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NO FREE LAUNCH: AT-RISK ENTRY BY GENERIC DRUG FIRMS

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### **ABSTRACT**

After receiving FDA approval, a generic drug manufacturer can launch “at risk” before conclusion of any patent infringement litigation, but it risks paying damages if it loses. The generic can eliminate the risk by waiting to launch until the appeals process is complete but waiting has downsides too. We develop a model that implies that, after the generic has won a district court decision, at-risk entry is generally profitable and will occur quickly unless the cost of waiting for the appeal is very low. We examine generic drug applications that have received FDA approval with “first-filer” status (which precludes later filing generics from entering before the first filer). In our data, the generic and brand usually settled prior to the conclusion of litigation. For the remainder, drugs that received FDA approval prior to a favorable district court decision were always launched at risk. Generics without FDA approval before a favorable district court decision launched upon approval unless the approval was close in time to the appeal decision or it had forfeited the first filer exclusivity (indicating a low cost of waiting). We also consider implications of at-risk entry for social welfare, arguing that at-risk entry is analogous to a “buy out” of the patent with favorable welfare implications in both the short run (consumer prices) and long run (efficient incentives for R&D).

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## I. Introduction

The central issue in regulation of pharmaceutical drug markets is managing the tradeoff between encouraging innovator firms to invest in development of new products and making drugs available to buyers at competitive prices.<sup>1</sup> In the pharmaceutical industry, a combination of patent protection and market exclusivities governed by the Food and Drug Administration (FDA) balances these objectives. Patent protection policy involves statutory exclusivities, requirements to obtain a patent, rules for challenging and defending a patent, and other elements, some of which are unique to the drug industry.<sup>2</sup> Market exclusivities are periods during which the FDA will not approve applications from follow-on competitors for an innovator drug (*e.g.*, generic manufacturers). The Hatch Waxman Act of 1984 changed the incentives for both innovator and generic pharmaceutical firms. For innovator firms, the new regulations increased incentives to invest in innovation by introducing new exclusivity periods and extending existing exclusivities. For generic firms, the Hatch Waxman Act created a mechanism for challenging the patents obtained by innovator firms.<sup>3</sup> This Hatch Waxman-created mechanism (described below) allows a generic firm to technically “infringe” on a brand firm’s patent(s) before selling its product, allowing a pathway for a patent infringement lawsuit without the generic challenger running the risk of paying damages to the patent holder. A district court’s decision about validity and infringement may be appealed so that final resolution of the litigation typically follows an appeals court decision.

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<sup>1</sup> For discussion of the tradeoff between investment in research and competitive pricing in pharmaceutical markets, see, for example, Berndt (2002) and Goldman and Lakdawalla (2011).

<sup>2</sup> For a discussion of how the patent system in the pharmaceutical industries differs from other industries, see Lemley (2008).

<sup>3</sup> The Hatch-Waxman Act’s official name is the Drug Price Competition and Patent Term Restoration Act (Pub. L. No. 98-418).

The technical-infringement mechanism created by Hatch Waxman has led to more patent challenges (Frank 2007; Hemphill and Sampat 2011), which frequently end with a negotiated entry date for the generic in a settlement agreement (Greene and Steadman 2010). If brand and generic litigants have not settled, the generic firm can elect to infringe in the conventional way by selling product prior to resolution of the patent litigation. After receiving FDA approval for its product (based on criteria unrelated to patent validity), the generic firm can, in the parlance of the drug industry, enter and sell “at risk.” This mode of entry is considered “at risk” because generic sales reduce profits of the patent holder, presenting the generic seller with a risk of paying compensation to the brand if the patent is found valid and infringed.

While the joint decision of a brand and a challenging generic about settlement has received a great deal of attention in the academic literature,<sup>4</sup> a generic firm’s unilateral decision to enter at risk has received much less, despite the potentially massive consequences for social welfare. The price at which the brand sells a drug typically vastly exceeds the price at which the generic sells a bioequivalent product (Berndt, McGuire, and Newhouse 2011). For example, at-risk entry that accelerates competitive pricing of a single “blockbuster” drug with annual sales of \$2 billion by one-year effects a transfer of \$1.4 billion or more from a brand firm to consumers, with both the short- and long-term welfare consequences.

Prior to a district court decision, a generic’s decision about at-risk entry is made in the presence of considerable uncertainty. Once the district court decision has resolved most (but not all) of the uncertainty, the generic’s calculus changes. This paper picks up the story at this point with a simple model of the benefits and costs to a generic in connection with the decision to enter

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<sup>4</sup> The concern is that an agreement about the terms and timing of competition between potential rivals may maximize their joint profits at the expense of consumers. See, for example, Shapiro (2003); Elhauge and Kruger (2012); Edlin *et al.* (2013); Edlin *et al.* (2015); and Drake, Starr, and McGuire (2015).

at risk after a district court decision. We use the model to generate predictions about the timing of at-risk entry and go on to compare the model's predictions with data on the frequency of at-risk launch opportunities and launches from 2005-2020 which we assembled for this purpose. Our data include information about whether the at-risk launch was found to infringe, and if so, what information we could glean about how much the generic paid in damages to the brand.

The model of benefits and costs implies that, assuming the chance of the generic winning on appeal is high, at-risk entry is generally profitable and will occur "as soon as possible" unless the cost of waiting for the appeals court decision is very low, in which case the generic will not launch at risk. Our empirical results support this prediction. In our data, the generic most often settled early in the litigation process. However, generics that did not settle, and that received FDA approval prior to a favorable district court decision, were launched at risk 100% of the time. If the generic did not have FDA approval at the time of a favorable decision, it launched upon approval unless the final approval was obtained close in time to the appeals court decision (indicating the cost of waiting was low) or they had forfeited the exclusivity period (also reducing the cost of waiting).

Section II provides background on the relevant regulations of the pharmaceutical industry. In Section III, we present a model of the benefits and costs of the generic's at-risk entry decision. Section IV describes the assembly of our novel data set on at-risk entry opportunities, empirical methods, and results. Section V broadens the perspective to consider the benefits and costs of at-risk entry from the standpoint of economic efficiency. We argue that more and faster at-risk entry would improve social welfare in both the short and the long term. In brief, as long as generic firms are liable for brand lost profits for patents found valid and infringed, incentives for innovator firms to pursue novel research and subsequently file for patents with a high likelihood

of withstanding a patent challenge are maintained. At the same time consumer prices are moved towards marginal cost. We observe that at-risk entry is roughly equivalent to the generic firm “buying out” the patent, paying the patent holder expected value of monopoly profits, and putting the patent in the public domain (Kremer 1998). Long-term incentives for research are actually improved because more frequent at-risk entry would direct financial incentives away from research leading to weak patents needlessly blocking generic entry and towards truly innovative research.

