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Market entrance, patents, and preliminary injunctions: a model of pharmaceutical patent litigation

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Abstract

The Patent Holder wishing to enforce her patent has several ways of doing so. In the world of patent litigation, however, one of the most important remedies is the preliminary injunction (PI), whereby an allegedly infringing competitor is forced to stop selling the goods in the market in the interim period before the court reaches its final decision on the merits. In spite of this, the economic literature has afforded little attention to PIs. This article uses a simple economic model to investigate how a Patent Holder and an Alleged Infringer will behave with and without the PI instrument. We show that party behavior depends on the probability that the Patent Holder does indeed have a valid patent and will prevail in a final court decision and on the extent to which courts can determine damages correctly. We find that while patent rights benefit the Patent Holder, the PI instrument to a large extent benefits the Alleged Infringer. It does so by insuring him against large damages payments and allowing him to receive compensation for actions not taken, i.e. for not being on the market in the interim period before the final court decision. Finally, we discuss different decision rules a court could use to decide whether to grant a PI, and propose a decision rule whereby courts can take into account the social benefits or losses of an erroneous PI decision.

Keywords Preliminary injunctions · Market entrance · Patents · Incentives · Innovation · Competition · Self-regulation

JEL Classification K19 · K42 · O31 · O34 · D42

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1 Introduction

The Patent Holder wishing to enforce her patent has several ways of doing so. In the world of patent litigation, however, one of the most important remedies is the preliminary injunction (PI), whereby an allegedly infringing competitor is forced to stop selling the goods in the market in the interim period before the court reaches its final decision on the merits. In spite of this, the economic literature has afforded little attention to PIs. This lapse is more so glaring in the EU, where PIs are the primary enforcement mechanisms, EU-Commission (2010).

Consider a lawsuit over a pharmaceutical patent. The Patent Holder believes that her competitor—the Alleged Infringer—sells an infringing product. The Alleged Infringer believes that the patent either is invalid, or valid but does not cover his product. Once the court reaches its final decision, the issue will be resolved conclusively. As patent litigation often lasts for several years, covering large parts of the patent term, what the court does before its final decision is also important.

If it does nothing, both parties will be on the market in the interim period before the final court decision. If the Patent Holder wins, she will receive damages for lost profits and the Alleged Infringer will be forced to stop selling the product after the final decision. If the Patent Holder losses, no damages are paid, and the Alleged Infringer stays on the market.

Before its final decision, the court can also issue a PI. If the Alleged Infringer wins at trial, he will be allowed to sell his products again and receive damages for his lost sales in the interim period before the final decision.

Both interim decisions come with added risks if damages are not correct. If the court does nothing, the Patent Holder risks receiving incorrect damages, which in turn may affect ex ante incentives to innovate. If the court grants a PI, the Alleged Infringer may not receive correct damages, and consumers will suffer from higher prices in the interim.

While the PI decision can have significant consequences for the Patent Holder, Alleged Infringer and society at large, PIs are only intended to be made on limited information and in a shorter time than normal decisions. This makes PI decisions error prone with the risk of harming the wrong party, see e.g. Siebrasse et al. (2019).[1]

To further understand the role of PIs and their implications, we suggest a simple economic model based on the Entrance Game and test the effects of a patent only regime as well as a patent and PI regime. Although simple, the model allows us to identify the different effects of both patents and PIs. In particular, we show that party behavior depends on the probability that the Patent Holder will prevail in a final court decision and on the extent to which courts can determine correct

[1] While patents are only registered after a rigorous registration process at the patent authority, patent authorities still make mistakes. Indeed, a large fraction of all registered patents are invalidated at some point during their life—either through invalidity proceedings at the patent authorities or through court proceedings, see e.g. Lanjouw and Lerner (2001), Lemley and Shapiro (2005). As such, the social value of a patent is uncertain until it is clear whether it indeed is valid or not, see Lemley and Shapiro (2005), Shapiro (2007).

damages. We also find that while patent rights benefit the Patent Holder, the PI instrument largely benefits the Alleged Infringer, as it insures him against having to pay large damages awards and allows him to be compensated for the period where he is out of the market.

Of course, one thing is party behavior; another is the court's decision whether to grant a PI. Here, courts seeking to optimize social welfare should take into account that patents help incentivize innovation and commercialization of new products, cf. Mazzoleni and Nelson (1998b), but also that these incentives come at the price of (short-term) losses due to limited competition.[2]

Prevailing law and economics models of PI decision rules are based on contract disputes. This means that they do not take into account the potential social loss of erroneous PI decisions that can occur in the patent setting, where consumers risk facing non-competitive pricing, if the PI is wrongly granted, and risk facing sub-optimal innovation if the PI is wrongly rejected.

In the final part of the paper, we discuss the existing rules and propose our own rule, which seeks to optimize consumer surplus by weighing ex ante incentives to innovate and consumer surplus from increased competition. Our rule suggests that PIs should be granted less often than is currently the case.

The article is outlined as follows: Sect. 2 provides a short overview of the literature most directly related to the present paper. Section 3 introduces the legal characteristics central to the paper. We especially emphasize the PI doctrines of Germany, the U.K. and the U.S., but also introduce a few statistics on how the doctrine is applied. Finally, we discuss a few current topics patent enforcement that tangentially relate to the model. In Sect. 4 we introduce our game theoretical framework. We think of the problem as a simple entry game with added decisions that are relevant in a patent and PI setting. In Sect. 5, we then analyze the outcome in a setting where patents exist, but the only available remedy is damages and permanent injunctions. Here, we show that the parties must rely on self-regulation to maximize joint profits in the interim period before the final court decision. Afterwards, in Sect. 6, we analyze the outcome with the added possibility of PIs. In Sect. 7, we provide a few numerical illustrations of how the PI impacts the Patent Holder and Alleged Infringer. In Sect. 8 we discuss how courts should decide on the PI question if they seek to optimize ex ante incentives. We do so in light of the existing proposals made by Leubsdorf and Posner, and Brooks and Schwartz. Final conclusions are provided in Sect. 9. We extend the analyzes in the appendix where we consider the possible effects of litigation costs as well as the outcomes if the court systematically over-compensate damages.

[2] On society's trade-off between long-term benefits of innovation and short-term losses from limited competition, see e.g. Nordhaus (1969) and Kaplow (1984).

2 Literature and background

The economic model in this paper is simple. We rely on basic game theory, cf. e.g. Gibbons (1992), and a classical market entry model, cf. e.g. Tirole (1988). In the usual manner, the dynamic (extensive form) game is solved backwards to get sub-game perfect equilibria.

There is a large theoretical and empirical literature on the optimal length and breadth of patents and on the benefits and costs of patent systems. We draw mainly on the insights from Arrow (1962) Kaplow (1984), Shapiro (2007), Gifford (2004), Mazzoleni and Nelson (1998a), Mazzoleni and Nelson (1998b), Mezzanotti and Simcoe (2019), Liu and La Croix (2015), and Hall and Harhoff (2011). Allison et al. (2014), and Cremers et al. (2017) provide empirical evidence of patent litigation in the U.S. and Europe.

Regarding PIs, Lanjouw and Lerner (1996) and Lanjouw and Lerner (2001) show that PIs can be used to create financial stress on competitors. As shown by Denicolo' et al. (2008) financial stress can come in the form of hold-up, where an Alleged Infringer who has already invested production facilities is forced to pay too high royalties, just to gain access to the market. In this paper, we assume that this is not a factor.[3] A paper somewhat related to ours is Boyce and Hollis (2007). They show that U.S. damages rules incentivize Alleged Infringers to limit output and acquiesce to a PI request. They also propose a damages rule, where the Patent Holder who obtains a PI that should not have been granted, shall pay damages to the Alleged Infringer and a fine equal to the social deadweight loss in order to create optimal incentives. The single most prominent law-and-economics rule for deciding a PI request is the so-called Leubsdorf-Posner rule, cf. Leubsdorf (2007), Lichtman (2003), and Laycock and Hasen (2019) with references. The rule seeks to minimize the risk of irreparable injury to both the Patent Holder and Alleged Infringer. The Leubsdorf-Posner rule has been criticised by Brooks and Schwartz (2005), who suggest that it embodies a compensatory, ex post view of the purpose of awarding damages as opposed to an ex ante, incentive-oriented view. Seeking to remedy this, they propose an interim efficiency rule.

Our model diverges from the existing literature by emphasizing the regulatory and market realities of European pharmaceutical patents and the doctrinal limits of PI law. These will be explained below. We will formalize a generalized version of the legal standard and the Leubsdorf-Posner and Brooks-Schwartz rules, and we will suggest modifications taking into account consumer loss.

2.1 The European pharmaceutical market

As shown by Habl et al. (2006) and Kanavos et al. (2009), the European pharmaceutical sector makes for a special case in several respects. Demand for pharmaceutical

[3] Likewise, we do not consider the special factors that can come into play with regards to Standard Essential Patents; a topic which recent litterature has given keen attention. See e.g. Layne-Farrar (2017), Lerner and Tirole (2015), Lemley and Shapiro (2007) and Miller (2007).

drugs is largely inelastic (see also Ringel et al. (2002) with a review of the empirical literature). This is partly due to the nature of the products, but also due to the regulatory framework surrounding pharmaceutical drugs. In Europe, drugs can only be prescribed by medical professionals and most consumers receive full or partial reimbursement of their costs. At the same time, allocation of output is highly price sensitive as most countries[4] require that pharmacies deliver the cheapest (generic) substitute. As such, small price differences can have a huge impact on market share. Finally, companies have difficulty controlling their output at the margins. Big parts of the sector is supplied through public procurement, whereby the winning company is contractually obliged to provide the requisite products and will be punished if it does not fulfill demand. And in some countries, such as Denmark, a company can only have a product on the market, if it has sufficient capacity to deliver to a substantial part of the market.

The pharmaceutical market is made up of a small group of financially strong, repeat players, many of which also form professional organizations together. While the companies are somewhat divided between original and generic producers, some like Teva are both. Even further, companies constantly survey the different national markets for entry and price changes.[5]

These institutional characteristics motivate our use of a simple entry game as the core of our model and explains why we do not focus on quantities supplied as in Boyce and Hollis (2007). The Alleged Infringer can be thought of as a generic player and the Patent Holder as a brand-name company.

3 Legal characteristics

In this section, we will introduce the central legal doctrines and developments relevant to this paper.

When enforcing their rights, Patent Holders have a multitude of avenues to pursue. In the following sections, we will shortly introduce the overall remedies landscape as well as emphasize avenues pertinent to our model, namely when courts will grant PIs and how and under what circumstances courts will provide damages to an infringed Patent Holder or a wrongfully enjoined Alleged Infringer. In doing so, we will introduce the doctrines of Germany, the U.K. and the U.S. and make minor comparisons to Denmark, France, and Poland. All countries are signatories to the international TRIPS agreement, which sets out a basic framework of remedies. The E.U. member states are also subject to the rules of the Enforcement Directive (Dir. 2004/48/EC). While the Directive leaves much room for member state implementation, the CJEU has in recent years made some clarifying rulings on the limits of the Directive.

[4] This includes some of the biggest markets in Europe–France, Germany, the Netherlands and the U.K.

[5] This was shown in a PI dispute over the product Seroquel in Denmark. See the Maritime and Commercial High Court of Denmark's decision of 24 January 2017 in case T-2-12 AstraZeneca v. Teva. Available at: http://domstol.fe1.tangora.com/Domsoversigt.16692/T-2-12.1816.aspx.

Generally speaking, Patent Holders have access to remedies in the form of damages for infringement and permanent injunctions, whereby infringing products are prohibited access to the market until the patent expires. Both damages and permanent injunctions are ordered after a final decision on the merits, which will often be years in the making. The infringed Patent Holder will almost always receive damages, but some jurisdictions, such as the U.S., will not necessarily grant a permanent injunction.

Other than these final remedies, the Patent Holder has several interim remedies at her hands. Examples are orders to preserve evidence (where the court secures evidence of the extent of infringement, prices etc.), freezing injunctions (where the Alleged Infringer's assets are frozen), and of course the PI, which we will explore in more detail below.

