418 (2014); see also, Erika Lietzan, *The History and Political Economy of the Hatch-Waxman Amendments*, 49 SETON HALL L. REV. 53, 55 (2018).

<sup>267</sup> See *supra* Part II.B.

<sup>268</sup> See Michael Abramowicz, *Orphan Business Models: Toward a New Form of Intellectual Property*, 124 HARV. L. REV. 1362, 1384-85 (2011).

<sup>269</sup> Rebecca Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 726 (2005) (citing Taxol and AZT as blockbuster drugs approved under the Orphan Drug Act).

<sup>270</sup> 35 U.S.C. § 282.

<sup>271</sup> *Microsoft Corp. v. i4i Ltd.*, 564 U.S. 91 (2011) (setting forth the “clear and convincing” standard).

<sup>272</sup> 37 C.F.R. 42.15(a).

and have it judged invalid. Congress (or the courts) could also declare that any case in which the owner of such a patent loses is per se an “exceptional case” for purposes of attorneys’ fee-shifting.<sup>273</sup> That would place the owner of such a patent on notice that if it asserted the patent and lost, it would necessarily have to pay the attorneys’ fees of the party it had sued. In turn, patent owners would be much less willing to threaten dubious lawsuits, including nuisance suits, for fear that they will lose and end up holding the bag.<sup>274</sup> Congress could also eliminate the possibility of receiving treble damages for willful infringement in a suit based on such a patent,<sup>275</sup> or even eliminate the possibility of asking for reasonable royalty damages and force the patent-owner to prove that it has lost profits.<sup>276</sup> This is a small sampling of the potential options, and one that largely focuses on the monetary costs and benefits of asserting a patent; one could imagine a wide variety of other approaches as well.<sup>277</sup>

We will illustrate the functioning of this mechanism with an example. Suppose that Pharma Firm creates Drug B, a “me too” drug that largely duplicates the effect of existing medication. (The existing medication might even be one of Pharma Firm’s previous drugs.) The Coalition for Affordable Prescription Drugs (“CAPD”)<sup>278</sup> observes the limited effect of Drug B and initiates a “futility” proceeding against it before the PTO. CAPD, aided by data provided by insurance companies and the FDA, succeeds in proving to the PTO that Drug B is futile—it has at best a very marginal effect on welfare. Pharma Firm appeals to the Federal Circuit, which affirms the PTO’s decision. Just as the patent on Drug B is entering its sixteenth year, then, all of the penalties of futility attach to Drug B. Pharma Firm cannot apply for an extension of its period of exclusivity under the Hatch-Waxman Act<sup>279</sup> or the Orphan Drug Act.<sup>280</sup> In addition, if Pharma Firm sues any party for infringing its patent on Drug B, the patent will not be presumed valid in litigation. And if Pharma Firm loses the infringement litigation, it will have to pay the

<sup>273</sup> 35 U.S.C. § 285; *Octane Fitness LLC v. ICON Health & Fitness Inc.*, 134 S. Ct. 1749 (2014).

<sup>274</sup> See Anup Malani & Jonathan S. Masur, *Raising the Stakes in Patent Cases*, 101 GEO. L.J. 637 (2012) (describing how loser-pays systems can deter weaker patent cases by raising the costs to the losing party that asserts a weak patent).

<sup>275</sup> 35 U.S.C. § 284.

<sup>276</sup> *Id.*; see generally Mark A. Lemley, *Distinguishing Lost Profits from Reasonable Royalties*, 51 WM. & MARY L. REV. 655 (2009) (explaining the differences between these two theories of damages, the advantages and disadvantages of each, and the manner in which plaintiffs might try to prove their theories of damages).

<sup>277</sup> For instance, Congress could directly adjust the legal standards that apply to such patents. It could weaken the threshold for finding such a patent anticipated or obvious under 35 U.S.C. § 102 & 103, or it could heighten the enablement or written description requirements for these types of patents under 35 U.S.C. § 112. These tools would require careful crafting, and they are not as straightforward to implement as the presumption- and fee-shifting approaches described above. The point is merely to illustrate the range of options available to policymakers.

<sup>278</sup> <https://www.affordableprescriptiondrugs.org/>

<sup>279</sup> Drug Price Competition and Patent Term Restoration Act, Pub. Law 98-417 (1984).

