

# Washington University Law Review

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Volume 98 | Issue 5

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2021

## Drugs, Patents, and Well-Being

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### Recommended Citation

Christopher Buccafusco and Jonathan S. Masur, *Drugs, Patents, and Well-Being*, 98 WASH. U. L. REV. 1403 (2021).

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# DRUGS, PATENTS, AND WELL-BEING

CHRISTOPHER BUCCAFUSCO\* & JONATHAN S. MASUR\*\*

## ABSTRACT

*The ultimate end of patent law should 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 underproduced, 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 significant 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 should 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

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1. U.S. CONST. art. I, § 8, cl. 8.

2. See, e.g., FACEBOOK, [www.facebook.com](http://www.facebook.com); TWITTER, [www.twitter.com](http://www.twitter.com).

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 spurs innovation.<sup>4</sup>

Because patent law relies on the market—and the possibility of monopoly profits—it necessarily incorporates all of the strengths—and 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 large 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 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 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

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3. 35 U.S.C. § 271(a) (“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.”).

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

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

6. See discussion *infra* notes 41–45.

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

8. See *infra* notes 69–71.

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 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 psychology is in its relative infancy, but there is an alternative as well: the medical concept of Quality-Adjusted Life Years (QALYs), which provides 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

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9. Amy Kapczynski, Samantha Chaifetz, Zachary Katz & Yochai Benkler, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1038 (2005).

10. Brita Pekarsky, *Should Financial Incentives Be Used to Differentially Reward ‘Me-Too’ and Innovative Drugs?*, 28 PHARMACOECONOMICS 1 (2010).

11. See *infra* notes 49–58.

12. See WELL-BEING: THE FOUNDATIONS OF HEDONIC PSYCHOLOGY (Daniel Kahneman, Ed Diener & Norbert Schwarz eds., 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); LAW AND HAPPINESS (Eric A. Posner & Cass R. Sunstein eds., 2010); THE OXFORD HANDBOOK OF WELL-BEING AND PUBLIC POLICY (Matthew D. Adler & Marc Fleurbaey eds., 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).

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

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 significant 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 the firms 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 remedying 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 diminished incentives for “futile” patents.

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14. See *infra* notes 119–121.

15. See *infra* Part III. CREATING INCENTIVES FOR WELFARE-ENHANCING DRUGS.

16. 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 theirs in a number of ways. See *infra* note 228 for further details.

Part IV responds to some potential objections and demonstrates 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 US Constitution gives Congress the power to grant patents to inventors in order “to promote the Progress of . . . 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-being they generate are unnecessary because market forces are better determinants of value than legal institutions.<sup>23</sup> We

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17. U.S. CONST. 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).

18. See, e.g., *Kewanee Oil Co. v. Bicon 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, *LAWS 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).

19. 35 U.S.C. § 101.

20. Michael Risch, *Reinventing Usefulness*, 2010 BYU L. REV. 1195, 1205 (2010); Christopher Buccafusco & Jonathan S. Masur, *Intellectual Property Law and the Promotion of Welfare*, in 1 RESEARCH HANDBOOK ON THE ECONOMICS OF INTELLECTUAL PROPERTY LAW 98 (Benjamin Depoorter & Peter S. 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).

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

22. Risch, *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 COMPUT. & HIGH TECH. L.J. 269, 298 (2006); Clarisa Long, *Our Uniform Patent System*, 55 FED. LAW. 44, 49 (2008).

23. Risch, *supra* note 20, at 1206 n.42.

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> In some ways, pharmaceutical innovations are the shining lights of the patent regime. In many others, however, including neglect of rare diseases or those that primarily afflict the poor, pharmaceutical 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 recite 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 lower prices than the inventors, because the copyists do not 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 they are often able to charge prices for access to their inventions that 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 market once the patent has expired.<sup>34</sup> By giving

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24. *Infra* notes 64–75.

25. 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).

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

27. Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials*, 105 Am. Econ. Rev. 2044, 2059–60 (2015); Margaret K. Kyle, *Are Important Innovations Rewarded? Evidence from Pharmaceutical Markets*, 53 REV. INDUST. ORG. 211, 215 (2018).

28. Kyle, *supra* note 27, at 213.

29. Long, *supra* note 22, at 45.

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

31. 35 U.S.C. § 101.

32. 35 U.S.C. § 283.

33. Long, *supra* note 22, at 45.

34. Kyle, *supra* note 27, at 213; Budish, Roin, & Williams, *supra* note 27, at 2059.

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 willing and able to purchase a given patented product if it were priced at marginal cost—that is, at the cost to the producer of making one additional unit of the product.<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 are not worth much if no one wants to buy their products. Just as a copyright in a movie 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 toward products that consumers want—which are generally products that will make their lives better off.<sup>43</sup>

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

36. See *infra* Part I.C.

37. 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).

38. If they're still alive then.

39. See generally Christopher Buccafusco, Stefan Bechtold & Christopher Jon Sprigman, *The Nature of Sequential Innovation*, 59 WM & MARY L. REV. 1 (2017).

40. 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.")

41. See Hemel & Ouellette, *supra* note 30, at 346.

42. Sources cited in Buccafusco & Masur, *supra* note 20, at 102–03.

43. On the relationship between patents and preference satisfaction, see *id.*

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 toward 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 US Patent and Trademark Office (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

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44. Amy Kapczynski, *Dangerous Times: The FDA's Role in Information Production, Past and Future*, 102 MINN. L. REV. 2357, 2363 (2018); Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation 1* (June 10, 2004) (unpublished manuscript), [https://www.researchgate.net/profile/Aidan\\_Hollis/publication/251697338\\_An\\_Efficient\\_Reward\\_System\\_for\\_Pharmaceutical\\_Innovation/links/5c895b88892851c1df93ff319/An-Efficient-Reward-System-for-Pharmaceutical-Innovation.pdf](https://www.researchgate.net/profile/Aidan_Hollis/publication/251697338_An_Efficient_Reward_System_for_Pharmaceutical_Innovation/links/5c895b88892851c1df93ff319/An-Efficient-Reward-System-for-Pharmaceutical-Innovation.pdf); Kyle, *supra* note 27, at 215.

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

46. 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.")

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

48. 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.")

49. 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. See discussion *infra* notes 117–122.

50. 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.

51. 35 U.S.C. § 101.

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 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 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 would 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

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

53. Sean B. Seymore, *Making Patents Useful*, 98 MINN. L. REV. 1046, 1091 (2014); Risch, *supra* note 52, at 65–66.

54. 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.” *Id.*

55. 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.”).

56. See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998) (discussing the ways in which the various holders of the many patents necessary for research can hold up innovation in a field by refusing to license their patents).

57. David S. Abrams & Bhaven N. Sampat, *Pharmaceutical Patent Citations and Real Value 2* (Jan. 2017) (unpublished manuscript) (on file with authors) (“Unlike many complex manufactured products that may involve hundreds or thousands of patents, drugs tend to depend on one or two key patents.”).

58. 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*.”) (emphasis omitted); Carroll, *supra* note 22, at 1374.

59. 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.”).

60. Risch, *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.”).

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 make 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, commentators 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 and thus provide much more useful disclosures to experts in the field.<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 an exhaustive 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 instead produce "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

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61. Risch, *supra* note 20, at 1206.

62. *Id.*

63. *Id.*

64. Carroll, *supra* note 22, at 1390; *see also* Burk & Lemley, *supra* note 45, at 1590.

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

66. Long, *supra* note 22, at 45.

67. Kyle, *supra* note 27, at 215.

68. Kapeczynski, *supra* note 44, at 997; Buccafusco & Masur, *supra* note 42, at 7.

69. Hollis, *supra* note 44, at 1; Kapeczynski, *supra* note 44, at 997.

70. Kyle, *supra* note 27, at 211.

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 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 of pharmaceutical costs,<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 provide by encouraging 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 toward the most socially valuable R&D.<sup>79</sup> As we have seen, this connection may break down when purchasers and payers

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71. *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 . . . 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.”).

72. *Id.* at 213.

73. Hollis, *supra* note 44, at 2 (“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 . . .”).

74. Owen Dyer, *Firm Bribed Doctors to Prescribe Overpriced Drug, US Alleges in Suit*, BRIT. MED. J. (May 2, 2019).

75. Mark A. Lemley, Lisa Larrimore Ouellette & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. 75, 81 (2020) (“[B]ut 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.”).

76. *Id.* at 77.

77. 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.”).

78. Kapczynski et al., *supra* note 9, at 1038; Neel U. Sukhatme & M. Gregg Bloche, *Health Care Costs and the Arc of Innovation*, 104 MINN. L. REV. 955 (2019); Hollis, *supra* note 44, at 3.

79. LANDES & POSNER, *supra* note 4, at 25–28.

are not the ultimate consumers of goods.<sup>80</sup> And it further erodes 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>

On the one hand, as we have 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 US Food and Drug Administration (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 entered the public domain and been 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 heterogeneous patient 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

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80. See Christopher Buccafusco, *Disability and Design*, 95 N.Y.U. L. REV. 952 (2020).

81. 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.")

82. 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.")

83. Lemley, Ouellette & Sachs, *supra* note 75, at 84 ("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.")

84. Hollis, *supra* note 44, at 5.

85. *Id.*

86. Joshua J. Gagne & Niteesh K. Choudhry, *How Many "Me-Too" Drugs Is Too Many?*, 305 JAMA 711 (2011).

87. *Id.* at 711.