3.1 PI doctrine in Germany, the U.K., and the U.S.

The PI comes in many different forms. In this paper, we focus on the prohibitory PI, where the Alleged Infringer is ordered to stop selling his products until the dispute is settled. Some jurisdictions, however, also allow for mandatory PIs, where the Alleged Infringer is ordered to take active steps to prevent further infringement, e.g. by recalling his products from the market.[6] Finally, we focus only on PIs ordered by the courts. Again, however, PI-like remedies are sometimes also available through other avenues. In Canada and the U.S., for example, medical patent holders can get an automatic stay against the approval for marketing of generic drugs.[7]

No matter the jurisdiction, the decision to grant or deny a PI generally revolves around 3 factors: (1) the likelihood that the Patent Holder will ultimately prevail on the merits; (2) the (irreparable) harm the Alleged Infringer will suffer if the PI is wrongly issued; and (3) the (irreparable) harm Patent Holder will suffer if the PI is wrongly denied. Lanjouw and Lerner (2001), Calame et al. (2011) and Cotter (2013). Other factors, such as third party interest, can also pay a role. As noted earlier, if the court grants a PI, which later proves wrongful, the Alleged Infringer can claim damages for the wrongful PI.

There are also a few common procedural limits on PIs: First, the Patent Holder must file a motion for proceedings on the merits at least shortly after the PI has been granted. Second, the Patent Holder can be ordered to give security for the Alleged Infringer's potential damages.

With these general remarks, we shall now turn to the individual doctrines related to when PIs can be granted.

In Germany, the Patent Holder must show that there is a likelihood that she will prevail on the merits—i.e. that a final decision will show that the patent is valid and infringed that the need for injunctive relief is urgent and that a weighing of interests

[6] Mandatory PIs are found in Denmark, Germany, and the U.K., cf. Cf. (Burrows 2019, p. 485) and (Plesner et al., p. 497).

[7] (Cotter 2013, p. 178, n. 60 with references).

favors her.[8] Third party interests could in principle also be taken into account, but they do not seem to carry much explicit weight. In practice, the prevailing question is whether it is sufficiently likely that the Patent Holder will prevail on the merits. The standard is one of more likely than not, but based on all means of prima facie evidence.[9] The weighing of interests does not seem to be of great importance, though the Patent Holder can lose the chance to get a PI if she acts too passively, as courts may conjecture this to indicate that there is no urgency.

The German approach may be seen as emblematic of other European civil law countries. At least on the letter, Denmark and France follow a similar test, albeit with some differences.[10] One example is the quality of evidence required: German courts normally require that infringement be uncontested or sufficiently clear without reference to expert consultation and that the patent's validity is sufficiently certain.[11] This contrasts with Denmark, where it is the practical rule that both parties present expert testimony on the validity and infringement question and where a patent is presumed valid, unless invalidity is proven with a high degree of certainty by the Alleged Infringer.

Whereas the German approach is highly focused on the case's merits, U.K. doctrine dictates a stronger emphasis on the weighing of interests (or weighing of convenience as it is more commonly known). The leading case, *American Cyanamid Co v Ethicon Ltd [1975] AC 396*, [12]thus only requires the Patent Holder to show a serious question to be tried. This merely means that the suit may not be frivolous or the like.[13] The Patent Holder must, however, show that that the balance of convenience favors granting the PI. *American Cyanamid* provides a thorough sequential test for this question: (1) Would damages adequately compensate the Patent Holder? If yes, the PI should not be granted. (2) Would damages to the Alleged Infringer adequately compensate him? If yes, there a strong case for PI. If no, then (3) the case turns to the (holistic) balance of convenience, where the main factor is the extent of the uncompensatable disadvantage to each party. If the uncompensatable disadvantage is somewhat equal, courts can look to the desirability of maintaining the status quo and the relative strength of each party's case.

[8] (Harguth and Carlson 2017, chapter 9) (Koschinka and Leanza 2015, p. 80 onwards)

[9] (Sikorski 2019, p.84).

[10] See e.g. (Plesner et al., p.497), (Koschinka and Leanza 2015, p. 209 onwards). In Denmark, the Patent Holder obtains a PI if she *proves or makes likely* that: (1) She has the alleged right. (2) The Alleged Infringer's actions make it necessary that a PI is granted. (3) The Patent Holder will lose her ability to be fully compensated, if injunction is not granted. And (4) the injunction would not cause the Alleged Infringer harm which would be *clearly disproportionate* to the interests of the Patent Holder.

[11] (Cotter 2013, p.244) This standard may be even higher now, since, recent case law suggests that as a main rule PIs should only be granted if the patent had already survived first instance nullity or opposition proceedings. see recent decisions from the Higher Regional Courts of Düsseldorf (judgment of 14 December 2017, Docket no. 2 U 18/17), Karlsruhe (GRUR-RR 2015, 509) and Munich (judgment of 12 December 2019, Docket no. 6 U 4009/19). Yet, some authors argue that German courts have developed several exceptions to the rule, and is is less restrictive than a strict reading indicates. See (Sikorski 2019, p.83).

[12] The reader will be aware of U.K. courts emphasis on precedence. (Burrows 2019, p. 469 onwards), (Cotter 2013, p. 176 onwards).

[13] (Koschinka and Leanza 2015, p. 117 onwards).

While not explicitly dealt with in *American Cyanamid*, later case law has also allowed for public interest considerations when balancing convenience, but mainly in outlier circumstances. One example is when a PI would harm the public by depriving it of a life-saving drug.[14]

While the letter of *American Cyanamid* seems dramatically different from the German approach, Cotter (2013) and Burrows (2019) argue that courts in practice put more emphasis on the merits[15] and apply a more holistic approach to the balance of convenience.[16] Even further, when the question comes to pharmaceutical patents, U.K. courts generally accept that neither party will receive adequate damages, and therefore tend to grant PIs for medical patents, unless the Alleged Infringer has attempted to "clear the way" before market entry.[17]

Finally, we have the U.S. doctrine.[18] Under U.S. Law, the Patent Holder must conjunctively show that (1) she is reasonably likely to prevail in the case on the merits, (2) she will suffer irreparable harm if the injunction is not granted, (3) a balancing of interests between the parties favors the Patent Holder, and (4) the public interest favors her.

Particularly relevant to patent cases is the question of irreparable harm. Up until 2006, U.S. courts presumed that a Patent Holder would suffer irreparable harm but for injunctive relief. This changed with the Supreme Court's decision in *eBay v. MercExchange, L.L.C., 547 U.S. 388 (2006)*, where it held that courts should always apply the above four factor test, and as such could no longer presume irreparable harm.[19] Both the concurring opinion by Justice Roberts and subsequent case law has clarified that there generally will be a risk of irreparable harm when when the Alleged Infringer is a direct competitor or the Patent Holder risks losing substantial market shares, suffer price erosion or lose customer goodwill.[20]Moore et al. (2018) further suggest that difficulty in awarding damages, past harm or the risk that the Alleged Infringer would not be able to pay correctly assessed damages will also point in the direction of irreparable harm.[21] Irreparable harm is akin to uncompensatable harm in the U.K. doctrine.[22]

[14] (Burrows 2019, p.472), with reference to *Roussel-Uclaf v GD Searle & Co [1977] FSR 125, aff'd [1978] 1 Lloyd's Rep 225]*.

[15] (Cotter 2013, p. 177 with reference to a lecture given by Sir Robin Jacobs).

[16] (Burrows 2019, p. 472).

[17] Cordery and Mumby (2020) Cohen and England (2013) Cordery notes, however, that there may be a shift in the trend.

[18] U.S. doctrine is laid out in the Federal Rules on Civil Procedure, Rule 65, and developed by case law. See (Cotter 2013, p.97 onwards) and (Sikorski 2019, p. 17 onwards).

[19] In the specific case, MerxExchange an NPE or non-practicing entity–sought an injunction against eBay's use of their patent. In it's decision, the Supreme Court remanded the case to the District Court, which (again) denied injunctive relief. In 2007, the parties settled the dispute. Although the Court in *eBay* ruled on the use of permanent injunctive relief, the decision has trickled down to PIs.

[20] (Sikorski 2019, p.9).

[21] (Moore et al. 2018, p. 861).

[22] (Burrows 2019, p. 472 onwards).

3.2 Damages for wrongful PIs or infringement

When a PI is wrongly granted, the Patent Holder can be subject to a claim for damages for the loss suffered due to the PI. On the other hand, if infringement is concluded, the Alleged Infringer is subject to damages for the Patent Holder's loss due to infringement. In either case, the goal is most often to compensate the injured party. To the best of our knowledge, neither of the discussed jurisdictions use calculations that take into account social or consumer loss due to wrongly granted/denied PIs.[23] Below, we will shortly introduce the three jurisdictions' rules on both types of damages, starting with damages for wrongful PIs.

In Germany, the Alleged Infringer has the right to damages for losses caused by the wrongfuld PI, unless the Patent Holder has a sufficient defense. In Germany (and Denmark and France), the Patent Holder is liable under a strict liability regime.[24] Of course, the classic defenses against liability are still available. An example of this is the injured party's assumption of risk. A recent decision by the CJEU indicates that member states generally have fairly free reign to decide on the availability of such defenses: In *C-688/17 Bayer* the CJEU accepted a rule under Hungarian law, where an Alleged Infringer who had launched at risk could not receive damages.

Looking to the U.K, PIs are normally granted only if the Patent Holder signs a cross-undertaking[25] to compensate the Alleged Infringer for any loss due to the PI. Although damages under a cross-undertaking are in principle contractual, the approach seems akin to what is found in other E.U. jurisdictions.[26]

In the U.S., there is no common standard for when a PI is wrongful and thus when the Patent Holder is liable.[27] Likewise, there is little clarity on what damages are available to the wrongly enjoined. As in other jurisdictions, the Patent Holder is normally required to post a bond in an amount, which the court finds adequate to compensate the defendant, should the PI prove wrongful. Unlike Germany and the U.K., however, the Alleged Infringer is generally not entitled to damages above the posted bond, yet there is no common standard for determining the bond's size.

On the question of damages for infringement, Germany, the U.K. and the U.S. have rules similar on the letter. Both Germany and the U.K. comply with the Enforcement Directive art. 13 and allow for damages calculated as a reasonable royalty calculated as what license fee the parties would have agreed on on market terms and actual damages for the loss suffered due to the infringement. Regardless

[23] For instance, consumers will suffer a at least short term loss of higher prices when a PI is wrongly granted. Conversely, a wrongly denied PI may prevent the Patent Holder from covering her R&D costs and diminish ex ante incentives to innovate, which in turn will lead to long term consumer loss.

[24] This follows directly from Art. 945 of the ZPO. In Denmark, this follows directly from the Danish Rules on Procedure Section 428(1), however, in France it follows from case law. See (Sikorski 2019, p.91).

[25] cross-undertaking because the Alleged Infringer signs an undertaking not to sell his products until a decision on the merits.

[26] See e.g. Wilson and Sharp (2010) and *Fiona Trust & Holding Corporation v Yuri Privalov & ors [2016] EWHC 2163 (Comm)*.

[27] (Sikorski 2019, p. 19).

of the approach applied, the goal is to calculate the Patent Holder's actual loss, cf. *C-99/15—Liffers*. Finally, under the Enforcement Directive, courts should take into account the infringer's illegal profits, whereas under U.K. law Patent Holder's have a right to an actual account of profits.[28] Likewise, in the U.S. damages can take the form of a reasonable royalty or loss caused by the infringement, but does not allow for account of profits (at least not as a stand alone measure of compensation).[29]

One should not be naive on the extent of these similarities. We here abstract away from questions such as apportionment on the reasonable royalty and actual damages, the award of attorney's fees (which may be substantial in complex litigation), and issues of proof. Further, Patent Holders prevailing in the U.S. can receive enhanced damages of up to triple the actual loss suffered when the infringement is willful.[30] Enhanced damages are not required under the Enforcement Directive, but allowed, cf. *C-367/15 OTK*, where the CJEU ruled that the Directive did not prohibit Polish law under which the right holder under certain circumstances could receive double or triple the reasonable royalty.

