

Do Patent Challenges Reduce Consumer Welfare?

A Response to Stephen Yelderman, *Do Patent Challenges Increase Competition?*,
83 U Chi L Rev 1943 (2016).

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INTRODUCTION

It is so often said that a patent is a grant of a monopoly power that one cannot be blamed for repeating or even believing this maxim.¹ Both for historical and rhetorical reasons it is easy to call patents monopolies,² but as Professor Stephen Yelderman points out in his paper, they are not always so, and in fact nearly always are not so. Yet, the moniker has stuck. And while inaccurate terminology is ubiquitous, the loose use of terminology can (and in the case of patents does) lead to legal conclusions that are flawed if not outright specious.

It is a basic tenet of economics that monopolies are often detrimental to consumers because they allow monopolists to extract excess rents from the consumer.³ In other words, in a competitive world, a consumer would pay less for a product than in a monopolistic world, because in the former one, different firms would compete with each other for the consumers' business and attract consumers by cutting prices, while in the latter one, the consumer

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¹ See, for example, *Bowman v Monsanto Co*, 133 S Ct 1761, 1766 (2013); *Dawson Chemical Co v Rohm & Haas Co*, 448 US 176, 215 (1980); *Morton Salt Co v G.S. Suppiger Co*, 314 US 488, 492 (1942), rev'd *Illinois Tool Works Inc v Independent Ink, Inc*, 547 US 28 (2006).

² See Adam Mossoff, *Rethinking the Development of Patents: An Intellectual History, 1550–1800*, 52 *Hastings L J* 1255, 1255 (2001) (“The history of patents does not begin with inventions, but rather with royal grants by Queen Elizabeth (1558-1603) for monopoly privileges that advanced her economic and industrial policies.”).

³ See Edmund H. Mantell, *Conglomerate Mergers, Allocative Efficiency, and Section 7 of the Clayton Act*, 56 *Tex L Rev* 207, 227 (1978).

will pay whatever price the monopolist sets.⁴ It therefore follows that if patents are indeed monopolies, then the abolition of patents would permit a (more) competitive market and therefore would lead to lower consumer prices.⁵ The logic is unassailable, but only if the premise is correct. If, on the other hand, patents are not monopolies, then removing patents from the equation may not necessarily lead to any consumer benefit.

To an untrained eye patents do indeed look like monopolies. A patentee receives an exclusive right to “make[], use[], offer[] to sell, or sell[] . . . or import[] into the United States” the invention covered by the patent grant.⁶ By definition then, the grant of a patent forbids others from selling the same product as the patentee,⁷ thus supposedly making a monopolist out of the patentee. However, as any student of antitrust law knows, monopolies are not a function of whether a single entity is the only one on the market selling a product, but whether that single entity has market power.⁸ As the saying goes, a patent is a reward for having built a “better mousetrap.”⁹ However, just because one has built a better mousetrap, it does not follow that he can charge whatever price he wishes, for if the price for that new mousetrap is exorbitant, a consumer may simply revert back to the old mousetrap, or just get a cat.¹⁰ The availability of such alternatives means that the patentee does not in fact have market power and therefore is not a monopolist.¹¹ This basic argument is not novel, and yet, it is often overlooked by courts and commentators alike when they discuss patents as a barrier (though perhaps a necessary one) to competition.¹²

In his article, Yelderman masterfully shows that the received wisdom that patent invalidation leads to more competition is simply false in a vast variety of cases because in a vast variety of

⁴ Id.

⁵ See Stephen Yelderman, *Do Patent Challenges Increase Competition?*, 83 U Chi L Rev 1943, 1951–52 (2016).

⁶ 35 USC § 271(a).

⁷ 35 USC § 271(a).

⁸ See, for example, *US Anchor Manufacturing, Inc v Rule Industries, Inc*, 7 F3d 986, 994–95 (11th Cir 1993); *State Oil Co v Khan*, 522 US 3, 18 (1997).

⁹ Timothy R. Holbrook, *The More Things Change, the More They Stay the Same: Implications of Pfaff v Wells Electronics, Inc and the Quest for Predictability in the On-Sale Bar*, 15 Berkeley Tech L J 933, 935 (2000).

¹⁰ See Donald S. Chisum, et al, *Principles of Patent Law* 61 (3d ed 2004).