88. *Id.*

89. *Id.*

90. 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); Aaron S. Kesselheim et al., *Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease: A Systematic Review and Meta-Analysis*, 300 JAMA 2514 (2008); Aidan Hollis, *Me-Too Drugs: Is There a Problem?* (Dec. 13, 2004) (unpublished manuscript), [http://www.who.int/intellectualproperty/topics/ip/Me-tooDrugs\\_Hollis1.pdf](http://www.who.int/intellectualproperty/topics/ip/Me-tooDrugs_Hollis1.pdf).

reduce the profits (and thus the incentives to invent) that accompany the first-in-class drug.<sup>91</sup>

On the other hand, some diseases that primarily affect small or poor populations will not attract much investment, 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 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.

The skewed nature of the US healthcare market also distorts pharmaceutical companies' incentives toward drugs that treat diseases rather than ones that cure them.<sup>95</sup> As Claire Xue and Lisa Ouellette argue, drugmakers deciding between developing a vaccine that cures a disease once and for all or developing a drug that merely treats the disease over time might find the latter opportunity much more profitable.<sup>96</sup> Selling daily, weekly, or monthly treatments may be far more lucrative than selling a single-dose cure, but the cure is hugely more valuable in terms of social welfare because it produces significant positive externalities and can lead, ultimately, to eradication of the disease.<sup>97</sup>

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91. Hollis, *supra* note 44, at 5.

92. See Michael Kremer, *Pharmaceuticals and the Developing World*, 16 J. ECON. PERSPS. 67, 68–69 (2002).

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

94. 21 U.S.C. § 360cc(a).

95. See Qiwei Claire Xue & Lisa Larrimore Ouellette, *Innovation Policy and the Market for Vaccines*, 7 J.L. & BIOSCIS. 1 (2020); Ana Santos Rutschman, *The Vaccine Race in the 21st Century*, 61 ARIZ. L. REV. 729 (2019); Lemley, Ouellette & Sachs, *supra* note 75, at 119–20.

96. Xue & Ouellette, *supra* note 95, at 20.

97. *Id.* at 21–24.

#### 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. When approving drugs, the FDA does not condition marketability on cost-effectiveness.<sup>98</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>99</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>100</sup> The considerable 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>101</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 wants to sell the drug (usually the patent owner) can prove that it is safe and effective.<sup>102</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>103</sup> This data often comes from studies run by the patent owners,<sup>104</sup> and there are many commentators who are concerned about statistical manipulation of trial results.<sup>105</sup> A burgeoning

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98. Denise 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>.

99. Budish, Roin & Williams, *supra* note 27, at 2044–45.

100. Vinay Prasad, *Do Cancer Drugs Improve Survival or Quality of Life?*, 359 BRIT. MED. J. (Oct. 4, 2017); John Mandrolia, Adam Cifu, Vinay Prasad & Andrew Foy, *The Case for Being a Medical Conservative*, AM. J. MED. 900 (2019); Diana Herrera-Perez, Alyson Haslam, Tyler Crain, Jennifer Gill, Catherine Livingston, Victoria Kaestner, Michael Hayes, Dan Morgan, Adam S. Cifu & Vinay Prasad, *A Comprehensive Review of Randomized Clinical Trials in Three Medical Journals Reveals 396 Medical Reversals*, 8 ELIFE 1, 2 (2019); Margaret Kyle & Heidi Williams, *Is American Health Care Uniquely Inefficient? Evidence from Prescription Drugs*, 107 AM. ECON. REV. 486 (2017).

101. Herrera-Perez et al., *supra* note 100, 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.”) (citation omitted).

102. *See* 21 U.S.C. § 355(d).

103. Sukhatme & Bloche, *supra* note 78, at 982.

104. Chi Heem Wong, Kien Wei Siah & Andrew Lo, *Estimation of Clinical Trial Success Rates and Related Parameters*, 20 BIOSTATS. 273, 273 (2019).

105. *See, e.g.*, Prasad, *supra* note 100; Kapczynski, *supra* note 44, at 2369.

medical literature has described numerous flaws in FDA clinical trials, including the use of non-clinical (i.e., non-human) data,<sup>106</sup> the lack of randomly-controlled trials,<sup>107</sup> and non-representative study populations,<sup>108</sup> all of which tend to overstate a drug's efficacy.<sup>109</sup>

Further, research by Eric Budish, Benjamin Roin, and Heidi Williams has shown how variations in the length of FDA clinical trials affect firms' R&D choices.<sup>110</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>111</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>112</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 pharmaceuticals 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>113</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 alternative treatments.<sup>114</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

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106. 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 AFFS. 1408 (2017).

107. Brett K. Beaulieu-Jones, Samuel G. Finlayson, William Yuan, Russ B. Altman, Isaac S. Kohane, Vinay Prasad, & Kun-Hsing Yu, *Examining the Use of Real-World Evidence in the Regulatory Process*, 107 CLINICAL PHARMACOLOGY & THERAPEUTICS 843 (2020).

108. See Chadi Nabhan, Andrew Klink & Vinay Prasad, *Real-World Evidence—What Does It Really Mean?*, 5 JAMA ONCOLOGY 781 (2019); see also Beaulieu-Jones et al., *supra* note 107.

109. See Mandrola et al., *supra* note 100.

110. Budish, Roin & Williams, *supra* note 27, at 2.

111. *Id.*

112. *Id.* at 3.

113. Laura Lorenzetti, *Is It Time for the FDA to Consider Cost when It Comes to New Drugs?*, FORTUNE (Feb. 4, 2015, 9:45 AM), <https://fortune.com/2015/02/04/is-it-time-for-the-fda-to-consider-cost-when-it-comes-to-new-drugs/>.

114. See 21 U.S.C. § 355(d). Many European countries have more advanced systems of health technology assessment than the US does. See Corinna Sorenson & Kalipso Chalkidou, *Reflections on the Evolution of Health Technology Assessment in Europe*, 7 HEALTH ECON., POL'Y & L. 25, 26 (2012).

thus its price is not yet known. Accordingly, there may be little the FDA can do to connect patents with aggregate social utility.

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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>115</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>116</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

The first challenge in connecting patents with their effects on welfare is isolating the patents involved in pharmaceutical products. Recent research

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115. Burk & Lemley, *supra* note 45, at 1578.

116. See Daniel Kahneman, *Objective Happiness*, in WELL-BEING: THE FOUNDATIONS OF HEDONIC PSYCHOLOGY (Daniel Kahneman, Ed Diener & Norbert Schwarz eds., 1999); Ed Diener, Richard E. Lucas, Ulrich Schimmack & John Helliwell, *Defining Well-being*, in WELL-BEING FOR PUBLIC POLICY (Ed Diener, Richard E. Lucas, Ulrich Schimmack & John Helliwell eds., 2009); William S. Comanor, Stuart O. Schweitzer & Tanja Carter, *A Hedonic Model of Pricing of Innovative Pharmaceuticals*, in HEALTH POLICY AND HIGH-TECH INDUSTRIAL DEVELOPMENT: LEARNING FROM INNOVATION IN THE HEALTH INDUSTRY (Marco R. Di Tommaso & Stuart O. Schweitzer eds., 2005); John Bronsteen, Christopher Buccafusco & Jonathan S. Masur, *Well-Being Analysis vs. Cost-Benefit Analysis*, 62 DUKE L.J. 1603 (2013).

by Scott Hemphill and Bhaven Sampat has shown this to be possible.<sup>117</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>118</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>119</sup> After this patent expires, generic versions of the drug tend to enter the market.<sup>120</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>121</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>122</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>123</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>124</sup>

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

118. Ctr. for Drug Evaluation & Rsch., Food & Drug Admin., *Approved Drug Products with Therapeutic Equivalence Evaluations* (40th ed. 2019).

119. Hemphill & Sampat, *Evergreening*, *supra* note 117, at 330.

120. Hemphill & Sampat, *Drug Patents*, *supra* note 117, at 615.

121. Abrams & Sampat, *supra* note 57, at 1, 8.

122. *Id.* at 8. There is now ample 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 Larrimore Ouellette, Note, *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.

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

124. *Id.*

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 their welfare, due to the numerous distortions of the drug market.<sup>125</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>126</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 solely in terms of patients' five-year survival rates ignores an enormous amount of information that we might care about.<sup>127</sup> Obviously, many drugs treat conditions that do not cause death. Knowing that the five-year survival rate of an acne medication is above 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>128</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>129</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 follow the practices of hedonic psychology by surveying people who are taking the drug and asking them how they are feeling.<sup>130</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.<sup>131</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>132</sup> People's self-reports about their current experiences generate

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125. See Bronsteen et al., *supra* note 116, at 1607; see also Tara O'Neill Hayes, *Market Distortions Caused by the 340B Prescription Drug Program*, AM. ACTION F. (Nov. 28, 2017), <https://www.americanactionforum.org/research/340bmarketdistortions/> [<https://perma.cc/RWU2-6DWJ>].

126. Wendy Netter Epstein, *Nudging Patient Decision-Making*, 92 WASH. L. REV. 1255 (2017); Hollis, *supra* note 44, at 3.