## **II. Background**

### **A. CIRCUMSTANCES OF AT-RISK ENTRY IN THE DRUG INDUSTRY**

The Hatch-Waxman Act balanced the competing goals of promoting competition by generic drugs, resulting in lower drug prices, while maintaining pharmaceutical companies’ incentives to develop new and better drugs. Hatch-Waxman increased the economic rewards for innovation by giving innovator, or brand name, drug manufacturers longer periods of market exclusivity for newly approved products (Hemphill and Lemley 2011). To expediate generic entry, Hatch-Waxman also introduced the Abbreviated New Drug Application (ANDA) process, which enabled generic manufacturers to apply for approval based on proof of bioequivalence to an approved brand drug, relying on clinical trial results from the associated brand drug. The Act also created incentives for generic manufacturers to challenge weak, invalid, or improperly listed patents to prevent such patents from blocking competition by lower-priced generics.

A generic drug manufacturer submitting an ANDA to the FDA with a “Paragraph IV” certification is asserting that patents purportedly covering the brand drug are invalid, unenforceable, or un infringed by its product. The generic has 30 days to notify the brand manufacturer of its ANDA filing. The brand then has 45-days from receipt of the notice to sue

the generic for patent infringement, which initiates a 30-month stay during which the FDA will not approve the generic's drug unless the generic wins the litigation. During the 30-month stay, the generic can receive "tentative approval," which essentially means that, aside from the stay, the generic product is approvable. After the 30-month stay expires, the FDA can approve the generic's product regardless of whether patent litigation is ongoing, which gives the generic the option to launch at risk. However, the brand can petition the court for an injunction that prevents the generic from launching during the litigation (21 U.S. Code § 314.107; Lietzan and Julia Post 2016).

Any launch before the conclusion of the patent infringement litigation is "at risk" because it exposes the generic to the risk of paying damages to the brand. The generic could end up paying more in damages than it earned in profits during the at-risk launch because the brand's profits are lost at a high price while the generic's profits are made at a lower price. Furthermore, a court may require the generic to pay triple damages if the generic is found to have exhibited willful or wanton infringement.<sup>5</sup> The generic can mitigate its risk of paying damages by waiting to launch until after a favorable district court decision, or it can eliminate the risk entirely by waiting until the appeals process is complete or by settling with the brand at any time.

However, waiting to launch can be costly, due to discounting of future revenues and potential unfavorable market developments. For example, the brand market may be getting smaller over time.<sup>6</sup> This is especially likely if the brand attempts to retain sales at a high price by claiming new patents for modifications of the original product, referred to as "line extensions," and works to move patients from the original formulation to the line extension prior to loss of patent

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<sup>5</sup> Triple damages, also referred to as "treble damages," are imposed at the discretion of the court. For further discussion of triple damages see Powers and Carlson (2001).

<sup>6</sup> Brand drug sales are sometimes described as having a natural "life cycle" described by an inverted U-shaped sales curve. See Fischer, Leeflang, and Verhoef (2010).

protection on the original product. Success with this strategy, referred to by critics as “product hopping,” greatly reduces sales of the generic version of the original formulation (Cheng 2008; Carrier and Shadowen 2016). Waiting to launch also provides other generics more time to receive FDA approval, which could result in a more competitive generic market after entry.

A generic submitting the first substantially complete ANDA with Paragraph IV certification is referred to as a “first filer.” First filers are granted a 180-day exclusivity period during which the FDA will not approve other ANDAs (Section 505(j)(2)(B) of the FD&C Act; Lietzan 2004). The exclusivity period begins on the first day that the first filer markets the product, meaning that subsequent filers cannot launch until 181 days after the first filer. The exclusivity period enables the first filer to charge prices above those with multiple generic competitors. This “prize” encourages applications that challenge weak patents unnecessarily restricting generic entry. Multiple generics can share first-to-file status and the associated right to the exclusivity period if they file on the same day, and any first filer can launch at risk after receiving FDA approval. Additionally, the brand can launch its own “authorized generic” at any time and so can compete with first filers after an at-risk launch, including during the 180-day exclusivity period.<sup>7</sup> Later filing generics cannot launch at risk unless the exclusivity period has expired or been forfeited.

A first filer must receive tentative FDA approval within 30-months of filing its ANDA to retain its right to the 180-day exclusivity period (Section 505(j)(2)(B) of the FD&C Act). If the first filer launches at risk, the exclusivity period begins upon launch; however, the 180-day period continues to run if the brand wins an injunction blocking the generic’s sales. If the first filer chooses not to launch at risk, it can use its right to the exclusivity period (thus blocking later

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<sup>7</sup> Authorized generics are typically launched within a few days of the first ANDA generic launch. See Farrell *et al.* (2011).



filers from entering) by either winning the litigation or settling for a licensed entry date, and it forfeits the exclusivity period if it loses the patent infringement litigation.

Brand and generic firms may negotiate a settlement at any point during the litigation process. The settlement will include an agreed upon entry date for the generic firm and may also include other terms.

## B. RESEARCH ON AT-RISK ENTRY

At-risk entry is the norm in many industries (Lemley 2008). Most entrants invent and begin selling products without notifying patent owners of potential infringement. Makers of most new products are not accused of patent infringement, but when litigation does occur, it begins after the products have been sold and patents have purportedly been infringed. In the pharmaceutical industry, the FDA prohibits entry of generic drugs during exclusivity periods awarded to newly approved brand drugs and strictly regulates entry after they expire. The Paragraph IV certification enables generic manufacturers to begin the required approval process for entry before applicable patents expire. However, unlike other industries, generic entrants in the drug industry must notify the patent owners before they start selling – at the time of application – triggering possible litigation. Generic firms are effectively kept out of the market for 30 months after the initiation of litigation because the FDA is prohibited from issuing final approval during this time.

Some authors have argued that, in the drug industry, generic companies file patent challenges indiscriminately hoping to obtain favorable settlement terms from the patent owner. These authors argue that the practice of “patent prospecting” undermines brand firms’ incentives to conduct R&D by diluting protection of intellectual property. Grabowski and colleagues found that Paragraph IV challenges have shortened the effective exclusivity period for brand drugs,

measured as the time from brand drug launch to first generic launch. Over time, a greater share of brand drugs face a Paragraph IV challenge and the challenges are occurring earlier, meaning the time between a brand drug launching and facing its first challenge has declined (Higgins and Graham 2009; Grabowski and Kyle 2007; Grabowski *et al.* 2011).

Other authors have investigated the other side of the story. Brand firms have increasingly acquired low-quality and late-expiring patents to extend their patent protection beyond the term of the active ingredient patent, a strategy referred to as “evergreening.” Based on their empirical analysis, Hemphill and Sampat found that patent challenges usefully target weak and late-expiring patents and offset the proliferation of lower-quality patents. Patent challenges are more common for higher sales drugs largely because higher sales drugs are more likely to be covered by multiple low-quality patents. The increase in patent challenges has not impacted the market term of active ingredient patents (Hemphill and Sampat 2012).