¹¹ Id. In addition, measures of market power rely on the degree of substitution feasible.

¹² See, for example, *Bilski v Kappos*, 561 US 593, 656 (2010) (Stevens concurring) (“Of course, patents always serve as a barrier to competition for the type of subject matter that is patented.”).

cases patents simply do not confer monopoly power on the patentee.¹³ As Yelderman explains, his article “scrutinize[s] the claim that patent challenges lead to increased competition. It identifies a number of conditions that must hold for a patent challenge to provide this particular benefit, and evaluates the reasonableness of assuming that the procompetitive benefits of patent challenges are generally available.”¹⁴ Among the conditions that Yelderman identifies are the following: (1) the challenged patent confers market power—that is, few alternatives to the patented product are available;¹⁵ (2) the challenge will reduce that power—that is, no other patents or other barriers such as trade secrets would continue to exist;¹⁶ (3) the patent challenge is timely—that is, the dispute arises and is resolved some significant period of time before the patent would have expired anyway;¹⁷ and (4) the challenge is successful.¹⁸

In short, according to Yelderman, absent multiple conditions a patent challenge or even invalidation may have no effect on the market and no benefit for consumers. Consequently, settling patent cases in a way that preserves the patents (and potentially insulates them from further challenges) is not detrimental to consumers unless the specified conditions are met.

There is little to disagree with in Yelderman’s basic argument, except perhaps to note that it in fact understates the issue, for litigation over patents doesn’t usually invalidate patents as a whole, but rather addresses itself to specific patent claims.¹⁹ Thus, even in situations in which a challenger manages to prevail in litigation, absent *complete* victory over *all* relevant claims, the

¹³ See Yelderman, 83 U Chi L Rev at 1963 (cited in note 5). Yelderman’s article focuses on patent challenges rather than invalidations, but, of course, a failed challenge, while useful in some respects, only reconfirms (and possibly increases) whatever power the patentee already had. See, for example, Gregory Dolin, *Dubious Patent Reform*, 56 BC L Rev 881, 908–09 (2015); Doug Lichtman and Mark A. Lemley, *Rethinking Patent Law’s Presumption of Validity*, 60 Stan L Rev 45, 72 n 59 (2007) (noting that “fact-finders might find themselves inclined to defer to the decisions of other fact-finders”). Thus, this response focuses on whether litigation that culminates in the finding of invalidity or non-infringement enhances competition more than settlements that preserve (in whole or in part) the patentee’s exclusive rights.

¹⁴ Yelderman, 83 U Chi L Rev at 1943 (cited in note 5).

¹⁵ *Id.* at 1959–72.

¹⁶ *Id.* at 1972–79.

¹⁷ *Id.* at 1979–93.

¹⁸ Yelderman, 83 U Chi L Rev at 1993–95 (cited in note 5).

¹⁹ See John R. Allison and Starling D. Hunter, *On the Feasibility of Improving Patent Quality One Technology at a Time: The Case of Business Methods*, 21 Berkeley Tech L J 729, 748 (2006).

effect on the market would be negligible at best.²⁰ Ultimately though, while I don't disagree with Yelderman's argument on its own terms, I wish to challenge some of the implied assumptions of his article. Yelderman's argument proceeds from the premise that patents are a barrier (albeit often a justified one) to competition. Having accepted that assumption, Yelderman argues that patent challenges can provide an appreciable benefit to consumers if the patent in question is the sole barrier to market entry. Conversely, patent challenges are of no consequence when other barriers continue to exist. In this Response, I intend to show that the initial premise—that patents are a barrier to competition—is not to be easily assumed, and that therefore the conclusion that patent challenges provide a benefit to consumers is not necessarily true even in the absence of other, nonpatent barriers to entry.

In Part I of this Response, I discuss the general theories of patent and antitrust laws and how the two regimes interact. I begin with the discussion of the “traditional” view of patents as an “exception” to antitrust's strictures, and will then move to explain how that approach fails to take into account market dynamism. Part II applies the generalized discussion of Part I to the specific case of pharmaceutical markets and the settlements between brand-name and generic drug manufacturers. For Yelderman, this specific case of patent challenges offers perhaps the best example of how concluded patent litigation increases competition and increases consumer welfare. I, on the other hand, endeavor to show that the landscape is far more complex and that settlements that do not result in conclusive adjudication of patent rights may well be just as, or perhaps more, beneficial to the consumers.