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

128. Milton C. Weinstein, George Torrance & Alistair McGuire, *QALYs: The Basics*, 12 VALUE HEALTH S5, S5 (2009).

129. Amiram Gafni, *Economic Evaluation of Health-Care Programmes: Is CEA Better than CBA?*, 34 ENV'T & RES. ECON. 407, 408 (2006).

130. Bronsteen et al., *supra* note 116, at 1617.

131. *Id.* at 1617–20.

132. See Iris H.L. Maes, Philippe A.E.G. Delespaul, Madelon L. Peters, Matthew P. White, Yvette van Horn, Koen Schruers, Lucien Anteunis & Manuela Joore, *Measuring Health-Related Quality of Life by Experiences: The Experience Sampling Method*, 18 VALUE HEALTH 44, 44 (2015); Alan B. Krueger,

the most valid and reliable data on how they are doing.<sup>133</sup> For our purposes, we could imagine studies that track individuals' 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>134</sup> Studies like these would provide extraordinarily precise data about individual treatment, including information about their health states and also their emotions and moods.<sup>135</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 could create considerable impositions on patients.<sup>136</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>137</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>138</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>139</sup> For example, researchers have

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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 USE AND WELL-BEING 9, 30 (Alan B. Krueger ed., 2009).

133. See Diener et al., *supra* note 116, at 71–73; Dylan M. Smith, Ryan L. Sherriff, Laura Damschroder, George Loewenstein, & Peter A. Ubel, *Misremembering Colostomies? Former Patients Give Lower Utility Ratings than Do Current Patients*, 25 HEALTH PSYCH. 688, 691 (2006).

134. See Inez Myin-Germeys, Zuzana Kasanova, Thomas Vaessen, Hugo Vachon, Olivia Kirtley, Wolfgang Viechtbauer & Ulrich Reininghaus, *Experience Sampling Methodology in Mental Health Research: New Insights and Technical Developments*, 17 WORLD PSYCHIATRY 123, 123 (2018).

135. Ingrid Kramer, Claudia J.P. Simons, Jessica A. Hartmann, Claudia Menne-Lothmann, Wolfgang Viechtbauer, Frenk Peeters, Koen Schruers, Alex L. van Bommel, Inez Myin-Germeys, Philippe Delespaul, Jim van Os & Marieke Wichers, *A Therapeutic Application of the Experience Sampling Method in the Treatment of Depression: A Randomized Controlled Trial*, 13 WORLD PSYCHIATRY 68, 68 (2014).

136. Alan B. Krueger et al., *supra* note 132, at 30.

137. Diener et al., *supra* note 116, at 19.

138. See William Pavot & Ed Diener, *Review of the Satisfaction with Life Scale*, 5 PSYCH. 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 their own unique set of criteria").

139. 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).

used life satisfaction data to explore patients' experiences with different treatments for breast cancer,<sup>140</sup> kidney transplants,<sup>141</sup> and ADHD.<sup>142</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>143</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. (Negative numbers represent experiences that are worse than unconsciousness, such as invasive dental work.) One WBU is equivalent to one point on the hedonic scale for one person for one year.<sup>144</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 ten people each took a drug that raised their well-being from 5 to 8, and they took these drugs over a period of ten years, this would yield an overall gain of  $10 \text{ people} \times 3 \text{ points} \times 10 \text{ years} = 300 \text{ WBUs}$ . 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, there are more available data that analyze medical treatments using a metric called Quality Adjusted Life Years (QALYs).<sup>145</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>146</sup> Many European countries mandate QALY comparisons for health technology

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140. Marianne Carlsson, Maria Arman, Marie Backman, Ursula Flatters, Thomas Hatschek & Elisabeth Hamrin, *Evaluation of Quality of Life/Life Satisfaction in Women with Breast Cancer in Complementary and Conventional Care*, 43 ACTA ONCOLOGICA 27 (2004).

141. Arthur J. Matas, R.J. Halbert, Mark L. Barr, J. Harold Helderman, Donald E. Hricik, John D. Pirsch, Felicia A. Schenkel, Bonita R. Siegal, Honghu Liu & Ronald M. Ferguson, *Life Satisfaction and Adverse Effects in Renal Transplant Recipients: A Longitudinal Analysis*, 16 CLINICAL TRANSPLANTATION 113 (2002).

142. Aribert Rothenberger, Andreas Becker, Dieter Breuer & Manfred Döpfner, *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).

143. Bronsteen et al., *supra* note 116, at 1643.

144. *Id.* at 1643–44.

145. Chisholm et al., *supra* note 127, 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. CANCER POL'Y 19, 20–21 (2017).

146. Chisholm et al., *supra* note 127, 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.").

appraisals and cost-effectiveness studies because QALYS provide a single measure for evaluating alternatives.<sup>147</sup> Accordingly, pharmaceutical companies also have significant experience with them.<sup>148</sup>

To measure QALYs, researchers assess the number of years of life gained from a new treatment relative to the status quo treatment.<sup>149</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>150</sup> HRQoL is assessed on a scale that runs from 0 to 1, where 1 indicates perfect health and 0 indicates death.<sup>151</sup> Negative numbers can represent states worse than unconsciousness or death.<sup>152</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>153</sup> The relative weights of each of these domains is judged by medical professions and members of the public, rather than patients themselves (an issue we discuss further below).<sup>154</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.<sup>155</sup> In the next Part, we argue that the PTO can use QALY data to manipulate the size of the incentives given to pharmaceutical companies.

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147. Hollis, *supra* note 44, 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 145, at 6 (“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 44, 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.”).

148. Hollis, *supra* note 44, at 17 (“Drug companies have also used QALY-type analysis themselves in order to demonstrate economic effectiveness of treatments.”) (citation omitted).

149. Devlin & Lorgelly, *supra* note 145, at 20.

150. *Id.*

151. Chisholm et al., *supra* note 127, at 68; *see also* Devlin & Lorgelly, *supra* note 145, at 20.

152. Devlin & Lorgelly, *supra* note 145, 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.”).

153. *Id.*

154. *Id.* at 19–20.

155. Hollis, *supra* note 44, at 2.

We should note, however, that QALY data are not a perfect proxy for human welfare.<sup>156</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>157</sup> Vaccines and treatments for communicable diseases help everyone in society, not just the people who receive them. And a pharmaceutical that enables patients to return to work can improve the lives of their children, spouses, and caregivers.<sup>158</sup>

In addition, as we explained, HRQoL weights are assessed by asking medical professionals and members of the public how bad they think various health states are.<sup>159</sup> There is extensive evidence, though, that healthy people make systematic mistakes when predicting how various health states would make them feel.<sup>160</sup> Because healthy people focus on *becoming* unhealthy rather than *being* unhealthy, and because they do not account sufficiently for the effects of hedonic adaptation to new experiences, they tend to overestimate both the magnitude and duration of negative experiences.<sup>161</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>162</sup> Accordingly, they may understate the value of treatments for mental health disorders or ones that increase pleasure. And they may less accurately assess the experiences of people with disabilities. For these reasons, we encourage

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156. Devlin & Lorgelly, *supra* note 145, at 21.

157. *Id.* at 21.

158. See Whitehead & Ali, *supra* note 145, at 17 (“[A]n 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 145, at 23 (“[T]here 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.”).

159. Whitehead & Ali, *supra* note 145, at 16.

160. *Id.*

161. 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 PSYCH. 111, 111 (2005); Peter A. Ubel, George Loewenstein, John Hershey, Jonathan Baron, Tara Mohr, David A. Asch & Christopher Jepson, *Do Nonpatients Underestimate the Quality of Life Associated with Chronic Health Conditions Because of a Focusing Illusion?*, 21 MED. DECISION MAKING 190, 197 (2001).

162. Rebecca Johnson, David Jenkinson, Chris Stinton, Sian Taylor-Phillips, Jason Madan, Sarah Stewart-Brown & Aileen Clarke, *Where's WALY?: A Proof of Concept Study of the 'Wellbeing Adjusted Life Year' Using Secondary Analysis of Cross-Sectional Survey Data*, 14 HEALTH & QUALITY LIFE OUTCOMES 126 (2016) (“[T]he fact that we found a ceiling effect in the EQ-5D-3L (as have others before us, 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.”) (citation omitted).

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>163</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>164</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>165</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 about 4.1 QALYs per person.<sup>166</sup> Although these drugs come with astronomical price tags (\$168,469 and \$151,746 costs, respectively),<sup>167</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>168</sup> Sixteen out of the 102 drugs in the sample produced at least half of a QALY on average.<sup>169</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

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163. Nabhan et al., *supra* note 108, at 781.

164. Kyle, *supra* note 27, at 219.

165. James D. Chambers, Teja Thorat, Junhee Pyo, Matthew Chenoweth & Peter J. Neumann, *Despite High Costs, Specialty Drugs May Offer Value For Money Comparable to that of Traditional Drugs*, 33 HEALTH AFFS. 1751, 1752 (2014).

166. *Id.* at 1756–57.

