ARTICLES

ORPHAN BUSINESS MODELS: TOWARD A NEW FORM OF INTELLECTUAL PROPERTY

Michael Abramowicz

CONTENTS

ORPHAN BUSINESS MODELS: TOWARD A NEW FORM OF INTELLECTUAL PROPERTY

Michael Abramowicz[*]

Drug companies will often have insufficient incentives to undertake clinical testing on drugs ineligible for patent protection. The Orphan Drug Act combats this problem by providing a limited term of exclusivity to companies willing to shepherd a drug through FDA approval. This strategy is a form of intellectual property protection that might be applicable in many contexts beyond drugs, but the literature has not previously addressed the design and potential scope of such protection. Sometimes, no company will pursue a risky business model even when experimentation with that business model would increase expected social welfare, because other companies would free ride on information from the experiment. The Supreme Court's recent holding in Bilski v. Kappos *may provide a basis for incorporating such concerns into patent law, but targeted exclusivity rights for orphan business models may provide a better tailored solution. Such rights should be awarded to the company that agrees to the shortest exclusivity term, and a decentralized bonding mechanism can further reduce the risk of unnecessary protection. This Article identifies a number of contexts in which orphan business model protections might be desirable and also considers the possibility of using exclusive rights to foster legal experimentation.*

Harold Demsetz famously observed that property rights will tend to emerge when the value from recognizing them is sufficiently great to make their transaction costs bearable.[1] Demsetz's theory is descriptive,[2] but when the tradeoffs inherent in particular property rights are nearly in balance, normative debate about the desirability of those rights is likely to be lively.[3] The business method patents con-

* Professor of Law, George Washington University. I am grateful to Kenneth Rodriguez for exceptional research assistance and to the Kauffman Foundation for financial support. For helpful comments and discussion, I am grateful to Thomas Colby, John Duffy, and anonymous reviewers, as well as participants in the workshops at Georgetown University Law Center, George Washington University Law School, and the University of Pennsylvania Law School.

[1] Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347, 350 (1967) ("[P]roperty rights develop to internalize externalities when the gains of internalization become larger than the cost of internalization.").

[2] Brett Frischmann, *Spillovers Theory and Its Conceptual Boundaries*, 51 WM. & MARY L. REV. 801, 814 & n.54 (2009) (noting, however, that the theory is sometimes used to defend the creation of a particular property right).

[3] Demsetz notes that property rights could "be the result of a conscious endeavor to cope with new externality problems," but that they usually arise "as a result of gradual changes in social mores and in common law precedents." Demsetz, *supra* note 1, at 350. James Krier notes that parts of Demsetz's theory "can be reasonably taken to suggest that he was thinking about an evolutionary account based on intentional design," but that "[o]ther bits and pieces of Demsetz's argument point in the direction of an unintended-consequences (invisible-hand) type of account." James E. Krier, Essay, *Evolutionary Theory and the Origin of Property Rights*, 95 CORNELL L. REV. 139, 147 (2009). This Article serves both to describe gradual changes that have led to protection of orphan business methods and to consider consciously the possibility of redefining such protection.

troversy underlying the Supreme Court's decision in *Bilski v. Kappos*[4] might thus be seen as an epiphenomenon of the broader sweep of Demsetzian institutional evolution. The immediate policy question is whether the costs inherent in a regime of patents on business methods (including patents on business models)[5] outweigh the benefits.[6] Over the long run,[7] however, if Demsetz's core insight is correct, we should expect evolving legal institutions to find some means of protecting business methods at least in those cases where such protection is most critical and can be accomplished most cheaply.

The form of protection that ultimately emerges, however, might be quite different from patent protection for business methods as understood today. Perhaps the Patent and Trademark Office (PTO) and courts will develop more effective doctrines for avoiding issuing unnecessary patents — for example by toughening the nonobviousness test.[8] At least as importantly, the subject matter of business method protection — not necessarily business method *patent* protection — could change. Business method patents protect ideas for new business methods[9] because of the longstanding rule that inventions need not be reduced to practice[10] or commercialized[11] to be entitled to patent protection. Yet there is a strong argument, reflected in recent literature[12]

---

[4] 130 S. Ct. 3218 (2010).

[5] A usage note: A "business method" may be either a method of operation useful in some set of businesses (for example, a new accounting system) or a type of business (for example, an accounting firm that would be the first to use such a system). This Article uses the phrase "business model" to refer to the latter — informally, an idea that a prospective entrepreneur might pitch in a business plan. The focus here is on business models, though the line is often thin, and much of the analysis applies to business methods as well.

[6] *See, e.g.*, *Bilski*, 130 S. Ct. at 3255–57 (Stevens, J., concurring in the judgment).

[7] *See* Stuart Banner, *Transitions Between Property Regimes*, 31 J. LEGAL STUD. S359, S360 (2002) (noting that "[t]he Demsetz story is a happy one, because it implies that over the long run, property rights will be reallocated in the direction of efficiency," though the story "fails to specify the mechanism by which the transition actually occurs").

[8] For a recent proposal, see Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. (forthcoming 2011), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1694883.

[9] The word "idea" is not meant here to be equivalent to an "abstract idea." In *Bilski*, the Court unanimously held that the particular business method patent at issue was ineligible patentable subject matter because it constituted an abstract idea. *See Bilski*, 130 S. Ct. at 3229–31.

[10] *See* Jeanne C. Fromer, *The Layers of Obviousness in Patent Law*, 22 HARV. J.L. & TECH. 75, 78 (2008) ("Many areas of patent law elevate the inventive role of conception over that of actual reduction to practice, be it with regard to what must be accomplished to secure a patent, what must be contributed to an invention to be recognized as a joint inventor, or the on-sale bar." (footnotes omitted)).

[11] *See, e.g.*, Amy L. Landers, *Liquid Patents*, 84 DENV. U. L. REV. 199, 234 & n.246 (2006) ("[C]ourts have made clear that the strength and existence of the patent right is unaffected where the owner decides not to commercialize or license the invention." *Id.* at 234.).

[12] *See generally* Michael Abramowicz & John F. Duffy, *Intellectual Property for Market Experimentation*, 83 N.Y.U. L. REV. 337 (2008) (arguing that intellectual property law should, and to some extent does, encourage commercial experimentation even absent technological innovation);

as well as in more dated literature,[13] that what may be especially important for intellectual property to protect is not so much investments in developing ideas for new business methods but investments in commercializing and experimenting with untested business models.[14] However society ultimately incentivizes new ideas for business models, property rights may emerge to protect at least particularly important *orphan* business models, that is, business models previously conceived and disclosed that no one has had sufficient incentives to implement. Although patents could perhaps provide such property rights, it is also possible to imagine new forms of intellectual property targeting the orphan business model problem more directly.

As this Article will show, the process of Demsetzian emergence of property rights in orphan business models has already begun — and it has begun precisely where Demsetz would expect — for a technology whose financial and welfare stakes are so high that the benefits of in-

---

Oren Bar-Gill & Gideon Parchomovsky, Essay, *A Marketplace for Ideas?*, 84 TEX. L. REV. 395 (2005) (suggesting separating property rights for ideas from rights in downstream invention and commercialization); Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503 (2009) (focusing on the problem specifically in the context of drugs); Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341 (2010) (proposing "commercialization patents"). Professor Ted Sichelman is the only recent commentator to propose creating property rights for commercialization. Sichelman recognizes:

> Just as the Orphan Drug Act supplements the patent laws to stimulate commercialization of drugs for rare diseases, there are arguably a number of other areas for which this sort of stimulus is justified, including environmental technologies, mobility technologies for the disabled, medical devices to diagnose rare diseases, reading aids for the blind, and so forth.

Id. at 387. As this description suggests, however, Sichelman does not view orphan drugs as a subcategory of business methods. The proposal that he ultimately develops is for a form of protection that is far narrower than patent protection. *See id.* at 400 (excluding processes and thus all business methods from his proposal); *id.* at 401 ("[T]he claims *should be limited exactly to the product described in the specification*."); *id.* at 405 (explaining that the primary benefits of the commercialization patent would be defensive, providing "complete immunity from injunctive relief from suits for invention patent infringement" and limitations on damages); *id.* at 408 (providing a term of only "five to eight years"). This Article, in contrast, explores the possibility of relatively broad protection, even if only for narrow classes of inventions (such as orphan drugs).

[13] *See* DIRECT PROTECTION OF INNOVATION 2–3 (William Kingston ed., 1987); William Kingston, *Innovation Patents and Warrants*, *in* PATENTS IN PERSPECTIVE 68–69 (Jeremy Phillips ed., 1985); Hermann Kronz, *Patent Protection for Innovations: A Model*, 5 EUR. INTELL. PROP. REV. 178 (1983).

[14] The topic of commercialization of intellectual property has received extended attention. *See generally* F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 703 (2001) (arguing that "the treatment of patents as property rights is necessary to facilitate investment in the complex, costly, and risky commercialization activities required to turn nascent inventions into new goods and services"); Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 265 (1977) (developing a "prospect theory" of the patent system that "reintegrates the patent institution with the general theory of property rights"). What differentiates the works in notes 12 and 13 from this treatment is that they focus on intellectual property for commercialization rather than on how intellectual property for new technologies may encourage commercialization.

ternalizing property rights have been recognized as exceeding the costs: pharmaceuticals. One area within pharmaceuticals where this phenomenon is true is in protection of what are known as "orphan drugs," that is, existing drugs that in the absence of protection would not be tested or marketed by pharmaceutical companies. Because the challenge for orphan drugs is not creating the compounds but bringing them to market, the business of shepherding an orphan drug through clinical testing and to market can be considered an orphan business model when no one has sufficient incentives to undertake it. There are at least two other areas of our drug laws that also can be seen as providing property rights in orphan business models.[15] Together, these three areas of drug law provide a window into the broader question of when and how orphan business models might best be protected.

Although property rights in orphan business models are beginning to emerge, legal scholarship has failed to explore how such property rights should be designed. One reason for this neglect is that the development of a new, sui generis regime of intellectual property that could apply across all categories of business models seems likely to occur, if at all, only in the distant future, once the benefits of internalizing property rights clearly exceed the costs. But systematic thinking about the design and administration of such property may be useful in determining whether it is possible to reduce the costs and increase the benefits of such rights. In the short term, this approach can be helpful in generating proposals for tweaking and reforming the areas in which such property rights already exist; in the medium term, in identifying other areas where such property rights might be useful; and in the long term, in sketching what a sui generis intellectual property regime for orphan business models might look like and how such a regime can avoid the disincentives to new business creation that business method patents can create.

Sometimes, the lack of implementation of an orphan business model is efficient — for example, because the social costs of bringing a drug to market exceed the benefits — but in other cases, the orphaning of a business model may be inefficient — for example, where others may free ride on clinical testing and other expenses of drug introduction. Any legal regime that seeks to combat the problem of orphan business models must seek to encourage commercialization only in the latter case, yet government officials are unlikely to be well positioned to distinguish the former from the latter. Thus, a simple subsidy mechanism, such as where the government pays private companies to bring drugs to market, will not work well if it is dependent on the discretion of individual decisionmakers. This Article will suggest

---

[15] *See* section II.A, pp. 1383–92.

mechanisms that harness private incentives so that those mechanisms should work effectively even if government information is poor.

Of course, this Article cannot itself confidently distinguish between efficiently and inefficiently orphaned business models, and so we cannot project precisely what business models a new governmental protection regime would encourage. We can, however, identify business models where free-riding on commercialization is especially pernicious and thus where the establishment of orphan business model rights might help. For example, private attempts to build networks of electrical car battery charging stations would be quite risky, and if successful would attract second-movers; so absent protection, such networks will take longer to emerge.[16] We can also compare the problem of orphan business models to the related problem that states and localities have insufficient incentives for legal experimentation;[17] as a result, this Article will consider how approaches used to protect business models might also be used to encourage legal experimentation by preventing free-riding on tests of legal models.[18]

A second reason for the failure of legal scholarship to address rights in orphan business models may be the great attention that has been focused on business method patents.[19] This focus has led to a debate on whether property rights are needed to encourage the creation of ideas for new business methods rather than a debate on whether and how to encourage entrepreneurs to bring to market the large subset of business methods that consist of new business models. To the extent that intellectual property scholars have considered whether it is worthwhile to encourage commercialization of business models, it has generally been as part of the assessment of whether business method patents should exist.[20] A possible benefit of business method patents is that the holder of a business method patent need not worry that others will

---

[16] *See* section III.A, pp. 1396–1407.

[17] *See* Susan Rose-Ackerman, *Risk Taking and Reelection: Does Federalism Promote Innovation?*, 9 J. LEGAL STUD. 593, 610–11 (1980) (noting that state legal innovation may be suboptimal because states will free ride on the experimentation of others).

[18] *See* section III.B.3.b, pp. 1419–21.

[19] *See, e.g.*, John R. Allison & Emerson H. Tiller, *The Business Method Patent Myth*, 18 BERKELEY TECH. L.J. 987 (2003); Jeffrey R. Kuester & Lawrence E. Thompson, *Risks Associated with Restricting Business Method and E-Commerce Patents*, 17 GA. ST. U. L. REV. 657 (2001); Kevin Michael Lemley, *Just Turn North on State Street and Then Follow the Signs Given by the Federal Circuit: A Sophisticated Approach to the Patentability of Computerized Business Methods*, 8 J. TECH. L. & POL'Y 1 (2003); Michael J. Meurer, *Business Method Patents and Patent Floods*, 8 WASH. U. J.L. & POL'Y 309 (2002); Sam Stake, In re Comiskey *and E-Commerce Patentability*, 90 J. PAT. & TRADEMARK OFF. SOC'Y 148 (2008).

[20] *See, e.g.*, Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263, 270 (2000) (arguing that "business method patents protect businesses from competition" and "[t]hus . . . can function in a way that preserves inefficiencies in the marketplace").

free ride on information that only the commercialization of the business model can produce — information, for example, about consumer demand for a novel good or service or the feasibility of providing it. But business method patents will not always encourage commercialization, and business method patents can discourage commercialization when the patents are held by nonpracticing entities.[21]

This Article's task is not to establish that the amount of commercialization of business models will generally be less than is socially optimal. The argument against the intuition that market competition will produce enough business innovation has already been made elsewhere,[22] and this Article assumes that absent intellectual property protection or other intervention, there will be socially suboptimal commercialization of new business models. This Article asks, if law is to protect orphan business models through the traditional strategy of intellectual property — that is, by granting limited exclusivity — what form should such property rights take?[23] This question has at least three components. First, even though patent law currently provides only indirect protection for orphan business models, should the existence of such orphan business models affect patent law doctrine on the margins? Second, in areas of drug law where property rights for orphan business models already exist, how might regulation be improved? And third, over the long term, what new forms of protection for orphan business models are possible and how should these forms be regulated to ensure that the Demsetzian emergence of property rights comes at the lowest possible cost?

The three questions correspond, respectively, to Parts I, II, and III of the Article. A theme developed in each Part is that a principal difficulty with using conventional strategies of intellectual property regulation for orphan business models is that governments may be ill suited to identify when orphan business models should receive property protection. Patent examiners, challenged enough in determining whether

---

[21] This explanation assumes, however, that the ideas for business methods would have emerged quickly without the patent and that the nonpracticing entity does not seek a partner to commercialize it exclusively. For an empirical defense of nonpracticing entities, see generally Sannu K. Shrestha, Note, *Trolls or Market-Makers? An Empirical Analysis of Nonpracticing Entities*, 110 COLUM. L. REV. 114 (2010).

[22] For previous work developing a model of the market experimentation problem, see Abramowicz & Duffy, *supra* note 12, at 353–63.

[23] This Article does not address issues of whether protection for orphan business methods outside the patent statute would be constitutional. For an argument that the Orphan Drug Act is unconstitutional, see John J. Flynn, *The Orphan Drug Act: An Unconstitutional Exercise of the Patent Power*, 1992 UTAH L. REV. 389. *But see* Thomas B. Nachbar, *Intellectual Property and Constitutional Norms*, 104 COLUM. L. REV. 272 (2004) (arguing that Congress can take advantage of its Commerce Clause powers to provide intellectual property protection not justified by the Constitution's Patent and Copyright Clause).

business methods are novel and nonobvious,[24] do not have the institutional capability to determine which business models will need legal exclusivity in order to be commercialized. History provides a lesson in the form of exclusive royal grants, which reflected government determinations that exclusivity would benefit commerce.[25] Unsurprisingly, royal prerogatives were sometimes abused, as when an exclusive charter for printing books allowed the Crown to exercise censorship.[26] Even well-intentioned government officials might be ill equipped to forecast whether exclusivity is necessary, and they seem especially unlikely to make good decisions in ex parte hearings in which the only arguments they hear are from companies seeking exclusivity.

The specter of governments arbitrarily granting monopolies is sufficient to counsel that protection for orphan business models should not be extended absent decisionmaking mechanisms that will prevent such abuse. Perhaps the most significant reform that could prevent this abuse is to give both orphan business model applicants and third parties, including competitors, the ability and incentive to block orphan business model applications when a long term of exclusivity is unnecessary to induce commercialization. It is easy enough for an applicant for government protection to argue that exclusivity is essential to creation of a new business model, or for a competitor to argue that it is not, but the government is unlikely to be able to evaluate such claims with high accuracy. A better approach is to create financial incentives for those with the best information to make accurate assessments and act on them.