I. PATENTS, ANTITRUST, AND COMPETITION

It is not unusual to see statements that patents are barriers to competition,²¹ and are in essence an exception to the policies pursued in our antitrust laws.²² The only reason to tolerate patents at all is to incentivize production of new technologies that

²⁰ See *id.*

²¹ See, for example, Lea Shaver, *Illuminating Innovation: From Patent Racing to Patent War*, 69 Wash & Lee L Rev 1891, 1895 (2012). See also, for example, *Schering-Plough Corp v Federal Trade Commission*, 402 F3d 1056, 1065–66 (11th Cir 2005), *rev'd Federal Trade Commission v Actavis*, 133 S Ct 2223 (2013).

²² *Actavis*, 133 S Ct at 2238 (Roberts dissenting).

would either not exist at all or would be significantly delayed absent the incentive.²³ Under this view of things, patents hurt today's consumers, but it is a price that these consumers are willing to pay in exchange for the ability to enjoy things that otherwise would not exist. As Professor John Duffy explains:

Patents in general allow prices to be held above marginal cost; they allow royalties to be collected. Those royalties have to come from somewhere, and basic economics predicts that, except in unusual circumstances not typically present in otherwise competitive markets, some or all of those royalties will come from consumers' pockets.²⁴

On the other hand:

[P]atent law spurs invention and innovation by providing creators of patentable inventions a period of exclusivity, during which the patentee has the right to exclude anyone from practicing and commercializing the invention. This exclusivity is intended to allow the patentee to impose a supra-competitive price for its innovation so that it can recoup its R&D investment. . . . Under patent law, static efficiency, or short-run consumer welfare, is sacrificed for dynamic efficiency.²⁵

In other words, once a product is invented, consumers benefit by having that product not protected by any patents so that other companies can enter the market and compete on price.²⁶ It is important to remember, though, that what is to be protected is *competition* rather than *competitors*.²⁷ After all, the ultimate goal is not maximizing the number of companies offering a particular product for sale, but improving consumer welfare.²⁸ And while

²³ See Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes*, Remarks at Northwestern University School of Law, Sixth Annual Health Care Antitrust Forum (Nov 3, 2000), archived at <http://perma.cc/TB7C-YKUL>; Erik Hovenkamp and Thomas F. Cotter, *Anticompetitive Patent Injunctions*, 100 Minn L Rev 871, 920 n 122 (2016).

²⁴ John F. Duffy, *Standing to Challenge Patents, Enforcement Risk, and Separation of Powers*, 83 Geo Wash L Rev 628, 634–35 (2015).

²⁵ Thomas Cheng, *Putting Innovation Incentives Back in the Patent-Antitrust Interface*, 11 Nw J Tech & Intell Prop 385, 388–90 (2013).

²⁶ See *Nash v CBS, Inc*, 899 F2d 1537, 1540 (7th Cir 1990) (“Once a work has been written and published, any rule requiring people to compensate the author slows progress in literature and art, making useful expressions ‘too expensive’, forcing authors to re-invent the wheel, and so on.”). Though *Nash* arose in the copyright context, given the kinship between patent and copyright, the logic applies to patent cases as well. See *Sony Corp of America v Universal City Studios, Inc*, 464 US 417, 439 (1984).

²⁷ *Leegin Creative Leather Products, Inc v PSKS, Inc*, 551 US 877, 906 (2007). See also *Brown Shoe Co, Inc v United States*, 370 US 294, 320 (1962).

²⁸ See *Wisconsin Music Network, Inc v Muzak Ltd*, 5 F3d 218, 223 (7th Cir 1993).

there is no doubt that competition is a primary force for advancing consumer welfare, the scope and avenues of competition should not be oversimplified to the point that it is viewed as merely a race between competitors to the lowest possible price.²⁹ Instead, competition is a dynamic and multifaceted process that proceeds along multiple dimensions.³⁰ Though competition on price increases consumer welfare along that particular dimension, the promise of patents increases competition on other nonprice axes.³¹