167. *Id.*

168. *Id.*

169. *Id.*

to one person's life is generally not as valuable as adding one QALY to one hundred people's lives.<sup>170</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>171</sup> Thus, from the perspective of a policymaker, what typically matters most 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 US incidence of diseases from the Centers for Disease Control and the National Cancer Institute.<sup>172</sup> They then calculated the aggregate number of QALYs per pharmaceutical if ten percent of the population with the condition received it.<sup>173</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 the particular form of leukemia that it treats.<sup>174</sup> If ten percent of the 64,000 people took the drug, its estimated aggregate benefit was only about 40,000 QALYs.<sup>175</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>176</sup> For example, approximately 67 million Americans 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>177</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 17 million people with the disease, it would create an additional 696,680 QALYs.<sup>178</sup> According to Chambers and colleagues'

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170. Bronsteen et al., *supra* note 116, at 1632–33. *But see* JOHN RAWLS, A THEORY OF JUSTICE 140 (2009) (“[T]he principle of average utility directs society to maximize not the total but the average utility (per capita).”).

171. 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, *IP3*, 59 STAN. L. REV. 257 (2006).

172. James D. Chambers, Teja Thorat, Colby L. Wilkinson, Mark Salem, Prasun Subedi, Sachin J. Kamal-Bahl & Peter J. Neumann, *Estimating Population Health Benefits Associated with Specialty and Traditional Drugs in the Year Following Product Approval*, 15 APPLIED HEALTH ECON. & HEALTH POL'Y 227, 228–30 (2017).

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

174. *Id.* at online supp., app. tbl.1, <https://link.springer.com/article/10.1007%2Fs40258-016-0291-9#Sec15>.

175. *Id.*

176. *Id.* at 231.

177. *Id.*

178. *Id.*

data, fourteen drugs would generate at least 100,000 QALYs under their assumptions.<sup>179</sup>

Unfortunately, for many more pharmaceuticals, the story is not as promising. 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, Chi Heem Wong, Kien Wei Siah, and Andrew Lo estimate that only 13.8% of drug development programs result in approval,<sup>180</sup> and their estimates are higher than some others.<sup>181</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>182</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>183</sup> But relying on surrogate endpoints rather than clinical ones can dramatically overestimate a drug’s total therapeutic effect.<sup>184</sup> Thus, most patented pharmaceuticals fail to meet the FDA’s standards for safety and effectiveness, and those that meet them may do so on data of dubious reliability.<sup>185</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 their series of studies, Chambers and his colleagues estimated that a significant fraction of new drugs were no more effective or less effective than existing options. That is, they produced zero or negative QALYs.<sup>186</sup> One of their studies found this to be true for 29% of the drugs studied,<sup>187</sup> and another estimated that 32% had zero or negative QALY

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179. *Id.*

180. Wong, Siah & Lo, *supra* note 104, at 277.

181. Michael Hay, David W. Thomas, John L. Craighead, Celia Economides & Jesse Rosenthal, *Clinical Development Success Rates for Investigational Drugs*, 32 NATURE BIOTECH. 40, 48 (2014) (estimating a 10.4% success rate); DAVID W. THOMAS, JUSTIN BURNS, JOHN AUDETTE, ADAM CARROLL, COREY DOW-HYGELUND & MICHAEL HAY, BIO, CLINICAL DEVELOPMENT SUCCESS RATES 2006–2015 3 (2016) (estimating a 9.6% success rate).

182. Asher Mullard, *2019 FDA Drug Approvals*, 19 NATURE REVS. 79 (2020). The five-year rolling average is forty-four approvals per year. *Id.* at 79.

183. Ross L. Prentice, *Surrogate Endpoints in Clinical Trials: Definition and Operational Criteria*, 8 STAT. MED. 431, 431–40 (1989); Beaulieu-Jones et al., *supra* note 107, at 844.

184. Robert Kemp & Vinay Prasad, *Surrogate Endpoints in Oncology: When Are They Acceptable for Regulatory and Clinical Decisions, and Are They Currently Overused*, 15 BMC MED. 134 (2017); *see also* Beaulieu-Jones et al., *supra* note 107, at 844.

185. 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* Herrera-Perez et al., *supra* note 100, at 2–3; Nabhan et al., *supra* note 108, at 781–82.

186. Chambers et al., *supra* note 106, at 1410.

187. *Id.*

impact.<sup>188</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>189</sup> Moreover, another one-third of the drugs in this study generated fewer than 0.1 incremental QALYs.<sup>190</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 United States between 1987 and 2011.<sup>191</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>192</sup>

Margaret Kyle analyzed 352 new pharmaceuticals that reached the market between 2000 and 2016.<sup>193</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>194</sup> Major improvements are scored 1, while those with no additional benefit are scored 5.<sup>195</sup> Perhaps unsurprisingly, imatinib (Gleevec) scored 1.<sup>196</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>197</sup> Despite their poor performance, however, these low scoring drugs were not significantly cheaper than their higher scoring counterparts.<sup>198</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 a sizeable 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

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188. Chambers et al., *supra* note 165, at 1755.

189. *Id.* at 1754.

190. *Id.*

191. Abrams & Sampat, *supra* note 57, at 11.

192. *Id.*

193. Kyle, *supra* note 27, at 219.

194. *Id.* at 218.

195. *Id.*

196. *Id.* at 219.

197. *Id.* at 219–20.

198. *Id.* at 226.

(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*

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 meaningful social costs.<sup>199</sup>

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>200</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>201</sup> And having discovered the existence of previously granted patents, competitors will expend costs either licensing or designing around those patents.<sup>202</sup> These expenses increase the costs of R&D and, potentially, the costs to consumers.<sup>203</sup>

There are important opportunity costs as well. When firms are incentivized to maximize private value rather than social value, they invest resources that could have been otherwise better spent.<sup>204</sup> As we have noted, pharmaceutical firms can obtain significant profits by producing “me too” drugs that treat conditions that are treated just as well by existing options.<sup>205</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>206</sup> so more money spent pursuing low

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199. Paul Grootendorst, *How Should We Support Pharmaceutical Innovation?*, 9 EXPERT REV. PHARMACOECON. OUTCOMES RSCH. 313, 315–16 (2009).

200. 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, 148 (2012). The FDA spends about \$2 billion of its annual budget on human drugs. U.S. FOOD & DRUG ADMIN., JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 73 (2020).

201. Clarisa Long, *Information Costs in Patent and Copyright*, 90 VA. L. REV. 465, 469 (2004).

202. Buccafusco et al., *supra* note 39, at 19.

203. *Id.*

204. Masur, *supra* note 47, at 687.

205. Stephane Régnier, *What Is the Value of ‘Me-Too’ Drugs?*, 16 HEALTH CARE MGMT. SCI. 300, 312 (2013); Wineinger, Zhang & Topol, *supra* note 77, at 7.

206. 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).

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>207</sup> Pharmaceutical companies determine the price of 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>208</sup> Additionally, the entry of more branded competitors into the market seems to result in slowed price increases over time.<sup>209</sup> However, Nathan Wineinger and colleagues’ recent analysis of trends in drug prices between 2012 and 2017 indicates that price increases are nearly universal, and branded drugs and their “me too” variants tend to have matching cost increases.<sup>210</sup>

Even if the introduction of a “me too” drug reduced the price of the drug, it might not increase the number of consumers who are able to access the drug. For instance, generic competition will typically reduce the price of a drug. But 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, likely because consumers were already able to afford the drug through insurance.<sup>211</sup> And although “me too” drugs may not meaningfully increase access to blockbuster drugs, they do, nonetheless, take market share.<sup>212</sup> This means that the competition created by “me too” drugs may fail to benefit consumers through greater access while simultaneously reducing returns to the pioneer drugs that made significant innovations.<sup>213</sup>

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207. Hollis, *supra* note 44, at 5 (“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 & Topol, *supra* note 77, at 7 (“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.”).

208. Régnier, *supra* note 205, at 307–08; Joseph A. DiMasi & Cherie Paquette, *The Economics of Follow-on Drug Research and Development*, 22 PHARMACOECON. supp. 2, 1 (2004).

209. 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.”).

210. Wineinger, Zhang & Topol, *supra* note 77, at 6.

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

212. Régnier, *supra* note 205, 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.”).

213. Hollis, *supra* note 44, 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.”).

### 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 considerable amounts of money and drugs that will significantly improve welfare. In this Part, we propose a linked pair 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>214</sup>

#### A. *Extending Patents for Beneficial Pharmaceuticals*

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>215</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>216</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. 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>217</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 is

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214. Gagne & Choudhry, *supra* note 86, at 711 (describing the relative uselessness of “me too” drugs).

215. Cf. Rena Goldman, *Cholesterol Count: 4 Natural Statins*, HEALTHLINE (Apr. 30, 2019), <https://www.healthline.com/health/high-cholesterol/natural-statins> [https://perma.cc/KCD5-QJ5K] (describing the many statins available to treat high cholesterol).

216. Beverly Wright, *Living and Dying in Louisiana’s “Cancer Alley,”* in THE QUEST FOR ENVIRONMENTAL JUSTICE: HUMAN RIGHTS AND THE POLITICS OF POLLUTION 87, 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).

217. Robert Capettini, David A. Dittman & Richard C. Morey, *Reimbursement Rate Setting for Medicaid Prescription Drugs Based on Relative Efficiencies*, 4 J. ACCT. & PUB. POL’Y 83, 86–91 (1985).