3.3 How doctrine is applied

Although there are seeming differences in doctrine, without a thorough empirical investigation, it is difficult to predict the impact of the different doctrines on the practical realities.[31] That differences in doctrine do not necessarily predict differences in outcome is supported by scholarship: Germany, Denmark and France have historically had quite similar doctrines focused on the merits of the case. Yet, German and Danish courts view the PI as the Patent Holder's primary remedy and thus are quite willing to grant PIs,[32] whereas PIs in France are a rarity.[33]Likewise, over time both the French and U.K. doctrines have shifted from a merits focused approach to putting more weight on the weighing of interests. This, however, has not quite changed the judiciary's willingness to grant PIs.[34] One reason for this might be the many other factors that affect whether parties pursue a PI and what evidence is available to them when doing so.

While we are not aware of recent empirical studies comparing case law on medical patents from the jurisdictions discussed in this paper, a study of France from 2011 found that yearly, about 350 first instance patent cases were lodged, and that PIs were granted in less than 1% of all such cases.[35] This may in part be due to PIs being requested less often in France. Indeed a study of French courts from 1984-2004 (before implementation of the Enforcement Directive) found that courts heard

[28] (Cotter 2013, p.198) Account of profits is also allowed under German law.
[29] (Moore et al. 2018, p.906 onwards) and (Cotter 2013, p.198).
[30] See 35 U.S.C. Section 284 and (Moore et al. 2018, p. 966).
[31] In the same direction related to Commonwealth case law and U.S. case law, see (Cotter 2013, p. 178).
[32] (Plesner et al., p. 497).
[33] (Cotter 2013, p. 242 onwards).
[34] (Cotter (2013), p. 242 onwards), (Burrows 2019, p. 474 with references).
[35] Romet and Véron (2011).

roughly 5 cases per year, amounting to 1–2% of all patent cases. Of the PI requests heard, 20% or 1 per year where granted.[36] It seems that PIs are more frequently granted in Germany and Denmark. A study from 2010 found that from 2006–2009 the first instance court in Düsseldorf (from where about 40% of German patent litigation occurs) granted PIs in 24 of 41 cases where a request was made.[37] According to the authors, this was the highest PI win rate in the 30 countries compared. A study by Lanjouw and Lerner (2001) of patent cases filed in U.S. district courts between January 1990 and June 1991,[38] found that out of 252 patent cases, PIs were requested in 48. 23 cases went to a decision on the PI request, and of those, 12 were granted. The rest were settled or the motions for PIs withdrawn. A more recent study by Gupta and Kesan (2016) seems to indicate that both the amount of PIs requested and granted has declined, in particular for NPEs, after the *eBay* decision. They find that from 2006–2012 (6 years after *eBay*). PIs were requested in less than 5 % of all patent cases filed and that of the 655 motions for PIs, only 125 were granted. Unlike Lanjouw and Lerner (2001), however, Gupta and Kesan (2016) do not seem to control for motions being withdrawn or cases being settled.

Neither of these studies single out medical patent cases, however, we would expect that courts are more prone to grant PIs in these cases. This at least follows from the discussion of the different doctrines, particularly that of the U.K. The Danish experience seems to mirror this. Since 2017, the Danish first instance court in patent cases—The Maritime and Commercial High Court has ruled on PI requests in 8 pharmaceutical patent cases, granting PIs in 6 of them.[39]

We are not aware of empirical reviews as to the level of damages. The view of the courts and some more general policy observations indicate that courts under compensate infringed Patent Holders or wrongly enjoined Alleged Infringers. See EU-Commission (2010), Cotter (2013), and more generally Golden (2018). This, however, is not a clear cut conclusion, and indeed we would expect at least specific instances of over compensation, given the availability of accounts of profits and enhanced damages in some jurisdictions.[40]

3.4 Current topics in patent enforcement

Before we move on to the model, we will introduce two important current topics in patent enforcement. One is the question of injunctive relief when the Patent Holder sues based on a Standard Essential Patent (SEP). The other is the legality of pay-for-delay agreements where a Patent Holder pays a potential generic competitor to

[36] See Véron and Mandel (2005).

[37] Elmer and Lewis (2010).

[38] (Lanjouw and Lerner 2001, p.594 onwards).

[39] See cases Sag BS-28893/2019-SHR, Sag BS-34191/2018-SHR, Sag BS-33415/2018-SHR, A-27-17, A-49-17, A-19-17, A-22-17, A-33-17. All available at https://domstol.fe1.tangora.com/default.aspx?id=16692.

[40] For the U.S., Shapiro (2007) seems to believe that reasonable royalties overcompensate Patent Holders. Denicolo' et al. (2008), however, provide strong arguments why that belief is not necessarily justified and provide a model which indicates that, on average, the Patent Holder will be under compensated.

stay out of the market for a given period of time. While neither is directly related to our model, both topics are relevant context when evaluating the benefits of the PI instrument.

On both sides of the Atlantic, courts have expressed the need to limit injunctive relief in circumstances where the patent in question is an SEP[41] and where the Patent Holder has agreed to license on FRAND (Fair, Reasonable, and Non-Discriminatory) terms. After the above mentioned *eBay* decision, courts have seemed reluctant to grant injunctive relief on SEPs, reasoning that there can be no irreparable harm.[42] For instance, in a dispute between Motorola and Apple, judge Posner reasoned that since Motorola had made a FRAND commitment, they by definition had acknowledged that monetary compensation would be adequate, and thereby that they could not prove irreparable harm.[43] In the U.S., SEP-based injunctive relief may also be challenged on anti-trust grounds.[44] Under President Obama, the Department of Justice took steps to limit SEP holders' use of injunctive relief, e.g. by approving a large patent acquisition between Apple, Google and Microsoft only after they agreed to not seek injunctions on the SEPs. The following administration, however, did not seem to agree on this approach.[45]

In the E.U., attention has mainly been given to the anti-competitive effects of SEPs receiving injunctive relief. In *C-170/13 Huawei* the CJEU ruled that if the Alleged Infringer refuses to enter into license negotiations, injunctive relief is not an abuse of dominance. If, however, he is willing to enter into negotiations, but the parties have difficulties reaching an agreement on FRAND terms, the use of injunctive relief may be abuse of dominance. In *Huawei*, the CJEU sought to solve this by setting out a standard for good faith negotiations.[46]

The second question is the use of pay-for-delay agreements, where the Patent Holder pays the Alleged Infringer to stay out of the market for an agreed amount of time, e.g. the patent term. Such pay-for-delay agreements may immediately seem anti-competitive, however, there can be pro-competitive justifications. The Patent Holder may for instance pay for access to the the Alleged Infringer's IP, distribution network, or the like.

[41] For economic perspectives on SEPs and FRAND, se the litterature referenced in footnote 3, above.

[42] In his concurring opinion, Chief Justice Roberts also acknowledged the risk of hold-up, as Alleged Infringers will likely already have invested heavily in production set-up etc. See Denicolo' et al. (2008).

[43] Se the district court decision in: *Apple, Inc. v. Motorola, Inc., 869 F. Supp. 2d 901, 913-914 (N.D. Ill. 2012) aff'd in part, 757 F.3 1286(Fe. Cir. 2014)* in this particular case, Posner who is normally member of the 7th Circuit Court of Appeals sat as a trial juge. (Sikorski 2019, p.21).

[44] (Gavil et al. 2017, p.1144 onwards).

[45] See (Sikorski 2019, p. 24) for a short overview.

[46] (Sikorski (2019), p. 45) with references to Commission decisions reiterating the above point. Particularly in Germany, there has been ample case law on how to apply the *Huawei* test. We refer the reader to the overview presented in (Sikorski (2019), p. 74 onwards).

These facts seem to be accepted in both the U.S. and E.U.[47]

In the leading U.S. case, *FTC v. Actavis, Inc., 570 U.S. 136 (2013)*, the Supreme Court ruled that pay-for-delay agreements where not per se anti-competitive and should be decided using the rule of reason test. In particular, the Supreme Court emphasised four factors: (1) Had the Patent Holder made a payment? (2) What was the size of the payment compared to future litigation costs? (3) Was the payment intimately linked to other services from the Alleged Infringer? (4) Were there other convincing reasons why the Patent Holder should make a payment to the Alleged Infringer? Interestingly, the Supreme Court explicitly stated that in deciding the anti-trust question, there was normally no reason to litigate the question of the patent's validity, as the payment's size would be a good surrogate for the Alleged Infringer's likelihood to prevail on the merits.[48]

In the E.U., the leading cases *C-591/16 Lundbeck*, *T-691/14 Servier* and *C-307/18 U.K. Generics* focus on the question whether such agreements are anti-competitive by object. The rulings seem to agree that one should ask if (1) the Alleged Infringer was a potential competitor, i.e. that there are real and concrete possibilities to enter the market. (2) the Alleged Infringer held back on trying to enter the market because of the agreement. (3) the agreement contained a transfer of value which substantially limits the Alleged Infringer's incentives to attempt to enter the market. And, (4) there are any pro-competitive effects of the agreement. In *U.K. Generics*, the CJEU also stated that there was not generally any reason to look at the parties' likelihood of prevailing on the merits.

Without purporting to provide a full analysis of the issue, it is relevant to discuss a bit further when the Alleged Infringer may be deemed a potential competitor. This will in particular be the case, where the generic manufacturer has a firm intention and an inherent ability to enter the market and does not meet insurmountable barriers to entry, cf. *Lundbeck*, paras 54-56. A process patent building on an active ingredient patent that has already fallen into the public domain is not an insurmountable barrier.

[47] One should be aware, however, of the different regulatory environments in the U.S. and E.U. and how they can affect the types of cases that occur and the further analysis of e.g. the settlement. For instance, whilst both U.S. and E.U. rules allow for truncated approval proceedings for generic drugs, the U.S. Hatch-Waxman Act incentivises generic companies to be the first challenger of a patent-protected product. This so through so-called paragraph IV certification filings (U.S.C. Section 355(j)(2)(A)(vii)(IV)) whereby the first generic applicant is granted a 180 day period of exclusivity. This in turn means that the majority of US cases concern generic entry before patent expiry through paragraph IV ceritfications filings. For data on the effects of the Hatch-Waxman act, see Branstetter et al. (2016), Grabowski and Kyle (2007), J. and H. (2009). On the other hand, in Europe, such incentives are not available, which arguably means that cases mainly arise once the compound patent has expired and where the question of infringement mainly revolves around secondary or process patents. This observation mirrors the cases referenced below; *Actavis* revolved around patents on the active ingredient, whereas the E.U. cases related to process patents, although the Alleged Infringer also agreed to not enter the market for the expired active ingredient patent. Another regulatory difference is that patents in the E.U. are obtained at the Member State level, which means that cases must be litigated in each Member State. This arguably weakens the Patent Holder's position and increases the incentives to settle disputes. For this view, see Clancy et al. (2014).

[48] After the Supreme Court remanded the decision to the District Court, the parties filed a settlement with the court. To our knowledge, the settlement has not yet been accepted.

Cf. para 57 with reference to *U.K. Generics*, paras 46-51. In determining whether there is a firm intention and inherent ability to enter the market, the Court in *Lundbeck* para 57 stated that it must be determined whether the Generic manufacturer "had taken sufficient preparatory steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure on the manufacturer of originator medicines." Relevant evidence in this regard could be investments made by the generic manufacturers, the steps that they took to obtain a marketing authorisation and the fact that they already concluded supply agreements.[49] Finally, it does not change the analysis if the Patent Holder has obtained a PI, prohibiting in the interim the Alleged Infringer from selling the product in question, when the PI is given in return for a cross-undertaking, cf. *U.K. Generics* para 53.[50]

4 Model

To model the combination of patents and PIs, we use a simple extension of a market entry game as illustrated in Fig. 1, below. An incumbent Patent Holder has used R&D to create a product that may be covered by a patent. The Patent Holder has a monopoly on the market up until the point where an Alleged Infringer enters the market with a product that if the patent is valid infringes the Patent Holder's rights. If entry takes place, the Patent Holder can sue, and must choose whether to move for a PI, which the court can grant or refuse. Later, the court makes its final decision on the merits, and final pay-offs are realized. For simplicity, we assume that both lawsuit and PI request are free. In the appendix, we extend our basic analyzess by studying the effects of litigation costs that are proportional to the damages at stake.[51]

Our analysis begins at the Alleged Infringer's decision whether to enter the market. The parties are aware of each other, and if Alleged Infringer enters, the Patent Holder must decide whether to sue and move for a PI. This initial part of the game tree is illustrated in Fig. 2. We do not allow the parties to bribe each other. As our model will build on a monopoly payoffs assumption,[52] i.e. the monopolist earns a higher profit than duopolists combined, the Alleged Infringer cannot profitably pay the Patent Holder to not bring suit. While the Patent Holder could in theory pay the Alleged Infringer to not enter the market in the interim period, we assume away this possibility by assuming that the Patent Holder would have no other reason to pay

[49] See e.g. Tayar and Ortoli (2021), p. 2. For a recent analysis on the definition of potential competition, see Dunne (2021).