To illustrate this point, consider Apple's products (computers, phones, etc.) and those of its competitors. On average, a comparable Apple product costs more than its Windows or Android counterpart.³² If competition were conducted strictly on the basis of price, Apple would have gone out of business long ago, because consumers would buy a lower-cost version of the same product. Yet, Apple is not only not out of business but is a wildly successful company. Why? Simply put, consumers buy Apple products because they value certain features that Apple offers (for example, user interface and design) that are not available in the products of its competitors.³³ Many of the features that Apple's consumers find to be attractive are protected by utility and design patents. Similarly, many of the features that customers of Android or Windows find attractive are also protected by patents.³⁴ The patent protection forecloses a particular avenue for competitors, forcing them to find alternative solutions, and thus benefits consumers by providing a greater menu of options to satisfy their range of preferences.³⁵

Because patents spur competition (albeit not necessarily on price), removing patent-based barriers would also remove the incentive to create alternative products, thus *reducing* rather than increasing competition, or rather invalidating patents may merely trade one type of competition (over particular features) for

²⁹ See generally Gregory Dolin, *Resolving the Patent-Antitrust Paradox: Promoting Consumer Welfare through Innovation* *1 (Center for the Protection of Intell Prop, May 2013), archived at <http://perma.cc/P3YF-UYXK>.

³⁰ Id at *1. See also Joshua D. Wright, *Antitrust, Multidimensional Competition, and Innovation: Do We Have an Antitrust-Relevant Theory of Competition?*, in Geoffrey A. Manne and Joshua D. Wright, eds, *Competition Policy and Patent Law under Uncertainty: Regulating Innovation* 228–51 (Cambridge 2011).

³¹ Dolin, *Resolving the Patent-Antitrust Paradox* at *2 (cited in note 29).

³² See Phillip Elmer-DeWitt, *The Apple iOS and Android Price Gap Just Gets Wider* (Fortune, Feb 15, 2016), archived at <http://perma.cc/FBH6-CHZE>.

³³ Dolin, *Resolving the Patent-Antitrust Paradox* at *2 (cited in note 29).

³⁴ For a full taste of the number and extent of Apple's and its competitors' patents, see generally *Apple, Inc v Samsung Electronics Co*, 678 F3d 1314 (Fed Cir 2012).

³⁵ Dolin, *Resolving the Patent-Antitrust Paradox* at *2 (cited in note 29).

another type of competition (over price).³⁶ It is not self-evident that consumers would come out the victors in such a trade-off. But if patents are not invalidated in litigation (and thus removed from the field),³⁷ but the legal dispute is settled on terms agreeable to the patentee and the challenger, such settlements may well enhance consumer welfare because they may both increase the competition on price while maintaining patent-based barriers that spur providers to offer a wider array of features to consumers. Consider a situation in which a patent holder and a challenger agree to settle on terms that would allow the challenger to enter the market under a license. Under such a settlement, the patent would remain valid and could still be asserted against third parties (thus maintaining the barrier and therefore the design-around incentive) while simultaneously permitting increased price-based competition between the original patent holder and the licensee. Invalidating the patent would allow not just the initial challenger to enter the market, but all other firms to do the same.³⁸ A number of them might choose to do so instead of looking for alternative avenues to satisfy consumer demands.³⁹ But such an entry may well reduce the total consumer choice.

Three objections may be made to the above argument. First, one might take issue with the definition of the market for a particular product. It is a basic tenet of competition law that in evaluating whether a particular behavior is anticompetitive, defining the relevant market is the first and perhaps the most important step.⁴⁰ To return to my example of Apple and its competitors, it matters whether the market is defined as computers (or mobile phones) overall or only those computers (or mobile phones) that run Apple's operating system. If the former definition is taken, then the existence of patents precluding competitors from copying Apple's OS may well foster more competition and increase consumer welfare by offering different choices in software (Windows, Android, Linux, etc.). If, on the other hand, the latter definition were to prevail, then patents would significantly limit consumer

³⁶ Id at *4.

³⁷ See *Blonder-Tongue Labs, Inc v University of Illinois Foundation*, 402 US 313, 338, 349 (1971).

³⁸ Id.

³⁹ Dolin, *Resolving the Patent-Antitrust Paradox* at *3 (cited in note 29) ("Instead of the uncertainty (and the potentially large pay-off) inherent in R&D, companies may settle for the certainty of low payoff. Indeed, this is not merely theory, as this is the business model of the companies producing generic medicines.").