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 significant welfare gains. Patents are valid for twenty years from the date on which an application is filed.<sup>218</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>219</sup> This means that the typical period of market exclusivity is only ten to fourteen years.<sup>220</sup>

Despite the relatively short patent term, the useful life of a pharmaceutical can extend for decades (or even centuries).<sup>221</sup> (Contrast this with technologies such as electronics, which are often obsolete after only a few years.<sup>222</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>223</sup> Extending the patent term would produce significant additional revenue. 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 inducement is necessary.<sup>224</sup> Rather, the point is that the possibility of obtaining these additional patent rewards should figure into the firm's decision about which drugs to pursue ex ante.<sup>225</sup> The potential for earning an extended patent term should place a thumb on the scale in favor of drugs that will meaningfully enhance welfare, thus increasing the number of such drugs that are produced and the rate at which firms undertake those projects.

In order for firms to be responsive to these enhanced incentives, they must (1) have some sense of the likely welfare gains from their drugs, and (2) take into account the possibility of enhanced patent terms. But there are

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218. 35 U.S.C. § 154.

219. ROBIN J. STRONGIN, NAT'L HEALTH POL'Y F., HATCH-WAXMAN, GENERICS, AND PATENTS: BALANCING PRESCRIPTION DRUG INNOVATION, COMPETITION, AND AFFORDABILITY (2002).

220. Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 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).

221. John R. Allison, Mark A. Lemley, Kimberly A. Moore & R. Derek Trunkey, *Valuable Patents*, 92 GEO. L.J. 435, 452 (2004) (explaining that pharmaceutical drugs often have a valuable market life that extends for many years after patenting).

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

223. *Id.* at 455 (explaining the economics of the drug patent system).

224. Jonathan S. Masur & Adam K. 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).

225. *Id.* (explaining how ex post changes can affect ex ante incentives).

strong reasons to believe that firms will satisfy both of these conditions. There is extensive evidence that pharmaceutical firms do significant research ahead of time to determine the potential market and likely effects of their drugs.<sup>226</sup> This is especially true given that the majority of pharmaceutical R&D expenses derive from the need to conduct clinical trials to assess the safety and efficacy of the drugs. Firms cannot undertake a clinical trial without knowing the potential market for their drug—after all, those are the subjects of the clinical trial—and they are unlikely to expend such resources without a strong sense of what effect the drug will have on health and welfare, and thus how much market share it could capture. In addition, there is even better evidence that the availability of patents (and the patent term) affects pharmaceutical firms' decision-making.<sup>227</sup>

Our mechanism for creating incentives for firms to pursue welfare-enhancing drugs 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>228</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>229</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 considerable increase in overall welfare, one that only a few drugs achieve.<sup>230</sup> In the study by Chambers and colleagues that we described in the previous Part, only 14 of 102 drugs (13.7%) yielded

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226. See generally Masur & Mortara, *supra* note 224 (describing the extent to which firms take ex post effects into account ex ante).

227. Budish et al., *supra* note 27; Roin, *supra* note 220, at 545.

228. The idea of increasing or decreasing the patent term in accordance with the welfare benefit of a patented drug was developed independently from and roughly contemporaneously with two excellent papers by Neel U. Sukhatme and co-authors, though their papers were published before the writing of this one was completed. See Son Le & Neel U. Sukhatme, *Reaching for Mediocrity: Competition and Stagnation in Pharmaceutical Innovation*, 64 *Int'l Rev. L. & Econ.* 1 (2020); Sukhatme & Bloche, *supra* note 78. Le, Sukhatme, and Bloche deserve credit for being the first (that we know of) in writing to propose adjusting the patent term in accordance with a drug's welfare effects.

However, our paper expands considerably upon the idea proposed in those two papers and differs from them 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, a central issue that those papers do not address; we explain why policymakers should focus on a patent's aggregate welfare effects, while Sukhatme and Bloche seem to support per capita welfare effects; we advocate for the use of WBUs as the proper measure of welfare; and we describe in detail how a system of patent term extensions (and limitations) would function and address potential objections to it.

229. Roin, *supra* note 220, 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.

230. Chambers et al., *supra* note 172, at 230.

predicted welfare gains of at least 100,000 QALYS.<sup>231</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>232</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>233</sup> But until there is sufficient data to denominate drug effects in WBUs, we advocate using QALYs as a second-best option.<sup>234</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 effect requires a correct understanding of the treatment options that both preceded and followed it.<sup>235</sup>

We draw our inspiration for this mechanism in part from the Orphan Drug Act.<sup>236</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>237</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>238</sup> In theory, this

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231. *Id.*

232. *Id.*

233. *See supra* notes 143–144.

234. *See supra* Part II (explaining the reasons to prefer WBUs over QALYs).

235. *Infra* Part III.B.

236. Pub. L. No. 97-414 (1983).

237. *See generally* 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).

238. 21 U.S.C. § 360cc(a).

additional seven years of market exclusivity will provide the necessary incentive to develop the drug in the first place.<sup>239</sup>

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. 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>240</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>241</sup> There are many widespread disease and conditions that predominantly afflict poorer people who cannot pay large sums of money for expensive medications.<sup>242</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 used in at least some cases to extend the patent term of already-profitable drugs that have only relatively small effects on welfare.<sup>243</sup> Needless to say, this is not how a sensible law would be structured.<sup>244</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, generic manufacturers, the government, or nongovernmental organizations—should be permitted to intervene in the proceeding in opposition to the patent owner's claim and present evidence

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239. Rohde, *supra* note 237, at 129–30 (explaining the incentives the Orphan Drug Act was designed to create).

240. *Id.* at 130.

241. *See supra* Part II.

242. *See, e.g.*, TRACY KIDDER, MOUNTAINS BEYOND MOUNTAINS 126–27 (2004) (discussing the prominence of TB and HIV in Haiti and other poor nations).

243. Jacquie Lee, *Rare Disease Drugs Turning Huge Profits Catch Congress' Eye*, BLOOMBERG LAW (Jan. 28, 2020, 4:41 AM), <https://news.bloomberglaw.com/pharma-and-life-sciences/rare-disease-drugs-turning-huge-profits-catch-congress-eye> [<https://perma.cc/E5CN-PVV5>]; Kao-Ping Chua & Rena M. Conti, *Policy Implications of the Orphan Drug Designation for Remdesivir to Treat COVID-19*, 180 JAMA INTERNAL MED. 1273, 1274 (2020) (explaining how FDA granted a seven-year extension to Sublocade, a drug with \$285 million in sales between 2002 and 2011).

244. We take up this issue further in Part IV.

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>245</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>246</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 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>247</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 eighteen months.<sup>248</sup> Inter Partes Review cases that are appealed to the Federal Circuit usually take approximately fifteen additional months to resolve.<sup>249</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>250</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

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245. 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.

246. 35 U.S.C. § 141.

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

248. Ryan Kenny, *Which Invalidity Avenue to Take: Inter Partes Review Verses Post-Grant Review*, IP WATCHDOG (July 31, 2018), <https://www.ipwatchdog.com/2018/07/31/which-invalidity-avenue-ipr-verses-post-grant-review/id=99460> [<https://perma.cc/EDJ2-UDUD>]. 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, 1731 (2016).

249. Kerry Taylor, Daniel Kamkar & Joel Broussard, *IPR Appeals in 2017: The Pendency and Success Rates*, LAW360 (Jan. 16, 2018, 1:39 PM), <https://www.law360.com/articles/1000442/ipr-appeal-s-in-2017-the-pendency-and-success-rates>.

250. Zachary Brennan, *GDUFA II: FDA Looks to Speed Up Generic Drug Approval Process*, REGUL. FOCUS (Sept. 26, 2016), <https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2016/9/gdufa-ii-fda-looks-to-speed-up-generic-drug-approval-process>.

counter-factual 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 1,000 people annually. Firm A introduces a drug to treat this disease. Of the 1,000 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 ten years when its patent reaches the sixteen-year mark, meaning that it saves the lives of 3,000 people. On average, the people whose lives are saved by the drug go on to live an additional forty years at an average HRQoL (health-related quality of life per year) 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:

$$W = n \times L \times H$$

in which  $W$  is the total welfare benefit (QALYs),  $n$  is the number of people who benefit from having taken the drug,  $L$  is the number of extra years of life preserved, and  $H$  is the welfare benefit per year of life (in HRQoL, or QALYs per year per person). Plugging in our values:

$$W = 3,000 \text{ people} \times 40 \text{ years per person} \times 0.7 \text{ HRQoL}$$

$$W = 84,000 \text{ QALYs}$$

We would perform the same calculation for a drug that improves lives, rather than saving them, simply by looking at the same variables in a different way. 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 per year 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 3,000 people). The overall welfare benefit of the drug is given by same equation:

$$W = n \times L \times H$$

in which  $W$  is still the total welfare benefit and  $n$  is still the number of people who benefit from having taken the drug, but  $L$  is the number of years the disease would have persisted and  $H$  is the welfare loss avoided per person per year. Plugging in our values:

$$W = 3,000 \text{ people} \times 5 \text{ years per person} \times 0.25 \text{ HRQoL}$$

$$W = 3,750 \text{ QALYs}$$

These equations are aimed at determining the same quantity: the difference in QALYs earned per year between a person taking and not taking the drug. That is, the total welfare benefit is more precisely given by the following final equation:

$$W = n \times L \times (H_1 - H_2)$$

in which  $W$  is still the total welfare benefit (QALYs) and  $n$  is still the number of people who benefit from having taken the drug, but  $L$  is the amount of years affected by taking the drug,  $H_1$  is the QALYs earned per person per year by those who took the drug, and  $H_2$  is the QALYs earned per person per year had they not taken the drug. In other words,  $(H_1 - H_2)$  is the well-being improvement to each person whose life is improved by the drug—note that it is possible that someone might take the drug but not improve. Plugging in our values:

$$\text{Example 1: } W = 3,000 \times 40 \times (0.7 - 0.0) = 84,000 \text{ QALYs}$$

$$\text{Example 2: } W = 3,000 \times 5 \times (0.7 - 0.45) = 3,750 \text{ QALYs}$$