There are different varieties of this approach, but a simple one would allow competitors of those seeking orphan business model applications to adopt the orphan business models themselves for a shorter period of time than the original applicant would receive. Suppose, for example, that *X* Corp. seeks a ten-year period of exclusivity on a drug that would not otherwise be entitled to patent protection — for example, because it was discovered long ago but never tested for its effectiveness against a particular disease. *X* Corp. argues, as it might today in an application under the Orphan Drug Act,[27] that no one would have adequate incentive to take the drug through the expensive

---

[24] *See, e.g.*, Gregory Mandel, *The Non-Obvious Problem: How the Indeterminate Nonobviousness Standard Produces Excessive Patent Grants*, 42 U.C. DAVIS L. REV. 57, 78 (2008) (identifying various challenges facing examiners).

[25] For this history, see Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part I)*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 697, 706–08 (1994).

[26] *See, e.g.*, Malla Pollack, *Purveyance and Power, or Over-Priced Free Lunch: The Intellectual Property Clause as an Ally of the Takings Clause in the Public's Control of Government*, 30 SW. U. L. REV. 1, 93–95 (2000).

[27] 21 U.S.C. §§ 360aa–360ee (2006); *see also* section II.A.1, pp. 1384–88.

FDA approval process without a guarantee of exclusivity. If a competitor, *Y* Corp., agrees to a significantly shorter period of exclusivity (say, seven years), and also commits to conducting at least as much research and development as *X* Corp.'s commitment, then it would receive the property right instead. Of course, if *Z* Corp. will do the same with just one year of exclusivity, then it would receive the property right, so such competition can drive the period of exclusivity close to zero.

An alternative approach would rely on information from competitors and third parties about whether an orphan business model would likely be created if an application for an exclusive business model adoption right were denied. For example, the applicant might be required to put up a sum of money as a bond to back up the applicant's claim that the business model will *not* be attempted in the application period requested if the application is refused. Others would then have the option of putting up a sum of money as a bond to back up the opposite claim. If anyone took this option, the application would be denied, and the bonds would ultimately be paid to the party who turned out to be correct. If no one did so, that would validate the original applicant's claim.

This mechanism is elaborated below,[28] but ultimately both this mechanism and the term competition mechanism have two significant advantages over existing systems of intellectual property: they are much simpler to administer, and they bear a much lower risk of providing unnecessary exclusivity. And so, while an absence of a perceived need for orphan business model protection helps to explain the absence of prior scholarship and the limited ambit of existing protections, the cost of providing protection is sufficiently low that it might be efficient even where the stakes are much lower than they are in pharmaceuticals. The chief obstacle to implementation may be congressional hesitance to experiment with unfamiliar approaches to intellectual property protection. This Article is but a first step toward demonstrating that such protection is both desirable and plausible.[29]

---

[28] *See* section III.B, pp. 1408–21.

[29] The ambition of this project is thus similar to the ambition of the economic literature on mechanism design: to create alternative ways of structuring markets and decisionmaking institutions. The path from theoretical construct to implementation, however, is a long one that demands many inputs beyond the initial theoretical framework. *See generally* Alvin E. Roth, *The Economist as Engineer: Game Theory, Experimentation, and Computation as Tools for Design Economics*, 70 ECONOMETRICA 1341 (2002) (describing the challenge for the mechanism design literature).

I. RESPONSES WITHIN PATENT LAW: BUSINESS METHODS AND RELATED DOCTRINES

Outside of drug law, the area of law that seems most likely to respond to concerns about orphan business models is, for better or worse, patent law. After *Bilski*, it appears that at least some business method patents survive. When such patents are granted, concerns about orphan business models will generally be alleviated, because at least one party will have an exclusive opportunity to enter a market without worrying about other parties' free-riding on information from such entry. To what extent should patent law directly take into account concerns about orphan business models? This Part suggests that a desire to foster market experimentation could play a more explicit role on the margins of patent law doctrine, but that patent law is ill suited to making orphan business models a central concern.

The relationship of orphan business models to the debate on business method patents can be spotted in *Bilski* itself. The majority opinion[30] focused primarily on legal arguments[31] rather than policy considerations in holding that business methods could not categorically be excluded from patenting,[32] but that some business methods, including the business models that were at issue, were "abstract ideas" unentitled to patent protection.[33] Justice Stevens's concurring opinion,[34] arguing in favor of a categorical bar, addressed the policy question more directly: "Business innovation . . . generally does not entail the same kinds of risk as does more traditional, technological innovation."[35] The words "same kinds of risk" reflect a recognition that the risks involved in business innovation are not the types patent law seeks to mitigate.

Typically, entrepreneurs face little risk that others will copy their *undeveloped* ideas. Even absent intellectual property protection,

---

[30] Five Justices supported the critical parts of the decision, though Justice Scalia declined to concur in part of the reasoning. *See id.* at 3223 (identifying the sections that are not part of the opinion of the Court).

[31] Central to the Court's decision not to bar business method patents categorically was its view that the existence of atextual exceptions to the patent statute, for example for abstract ideas, does not give "the Judiciary *carte blanche* to impose other limitations that are inconsistent with the text and the statute's purpose and design." *Id.* at 3226.

[32] This conclusion may be dicta because the Court ultimately found the invention unpatentable. *See* Michael Abramowicz & Maxwell Stearns, *Defining Dicta*, 57 STAN. L. REV. 953, 1029–32 (2005) (explaining why "nonsupportive propositions" should generally count as dicta, but noting that the Supreme Court has more latitude than other courts to define its holdings broadly).

[33] *Bilski*, 130 S. Ct. at 3229–31.

[34] *Id.* at 3231 (Stevens, J., concurring in the judgment).

[35] *Id.* at 3254 & n.52 (citing Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1618 (2003)); *see also* Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 826 (2002); David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 181, 231 (2009).

would-be entrepreneurs commonly hawk their ideas to angel investors or venture capitalists without any protection from nondisclosure agreements.[36] Although informal norms may help explain why the stealing of prospective business models is rare, another explanation is that often the relevant scarcity in the business world is not a scarcity of ideas, but of funds for implementing them. Providers of financing generally would not expect to benefit by stealing an idea and potentially competing against the team of entrepreneurs who developed that idea and likely have a comparative advantage in its implementation. Both entrepreneurs and financiers must worry, however, about the prospect of competition should their ideas prove successful in the market. Anticipation of "second-mover advantages,"[37] including the ability to withhold investment until it is proven that there is a market for a good or service and the ability to gain information about how to avoid mistakes made by the first mover, will sometimes mean that the anticipated profits from first moving in the event of success will not compensate for the risks of initial failure and subsequent defeat by the second entrant. Thus, free-rider problems may cause as much or more inefficiency from socially suboptimal new business model commercialization as from socially suboptimal new business model idea development. But business method patents focus entirely on the latter.

Justice Stevens's opposition to business method patents on policy grounds does not appear to stem from a view that competition will magically produce an optimal amount of business innovation. "[F]irms that innovate," Justice Stevens noted, "often capture long-term benefits from doing so, thanks to various first mover advantages, including lockins, branding, and networking effects."[38] But he conceded that "there may [be] some methods of doing business that do not confer sufficient first-mover advantages,"[39] acknowledging a recent article arguing that intellectual property can and should protect market experimentation.[40] Just as technological experimentation produces information about whether a particular set of scientific steps will produce a useful result that can bring market rewards,[41] market experi-

---

[36] *See* Arthur R. Miller, *Common Law Protection for Products of the Mind: An "Idea" Whose Time Has Come*, 119 HARV. L. REV. 705, 714–15 (2006) (suggesting that, except during brief booms, angel investors generally refuse to sign nondisclosure agreements).

[37] *See, e.g.*, Kieff, *supra* note 14, at 708–09 (identifying second-mover advantages).

[38] *Bilski*, 130 S. Ct. at 3254 (Stevens, J., concurring in the judgment).

[39] *Id.* at 3254 n.51.

[40] *Id.* (citing Abramowicz & Duffy, *supra* note 12, at 340–42).

[41] Although the utility doctrine is often viewed as not demanding, the courts seem to use the nonobviousness doctrine to protect only inventions that are in some sense useful. *See, e.g.*, *In re* Dow Chem. Co., 837 F.2d 469, 473 (Fed. Cir. 1988). The *Dow* approach is sensible where what is scarce is the willingness of scientists to test chemicals that may require minimal creativity to synthesize.

mentation produces information about whether a particular type of business or business model is likely to be effective and embraced by consumers. Sufficient motives may not exist to invest in either technological or market experimentation when future competitors will dissipate profits if experimentation proves successful.

This phenomenon does not mean, though, that the same type of intellectual property protections should be used to incentivize both the creation of business methods and their commercialization. Business method patents are a crude mechanism for encouraging commercialization because the criteria for granting such patents reflect the risk inherent in developing business model ideas rather than the risk inherent in bringing business models to market. Some business models that receive patent protection might well be implemented by entrepreneurs even absent patent protection; in that case, patent protection is unnecessary and will lead to high prices and deadweight loss.[42] Much of the debate about whether the *Bilski* Court should have found business methods to be unpatentable subject matter has focused on this concern.[43] Meanwhile, other business methods may not qualify for patent protection because the ideas underlying them are abstract or do not meet some of patent law's other requirements, such as that an invention be novel[44] and nonobvious.[45] These include our eponymous "orphan business models."

A. Market Experimentation After Bilski

Neither Justice Stevens nor the majority opinion in *Bilski* considered whether courts can or should directly assess market experimentation considerations. Nonetheless, the overall approach of the *Bilski* majority does provide some basis for incorporating market experimentation in patent doctrine, and other aspects of the statute also allow some role for such considerations.

1. Abstractness and Suitability for Experimentation. — The *Bilski* Court found Bilski's invention unpatentable on the ground that it was an "abstract idea." Yet the Court did little to make clear just what

---

[42] It is plausible that the nonobviousness doctrine can combat this problem if the Supreme Court takes seriously its admonition that the purpose of the doctrine is to identify inventions that need the patent incentive. *See* Graham v. John Deere Co., 383 U.S. 1, 11 (1966); Abramowicz & Duffy, *supra* note 8 (arguing that courts should consider whether inventions are patent induced). In that case, the only business methods to receive patents would be those that would not have ended up in the public domain absent patent protection because they would not have been invented in the first place.

[43] *See, e.g.*, Alan Devlin & Neel Sukhatme, *Self-Realizing Inventions and the Utilitarian Foundation of Patent Law*, 51 WM. & MARY L. REV. 897, 902, 945–50 (2009) (recommending a new approach before the Court issued its opinion in *Bilski*).

[44] 35 U.S.C. § 102 (2006).

[45] *Id.* § 103.

constitutes an abstract idea, and indeed it explicitly rejected the possibility of "adopting categorical rules that might have wide-ranging and unforeseen impacts."[46] Instead, the Court summarized its line of cases distinguishing abstract from concrete ideas,[47] without engaging either scholars who insist that the Court's previous cases had distinguished the indistinguishable[48] or Justice Stevens's arguments that the patent claims at issue arguably are closer to the concrete than to the abstract side of the line.[49] What does appear clear from Justice Kennedy's opinion is that the test for abstractness is fact specific and that it embraces considerations that patent lawyers ordinarily might consider only under other sections of the patent statute. Justice Kennedy noted, for example, that the basic concept of hedging is old in the art,[50] even though under orthodox patent law that fact might be more relevant to novelty or nonobviousness than to patentable subject matter.[51]

Lower courts thus must either assess abstractness in a fact-specific but unsystematic way or develop tests for determining abstractness in the business method context.[52] Evaluating abstractness may appear challenging in part because the Court rejects the proposition that a business method must transform matter or be embodied in a machine.[53] What does it mean for an idea to be concrete? A starting point is the recognition that intellectual property is designed to encourage the production of useful information. The particular type of information relevant here is information derived from experimentation, whether technological or market, with ideas. When an idea is sufficiently abstract, experimentation is unlikely to produce valuable information about the potential usefulness of the idea. Concrete ideas, in contrast, can be tested, and experimentation with them will generally produce useful information. This distinction links the abstractness inquiry to the traditional scientific insistence on falsifiability,[54] though

---

[46] Bilski v. Kappos, 130 S. Ct. 3218, 3229 (2010).

[47] *See id.* at 3229–30 (discussing *Diamond v. Diehr*, 450 U.S. 175 (1981); *Parker v. Flook*, 437 U.S. 584 (1978); and *Gottschalk v. Benson*, 409 U.S. 63 (1972)).

[48] *See* Gerard N. Magliocca, *Patenting the Curve Ball: Business Methods and Industry Norms*, 2009 BYU L. REV. 875, 882 n.29 (noting that "*Diehr*'s effort to distinguish the Court's precedents rejecting software patents, especially *Parker v. Flook*, was unpersuasive and is widely criticized," and citing other critical scholarly commentary).

[49] *See Bilski*, 130 S. Ct. at 3235–36 (Stevens, J., concurring in the judgment).

[50] *Id.* at 3231 (majority opinion).

[51] *See* 35 U.S.C. § 101 (2006) (patentable subject matter); *id.* § 102 (novelty); *id.* § 103 (nonobviousness).

[52] In proposed regulations, the Patent and Trademark Office has taken the approach of suggesting that examiners may consider a wide range of factors. *See* Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*, 75 Fed. Reg. 43922, 43925–26 (July 27, 2010).

[53] *See Bilski*, 130 S. Ct. at 3226.

[54] The Supreme Court embraced the relevance of falsifiability in the scientific evidence context in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). *See id.* at 593 ("[T]he criterion

what matters is not whether an idea is falsifiably correct (as with a mathematical theorem), but whether it is falsifiably useful.

The usefulness of a business-method idea can be falsifiably tested. When a business-method patent has many potential embodiments, market experimentation with any one embodiment will provide relatively little information about whether the various embodiments described in and claimed by the patent will be effective. In this case, there is a strong argument that the business method is abstract. A business method could be viewed as concrete where experimentation with any particular business method falling within the patent's scope seems likely to produce valuable information about the market feasibility of the specific techniques invented. Claims that narrow a business-method idea to arbitrary contexts will not help make the idea more concrete, however, unless testing in these contexts will provide especially useful information about the innovative idea as a whole. Meanwhile, if an idea is already well established, a new application of that idea often will not benefit from testing because it will be clear in advance what the effect of the application will be.

The argument is perhaps best understood through an example. In an earlier patentable subject matter case,[55] the Supreme Court reasoned that the Pythagorean Theorem was an unpatentable abstract idea and "would not have been patentable, or partially patentable, because a patent application contained a final step indicating that the formula, when solved, could be usefully applied to existing surveying techniques."[56] The analysis here calls the Court's conclusion into question.[57] The Theorem by itself would have been abstract. There are so many contexts in which it might be applied that information that someone was able to use it profitably in one context (say, to improve origami designs) would not be very relevant to an assessment of whether it would be profitable in some other context (say, to improve architectural rendering). But narrowing the patent to surveying makes the idea much more concrete. If the formula turns out to be useful for some type of surveying businesses, it is likely to be useful for others as well. Meanwhile, once the Theorem has long been known, a patent for some new application of the Theorem (say, use of the Theorem to survey grassy lands) seems unlikely to be within patentable subject

---

of the scientific status of a theory is its falsifiability, or refutability, or testability." (alterations in original) (quoting KARL POPPER, CONJECTURES AND REFUTATIONS: THE GROWTH OF SCIENTIFIC KNOWLEDGE 37 (5th ed. 1989)) (internal quotation marks omitted)).

[55] Parker v. Flook, 437 U.S. 584 (1978).

[56] *Id.* at 590.

[57] I borrow the Court's implicit assumption that the patent system existed at the time of Pythagoras's invention and that Pythagoras sought the patent. *See id.*

matter, since experimentation does not seem likely to provide any additional information about whether the Theorem is useful.[58]

Justice Kennedy did not explain abstractness in this way, but this approach helps make sense of some of his logic. Justice Kennedy began by noting that "[h]edging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class."[59] It is possible to view this statement as simply importing novelty and nonobviousness concerns into the patentable subject matter inquiry, but an alternative interpretation is that, because some claims of the patent[60] seem similar to broad swaths of economic activity, the exercise of the patented method would not provide much information about the feasibility of accomplishing business ends with the techniques described in the patent. In the next paragraph, Justice Kennedy characterized some other claims in the patent as "broad examples of how hedging can be used in commodities and energy markets," noting that the examples "instruct the use of well-known random analysis techniques."[61] These claims are certainly narrower than others made in the patent application, but Justice Kennedy did not view them as more concrete. A justification for this conclusion is that implementation of these business methods seems unlikely to produce valuable information about the allegedly innovative idea in the patent.

In *Bilski*, it seems likely that, had the questions been before the Court, the majority would have also found the patent invalid on other grounds, at least based on § 103 of the patent statute.[62] But the Court's approach to understanding abstractness suggests the possibility of a business method patent that is clearly nonobvious, a stroke of

---

[58] The test for concreteness also could be applied to the facts of *Flook* itself. *Flook* involved a method for updating alarm limits during catalytic conversion processes. *See id.* at 585. The patent included a formula for calculating

> an updated alarm limit once [an operator] knows the original alarm base, the appropriate margin of safety, the time interval that should elapse between each updating, the current temperature (or other process variable), and the appropriate weighting factor to be used to average the original alarm base and the current temperature.

Id. at 586. Whether such a formula is likely to be useful, relative to alternatives such as determining when the process is complete by using expert judgment, seems eminently testable, and the idea is likely to be concrete. A caveat, however, is that the patent covered use of the formula in "numerous processes . . . in the petrochemical and oil refining industries." *Id.* If these processes are so varied that the fact that the formula was useful in one context would tell little about whether it was useful in another, then the idea might be too abstract. Considering whether an idea is abstract or concrete in this way is not mechanical, but it does highlight the type of testimony that might be relevant. Of course, even if an idea is concrete, that fact does not mean that it is patentable; it still must meet the other criteria of patentability, including nonobviousness.

