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Delayed entry settlements at the patent office☆

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ABSTRACT

The Patent Trial and Appeal Board (PTAB) is a recently-formed division of the Patent Office in which patents can be challenged as invalid, and which differs from federal courts in a number of respects. We investigate whether monopolist-patentees and their prospective rivals are using the PTAB—which has not previously received antitrust attention—as a platform for striking settlements that delay the rivals' entry. Such settlements are common in pharmaceutical markets, and are typically antitrust violations in cases where the patentee pays the challenger ("pay for delay"). However, problematic statutory inducements lead to excessively-delayed competition even in lieu of such payments. Our empirical findings suggest that delayed entry settlements are now commonly executed in the PTAB, and that they comprise a large majority of all PTAB settlements reached between pharmaceutical rivals. Further, nearly half of the delayed entry settlements were reached after the relevant patent claims were deemed "reasonably likely" to be invalid.

1. Introduction

The availability of generic alternatives to brand-name drugs is a major policy concern in economics and law. Our paper investigates the role of the Patent Trial and Appeal Board (PTAB) in shaping generic availability, by discerning what kinds of settlements rivals are striking within it. Since its inauguration in 2012, the Patent Trial and Appeal Board (PTAB) has substantially broadened the scope of post-grant patent reexamination, making it substantially less expensive and time-consuming to challenge patents as invalid.[2] By and large, the PTAB has made the patent system more efficient by diminishing the extent to which low quality patents can be shielded from scrutiny by the high costs of district court litigation. However, the PTAB's impact on the patent landscape is broad and far-reaching, and it raises some policy questions outside the boundaries of pure patent law. An important example is that the PTAB has not yet received significant antitrust attention.[3] For instance, the American antitrust agencies (the DOJ and FTC), which commonly undertake litigation or investigations of anticompetitive patent settlements, have not yet directed such efforts at a PTAB settlement, notwithstanding that many PTAB adjudications arise between competitors.

This paper addresses the significance of the PTAB to the antitrust-patent interface. The PTAB provides a new platform in which competitors can enter into settlement agreements that restrain competition, but whose judges have no jurisdiction to administer the antitrust laws. Its distinct rules, procedures, and jurisdiction present a number of policy challenges, for some existing antitrust machinery is not well-equipped to police settlements in the forum. These conditions can make the PTAB a strategically advantageous avenue to strike settlements that potentially run afoul of the antitrust laws.

We undertake an empirical assessment of competing firms' propensity to enter into *delayed entry settlements* in the PTAB. Such settlements arise between a monopolist-patentee and a prospec-

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[2] PTAB adjudications address only patent validity, not infringement claims. A patent (or more accurately a patent claim) is invalid if it fails to satisfy one or more of the legal requirements for patentability, implying it was granted in error.

[3] A recent exception is Sturiale (2016), which provides qualitative discussion of how the PTAB could help to deter reverse payment settlements.

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tive entrant that had challenged the monopolist's patent, and involve the challenger's agreement to terminate the challenge (thereby preserving the patent's presumptive enforceability) and delay its entry into the market for some number of years.[4] Such agreements are best-known for their prevalence in pharmaceutical markets. Until recently, virtually all of these agreements involved a "reverse payment"—a large lump sum transfer from the patentee to the challenger.[5]In these cases the agreements are usually called "reverse payment" or "pay for delay" settlements. These arrangements have been addressed extensively in the antitrust literature, albeit in the context of district court litigation.[6] In 2013, the Supreme Court's *Actavis* decision held that pay for delay agreements may violate the antitrust laws.[7] However, delayed entry settlements not involving reverse payments—a format we call "pure delay"—are presumptively legal.[8]

Our analysis allows us to infer delayed entry settlements reached at the PTAB between pharmaceutical rivals. We begin by gathering data on all PTAB adjudications, in particular *inter partes review* (IPR) proceedings, in which the patentee is a brand-name drug seller and the petitioner is a generic drug maker challenging a patent on the brand-name drug. We then merge this with data from the Food and Drug Administration's (FDA's) Orange Book listings, which provides information on approved pharmaceutical drugs; the patents that cover them; and firm identifiers for both the brand-name seller and any approved generics, among other things. If a generic drug maker does not appear in the Orange Book, then we can rule out the possibility that it is selling a generic version of the relevant brand-name drug.[9] Using the combined data, we can look for pharmaceutical settlements and discern whether the petitioner (the challenger) began selling a generic version of the patentee's drug after the settlement. When the generic firm remains inactive well after the settlement, we infer a likelihood of delayed entry.