There are some reports on the frequency of at-risk launches in the drug industry but none, so far as we know, containing recent data. After winning a district court decision on summary judgment, Geneva Pharmaceuticals was the first firm to launch at-risk in 2002 with its generic version of Augmentin (Manspeizer 2014). By 2007, some larger generic companies launched products even before a district court decision (O’Malley, Jr. *et al.* 2011). A 2010 financial analyst report identified 28 at-risk launches between 2003 and 2009.<sup>8</sup> A January 2014 legal publication reported that at-risk launches have occurred “at least 26 times” since the Augmentin launch (Manspeizer 2014). While these findings indicate that at-risk launches are occurring, the drugs subject to at-risk launch are still a small fraction of the thousands of drugs subject to patent protection.

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<sup>8</sup> Greene & Steadman (2010) defined at-risk launches narrowly “as launch prior to a trial court decision” and thus excluded at-risk launches after a district court decision.

When the generic launches at risk and then loses the patent infringement case, the brand is entitled to damages based on its lost profits (Manspeizer 2014). However, determining the magnitude of those lost profits can be complicated from both an economic and legal standpoint. For example, the brand often launches its own “authorized generic” in response to the infringing generic, and the question arises of whether the generic should be held responsible for lost brand sales and price erosion caused by the brand’s own authorized generic. The small number of legal trials determining damages, usually taking place after the generic has lost a separate patent infringement trial, have all ended in settlement.<sup>9</sup>

### **III. Weighing The Benefits And Costs Of An At-Risk Launch After A Favorable District Court Decision**

To launch at risk, a generic firm needs final FDA approval, which it can receive at any point during the patent infringement litigation after any relevant exclusivity periods, such as the 30-month stay, expire. The generic often (but not always) receives FDA approval soon after a district court decision, which can end an injunction or 30-month stay.<sup>10</sup> Here we characterize the generic’s decision to enter at risk after both winning a district court decision and receiving final FDA approval. At the end of this section, we comment on how the decision differs for a generic that has received FDA approval and is considering a launch before a district court decision, a decision by the generic which involves more uncertainty and a greater risk of paying damages.

The generic manufacturer with final FDA approval in patent litigation with a brand must decide whether and when to launch at risk as information emerges in discovery and in court

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<sup>9</sup> As described below, the lone case that did not end in settlement involved the drug Plavix. But in that case, the brand and generic had previously agreed on how damages would be calculated in a settlement.

<sup>10</sup> During the 30-month stay, the FDA cannot grant final approval unless the court makes a decision in favor of the generic drug. If a generic drug has otherwise met the requirements for FDA approval, a district court decision in favor of the generic firm enables the FDA to grant final approval.

decisions, and against the background of ongoing settlement negotiations.<sup>11</sup> One option is to wait for an appeals court decision. We refer to the expected payoff from waiting to enter until after appeals as  $p\pi_0$ , where  $p$  represents the probability of a favorable final litigation outcome for the generic (*i.e.*, win on appeal contingent on a win at district) and  $\pi_0$  the present value of the profits to be made with entry at that time.<sup>12</sup> There is no risk of paying damages after a favorable appeals court decision.

A generic's expected profits from entry at risk after a favorable district court decision depend on the profits the generic can make during an at-risk entry, and the expected value of any damages it must pay to the brand. Let  $\pi_g$  be the profits the generic gains by launching at risk prior to an appeals court decision and after final FDA approval, and  $\pi_b$  be the profits lost by the brand during the generic's at-risk entry. If the patent is ultimately found valid and infringed, the generic can expect to pay some share,  $s$ , of the brand profits in damages, where  $s$  could be less than or greater than one. The expected damages are thus  $(1 - p)s\pi_b$  where  $(1 - p)$  is the likelihood that the generic does not win patent litigation. Note that the generic keeps any profits it makes during the at-risk entry even if it must pay damages to the brand.

The generic will launch at risk if expected profits from launching at risk exceed expected profits from waiting to launch until after the appeals court decision.

$$\pi_g - (1 - p)s\pi_b > p\pi_0 \quad (1)$$

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<sup>11</sup> The generic may settle with the brand at any time during the litigation. Theoretical literature on brand-generic patent litigation has focused on the factors influencing whether a settlement is possible. For example, see Elhauge and Krueger (2012) and Ghili and Schmitt (2017). The likelihood and terms of the settlement depend on the expected payoffs to both parties in the absence of a settlement, which are heavily influenced by the likelihood of at-risk entry (Elhauge and Krueger 2012). Our focus is more limited. We examine the generic's decision-making process about at-risk entry in the absence of a settlement.

<sup>12</sup> After an unfavorable appeals court decision, the generic cannot launch until after patent expiry and launches without exclusivity. We assume these profits equal zero.

We expect  $\pi_g > \pi_0$  due to discounting of revenue in future periods relative to the current period, potential declines in profitability due to decreased demand for the drug, and presence of additional generic competitors with a later entry.

The first observation to make from (1) is that if the left-hand side of the expression is positive, indicating at-risk entry is profitable, the expected value of profit is likely to be maximized by at-risk entry “as soon as possible.” Both  $\pi_g$  and  $\pi_b$  are roughly proportional to the volume of sales a generic makes at risk. Each sale generates a certain profit for the generic and causes a certain loss to the brand for which the generic risks being liable. On expectation, the generic pays  $(1 - p)s$  dollars for each dollar of potential gain from at risk entry. If the risk is worth it to the generic for 100 sales it will be worth it for 1,000 or for 100,000. The more at-risk entry sales made, the higher the expected profit.

The second observation is that at some point, unless a generic can make enough sales, a positive left-hand side can fall below the expected profits from waiting until after appeal,  $p\pi_0$ . This would likely occur, for example, if FDA approval comes just prior to the expected timing of an appeals court decision. In this case, even though a generic’s expected profits from at risk entry are positive, they still fall below what the firm could expect by waiting for an appeals court decision.

Putting these two observations together, the decision rule in (1) leads to the prediction that generic firms will either enter “as soon as possible” after a favorable district court decision, or if regulatory or other reasons interfere with an early at-risk entry, they would wait until after the appeals court decision.

We can use (1) to solve for the threshold probability required to make at-risk entry more profitable than waiting for an appeals court decision.

$$p^* = \frac{s\pi_b - \pi_g}{s\pi_b - \pi_0} \quad (2)$$

So long as the generic believes its likelihood of a win at the appeals level is at least  $p^*$ , at-risk entry is profitable on expectation. A calculation shows how (2) works: let  $\pi_g = 1$ ,  $\pi_0 = 0.8$ , and  $\pi_b = 2.0$ , and  $s = .90$ . With these parameters, conditional on a win at the district court, the generic must expect a likelihood of winning of 0.8 or greater to enter at risk.