<sup>280</sup> Orphan Drug Act, Pub. Law 97-414 (1983).

attorneys' fees stemming from the litigation.<sup>281</sup> This, in turn, will invite generic manufacturers to enter the marketplace and challenge Drug B. Those challenges will be both easier to win and cheaper for the challengers. All of this will make Drug B substantially less valuable to Pharma Firm and, we hope, convince Pharma Firm and its similarly situated competitors not to pursue such drugs in the future.

To be clear, our goal is explicitly not to punish pharmaceutical companies for drug innovations that turn out not to work well. Instead, our objective is to minimize the expected returns, either from the market or from litigation, to low or negative welfare patent holders. This, in turn, will alter the incentive structure for pursuing different sorts of treatments. Because firms will know that their "me too" drugs may not receive term extensions, they will have less reason to invest in developing them and should instead invest in innovations with more promising welfare benefits. The mechanisms we describe here would not decimate a patent's value; even if some number of encumbrances were attached, the patent would still retain value if used properly. But since the effective exclusivity period for pharmaceutical patents is already well below twenty years,<sup>282</sup> reductions in the value of the last five years of the patent term should substantially reduce the incentives for firms to pursue these types of patents in the first place.

#### D. Harnessing the Power of Markets

We are certainly not the first scholars to propose mechanisms for solving the problems with the pharmaceutical industry's incentives.<sup>283</sup> And we do not mean to suggest that any of these other solutions is inferior to ours. Nonetheless, we wish to point out several strengths that our proposed amendments to patent duration have over other options. In particular, our proposal harnesses the power of markets to help discipline pharmaceutical companies.

In a number of European countries, the governmental body that is equivalent to the FDA decides whether to approve a drug, in part, based on its assessment of whether the drug is cost-effective. These countries consider the estimated number of QALYs that a treatment will create relative to the treatment's cost.<sup>284</sup> Only if the treatment meets a certain threshold (e.g. no more than €50,000/QALY) will it be approved. Although systems like these have much to recommend them, we think they fall short in a number of ways. First, they tend to

<sup>281</sup> See 35 U.S.C. § 285 (providing for payment of attorneys' fees by the losing party in exceptional cases).

<sup>282</sup> Grabowski & Vernon, *supra* note 218, at 103-105 (2000) (finding that the effective exclusivity period for pharmaceutical drugs is less than 20 years, and more like 10-15 years in most cases).

<sup>283</sup> AIDAN HOLLIS & THOMAS POGGE, *THE HEALTH IMPACT FUND: MAKING NEW MEDICINES ACCESSIBLE FOR ALL* (2008); Carl Nathan, *Aligning Pharmaceutical Innovation with Medical Need*, 13 *NATURE MED.* 304 (2007); Grootendorst, *supra* note 214, at 316-17; Lisa Larrimore Ouellette & Q. Claire Xue, *Innovation Policy and the Market for Vaccines* (working paper 2020); Sukhatme & Bloche, *supra* note 78, at 976.

<sup>284</sup> Li Huang, Paul Frijters, Kim Dalziel & Philip Clarke, *Life Satisfaction, QALYs, and the Monetary Value of Health*, 211 *SOC. SCI. & MED.* 131 (2018)

ignore aggregate welfare in favor of welfare per person. Accordingly, a medicine that is hugely successful at treating a disease for a small population might be approved, but one that makes a smaller improvement for a large population might not be. Second, by restricting access to the market for some treatments, they eliminate the salutary effects of price competition. With fewer drugs approved to treat a condition, those that make the cut could reap even greater profits.<sup>285</sup>

Rather than having the FDA make robust cost-effectiveness decisions early in a drug's lifetime, our proposal allows the PTO to determine the strength of patent law's incentives after it has been on the market for a while. And because our proposal is based on aggregate welfare rather than per-person welfare, pharmaceutical companies will be motivated to increase the number of people taking their drugs. One way they can do this is to reduce prices.

Return to the scenario above where Drug 1 creates a substantial improvement in treatment outcomes relative to the status quo but is quickly followed by Drug 2 which yields slightly better results. Under the current regime, the duopoly may reach an equilibrium in which both drugs charge high prices, splitting the market in half.<sup>286</sup> Neither one wants to start a price war, especially if the pharmaceutical firms may also be competing with each other on other drugs. Under our approach, however, either firm could obtain a substantial increase in its patent term—and, thus, its potential profit—by dropping its price to capture a greater share of the market.