[50] As the case title would indicate, U.K. Generics was enjoined in the U.K., which explains the reference to cross-undertakings, cf. the discussion above. A so far unanswered question is whether the ruling in *C-688/17 Bayer*, referenced above, may affect the analysis. Under Bayer, Alleged Infringers who prevail on the merits may not receive damages if they launched at risk. This may limit the access to cross undertakings or the like, which again may limit the extent of the wording used in *U.K. Generics*.

[51] In Bogetoft (2021), we further study in more details the impact of legal costs in a related framework. There is an extensive literature on patent settlements, where litigation costs play a role in incentivising settlements. See e,g, Bebchuk (1984), Reinganum and Wilde (1986), Meurer (1989), Somaya (2003), Merges and Farrell (2004), Bessen and Meurer (2006), Llobet and Suarez (2012), and Melamed and Lee (2016).

[52] In the patent race literature, this is referred to as the efficiency effect.

the Alleged Infringer other than to secure monopoly profits from the current market, making such an agreement most likely illegal under E.U. and U.S. law.[53] If the Patent Holder does sue and seek a PI, the game tree unfolds as in Fig. 3. Here and subsequently, Win / Lose refers to the outcome for the Patent Holder in the final court decision. If the Patent Holder does not seek a PI, the game tree simplifies to Fig. 4.

As discussed in Sect. 2, patent infringement suits contain multiple alternative event flows, such as pay-for-delay agreements, settlements after the request for a PI, and permanent injunctions not being available. For us to create a manageable model with useful insights, we focus specifically on the prohibitory PI, which is present in most jurisdictions. Further, we discuss alternative event flows in general terms, namely as bribing, self-regulation, and settlements.

We use the following notation

D_t, d_t are the respective duopoly profits of the Patent Holder and Alleged Infringer in Period $t \in \{1, 2\}$, where $t = 1$ is the period from market entry to the final court decision, and $t = 2$ is the period after. For example D_1 is the duopoly profit for the Patent Holder before the final court decision, and d_2 is the Alleged Infringer's profit after the court decides in the Alleged Infringer's favor. For simplicity, we assume that there are no profits before the PI decision.[54]

M_t is the monopoly profit for the Patent Holder in Period $t \in \{1, 2\}$. We make the standard assumption

$$D_t + d_t \leq M_t$$

i.e. the cumulative profits in a duopoly market is (weakly) less than monopoly profit. This corresponds to a typical case of the Alleged Infringer and Patent Holder producing substitute products, and it eliminates the possibility that Alleged Infringer can profitably pay Patent Holder to not sue.

ρ is the probability that a PI is granted when requested by the Patent Holder but opposed by Alleged Infringer. If both Alleged Infringer and Patent Holder support a PI, we assume that it is granted. To avoid a too large game tree, we have suppressed this branch.

π is the probability that the Patent Holder wins in the final court decision on the merits. If Patent Holder wins, the Alleged Infringer is not allowed on the market in $t = 2$. We assume that π is given exogenously.[55]

[53] See the discussion of pay-for-delay agreements above.

[54] We do not include explicit discounting below. This is without loss of generality however as we might just think of all payoffs in Periods 1 and Periods 2 as being discounted to the same point in time, say the time where the court makes its final decision.

[55] The π parameter depends on many factors in reality, including the court's precedents, the quality of the legal team, the details of the product of the Alleged Infringer, and the quality of the patent itself. Given these factors, we also consider it a reasonable simplification to assume that no party has superior information about π.

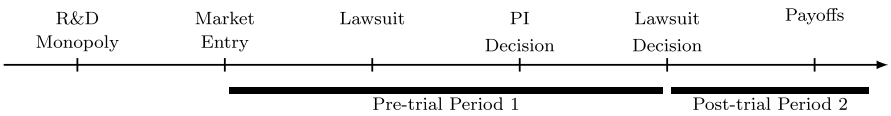

Fig. 1 Timeline

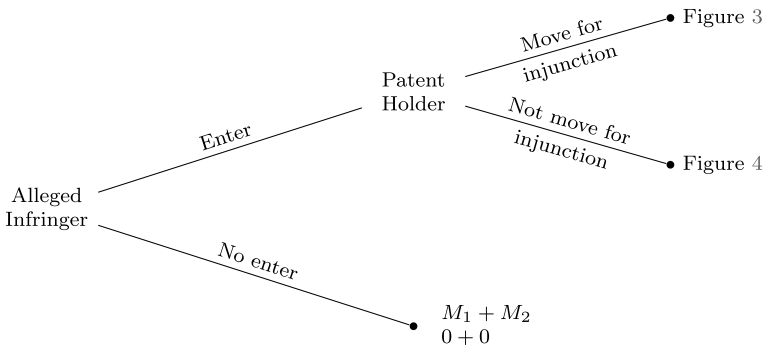

Fig. 2 Initial game tree

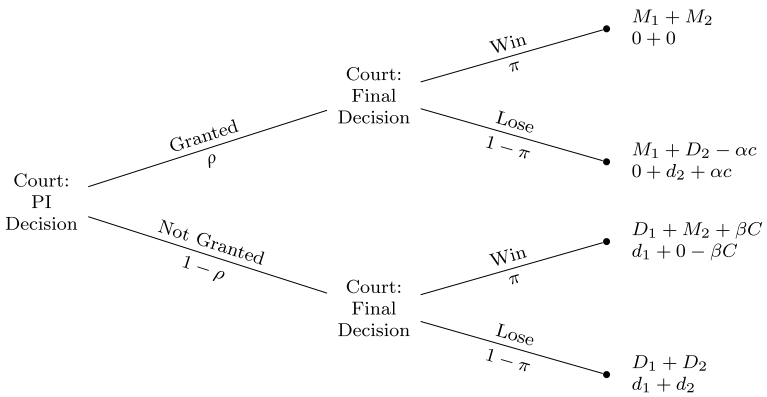

Fig. 3 Game tree following a move for injunction

C, c are measures of perfect damages awards to the Patent Holder and Alleged Infringer, respectively. In our monopoly setting, this is the lost profits of the Patent Holder who suffer infringement

$$C = M_1 - D_1$$

and the lost profits of the Alleged Infringer that is wrongly enjoined

$$c = d_1$$

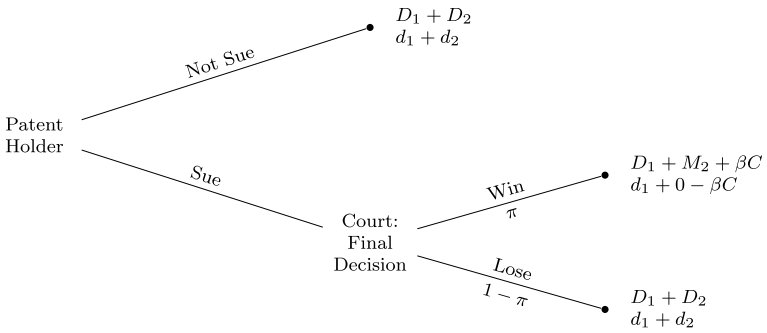

Fig. 4 Game tree following no move for injunction

Note that according to our monopoly assumption there exists an inherent asymmetry in the size of damages. The damages to Patent Holder will always be larger than the damages to the Alleged Infringer.

$$C = M_1 - D_1 \geq d_1 = c$$

We therefore only need to analyze cases, where this holds.

α, β are the fractions of perfect damages that the Patent Holder (α) and Alleged Infringer (β) will pay to the other party upon a final decision on the merits. Assuming risk neutrality, we may think of $\alpha \in [0, 1]$ ($\beta \in [0, 1]$) as the expected fraction of c (C) that the Patent Holder (Alleged Infringer) is compelled to pay to the Alleged Infringer (Patent Holder). Such fractions could be created by the court's downward bias in the damages estimations, cf. Sect. 3 . Note that this does not exclude the possibility of over-compensation in specific cases as long as the parties do not know ahead of time that their particular case will lead to over-compensation. In reality, it is of course possible that the court systematically over-compensates, i.e. uses $\alpha > 1$ and $\beta > 1$, as also discussed in Sect. 3, and we will therefore also briefly discuss how this will impact our results in the appendix. When $\alpha \neq 1$ or $\beta \neq 1$, we will talk about imperfect damages.

We assume that all parameters are common knowledge, i.e. the parties have symmetric information and hold symmetric beliefs. While idealized, the assumption finds support in the European pharmaceutical industry with repeat players and a highly transparent market.

We will generally assume that the probabilistic events are independent, i.e. the event that a preliminary injunction is granted does not affect the probability that the final court decision will be in the Patent Holder's favor, and neither of these events have an impact on the share of damages paid. In reality, of course, this may not always be realistic assumptions.

In the bulk of the paper, we define efficiency in terms of the combined profit to the Patent Holder and the Alleged Infringer. Under our monopoly profits assumption,

efficiency dictates that only the Patent Holder is on the market. This follows the model proposed by Brooks and Schwartz (2005). While we return to a possible extension with consumer surplus later, here, we will simply note that joint surplus efficiency in the monopoly setting differs from short run social efficiency, because consumers will benefit from a duopoly outcome. Society, however, has acknowledged that companies may not be willing to spend on R&D if they cannot enjoy some of the monopoly profits granted by patents. Patent Holders' interim profits may therefore be important for long term innovation and social gains. This motivates our objective of maximizing and measuring efficiency in terms of the joint profits of the Patent Holder and Alleged Infringer in the interim period before a final court decision.

5 Patents but no PI instrument

To understand the effects of the PI instrument, we first consider a scenario where it is not available. In this case—the patent only scenario—patents exist, but the Patent Holder's only remedies are damages for lost profits and the ability to prevent the Alleged Infringer from being on the market after the final court decision (so-called permanent injunctions). Both remedies, of course, are contingent on the Patent Holder prevailing in court.

If the Alleged Infringer enters, the Patent Holder will sue if and only if:

$$D_1 + \pi(M_2 + \beta C) + (1 - \pi)D_2 \geq D_1 + D_2$$

The left hand side is the expected pay-off to the Patent Holder if she sues and the right hand side is the pay-off if she does not. Rewriting, we see that Patent Holder will sue if and only if:

$$C \geq \frac{D_2 - M_2}{\beta} \tag{1}$$

Because of our monopoly pay-off assumption, the right hand side is negative. Hence, the Patent Holder will always sue, even though the chance of success is very low. This result is to be expected, as our assumption of a lawsuit being cost free essentially gives the Patent Holder a free lottery ticket.

Knowing this, the Alleged Infringer must decide whether to enter the market or not. If he stays out, he makes 0.[56] If he enters, the Patent Holder sues and he makes $d_1 - \pi\beta C$. The Alleged Infringer will stay out of the market, when

$$\pi\beta C \geq d_1 \Leftrightarrow C \geq \frac{c}{\pi\beta} \tag{2}$$

[56] Note that we focus here only on the Period 1 payoffs. This is possible since we disregard litigation costs and therefore assume that the Alleged Infringer can stay out of the market in Period 1 and sue the Patent Holder claiming invalidity of the patent. Doing so would give $0 + (1 - \pi)d_2$ which shall be compared to the two period payoff if he enters, which is $d_1 - \pi\beta C + (1 - \pi)d_2$. Note that since Period 2 payoffs are always the same, it is sufficient to focus on Period 1 payoffs here.

We say that Alleged Infringer "self-regulates". As one would expect, the set of environments, i.e. the set of (C, c) values, leading to self-regulation increases in π and β.

The different solutions are illustrated in Fig. 5[57]. For combinations of C and c where Alleged Infringer self-regulates and stays out of the market, i.e. in Setting 'I', the outcome is efficient in the sense of maximizing the joint surplus of the Patent Holder and Alleged Infringer. The inefficiency in Setting 'II', where the Alleged Infringer enters despite the potential lawsuit, is the result of uncertainty about the court decision on the merits and the fact that Alleged Infringer may not pay perfect damages.