In many instances, several IPRs correspond to the same parties and to a single drug, and are all settled simultaneously. These therefore correspond to a single settlement that happens to span two or more patents, and we therefore lump them together into what we call "consolidated settlement agreements" (CSAs). Over the PTAB's 4-years of existence, there are 32 applicable CSAs in the data, which subsume a total of 52 IPRs. 24 of the CSAs (75%) satisfy our criteria for inferring delayed entry. Among these 24 CSRs, 10 (42%) occurred after the PTAB judge has "instituted" the IPR, which is a procedural step (discussed further below) reflecting the PTAB judge's determination that the challenged patent is "reasonably likely" to be invalid.[10] Thus, in these post-institution settlements, the parties anticipate a likely victory for the petitioner.

Hovenkamp and Lemus (2017) show that, in lieu of any exogenous frictions on challenger entry, pure delay is a socially efficient manner of settlement. The reason is that, without a reverse payment, the firms cannot agree on terms that restrain competition beyond the level necessary for settlement to be mutually-acceptable. But this desirable property does not hold up in the pharmaceutical context, due to some limitations created by the Hatch-Waxman Act. The relevant statutory provisions, discussed in detail below, were designed to bolster the incentive to challenge drug patents. But in fact they do so only for the first generic to file a drug application with the FDA, while *diminishing* the incentive to challenge among all later-filing generic firms. Consequently a settlement between the first-filer and patentee acts to forestall entry by most of the generics that would otherwise enter. The result is ultimately that this settlement will restrain competition excessively, i.e. it will produce significantly less competition over the patent term than litigation would provide in expected value.[11]

The fact that a PTAB challenger stays out of the market after a settlement agreement is not irrefutable evidence of a reverse payment, although a payment is inferentially more likely in a post-institution settlement in which the generic firm remains out of the market for a significant period of time. But because of the problems created by Hatch-Waxman, even pure delay settlements present serious competition policy concerns in the pharmaceutical context, notwithstanding that they are probably not vulnerable to antitrust intervention. They contribute to a problem that many other papers have identified, which is that contractual restraints on generic entry pose a serious threat to consumer welfare. For example, Helland and Seabury (2016) estimate that restricting the entry of generic drugs reduced consumer surplus by about $800 million over a 5-year period.

Although our findings on PTAB settlements illustrate serious competition policy concerns, we think that some relatively simply measures could help to address this issue. To that end, we conclude the paper with a number of policy proposals, some of which make use of the PTAB's unique institutional rules and procedures.

1.1. Generic competition with patented drugs

Under the Hatch-Waxman Act, generic drugs can receive expedited FDA approval through an Abbreviated New Drug Applications (ANDA). This requires a demonstration that the generic drug is "bioequivalent" to one that has already gone through the full FDA approval process. This legislation avoids redundant testing of safety and therapeutic efficacy. ANDA approval is predicated on the applicant's certification that, to the best of its knowledge, its generic drug will not infringe any active patent that is valid and enforceable. If the brand-name drug is indeed patented, the ANDA applicant must certify that the patent is either invalid or would not be infringed by its proposed generic—an option known as "Paragraph IV certification." If the applicant takes this route, it must immediately provide notice to the patent holder, which will typically then sue the applicant.

If the patent holder sues the generic producer within 45 days of receiving notice, ANDA approval is stayed for up to thirty months to allow litigation to proceed. That is, assuming the generic applicant does not obtain a license in a settlement, the ANDA will not be approved until the earlier of the dates on which (a) the ANDA applicant wins in court; or (b) litigation reaches the 30-month mark. Thus, if litigation lasts for more than 30 months, the ANDA will be approved at the 30-month mark, notwithstanding that the patent litigation has not yet concluded. If, by contrast, the generic maker receives a license, the ANDA would then be approved with-

[4] To be clear, the challenger gets a license that does not take effect until the end of the contractual delay period.

[5] The term "reverse" is used because, in most conventional settlements, money runs in the opposite direction.

[6] E.g. Hemphil, 2006; Edlin et al., 2015; Cotter, 2014; Carrier 2009; Dolin, 2011; Shapiro, 2003; Hovenkamp and Lemus, 2017.

[7] FTC v. Actavis, Inc., 570 U.S. ____, 133 S. Ct. 2233 (2013). The court was persuaded that we can infer a high likelihood of invalidity when there is a large reverse payment—a claim that many scholars had advocated. (Dolin, 2011; Edlin et al., 2015).

[8] The *Actavis* opinion expressly states that firms could settle without a payment as an alternative to reverse payment, which would result in a shorter delay period.

[9] However, a generic maker that does show up in the Orange Book is not necessarily actively selling the drug in commerce. We thus use a separate resource, described below, to identify which Orange Book-listed generics are indeed commercially active.

[10] The other settlements occur before the PTAB judge makes any institution decision, so in these cases we cannot make any inferences about what the judge thinks about the patent's validity.

[11] We demonstrate explicitly in the online appendix, using a model that builds on Hovenkamp and Lemus (2017). We discuss the results and intuition in Section II(A), below.

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