Importantly, our proposal does not just influence the *ex ante* incentives that pharmaceutical firms have to produce high value drugs, it also influences their behavior once their drugs enter the market. Should a firm find itself in a position where it has created a “me too” drug unintentionally, it won't be barred from the market. And more importantly, it will have stronger incentives to reduce the drug's price either to qualify for a patent term extension<sup>287</sup> or to stave off challenges and penalties.<sup>288</sup>

Finally, our proposal gives the manufacturer additional incentives to obtain FDA approval for new uses of existing therapies.<sup>289</sup> Although the FDA approves drugs for marketing based on their treatment of particular diseases, physicians can prescribe the drugs for so-called “off label” uses.<sup>290</sup> For example, although clonidine is approved only for treatment of hypertension, it is often prescribed for people suffering from ADHD, cancer pain, nicotine dependence, and restless leg

<sup>285</sup> Note that many European countries have other mechanisms in place to control the prices that pharmaceutical companies can charge. Absent those controls in the US, we could see even higher prices if the FDA restricted approvals.

<sup>286</sup> See Wineinger, Zhang & Topol, *supra* note 77, at 6 (noting the high correlation between the prices of competitor drugs).

<sup>287</sup> See *supra* Part III.A.

<sup>288</sup> See *supra* Part III.C.

<sup>289</sup> Eisenberg, *supra* note 269, at 717.

<sup>290</sup> Dominique Leveque, *Off-Label Use of Anticancer Drugs*, 9 LANCET: ONCOLOGY 1102 (2008).

syndrome.<sup>291</sup> While some of off-label uses are supported by scientific data, most lack evidence of therapeutic value.<sup>292</sup> The FDA does not have the authority to prevent this practice, and manufacturers may secretly encourage off-label uses of their drugs.<sup>293</sup> But firms have little reason to seek formal FDA approval for new indications of their drugs, because doing so is expensive and could reveal damaging information about the drug's effects.<sup>294</sup> Our proposal could address this concern by only counting the welfare benefits that arise from FDA-approved uses. If a firm wants credit for treating other disorders for purposes of obtaining a patent term extension, it would need to seek FDA approval for them. In order to do so, it would need to conduct new clinical trials and generate new valuable data about safety and effectiveness.

\* \* \*

We have proposed the outline of a new system for properly calibrating patent law's incentives to a drug's therapeutic value. Although much remains to be filled in, our proposal, along with the data that we cite in Part II, offers a proof of concept that scholars and policymakers can begin to use. Our proposal includes both carrots and sticks to influence pharmaceutical companies' innovative behavior when they are setting R&D priorities. Moreover, those incentives carry over to the time when drugs are being marketed in ways that can have salutary effects on prices and on data.

#### IV. OBJECTIONS AND FURTHER CONSIDERATIONS

We anticipate that our proposal will meet with objections from some scholars. In this Part, we address some of the potential objections we anticipate. We also offer some further considerations about the future of medical technology.

##### A. Additional Rewards for Successful Drugs?

We suspect that some scholars will be concerned that our proposal would lead to additional rewards from drugs that are already successful on the market—drugs for which no additional reward is necessary.<sup>295</sup> In some cases, this is indeed

<sup>291</sup> *10 Surprising Off-Label Uses for Prescription Drugs*, PHARMACY TIMES, Jan. 5, 2016, at <https://www.pharmacytimes.com/contributor/timothy-o-shea/2016/01/10-surprising-off-label-uses-for-prescription-medications>.

<sup>292</sup> David C. Radley, Stan N. Finkelstein & Randall S. Stafford, *Off-Label Prescribing Among Office-Based Physicians*, 166 ARCH. INTERNAL MED. 1021, 1023 (2006).

<sup>293</sup> Eisenberg, *New Uses*, *supra* note 269, at 733.

<sup>294</sup> *Id.* at 725.

<sup>295</sup> Richard Posner, *Pharmaceutical Patents—Posner*, THE BECKER-POSNER BLOG (Dec. 12, 2004), <https://www.becker-posner-blog.com/2004/12/pharmaceutical-patents--posner.html> (“The entire patent prize goes to the firm that crosses the finish line first, and so a firm might spend a huge

what would occur. If a firm invents a drug that treats a very serious condition—meaning that it has a significant effect on welfare—that afflicts a large number of people, and it is able to sell the drug at a meaningful price, the drug will be both commercially successful and will qualify for a patent term extension under our framework.