[59] Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010) (quoting *In re* Bilski, 545 F.3d 943, 1013 (Fed. Cir. 2008) (Rader, J., dissenting)) (internal quotation marks omitted).

[60] Specifically, Claims 1 and 4, which "explain the basic concept of hedging, or protecting against risk." *Id.* at 3222.

[61] *Id.*

[62] *See* 35 U.S.C. § 103 (2006).

genius even,[63] while still being too abstract. Imagine, for example, that in the early years of the internet, someone sought a patent on internet-based e-commerce, and included both broad claims and narrow claims targeted to particular areas of e-commerce (books, flowers, and so on). Even if novel, the patent as a whole might be too abstract. Patent-induced experimentation with any single e-commerce embodiment would provide little information that would help entrepreneurs improve their evaluations about the feasibility of e-commerce as a whole. Admittedly, assessing abstractness in this context requires some subjective judgment, for experimentation with any one implementation of e-commerce likely would provide some information, but all approaches to defining abstractness will require some degree of line drawing.

For an example of this kind of e-commerce, consider experimentation with selling books. Such experimentation might give information about the feasibility of selling books online, but if the patent's innovations do not relate directly to book sales, that idea will not suffice. A concrete idea is one where experimentation will provide useful information about the feasibility of that specific idea, and an actual online bookstore does not provide much information about the feasibility of the idea of e-commerce. The narrowing does not help make the idea any more concrete than would narrowing to e-commerce sites beginning with the letter "E." A patent or patent claim targeted toward specific techniques for selling books online might be more concrete.

Abstract patents in the sense identified here are the patents that seem least likely to promote market experimentation and reduce the problem of orphan business models. In sum, the *Bilski* Court has divided business methods into two groups: abstract ones, which are unpatentable, and concrete ones, which are potentially patentable. The question whether any given experiment on a business method described in a patent seems likely to produce useful information would determine whether that business method counts as concrete or abstract. Because of the additional requirements of patentability, some business methods that could benefit greatly from market experimentation might still be excluded from patentability, just as many orphan drugs are not entitled to patents even though they clearly fall within patentable subject matter. This approach would, however, roughly limit patentability to cases in which patent law may have been needed both to induce the idea of a business method *and* to provide incentives

[63] The patent statute's legislative history rejects the notion that a flash of genius is required. *See id.* § 103 note ("The second sentence states that patentability as to this requirement is not to be negatived by the manner in which the invention was made, that is, it is immaterial whether it resulted from long toil and experimentation or from a flash of genius."). But such a flash will still generally be sufficient to meet the nonobviousness requirement.

to conduct useful experiments on it. This Article will consider reasons that this regime might be counterproductive,[64] though it may well make as much policy sense as other approaches to distinguishing abstract from concrete business methods.

2. Other Patent Doctrines. — A desire to encourage market experimentation and reduce the danger of orphan business models may be relevant to other areas of patent law, as well. One statutory section of the patent laws directly reflects concerns about market experimentation. This section grants prior use rights for business methods in certain situations, providing a defense for someone who commercially used a business method at least one year before someone else filed a patent.[65] Concerns about orphan business models seem relatively more important for business methods than for many other types of technologies. Ordinarily, patent rights *reduce* the danger of orphan business models, but where business models are already being practiced, patents may serve as a tax on the continuation of such experiments. Congress might have done even more to reduce the risk that patents could discourage business innovation, such as prohibiting nonpracticing entities from receiving business method patents. Nonetheless, the congressional recognition of the importance of encouraging the practice of business methods highlights the potential relevance of this policy consideration to patent law more broadly.

The goal of encouraging market experimentation may already be relevant in the Supreme Court's decision regarding whether an injunction should issue after a court determines that patent infringement has occurred. In *eBay Inc. v. MercExchange, LLC*,[66] the Court held that injunctions should not automatically issue and that the Court's traditional four-factor test for injunctive relief applies in the patent context.[67] Since *eBay*, a number of district courts have taken the status of a patentee as a nonpracticing entity into account in refusing to issue injunctions.[68] Concerns about orphan business models provide some support for such considerations. An injunction by a nonpracticing entity against a practicing entity, along with the threat of such injunctions, makes market experimentation less desirable and increases the risk of orphan business models. Although there may be countervailing considerations, this consideration should be particularly powerful where the underlying technology is a business model because market experimentation is particularly critical to establishing the usefulness of business technologies.

---

[64] *See* section II.B, pp. 1392–96.

[65] *See* 35 U.S.C. § 273(b)(1).

[66] 547 U.S. 388 (2006).

[67] *Id.* at 391, 394.

[68] *See* Shrestha, *supra* note 21, at 134–35 & n.112 (citing sources).

A final area in which the goal of encouraging market experimentation may be relevant is in nonobviousness analysis, and in particular in the courts' analysis of the "secondary considerations" of patentability.[69] Under Federal Circuit doctrine, the most important factor in patentability is whether the invention has produced commercial success.[70] Commentators have generally been skeptical of the relevance of commercial success.[71] But with a qualification, this criterion makes some sense as a partial antidote to orphan business models. For an invention to be commercially successful, it must be marketed, and marketing creates a danger that imitators will free ride not only on the patent disclosure, but also on information developed in marketing. So, in a close obviousness case, successful marketing by the patentee should tilt the inquiry in the direction of nonobviousness. On the other hand, when a nonpracticing entity seeks to use a patent offensively against an alleged infringer, commercial success by the alleged infringer should not count in the patentee's favor and arguably should count against the patentee.

B. Problems with Incorporating Market Experimentation Concerns

In short, there exist doctrinal means through which the courts could seek to encourage market experimentation and discourage orphan business models, and consideration of such goals could help rationalize some areas of patent doctrine that have little foundation in theory. This fact should not be taken to suggest, however, that encouraging market experimentation should emerge as a coequal goal of the patent statute, as important as encouraging technological experimentation,[72] with the PTO awarding patents wherever needed to avoid the problem of an orphan business model. There are several reasons that this course is not desirable, and to a lesser extent, these reasons may even counsel against considering market experimentation goals on the margins of patent law.

The most obvious problem is that the patent statute focuses on the goal of encouraging technological experimentation rather than on the goal of encouraging market experimentation. Sometimes these goals align, but at other times they do not. From the perspective of rewarding only new ideas for business methods, it may make sense, as Justice

---

[69] Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966) (introducing the secondary considerations).

[70] *See* Andrew Blair-Stanek, Note, *Profits as Commercial Success*, 117 YALE L.J. 642, 647–49 (2008); *see also In re* Sernaker, 702 F.2d 989, 996 (Fed. Cir. 1983).

[71] *See, e.g.*, Edmund W. Kitch, Graham v. John Deere Co.*: New Standards for Patents*, 1966 SUP. CT. REV. 293, 332–34.

[72] *See* Abramowicz & Duffy, *supra* note 12, at 405–08 (considering whether the patent system can embrace pure "commercialization patents").

Kennedy suggested, to have a vigorous nonobviousness doctrine.[73] But that may tend to discourage market experimentation. If market experimentation becomes a factor in such analysis, it could complicate the nonobviousness inquiry, especially because there is no straightforward way of balancing the concerns about encouraging technological and market experimentation. Similarly, if abstractness of an idea is defined with reference to its falsifiability, then there might be insufficient incentives to develop novel and nonobvious business models that are abstract in this sense. The goals of the patent system are different from those of statutes encouraging adoption of orphan business models (such as the Orphan Drug Act), and seeking to serve both of these goals in a single intellectual property regime would produce inevitable tensions.

An additional problem is the question of institutional competence. There have been challenges enough to the effectiveness of the PTO in making determinations such as the nonobviousness of inventions,[74] but at least examiners currently focus on retrospective inquiries. It would be far more difficult for the PTO (or a foreign patent office) to assess how a decision to grant a property right will affect a business's potential development. That determination cannot easily be made just on the basis of papers, and requires familiarity with a particular industry. It also requires a willingness to make decisions that ultimately are subjective and probabilistic, and the PTO has generally veered toward more objective standards even where it is impossible for bright-line rules to capture needed nuance adequately.[75] In administering the Orphan Drug Act, the Food and Drug Administration at least is specialized in a particular industry, though even in this instance the agency has preferred bright-line thresholds to more open-ended inquiries into whether protection is necessary.[76]

A final problem is that the patent term is fixed. Even if a patent office could identify business models that will not be commercialized in the near future absent some form of exclusivity protection, the full patent term in many cases may not be needed to encourage market entry. In a very small number of situations, it is possible that a full patent term might be insufficient to encourage entry, yet one should hesitate to empower an agency with discretion to grant protection longer

---

[73] *See* Bilski v. Kappos, 130 S. Ct. 3218, 3229 (2010) (plurality opinion) (noting that "business method patents raise special problems in terms of vagueness and suspect validity" and that the nonobviousness requirement is one tool to avoid "granting patents when not justified by the statutory design").

[74] *See, e.g.*, Mandel, *supra* note 24, at 78.

[75] Michael Abramowicz & John F. Duffy, *Ending the Patenting Monopoly*, 157 U. PA. L. REV. 1541, 1560 (2009).

[76] *See infra* p. 1388.

than twenty years. The PTO likely does not have the competence to customize patent terms on the basis of all possible relevant factors, including those relating to both technological and market experimentation.[77] The proposal described in Part III for competition to provide the shortest protection term provides an antidote, but it would not fit well within the patent system because patents must be awarded after inventions are produced.

The patent system, of course, is not the only form of existing intellectual property protection that may encourage market experimentation. Trade secret law may help by making it easier to protect financial and scientific data about the success of market and technological experiments, thus making it more difficult for competitors to free ride.[78] But sometimes, even casual analysis by consumers suffices to reveal the success of a new business model. In addition, if copyright law were expanded to entail data exclusivity,[79] that might help as well, but only incompletely. In principle, protecting orphan business models requires only protection of the information resulting from market experiments, but in practice this protection is often impossible, and so a targeted, effective protection scheme must protect the right to utilize and implement the business model. An expansion of copyright law to include data exclusivity would not be able to accomplish this task.

II. SUBJECT-SPECIFIC RESPONSES: THE CASE OF PHARMACEUTICALS

Among most intellectual property scholars, the case for patent law is generally considered to be stronger for pharmaceuticals than for other areas of technology.[80] It seems plausible that other technologies could advance relatively rapidly even without patent protection, but in pharmaceuticals, removal of the patent incentive would virtually eliminate private sector drug research. Private sector research depends on the patent reward because of the extraordinary costs associated with research into new drugs and the relative ease with which generic drug

---

[77] For examples of such factors in proposals for tailored patent terms, see sources cited *infra* note 163.

[78] For an explanation of how trade secret doctrine helps promote market experimentation, see Abramowicz & Duffy, *supra* note 12, at 389–91.

[79] *See, e.g.*, Amol Pachnanda, Comment, *Scientific Databases Should Be Protected Under a* Sui Generis *Regime*, 51 BUFF. L. REV. 219, 241 (2003).

[80] *See, e.g.*, JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE 120–21, 138–41 (2008) (finding net benefits of patent protection only for the pharmaceutical and chemical industries). In the general public, the opposite may be true because of concerns that legal regulation will prevent individuals from obtaining affordable drugs. For a proposal for a system of tradable patent terms that would seek to improve access to medicines, see Michael Ilg, *Market Competition in Aid of Humanitarian Concern: Reconsidering Pharmaceutical Drug Patents*, 9 CHI.-KENT J. INTELL. PROP. 149, 169–73 (2010).

manufacturers can copy drugs. But scholars' embrace of patent protection for pharmaceuticals does not imply that the general patent framework is optimally tuned for pharmaceuticals. Indeed, the existence of many exclusivity provisions that are specific to drugs reveals that, because of the importance of drug development, Congress has sought to address inefficiencies and imperfections of the patent system in that context.[81] This Part describes some of the patent-specific exclusivity provisions in the pharmaceuticals industry and explains how they partly allay concerns about orphan business models. It also describes remaining weaknesses in these approaches and how they might be fixed.

The existing system, even with these drug-specific fixes, is suboptimal. In an important recent article, Professor Benjamin Roin explains in detail how the patent system fails to give sufficient incentives to develop many potentially useful drugs.[82] Pharmaceutical firms, Roin explains, weed out of their pipelines drugs that they do not expect to be able to patent, even though these drugs are generally not available on the market.[83] The requirements of patentability, particularly the requirements of novelty and nonobviousness,[84] make sense to the extent that the goal of patent law is viewed as the *conception* of drugs that might turn out to be clinically beneficial after a long testing process. But if a goal is actually to encourage drug manufacturers to undertake that testing process, patent law will work only so long as the firm that conceives of a drug proceeds to seek a patent and then undertake the clinical testing process. Ironically, Roin notes, if a third party observes in a scientific publication that a particular compound seems like a very promising drug candidate, it is less likely that an unrelated pharmaceutical company will research that compound, because the company will be concerned that the drug will be unpatentable even if the research turns out to be successful.[85]

In such a case, the business model of researching a compound, shepherding it through the FDA approval process, and bringing it to market is an orphan business model. As with other orphan business models, the problem is that second movers can take advantage of information produced by the first mover and dissipate the profits that

---

[81] Judicial doctrine may also tailor patent law to particular technological contexts. *See* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1160 (2002). But technology-sensitive orphan business method protection has not emerged from such customization.

[82] *See* Roin, *supra* note 12, at 515–45.

[83] *Id.* at 545–56.

[84] 35 U.S.C. §§ 102, 103 (2006).

[85] Roin, *supra* note 12, at 537 ("The most troubling aspect of the nonobviousness requirement is that it denies patent protection to inventions *because* they seem likely to work while ignoring the question of whether a patent is needed to motivate that invention's development.").

the first mover could have expected to receive. Being first to market and being able to offer the brand-name drug may, as a result of trademark law,[86] furnish some first-mover advantages,[87] but at least in many cases these benefits will be insufficient to make the research path appear profitable, even if it would be socially beneficial. The type of information on which the second mover is free-riding is different from the relevant information in a typical orphan business model case, where the second mover might wait to see whether there is consumer demand rather than regulatory approval. As with all orphan business models, though, there is a private risk that it will not be feasible to earn a profit providing a good or service, and first movers may not be willing to make expensive investments that have a high chance of producing no profits if second movers can enter the market in the unlikely case success is achieved.

Section II.A describes ways in which the drug laws already respond to concerns about orphan business models, and it notes the danger that these approaches sometimes may provide too little protection and other times may provide too much. Section II.B explores various possible improvements to the existing regimes, concluding that existing proposals and other familiar solutions will not likely be adequate. The best solution, to be considered later,[88] may be to have potential adopters of an orphan business model compete with one another based on length of proposed exclusivity period.

A. Statutory Regimes

Drug laws reflect concerns about orphan business models in at least three ways. First, the Orphan Drug Act provides protection for a class of drugs where pharmaceutical companies might not have sufficient incentives to undertake the process of clinical testing and regulatory approval. Second, an unrelated part of the drug laws with a similar effect generally assures some period of exclusivity to the first company that obtains approval for a drug by delaying approval of generic versions. Finally, the Hatch-Waxman Act,[89] which provides incentives for generic drug manufacturers to challenge drug patents, reflects a concern about a different type of free-riding: free-riding by additional

---

[86] For a discussion of the extent to which trademark law encourages market experimentation, see Abramowicz & Duffy, *supra* note 12, at 381–89.

[87] Trademark law also can accent existing first-mover advantages by allowing brand-name drug manufacturers to earn rents even after the patent term. *See* Gideon Parchomovsky & Peter Siegelman, *Towards an Integrated Theory of Intellectual Property*, 88 VA. L. REV. 1455, 1473–81 (2002).

[88] *See* section III.A, pp. 1396–1407.

[89] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355), *amended by* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified in scattered sections of the U.S. Code).

generic manufacturers on the litigation endured by a first generic challenger.

1. Orphan Drug Act. — The Orphan Drug Act seeks to protect "orphan" drugs, that is, drugs that need to be adopted by a pharmaceutical company if they are to be brought to market.[90] The title of the statute might at first appear to be a misnomer because it applies to any drug that is for a "rare disease or condition,"[91] but the definition of "rare disease or condition" is expansive. It includes not only any disease that "affects less than 200,000 persons in the United States,"[92] but also any disease that "affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug."[93] In other words, the statute presumes that a drug for a disease affecting a relatively small number of people needs protection[94] because there will generally be reduced incentives to develop drugs for smaller patient populations.[95] The statute, however, in theory also allows drug manufacturers to demonstrate that a drug affecting a larger number of people needs protection. For any drug designated for a rare disease or condition, the statute provides for seven years of marketing exclusivity.[96] However, exclusivity can be cancelled if the holder "cannot assure the availability of sufficient quantities of the drug."[97] Out-

---

[90] Representative Henry A. Waxman explains the name, saying that these drugs "are like children who have no parents, . . . and they require special effort." Thomas Maeder, *The Orphan Drug Backlash*, SCI. AM., May 2003, at 82 (internal quotation marks omitted).

[91] 21 U.S.C. § 360bb(a)(1) (2006).

[92] *Id.* § 360bb(a)(2)(A). For an analysis of whether the Orphan Drug Act's subsidy provisions are justified on distributive justice grounds, see Arti K. Rai, *Pharmacogenetic Interventions, Orphan Drugs, and Distributive Justice: The Role of Cost-Benefit Analysis*, SOC. PHIL. & POL'Y, Aug. 2002, at 246, 253–69.

[93] 21 U.S.C. § 360bb(a)(2)(B).