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>251</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>252</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>253</sup> In the typical “me too” drug scenario, a first drug is developed 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>254</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

251. Hollis, *supra* note 44, at 5.

252. *Id.*

253. Gagne & Choudhry, *supra* note 86, at 711.

254. Hollis, *supra* note 44, at 5; Gagne & Choudhry, *supra* note 86, at 711.

for their various drugs; duopoly pricing is typically lower than monopoly pricing,<sup>255</sup> although as we showed in Part II, the evidence of this effect on drug consumption is mixed.<sup>256</sup> Nonetheless, competition could have the salutary effect of increasing the number of people who are able to afford one of the two drugs.<sup>257</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>258</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 series of equations:

Starting with Equation 1:

$$\begin{aligned} \text{Total welfare gain from Drug 2} &= \text{marginal welfare gain from patients} \\ &\quad \text{who switched from Drug 1 to Drug 2} \\ &\quad + \text{total welfare gain from new Drug 2 patients} \\ &\quad + \text{total welfare gain from new Drug 1 Patients} \end{aligned}$$

or

$$W = (W_{\text{Marginal}}) + (W_{\text{Drug 2 new}}) + (W_{\text{Drug 1 new}})$$

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255. 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).

256. See *supra* notes 207–213 and accompanying text.

257. Gagne & Choudhry, *supra* note 86, at 711.

258. 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., *supra* note 172, 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.

where  $W$  is total welfare gain from introducing Drug 2 to the market,  $W_{Marginal}$  is the total marginal welfare gain from patients who switched from Drug 1 to Drug 2, and  $W_{Drug\ 1\ new}$  and  $W_{Drug\ 2\ new}$  are the total welfare gains from new patients—“new” meaning patients not previously taking Drug 1 prior to the introduction of Drug 2—taking Drugs 1 and 2.

Expanding these terms yields Equation 2:

$$\begin{aligned} W &= [(welfare\ gain\ from\ Drug\ 2\ per\ person \\ &\quad -\ welfare\ gain\ from\ Drug\ 1\ per\ person) \\ &\quad \times\ number\ of\ patients\ who\ switched\ from\ Drug\ 1\ to\ Drug\ 2] \\ &\quad +\ (Drug\ 2\ welfare\ gain\ per\ patient\ \times\ number\ of\ new\ Drug\ 2\ patients) \\ &\quad +\ (Drug\ 1\ welfare\ gain\ per\ patient\ \times\ number\ of\ new\ Drug\ 1\ patients) \end{aligned}$$

or

$$\begin{aligned} W &= [(H_{Drug\ 2} - H_{Drug\ 1}) \times n_{switch}] + (H_{Drug\ 2} \times n_{Drug\ 2\ new}) \\ &\quad + (H_{Drug\ 1} \times n_{Drug\ 1\ new}) \end{aligned}$$

where  $H_{Drug\ 1}$  and  $H_{Drug\ 2}$  are the welfare gains per patient taking Drugs 1 and 2,  $n_{Drug\ 1\ new}$  and  $n_{Drug\ 2\ new}$  are the number of new patients taking Drugs 1 and 2, and  $n_{switch}$  is the number of patients who switched from Drug 1 to Drug 2.

Regrouping these terms yields Equation 3:

$$\begin{aligned} W &= (welfare\ gain\ for\ each\ Drug\ 2\ patient\ \times\ number\ of\ Drug\ 2\ patients) \\ &\quad -\ [Drug\ 1\ welfare\ gain\ per\ patient \\ &\quad \times\ (number\ of\ Drug\ 1\ patients\ before\ Drug\ 2\ is\ introduced \\ &\quad -\ number\ of\ Drug\ 1\ patients\ after\ Drug\ 2\ is\ introduced)] \end{aligned}$$

or

$$W = (H_{Drug\ 2} \times n_{Drug\ 2}) - [H_{Drug\ 1}(n_{Drug\ 1\ before\ Drug\ 2} - n_{Drug\ 1})]$$

where  $n_{Drug\ 1}$  and  $n_{Drug\ 2}$  are the number of patients taking Drugs 1 and 2 after Drug 2 was introduced, and  $n_{Drug\ 1\ before\ Drug\ 2}$  is the number of patients who were taking Drug 1 prior to the introduction of Drug 2.

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. Suppose that a disease afflicts 1,000 people and causes them to lose 0.3 QALYs annually. Drug 1 is introduced, 500 people begin taking Drug 1, and each of those people sees an increase in their welfare of 0.2 QALYs each year. Subsequently, Drug 2 is introduced. Drug 2 improves the welfare of someone afflicted with Disease by 0.3 QALYs, which is slightly better than Drug 1. 300 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 120 QALYs in yearly welfare gains and Drug 1 is producing 50 QALYs in welfare gains for a total of 170 QALYs in yearly welfare gains. However, the welfare gain attributable to Drug 2 is only:

$$W = (H_{Drug\ 2} \times n_{Drug\ 2}) - [H_{Drug\ 1}(n_{Drug\ 1\ before\ Drug\ 2} - n_{Drug\ 1})]$$

$$W = (0.3\ \text{QALYs per person} \times 400\ \text{people}) \\ - [0.2\ \text{QALYs per person} (500\ \text{people} - 250\ \text{people})]$$

$$\text{Drug 2 total welfare gain} = 120\ \text{QALYs} - 50\ \text{QALYs} = 70\ \text{QALYs}$$

Or, put another way, Drug 2 gets credit for 0.1 QALYs for each of the 300 people who switched over (30 QALYs total), plus 0.3 QALYs for each of the 100 new people who started taking Drug 2 (30 QALYs), plus 0.2 QALYs for each of the 50 new people who started taking Drug 1 because of the introduction of Drug 2 (10 QALYs) for a total of 70 QALYs. Drug 1 is credited with the remaining 170 QALYs – 70 QALYs = 100 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 significant 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 overall welfare gains. Accordingly, Drug 1 would receive 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, and thus exploiting the market structure of pharmaceutical drugs, is precisely the sort of behavior 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 these mechanisms 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 of a counterfactual world in which 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>259</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 intervene to present evidence of 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 sufficiently in advance of the end of the effective patent term.

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

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259. Chambers et al., *supra* note 165, at 1755.

utility requirement.<sup>260</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>261</sup> It weeds out inventions for which there is no known use, but little more than that.<sup>262</sup> But there is no reason that it should be so limited, and as we have explained there are good reasons to eliminate and discourage patents that make no meaningful welfare contribution.<sup>263</sup> 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 change 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>264</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>265</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>266</sup> A mechanism to disincentivize the creation of these types of drugs must therefore rely on other policy levers.<sup>267</sup>

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260. 35 U.S.C. § 101.

261. Risch, *supra* note 52, at 1200–06; Robin Feldman, *The Cancer Curse: Regulatory Failure by Success*, 21 COLUM. SCI. & TECH. L. REV. 1 (2019).

262. *See supra* Part I.

263. *See supra* notes 37–40 (discussing the administrative, search, and design-around costs of useless patents).

264. Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983); Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

265. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 33, Apr. 15, 1994 (“The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”).

266. *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).

267. 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

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. 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>268</sup> or the Orphan Drug Act.<sup>269</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>270</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>271</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>272</sup> And as scholars have shown, pharmaceutical companies may be manipulating the law to receive added protection for blockbuster high-profit drugs.<sup>273</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>274</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

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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. Kapeczynski & Syed, *supra* note 5, at 1927. This may reduce the rate at which competitors decide to challenge existing patents as futile, because 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.

268. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (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.

269. Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983).

270. 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, 65 (2018).

271. See *supra* Part II.B.

272. See Michael Abramowicz, *Orphan Business Models: Toward a New Form of Intellectual Property*, 124 HARV. L. REV. 1362, 1384–85 (2011).

273. Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 726 n.39 (2005) (citing Taxol and AZT as blockbuster drugs approved under the Orphan Drug Act).

274. 35 U.S.C. § 282.

convincing evidence” standard.<sup>275</sup> The PTO could waive the Inter Partes Review filing fee, which currently stands at \$15,500, for challenges to futility patents.<sup>276</sup> This would make it less expensive for any third party to challenge the patent before the PTO 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>277</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>278</sup> Congress could also eliminate the possibility of receiving treble damages for willful infringement in a suit based on such a patent,<sup>279</sup> or Congress could even eliminate the possibility of asking for reasonable royalty damages and force the patent-owner to prove that it has lost profits.<sup>280</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>281</sup>

We envision the Futility Patent process resembling the process of Inter Partes Review (and the process for adjudicating patent term extensions). Any interested party could pay a fee, initiate a Futility Patent proceeding, and attempt to prove that a patented invention is generating few or zero welfare gains. The list of potential filers includes competitors or generic manufacturers who seek to weaken a competitor’s patent; insurance companies, who would benefit from seeing a drug patent expire sooner (leading to price reductions); public-interest organizations with an interest

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275. *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91 (2011) (setting forth the “clear and convincing” standard).