That the Patent Holder receives imperfect damages, $\beta \leq 1$, does not in any relevant manner affect her incentives to file a lawsuit. Suing is better than not suing since the cost is zero and there is a chance she will win and get a partial damages payment. Smaller β, however, limits when Alleged Infringer will self-regulate, i.e. the combinations in Setting 'I' shrink. This is natural since the Alleged Infringer's expected costs of a lawsuit are less when he only has to pay a fraction of the actual damages suffered by the Patent Holder.

To see the efficiency gains of patents (with damages and permanent injunction as remedies), let us take a step back and assume that there exists a monopoly situation, but no patent rights. Since the parties have perfect information, full efficiency could be obtained by the Patent Holder paying Alleged Infringer $c = d_1$ to stay out of the market. Here, the Patent Holder would make a Period 1 profit of $M_1 - d_1$, i.e.

$$\begin{aligned} \text{Profit(Patent Holder)} &= M_1 - d_1 \\ \text{Profit(Alleged Infringer)} &= d_1 \end{aligned}$$

An agreement where the parties share monopoly profits will, however, violate EU Competition rules. The parties therefore cannot agree on an efficient allocation and instead get duopoly profits:

$$\begin{aligned} \text{Profit(Patent Holder)} &= D_1 \\ \text{Profit(Alleged Infringer)} &= d_1 \end{aligned}$$

In both cases, the Alleged Infringer receives d_1 and is therefore indifferent between profit sharing agreements being legal or illegal. But the Patent Holder strictly prefers being able to make a profit sharing agreement with the Alleged Infringer.

When patents are introduced, the Alleged Infringer self-regulates in Setting 'I'. Patents thereby create efficiency in all cases falling into Setting 'I'.

Patents also affect the allocation of pay-offs. In the patents only scenario, we get Period 1 profits of

[57] While Fig. 5 shows the solutions in a two-dimensional space, they could also be shown in a one-dimensional space, where the x-axis is the ratio $\frac{C}{c}$. This method is applied in Appendix B. Using the one-dimensional space has the advantage of clearly identifying the thresholds for different Settings, however, it also hides the importance of the ratio between C and c.

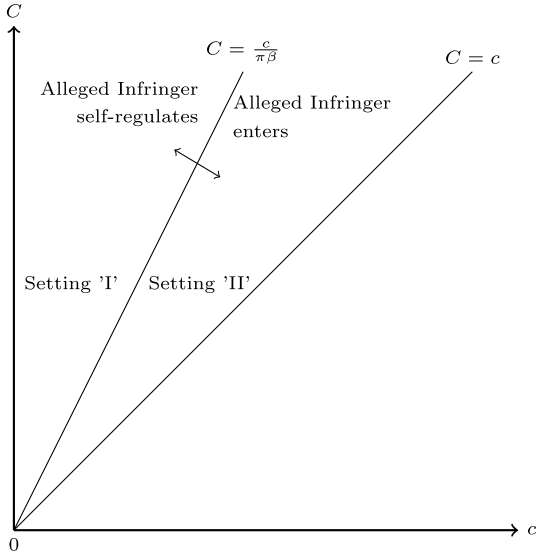

Fig. 5 Outcome in patent only scenario

$$\text{Profit(Patent Holder)} = \begin{cases} M_1 & \text{if Setting 'I'} \\ D_1 + \pi\beta C & \text{if Setting 'II'} \end{cases}$$

$$\text{Profit(Alleged Infringer)} = \begin{cases} 0 & \text{if Setting 'I'} \\ c - \pi\beta C & \text{if Setting 'II'} \end{cases}$$

The existence of patents, thereby harms the Alleged Infringer as he now must bear the cost of expected damages payments to the Patent Holder. On the other hand, the Patent Holder benefits from the existence of patents. The efficiency gains created by patents are entirely captured by the Patent Holder and the Alleged Infringer may now be forced to partially cover any monopoly losses that the Patent Holder faces. As such, this supports the goal of patents; providing the Patent Holder with monopoly gains for a limited time period, seeking to incentivize innovations and hereby advance long term societal gains.

6 Patents and PI instrument

Now that we have seen that patents benefit the Patent Holder by subjecting the Alleged Infringer to potential damages payments, we will investigate the effect of the PI instrument.

As noted in the introduction, a granted PI gives the Patent Holder full monopoly profits in Period 1 as compensation for her assuming the risk of having to pay

damages to Alleged Infringer upon the final court decision. The pay-off structures were given in Figs. 3 and 4.

Let us first consider when the Patent Holder will request a PI. This happens when

$$M_1 + \pi M_2 + (1-\pi)(D_2 - \alpha c) \geq D_1 + \pi(M_2 + \beta C) + (1-\pi)D_2$$

where the left hand side is the expected profit to the Patent Holder when a PI is granted and the right hand side is when it is not. This condition can be reduced to

$$C \geq \frac{(1-\pi)\alpha}{1-\pi\beta} c \tag{3}$$

It can be shown that the Patent Holder will in effect request a PI for all values of C and c consistent with the monopoly property $C \geq c$.[58] Hence, in our model, the Patent Holder will always ask for a PI.[59]

Consider now the Alleged Infringer. Since Inequality (3) holds, he knows that the Patent Holder will ask for a PI if he enters the market. This leads to three possible actions:

1. Stay out of the market (self-regulate) and receive a Period 1[60] payoff of 0.
2. Enter the market, support a PI and receive an expected Period 1 payoff of $(1-\pi)\alpha c$.
3. Enter the market, object to a PI and receive an expected Period 1 payoff of $\rho(1-\pi)\alpha c + (1-\rho)(d_1 - \pi\beta C)$.

Recall that ρ is the probability of the court granting a PI when it is requested by the Patent Holder and opposed by the Alleged Infringer.

We see that the Alleged Infringer will no longer self-regulate and always enter the market. The second strategy (weakly) dominates the first. He can now enter the market, accept a PI and potentially obtain damages from the Patent Holder. As there are no costs in our model, this is a free lottery ticket.

[58] To see this, we must show that

$$\frac{(1-\pi)\alpha}{(1-\beta\pi)} \leq 1 \tag{4}$$

The proof follows by way of contradiction. Assume that

$$\frac{(1-\pi)\alpha}{(1-\beta\pi)} > 1 \tag{5}$$

This is equivalent to $\pi(\beta - \alpha) > 1 - \alpha$. It follows that we must have $\beta > \alpha$. We see also that we must have $\beta = 1$ since if $\beta < 1$ we have $\frac{(1-\pi)\alpha}{(1-\beta\pi)} < \frac{(1-\pi)\alpha}{(1-\pi)} = \alpha \leq 1$ which contradicts the assumed Inequality (5). Now, with $\beta = 1$, it is clear that $\frac{(1-\pi)\alpha}{(1-\beta\pi)} = \alpha \leq 1$, which proves Inequality (4) as desired. In summary, for all $C \geq c$ the Patent Holder will seek a PI.

[59] This, of course, is not always a reasonable prediction. As mentioned elsewhere in particular litigation costs may affect the parties' willingness to litigate and encourage settlements.

[60] As noted earlier, it suffices to look at Period 1 payoffs since we assume no legislation costs and therefore the Alleged Infringer can freely test the validity of the patent in Period 1. The expected Period 2 payoffs are therefore the same in all cases.

Now, comparing of the second and third strategy, we see that the Alleged Infringer will accept a PI rather than fight it if and only if

$$(1-\pi)\alpha c \geq \rho(1-\pi)\alpha c + (1-\rho)(d_1 - \pi\beta C)$$

which reduces to

$$(1-\pi)\alpha c \geq d_1 - \pi\beta C$$

i.e.

$$C \geq \frac{1-(1-\pi)\alpha}{\pi\beta} c \tag{6}$$

When this is not the case, the Alleged Infringer will oppose the PI.

Comparing the Patent Holder's and the Alleged Infringer's constraints for accepting a PI, we note that for all α, β, π, we have

$$\frac{1-(1-\pi)\alpha}{\pi\beta} \geq \frac{(1-\pi)\alpha}{1-\pi\beta} \tag{7}$$

This implies that there exists a subset of PI requests that the Alleged Infringer will accept, but there are no cases where the Alleged Infringer supports a PI and the Patent Holder does not.[61]

To sum up, we have the outcomes illustrated in Fig. 6 below.

It is interesting to consider a bit further the cases where the Alleged Infringer accepts a PI. This happens when C is sufficiently large compared to c. That is, the potential damages award to the Patent Holder is sufficiently large relative to the potential damages to the Alleged Infringer. Moreover, the Alleged Infringer is more willing to support a PI when

$$\frac{1-(1-\pi)\alpha}{\pi\beta}$$

is low. That is, Alleged Infringer is more accepting of a PI request, when he is likely to lose the court case large π when he expects to pay a large share of possible damages to the Patent Holder—large β—and when he gets a large share of his foregone profits large α should he prevail at trial.

[61] To see this, rewrite (7) as

$$(1-(1-\pi)\alpha)(1-\pi\beta) \geq (1-\pi)\alpha\pi\beta$$

which reduces to

$$1 \geq \pi\beta + (1-\pi)\alpha$$

This holds since the right hand side is the convex combination of β and α both of which are at the most 1. Hence, condition (7) holds.

Finally, when damages are paid in full, $\alpha = \beta = 1$, the Patent Holder will always suggest, and Alleged Infringer will always accept, a PI. With perfect damages, the interim outcome is therefore efficient in the sense of maximizing joint surplus. In our model, it is the imperfect damages that create the discord.[62]

We also note that with perfect damages, the parties' preferences for a PI are not affected by the likelihood of the final decision's outcome, π. This is at odds with the classic legal doctrine, where at least some focus is on who is likely to prevail in the end. With imperfect damages, however, preferences depend on π, indicating closer alignment with legal doctrine.

Introducing the PI instrument thereby has two direct effects. First, it improves efficiency since the parties either avoid competing in Period 1, Setting 'III', or avoid competing with probability ρ, due to a granted PI, Setting 'IV'. This can also be seen by comparing Figs. 5 and 6. Setting 'III' extends Setting 'I' and in Setting 'IV' there is now at least some chance of an efficient outcome with only the Patent Holder on the market in Period 1.

Second, the introduction of the PI instrument strongly favors the Alleged Infringer. He no longer avoids entry to protect himself from possible damages claims, but enters and if a PI is granted potentially receives damages of his own. The resulting Period 1 payoffs in the combined patent and PI case are

$$\text{Profit(Patent Holder)} = \begin{cases} M_1 - (1-\pi)\alpha c & \text{if Setting 'III'} \\ \rho(M_1 - (1-\pi)\alpha c) + (1-\rho)(D_1 + \pi\beta C) & \text{if Setting 'IV'} \end{cases}$$

$$\text{Profit(Alleged Infringer)} = \begin{cases} (1-\pi)\alpha c & \text{if Setting 'III'} \\ \rho(1-\pi)\alpha c + (1-\rho)(d_1 - \pi\beta C) & \text{if Setting 'IV'} \end{cases}$$

7 Illustrations of the PI impacts

To see how the introducing the PI instrument affects profits, Figs. 7, 8 and 9 illustrate the Period 1 payoffs on the y-axis as a function of $\frac{C}{c}$ on the x-axis.

Starting with Fig. 7 where the court can calculate perfect damages, we see that the Alleged Infringer strictly prefers the PI regime to the patent only regime. This mirrors our result that the Alleged Infringer will always accept a PI request when damages are perfect. The reason is twofold. Under the PI regime, he (1) avoids the risk of full damages payments to the Patent Holder, and (2) will receive perfect damages if he prevails in the final decision.

The story for the Patent Holder is less clear. She is better off when the Alleged Infringer self-regulates, which he will do in the patent only regime when $\frac{C}{c}$ is large. In the PI regime, the Alleged Infringer will enter and accept a PI. When $\frac{\epsilon}{c}$ is small and the Alleged Infringer enters in the patent only regime, the Patent Holder prefers a PI regime since it gives her at least a chance of ρ that the Alleged Infringer is

[62] The same result would follow, if we assumed asymmetric information on the parties' damages. With both imperfect damages and asymmetric information, the inefficiencies increase even further.