[94] The initial version of the statute passed in 1983 did not include this provision because Congress "considered such definitions too rigid and impractical." Stephan E. Lawton, *Controversy Under the Orphan Drug Act: Is Resolution on the Way?*, 46 FOOD DRUG COSM. L.J. 327, 328 (1991). Concerns emerged, however, that too few drugs were being approved under the statute. *See Orphan Drug Act Oversight Hearings Before the Subcomm. on Health & the Env't of the H. Comm. on Energy & Commerce*, 98th Cong. 719–20 (1984), *discussed in* Lawton, *supra*, at 328–30.

[95] For economic evidence that patients benefit from increased research when many others have the same conditions they do, see Frank R. Lichtenberg & Joel Waldfogel, *Does Misery Love Company? Evidence from Pharmaceutical Markets Before and After the Orphan Drug Act*, 15 MICH. TELECOMM. & TECH. L. REV. 335, 348 (2009).

[96] 21 U.S.C. § 360cc(a) ("[T]he Secretary may not approve another application . . . for such drug for such disease or condition . . . until the expiration of seven years from the date of the approval of the approved application . . . .").

[97] *Id.* § 360cc(b)(1).

side the United States, a number of countries, plus the European Union, have adopted statutes similar to the Orphan Drug Act.[98]

Most studies of the Orphan Drug Act indicate that it has helped promote further research into drugs for rare diseases. Professor Wesley Yin, for example, finds that the Orphan Drug Act promotes drug development, and the effect is greater for more prevalent rare diseases.[99] Even skeptics of the Orphan Drug Act generally conclude that it has done more good than harm.[100] There is dispute, however, about whether the Orphan Drug Act itself provides the primary incentives that induce the development of drugs that are brought to market. Robert Rogoyski, for example, argues that even for orphan drugs, patent incentives dwarf the incentives provided by the Orphan Drug Act, though he concedes that the Orphan Drug Act may have some effect in encouraging the introduction of drugs to market.[101] At the least, it serves "as a form of insurance" in the event that "patents are weak or invalidated through litigation."[102]

Many critics, meanwhile, argue that the Orphan Drug Act has in some instances provided protection that was unnecessary to induce drug development. These critics note that some orphan drugs have earned more than $1 billion per year, suggesting that they could have been developed even without an orphan designation.[103] Based on concerns about blockbuster orphan drugs, both houses of Congress approved the Orphan Drug Amendments of 1990,[104] which would have allowed shared exclusivity in certain circumstances, for example when

---

[98] Maeder, *supra* note 90, at 87. *See generally* Mae Thamer, Niall Brennan & Rafael Semansky, *A Cross-National Comparison of Orphan Drug Policies: Implications for the U.S. Orphan Drug Act*, 23 J. HEALTH POL., POL'Y & L. 265 (1998) (comparing different countries' approaches).

[99] *See* Wesley Yin, *Market Incentives and Pharmaceutical Innovation*, 27 J. HEALTH ECON. 1060, 1073 (2008); *see also* Daron Acemoglu & Joshua Linn, *Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry*, 119 Q.J. ECON. 1049, 1049 (2004) (finding that increased market size increases research and development).

[100] *See, e.g.*, Alan M. Garber, *Benefits Versus Profits: Has the Orphan Drug Act Gone Too Far?*, 5 PHARMACOECONOMICS 88, 91 (1994) (concluding that despite a tendency of the Orphan Drug Act to contribute to health care inflation, the Act still should not be overhauled).

[101] *See* Robert Rogoyski, *The Orphan Drug Act and the Myth of the Exclusivity Incentive*, 7 COLUM. SCI. & TECH. L. REV. 1, 22 (2006).

[102] *Id.*

[103] *See, e.g.*, Maeder, *supra* note 90, at 82 ("Several orphan drugs — notably epoetin alfa [Epogen], which builds up red blood cells — have now become blockbusters, leading critics to question whether drug companies are abusing the Orphan Drug Act."). The FDA refused to revoke the market exclusivity for Epogen, concluding that in 1989 it had correctly determined that the patient population was under 200,000, because fewer than 200,000 patients had been diagnosed, even though subsequent diagnoses led to a great increase in the patient population. *See* Lawton, *supra* note 94, at 337–38 (citing Letter from Ronald G. Chesemore, Assoc. Comm'r for Regulatory Affairs, FDA, to Joseph T. Sobota, M.D., Chugai-Upjohn, and Bruce M. Eisen, Genetics Inst. (Jan. 11, 1991)).

[104] H.R. 4638, 101st Cong. (1990); S. 2576, 101st Cong. (1990).

subsequent applicants rapidly initiated their own clinical trials.[105] The Amendments would have also allowed FDA revocation of exclusivity were the population of potential consumers to grow beyond the 200,000 threshold.[106] President George H.W. Bush, however, vetoed the bill, worried that permitting multiple winners of a race to develop orphan drugs would decrease development incentives.[107]

One strategy that pharmaceutical companies have used to obtain potentially unnecessary Orphan Drug Act protection is to design studies so that drugs will be indicated only for a small segment of the population. Later, the companies may seek through additional testing to have the drugs, already guaranteed exclusivity, approved for other groups.[108] Commentators often refer to this strategy as "salami slicing," and as Patricia Kenney explains, "companies can use the exclusivity provision . . . to create an unintended windfall and a barrier to innovation."[109] Empirical studies suggest that at least some research and development after "salami slicing" would have been conducted even absent the Orphan Drug Act.[110]

To try to prevent drug makers from receiving Orphan Drug Act protection by arbitrarily specifying a small subset of the real patient population, the FDA requires an explanation for why the drug seems likely to work better for that subset.[111] But it is not uncommon for a drug to be particularly beneficial for one group, and the FDA will not generally reject an orphan drug application merely because a drug might also be helpful to some other segment of the population that would push the class of potential consumers above the Act's population threshold. The phenomenon of indicating a drug for a small segment of the population is likely to become more frequent with the development of pharmacogenomic technology that targets particular patients based on their genes, because that technology will likely make

---

105 *See id.* § 3(a).

106 *See id.* § 2(b).

107 *See* Lawton, *supra* note 94, at 343 (discussing this and other reasons for the veto).

108 In addition, "once a drug has obtained marketing approval for a particular indication, it subsequently may be prescribed for any number of diseases or conditions." David B. Clissold, *Prescription for the Orphan Drug Act: The Impact of the FDA's 1992 Regulations and the Latest Congressional Proposals for Reform*, 50 FOOD & DRUG L.J. 125, 134 (1995).

109 Patricia J. Kenney, *The Orphan Drug Act — Is It a Barrier to Innovation? Does it Create Unintended Windfalls?*, 43 FOOD DRUG COSMETIC L.J. 667, 678 (1988).

110 *See* Wesley Yin, *R&D Policy, Agency Costs and Innovation in Personalized Medicine*, 28 J. HEALTH ECON. 950, 959–60 (2009).

111 21 C.F.R. § 316.20(b)(6) (2010) (requiring "[w]here a drug is under development for only a subset of persons with a particular disease or condition, a demonstration that the subset is medically plausible"). "This requirement exists to prevent an applicant from unduly restricting the cited orphan disease prevalence or unnecessarily subdividing its characteristics into artificial and medically implausible subsets, thus creating unreasonable market niches that allow the applicant to reach the prevalence threshold." Paul V. Buday, *Hints on Preparing Successful Orphan Drug Designation Requests*, 51 FOOD & DRUG L.J. 75, 80–81 (1996).

it easier to identify discrete subsets of the potential patient population that might especially benefit from drugs.[112] One commentator anticipates the possibility that pharmacogenomic orphan drug applications will flood the FDA and "slow down the application process for all drugs,"[113] and therefore argues that Congress should create a separate regulatory structure to incentivize pharmacogenomic drugs.[114] In short, as one critic observed: "[T]he Act is overinclusive. The Act extends the benefits of orphan status to drugs that would be profitable without the incentives."[115]

Salami slicing, meanwhile, is not the only problem. Additionally, because the Act refers only to the number of patients in the United States, it also may grant unnecessary protection when there are large numbers of patients outside the United States, as is the case for some drugs that treat parasitic diseases.[116] The result of unnecessary protection is unnecessarily high prices for consumers.[117]

What the literature does not address is that the Act is also underinclusive. Some drug candidates will not be developed because neither the patent statute nor the Orphan Drug Act provides enough of an incentive for companies to do so. Roin makes this point about the patent laws,[118] and in a footnote he notes that the Orphan Drug Act provides an occasional means of encouraging drug development.[119] But he does not explore the possibility of expanding the Orphan Drug Act to address concerns about insufficient incentives to develop unpatentable drugs.

A simple illustration of the underinclusiveness of the Orphan Drug Act can be seen in the current crisis over the impending absence of antivenom for coral snake bites, which affect about 100 people per year.[120] Wyeth, the manufacturer of the current antivenom treatment, stopped production several years ago because it was unprofitable.

---

112 "Pharmacogenomics might allow drug sponsors to nudge salami slicing from the arena of medical judgment towards the arena of scientific fact." David Loughnot, *Potential Interactions of the Orphan Drug Act and Pharmacogenomics: A Flood of Orphan Drugs and Abuses?*, 31 AM. J.L. & MED. 365, 374 (2005).

113 Dov Greenbaum, *Incentivizing Pharmacogenomic Drug Development: How the FDA Can Overcome Early Missteps in Regulating Personalized Medicine*, 40 RUTGERS L.J. 97, 126 (2008).

114 *See id.* at 126–27.

115 Cynthia A. Thomas, *Re-Assessing the Orphan Drug Act*, 23 COLUM. J.L. & SOC. PROBS. 413, 414 (1990).

116 *Id.* at 429.

117 High prices have generated some controversy even for drugs that appear to have been induced by the Act's protections. Industry advocates insist that drug companies charge much less than they could. *See* Maeder, *supra* note 90, at 86. Nonetheless, public concern about orphan drug pricing has risen with more general concern about pharmaceutical prices. *See, e.g.*, Carolyn H. Asbury, *The Orphan Drug Act: The First 7 Years*, 265 JAMA 893, 896–97 (1991).

118 Roin, *supra* note 12, at 515–56.

119 *Id.* at 552 n.259.

120 *See* Glenn Derene, *The Venom Crisis*, POPULAR MECHANICS, June 1, 2010, at 26.

Supplies are currently running low, so future victims may need to be intubated on ventilators for weeks, potentially at a cost of hundreds of thousands of dollars per treatment.[121] An alternative candidate treatment, Coralmyn, exists, but the snake bites are sufficiently rare that it appears the manufacturer does not want to pay the several million dollars that it would likely cost to test the treatment. It is possible that for some hypothetical long term of exclusivity, the manufacturer would be willing to bear these costs, but the Orphan Drug Act does not allow extra-long terms of exclusivity for especially rare diseases.

The absence of proposals to extend Orphan Drug Act protection may seem sensible given both political and practical constraints. Congress's recent concern that the Orphan Drug Act has extended too much protection renders unlikely congressional action to allow even more overinclusivity. Thus, extending the term or simply changing the threshold patient population size to a number greater than 200,000 seems undesirable. Meanwhile, the FDA already has the authority to approve orphan drug status for drugs targeting more than 200,000 patients, and so no additional legislation is needed to allow the FDA to ignore this threshold. Apparently, the FDA, already under criticism for approving drugs unnecessarily, is hesitant to invoke that power.[122] Ideally, the FDA should be more willing to grant an orphan drug designation the *less* likely clinical testing is to be successful, because the lower the ex ante probability of success, the greater the expected return companies will require when testing *is* successful. This logic places in an awkward position both the FDA and orphan drug status applicants, who will need to maintain that their plans are promising enough to justify testing on human subjects.[123] Even when the FDA correctly concluded that orphan drug status is necessary because success is unlikely, it would be criticized in the few cases in which clinical testing proved successful for having made a poor forecast.

2. Protection from Generic Competition. — Although Roin does not address the possibility that Congress might modify the Orphan Drug Act to increase the incentives for pharmaceutical companies to develop unpatentable drugs, he does identify another feature of drug law that lawmakers might easily modify to increase such incentives. After it approves a drug, the FDA cannot approve the same drug from

---

[121] Part of the problem may be that Wyeth charged less than $5000 for a basic course of treatment. *See* Keith Morelli, *Red Touches Yellow — Kills a Fellow*, TAMPA TRIB., May 24, 2010, at 1, *available at* http://www2.tbo.com/content/2010/may/24/na-red-red-touches-yellow---kills-a-fellow-touches. Perhaps Wyeth believed that price to be the most it could charge without suffering adverse public relations.

[122] *See supra* p. 1380 (noting that the FDA is similar to other agencies in preferring bright-line tests).

[123] *See* 21 C.F.R. § 50.25(a)(3) (2010) (noting that to obtain informed consent, each human subject must receive a description of the expected benefits of the treatment).

another manufacturer for five to seven and a half years.[124] Roin notes that the legislative history suggests that one justification for these regulatory delays may specifically have been to encourage development of unpatentable drugs.[125] This protection from generic competition is more inclusive than the Orphan Drug Act in that it applies to every drug, not just those intended for diseases with fewer than 200,000 patients or where the expenses of research and development cannot be recouped. The concerns about the Orphan Drug Act's overinclusiveness thus have an even more powerful analogue here; some firms may have been willing to go through the clinical trial process even without these built-in regulatory delays.

At the same time, however, this form of protection is considerably weaker than that provided by the Orphan Drug Act in one respect: generic manufacturers can still enter the market if they furnish their own clinical testing data,[126] whereas the Orphan Drug Act has no such exception. Thus, the built-in regulatory delays still leave a significant danger that bringing drugs to market will be an orphan business model. If the problem is not merely the *expense* of trials, but also the *risk* that trials may fail, a second mover may free ride on the information from successful clinical tests by beginning its own. In sum, regulatory delays can potentially ameliorate the problem of orphan business models for drugs other than the select few targeted by the Orphan Drug Act, but in other respects the mechanism suffers more from both overinclusion and underinclusion than the Act.

3. Encouragement of Generic Competition. — Ironically, the final area of drug law that reflects concerns about orphan business models has the opposite goal of delaying generic competition. Under the Hatch-Waxman Act, a generic drug company that challenges the patent protecting a pioneer drug receives a 180-day exclusivity period,[127] meaning that no other generic drug manufacturer can enter the market during that time. The goal is thus to accelerate generic competition. The authorized generic manufacturer can charge considerably above marginal cost, allowing it to earn a profit and providing it an incentive

---

[124] *See* 21 U.S.C. § 355(c)(3)(E) (2006). Roin details the calculation of the waiting period. *See* Roin, *supra* note 12, at 565 n.332.

[125] Roin, *supra* note 12, at 566 n.333 (citing H.R. REP. NO. 98-857, pt. 1, at 29 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2662). Roin further adds that "scholars and policymakers have (until now) been unable to identify categories of unpatentable drugs that would justify the delays." *Id.* The Orphan Drug Act has long been understood to be justified by the desire to encourage development of unpatentable (as well as patentable) drugs, but Roin is correct that scholars have not generally noted that regulatory delays serve a similar purpose.

[126] As Roin notes, "generic companies can bypass the FDA-enforced exclusivity periods by submitting their own clinical-trial data." Roin, *supra* note 12, at 566 n.332.

[127] The 180-day exclusivity period applies only when the generic manufacturer justifies filing an Abbreviated New Drug Application on the ground "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug." *Id.* § 355(j)(2)(A)(vii)(IV).

to challenge pioneer patents. In the absence of this protection, Congress worried that a generic drug manufacturer might have insufficient incentives to undertake the risk of filing an Abbreviated New Drug Application and weathering patent litigation against a party that will have much more at stake than it does. Each generic manufacturer would want to free ride on the litigation efforts of others, and often, none would have sufficient incentive to challenge the patentee.

That the drug laws serve opposing goals in providing incentives for orphan business models does not mean that those laws are necessarily in tension. Congress is willing to grant the relatively long term associated with a patent only to a relatively small class of drugs, relegating those that do not meet the requirements of patentability to rely on the Orphan Drug Act or regulatory approval delays. Patent litigation is a component of the regulatory system that helps ensure that drugs that are not entitled to patent protection do not receive it, and Congress was concerned that incentives to engage in patent litigation might be inadequate. Thus, just as the Orphan Drug Act reflects concern that few would be interested in launching a business if the first step were expensive regulatory approval and success would allow everyone to enter, so too does the Hatch-Waxman Act reflect concerns when the first step is expensive litigation. The existence of laws reflecting orphan business model concerns to both discourage and encourage generic entry reinforces that where property rights are sufficiently valuable, and where entry into a market is particularly expensive and prone to free-riding, some form of exclusivity protection is likely to emerge. The problem of free-riding on litigation is, of course, a much more general one,[128] and some scholars have proposed general incentives to challenge invalid patents,[129] but Congress has focused on the problem only in one area where the social costs of not providing protection are especially apparent.

The example of the Hatch-Waxman Act, however, also illustrates that poorly designed orphan business model protections may fail to advance the goals of those who create them. The stakes are sufficiently high for pioneer drug manufacturers to identify and exploit loopholes. And loopholes they have found. The most infamous involves "reverse payments" — settlements where the generic manufacturer delays market entry in exchange for cash.[130] Though it is possible to de-

---

[128] *See* Steven Shavell, *The Level of Litigation: Private Versus Social Optimality of Suit and of Settlement*, 19 INT'L REV. L. & ECON. 99, 99–100 (1999) (noting that incentives to sue may be socially suboptimal because others benefit from the deterrence provided by lawsuits).

[129] *See, e.g.*, John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 340–42.