⁴⁰ See, for example, *Funeral Consumers Alliance, Inc v Service Corp*, 695 F3d 330, 348 (5th Cir 2012); *City of New York v Group Health Inc*, 649 F3d 151, 155 (2d Cir 2011).

choices within that market. Generally, “[t]wo products belong in a single product market if they are ‘regarded by consumers as . . . close substitutes.’”⁴¹ But this view doesn’t always prevail. For example, in recent Third Circuit litigation a generic drug company (supported by a number of amici, including prominent law professors) argued that the relevant market was limited to a particular medication rather than all medications in the same class used to treat the same condition.⁴² Though the Third Circuit ultimately rejected that argument, the case does serve as an illustration that defining the scope of the market is of paramount importance in evaluating any given action’s effect on competition and consumer welfare.⁴³ Thus, to the extent one takes the view that the market is defined by consumers’ desire for a particular product⁴⁴ (for example, Apple’s OS), one would be unconvinced by my argument that patents promote competition and consumer welfare. But this disagreement stems not from any weakness in my argument regarding the role of patents generally, but from divergence in understanding and evaluation of consumer behavior regarding substitute products.

Second, it may be objected that the mere fact that patent litigation exists is evidence that at least some firms wish to compete on price rather than on other features and that insulating patents in that context (provided all of the other conditions set out by Yelderman are met) is necessarily detrimental to consumer welfare. In other words, if the patent challenger were able to come up with an alternative design, he very well would have, but because he did not, it should be some evidence that absent patent invalidation consumers may get neither price-based nor nonprice-based competition. The objection is well-taken insofar as it suggests that not all settlements are necessarily consumer-friendly. Nonetheless, my critique of Yelderman’s approach doesn’t claim that *all* settlements that preserve the patent are beneficial to consumers; rather, my contention is limited to the proposition that there exist cases in which, even assuming all of the conditions listed by

⁴¹ *Central Vermont Railway, Inc v Interstate Commerce Commission*, 711 F2d 331, 336 (DC Cir 1983), quoting Phillip Areeda and Donald F. Turner, 2 *Antitrust Law* ¶ 52a (1978).

⁴² See *Mylan Pharmaceuticals Inc v Warner Chilcott PLC*, 838 F3d 421, 436 (3d Cir 2016). But see *New York v Actavis PLC*, 787 F3d 638 (2d Cir 2015) (agreeing with the rather narrow view of the market).

⁴³ See *Mylan*, 838 F3d at 436.

⁴⁴ See, for example, Michael A. Carrier and Steve D. Shadowen, *Product Hopping: A New Framework*, 92 *Notre Dame L Rev* 167, 179 (2016).

Yelderman are met, consumers may still be worse off if the case were to go to a trial that results in patent invalidation rather than if the case were to be settled and the patent validity preserved. Depending on the size of the market, challengers may, “[i]nstead of [pursuing] the uncertainty (and the potentially large pay-off) inherent in [innovation], . . . settle for the certainty of low payoff.”⁴⁵ The consumer may then get a short-run benefit in reduced prices, but be deprived (perhaps improperly, as further discussed below) of a long-run benefit of more innovation.

The third objection is in many ways tied to the preceding one and is perhaps even antecedent to it. Professor Duffy observes that “the promise of high prices is economically beneficial only if the patent is deserved—i.e., only if it is valid.”⁴⁶ If a patent is invalid (or not infringed by a particular product), then consumers end up bearing the economic cost of the patent remaining an enforceable barrier to the competitors without any justification for allocating this cost to them. On this account, precluding adjudication of these invalid patents and allowing the patentee and the challenger (who after all wishes to produce an identical product and compete on price) to settle improperly allocates consumer surplus to the producers.⁴⁷ The problem with this account is that it fails to recognize that it is quite possible that even an invalid patent will provide a sufficient spur to other market participants to design around the patent and thus engage in nonprice-based competition. In this sense, an invalid patent is no different than a valid one as they both channel competitors’ energies toward the production of alternative goods that may well be valued by consumers. To be clear, I do not wish to be understood as defending invalid patents, as they violate the basic bargain between the public and the patentee. They may present a host of other problems, such as stifling downstream innovation that would otherwise build on freely available technology. Randomly granted patents (which have an equal chance of being valid or invalid) also fail to properly incentivize *innovation*, and may instead encourage rent-seeking.