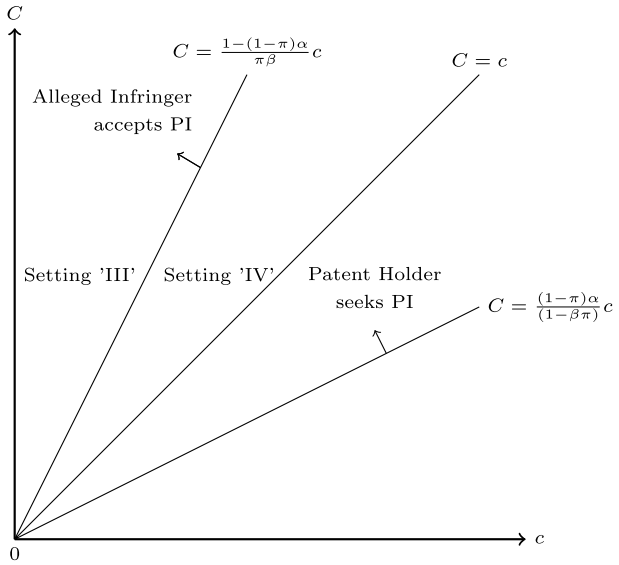

Fig. 6 Outcome in patent and PI scenario

initially kept out of the market. This leads to a larger joint surplus, which the Patent Holder enjoys. Even if the patent is found invalid, the Patent Holder will earn Period 1 profits of M_1, only to pay damages of d_1. This lets her wrongfully capture the consumer surplus of $M_1 - D_1 - d_1 \geq 0$.

Consider now the cases with imperfect damages payments in Figs. 8 and 9. For larger values of $\frac{C}{c}$, the Alleged Infringer benefits from the introduction of PIs, while the Patent Holder is harmed. This is so because the Alleged Infringer substitutes his self-regulation with entering the market and accepting a PI request from the Patent Holder. For smaller values of $\frac{C}{c}$, mainly the Patent Holder benefits from a PI regime as it grants her some monopoly profits in Period 1 as explained above.

To understand the details of these cases it is useful to compare Figs. 5 and 6.

Regarding the Alleged Infringer, we see that when $\frac{C}{c}$ is relatively large, he stays out in the patent only regime, since he risks having to pay large damages awards. With PI, he has a free lottery ticket since he can enter and accept a PI request from the Patent Holder. He can therefore potentially get damage payments if the court rules in his favor, and he does not risk having to pay large damages.

For small values of $\frac{C}{c}$, the Alleged Infringer would enter in the patent only regime, since his gain of c is relatively large and his potential damages payment to the Patent Holder, βC, is relatively small. In these cases, it is the Patent Holder that mainly benefits from the PI, since if a PI is granted, the Alleged Infringer is kept out for the interim period and the Patent Holder only has to pay damages if the Alleged Infringer prevails in the final decision.

For intermediate values of $\frac{C}{c}$, the results are mixed. If in the patent only regime, the Alleged Infringer would just barely enter the market, he benefits from a PI regime, since the PI will eliminate his risk of having to pay damages to the Patent

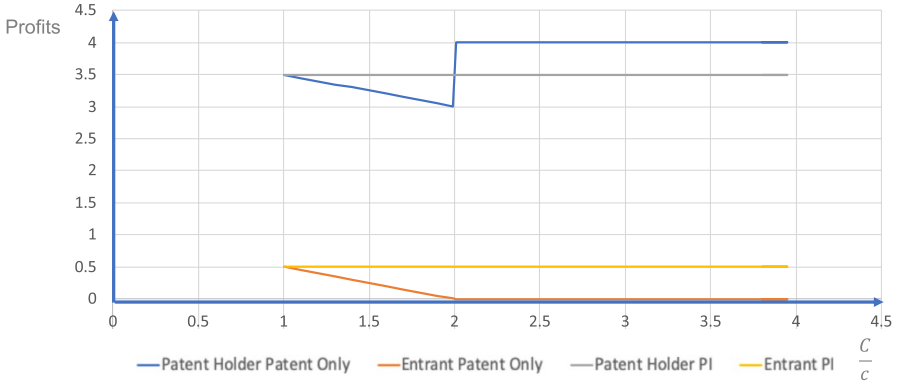

Fig. 7 Payoffs as function of C in setting with $M_1 = 4, c = 1, \pi = 0.5, \rho = 0.7, \alpha = 1, \beta = 1$ Without PI doctrine, Alleged Infringer will self-regulate for values larger than: 2, With PI doctrine, Alleged Infringer will accept PIs for values larger than: 1

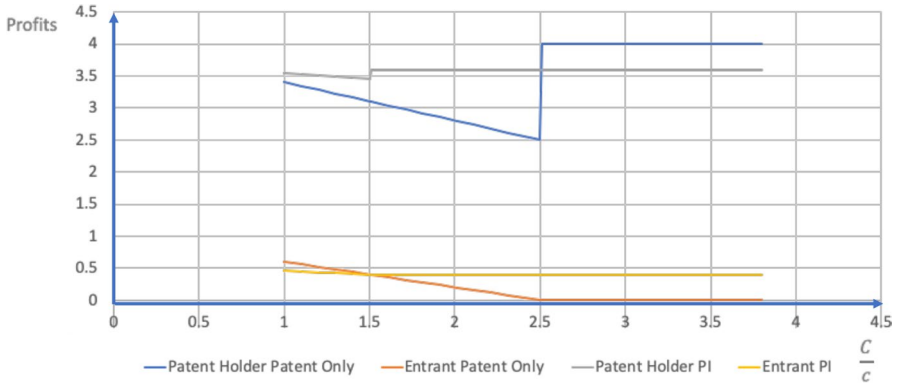

Fig. 8 Payoffs af function of C in setting with $M_1 = 4, c = 1, \pi = 0.5, \rho = 0.7, \alpha = 0.8, \beta = 0.8$ Without PI doctrine, Alleged Infringer will self-regulate for values larger than: 2.5, With PI doctrine, Alleged Infringer will accept PIs for values larger than: 1.5

Holder and instead grant him a lottery ticket for potential future damages. But if it is more attractive to enter in the patent only regime, PIs harm the Alleged Infringer. He is excluded from the Period 1 market with probability ρ, and even if he prevails in court, he will only receive imperfect damages, i.e. αc.

Regarding the Patent Holder, we see that her preferences depend intimately on the Alleged Infringer's characteristics.

Against an Alleged Infringer with a relatively large c, the PI provides the Patent Holder with monopoly profits in Period 1, with little extra cost to the Patent Holder. Against an Alleged Infringer with a relatively low c, however, the PI option is costly to the Patent Holder. Such an Alleged Infringer would not risk large damages payments in the patent only regime and would prefer to stay out of the market. The PI regime makes such an Alleged Infringer more aggressive and the Patent Holder ends

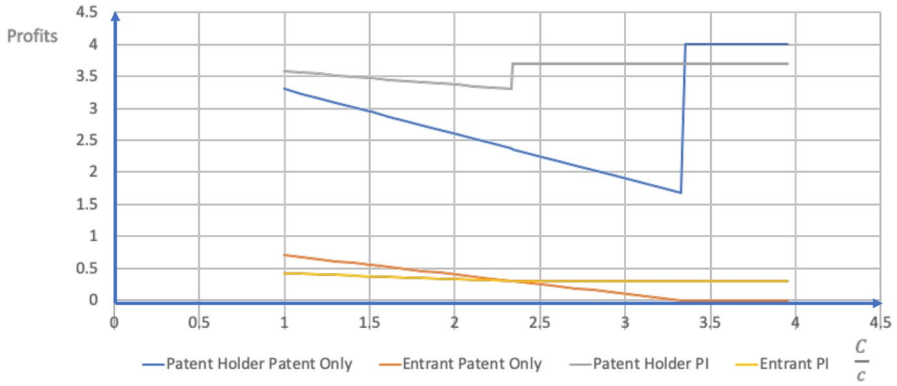

Fig. 9 Payoffs af function of C in setting with $M_1 = 4, c = 1, \pi = 0.5, \rho = 0.7, \alpha = 0.6, \beta = 0.6$ Without PI doctrine, Alleged Infringer will self-regulate for values larger than: 3.33, With PI doctrine, Alleged Infringer will accept PIs for values larger than: 2.33

up being challenged more often and having to potentially pay damages to Alleged Infringers that have been subject to wrongly granted PIs.

Finally, the parties' preferences depend on how correctly damages are calculated. When damages payments become more correct, i.e. when α and β increase, the PI regime becomes more attractive to the Alleged Infringer while it becomes less attractive to the Patent Holder. Further, the Patent Holder's benefit from a PI regime increases when damages payments, β, decline. In that case, it is better to keep the Alleged Infringer out of the market in Period 1. When the Alleged Infringer is not able to pay perfect damages or the court has a downward bias, the Patent Holder will likely prefer a PI regime, since it at least protects her Period 1 monopoly profits.

8 Court decision rules

Until now, the discussion has been on the parties' own incentives and the efficiency of their choices. In this section, we move our focus to the court's decision whether to grant a PI. As shown in Sect. 3, national rules differ, but at the general level the decision rules center on three factors: the likelihood that the Patent Holder will ultimately prevail in the final court decision, the harm the Alleged Infringer will suffer if the PI is wrongly granted; and the harm the Patent Holder will suffer if the PI is wrongly denied.[63] One could also add the public interest.

We begin by introducing the perhaps best known attempt at formalizing U.S. doctrine the Leubsdorf-Posner rule.[64] We show how the rule changes over different combinations of the parameters introduced above and shortly discuss that the rule

[63] See also Lanjouw and Lerner (2001), Calame et al. (2011). Cotter (2013), Laycock and Hasen (2019), Lichtman (2003), Schwartz (1964).

[64] see e.g. Leubsdorf (2007), Brooks and Schwartz (2005).

may not match the letter of (U.S.) doctrine. We then move on to an efficiency based framework, first introducing the interim efficiency rule as proposed by Brooks and Schwartz (2005) before introducing our own consumer focused decision rule.

The Leubsdorf-Posner rule seeks to minimize error costs: The error cost of denying a PI to one who in fact has the alleged patent, and the error cost of granting an injunction to one who in fact does not. According to the rule, a PI should be granted if the product of the probability that the Patent Holder will prevail and the amount of uncompensated harm she will suffer in the interim, is greater than the product of the probability that Alleged Infringer will prevail and his uncompensated loss from complying with the PI. A court should in other words grant a PI when

$$\pi(1-\beta)C \geq (1-\pi)(1-\alpha)c$$

The left hand side is the uncompensated cost to Patent Holder when she does not get a PI, but wins at trial. In that case she is not fully compensated but only gets damages of βC, implying that her uncompensated loss is $(1-\beta)C$. The right hand side is the uncompensated harm to the Alleged Infringer when a PI prohibits him from being on the market. With probability $(1-\pi)$ this is a mistake and since he is only compensated αc, he foregoes $(1-\pi)(1-\alpha)c$.

Rewriting, we see that the Leubsdorf-Posner rule suggests granting a PI when

$$C \geq \frac{1-\pi}{\pi}\frac{1-\alpha}{1-\beta}c$$

The Leubsdorf-Posner rule is visualized in Fig. 10. $\frac{C}{c}$ is our y-axis, while π is our x-axis. The three curves show different combinations of α and β, using the notation LP_α_β. The curves show cut-offs, meaning that the Leubsdorf-Posner rule will grant a PI for all combinations of $\frac{C}{c}$ above the respective curve.

In the case where α and β are equivalent, we see that the Leubsdorf-Posner rule leads to PIs for all $\pi \geq 0.5$. This is partially due to our monopoly assumption, where $\frac{C}{c} \geq 1$. Asymmetry in the fraction of final damages moves the curves horizontally and affects their slope. If the fraction of damages awarded to Patent Holder is lower than the fraction awarded to the Alleged Infringer, the curve moves left and the slope flattens. The opposite happens when the fraction of damages awarded to the Patent Holder is higher than to the Alleged Infringer. In the case where $\alpha = 0.8$ and $\beta = 0.9$, C must be relatively large compared to c, or π—the likelihood that Patent Holder will win must be large in order for the Leubsdorf-Posner rule to grant a PI.