[130] *See, e.g.*, Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, 4 INNOVATION POL'Y & ECON. 145, 165–68 (2004); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New*

fend such settlements,[131] they clearly seem inconsistent with the legislative intent of encouraging generic entry. Another loophole, under which pioneer drug manufacturers took advantage of a provision allowing a thirty-month stay of generic entry during patent litigation by using multiple patents to obtain repeated thirty-month stays, was closed by later legislation.[132] Another bug in the original legislation started the 180-day clock running as soon as a court decision was issued, even though generic entry would often be stayed pending appeal.[133] Finally, pioneer drug manufacturers have licensed authorized generics to compete with the generics entitled to the 180-day period of exclusivity, cutting the profits from exclusivity by about eighty percent and deterring future patent challenges.[134]

Although these statutory design bugs involve technical issues specific to drug law, they highlight some general points about the design of orphan business model protections. First, statutes should anticipate side deals by parties whose interests the statutes would harm. For example, in order to regulate such side deals, the Hatch-Waxman Act might have tolerated settlements between generic challengers and pioneer drug manufacturers, but required that any such settlements affect only the date of generic entry and not involve exchanges of money or other consideration. Second, statutes should identify any actions that would terminate one litigant's exclusivity and give others the opportunity to receive exclusivity. A decision to stop pursuing invalidation of a patent should presumably qualify, allowing others to pursue litigation. A pioneer drug manufacturer may be willing to pay "greenmail"[135] only so many times. Third, the statutes should carefully delin-

---

Data and Rulemaking to Preserve Drug Competition, 109 COLUM. L. REV. 629, 634–41 (2009) [hereinafter Hemphill, *An Aggregate Approach*]; C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1557 (2006).

131 "The most fundamental [defense] is that permitting settlement increases the brand-name firm's profit, and hence its expected reward for developing innovative drugs . . . ." Hemphill, *An Aggregate Approach*, *supra* note 130, at 637.

132 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 21 and 42 U.S.C.), *amended by* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified in scattered sections of the U.S. Code). *See generally* Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309 (2005).

133 For a discussion of amendments that eliminated this bug, see John R. McNair, Note, *If Hatch Wins, Make Waxman Pay: One-Way Fee Shifting as a Substitute Incentive to Resolve Abuse of the Hatch-Waxman Act*, 2007 U. ILL. J.L. TECH. & POL'Y 119, 126–27 & n.69.

134 *See* NARINDER S. BANAIT, FENWICK & WEST, AUTHORIZED GENERICS: ANTITRUST ISSUES AND THE HATCH-WAXMAN ACT 4 (2005), http://www.fenwick.com/docstore/publications/IP/Authorized_Generics.pdf; *see also* Beth Understahl, Note, *Authorized Generics: Careful Balance Undone*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 355, 374–77 (2005).

135 In the corporate context, "greenmail" consists of payments by a target of an acquisition attempt to the potential acquirer in exchange for ceasing the attempted takeover. For a discussion

eate the scope of the exclusivity. Hatch-Waxman, for example, likely should have specified that authorized generics were prohibited, but in the absence of a specific statement to that effect, the courts concluded otherwise, recognizing the general power of a patent holder to license and market inventions.[136] Fourth, the term of exclusivity, including the identification of which events can toll the statute of limitations, should be clear.

Those design features do not necessarily mean, however, that the term should be of fixed length. Indeed, the history of the Hatch-Waxman Act shows that the fixed 180-day term is likely longer than necessary in some cases to induce litigation. One problem that the FDA faces is that, sometimes, two or more generic manufacturers file Abbreviated New Drug Applications on the same day. These cases are no coincidence, but occur when there is a clear first day on which such challenges could be filed.[137] In those cases, 180 days is an unnecessarily large incentive. The FDA and later congressional response — to allow shared exclusivity — may address this problem in part by effectively reducing the size of the reward in such cases, but it is a crude solution. And, of course, 180 days may be too short a period of exclusivity in other cases to justify the burdens of filing the first Abbreviated New Drug Application and undertaking litigation risk. Section III.A considers the possibility of a term not fixed by statute.[138] First, however, we will consider other possible reforms to the various protections of orphan business models in the drug laws.

B. Potential Reform Paths

1. Longer Protection Term. — Perhaps the simplest reform to reduce problems of orphan business models in the drug context would be to lengthen the relevant periods of exclusivity. There has been renewed media attention given to the relatively limited incentives that drug companies have to develop their products through the FDA approval process,[139] and extending the term of the Orphan Drug Act

---

of greenmail, see generally Jonathan R. Macey & Fred S. McChesney, *A Theoretical Analysis of Corporate Greenmail*, 95 YALE L.J. 13 (1985).

136 *See, e.g.*, Teva Pharm., Indus. v. FDA, 355 F. Supp. 2d 111, 117 (D.D.C. 2004).

137 *See* CTR. FOR DRUG EVALUATION & RESEARCH, U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAS ARE SUBMITTED ON THE SAME DAY 4 (July 2003), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072851.pdf ("Same day patent challenges generally occur when the expiration of 4 years of a 5-year exclusivity period under section 505(j)(5)(D)(ii) permits submission of ANDAs containing a paragraph IV certification as of a specific date, and multiple applicants vie to be first to make such a submission."); *id.* (identifying a separate scenario in which applicants also submit applications on the same date).

138 *See* section III.A, pp. 1396–1407.

139 *See, e.g.*, Sharon Begley & Mary Carmichael, *Desperately Seeking Cures; How the Road from Promising Scientific Breakthrough to Real-World Remedy Has Become All but a Dead End*,

might improve incentives. Roin, meanwhile, proposes that the regulatory delay term be lengthened "to somewhere between ten and fourteen years," noting that this change would "at least provide a rough substitute for patent protection" and "eliminate the distortions arising from the novelty and nonobviousness requirements."[140] Similarly, once the problems in the Hatch-Waxman Act are ironed out, if there is still inadequate incentive to seek invalidation of patents, Congress could extend the 180-day exclusivity period afforded to the first generic. These solutions might well be justified compared to the alternative of doing nothing. But a significant drawback of each proposed solution is that it would lead to more protection in cases in which that protection is not needed, just as extending the patent term would induce more discoveries but also lead to protection in some cases where it would not be necessary. In addition, the terms might still be too short for some orphan business models.

2. Ceilings on Exclusivity Based on Inputs or Success. — The problem of unnecessary protection could be combated by placing ceilings on profits earned by drug manufacturers. This strategy has been debated and proposed in the context of the Orphan Drug Act,[141] and it could be adopted in conjunction with a strategy to increase the available protection term. A statistical justification for this approach is that the distribution of sales of approved orphan drugs is highly skewed, with a small number of orphan drugs accounting for a high percentage of overall revenues.[142] A ceiling could thus be set at a relatively high level and would likely affect only a relatively small number of orphan drugs. A similar approach could be used for generic exclusivity under the Hatch-Waxman Act, with the period of generic exclusivity ending after some revenue (or, harder to measure, profit) threshold is reached.

This approach, however, works poorly if the goal is to encourage clinical testing on a drug that has only a small chance of being successful but a large impact if successful. The Orphan Drug Act, after all, is designed to give incentives where there is some probability of failure; if it were certain that a drug would be successful and approved, there would be little need for an expensive approval process. High revenues

---

NEWSWEEK, May 31, 2010, at 38, 39 (arguing that "potential cures, or at least treatments, are stuck in the chasm between a scientific discovery and the doctor's office: what's been called the valley of death"). Sharon Begley and Mary Carmichael tell the story of a researcher who has been unable to develop what he believes is a possible cure for osteoporosis because he is unable to obtain a patent. *See id.* at 40.

140 Roin, *supra* note 12, at 567.

141 *See* 136 CONG. REC. 20,901 (1990) (statement of Rep. Fortney Hillman "Pete" Stark, Jr.); *see also* Gary A. Pulsinelli, *The Orphan Drug Act: What's Right with It*, 15 SANTA CLARA COMPUTER & HIGH TECH. L.J. 299, 336 (1999).

142 Sheila R. Shulman et al., *Implementation of the Orphan Drug Act: 1983–1991*, 47 FOOD & DRUG L.J. 363, 379–80 (1992) (noting skewed distribution of sales).

may indicate that there was more than enough incentive to develop the treatment even absent the Orphan Drug Act, though that conclusion raises the question why no one developed the drug earlier.[143] It may be that the treatment was simply thought to have only a small probability of success, in which case the large revenues in the event of success may be a necessary inducement.

An additional problem is that a revenue limitation amounts to a price control, and the usual drawbacks of price controls apply.[144] Facing an artificially limited profit potential, a manufacturer might not market the drug even if many doctors and patients do not know of its existence, or a manufacturer might decide to cut back on quality controls to save money.[145] More relevantly from this Article's perspective, a manufacturer of an orphan drug will only have incentives to seek approval to market the drug to additional groups of the patient population when expected revenues are below the threshold at which exclusivity will be lost. Once the manufacturer is sure to make the maximum amount of money permitted before exclusivity is lost, the problem of orphan business models arises again, as the manufacturer will have no incentive to seek FDA approval for additional patient subpopulations. There are potential solutions: perhaps other manufacturers could be given a chance to seek approval. Such solutions, however, would tend to undercut the scope of the Orphan Drug Act's protection more generally, so that the protection would no longer extend to a drug, but only to a particular use of a drug.

Similar critiques apply to proposals that seek to tailor the protection to the amount spent on research and development (or, in the case of Hatch-Waxman, the amount spent on prosecuting an Abbreviated New Drug Application and on patent litigation). This expenditure-based limitation is in effect equivalent to setting higher maximum revenue thresholds when a drug manufacturer has invested more in the clinical trial process, and this approach may be an improvement on a plan to set a fixed threshold. But in focusing on one variable — the expense of the process — this proposal ignores another equally important, but much harder to measure, variable: the probability that efforts will be successful. Meanwhile, if the system is not administered well,

---

143 There may be an answer: for example, a recent scientific discovery that made a treatment seem more likely to be successful than before. *Cf.* WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 304 (2003) (noting that when an exogenous shock occurs, simultaneous invention is common).

144 For a discussion of a past legislative attempt to enact a windfall profit tax on oil, see Eric Kades, *Windfalls*, 108 YALE L.J. 1489, 1546–52 (1999).

145 One commentator sees an analogous effect as potentially beneficial: "A ceiling on the length of exclusivity would induce companies to keep costs down, knowing that at some level the marginal benefit of additional research expenditures will not be reflected in the length of exclusivity." Greenbaum, *supra* note 113, at 136.

it may lead to inefficient expenditures. If, for example, firms are allowed some multiple of what they invest in the clinical trial process, and a pharmaceutical company is confident that it will succeed in clinical trials, it may spend unnecessarily high amounts of money on clinical trials to get a longer exclusivity term.

3. Administrative Discretion. — An alternative remedy would be for the government to exercise greater discretion, perhaps by offering longer terms when research and development is more expensive or when it seems less likely to succeed. Roin, for example, notes that protection terms "could be tailored in accordance with the varying R&D costs and risks of different drugs."[146] The extent to which this approach is an improvement depends, of course, on the performance of the agency charged with making these assessments. It is possible, for example, that the agency might systematically err in one direction, such as by granting longer terms than are necessary. This bias seems especially plausible if such decisions, like current ones, are made ex parte.[147] Or the agency might err in particular cases, for example by overestimating or underestimating the chance that a particular set of clinical trials would be successful. One potential contributor to misestimation is that the applicant is placed in an odd position: it must argue that its plans have a sufficient chance of success to justify the launching of human trials, but a relatively low chance of success to garner a long protection term.[148]

Another problem is that the FDA may lack institutional competence to make such assessments. Such assessments depend on many empirical considerations, including the cost of testing, the probability of a successful outcome, the level of consumer demand, and the potential existence of competing products. A commentator on the Orphan Drug Act notes: "Predicting which drugs will be profitable during the developmental stages is difficult. Using the size of the patient population does not always work."[149] Presumably, the FDA's general reliance on the 200,000 patient threshold reflects its greater comfort in administering tests that require it to make medical determinations rather than

---

[146] Roin, *supra* note 12, at 568; *see also id.* ("Longer and more expensive clinical trials likely require more protection, whereas shorter and cheaper trials could be motivated by a briefer period of exclusivity."). Roin notes that the FDA is likely to be institutionally more capable than the PTO of making judgments about extending term and that it is better positioned to prevent unnecessary races to run clinical trials, because it must authorize such trials. *See id.*

[147] Thomas, *supra* note 115, at 437 ("The application for orphan designation is a confidential, ex parte procedure. The FDA gives neither other researchers nor groups interested in the disease notice of pending applications, nor does the FDA grant them an opportunity to present their views on whether the proposed drug deserves orphan status."). Cynthia Thomas argues that the FDA should make decisions through notice-and-comment procedures. *See id.* at 438–40.

[148] *See supra* p. 1388.

[149] Kenney, *supra* note 109, at 675.

economic forecasts. Ideally, the term of orphan drug protection would be variable, but the length of the term would not depend on the caprice of a governmental decisionmaker.

III. New Approaches to Intellectual Property Protection for Orphan Business Models

The goal of achieving variable terms without government intervention motivates two different potential approaches to providing intellectual property protection for orphan business models. The first approach involves an auction design, with the exclusive right granted to the company offering the shortest term, but with the initial proponent of protection receiving some advantage as a reward for developing the initial proposal. This approach addresses several structural challenges with the proposals considered above: their tendency to be over- or under-inclusive, the strategic behavior of drug manufacturers, and the limits of government officials in exercising discretion. The second approach involves a bonding mechanism encouraging third parties to assess the probability that a business model would be tested even without protection. The applicant can choose a term without an auction but has an incentive to choose a relatively short term lest third parties conclude that the business model would be developed anyway within a longer proposed period.

A. Term Competition

1. The General Mechanism. — Providing orphan business model protection to the company willing to accept such protection for the shortest term, as summarized in the introduction,[150] would be straightforward in the pharmaceutical context. The first party willing to adopt an orphan business model in exchange for an exclusive right files an application. Depending on the context, this could be an Orphan Drug Act application or an Abbreviated New Drug Application. The purpose of these applications need not be to give regulators all the information that they would need to allow a new drug onto market. Rather, the applicant would need to establish that the relevant orphan business model is indeed an orphan business model. In the Orphan Drug Act context, this approach would require a showing that no other manufacturer is marketing the drug or taking it through clinical trials; in the Hatch-Waxman context, the applicant would need to show that no one else has yet challenged the validity of the pioneer drug patent.

---

[150] *See supra* p. 1369.

The applicant also would specify the protection term that it is requesting. The goal is to eliminate the arbitrary seven-year or 180-day terms specified in the respective acts, so the applicant might be able to request a longer term, though there might still be some statutory maxima (such as twenty years for the Orphan Drug Act and two years for Hatch-Waxman). The applicant also would need to provide some information about itself to demonstrate its preparedness to undertake steps to adopt the business model, for example by demonstrating its financial ability to carry out clinical trials or to undertake the patent litigation. Competitors would then be given some period during which to submit their own proposals to adopt the orphan business model, each proposal indicating the term sought and the investment its applicant will make if it receives the right. The original applicant and various competitors might then be allowed to revise their investment proposals based on those of others. The term proposals could be sealed, or applicants might be allowed to view the terms proposed by others and lower their own proposals if they deem it necessary.[151]

The agency's task would then be to choose the best proposal, but to give some incentive to be the first applicant, who must alone bear the cost of filing the original application.[152] One possible implementation, involving relatively little administrative discretion, would be for the agency to consider the proposal for the shortest term first, but apply some statutorily specified discount to the first applicant's requested term. So, if the discount were thirty percent and the first applicant requested ten years and the second applicant requested eight years, the first applicant's application would be considered first. If that applicant demonstrated a sufficient commitment to pursuing the orphan business model — for example, by promising to spend at least a certain amount of money on trials or, in the Hatch-Waxman context, to hire a qualified law firm — then its application would be accepted. Otherwise, the agency would look to the next application. In an alternative regime, requiring more discretion, the agency would simply consider all applications and choose the best one, allowing the first applicant a substantial, but not mathematically determined, advantage.

---

[151] If sealed bids are used and the government chooses the shortest exclusive right meeting some minimum investment criteria, then the exclusive right granted should be equal to the shortest exclusive term offered among the unsuccessful bidders. The resulting dynamic is akin to a Vickrey auction and ensures that each bidder will bid the shortest exclusive term it can afford. *Cf.* William Vickrey, *Counterspeculation, Auctions, and Competitive Sealed Tenders*, 16 J. FIN. 8, 24 (1961).

[152] Preparing an Orphan Drug Act application can be expensive. *See* Buday, *supra* note 111, at 83 ("For sponsors to succeed in gaining designation awards, considerable library and in-house research and documentation, as well as clear, expositive, and enthusiastic replies and answers to the information sought by the FDA are needed.").

If the advantage to the first applicant is measured as a specific percentage or in some other quantifiable way, it would still be possible to design a system that would eliminate the need for the legislature to determine the precise amount measured. The core insight of the auction can be applied recursively. So, for a particular drug, there could first be an auction for the duty to write the proposal, and the winner of that auction would be the party that agrees to write the proposal for drug testing in exchange for the smallest advantage in the second auction. For example, a first-auction bidder who offers to write the proposal if a ten percent discount would be applied to its bid for an exclusivity term in the second auction would defeat a first-auction bidder who insists on a twenty percent discount, because the ten percent discount would be less of an advantage than a twenty percent discount. Of course, either the government would then need to initiate the first auction, or some smaller advantage would be needed as an incentive for a private party to initiate the auction. Because specifying the drug, however, is likely less work than explaining what testing of that drug is required, less of an inducement, if any, will be necessary. This recursive approach may be more complicated than is necessary, but it helps illustrate the logic underlying the auction proposal.