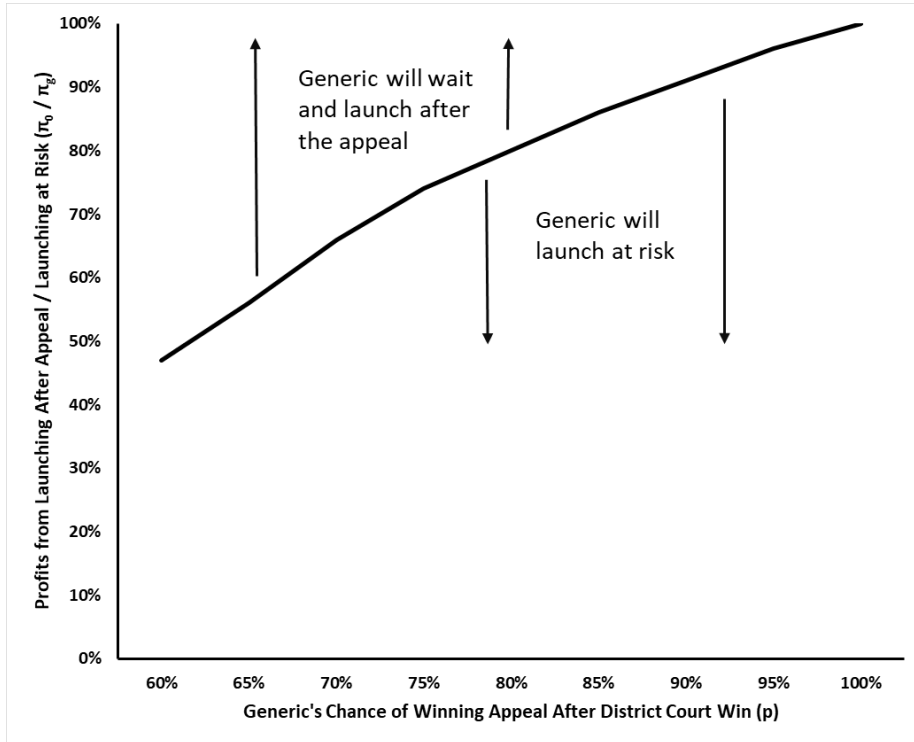
In practice, appellate courts rarely overturn district court decisions in drug patent litigation and a generic that has won a district court decision has a low risk of paying damages (*i.e.*,  $p$  is near 1.0).<sup>13</sup> The generic must decide whether the small risk of paying damages outweighs the cost of waiting to launch until after the appeal. The cost of waiting depends on the time remaining in the litigation, the market's growth (up or down), and the development of other generic competition, factors which vary from case to case. Normalizing on the generic's profits from launching at risk ( $\pi_g = 1$ ), the cost of waiting can be expressed in percentage terms as one minus the generic's profits from waiting to launch until after an appeal ( $1 - \pi_0$ ). Figure 1 illustrates the tradeoff between the generic likelihood of a win at appeal ( $p$ ) and the cost of waiting in percentage terms. The line in Figure 1 divides the space based on the same value of expected damages as above,  $s\pi_b = 1.8$ . With these parameters, and as shown in Figure 1, if the generic's chance of winning the litigation is 95% it will launch at risk unless it can retain 96% or

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<sup>13</sup> In our data, described below, the observed probability of the generic winning a final appeals court decision when it had already won a district court decision ( $p$ ) was 96.4%.

more of its expected profits by waiting and launching after the appeals court decision. A generic would have to retain 80% of the profits by waiting in order to overcome the incentives to launch at risk when the likelihood of the generic winning on appeal is 80%.

**Figure 1.** The generic’s threshold for launching at risk based on the cost of waiting and its probability of winning the patent litigation on appeal



To now in this Section, we assumed the generic won a district court decision and was deciding whether to launch at risk based on its risk of losing on appeal and other factors described in (1). A generic with FDA approval prior to a district court decision can enter at risk at that point as well. At this early stage, the generic’s perceived probability of winning is compound: the generic awaits a district as well as possibly an appeals court decision. Furthermore, the generic’s subjective probability of winning is likely to change as the case develops during the discovery and pre-trial hearing process and becomes clarified but not fully

resolved after a district court decision. Settlement negotiations are going on in the background. We do not write an expression analogous to (2) for this more complicated dynamic optimization decision depending heavily on the generic's evolving subjective probability of a litigation win. We do include data about at-risk launches prior to a district decision in our empirical analyses.

#### **IV. Data And Empirical Results**

##### **A. DATA ON AT-RISK LAUNCH OPPORTUNITIES**

We started with a list of 538 drug products with at least one ANDA that was approved after January 1, 2005 and were listed in the “180-Day Exclusivity Tracker” on Hyman, Phelps, and McNamara PC’s FDA Law Blog website.<sup>14</sup> We compared our list to the FDA’s list of Paragraph IV Patent Certifications, updated November 17, 2020, and added 161 additional ANDAs. Finally, we found 27 additional approved ANDAs by conducting internet searches for all the drugs in the data sources that were listed as not having an approved ANDA. Thus, our list included 726 drug products with at least one ANDA approved in 2005 or later.

We consulted the FDA’s ANDA approval letters and conducted internet searches to see which generics were first filers, to see if they were sued by the brand manufacturer, and to find the case identifiers for the litigation (the case number) that would enable us to look up additional case information on legal databases.<sup>15</sup> We also examined Lex Machina data to check if litigation had been initiated. For drugs with associated patent infringement litigation, we used Lex Machina data and the Public Access to Court Electronic Records (PACER) service to identify district and appeals court rulings. We classified a decision as a generic win if every relevant patent were found to be invalid, unenforceable, or un infringed. If the court found that at least

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<sup>14</sup> Last updated January 29, 2020. FDA and FDA Law Blog <https://www.fdalawblog.net/wp-content/uploads/180-Day.xlsx>.

<sup>15</sup> FDA approval letters are available at [Drugs@FDA.com](mailto:Drugs@FDA.com), although some are not available.



one valid patent blocked the generic's immediate entry, we classified it as a brand win because it prevented the generic from entering at risk. We also checked to see if an injunction had prevented the generic from entering.

We used the generic manufacturer's press release or another publicly available source to determine when a product launch occurred. We compared the dates of the legal decisions to the generic's entry date to determine whether the drug had been launched at risk during the litigation. For cases where the generic launched at risk and then lost the patent infringement litigation, we conducted internet searches to gather information on damages paid from the brand to the generic.