My argument is limited to cases in which a granted patent’s validity is at the very least debatable and either finding could be supportable. In those instances, it is not clear whether patent invalidation is to be preferred to patent preservation. As the saying

⁴⁵ Dolin, *Resolving the Patent-Antitrust Paradox* at *3 (cited in note 29).

⁴⁶ Duffy, 83 *Geo Wash L Rev* at 634–35 (cited in note 24).

⁴⁷ See Joshua B. Fischman, *The Circular Logic of Actavis*, 66 *Am U L Rev* 91, 102 (2016).

goes, “necessity is the mother of invention,” and if it is necessary to avoid infringing a patent—even an invalid one—it may well in the long run result in more innovation that benefits the consumers. Whether that general proposition is true in any specific case is of course an empirical question and not amenable to a purely theoretical answer; however, the possibility ought to at least be considered when evaluating whether patent settlements enhance or erode consumer welfare. Furthermore, it ought to be remembered that courts can (and do) make both Type I (false positive) and Type II (false negative) errors⁴⁸ in adjudicating patent disputes—that is, they may find a valid patent to be invalid and vice versa. As I have noted elsewhere:

The mere fact that a patent has been invalidated in litigation does not necessarily (though it may well) indicate that the patent was inherently weak. Rather, it may simply be an artifact of the hierarchical justice system where a mistake made by a “final” arbiter is “infallible,” but only because of the nature of the arbiter.⁴⁹

The net benefit or loss to consumers from patent litigation can be thought of as the benefit obtained from actually invalid patents being found as such discounted by the sum of losses from actually valid patents being invalidated, plus the actually invalid patents being found valid, plus the cost of litigation overall. From the consumer’s perspective, on the positive side, settlements reduce or eliminate litigation costs and avoid the possibility of a valid patent being invalid. On the negative side, settlements maintain the possibility that an invalid patent will remain in force. Whether the equation balances in favor of the consumer depends on the rate of both Type I and Type II errors, the cost of litigation, and the terms of the settlement. Depending on these factors, settlements may end up being procompetitive and pro-consumer, even when all of the conditions posited by Yelderman are met.

II. PHARMACEUTICAL PATENTS, THE HATCH-WAXMAN ACT, AND “REVERSE” SETTLEMENTS

In his article, Yelderman suggests that pharmaceutical patents are perhaps the best candidates to meet all of the conditions

⁴⁸ In other words, courts sometimes erroneously invalidate a valid patent (a Type I error in this context), and sometimes uphold a truly invalid patent (Type II error).

⁴⁹ Gregory Dolin, *Dubious Patent Reform*, 56 BC L Rev 881, 948 n 196 (2015).

that may make settlements anticompetitive.⁵⁰ In the pharmaceutical world, a drug is often protected by a single patent,⁵¹ and the regulatory regime restricts entry to the market in such a way as to preclude easy entry of competitors selling either the same or a substitute drug. In addition, the Hatch-Waxman regime creates opportunities for settlements between two competitors to not just resolve their private dispute, but to freeze out other producers.⁵² Yelderman does a thorough job covering the operation and intricacies of the Hatch-Waxman Act⁵³ and so there is no need to delve into the great details in this response, but some recapitulation of the Act's workings are in order.

The main goal of the Act is to reduce the cost of pharmaceuticals by encouraging more competitors to enter the market.⁵⁴ Recognizing that patent litigation is costly and outcomes are often uncertain, Congress created a bounty system in which the first generic firm to challenge a patent would receive an exclusive license from the FDA that would allow it to be the sole generic provider for 180 days.⁵⁵ Because of this system, an incentive exists for the challenger and the patentee to agree to settle their case, with the patentee retaining their patent and the challenger retaining their extraordinarily valuable exclusivity period, thus excluding all other competitors from the market and maintaining higher than competitive prices.⁵⁶ The patentee would agree to pay the challenger in exchange for the challenger's agreeing to drop the patent challenge and stay off the market for the time being (while saving its period of exclusivity).⁵⁷ The "compensation" comes from the patentee and the challenger splitting the income from the supra-competitive prices, which are in turn borne by the consumer.⁵⁸ As the Supreme Court explained, "[P]ayment in re-

⁵⁰ Yelderman, 83 U Chi L Rev at 2012–17 (cited in note 5).