Nonetheless, the agency will still need to exercise some discretion. (Later, we will consider a decentralized approach that would eliminate the need for governmental discretion.[153]) Specifically, it must determine whether a bid is a serious one. One would not want a bidder to be able to submit a bid for a very short term and hold on to the right as an option to proceed with further development. This burden, however, is not new; the agency must already ensure that proposals are serious today. Moreover, this is a far simpler task than that of figuring out the minimum term length needed to induce development. The agency need merely monitor to assure itself that the bidder is proceeding with implementation. Monitoring need not be complicated. An Orphan Drug Act rightsholder would be expected to document that it was proceeding with trials, and a Hatch-Waxman applicant, that it was proceeding with litigation. In any event, the agency need not perform this monitoring itself. Rather, the statute could provide that a new application may be filed by any party when a previous recipient of an exclusive term failed to meet the obligations to which it committed.[154] At that point, the agency could adjudicate in an adversarial proceeding whether the award process should begin anew. Challenging an awardee is an expensive process on which others might free

---

[153] *See infra* section III.B, pp. 1408–21.

[154] This mechanism would require public release of both the initial application and information needed to show compliance.

ride, but the successful challenger would receive the advantage of being a first applicant in the new bidding process if the right were taken away from the initial awardee.

One slight complication for term competition may occur when the scope of the right is potentially ambiguous. In an Orphan Drug Act application, for example, an applicant might seek to adopt only a particular compound or a set of closely related compounds. Allowing a relatively broad scope may be justified when clinical testing on one compound produces information about whether a closely related compound will likely also be effective, and it may be important to protect the adopter of the orphan drug from another party's free-riding on the result of clinical trials. But the FDA already faces this problem, when it determines whether a new drug is the "same drug" as one already approved for exclusivity.[155] In theory, the FDA might apply its current definition of sameness to solve this problem and also continue its policy that "if the subsequent drug can be shown to be clinically superior to the first drug, it will not be considered to be the same drug."[156] Often, though, it may be useful to resolve such issues ex ante, and the original applicant might be expected to identify any situation in which there might be a case for more expansive scope than is ordinarily permitted, allowing the agency to make an early determination.[157]

An additional complication is the question of what occurs if the agency receives only one (or perhaps even only two) bids, giving rise to the concern that there might be insufficient competition for the agency to be confident that it has given away the right at the lowest possible term. An absence of competition is particularly likely if the first applicant is viewed by others as likely to be unbeatable given the statutory advantage that it receives. A rule providing for publication of bids and preventing the first applicant from lowering its bid later in the process would increase agency confidence in competition in the single-bid context. Under this approach, other applicants would presumably enter bids if they thought it possible to undercut the first applicant's bid by a sufficient amount. This structure presents a disadvantage for

---

[155] The courts generally have been willing to defer to the FDA on this issue. *See, e.g.*, Genentech, Inc. v. Bowen, 676 F. Supp. 301, 313 (D.D.C. 1987) (resolving a dispute, but indicating a willingness to defer to FDA determinations).

[156] 21 C.F.R. § 316.3(b)(13)(i) (2010).

[157] Some commentators have argued that the FDA has not done a good job of adjusting its inquiry to different categories of drugs. Professor Robert Bohrer suggests that the FDA's approach should depend on the type of drug, with that classification driving the breadth of a presumption that other substances will offer no significant clinical advantage and thus cannot be sold until after the orphan drug's exclusivity period is over. *E.g.*, Robert A. Bohrer, *It's the Antigen Stupid: A Risk/Reward Approach to the Problem of Orphan Drug Act Exclusivity for Monoclonal Antibody Therapeutics*, 5 COLUM. SCI. & TECH. L. REV. 1, 4, 20–21 (2003); *see also* Robert A. Bohrer & John T. Prince, *A Tale of Two Proteins: The FDA's Uncertain Interpretation of the Orphan Drug Act*, 12 HARV. J.L. & TECH. 365, 416 (1999).

the first applicant, but the built-in advantage for the first applicant could still sufficiently incentivize applying first. If this approach is viewed as potentially insufficient to address the concern of uncompetitive auctions, an agency might be given discretion to negotiate with the applicant deemed the best bidder when there are a small number of applications.

2. The Unconventionality of the Mechanism. — The term competition auction is admittedly an unconventional mechanism from the perspective of patent law in at least three ways. But each of these unconventional aspects highlights a significant difference between patents and exclusive rights to adopt orphan business models and thus helps to justify the exercise of conceiving of intellectual property rights tailored to those business models. First, assessments are made *before* the occurrence of what the intellectual property system seeks to induce. The patent law system seeks to induce inventions, yet assessments of the requirements of patentability are made *after* the conception of an invention.[158] Ex ante forecasts of the effects of granting patent rights are generally infeasible, because it will often be impossible to conceive of what might be invented before a process of technological experimentation. A resulting significant challenge in the patent context is evaluating incentives in hindsight.[159] By contrast, a system of intellectual property protection for orphan business models seeks to induce commercialization, and it is feasible to grant rights well before commercialization will occur. Currently, the Orphan Drug Act permits designations of orphan drug status to be made before completion of clinical investigations,[160] but the ultimate prize of exclusivity is not granted until the completion of clinical trials.[161]

Second, with exclusivity term competition, the party that applies for intellectual property protection is not necessarily the party that ultimately will receive such protection. This unconventional aspect follows directly from the previous one; because the party that files for orphan business model protection need not yet have expended the resources to commercialize the business model, that party need not receive the exclusivity protection. The social benefit is that the system gives competitors incentives to credibly reveal to the government that a long period of protection is not necessary. The original applicant should still receive some advantage in the process, lest there be insuffi-

---

158 *See* 35 U.S.C. § 112 (2006) (allowing filing of a patent after conception of the invention to serve as a constructive reduction to practice).

159 *See* Mandel, *supra* note 24, at 76–79 (discussing the hindsight problem in the context of the nonobviousness requirement).

160 21 U.S.C. § 360bb(a)(1) (2006) ("A request for designation of a drug shall be made before the submission of an application . . . .").

161 For a discussion of the effects of orphan drug races, see Kenney, *supra* note 109, at 675–77.

cient incentives to go through the work of applying, as each potential applicant would hope to free ride on the orphan business model applications of others. The logic underlying this point should be familiar: it is the general logic to justify intellectual property protection for orphan business models, with the business model now defined narrowly as the application for protection of another orphan business model.

Third, the term of protection is not fixed, but depends on the competition. This distinctive aspect also is possible as a result of the previous one. The competition among potential owners of the intellectual property right can be expected to create a kind of auction in which the winner is the company that agrees to undertake the relevant expenses for the shortest period of exclusivity.[162] Some patent scholars have proposed a variable term, with duration depending on any of a number of factors.[163] Objections to such proposals are that the decision-making process would become intractable and that the government would have too much discretion. Competition for exclusivity terms saves the government from the necessity of making optimal term calculations.

3. Extensions. — Could orphan business model protection rights be offered beyond the drug context? There are two possibilities: First, Congress might authorize additional regimes similar to the Orphan Drug Act for specific instances of what otherwise would be orphan business models. Second, Congress might create a full-fledged intellectual property system to offer exclusive rights for adoption of any orphan business models either within a specific domain (such as software) or across domains. The second is not likely to occur, if at all, until more targeted protections can be reformed to establish palpable social benefits and decrease currently extant controversy over false positives. A badly designed system of protection could do far more harm than good. This section seeks to explore how orphan business model rights might be offered in a limited way, potentially not covering some situations in which they could be useful but almost certainly not providing counterproductive protection.

Drug law addresses orphan business models because the stakes are sufficiently high that Congress believed it worthwhile to create a customized property rights protection regime. If Congress is to extend orphan business model protections over the coming decades, it is likely

---

[162] For a discussion of whether patents might be auctioned in a similar way, see Michael Abramowicz, *The Uneasy Case for Patent Races over Auctions*, 60 STAN. L. REV. 803, 847–49 (2007).

[163] *See, e.g.*, Eric E. Johnson, *Calibrating Patent Lifetimes*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 269, 292–93 (2006); Amir H. Khoury, *Differential Patent Terms and the Commercial Capacity of Innovation*, 18 TEX. INTELL. PROP. L.J. 373, 405–12 (2010); Frank Partnoy, *Finance and Patent Length* 27–38 (Univ. San Diego Sch. of Law, Law & Econ. Research Paper No. 19, 2001), *available at* http://papers.ssrn.com/abstract=285144.

to do so only in areas where the stakes seem similarly high. This section identifies some possibilities, though the specific contexts identified are of less significance than the general problems they are meant to illustrate.

(a) Nonappropriable Network Effects. — In the past two decades, the law and economics literature has considered the policy implications of "network effects," specifically where the fact that some people use a particular good or service makes that good or service more valuable to others.[164] For example, computer users may be more likely to choose an operating system that others also choose because of interoperability concerns. Much of the literature addresses the policy challenge of ensuring that such networks do not lead to abuse of monopoly power,[165] though the literature also recognizes that sometimes the existence of network effects means that centralized institutions could promote the development of such networks.[166] Promoting network effects will be most challenging when no private party can appropriate a portion of the benefits of the networks. If company *A* builds a network with which company *B* can interoperate, then the orphan business model problem arises. *A* may have insufficient incentives to make risky investments to build a network when competition from *B* will erode profits *A* otherwise would earn.

Consider the following example: the development of battery charging or switching stations for electric cars.[167] A principal challenge facing developers of all-electric cars is the absence of battery stations at which drivers can charge batteries or swap out near-empty batteries for full ones. Customers may have little incentive to buy electric cars in the absence of battery stations, and there may be little incentive to create battery stations until there are a sufficient number of customers. If a company invests in building large numbers of battery stations, it may jumpstart the electric car market, but then other companies may take advantage and open their own battery stations. If creating the network is sufficiently risky — for example, because electric cars may

---

[164] *See generally* Amitai Aviram, *Regulation by Networks*, 2003 BYU L. REV. 1179; David A. Balto, *Networks and Exclusivity: Antitrust Analysis to Promote Network Competition*, 7 GEO. MASON L. REV. 523 (1999); Mark A. Lemley & David McGowan, *Legal Implications of Network Economic Effects*, 86 CALIF. L. REV. 479 (1998); S.J. Liebowitz & Stephen E. Margolis, *Network Externality: An Uncommon Tragedy*, J. ECON. PERSP., Spring 1994, at 133.

[165] *See, e.g.*, Lemley & McGowan, *supra* note 164, at 496.

[166] *See* Bruce H. Kobayashi & Larry E. Ribstein, *Uniformity, Choice of Law and Software Sales*, 8 GEO. MASON L. REV. 261, 287–88 (1999) (noting this possibility but also noting that centralized institutions may not choose the optimal network). A counterargument is that inefficient standards may win a standards race, and collective action problems will prevent a better standard from emerging. *See id.*; Lemley & McGowan, *supra* note 164, at 497–98.

[167] *See, e.g.*, Nelson D. Schwartz, *In Denmark, Ambitious Plan for Electric Cars*, N.Y. TIMES, Dec. 2, 2009, at A1 (discussing difficulties in creating a sufficient number of charging stations for electric cars in Denmark).

fail to catch on for reasons other than an absence of battery stations — incentives may be too low even though it would be socially beneficial to try.

Theory cannot tell us, though, whether exclusivity is genuinely necessary or even whether it would be helpful. Similar problems have been overcome previously; we do, after all, have gas stations. Perhaps there will be a tipping point at which the development of electric cars becomes inevitable and entrepreneurs begin opening battery stations. Or, battery station owners may find other means of ensuring that their investments are appropriable, for example by patenting machines that can charge a particular type of battery. Patent law is a crude mechanism for achieving this goal, however. A patent will issue so long as such machines are nonobvious and meet the other requirements of patentability, but the most important investments might be opening battery stations rather than designing the machines. Moreover, if battery station owners are successful in using patent law to make the network effects appropriable, they may enjoy a term that is longer than necessary to induce building the network, and consumers may pay higher prices as a result.

Congress could solve the problem with a system similar to that suggested for the Orphan Drug Act above, but with the goal of creating a single exclusive right.[168] A statute (or regulation) might specify a minimum number of battery stations, which must be opened within a specified period of time, and could identify any characteristics such stations must meet, such as an ability to serve at least a specified number of motorists per day. Private firms would then offer to meet these requirements in exchange for an additional exclusivity period after the specified period of time. This description is, of course, a simplified account of such a regime, which would need to include means of assessing the bidders' ability to meet the promised goals and of assessing progress. But it is similar to familiar regimes of bidding for government contracts, with the exception that the winning bidder receives an exclusivity period instead of government money.

The approach described above suggests that government subsidies will often be an alternative approach to encouraging development of orphan business models. But an advantage of the approach described here is that there is a smaller cost associated with the risk that the government will overestimate the benefits of the network. In a standard government subsidy arrangement, the government might spend $100 billion to build battery stations, which would be wasted if other

[168] Ideally, such a decision would be made at an international level, but it seems unlikely that existing intellectual property coordination systems could easily be harnessed to create a property right quite different from existing ones, at least until such rights become commonplace in individual countries.

impediments prevent the development of the electric car. With the orphan business model approach, private sector judgments can serve as an additional check on the government's positive view of the business model, because if private actors expect the battery stations to be a waste, no one will bid. Meanwhile, the framework might allow the winning bidder to back out, for example, after paying some penalty, should the market appear not to be as promising as previously thought. At that point, the government might hold a new auction to find a new company willing to adopt the orphan business model, if such a company exists.

(b) Long Time Horizons. — An exclusive right of just a few years might someday sufficiently incentivize the building of a network of battery stations, but in other situations even the current twenty-year length of the patent term may be insufficient to spur needed research and commercialization. Consider, for example, proposals to build machines that would remove carbon dioxide from the air to offset global warming.[169] It is not clear whether such machines could ever be made sufficiently cost-effective to have a significant impact on global warming, making any private research risky. Suppose, however, that against all odds, a company succeeded in developing such a machine. This development would considerably lessen concerns about global warming, and governments might retrench on efforts to tax or cap carbon emissions. Unless catastrophe is imminent, potential users of the carbon removal technology might wait for it to enter the public domain to purchase it. The time between the present and when global warming is expected to cause major problems is likely greater than the length of the patent term,[170] so patent incentives to reverse global warming may be absent.

In this case, an orphan business model exclusive adoption right again could be helpful. The government might set a minimum amount of research and development that the recipient of such a right would need to invest as a condition of retaining the right. It would then award the exclusive right to the company willing to engage in this amount of research for the shortest term of exclusivity, even if that term were fifty or sixty years. A risk of this approach, though, is that the government might set the required investment at too low a number, making real progress unlikely, or too high a number, resulting in

---

169 *See, e.g.*, Klaus S. Lackner, *Washing Carbon Out of the Air*, SCI. AM., June 2010, at 66–67.

170 Many of the serious anticipated effects of climate change noted by the Intergovernmental Panel on Climate Change are expected to begin by mid-century. *See* Intergovernmental Panel on Climate Change, *Summary for Policymakers*, *in* CLIMATE CHANGE 2007: IMPACTS, ADAPTION AND VULNERABILITY 7, 11–18 (Martin Parry et al. eds., 2007), *available at* http://www.ipcc.ch/publications_and_data/publications_ipcc_fourth_assessment_report_wg2_report_impacts_adaptation_and_vulnerability.htm.

terms longer than necessary to accomplish the desired result. An alternative is for the government to set the term and grant the right to the company willing to invest the most in research and development. The government should do this, however, only if it is relatively confident that sufficient research and development activity would not occur in the absence of the exclusive rights incentive.

(c) Deregulation and Reregulation Incentives. — Orphan business models may also merit property rights protection where the principal obstacle to development is that government regulation may impede progress. Take, for example, supersonic jet travel. An obstacle to the development of new supersonic jets is the existence of regulations that prevent supersonic travel over land.[171] To succeed both technologically and legally, the prospective developer of a jet design that would reduce sonic booms[172] must persuade Congress or the Federal Aviation Administration to permit certain types of supersonic jet aircraft. The problem is that given such success, other jet designers may invent other forms of sonic boom reduction technology and free ride on the lobbying efforts of the first manufacturer.

An orphan business model protection scheme might involve an auction of an exclusive right to sell supersonic aircraft, either to the firm that promises to commit at least a specified amount of money to research in exchange for the shortest exclusive right or to the firm that promises to commit to conducting the most research in exchange for a fixed exclusivity period. Congress might create such a scheme as a less drastic step than immediately removing regulatory impediments to supersonic travel. This might make sense if the policy question depends in part on the quality of technology developed, and if there is no easy way ex ante to specify minimal technical standards that must be achieved. In creating such a scheme, Congress does not promise deregulation, but it gives some firm an incentive to create a technology that can persuade Congress to ease the regulation.

The example, meanwhile, illustrates a potential hazard of orphan business model protection: it could produce undesirable lobbying. The creation of the property right in supersonic travel yields a new special interest. This property right may be desirable as a means of encouraging technology research and of avoiding the orphan business model problem that may arise where some firms would like to free ride on the lobbying of others, for much the same reason that the Orphan Drug Act is effectively an inducement to lobby the FDA to approve a

---

[171] For a discussion of the origin of such regulation, see John R. Thomas, *The Question Concerning Patent Law and Pioneer Inventions*, 10 HIGH TECH. L.J. 35, 93–94 (1995).