Nonetheless, we believe that we should be willing to tolerate this possibility. The reason is that, in a world of finite drug development investment, the question is not merely whether a particular drug is profitable or not; the question is how the profitability of one drug compares to the profitability of the foregone alternatives.<sup>296</sup> Our animating concern is that a firm might elect to pursue a highly profitable drug that targets only a small number of wealthy individuals<sup>297</sup> instead of a slightly less profitable drug that would target a broader number of less wealthy individuals but produce greater welfare gains.<sup>298</sup> Under these circumstances, a potential patent term extension for the broader—but still profitable—drug constitutes a feature of the system, not a bug. Our goal is to increase the likelihood that firms will choose that drug over the alternative.

In addition, our mechanism is self-regulating when it comes to the price and availability of a drug. Suppose a pharmaceutical firm invents a new blockbuster drug that is very successful in treating a serious disease. If the firm raises the price of that drug significantly, such that only the wealthiest patients can afford the drug, that will affect the drug's overall impact on welfare. Even if the drug is saving or dramatically improving the lives of the people who take it, it will not have a great impact on overall welfare if only a few people can afford it. This is part of the reason why we propose basing patent term extensions on a drug's overall impact on welfare, rather than (for instance) the welfare increase per person who takes the drug.<sup>299</sup> Using the overall welfare impact as the operative metric forces pharmaceutical firms to price their drugs at a level that makes them accessible to the patient population if they want to obtain a term extension. Accordingly, as we explained above, our mechanism creates incentives not merely for drug development but also for drug distribution and uptake. This is in contrast to the

amount of money to beat its nearest rival by one day even though the value to the public of having the invention one day earlier might be negligible.”); *see also*, Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J. L. & BIOSCI. 590 (2018).

<sup>295</sup> Feldman, *supra* note 295, at 596-97.

<sup>296</sup> *Id.* at 596-97.

<sup>297</sup> *See*, Sarah Jane Tribble and Sydney Lupkin, *Drugs for Rare Diseases Have Become Uncommonly Rich Monopolies*, NPR ONLINE (Jan. 17, 2017), <https://www.npr.org/sections/health-shots/2017/01/17/509506836/drugs-for-rare-diseases-have-become-uncommonly-rich-monopolies>; *see also*, Koichi Mikami, *Orphans in the Market: The History of Orphan Drug Policy*, 32 SOC. HIST. MED. 609, 628 (Aug. 2019), <https://doi.org/10.1093/shm/hkx098/>.

<sup>298</sup> *See, e.g.*, Zulfiqar Bhutta et al., *Global Burden, Distribution, and Interventions for Infectious Diseases of Poverty*, 3 INFECTIOUS DISEASES OF POVERTY 21 (2014), <https://doi.org/10.1186/2049-9957-3-21>.

<sup>299</sup> *See supra* Part III.D.

Orphan Drug Act, which can lead to term extensions even for drugs with incredibly high prices that help relatively few people.<sup>300</sup>

Two caveats are in order. First is the potential concern that a firm might hold down the price of its drug until Year 18 in order to qualify for a patent term extension, and then raise the price of the drug after the extension has been granted. We believe that such a practice should be prohibited. As a condition of receiving a patent term extension, the firm owning the patent should be required to aver that it will price the drug no higher it was priced before the extension was granted. The term extension should be revoked if the firm deviates from this agreement. Second, we do not mean to imply that the mechanism we describe in this Article is first-best, or that it is perfect and cannot be improved upon. One could imagine superior—and more complicated—alternatives in which a drug would qualify for a term extension if and only if it had sufficiently low profits, in addition to sufficiently great welfare effects. We do not mean to disclaim the possibility or value of such options.

Finally, what the law gives, it also takes away. Alongside additional rewards for welfare-enhancing drugs, we proposed reductions in the effective term, power, and value of patents that produce only negative or negligible therapeutic effects. The overall effect on the patent system, then, is indeterminate. It is possible that our mechanisms would make drug patents more powerful and valuable on the whole; it is also possible that they would be weakened overall. The one thing we can know for sure is that they would generate a split between highly welfare-enhancing inventions and inventions that are disappointing from a welfare perspective. The former would become more valuable and more attractive to firms deciding on resource allocation; the latter would become less so. This is precisely the arrangement that a welfarist policymaker should hope to generate.<sup>301</sup>