In total, after a series of exclusion decisions, we identified 75 drugs where at least one first-to-file generic had the opportunity to launch at risk. ANDAs cover unique drug-form combinations and sometimes cover multiple strengths. From our list of 726 drug products with at least one approved ANDA of a first filer, we excluded 167 "duplicate" drugs that involved the same pair of brand-generic litigants, the ANDAs received FDA approval at the same time, and the drug products were launched at the same time. In essence, we treated these duplicates as one observation. Because we were interested in the generic's decision to launch at risk, we excluded 122 drugs for which the brand had opted not to sue the generic. We excluded 168 where the generic received FDA approval, did not launch at risk, and then settled before a district court decision. We excluded 115 drugs where the litigation had settled or was dropped before the generic received FDA approval and 39 drugs where the generic lost a district court decision before FDA approval. We excluded 7 drugs where the approved generics did not have exclusivity or first-filer status or it could not be determined; 13 where the generic received FDA approval after the final appeal (and thus could not launch at risk); 2 where the generic received

FDA approval after a district court win but there was no further appeal; 3 where litigation was ongoing and no legal decisions had been made; 9 where the drug is classified as over-the-counter (OTC); and 5 where an injunction prevented the generic from launching at risk. We also excluded 1 drug where the brand company reformulated its drug to prevent generic competition, discontinued the original formulation, and the generic never launched a generic version of the original formulation (even after winning the appeal).

We also gathered data on potential predictors of at-risk launches. Brand manufacturers must submit all patents that protect their approved drug to the FDA including the patent number, patent expiration date and an indication of whether the patent is a drug substance, drug product, or method of use patent.<sup>16</sup> As an indicator of patent strength, patent numbers in PACER were used to determine whether a substance or product patent was involved in the litigation. We classified substance and product patents based on how they are classified in the Orange Book. We also gathered data on the brand market sales prior to generic entry using internet searches. The FDA approval letters, the FDA's website, and the 180-Day Exclusivity Tracker were used to determine whether the first filer had retained its 180-day exclusivity period. We obtained information on generic formulation from the FDA Orange Book and Drugs@FDA databases. Drugs are classified as oral solids, injectables, and topicals (including patches and inhalers).

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<sup>16</sup> As defined by the FDA, "drug product is a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients. Drug substance is an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient." See 21 U.S. Code § 314; Brand manufacturers must submit patent number, patent expiration date and indicate if the patent is a drug substance, drug product, or method of use patent. see 21 U.S. Code § 355. Active ingredient patents have been shown to be more likely than method of use patents to be upheld in court. We use the drug substance and drug product designations as proxies for patent strength. See Hemphill & Sampat (2011).

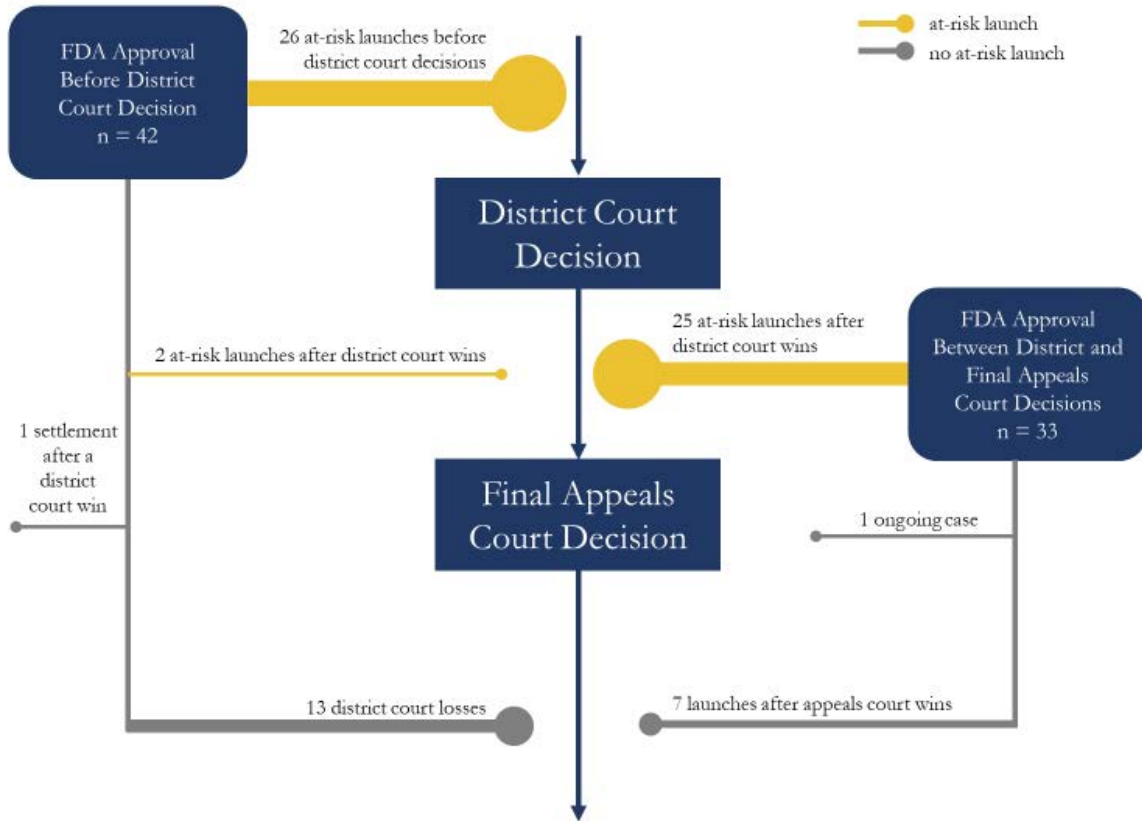
## B. EMPIRICAL RESULTS

Figure 2 illustrates our data on at-risk launch opportunities and decisions. Of the 42 generic drugs that had received FDA approval before a district court decision and were not prevented from entering by an injunction, 26 were launched at risk before a district court decision and 16 were not. Of the 16 generic drugs that were not launched at risk before a district court decision, two were launched at risk after the generic's district court win; the litigation for one drug was settled after the generic's district court win; and no generics were launched at risk after the 13 district court decision losses, necessarily so because entry would be blocked by an injunction.<sup>17</sup> Of the 33 generic drugs that received FDA approval after a favorable district court decision, 25 were launched at risk before the appeals court decision and 8 were not. Of the generic drugs that were not launched at risk, 7 launched after a favorable appeals court win and for 1 drug in our data the litigation was ongoing.

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<sup>17</sup> There were two drugs, Norvasc and Aloxi, for which the generic lost at district court, but won at appeals and launched thereafter.

**Figure 2.** Generic At-Risk Entry Opportunities and Launches



We present descriptive results comparing drugs on factors that may have influenced the at-risk entry decision. We test the statistical significance of variation between the groups, using Fisher’s exact test due to small sample size. In Table 1 we present results for drugs that received FDA approval before the district court decision and in Table 2 for drugs that received FDA approval after the district court decision, but before the appeals court decision.

Generics that launched at risk before the district court decision were more likely to win or settle the patent litigation compared to generics that received FDA approval but did not launch at risk before the district court decision (see Table 1). This may imply that generic manufacturers can anticipate the outcome of the litigation to some degree. Drugs that were not launched at risk were more likely to have a drug substance or drug product patent than those that were launched

at risk, suggesting that patent strength factors into the decision to launch at risk. The number of patents, however, was not statistically different between drugs that were and were not launched at risk. Drugs launched at risk before a district court decision were more likely to have under \$50 million in sales, to receive FDA approval more than three months before the date of the district court decision, and to have retained their exclusivity status compared to drugs that were not launched at risk. The generic's decision calculus is different for a generic firm that has forfeited its exclusivity period. While an at-risk launch still puts the generic at risk of paying large damages, its profit prospects are substantially lowered. Dosage form was distributed similarly across the two groups.