276. 37 C.F.R. § 42.15(a).

277. 35 U.S.C. § 285; *Octane Fitness, L.L.C. v. ICON Health & Fitness, Inc.*, 572 U.S. 545 (2014).

278. See Anup Malani & Jonathan S. Masur, *Raising the Stakes in Patent Cases*, 101 GEO. L.J. 637 (2013) (describing how loser-pays systems can deter weaker patent cases by raising the costs to the losing party that asserts a weak patent).

279. 35 U.S.C. § 284.

280. *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).

281. 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 and 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.

in cheaper drug prices for consumers;<sup>282</sup> or even the government, if it believes that a firm is creating social waste via its patents. The party that initiates a Futility Patent proceeding is creating a public good by reducing the patent term in a way that will redound to the benefit of many people. So it is important not to dissuade potential filers. On the other hand, it is also important to avoid nuisance filings meant only to harass the patent owner. Accordingly, we envision requiring a significant filing fee on the order of \$50,000, similar to the fee that accompanies the filing of an Inter Partes Review. But the fee could be refundable (or payable by the patent holder) in the event the challenger prevails.

In addition, challengers could receive a type of bounty akin to the mechanism in the Hatch-Waxman Act—whether in the form of a cash payment or a period of regulatory exclusivity—if they prevail.<sup>283</sup> And if necessary to deter frivolous suits, challengers could be forced to pay patent owner's costs in the event that the patent is not adjudged futile.<sup>284</sup> It is beyond the scope of this paper to fill in every last detail of how Futility Patent challenges would operate.<sup>285</sup> The point is that such a system would be effective and workable, particularly given the extent to which it resembles existing patent processes.

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 (“The Coalition”)<sup>286</sup> observes the limited effect of Drug B and initiates a “futility” proceeding against it before the PTO. The Coalition, 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

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282. One of the most famous Supreme Court patent cases of recent vintage was filed by a public interest organization seeking to invalidate DNA patents. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

283. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

284. These types of loser-pays agreements are useful at providing incentives to bring meritorious lawsuits and not to bring non-meritorious lawsuits. *See Malani & Masur, supra* note 278 (describing how loser-pays systems can deter weaker patent cases by raising the costs to the losing party that asserts a weak patent); Neel U. Sukhatme, “*Loser Pays*” in *Patent Examination*, 54 Hous. L. Rev. 165 (2016).

285. The PTO could flesh out such details through rulemaking, as it did with Inter Partes Review. Masur, *supra* note 248.

286. *See generally* COALITION FOR AFFORDABLE PRESCRIPTION DRUGS, <https://www.affordableprescriptiondrugs.org/> [<https://perma.cc/7EQM-2MZ5>].

the Hatch-Waxman Act<sup>287</sup> or the Orphan Drug Act.<sup>288</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 attorneys' fees stemming from the litigation.<sup>289</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, for 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>290</sup> reductions in the value of the last five years of the patent term should markedly 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>291</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

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287. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. Law 98-417, 98 Stat. 1585 (1984).

288. Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983).

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

290. Grabowski & Vernon, *supra* note 220, at 103–05 (finding that the effective exclusivity period for pharmaceutical drugs is less than 20 years, and more like 10–15 years in most cases).

291. 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 199, at 316–17; Xue & Oullette, *supra* note 95; Sukhatme & Bloche, *supra* note 16, at 976.

proposal harnesses the power of markets to help discipline pharmaceutical companies.

In a number of European countries, governmental bodies engage in health technology assessments (HTA) that evaluate the cost effectiveness of treatment options and make recommendations about whether they should be paid for by national health systems.<sup>292</sup> These offices consider the estimated number of QALYs that a treatment will create relative to the treatment's cost.<sup>293</sup> Only if the treatment meets a certain threshold (e.g., no more than €50,000/QALY) will it be approved for payment. We believe that the United States should also adopt an office of health technology assessment to provide valuable data to patients, physicians, insurers, and drug companies about treatment options. But our proposal would still be valuable even with such an agency. First, European HTA agencies tend to ignore aggregate welfare in favor of welfare per person. That might be a reasonable choice for an insurer to make *ex post* between two existing treatment options, but, as we explained above, it does not adequately align incentives *ex ante*.<sup>294</sup> Because the patent system's principal goal is to maximize social welfare, it should be encouraging the production of drugs that generate the greatest net effects.<sup>295</sup>

Second, by restricting access to the market for some treatments, HTA offices may 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>296</sup> Rather than having the FDA or an HTA 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 the drug 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 considerable improvement in treatment outcomes relative to the status quo but is quickly

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292. Sorenson & Chalkidou, *supra* note 114, at 29–30 (describing the scope of health technology assessment offices across Europe).

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

294. When insurers decide whether to approve a drug for treatment of a condition, the question they face is largely one of per-person value. Given a certain number of people with a disease, what is the most cost effective way of treating it? But the patent system addresses a different question. How can the law establish incentives that encourage private actors to address diseases where there are the biggest potential gains to human welfare?

295. *See supra* notes 26–35.

296. 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.

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>297</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>298</sup> or to stave off challenges and penalties.<sup>299</sup>

Finally, our proposal gives the manufacturer additional incentives to obtain FDA approval for new uses of existing therapies.<sup>300</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>301</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 syndrome.<sup>302</sup> While some off-label uses are supported by scientific data, most lack evidence of therapeutic value.<sup>303</sup> The FDA does not have the authority to prevent this practice, and manufacturers may secretly encourage off-label uses of their drugs.<sup>304</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>305</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

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

298. See *supra* Part III.A.

299. See *supra* Part III.C.

300. Eisenberg, *supra* note 273, at 717.

301. Dominique Levêque, *Off-Label Use of Anticancer Drugs*, 9 LANCET ONCOLOGY 1102 (2008).

302. Timothy O’Shea, *10 Surprising Off-Label Uses for Prescription Medications*, PHARMACY TIMES (Jan. 5, 2016, 9:01 AM), <https://www.pharmacytimes.com/contributor/timothy-o-shea/2016/01/10-surprising-off-label-uses-for-prescription-medications> [<https://perma.cc/2HYZ-X2Q4>].

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

304. Eisenberg, *New Uses*, *supra* note 273, at 733.

305. *Id.* at 725.

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.

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We have outlined a new system for properly calibrating patent law's incentives to a drug's therapeutic value. The owners of patents on drugs that greatly improved human welfare would have the capacity to apply for patent term extensions of up to five years, as an additional reward for the drug's beneficial impact. Conversely, drugs that have minimal or negative impacts on welfare could be challenged in "futility" proceedings, where the power of their patents could be reduced. In combination, the possibility of carrots for patents with large effects on welfare and sticks for patents with small effects should orient pharmaceutical firms' R&D priorities toward the drugs that will produce the greatest welfare effects—precisely what would be best for society, and what the patent system is intended to accomplish. 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. 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.

#### 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 some scholars will be concerned that our proposal would lead to additional rewards for drugs that are already successful on the market—drugs for which no additional reward is necessary.<sup>306</sup> In some cases, this is indeed 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, then the drug will be both commercially successful and will qualify for a patent term extension under our framework.

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306. Richard Posner, *Pharmaceutical Patents*, THE BECKER-POSNER BLOG (Dec. 12, 2004), <https://www.becker-posner-blog.com/2004/12/pharmaceutical-patents--posner.html> [<https://perma.cc/GY8K-FYXW>] (“The entire patent prize goes to the firm that crosses the finish line first, and so a firm might spend a huge 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. & BIOSCIS. 590 (2018).

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>307</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>308</sup> instead of a slightly less profitable drug that would target a broader number of less wealthy individuals but produce greater welfare gains.<sup>309</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>310</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 Orphan Drug Act, which can lead to term extensions even for drugs with incredibly high prices that help relatively few people.<sup>311</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

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307. *Id.* at 596–97.

308. See Sarah Jane Tribble & Sydney Lupkin, *Drugs for Rare Diseases Have Become Uncommonly Rich Monopolies*, NPR (Jan. 17, 2017, 4:59 AM), <https://www.npr.org/sections/health-shots/2017/01/17/509506836/drugs-for-rare-diseases-have-become-uncommonly-rich-monopolies> [<https://perma.cc/G4HB-UUTB>]; see also Koichi Mikami, *Orphans in the Market: The History of Orphan Drug Policy*, 32 SOC. HIST. MED. 609, 628 (2017).

309. See, e.g., Zulfiqar A. Bhutta, Johannes Sommerfeld, Zohra S. Lassi, Rehana A. Salam & Jai K. Das, *Global Burden, Distribution, and Interventions for Infectious Diseases of Poverty*, 3 INFECTIOUS DISEASES POVERTY 21 (2014).

310. See *supra* Part III.D.

311. Jacquie Lee, *Rare Disease Drugs Turning Huge Profits Catch Congress' Eye*, BLOOMBERG L. (Jan. 28, 2020, 5:41 AM), <https://news.bloomberglaw.com/pharma-and-life-sciences/rare-disease-drugs-turning-huge-profits-catch-congress-eye> [<https://perma.cc/C74Z-MCNE>].

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>312</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>313</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>314</sup> The concern is that extending a welfare-enhancing drug's patent term by five years may lead to foregone welfare—through the individuals who cannot

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312. See, e.g., Eric A. Posner & Cass R. Sunstein, *Moral Commitments in Cost-Benefit Analysis*, 103 VA. L. REV. 1809, 1812 (2017).