One may fairly question whether the Leupsdorf-Posner rule correctly distills legal doctrine. Notably, the rule takes the product of the parties' likelihood to prevail on the merits and irreparable harm. This squares poorly with the conjunctive wording found in both German, U.K. and U.S. doctrine.[65] U.S. doctrine, for instance, requires the Patent Holder to show that (1) she is reasonably likely to prevail in the case on the merits, (2)

[65] See the review of doctrine in Sect. 3, above. Laycock (1991) and Laycock and Hasen (2019) have also argued that the rule fails to distill U.S. law in other ways. Lichtman (2003), however, seems to argue that this is only a question of how the parameters are weighed.

she will suffer irreparable harm if the injunction is not granted, (3) a balancing of interests between the parties favors the Patent Holder, *and* (4) the public interest favors her.

If we (as is done in the Leubsdorf-Posner rule) forgot condition 4), we can formalize the conjunctive test as

$$\pi \geq \frac{1}{2}$$

And

$$\frac{(1-\beta)C}{(1-\alpha)c} \geq 1$$

where the first inequality formalizes condition (1), and the second formalizes conditions (2) and (3). To see the latter, note that if $\beta = 1$, the the Patent Holder will not suffer any irreparable harm and the numerator cannot hold. Hence, it guarantees the second condition. The inequality also reflects that the Patent Holder's irreparable harm is at least as large as that of the Alleged Infringer, i.e. condition (3) in the conjunctive test. We can show the difference between the Leubsdorf-Posner rule and the conjunctive test in Fig. 11.

The conjunctive test will on average be more restrictive than the Leubsdorf-Posner rule. The conjunctive test will never grant PIs when the Patent Holder's chances of prevailing in the final case are less than 50%. No amount of expected losses from possibly unjust competition can change that. Likewise, the test does not become any more lenient when the Patent Holder's likelihood of prevailing increases. Indeed, while there can be combinations where the Leubsdorf-Posner rule will lead to a PI, but the conjunctive test will not, there are no combinations where the reverse is the case. We see this by rewriting the second term of the conjunctive test as

$$\frac{(1-\beta)}{(1-\alpha)} \geq \frac{c}{C}$$

and the Leubsdorf-Posner rule as

$$\frac{\pi}{(1-\pi)}\frac{(1-\beta)}{(1-\alpha)} \geq \frac{c}{C}.$$

Since the conjunctive test requires that $\pi \geq \frac{1}{2}$, we see immediately that when the conditions of the conjunctive test are met, so are the conditions of the Leubsdorf-Posner rule. This result holds for any conjunctive test where π must be equal to or greater than $\frac{1}{2}$. If π can be smaller, as e.g. under U.K. law where the Patent Holder must only show a serious question to be tried, the Leubsdorf-Posner rule may sometimes deny a PI when the conjunctive test grants it.[66]

Neither the Leubsdorf-Posner rule, nor the conjunctive test, is explicitly concerned with the efficiency of the decision. This has been critized by Brooks and

[66] Of course, as shown in Sect. 3, some authors suggest that courts do not necessarily follow a strictly conjunctive approach.

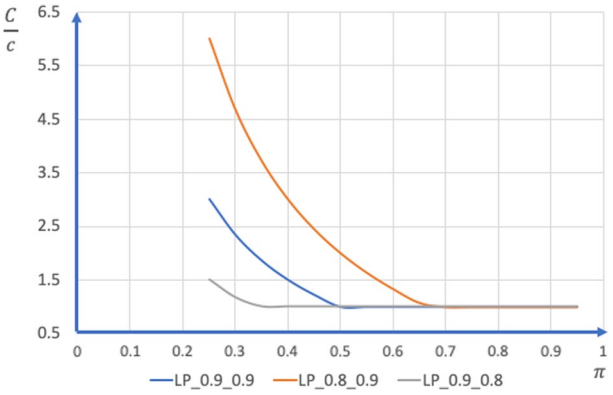

Fig. 10 Leubsdorf-Posner Cutoffs, *LP_α_β*

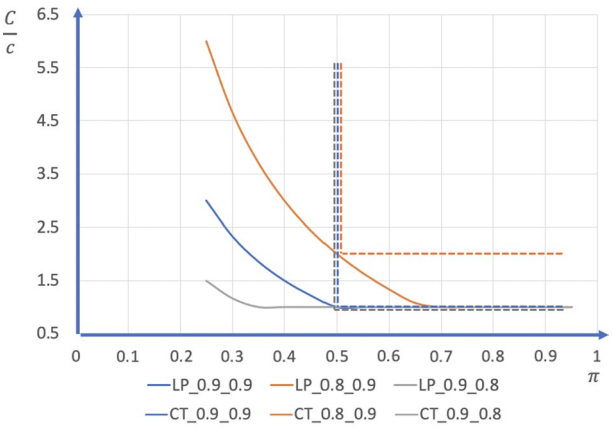

Fig. 11 Leubsdorf-Posner and Conjunctive Cutoffs, *LP_α_β* and *CT_α_β*

Schwartz (2005) who argue that the Leubsdorf-Posner rule (and by extension the conjunctive test) embodies a compensatory, ex post view of the purpose of awarding damages, and fails to create ex ante efficiency. They therefore suggest a rule, which seeks to maximize joint surplus efficiency in the interim period before the final court decision. In our context, where the choice is between a monopoly or duopoly outcome, their rule is to grant a PI when

$$C \geq c$$

which implies that PIs should always be granted.

Figure 12, again shows the $\frac{C}{c}$ cutoffs on the y-axis with π on the x-axis. Here, the curves represent the Leubsdorf-Posner rule, the Brooks-Schwartz rule and the threshold above which the Patent Holder and Alleged Infringer agree on a PI. For

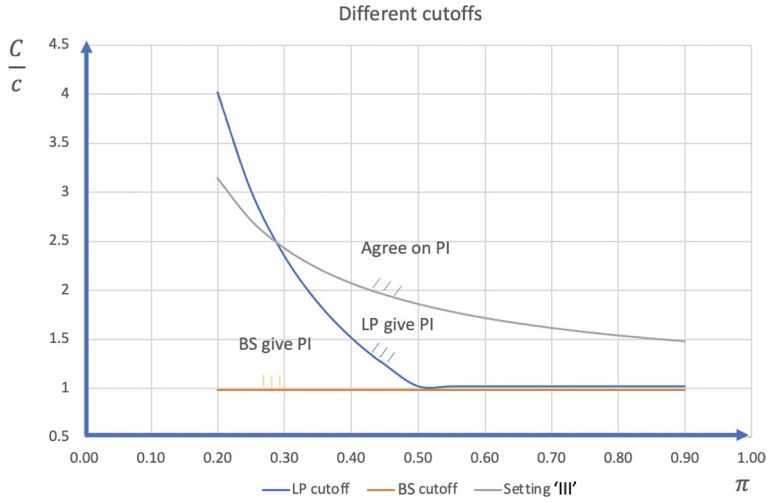

Fig. 12 Different Cutoffs $\alpha = 0.7, \beta = 0.7$

simplicity, we have left the conjunctive test of the Figure, but the reader can note that the test will allow for a PI for all $\pi \geq \frac{1}{2}$.[67]

For most combinations of $\frac{C}{c}$, the Leubsdorf-Posner rule (and conjunctive test) does not come into play, as the parties will agree that a PI should be granted (Figs. 11 and 12). When $\alpha = \beta$ the Leubsdorf-Posner and Brooks-Schwartz rules coincide for $\pi \geq 0.5$.[68]

Although both the Leubsdorf-Posner and Brooks-Schwartz rules have relevant properties, we believe they are inappropriate in the context of patents. Both rules focus only on the properties of the parties, i.e. their irreparable harm or their joint surplus. In doing so, they fail to appreciate the social efficiency goals of patents; long term gains through innovation paid for by short term consumer loss. An efficiency optimizing rule should take this into account, see also Sidak (2017).

We propose a rule based on the theory that a rational society ex ante will accept a patent system as long as the average marginal benefits to society equal the average marginal costs due to the deadweight loss of monopoly. See for this theory Nordhaus (1969), Kaplow (1984), Gifford (2004). This also follows the assumptions made in most public policy decisions, see Williams (2016) who here and in Williams (2017) provides a more up to date discussion of recent empirical evidence.

In our model, this means that the marginal benefit and cost of the patent system is $M_t - D_t - d_t$ for every period of the patent term. If the patent system had not existed, the Patent Holder would not have had sufficient ex ante incentives to invest

[67] This so because of symmetric α and β parameters.

[68] Brooks and Schwartz actually argue that their rule should only be applied, when there is complete uncertainty as to who holds the legal entitlement. This can reasonably be interpreted to mean that they would only apply their rule when $\pi = 0.5$. In this case, the practical relevance of their rule is significantly diminished.

in innovation. On the other hand, if innovation had occurred without the investment, consumers would have received value at least equal to the monopoly profit created by the patent.[69] As such, we know that society ex ante is willing to pay at least $M_t - D_t - d_t$ per period for the entire patent term in order to receive innovation.

Of course, some of these considerations are covered by simple damages calculations. If a PI is wrongly rejected, the Patent Holder will receive damages. If they are perfectly calculated, it will not affect her ex ante incentives to innovate. If they are not, she will forego profits necessary to incentivize optimal R&D investment. If a PI is wrongly granted, however, only the Alleged Infringer will receive damages, consumers will not simply as a matter of law. As such, even if courts were able to calculate damages correctly, there is no way to compensate society for the lost consumer surplus.

A court must take these facts into account if it wishes to decide a PI request on efficiency grounds. In order to optimize ex ante efficiency, it must minimize the costs of two errors: (1) Granting a PI when the patent is invalid, allowing the Patent Holder to extract monopoly rents even when the market should have been governed by (oligopolistic) competition. (2) Rejecting a PI request, when the Patent is valid, forcing the Patent Holder to forego, $(1-\beta)C = (1-\beta)(M_1 - D_1)$, which is the unrecoverable portion of her actual loss.

A court wishing to optimize the consumer surplus of its interim decision should grant a PI when

$$(1-\pi)(M_1 - D_1 - d_1) \leq \pi(1-\beta)C$$

The left hand side is the loss to consumers from a lack of competition when the patent is invalid but a PI is granted. The right hand side is the indirect harm to consumers created by the wrongly denied PI, which undermines the Patent Holder's ex ante incentives to innovate. We can rewrite the condition as $(1-\pi)(C-c) \leq \pi(1-\beta)C$ which reduces to

$$\frac{c}{C} \geq \frac{1-\pi(2-\beta)}{1-\pi}$$

By the monopoly condition the left hand side is less than 1. We therefore see right away, that if $\beta = 1$, this condition can never hold, and the court should never grant a PI. This is intuitive as the Patent Holder will not lose ex ante incentives to innovate. An added bonus is that consumers will benefit from interim competition.

Further, when the numerator on the right hand side is negative, the condition always holds. In other words, when $1-\pi(2-\beta) \leq 0$ the court should always grant a PI. This happens when

[69] This assumes inelastic demand as described above. With elastic demand, society pays a higher price for innovation, as it accepts a deadweight loss larger than the monopoly benefit. See Ayres and Klemperer (1997) and Gifford (2004) for model examples.

$$\pi \geq \frac{1}{2-\beta}$$

For all other values of π, the court should grant a PI, when:

$$\frac{C}{c} \leq \frac{1-\pi}{1-\pi(2-\beta)}$$

In Fig. 13 we show different cut-offs for the rule when β changes, whereas in Fig. 14 we compare the rule to the Leubsdorf-Posner and Brooks-Schwartz rules. Note that while the previous rules require a PI for all values above the curve, our new rule requires a PI for all values below the curve.

For large values of π our new rule tends to agree with the Leubsdorf-Posner and Brooks-Schwartz rules. But for smaller values of π, the rule is much less willing to grant a PI. Generally, the consumer focused rule leads to fewer PIs than both of the other rules. This is not entirely surprising since the idea now is not to focus on the firms but on consumers and when a PI is granted they risk losing their entire surplus, whereas when it is rejected, they only risk losing a fraction of their surplus. Unlike the Brooks-Schwartz and Leubsdorf-Posner rules, our consumer focused rule will sometimes deny a PI even if the conjunctive test grants it. With symmetric α and β parameters, the conjunctive test will lead to PIs for all $\pi \geq \frac{1}{2}$, however, this is not the case for the consumer focused rule. This seems to mirror the fact that jurisdictions where public welfare plays an explicit role (such as the U.K. and the U.S.) seem less willing to grant PIs than Germany, where third party interests play a very limited role.