[172] *See generally Fixing What Yeager Broke: Reducing Sonic Booms*, NASA (Jan. 28, 2004), http://www.nasa.gov/missions/research/sonic_booms.html (discussing development of sonic boom reduction technology).

particular drug. But it also can increase the danger of a bad regulatory decision, if lobbyists can persuade the decisionmakers to make such a choice. This threat is more generally a danger of any broad property right over orphan business models. Granting broad rights will likely increase incentives for lobbying, and that may or may not be a positive development.[173]

Use of orphan business models protection need not be a one-way ratchet toward deregulation. The same approach could be used to encourage regulation or reregulation. Suppose, for example, that there is insufficient support in Congress for a carbon tax. There might yet be enough support to try to balance lobbying spending on the issue, if anti-tax forces were seen as having a lobbying advantage. Congress might then auction an orphan business model to a firm that promises to spend the most over some period to lobby for the carbon tax. In exchange, the firm would receive a small percentage of the tax, for a period of time determined by the auction, if the effort were successful.

(d) Industry-Specific Statutory Compromises. — Admittedly, some of the previous examples seem fanciful, and they are intended to be illustrations of the range of potential applications of protections for orphan business models rather than proposals. Congress would not consider adopting such approaches until the basic framework for giving orphan business model rights became commonplace. The most likely trajectory by which such rights would become commonplace would be for them to emerge in specific industries in response to perceived problems, in much the same way as the Orphan Drug Act emerged. It is possible that greater awareness of the existence of mechanisms for protecting orphan business models could spur regulatory compromises in areas in which intellectual property protection is particularly controversial.

One such area is software. Many observers have complained about software patents, contending that they are an impediment to innovation.[174] But there are enough competing interests that benefit from accumulating software patents that lobbying on the issue may be at a stalemate. It is possible that some software companies' sympathy for software patents may stem more from concerns about protecting market experimentation than from concerns about protecting technological experimentation. Microsoft, for example, took a substantial business

---

[173] Lobbying costs arising from rent-seeking opportunities may be inefficient regardless of the success of such lobbying. *See* Gordon Tullock, *The Welfare Costs of Tariffs, Monopolies, and Theft*, 5 W. ECON. J. 224, 228, 231–32 (1967).

[174] For a summary of one strain of such a criticism, see Ronald J. Mann, *Do Patents Facilitate Financing in the Software Industry?*, 83 TEX. L. REV. 961, 999 (2005).

risk in replacing menu bars with a "ribbon" in its Office software.[175] Patent protection for this user interface may seem a bit silly, because the idea of the ribbon probably would have emerged even absent patent incentives.[176] But Microsoft might not have been willing to introduce the ribbon if it thought that there were a substantial chance of failure or that, in the event of success, competitors would rip off the user interface.[177] The ribbon is really an orphan business model, but it is understandable that Microsoft would protect it with whatever tools are available. Similarly, Google's founders likely did not need patent protection to conceive of the core algorithm underlying their company's success, but they may well have needed it to protect their investments in building server farms to implement their idea.[178]

Once the possibility of orphan business model protection emerges, there is an alternative to software patents. A possible statutory compromise would be some weakening of the software patent regime — at least a statutory strengthening of the nonobviousness requirement, and perhaps a decrease in patent term, if not an outright block on new software patents — in exchange for the creation of a system of protection to avoid the problem of orphan business models in software. One reason this compromise may make particular sense in the software context is that the patent term seems absurdly long in an industry where progress is rapid.[179] With competition determining orphan business model terms, the resulting periods of exclusivity would likely be relatively short (perhaps just a couple of years for a significant software innovation), but that might be enough to justify greater risk-taking in software development and thus accelerate improvements in software design without the full costs of software patents.

---

[175] *See, e.g.*, Jack Schofield, *Don't Get Lost on Your Way to the Office: Prepare for the Most Dramatic Changes Ever Made to a Major Suite of Applications, as Microsoft Opts for a New User Interface*, GUARDIAN (London), July 6, 2006, Technology Guardian, at 3. (A disclosure: Microsoft has supported the intellectual property program at the author's law school, including supporting a conference at which this paper was presented.)

[176] For arguments that the patented technology is similar to prior art, see *KDE to Sue MS Over Ribbon GUI?*, KDE DEVELOPER'S JOURNALS, http://kdedevelopers.org/node/1617 (last visited Feb. 26, 2011).

[177] Indeed, Microsoft's strategy has been to license many software developers to use the ribbon, but to refuse such licensing to competitors. *See* Jordan Running, *Microsoft Sets Office's Ribbon UI Not-Quite-Free*, DOWNLOAD SQUAD, (Nov. 22, 2006, 2:00 PM), http://www.downloadsquad.com/2006/11/22/microsoft-sets-offices-ribbon-ui-not-quite-free.

[178] For a discussion of how the validity of Google's PageRank patent may be in doubt following recent court decisions, see John F. Duffy, *The Death of Google's Patents?*, PATENTLY-O, http://www.patentlyo.com/patent/law/googlepatents101.pdf (last visited Feb. 26, 2011).

[179] *See* Daniel R. Cahoy, *An Incrementalist Approach to Patent Reform Policy*, 9 N.Y.U. J. LEGIS. & PUB. POL'Y 587, 648 & n.254 (2006); Allen Clark Zoracki, *When Is an Algorithm Invented? The Need for a New Paradigm for Evaluating an Algorithm for Intellectual Property Protection*, 15 ALB. L.J. SCI. & TECH. 579, 594–95 (2005).

B. A Bonding Mechanism

A regime of orphan business model protection for software would require careful design. One challenge is in determining when any protection is necessary: competition can make protection terms short, but the transaction costs of the system are likely not worthwhile for very short terms. Another challenge is in defining the requirements on the holder of an exclusive right and the scope of protection for such a right. These details appear relatively straightforward in the context of the Orphan Drug Act. The recipient of protection must take the drug through clinical trials, and then no one else can market the same drug. Even in the context of the Orphan Drug Act, however, there may be ambiguity about the scope of a "drug,"[180] and there may be greater ambiguities of this type if orphan business model protection is applied to a field such as software. Another danger is that a holder of an exclusive right may perform inadequately (crafting software that does not work well) and use its right primarily to extract revenues from anyone else using the right. It may be too much to expect an administrative agency to make sufficiently good decisions on a case-by-case basis to avoid this problem.

It is possible, however, to imagine a decentralized approach to defining the scope of orphan business model protection, enforcing the business model rights, and even determining when such rights should be granted. Such a system could greatly simplify the challenge of creating orphan business model rights in a particular field, such as software, or even across all fields of business. The possibility of such a system highlights that novel forms of intellectual property need novel systems for protection.

One means of implementing a decentralized approach for determining whether an exclusive right should be offered is through a bonding mechanism. For example, a party seeking exclusivity would offer to bet that the proposed business concept will *not* be developed in the time period of the requested exclusive right if no right is given. If no third party accepts the bet, that absence of action establishes a presumption that the right should be granted to the applicant. If a third party does accept the bet, then there ordinarily would be no exclusive right, and the resolution of the bet would depend on whether a firm — either the firm originally requesting exclusivity or another — implements the specified business concept. This system provides incentives for the prospective rightsholders to specify the scope and terms of the intellectual property protection, preventing a prospective rightsholder from including within the scope of the business model a business that likely would have been created anyway.

---

[180] *See* discussion and sources cited in *supra* note 157.

In a minimalist "first step scenario," the odds for such a mechanism could be set to make false positives (unnecessary protection) extremely unlikely.[181] Thus, if Congress were to consider extending protection for orphan business models, either in the software industry or in other areas, it could ensure that the only rights initially granted would be those for which the case for protection is especially strong. Over time, the mechanism could evolve in ways that would tolerate some false positives in exchange for additional market experimentation. In addition, a possible extension of the mechanism would limit rights to situations in which bonding transactions reveal that the right is likely to lead to a sufficiently large increase in the probability that the business will in fact be developed. Under this proposal, an initial system with only very modest, but almost certainly positive, effects within a given area could be gradually changed into a more economically significant, new intellectual property regime. Section III.B.1 elaborates the mechanism that can serve as this first step scenario, and section III.B.2 explains how protection might be expanded if the initial experiment proves successful.

1. First Step Scenario: A Bonding Mechanism. — To apply for intellectual property protection for market experimentation, an entrepreneur would first delineate the property right, describing the market experiment to be performed and selecting a term of years over which the right would run. The description would specify the nature of the market experiment, and the application might limit the proposed protection, for example, by specifying a minimum scale for the proposed business or other aspects of how the business would operate. The entrepreneur would then deposit the application with a government agency, paying a deposit (say, $10,000, although the required deposit might usefully vary depending on the proposed scale of the market experiment). The agency in turn would make the application publicly available on the internet. Any private third party would be allowed to reject the market experiment by placing a separate deposit with the government agency.[182] At least in the initial experiment, this deposit

[181] The mechanism would also have the socially beneficial effect of generating rigorous information about the degree to which free competition discourages entrepreneurial entry. Such empirical information is currently nonexistent because it is impossible to point to the businesses that would have been launched but that never were. The system described here would reveal this information in cases in which a rightseeker was thwarted from obtaining an exclusive right because some third party bet that the marketplace would produce the relevant market experimentation. If the third party ultimately loses that bet, then society would have good evidence that an exclusive rights system would have been superior in encouraging entrepreneurial entry.

[182] The advantage of a higher deposit is that it provides additional incentives for third parties to investigate carefully the possibility of placing deposits to cancel the property right. There is at least a strong case for allowing the party placing a deposit to offer more than the minimum, with the required deposits of third parties rising proportionately. If a proposed market experiment would be conducted in any event, a larger deposit increases the probability that a third party will

should be considerably lower (say, $1000) than that paid by the entrepreneur.

If no third party rejects the property right, then the property right would be granted to the applicant, and it would be published on the internet as an accepted application. The recipient of the right would then be able to enforce it against third-party infringers. While the precise contours of this enforcement regime could be debated, at least the rightholder would be able to receive damages for any infringement.[183] As with any intellectual property regime, the enforcement mechanism will be somewhat costly. If the property right is poorly drafted, or if it is well drafted but nonetheless includes some vague or ambiguous provisions, expensive litigation to determine the scope of the property right may result. But the original applicant will at least have an incentive to draft the property right with sufficient clarity to avoid expensive litigation.[184] To reduce the danger that this intellectual property regime might impose costs on innocent third parties, it might be appropriate in the initial experiment to impose a one-way fee-shifting rule, requiring the rightholder to pay the attorneys' fees of the challenging party if the latter party prevails.

If, by contrast, a third party rejects the property right by tendering a deposit, then no property right would be granted. The fate of the deposits would then depend on whether the market experiment nonetheless occurs in a way that matches the parameters of the rejected property right in the specified time frame. If the market experiment occurs despite the absence of the property right, then the deposits

---

be willing to challenge the proposed property right. But if the entrepreneur is correct in its confidence that the property right is necessary to justify the experiment, a larger deposit should improve the analysis of potential challengers and thus decrease the probability of a challenge.

183 A significant question would be whether the holder of the intellectual property right would also be able to obtain injunctive relief. A tentative conclusion is that injunctive relief should generally be appropriate in such cases. In patent cases, an argument against injunctive relief is that a patented technology may be bundled with many other technologies in an infringing product, and the patentee therefore may be able to extract value beyond that of the patented technology with the threat of an injunction. *See* eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 396–97 (2006) (Kennedy, J., concurring) ("When the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest."). Whatever the validity of this argument, it seems less likely to be applicable in the case of market experimentation. Allowing injunctive relief can ensure that infringers cannot take advantage of situations in which courts might be expected to undervalue damages.

184 A counterargument is that the original applicant will draft a vague property right in the hope that this will discourage suit by increasing the threat of litigation costs. The possibility of settlement, however, weakens this counterargument. The phenomenon of "strike suits," in which plaintiffs file weak cases in the hope of extracting settlements, suggests that defendants will have incentives to demarcate property boundaries relatively clearly. *See generally* Robert G. Bone, *Modeling Frivolous Suits*, 145 U. PA. L. REV. 519 (1997) (discussing plaintiff incentives to engage in frivolous litigation).

(plus any interest accrued) would be awarded to the third party; if it does not, then the deposits would be awarded to the original applicant. As with patent claims, there may be difficult questions of interpretation, though as noted above, the original applicant will have an incentive to draft a clear application to reduce the possibility of litigation. A drawback is that any litigation may necessarily involve third parties, who could be required to answer subpoenas about the extent of their business practices. This spillover cost too could be reduced, for example, by requiring compensation of third parties for their time, and by placing any trade secrets produced during the litigation under seal.[185]

The intuition behind the system is simple. If there is even a small probability (given the deposits suggested above, at least a one in eleven chance) that the market experimentation described will occur over the time frame, then a third party will have an incentive to tender a deposit and reject an application, in effect entering into a bet with the property rights applicant.[186] Anticipating this bet, the prospective entrepreneur will not apply in the first place. There is a danger that third parties might sometimes reject applications without adequate warrant. That is by design, however, because we are more concerned in the initial implementation of this system with avoiding false positives (inefficient grants of rights) than false negatives (inefficient rejections of rights). If no third party is willing to tender a deposit on such attractive terms, that provides a strong indication that no market experiment is likely to take place in the absence of an intellectual property right. Given the stakes, some private parties presumably would go into the business of evaluating applications, so there should be no shortage of potential challengers. When a right is granted, there is thus little risk that it will merely enhance the profits of an entrepreneur who would have entered the market in any event.

After a third party rejects an application by tendering a deposit, both the original entrepreneur and the third-party challenger remain free themselves to initiate the market experiment. These rules will make seeking an application somewhat less attractive, further reducing the costs of false positives. When the original entrepreneur engages in the market experimentation despite a rejection, the bonding system has worked effectively. In this case, the entrepreneur does not really need

---

185 Trade secrets are not absolutely privileged in the course of litigation, but a party can seek a protective order from discovery pursuant to FED. R. CIV. P. 26(c)(1)(G). A protective order may require "that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way." FED. R. CIV. P. 26(c)(1)(G); *see also* E. I. du Pont de Nemours Powder Co. v. Masland, 244 U.S. 100, 103 (1917) (recognizing the trial judge's discretion to determine to whom trade secrets should be revealed).

186 Note that 1/11 · $10,000 = 10/11 · $1000, so at that probability, total expected winnings equal total expected losses. Of course, for simplicity, this analysis ignores transaction costs.

the intellectual property incentive to create the market experimentation; the entrepreneur will enter the market even without a right, and even though the entry entails forfeiture of the deposit to the third party. Meanwhile, the prospective entrepreneur's deposit serves as a subsidy to anyone else who might be considering entering the market. A third party that places a bet that the market experimentation will occur can be sure of winning that bet by entering. The regime thus has the potential to encourage market experimentation even in cases where an application is rejected.[187]

Not every entrepreneur is likely to seek a business model adoption protection right. In addition to the cost associated with the danger of losing the bond, there are two other costs: first, the legal expenses of filing the application; and second, any loss of trade secrecy from filing the application. With respect to the first, potential litigation costs will likely be lower than those associated with patents, because there is no need to meet legal hurdles such as nonobviousness. Still, entrepreneurs would presumably benefit from experienced counsel in determining how broadly to define a right and from business consultants in anticipating whether third parties are likely to challenge the application.

The loss of trade secrecy, meanwhile, will mean that some will forego the opportunity to receive a business model adoption right because of the possibility that others will be able to bring the idea to market even earlier. This situation is most likely to occur if the business model is rejected, though publication might also give competitors a head start even when a short period of exclusivity is granted. Entrepreneurs, of course, are put to a similar choice between trade secrecy and patent protection. In any event, the potential loss of trade secrecy is likely to be a minor consideration in the cases where business model protection is most necessary: those where the business model is easily reverse-engineered and inadequate incentives exist to try the business model without exclusivity.

In some instances, an entrepreneur might first attempt to obtain a broad property right, and failing that, to apply again with narrower claims and a new deposit. An entrepreneur also might reapply with the same application if the entrepreneur believes that the third party's rejection was erroneous; the third party would then have to decide whether to reject the application again and bet that the market experiment will occur in any event. One advantage of the possibility of such repeated filing is that it decreases the chance that a third party

---

[187] In a limited subset of cases, this regime could discourage market experimentation. An entrepreneur who would have engaged in a market experiment in the absence of the system might decide, once the property right is rejected, not to engage in the experiment in the hope of winning the bet instead. In the few cases in which the deposits would be as large as the expected profits, the market experiment is unlikely to be worthwhile in any event.

will repeatedly reject an application for reasons other than seeking to obtain the entrepreneur's deposit. For example, the third party might worry that the entrepreneur's business model would challenge the third party's own business model. It may be feasible to reject an application for reasons such as this once or twice, but a competitor is unlikely to be willing to take on repeated bets unless the competitor is confident that business model protection is unnecessary. A social advantage of the repeated filing system is that it allows an entrepreneur to take advantage of market feedback to refine a proposal for exclusivity.

In this system, then, a prospective entrepreneur has the incentive to draft the proposed property right as broadly as possible, but not so broadly that a third party will reject the application. For example, imagine that this regime had existed some years ago and Netflix had sought protection for its software-based DVD rental business.[188] Had it sought a right on all DVD-by-mail rentals someone surely would have taken up the challenge, because there was a high ex ante probability that at least one small business would rent DVDs by mail somewhere in the United States. So Netflix might instead have limited its proposal by carefully elaborating a set of features that any software would need to have, including queues and the availability of different plans under which customers could rent different numbers of movies.

At least as importantly, Netflix might have narrowed its right by focusing on large businesses, such as those renting at least a million DVDs a year or those spending at least ten million dollars a year on marketing. Such limitations should be permissible. An orphan business model protection scheme should seek not only to encourage someone to try a business model in a particular way, but also to encourage a firm to try a particular business model on a large scale. An experiment on a small scale, after all, might tell us little about the feasibility of operating the business on a large scale. Such a limitation would entail a concession that smaller entities could compete against it, but could have protected Netflix from major competitors such as Blockbuster and Wal-Mart.