⁵¹ See Geertrui Van Overwalle, *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches*, 1 UC Irvine L Rev 435, 438 (2011). While there may be multiple patents protecting a particular formulation, the active ingredient is often protected by a single patent, if not a single claim. *Id.*

⁵² See Gregory Dolin, *Reverse Settlements As Patent Invalidity Signals*, 24 Harv J L & Tech 281, 283–84 (2011).

⁵³ Pub L No 98-417, 98 Stat 1585.

⁵⁴ Dolin, 24 Harv J L & Tech at 286–90 (cited in note 52).

⁵⁵ *Id.* at 289.

⁵⁶ See *Federal Trade Commission v Actavis*, 133 S Ct 2223, 2235 (2013).

⁵⁷ See Glynn S. Lunney, Jr., *Federal Trade Commission v Actavis: The Patent-Antitrust Intersection Revisited*, 93 NC L Rev 375, 418 (2015).

⁵⁸ See Erica N. Andersen, *Schering the Market: Analyzing the Debate over Reverse-Payment Settlements in the Wake of the Medicare Modernization Act of 2003 and In re Tamoxifen Citrate Litigation*, 93 Iowa L Rev 1015, 1059 (2008).

turn for staying out of the market—simply keeps prices at patentee-set levels, potentially producing the [multi-]million monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses.”⁵⁹

On the surface, this does seem like a perfect case for concluding that a completed patent challenge would increase competition, while a settlement may well stifle it. Indeed, due to the FDA clinical trial requirements, it is extraordinarily expensive to “invent around” a pharmaceutical patent.⁶⁰ The problem is that this is an overly simplistic view of these settlements. If the settlements really did look like they are usually described—that is, large payments in exchange for staying off the market and insulating the patent from further challengers—then it would be easy to conclude that these settlements are an attempt at wealth transfer from consumers to producers. What often goes unmentioned, however, is that nearly every one of these settlements involves an agreement by the patentee to let the challenging generic enter the market prior to the patent’s expiration date.⁶¹ Because of this feature:

[S]ettlements are detrimental to consumers only if the generic challenger would have prevailed in litigation. These settlements serve to prevent market entry for generic manufacturers and therefore force consumers to pay higher, monopoly rents for longer periods than they would have had the suits gone to judgment and the generic manufacturers prevailed. On the other hand, if the patentee would have prevailed, then the consumers benefit from a reverse settlement, as it allows for the generic’s entry prior to the expiration of the patent. Thus, consumers obtain lower, non-monopolistic prices earlier than they otherwise would have.⁶²

As already mentioned, in any patent litigation courts can commit either a Type I or Type II error. Thus, a fully valid pharmaceutical patent may be erroneously found to be invalid (or not

⁵⁹ *Actavis*, 133 S Ct at 2235.

⁶⁰ See W. Nicholson Price II, *Regulating Secrecy*, 91 Wash L Rev 1769, 1789–90 (2016). At the same time, it is unclear whether, in the long run, consumers benefit more when additional companies are trying to get into a proven lucrative market or when companies are forced to develop substitute drugs. See Dolin, *Resolving the Patent-Antitrust Paradox* at *2–3 (cited in note 29).

⁶¹ Dolin, 24 Harv J L & Tech at 293–305 (cited in note 52) (discussing various settlements that were the subject of litigation or FTC challenge).

⁶² *Id* at 284.

infringed) and vice versa. Consider then a situation in which a brand-name manufacturer holds a “strong” patent—that is, one that has a 75 percent chance of being found both infringed and not invalid in litigation, thus leaving the challenger with only a 25 percent chance of prevailing on their challenge. In this case the patentee realizes that there is a not insignificant chance that the court will rule in error and they will lose their valuable property right.⁶³ In order to avoid that possibility, the patentee is willing to settle with the challenger on terms that would allow the challenger to enter the market prior to patent expiration.⁶⁴ A difficult question then arises: Are consumers better off with the *certainty* of an entry by a competitor that is earlier than patent expiration but later than what would have been achieved had the challenger prevailed in litigation, or are they better off with a chance of an even earlier entry? In other words, is 100 percent of X worth more than 25 percent of Y, when Y is larger than X? The answer to that question would certainly depend on the relative values of Y and X—something that likely differs from case to case (as does the chance of success in litigation).