**Table 1.** Generic drugs that received FDA approval and could launch before a district court decision

	Launched Before District Court Decision		p-value
	Yes	No	
Total, <i>n (col %)</i>	26 (100%)	16 (100%)	
Litigation Outcome, <i>n (col %)</i>			
Generic Win	7 (27%)	4 (25%)	0.087
Brand Win	5 (19%)	8 (50%)	
Settled	14 (54%)	4 (25%)	
Patent Type, <i>n (col %)</i>			
Has Drug Substance Patent	4 (15%)	8 (50%)	0.032
Has Drug Product Patent	11 (42%)	14 (88%)	0.004
Has Drug Substance or Product Patent	11 (19%)	14 (76%)	0.004
# of Patents Asserted, <i>n (col %)</i>			
1	16 (62%)	6 (37%)	0.204
>1	10 (38%)	10 (63%)	
Drug Sales, <i>n (col %)</i>			
<\$50 million	8 (31%)	0 (0.0%)	0.041
\$50 - \$350 million	8 (31%)	7 (44%)	
>\$350 million	10 (38%)	9 (56%)	
Form, <i>n (col %)</i>			
Oral	22 (85%)	13 (81%)	1.000
Topical or Injection	4 (15%)	3 (19%)	
Months between FDA approval and district court decision, <i>n (col %)</i>			
<3	2 (18%)	9 (56%)	0.109
>= 3	9 (82%)	7 (44%)	
Exclusivity Status, <i>n (col %)</i>			
Retained	24 (96%)	11 (69%)	0.026
Forfeited	1 (4%)	5 (31%)	

Table 2 assesses whether certain measured factors were related to the generic's decision to launch at risk for generics that received FDA approval after a district court decision. The generic won 100% of the appeals in Table 2 – and 96.4% if appeals after district court wins from Table 3 are included. Differences were not statistically significant because of the small sample size in each group, but the results point to some potentially important differences. Drugs that were launched at risk involved only one patent (44%) more frequently than drugs that were not launched at risk (13%), again indicating that the generic's likelihood of losing the appeal may impact its decision. The timing of the FDA approval and the status of the generic's 180-day exclusivity period both appear to factor into the generic's decision. The generic was more likely to launch at-risk if it was approved 3 months or more before the appeals court decision or if it had retained its 180-exclusivity period. Specifically, in a comparison that tested significance at the 10% level ( $p=0.09$ ), among drugs with a retained exclusivity period, drugs approved more than three months before the appeals court decision were more likely to be launched at risk (10 out of 11) compared to drugs approved less than three months before the appeals court decision (1 out of 3).

**Table 2.** Generic drugs that received FDA approval after a favorable district court decision

	Launched Before Final Appeals Court Decision		p-value
	Yes	No	
Total, <i>n (col %)</i>	25 (100.0%)	8 (100.0%)	
Litigation Outcome, <i>n (col %)</i>			
Generic Win	17 (74%)	7 (100.0%)	0.290
Brand Win	0 (0%)	0 (0.0%)	
Settled	6 (26%)	0 (0.0%)	
Patent Type, <i>n (col %)</i>			
Has Drug Substance Patent	6 (76%)	3 (63%)	0.651
Has Drug Product Patent	12 (48%)	6 (75%)	0.242
Has Drug Substance or Product Patent	13 (52%)	6 (75%)	0.416
# of Patents Disputed, <i>n (col %)</i>			
1	11 (44%)	1 (13%)	0.206
>1	14 (56%)	7 (88%)	
Drug Sales, <i>n (col %)</i>			
<\$50 million	4 (16%)	1 (12%)	0.418
\$50 - \$350 million	15 (60 %)	3 (38%)	
>\$350 million	6 (24%)	4 (50%)	
Form			
Oral	18 (72%)	7 (88%)	0.643
Topical or Injection	7 (28%)	1 (12%)	
Months between FDA approval and appeal, <i>n (col %)</i>			
<3	1 (6%)	2 (25%)	0.215
>= 3	17 (94%)	6 (75%)	
Exclusivity Status, <i>n (col %)</i>			
Retained	16 (70%)	3 (37%)	0.206
Forfeited	7 (30%)	5 (63%)	

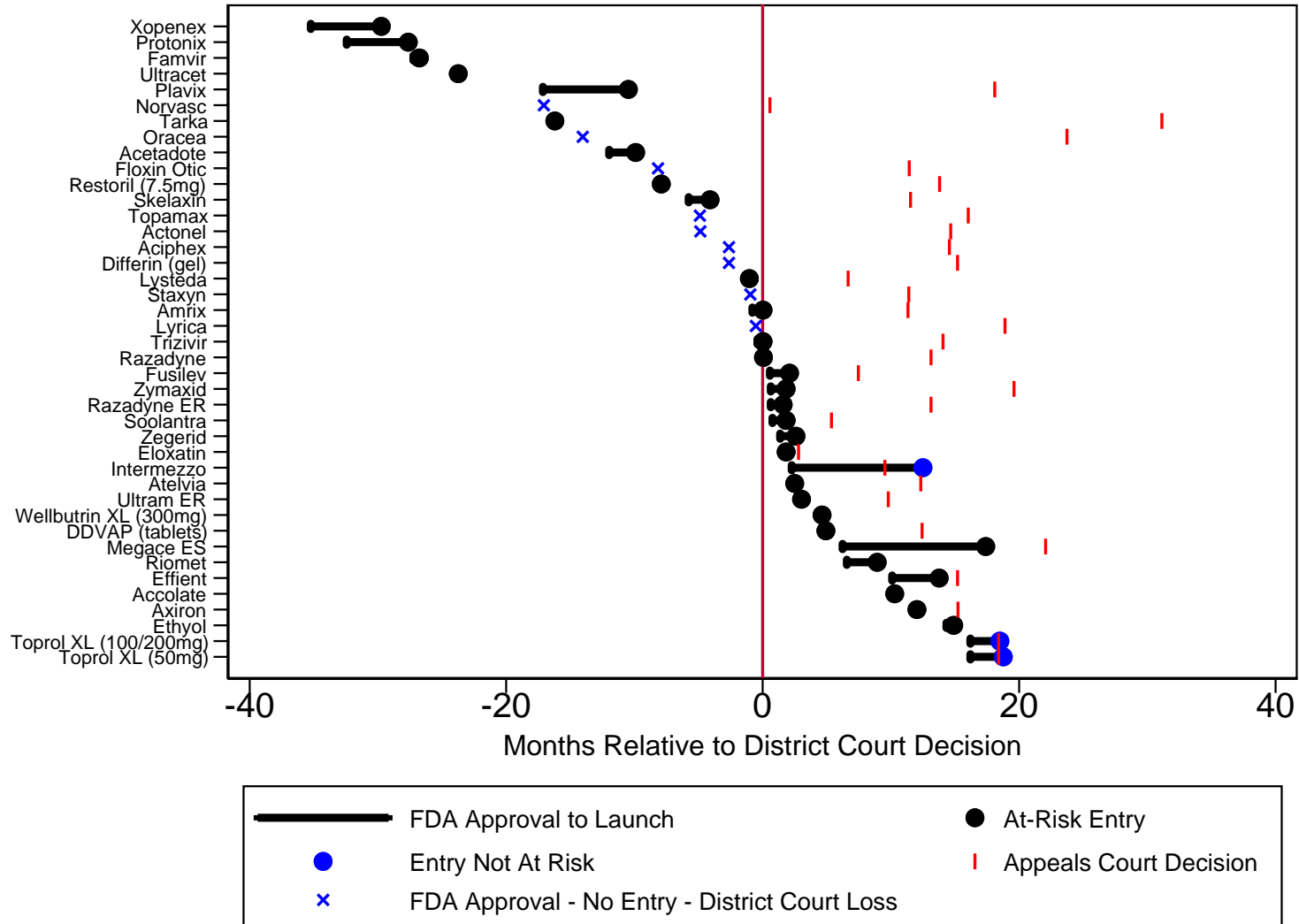
Figure 3 illustrates the time between the generic's FDA approval and launch relative to the court decisions for drugs with a retained exclusivity period. The top portion of the figure shows