A principal difference between this proposal and others requiring competition is that in this proposal, the initial applicant receives the right; there need not be an auction of the right to the party who agrees to the shortest possible enforcement term. What makes it possible to dispense with the auction is that there is an alternative incentive system that should ensure terms of appropriate length. An applicant will not want to seek a term so long that someone else will be able to adopt

---

[188] For an explanation of why Netflix would have been a strong candidate for orphan business method protection, see Abramowicz & Duffy, *supra* note 12, at 366–71.

the orphan business model in the interim, leading a challenger to reject the right. Thus, third parties continue to constrain the length of exclusivity terms, but in a different way. To be sure, it would be possible to have some type of auction of the right, but this new mechanism has a significant advantage over an auction: it reduces the informational demands on an administrative agency overseeing the process. Under this regime, the agency is required neither to make its own assessment regarding the need for or scope of protection, nor to determine what constitutes sufficient exercise of the exclusive right. With the simple term auction, the agency must guard against the possibility that bidders will bid very short protection terms and then not vigorously adopt the orphan business model. Lowball bidding and neglect of adopted orphan business models will be of much less concern under the bonding mechanism proposal, because the initial applicant will seek the longest term that it thinks it will be able to obtain.

It is still possible, though, that some recipients of orphan business model rights will not engage in market experimentation. Suppose it is highly unlikely that it will make sense for anyone to enter a market in the next ten years, but that there is a small chance (say, one in twenty) that demand conditions will change in a way that will make entry obviously advisable. If the market is sufficiently large, then it might be worthwhile to secure the intellectual property right just in case demand conditions evolve in the above way. Warehousing of market experimentation intellectual property rights could mean that some rights will protect entry that might have occurred even in the absence of the issuance of the right. This outcome is not necessarily inefficient — perhaps entry will occur somewhat earlier as a result of the property right, and even in such cases the probability of entry may rise — but this situation is undesirable if the principal goal of an initial regime is to avoid false positives.

There is, however, a simple solution to this problem. The regime can be flipped so that a third party is also allowed to challenge a claim that entry will occur if the intellectual property right is granted. If no one rejects the entering party's application on the ground that entry would occur anyway, then a third party would be permitted to tender a deposit (once again, perhaps just $1000) on the prediction that entry will not occur despite the grant of the right. This action produces a choice for the applicant: the applicant can withdraw the application, in which case the deposits are awarded to the third party, or the applicant can tender another deposit (say, $1000 again) to keep the intellectual property right. When this step occurs, the process can repeat recursively, with further third-party challenges and further deposits. If, however, this process ends with an unchallenged deposit by the applicant, then the intellectual property right is auctioned. All challenges are then resolved based on whether the recipient of the right in fact carries out the proposed market experiment.

Under this system, the probability that the applicant will follow through and perform the market experiment must be very high (at least about a nine in ten chance) if the applicant hopes to receive the intellectual property right. If the recipient of the right does not seem very likely to follow through, there should be no shortage of third parties willing to challenge the applicant, especially with such favorable odds on the challenger's side. An applicant hoping simply to warehouse intellectual property rights in the unlikely event that they should become useful will be unable to withstand these challenges. At some point, the total amount deposited will begin to approach the expected benefits of the intellectual property right, and the amount deposited will be lost if the market conditions do not change in ways that would make entry worthwhile. The challenges themselves provide additional incentives for the third party to engage in the market experiment, further promoting the goal of market experimentation. If those who are unwilling to take on risk end up subsidizing those who genuinely wish to embark on risky experiments, so much the better.

2. Potential Improvements to the Bonding Mechanism. — This proposal entails little risk. It covers only orphan business models that are highly unlikely to be adopted in the absence of protection and that are highly likely to be adopted with protection. More traditional approaches to intellectual property reform cannot make such promises, because no matter what legal standard applies, there are empirical uncertainties about how administrative officials will interpret the established standard. If this proposal is to be criticized, it should be criticized for providing too little reward. With the specifications provided here, perhaps too few market experiments will be covered, in which case the apparatus devoted to the system might not be worthwhile.

One answer to this criticism is that the proposal could easily be adapted to cover the next best set of proposed market experiments. If the applicant need deposit only a smaller amount of money, or if third-party challengers must deposit a larger amount, then a greater number of proposals will be accepted. One useful aspect of this decentralized system is that transitions can easily be controlled. A legislature[189] need only change the applicable numbers; it need not choose among vague verbal formulations. Depending on the experience with the initial proposal, it should be straightforward to change the approach so that some applications are accepted even when there is a nontrivial probability that intellectual property protection is not necessary or that intellectual property protection will be insufficient to prompt any actual experimentation. Empirical analysis to determine the optimal

[189] A national legislature could implement the system, as could a state legislature for local experiments.

numbers will not be easy, and there will be some danger that the legislature will grant excessive protection. This risk provides perhaps the strongest argument against this mechanism and the best reason for waiting to adopt the mechanism until the benefits from doing so in a particular field seem especially high.

Experience might also lead to the development of structurally different approaches to decentralized assessment of the need for intellectual property protection. One possibility is that conditional prediction markets might be used to assess the probabilities that entry will occur with and without the grant of intellectual property protection.[190] A burgeoning literature shows that prediction markets can serve as useful tools for making probabilistic assessments,[191] and that such markets may not be easily manipulated by private parties.[192] Other market mechanisms, such as Professor Michael Kremer's proposed auctions to facilitate government buyouts of intellectual property rights,[193] could also be combined with this system, so that the government generally would be subsidizing market experimentation with dollars instead of with exclusive rights. Assessments of prediction markets and Kremer's proposal are beyond the scope of this discussion, but the proposal here is not intended as an insistence on a particular means of effecting a decentralized approach to the issuance of intellectual property rights for market experimentation. The goal here is to illustrate the feasibility of such a system, not to identify conclusively the optimal system.

3. Further Applications: Beyond Conventional Business Models. — If a general sui generis regime for orphan business model protection or a number of targeted regimes ever developed, questions would arise about contexts that ordinarily might not be conceived as involving orphan business models, yet where similar dynamics are present and where exclusive rights could in theory advance efficiency. This section offers preliminary consideration of two such contexts: scientific research and legal experimentation. Although in both cases it is possible to imagine relying on a version of term competition, this choice would

---

190 For a discussion of conditional prediction markets, see Michael Abramowicz & M. Todd Henderson, *Prediction Markets for Corporate Governance*, 82 NOTRE DAME L. REV. 1343, 1353–54 (2007).

191 *See, e.g.*, MICHAEL ABRAMOWICZ, PREDICTOCRACY: MARKET MECHANISMS FOR PUBLIC AND PRIVATE DECISION MAKING (2007); INFORMATION MARKETS: A NEW WAY OF MAKING DECISIONS (Robert W. Hahn & Paul C. Tetlock eds., 2006).

192 *See, e.g.*, Robin Hanson et al., *Information Aggregation and Manipulation in an Experimental Market*, 60 J. ECON. BEHAV. & ORG. 449 (2006); Paul W. Rhode & Koleman S. Strumpf, Manipulating Political Stock Markets: A Field Experiment and a Century of Observational Data (June 2008) (unpublished manuscript) (on file with the Harvard Law School Library), *available at* http://www.unc.edu/~cigar/papers/ManipIHT_June2008(KS).pdf.

193 *See* Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q.J. ECON. 1137, 1146–48 (1998).

necessitate a fair degree of governmental discretion in determining the scope of the applicable rights,[194] and the proposals advanced in this Article would be more feasible if a general system for protecting orphan business models developed.

(a) Scientific Research. — It may seem odd to apply the orphan problem to research, because patent law already provides incentives to conduct scientific research. Indeed, the premise of this Article is that intellectual property law should focus not only on encouraging technological experimentation, but also on encouraging market experimentation. Yet conducting scientific research in a given area is itself a business model, and some free-riding is inevitable even given the existence of patent protection. Suppose, for example, that a drug company is considering research into a particular metabolic pathway specific to a disease. Assume that it seems unlikely but possible that such research ultimately could lead to the development of effective treatments. There are two dangers: First, a drug company may worry that if it makes some preliminary unexpectedly positive research findings, it will be unable to keep those secret, and other drug companies will begin exploring the same pathway. Second, the company may worry that even if it finds a successful drug, further research into the molecule that the drug targets will produce many other drugs, thus reducing the company's market share. As a result, the company — and indeed, all drug companies — may decide that research on that pathway is not yet cost-justified. Perhaps it will be someday, once society is rich enough to pay more for the drug or once new tools reduce the cost of research. Yet such research may be socially worthwhile right away, and it might be privately worthwhile as well if it were possible to prevent free-riding on research successes.

Patent law scholars might argue that the patent term should be made longer or the patent scope made broader. These suggestions, however, are crude solutions with costs potentially larger than the benefit of accelerated research. The proposals developed above provide alternative solutions with potentially smaller costs. In a decentralized regime like that described here, an exclusive right might be awarded only if third parties are confident both that no drug targeting the pathway would otherwise be developed during the exclusive right and that granting the exclusive right considerably increases the probability that such a drug will be developed. A firm that receives the exclusive right to conduct research ultimately would seek patents on any drugs developed. The orphan right is to the business model of conducting

---

[194] Indeed, concerns about governmental discretion help explain why the patent system is likely to be superior to a system of governmentally decreed auctions of intellectual property rights. *See* Abramowicz, *supra* note 162.

research in the area, and this right can complement patent rights in drugs that are developed.

Orphan business model adoption rights are thus responsive to a problem addressed in the patent literature: that patent races can be needlessly duplicative and that research competition can thus create inefficient rent dissipation.[195] Professor John Duffy has shown that the prospect of such rent dissipation will generally delay innovation.[196] Duffy argues that when a long, drawn-out patent race is expected, the patent race will begin *later* than it otherwise would. Early grants of exclusive rights are thus justified as a means of assuring patent racers that their losses will be relatively limited, thereby stimulating early patent racing at the cost of less ex post competition. Thus, Duffy's article is a defense of the patent prospect theory claim that patents should be awarded relatively early.[197] But early grants of exclusive rights are not a complete solution, particularly if the patent system will issue patents only to those inventors who have made substantial contributions. There will often still remain a period of time in which no one will bother racing, even though research would be socially beneficial. A number of companies may each recognize that if it were worthwhile for them to race, it would also be worthwhile to several other companies. Thus, the patent race will not begin until each potential racer recognizes that the anticipated rewards of a patent are sufficiently great that the risk of wasted research and development expenses from a lost patent race is worth bearing.

Before this point, research might be worthwhile only if a company could be assured it would be the only racer. The grant of exclusive research rights even for short periods of time, such as two or three years, might then accelerate research. If the only way to generate research during a time period is to grant exclusivity, there is little loss from granting such exclusivity. An interesting aspect of this application of orphan business model protection is that it does not rely on the prospect of free-riding on information. Concerns about rent-dissipating simultaneous development of information can also generate a case for orphan business model protection. CVS and Walgreens, for example, may each delay entry into any given market for some period because of a concern that the other may enter the market simultaneously. Entry becomes justified only once the anticipated returns are sufficiently great to compensate for the possible redundancy. Orphan business model protection could thus in theory lead to earlier entry of stores.

---

[195] *See, e.g.*, Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115, 181–93 (2003) (discussing how the patent system may entail a common pool problem).

[196] *See* John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 469–75 (2004).

[197] *Id.* at 443; *see also* Kitch, *supra* note 14 (introducing the patent prospect theory).

The most relevant questions in assessing whether such protection is justified are empirical ones about whether an agency or a decentralized bonding regime can make sufficiently accurate assessments about the prospects of research in particular areas and about the size of transaction costs from administration of such a system.

(b) Legal Innovation. — Ordinarily, orphan business models involve potential businesses that might be created by private sector firms, but, in principle, legal regimes that provide exclusivity to encourage adoption of orphaned ideas and inventions also could be used to foster public sector innovation. This is obvious where public entities compete with private entities. A public university, for example, should be able to receive exclusivity if it conducts the clinical testing demanded by the Orphan Drug Act. Exclusivity should also be available where legal goods are provided entirely by multiple public entities. Indeed, many governmental programs can be analogized to business models, with the caveat that the government is a nonprofit entity rather than a for-profit entity. Just because an entity is nonprofit does not mean that it maximizes social welfare,[198] so free-riding on information from legal experiments can pose much the same problem as free-riding on information from market experiments.[199] The concept of free-riding may seem alien in the legal experimentation context, but legal experimentation, like market experimentation, can generate useful information that others may seek to appropriate, and the possibility of licensing revenues could improve incentives to be the first innovator.

For example, suppose that health care were provided entirely by states, and that it appeared that there is a ten percent chance that paying nurses to telephone chronic care patients regularly with reminders would decrease overall medical costs, but a ninety percent chance that such a program would increase costs with no attendant health benefits.[200] This experiment might be socially worthwhile, because if it were successful, many states could benefit from that information. But any given state might have little incentive to take the risk. A state might be more willing to do so if for some period of time it had an exclusive right, under federal law, to license the program to other states. A federal agency committed to health care innovation might auction

---

198 State officials, for example, may care more about that state's citizens than about citizens of other states.

199 *See* Rose-Ackerman, *supra* note 17, at 594.

200 This example is chosen because it was recently the subject of a federal Medicare experiment. *See* NANCY MCCALL ET AL., CENTERS FOR MEDICARE & MEDICAID SERVICES, EVALUATION OF PHASE 1 OF MEDICARE HEALTH SUPPORT (FORMERLY VOLUNTARY CHRONIC CARE IMPROVEMENT) PILOT PROGRAM UNDER TRADITIONAL FEE-FOR-SERVICE MEDICARE 12 (2007).

the exclusive licensing right to the state that agrees to undertake the experiment in exchange for the shortest period of exclusivity.

This example involves experimentation in an area in which governments are acting as market participants, performing services that private sector actors could perform. But it is also possible to imagine exclusive rights for innovations in areas in which the government is not acting as a market participant, at least as market participation is conventionally conceived. For example, we might imagine exclusivity rights being granted to a state that experiments with a new form of policing, that replaces jail terms for drug possession with treatment programs, that tries a new approach to education, that implements a set of civil procedure reforms, that implements a new set of corporate governance rules, and so on. Innovation exists in all these areas, but the overall level is likely to be inefficiently low, and states are unlikely to experiment with dramatic reforms, in part because they do not internalize the benefits of such experimentation. The result is that we do not have as much empirical data about the effects of legal innovations as we otherwise would. Exclusivity could increase both incentives for experimentation and incentives for conducting such experimentation in a way that would maximize its informational value.[201]

That possibility does not mean that the case for rewarding legal experimentation with exclusive rights is the same as the case for rewarding market experimentation. Using orphan business model protection to increase legal experimentation raises a number of questions specific to legal innovation. For example, could the federal government insist that a state that copies another state's innovation pay a licensing fee?[202] Will state actors be as motivated by financial incentives as private actors to undertake experiments and to copy successful ones? Can the success of legal experiments be judged as easily as the success of market experiments? Is it better for the federal government to encourage experimentation by paying states that agree to undertake pilot programs? Should exclusive rights be given to private firms instead of states, with the private firms then having incentives to enter into contracts with governments willing to engage in experimentation?

Answers to these questions are beyond this Article's scope, and their existence suggests that careful design would be needed to import a scheme of orphan business model protection to a legal context. The failure of legal scholarship to consider the possibility of granting exclusive rights to legal innovators, however, highlights that the orphan

---

[201] For example, states might wish to conduct randomized experiments to better isolate the effects of a legal change. *See generally* Michael Abramowicz et al., *Randomizing Law*, 159 U. PA. L. REV. (forthcoming 2011).

[202] *Cf.* Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 634, 646–47 (1999) (finding a state patent defendant protected by sovereign immunity).

business model problem in general is undertheorized — it is assumed to be present only in specific exceptional contexts, such as orphan drugs, rather than pervasive in the legal system. A literature does exist on the permissibility of patents for *private* innovations in legal contexts, such as novel tax strategies, litigation positions, or poison pills.[203] But the legal literature does not appear to consider protection of innovations in law itself. Perhaps this is because the normative case for incentivizing new ideas for legal innovation is weak, given the surfeit of ideas in law reviews and elsewhere. It is experimentation itself that is lacking, and intellectual property theorists have generally assumed that promoting nontechnological experiments is outside the concerns of intellectual property.

IV. CONCLUSION

The absence of robust intellectual property frameworks for protecting orphan business models suggests, under the Demsetz framework, that either the benefits of providing such protection are smaller than the benefits of providing existing forms of intellectual property protections such as patent and copyright, or that the costs of providing the protection are larger. Even so, some level of social inefficiency likely occurs as a result of orphan business models, yet the absence of past scholarly attention to this potential category of intellectual property has prevented policymakers from viewing seemingly unrelated problems in a unified policy framework. The goal of this Article is to provide such a framework, not to advocate a rush to create a new form of intellectual property prematurely. This framework shows that existing systems of orphan business model protection in the pharmaceutical context could be made more efficient. Perhaps someday such improvements might evolve into additional or broader protections for orphan business models. With careful design, the risks of this new form of protection can be reduced, and at least some drawbacks of existing property rights protection schemes, such as patent law, can be avoided.

---

[203] *See, e.g.*, Andrew A. Schwartz, *The Patent Office Meets the Poison Pill: Why Legal Methods Cannot Be Patented*, 20 HARV. J.L. & TECH. 333 (2007).