## B. Longer-Term Declines in Welfare

A related possibility is that our proposal may be self-defeating. Extending a drug's patent term gives rise to precisely the same tradeoffs that are implicated by any sort of patent term. On the one hand, the potential for an increased term can spur firms to invest resources in inventing the drug in the first place. This is the dynamic efficiency of patents.<sup>302</sup> But on the other hand, increasing a patent's term will prevent generic drugs from entering the marketplace for that much longer, keeping the price higher and potentially reducing the number of people who have access to the drug. This is the deadweight loss created by patents—the static inefficiency.<sup>303</sup> The concern is that extending a welfare-enhancing drug's patent

<sup>300</sup> Jacquie Lee, *Rare Disease Drugs Turning Huge Profits Catch Congress' Eye*, BLOOMBERG LAW, Jan. 28, 2020.

<sup>301</sup> See, e.g., Eric Posner & Cass Sunstein, *Moral Commitments in Cost-Benefit Analysis*, 103 VA. L. REV. 1809, 1812 (2017).

<sup>302</sup> See *supra* notes 31-35.

<sup>303</sup> See *supra* notes 36-48.

term by five years may lead to foregone welfare—through the individuals who cannot afford it during those five years—that exceeds the increase in welfare from the additional patent incentives. This type of concern is present whenever a patent is granted or, in this case, extended.

This is ultimately an empirical question—just as it is for the patent system as a whole—and thus we cannot dismiss it. But there are at least two reasons for optimism. First, as we described in Part II, firm incentives for drug development are severely skewed by the marketplace, and there is ample evidence that firms are not prioritizing the types of drugs that will lead to the greatest welfare gains. There are thus strong reasons to believe that the effect of altering firm incentives—offering longer patent terms for welfare-enhancing patents and weakening disappointing patents—will have a significant effect. Our mechanism takes advantage of thick margins. Even if the extended patent term means that some people are unable to afford the drug for an additional five years, the value of these additional incentives may swamp the static inefficiency.

The existing empirical evidence suggests that patent term alterations such as the ones we propose could have significant effects on R&D allocations. For example, Budish, Roin, and Williams studied firms' decisions to invest in cancer treatments based on the length of clinical trials for different sorts of treatments<sup>304</sup>. Potential treatments for late-stage cancer take less time in clinical trials than do treatments for early-stage cancer, because the outcome variable (survival) occurs more rapidly with late-stage cancer. This means that the effective patent term for late-stage treatments is longer than for early-stage treatments, and thus the size of patent incentive is larger for late-stage treatments.<sup>305</sup> Consistent with expectations, the authors find that firms invest significantly more resources in late-stage than in early-stage cancer treatments, suggesting that they are responsive to changes in effective patent duration.<sup>306</sup> Thus, we anticipate meaningful dynamic effects from enhanced R&D.

In addition, we expect that the static inefficiency from increasing a patent term by five years will be relatively muted. The cost of prescription drugs has recently become a significant political issue,<sup>307</sup> but it remains the case that most Americans have health insurance plans that cover the cost of most prescription drugs. Moreover, as we have explained, the mechanism we propose will be self-regulating along this dimension as well. In order for a drug to increase welfare sufficiently to qualify for a term extension, it will almost necessarily need to be accessible to a large number of people. In order for it to be accessible to that many people, it will have to be priced reasonably or covered by most insurance plans. If

<sup>304</sup> Budish, Roin & Williams, *supra* note 27, at 5.

<sup>305</sup> *Id.* at 8.

<sup>306</sup> *Id.*

<sup>307</sup> KFF, *Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult to Afford Their Medicines, including Larger Shares Among Those with Health Issues, with Low Incomes and Nearing Medicare Age*, March 1, 2019, at <https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/>.

access during the first 18 years of the patent term is relatively widespread, there is no reason to believe that it would narrow significantly during any patent term extension. Therefore, while we are sensitive to the possibility that the longer patent term will deny some people access to the drug, and while such a possibility cannot be ruled out, we suspect that the effect will be smaller than it would be for other types of inventions or for drugs that did not meet the standard for an extension.

Of course, as we alluded to above, there is the residual possibility that a firm will attempt to game the system by holding down the price through the eighteenth year of the patent term in order to qualify for an extension and then raising it once the extension has been granted. As we explained, we would explicitly prohibit this pernicious practice as a condition of receiving a patent term extension.