the timing for drugs that were approved before the district court decision. The generic either launched at risk, usually before the district court decision (the black lines ending with black circles), or did not launch at risk and then lost the district court decision (the blue Xs), so no longer had the option to launch at risk. As described in more detail below, after some of the at-risk launches, the generic eventually lost the patent litigation and paid damages to the brand.

The bottom portion of Figure 3 (beginning with the drug Razadyne) shows the timing for drugs that were approved after the district court decision. The majority were launched at risk (16 of 19), usually immediately after approval, with three exceptions: Intermezzo, Toprol-XL 50mg (launched by Sandoz), and Toprol-XL 100mg and 200 mg (launched by KV), represented as black lines ending in blue circles. The first filer for Intermezzo, Novel, was in the process of being acquired when it received FDA approval (Lupin 2015), which may have affected the timing of its launch. Toprol-XL's experience confirms that the timing of FDA approval is an important factor. Sandoz received FDA approval for the 50mg version of Toprol-XL just two months before the appeals court decision and chose not to launch at risk. However, Sandoz received FDA approval of the 25mg version twelve months before the appeals court decision, and Sandoz did launch the 25mg version at risk. Similarly, KV did not launch the 100mg and 200mg versions of Toprol-XL at-risk when it received FDA approval two months before the appeals court decision.

**Figure 3.** Months Between Generic FDA Approval and Launch Relative to Legal Decisions



### C. DAMAGES PAID BY GENERICS AFTER A LOSS IN THE PATENT INFRINGEMENT LITIGATION

Finally, we investigated damages paid by generics that launched at risk and then lost a court decision. As a reminder, regulations make generic firms entering at risk liable for brand lost profits. In practical terms, how much a generic manufacturer pays is subject to settlement negotiation between the parties. Five of the six cases we identified in which an at-risk entry was found to infringe on a valid patent resulted in a settlement over the damages either during a separate damages trial or during the appeals process. Some information on damages was publicly reported for three of the six cases:<sup>18</sup>

1. Apotex launched a generic version of Plavix at risk on August 8, 2006 (Apotex 2006). After antitrust authorities rejected a proposed settlement between Apotex and Sanofi (the brand manufacturer), Apotex lost district and appeals court decisions regarding the patent's alleged invalidity (Sanofi-Aventis v. Apotex 2011). The settlement specified that, if the authorities rejected the settlement and Apotex were to lose the litigation, damages would be set to 50% of Apotex's net sales, and the district court accepted Sanofi's summary judgment motion calculating this amount. On October 18, 2011, the appeals court rejected the district court's decision to grant prejudgment interest, but otherwise affirmed its decision (Reuters 2011). On February 8, 2012, Apotex paid Sanofi \$444.4 million in damages, post-judgment interest, and costs (FiercePharma 2012).

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<sup>18</sup> The amount was not publicly reported after settlements of litigation related to the drugs Amrix, Famvir, and Xopenex. Terms of the Amrix settlement were not disclosed. The Famvir settlement obligated Teva to "make a one-time payment to Novartis in addition to an ongoing royalty on U.S. sales of generic" Famvir. See Teva Pharmaceutical Industries Limited, Form 6-K, Feb. 15, 2010. The Xopenex settlement released Mylan from a \$18 million jury damage award, provided a license for Mylan to continue generic sales, and included other confidential details (Mylan 2012).

2. Teva and Sun launched generic versions of Protonix at risk on December 24, 2007 and January 30, 2008, respectively (Reuters 2007). A jury rejected the generics' claims of alleged noninfringement and invalidity of Protonix's active ingredient patent on April 23, 2010 and the district court judge confirmed the jury verdict in a July 15, 2020 opinion. During a damages trial in June 2013, an expert witness for Pfizer (the brand manufacturer) testified that damages should total \$3.0 billion, which included lost profits of \$2.8 billion and pre-judgment interest of \$0.2 billion (Altana and Wyeth v. Teva 2013). On June 12, 2013, the parties agreed to pay a total of \$2.15 billion to settle the litigation (Gabi Online 2013). Teva agreed to pay \$800 million in 2013 and another \$800 million by October 2014. Sun agreed to pay \$550 million in 2013.
3. Glenmark launched a generic version of Sanofi-Aventis' Tarka at risk in June 2010 (Patent Law Weblog 2011). In 2011, a jury ruled against Glenmark's allegations that the patents were invalid and awarded \$16.0 million in damages. On April 21, 2014, the appeals court affirmed the rulings regarding patent validity and remanded "to the district court for the reserved accounting of any post-verdict damages" – Glenmark did not appeal the damage amount (Sanofi-Aventis v. Glenmark 2014). Glenmark had continued selling the remaining stock of its product for two to three months after filing its appeal, which may have resulted in an additional \$9.0 million in damages (and \$25 million in total).<sup>19</sup> The parties settled the case on October 7, 2015, presumably agreeing on the amount of supplemental damages to be paid (Sanofi-Aventis v. Glenmark 2015).

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<sup>19</sup> This was described by "a person familiar with the development, who didn't want to be identified" (Unnikrishnan 2014).