313. See *supra* notes 31–35.

314. See *supra* notes 36–48.

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>315</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>316</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>317</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>318</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

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315. Budish, Roin & Williams, *supra* note 27, at 5.

316. *Id.* at 8.

317. *Id.*

318. *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*, KFF (Mar. 1, 2019), <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/> [<https://perma.cc/9YWS-42J5>].

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 access during the first eighteen 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, Age, and Disability*

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>319</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>320</sup> We should want firms to invest additional resources in drugs and treatments

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319. See, e.g., Joseph E. Aldy & W. Kip Viscusi, *Age Differences in the Value of Statistical Life: Revealed Preference Evidence*, 1 REV. ENV'T ECON. & POL'Y 241 (2007).

320. John Bronsteen, Christopher Buccafusco & Jonathan S. Masur, *Welfare as Happiness*, 98 GEO. L.J. 1583 (2010).

that will save the young, 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.

Separately, some people object to the use of QALYs in healthcare decision-making, because, in certain circumstances, it could create biases against people with disabilities.<sup>321</sup> One possible source of bias is that QALYs, because they are largely based on the judgments of nondisabled people, do a poor job of estimating HRQoL for people with disabilities. Yet while this is potentially a problem for QALYs generally, it should not pose a concern in the context of our proposal. First, consider drugs that improve the quality of one's life. In calculating the welfare effect of this type of drug, the individual's baseline is irrelevant. All that matters is how much the drug improves one's quality of life above that baseline. If QALYs are underestimating the baseline for people with disabilities, this should not affect the calculation of the drug's contribution to welfare.<sup>322</sup>

A second, related objection to the use of QALYs and other attempts to quantify health is more forceful, but it simply does not apply to our proposal. Consider, for example, a policymaker or insurer who could only save the lives of one hundred people, and who had to choose between saving the lives of either one hundred nondisabled people or one hundred people with disabilities who would (according to the argument) have shorter life expectancies at lower HRQoL. If she tried solely to maximize net QALYs, she might choose to save the lives of the nondisabled people, again because of the fact that QALYs do a poor job of estimating the quality of life of disabled people.<sup>323</sup> This could be wrongful and discriminatory.

But pharmaceutical companies are very rarely faced with decisions such as this one. They are rarely forced to decide whether to pursue research on a drug that would save the lives of some number of people with disabilities versus another drug that would save the lives of nondisabled people. Few such drugs exist. Instead, they are deciding between drugs that treat different conditions and that, in theory at least, improve the lives of

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321. For discussions of these issues, see Peter A. Ubel, Jeff Richardson & Jose-Luis Pinto Prades, *Life-Saving Treatments and Disabilities: Are All QALYs Created Equal?*, 15 INT'L J. TECH. ASSESSMENT HEALTH CARE 738 (1999); Govind Persad, *Considering Quality of Life While Repudiating Disability Injustice: A Pathways Approach to Setting Priorities*, 47 J.L. MED. & ETHICS 294 (2019).

322. In fact, if the drug improves some aspect of life that is related to the individual's disability, QALY-based measures could actually overstate the value of the drug if they underestimate the baseline quality of life of individuals with disabilities.

323. Paul Menzel, *How Should What Economists Call "Social Values" Be Measured?*, 3 J. Ethics 249, 256 (1999).

everyone being treated. If, under our proposal, drug companies are increasingly motivated to search for research opportunities that will generate the most net welfare, they will tend to pursue pharmaceuticals that improve the lives of people whose ailments limit their survival or depress their quality of life—including people with disabilities. Thus, to the extent that people with disabilities start with lower baselines in terms of longevity or HRQoL, we expect that drug companies will find it more efficient to show significant therapeutic improvements by treating those communities than they will by addressing issues of otherwise healthy communities.<sup>324</sup>

In any event, we agree that QALYs are flawed,<sup>325</sup> and this is one of the principal reasons that we favor adopting WBUs over QALYs to measure patient welfare.<sup>326</sup> At the same time, we are confident that using QALYs to estimate patient value is far superior to the current alternative: the United States' deeply imperfect market for healthcare.<sup>327</sup> All told, our proposal would be an improvement upon the status quo for people with disabilities.

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

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>328</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>329</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

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324. People with disabilities generally have lower wealth than nondisabled people, so they may also have diminished ability to pay for improved health technology that is not covered by their insurance. See Buccafusco, *supra* note 80. Again, interventions that decouple research incentives from wealth and that connect them to therapeutic value are likely to assist people with disabilities.

325. This is why we have argued elsewhere that net social welfare is not the only desideratum that policymakers should care about. Bronsteen et al., *supra* note 320, at 1588–1600.

326. See discussion *supra* Part II.A.

327. See *supra* notes 156–157 and accompanying text.

328. Michael Kremer, *Creating Markets for New Vaccines, Part I: Rationale* (Nat'l Bureau of Econ. Rsch., Working Paper No. 7716, 2000).

329. ERNST R. BERNDT, RENA N. DENONCOURT & ANJLI C. WARNER, U.S. MARKETS FOR VACCINES: CHARACTERISTICS, CASE STUDIES, AND CONTROVERSIES 24–25 (2009); see also Xue & Oullette, *supra* note 95, at 22–23.

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.<sup>330</sup> For example, five million people die each year from tuberculosis, and many more are made very sick from the disease.<sup>331</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>332</sup> Researchers have compiled estimates of the QALY benefits that accrue from a number of vaccines, including for HPV,<sup>333</sup> Lyme disease,<sup>334</sup> and rotavirus,<sup>335</sup> among others.<sup>336</sup> It will also be possible to estimate the effects of vaccines for COVID-19 based on the number of lives saved and suffering averted.<sup>337</sup> These numbers could be used for determining the relative welfare benefits of patented vaccines.<sup>338</sup>

Importantly, our proposal would help moderate the distortion that the market for pharmaceuticals creates in favor of treatments over cures. As we noted above, pharmaceutical companies may find selling regular treatments to be more lucrative than selling cures, and they will tend to invest in the

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330. Although some estimates will be better than others. See Isaac Chotiner, *The Contrarian Coronavirus Theory that Informed the Trump Administration*, NEW YORKER (Mar. 30, 2020), <https://www.newyorker.com/news/q-and-a/the-contrarian-coronavirus-theory-that-informed-the-trump-administration> [<https://perma.cc/5S2F-QL4M>].

331. Kremer, *supra* note 328, at 36.

332. 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.”) (emphasis omitted).

333. Sarah C. Woodhall, Mark Jit, Chun Cai, Tina Ramsey, Sadique Zia, Simon Crouch, Yvonne Birks, Robert Newton, W. John Edmunds & Charles J. N. Lacey, *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).

334. Nancy A. Shadick, Matthew H. Liang, Charlotte B. Phillips, Karin Fossel & Karen M. Kuntz, *The Cost-Effectiveness of Vaccination Against Lyme Disease*, 161 ARCHIVES INTERNAL MED. 554 (2001).

335. Baudouin Standaert, Nathalie Perez, Bertrand Tehard, Xavier Colin & Bruno Detourmay, *Cost-Effectiveness Analysis of Vaccination Against Rotavirus with RIX4414 in France*, 6 APPLIED HEALTH ECON. & HEALTH POL’Y 199 (2008).

336. 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).

337. Of course, earlier introduction of a vaccine for COVID-19 generates substantially more benefit than just lives saved, because it speeds the rate at which society can return to normal and people can return to work. While enormous, we do not anticipate estimating these welfare gains for use in our patent analysis, largely because they will be supernumerary.

338. See Berndt et al., *supra* note 329, at 32–34; Paul Fine, Ken Eames & David L. Heymann, “Herd Immunity”: *A Rough Guide*, 52 CLINICAL INFECTIOUS DISEASES 911, 915 (2011) (describing the dynamics of herd immunity).

former at the expense of the latter.<sup>339</sup> Under the current system, firms cannot internalize the benefits of vaccines that extend to people who do not receive the vaccine but who are helped through herd immunity or eradication. But our proposal would allow patentees to include those benefits in their estimates. The possibility of reaping monopoly prices over an extended patent term could help reduce the market distortion favoring repeated-use treatments.

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>340</sup> No two treatments (for two different individuals) are identical.<sup>341</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>342</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>343</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

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339. See *supra* notes 95–97 and accompanying text.

340. Margaret A. Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 *NEW ENGLAND J. MEDICINE* 301, 302 (2010) (explaining and describing personalized medicine).

341. M. Whirl-Carrillo, E.M. McDonagh, J.M. Hebert, L. Gong, K. Sangkuhl, C.F. Thorn, R.B. Altman & T.E. Klein, *Pharmacogenomics Knowledge for Personalized Medicine*, 92 *CLINICAL PHARMACOLOGY & THERAPEUTICS* 414, 415–16 (2012) (describing the ways in which different treatments can vary among individuals).

342. 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 (2012) (describing the ways in which patents interact with personalized medicine).

343. We say “all else equal” because we would want to consider the relative R&D costs of these two improvements as well as their benefits.

inventions.<sup>344</sup> Our approach will be no less straightforward or easily applied than what the courts have 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.

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344. Burk & Lemley, *supra* note 45, at 1578.