### C. Welfare Measurement and Age

Finally, we can imagine an objection to our proposed mechanism as favoring younger people—and drugs that will cure diseases that afflict them—over older people. Any calculation of human welfare that incorporates duration as a component, be it WBUs or QALYs, will tend to place greater weight on a drug that saves (that is, prolongs) the life of a younger person than a drug that saves (prolongs) the life of an older person. The simple reason is that the younger person has more life yet to live, and so a drug that prevents that person from dying of that disease will yield greater increases in welfare. Allowing a ten-year-old to live an additional seventy years is worth more, in welfare terms, than allowing a seventy-year-old to live an additional ten years.

This built-in preference may seem barbaric to some. It seems to fly in the face of the deontological view that all lives have equal value. And economists would undoubtedly point out that the elderly typically exhibit greater willingness to pay for drugs and other medical treatments than the young.<sup>308</sup> But we think this preference is a natural consequence of adopting a welfarist approach, and we view it as a feature, not a bug, of this system.<sup>309</sup> We should want firms to invest additional resources in drugs and treatments that will save the young, people who could have long, fruitful lives ahead of them. Indeed, the fact that the elderly exhibit greater willingness to pay for drugs is part of the economic problem that motivates our proposal. Their greater willingness to pay is almost certainly driven by their greater ability to pay: the elderly have amassed more wealth than the young (and their parents). Welfare, not wealth, should be the motivating criterion of the patent system.

### D. Measurement Challenges for Vaccines and Personalized Medicine

<sup>308</sup> See e.g. Joseph E. Aldy & W. Kip Viscusi, *Age Differences in the Value of Statistical Life: Revealed Preference Evidence*, 1 REV. ENVIR. ECON. & POL'Y 241 (2007).

<sup>309</sup> John Bronsteen, Christopher Buccafusco & Jonathan S. Masur, *Welfare as Happiness*, 98 GEORGETOWN LAW JOURNAL 1583 (2010)

Finally, we address possible complications that might arise from attempts to assess the welfare benefits of vaccines and personalized medicines. To this point, our paradigm case has concerned a standard drug that comes in one form, provides benefits only to the person who takes the drug, and improves the individual's health condition *ex post*. But not all pharmaceutical innovations follow this form. Most obviously, vaccines are administered *ex ante*—before an individual has contracted a disease—rather than *ex post*. They are preventions, not treatments. In addition, vaccines often create positive externalities or produce dynamic effects.<sup>310</sup> Each person who is vaccinated against a disease helps reduce the spread of that disease to other people, lowering their risk as well.<sup>311</sup> In theory, then, measuring the welfare effects of a given individual dose of a vaccine could be more complex than measuring the welfare effects of a standard drug treatment. It might depend on how many other people in the relevant population receive the vaccine, the risk factors of the vaccinated individual, or any number of other factors.

This is not, however, an insurmountable hurdle. It is possible to estimate the amount of well-being that is currently being lost from diseases that do not have vaccines. For example, 5 million people die each year from tuberculosis, and many more are made very sick from the disease.<sup>312</sup> If a firm introduces a vaccine that reduces the incidence of the disease, it should be credited for the reductions in mortality and morbidity not just of those who receive the vaccine but also of those who benefit from “herd immunity.”<sup>313</sup> Researchers have compiled estimates of the QALY benefits that accrue from a number of vaccines, including for HPV,<sup>314</sup> Lyme

<sup>310</sup> Martin Kremer, *Creating Markets for New Vaccines, Part I: Rationale*, NBER Working Paper No. 7716, at <https://www.nber.org/papers/w7716>.

<sup>311</sup> ERNST R. BERNDT, RENA N. DENONCOURT & ANJLI C. WARNER, U.S. MARKETS FOR VACCINES: CHARACTERISTICS, CASE STUDIES, AND CONTROVERSIES 24-25 (2009); *see also* Ouellette & Xue, *supra* note 283, at 22-23.

<sup>312</sup> Kremer, *supra* note 310, at 36.

<sup>313</sup> M. Brisson & W.J. Edmunds, *Economic Evaluation of Vaccination Programs: The Impact of Herd-Immunity*, 23 MED. DECISION MAKING 76, 76 (2003) (“Mass vaccination not only reduces the incidence of disease in those immunized but also indirectly protects nonvaccinated susceptibles against infection. The concept of indirect protection of susceptibles (e.g., nonvaccinees) is termed herd-immunity.”).