As these case studies indicate, paid damages are offset, in part, by the profits earned by the generic from the at-risk launch. We estimate the generic’s profits using publicly available sources and compare it to the paid damages to arrive at an estimate of a net figure from the generic’s point of view. We calculate the net present value of profits and damages as of the date the generic decided to launch at risk. Table 3 indicates that, for the cases for which we could find data to make the calculations, generic profits offset 59% to 100% or more of the paid damages.<sup>20</sup>

**Table 3.** Damages and Profits of Generics for Cases that the Generic Lost a Court Decision

	Years Between Launch and Paid Damages	Generic Profits (\$M)	Paid Damages (\$M)	Profits / Damages
Plavix	3.5	3,770	339.4	> 100%
Protonix – Teva	5.5-6.8	664.7	1,043.8	63.7%
Protonix – Sun	5.4	316.7	312.1	101.5%
Tarka	5.3	8.4	14.2	59.2%

## V. At-Risk Entry And Social Welfare

The empirical orientation of our paper was framed in terms of the benefits and costs of at-risk entry from the point of view of the generic firm making the decision. For generic firms that have won a district court decision, our model predicted that generics should launch at risk unless the cost of waiting for the appeals court decision is low, and our empirical results support this prediction. In our dataset of at-risk launch opportunities, at-risk entry was extremely common. Drugs with FDA approval before a favorable district court decision were always launched at risk at or before the favorable decision. Drugs that received FDA approval after a favorable district court decision were launched at risk unless approval was received close in time to the appeals

<sup>20</sup> Calculations for Table 3 are provided in supplemental materials.

court decision or the generic had forfeited the exclusivity period, both of which reduce the cost of waiting. Generally, our model depicting generic firms as maximizing the expected value of future profits within the current regulatory structure fit the data well.<sup>21</sup>

Although generic firms often launch at risk when given the opportunity, opportunities are limited by regulation. In terms of the overall number of drugs protected by patents, the rate of at-risk entry is low. Our research uncovered 75 at-risk entry opportunities, bearing on about 13% of all drugs with approved ANDAs. The last time a generic launched at risk before a district court decision was in 2013. All of the 12 recent at-risk entries we observed (after 2013) were approved and launched after the district court decision, and each decision was affirmed on appeal.

A broader perspective on at-risk entry considers the benefits and costs to consumers in both the short and the long term. The frequency and timing of at-risk generic entry is highly consequential for the functioning of markets for drugs. An at-risk entry can transfer hundreds of millions of dollars from the brand firm to consumers. Earlier generic entry produces considerable short-term welfare gains driven by cost-savings for insurers, consumers, and government programs (Bransetter, Chatterjee, and Higgins 2016; Berndt *et al.* 2007). While a consumer price reduction improves short-term efficiency by moving price much closer to marginal cost, at-risk entry may disturb efficient long-term incentives to invest in R&D.

At-risk entry presents less of a tradeoff of short versus long-term efficiency than it may first appear. Indeed, so long as the generic firm is liable for the brand firm's lost profits, *it is efficient in both the short and the long term for at-risk entry to occur immediately and for all brand*

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<sup>21</sup> Our model applied to the at-risk decision after a district court decision. Generics with a retained exclusivity period that received FDA approval before the district court decision appeared, if anything, to err on the side of launching at risk. They lost the patent litigation in all of the cases where they chose not to launch at risk and some of the ones where they did.

*products*.<sup>22</sup> Regarding the short term, immediate at-risk entry makes drugs available to consumers at low prices, achieving short-term efficiency. Regarding the long term, with infringing generics liable for lost profits, brands with valid and infringed patents receive the full profits associated with exclusivity. Brands winning the patent litigation are compensated for their lost profits from the time the at-risk entry occurred and are free once the infringing generic is no longer selling to make high profits associated with exclusivity until patent expiry. In other words, immediate at-risk entry with generics subject to paying damages does not diminish the profits for valid and infringed patents.

Immediate at-risk entry eliminates brand profits for invalid or un infringed patents; this, too, is efficient. The patent system is not intended to encourage research resulting in obvious or unoriginal patents which might, nonetheless, be used by the patent holder to deter competition.

Perhaps surprisingly, from a welfare standpoint, immediate at-risk generic entry with time needed to litigate any patents is superior even to immediate legal resolution of patent validity. With generics liable for lost profits, aside from costs of the legal process itself, immediate at-risk entry generates improved innovation incentives for brand firms while giving consumers access to drugs at low prices. Indeed, while the legal process plays out, consumers get the low prices for some time even for drugs protected by valid patents, and for these cases, consumer welfare is improved over immediate legal resolution.

A useful analogy is the “buy out” of patents by a regulator or international organization proposed by Kremer (Kremer 1998). A government could buy out a patent by paying the patent

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<sup>22</sup> If the United States Patent and Trademark Office (USPTO) were a perfect arbiter of patent applications, a patent would be awarded if and only if it were valid and enforceable, obviating the need for patent litigation based on patent validity. The USPTO is not a perfect arbiter (nor should it be from the standpoint of efficiency recognizing the costs of resolving patent-related issues) as evidenced by, among other things, generic firms’ success rate in patent challenges.

holder the estimated present value of expected profits, and then put the patent in the public domain, eliminating patent barriers to competition. With at-risk entry, the generic firm fulfills the same role. For a valid patent, the generic firm essentially “buys out” the patent for the expected profits and sells for a much lower price, at least during the time prior to a court decision. At-risk entry achieves some patent buy out for affected drugs with financing from private companies rather than the public sector.

Recognition of two forms of uncertainty do not change the basics of the argument. At the time research is undertaken, innovator firms do not know with certainty whether a given line of investigation will or will not lead to patents likely to be found valid and infringed. Although subject to uncertainty, innovator firms are not blind to prospects either, and are guided by profit incentives regarding investments to undertake. Social welfare is advanced if investment in R&D is directed to attaining successful patents. Immediate at-risk entry with patent validity determined by a court achieves this by transmitting incentives exactly proportional to the likelihood of patent validity.

In another form of uncertainty, courts make mistakes (in both directions) about patent validity. A court may judge a patent to be “new and useful” when it is not, or the other way around. Mistakes imply that expected rewards for new and useful innovation is reduced some and expected rewards for low-value innovation is increased. Overall, incentives for research might be higher or lower (depending on which form of mistake was more common). In any case, immediate at-risk entry maintains the favorable effects of maximizing short-term efficiency while directing profit rewards towards research that will result in patents found to be valid by courts.



At-risk entry and resolution of patent validity and infringement involve transaction costs for the legal system. The median cost of cases litigated under the Hatch-Waxman Act was \$3.5 million in 2019 (Nayak 2019). While these costs are not trivial, they are small in relation to the welfare gains from at-risk entry for important drugs.

While the first-best, immediate at-risk entry with generics liable for brand lost profits, is useful as a welfare benchmark, it is infeasible in practice. A generic firm decides about at-risk entry on the basis of its expected profits, not social welfare. Since a generic firm does not appropriate the full social benefit from at-risk entry, for this fundamental reason, and even before any regulatory barriers to at-risk entry are considered, at-risk entry will occur less frequently than is socially optimal.

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