An additional complication is that while Hatch-Waxman litigation is often talked about as a monolithic entity, in reality two distinct subtypes exist. When a generic manufacturer wishes to enter the market prior to the expiration of patents that cover the drug the generic wishes to copy, it must certify that said patent is either invalid or will not be infringed.⁶⁵ Should the generic manufacturer prevail in either of its arguments, the same result obtains—it may enter the market (and enjoy the earned statutory exclusivity).⁶⁶ Thus, from the challenging generic manufacturer’s viewpoint it matters not whether the patent will be adjudicated invalid or not infringed. But from the viewpoint of other generics and of the consumers it matters a great deal. If the patent is adjudicated to be invalid, then it cannot be asserted against anyone

⁶³ See Bruce H. Kobayashi, et al, *Actavis and Multiple Anda Entrants: Beyond the Temporary Duopoly*, 29 *Antitrust* 89, 89, 94 (2015).

⁶⁴ See Jonathan D. Putnam, *Reverse Payment Settlements: Structure, Purpose, and Reform*, 6 *Antitrust Source* 1, 9–10 (2006). Indeed, “[e]ven when both parties in the example estimate that the patent will be upheld 90 percent of the time,” the patentee may be willing to pay significant sums to avoid Type I error. Bruce H. Kobayashi, et al, 29 *Antitrust* at 94 (cited in note 63).

⁶⁵ See 21 USC § 355(j)(2)(A)(vii)(IV); Dolin, 24 *Harv J L & Tech* at 328 (cited in note 52).

⁶⁶ 21 USC § 355(j)(5)(B)(iii) (directing the FDA to approve a generic’s entry when the patent is found or admitted to be either invalid or not infringed); Dolin, 24 *Harv J L & Tech* at 328–29 (cited in note 52).

else, thus allowing further market entry once the 180 day exclusivity period expires.⁶⁷ As more generics enter the market, prices would be expected to drop with consumers reaping the benefits of this competition.⁶⁸ On the other hand, if the patent is declared to be merely not infringed though valid, it can still be asserted against other generics who may wish to enter the market.⁶⁹ Because second- (and subsequent-) comers are not entitled to any exclusivity, and because they will be entering a more and more saturated market that will generate lower and lower returns, they will become less and less likely to spend significant amounts of money litigating over the brand-name manufacturer's patent.⁷⁰ The upshot for consumers is that with the competition limited to the duopoly of the brand-name manufacturer and the first generic, they are not likely to see significant savings.⁷¹ In these situations, a settlement-guaranteed earlier entry is more likely to be a better value than a crapshoot of litigation that may or may not result in any generic being available.

In short, while the Hatch-Waxman regime may well be the best-case scenario for challenges resulting in increased competition and settlements depriving consumers of that benefit, the reality is significantly more complex. Whether consumers benefit from settlements that retain the patent or litigation that invalidates it, even in situations in which the patent serves as essentially the sole barrier to entry, is very much open to question and highly dependent on the strength of the patent and the settlement's terms.

CONCLUSION

Professor Yelderman's article has significant implications for the reforms enacted by the America Invents Act,⁷² proposed future reforms, and the continued litigation over settlements in the pharmaceutical context. The issues and limitations of patent challenges that Yelderman has identified should give some pause to those who almost reflexively believe in the ability of such challenges to increase competition. Nonetheless, the article does not

⁶⁷ See *Blonder-Tongue Labs, Inc v University of Illinois Foundation*, 402 US 313, 330 (1971).

⁶⁸ David E. Korn, et al, *A New History and Discussion of 180-Day Exclusivity*, 64 *Food & Drug L J* 335, 383–84 (2009).

⁶⁹ Dolin, 24 *Harv J L & Tech* at 329 (cited in note 52).

⁷⁰ See Korn, 4 *Food & Drug L J* at 383–84 (cited in note 68).

⁷¹ *Id* (noting that “the first generic manufacturer in the market, on average, sold its product at a price that was only six-percent lower than the brand-name price”).

⁷² Pub L No 112-29, 125 Stat 284 (2011).

go far enough in that it accepts without challenging the basic assumption that patent-created barriers necessarily reduce rather than enhance competition and that settlements that preserve patents that could be invalidated in litigation may be anticompetitive. Both of those assumptions, though often made, are, upon deeper analysis, not indisputable. Even so, the article is an excellent refutation of the overly simplistic and uncritical approach to the virtue of patent challenges and significantly contributes to the understanding of and the debate over the role of patents and patent litigation in consumer welfare.