<sup>314</sup> Sarah C. Woodhall et al., *Cost of Treatment and QALYs Lost Due to Genital Warts: Data for the Economic Evaluation of HPV Vaccines in the United Kingdom*, 36 SEXUALLY TRANSMITTED DISEASES 515 (2009).

disease,<sup>315</sup> and rotavirus,<sup>316</sup> among others.<sup>317</sup> These numbers could be used for determining the relative welfare benefits of patented vaccines.<sup>318</sup>

Personalized medicine raises a different set of concerns. Personalized medicine involves treatments that are specially designed and targeted to the individual patient, often involving small variations of a common treatment at the molecular level.<sup>319</sup> No two treatments (for two different individuals) are identical.<sup>320</sup> This means that in some cases it may not be obvious where one drug ends and another begins—or, put another way, which outcomes to attribute to a single drug or a single patent. Personalized medicine can give rise to tricky line-drawing problems where treatments are similar but not identical and multiple patents overlap.<sup>321</sup>

Certainly it would be wrong to decrease incentives for the development of personalized medicine merely because each separate treatment affects fewer people than do traditional medicines. All else equal, we would rather a pharmaceutical company develop one hundred medicines for one hundred separate people, improving each one's life by five QALYs than have it develop one medicine to treat one hundred people, improving each one's life by only three QALYs.<sup>322</sup> We believe, however, that these issues could be resolved by the PTO. The connection between treatments and patents—and the question of which treatments should collectively fall under the heading of which patents—are the types of issues that courts and the PTO should be able to sort through. To be sure, there will be litigation over these line-drawing questions. But that type of litigation is inevitable any time the law attempts to create classifications or sort different types of conduct. Despite the fact that patent law is not facially technology-specific, it is well known by this point that the law applies differently to different types of inventions.<sup>323</sup> Our approach will be no less straightforward or easily applied than what the courts have

<sup>315</sup> Nancy A Shadick et al., *The Cost-Effectiveness of Vaccination against Lyme Disease*, 161 ARCH. INTERNAL MED. 554 (2001).

<sup>316</sup> Baudouin Standaert et al., *Cost-Effectiveness Analysis of Vaccination Against Rotavirus with RIX4414 in France*, 6 APPLIED HEALTH ECON & HEALTH POL'Y 199 (2008).

<sup>317</sup> For one example, see Edward Miguel & Michael Kremer, *Worms: Identifying Impacts on Education and Health in the Presence of Treatment Externalities*, 72 ECONOMETRICA 159 (2004) (performing a welfare calculation on a type of preventative medicine).

<sup>318</sup> See Berndt et al., *supra* note 311, at 32-34; Paul Fine, Ken Eames & David L. Keymann, "Herd Immunity": A Rough Guide, 52 CLINICAL INFECTIOUS DISEASES 911, 915 (2011) (describing the dynamics of herd immunity).

<sup>319</sup> Margaret A Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 NEW ENGLAND J. OF MED. 301, 302 (2010) (explaining and describing personalized medicine).

<sup>320</sup> M. Whirl-Carrillo et al., *Pharmacogenomics Knowledge for Personalized Medicine*, 92 CLINICAL PHARMACOLOGY & THERAPEUTICS 414, 415-16 (2012) (describing the ways in which different treatments can vary among individuals).

<sup>321</sup> See W. Nicholson Price II, *Unblocked Future: Why Gene Patents Won't Hinder Whole Genome Sequencing and Personalized Medicine*, 33 CARDOZO L. REV. 1601, 1625-26 (2011) (describing the ways in which patents interact with personalized medicine).

<sup>322</sup> We say "all else equal" because we would want to consider the relative R&D costs of these two improvement as well as their benefits.

<sup>323</sup> Burk & Lemley, *supra* note 45, at 1578.

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already been doing, and the potential benefit to human welfare is, if anything, much greater.

### CONCLUSION

Advances in medical, social, and behavioral sciences have given policymakers the tools to craft a patent regime that calibrates legal incentives with an innovation's effects on well-being. Failing to do so leads to underinvestment in truly valuable drugs and overinvestment in less socially valuable drugs. Given the enormous stakes for the US healthcare market, immediate changes to patent law are vital. In this Article, we have provided a framework for policymakers to adapt patent law to maximize well-being. Our proposals will certainly be resisted by some stakeholders. But we hope that they will draw widespread support as a means of lowering pharmaceutical costs while maintaining cutting-edge innovation.