A somewhat counterintuitive result is the fact that our rule will allow for fewer PIs when $\frac{C}{c}$ is large. This is due to the fact that the Patent Holder's profits are correlated with consumer loss. When $\frac{C}{c}$ is large, so is the (irreparable) consumer loss when a PI is wrongly granted. On the other hand, when $\frac{C}{c}$ is small, so is the expected consumer loss of a PI.

9 Conclusions

In a society wishing to incentivize costly and risky innovation, patents play an important role. As patents create market power, it is equally important that non-infringing competition exists unhindered. A central aspect of patent policy is therefore how to secure the value of valid patents without undermining legitimate competition. A key instrument here is the PI, whereby the court can order an Alleged Infringer to stop selling their product until the infringement suit is finally settled.

This article develops a simple economic model based on the Entrance Game to show the effect of regimes with and without the PI remedy. We investigate how a Patent Holder and an Alleged Infringer behave in the patent only scenario, where only damages and permanent injunctions are available, and in the PI scenario, where the Patent Holder can also seek a PI. We show that the parties' behavior depends on

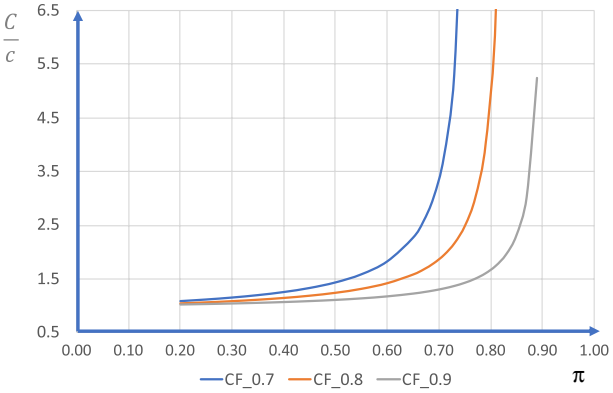

Fig. 13 Consumer Focused Cutoffs CF_β *Note* PI should always be granted for $\pi \geq \frac{1}{2-\beta}$, which gives 0.77, 0.83 and 0.91 in the three cases

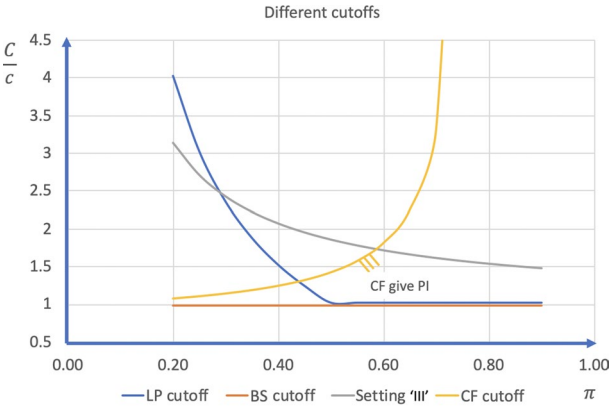

Fig. 14 Comparison with previous rules $\alpha = 0.7, \beta = 0.7$

the probability that the Patent Holder will prevail in the final court decision and on the extent to which courts can determine damages correctly.

We find that while the Patent Holder benefits from a patent only regime, introducing the PI instrument largely benefits the Alleged Infringer. While a PI prevents the Alleged Infringer from selling his products, it also insures him against large damages payments to the Patent Holder and in return allows him to receive damages for not being on the market.

A PI regime increases competitive pressure by encouraging entry. Because only the Patent Holder and Alleged Infringer can receive damages payments, the PI regime may also harm consumers, both when a PI is wrongly granted and wrongly rejected. Therefore, a court seeking to optimize incentives to innovate should take into account the uncompensated consumer loss. In doing so, it is possible that courts will use PIs less often than is currently the case. This is

somewhat supported by the fact that U.K. and U.S. courts are more prone to take into account the social costs of PIs and empirically seem to grant PIs less often than Germany or Denmark; two jurisdictions where social costs are not taken into account. This suggests that PIs are a useful tool in the balancing act between innovation and competition.

While there are many potential extensions to our model, we see three of particular relevance.

First, it would be interesting to introduce asymmetric information about the parties' profits in the different outcomes, i.e. asymmetric information about M_1, D_1 and d_1. This is likely to introduce additional inefficiencies, but it is not obvious how the inefficiencies will be shared among the Patent Holder, the Alleged Infringer, and consumers.

Second, one could further study the role of litigation costs. We have ignored these in the main part of this paper because is complicates the analysis and it is difficult to motivate any particular cost structure. Still, it may be possible to identify some cost structures that are particularly likely.

We introduce one such structure in the Appendix and show the likely impacts. In the patent only setting, legal costs increase the Alleged Infringer's incentives to self-regulate. At the same time, however, legal costs reduce the Patent Holder's interest in legal action which may lead to more entrance. The balance between these forces depends on the setting as shown in the Appendix. In a PI environment, legal costs make the Patent Holder less likely to ask for the PI. At the same time, however, the Alleged Infringer is less likely to object to a PI request since it comes at extra legal costs. In turn, this makes the likely success of a PI request higher, which can encourage the Patent Holder to ask for a PI. Again the balance of these forces depends on the more specific setting.

Further analysis of more elaborate legal cost structure may also lead to interesting insights. One hypothesis could be that Alleged Infringers can use the PI instrument to help finance invalidity proceedings against the Patent Holder.[70]

Third, one could also extend the model to include an R&D phase, or more broadly speaking an initial investments phase, as the Alleged Infringer will also have costs of creating a supply chain, obtaining the marketing authorization etc. Whilst the above discussed litigation cost model could fairly be interpreted as encompassing initial investments from the Alleged Infringer, the model does not quite capture the Patent Holder's initial investment decision.

Moving beyond model extensions, it would of course be relevant to seek empirical tests of the predictions of our model. Empirical tests in this area will likely be challenging by lack of easily accessible statistics from the judicial system. Still, it is not impossible, cf. also Jaffe (2000). Let us just give three examples. The model suggests that the introduction of a PI system increases the number of patent challenges and hereby competition. One possibility would therefore be to compare jurisdictions

[70] In our working paper Bogetoft (2021), we discuss how litigation can finance patent invalidity proceedings. This unpublished paper also illustrates the complications of analyzing litigation in settings where we have limited a priori information about the structure of litigation costs in the final merits case.

with and without PI possibilities or jurisdictions where the availability or scope of PI remedies have changed over time. The model also suggests that Alleged Infringers will be less willing to accept a PI request if their damages compensation is low, i.e. if α is low. In some countries, such as Hungary, generic Alleged Infringers do not receive damages for wrongly granted PIs[71]. According to our model, this will lead to more resources spent on PI hearings. A third testable prediction could be that as our model suggests the use of patent PIs are less likely when pay-for-delay agreements are more easily available. Finally, our decision rule proposes that courts seeking to optimize innovation should focus on consumer surplus. One might be able to test if jurisdictions with more consumer focused PI doctrines fare better in the balancing of innovation and competition. This would continue the work by Mezzanotti and Simcoe (2019), who found no ostensible impact on U.S. innovations from changes to the PI doctrine.

Appendix

Litigation costs

As discussed briefly in the main part of the paper, litigation costs may also impact the outcomes. There are many ways to model ligation costs and there are many factors that may influence litigation costs. In some jurisdictions, the winning party is partially compensated by the loosing party while this is not the case in others. In Bogetoft (2021), where the main focus is on the role of litigation costs, we use four additional parameters corresponding to the legal cost of the Alleged Infringer and the Patent Holder in both the injunction and the merit cases.

In this appendix, we will make the assumption that the litigation costs are proportional to the potential damages. This reflects nicely that the fees the parties are willing to spend depend on the potential damages at stake. It may similarly reflect that more work is required to document larger damages than smaller ones.

Patent only scenario

Specifically, in the Patent only scenario, we assume that

$$\begin{aligned} \text{IP litigation costs Alleged Infringer} &= \gamma c \\ \text{IP litigation costs Patent Holder} &= \gamma C \end{aligned}$$

where $\gamma \leq 1$ is the share of potential damages spend on legal costs. Ignoring legal costs, as we have done above, corresponds to assuming $\gamma = 0$.

[71] See *C-688/17 Bayer* referenced above.

Now it is easy to see that the Patent Holder's condition for suing, Inequality (1), becomes more complicated, namely

$$C \geq \frac{D_2 - M_2}{\beta - \frac{\gamma}{\pi}} \tag{8}$$

Hence for modest values of γ, such that $\beta - \frac{\gamma}{\pi} > 0$, there is no changes. The Patent Holder continues to sue. When, however, the legal costs become too large compared to the chance of winning π and the share of damages being awarded, β, $\gamma > \pi\beta$, the denominator in Inequality (8) becomes negative, and the Patent Holder may not want to sue. Whether he will sue or not depends in the case on the relative size of the competitive losses in the two periods. The larger the losses from competition in Period 2, $M_2 - D_2$ compared to Period 1, C, the more likely it is that he will sue. As the relative losses from competition in Period 2 increase, suing becomes the more viable option, as Patent Holder is paying a relatively low price for the chance to keep the Alleged Infringer out of Period 2. Specifically, we see that the Patent Holder will sue as longs as

$$\gamma \leq \pi\left(\beta + \frac{M_2 - D_2}{M_1 - D_1}\right) = \pi\left(\beta + \frac{M_2 - D_2}{\frac{C}{c}}c\right) \tag{9}$$

Turning now to the Alleged Infringer, it is clear that he will never self-regulate when he can foresee that the Patent Holder will not sue due to too high legal costs.

But when the Patent Holder intends to sue, the Alleged Infringer is more inclined to self-regulate since he will also face legal costs. To see this, the Alleged Infringer's old condition for self-regulation, i.e. Inequality (2) becomes

$$C \geq \frac{1 - \gamma}{\pi\beta}c \tag{10}$$

Again, the results are as expected. The Alleged Infringer will self-regulate more when his legal costs are high. More specifically, we see that the Alleged Infringer will self-regulate as long as the Patent Holder plans to sue and

$$\gamma \geq 1 - \pi\beta\frac{C}{c} \tag{11}$$

It follows whenever the Patent Holder will sue, the introduction of legal costs increases the Alleged Infringer incentives to self-regulate. Further, legal costs reduce the Patent Holder's incentives to sue, which in certain settings may increase the Alleged Infringer's incentives to enter. As can be seen in Fig. 15, the larger the legal costs γ, the larger the $\frac{C}{c}$ settings with self-regulation until we reach the legal costs treshold where Patent Holder abstains from pressing charges which in turn makes the Alleged Infringer enter.

PI setting

Consider now the possible effects of legal costs in the PI setting. We will assume that the Patent Holder's litigation costs of a full PI and IP case is larger than the cost of a pure IP case. The same goes for the Alleged Infringer unless he accepts a PI request from the Patent Holder. In this case, we assume that the Alleged Infringer only have to cover the pure IP litigation costs. Specifically, we assume that

$$\begin{aligned}\text{PI-IP litigation costs Alleged Infringer} &= \begin{cases} \gamma c & \text{if he accepts a PI request} \\ \Gamma c & \text{if he objects to a PI request} \end{cases} \\ \text{PI-IP litigation costs Patent Holder} &= \begin{cases} \Gamma C & \text{if she aks for PI} \end{cases}\end{aligned}$$

where where $\Gamma > \gamma$. Ignoring legal costs as we did in the main text corresponds to $\Gamma = \gamma = 0$.

Consider now the Patent Holder's decisions of whether to ask for a PI. Without legal costs, the Patent Holder would always ask for a PI, but legal costs obviously reduce the attractiveness of a PI. Moreover, the decision depends on the expected reaction of the Alleged Infringer. If Alleged Infringer responds by objecting to the PI, the chance of getting the gains from an actual PI is only ρ. In this case the Patent Holder will ask for a PI if and only if

$$\begin{aligned}&\rho[M_1 + \pi M_2 + (1-\pi)(D_2 - \alpha c)] + (1-\rho) \\ &[D_1 + \pi(M_2 + \beta C) + (1-\pi)D_2] - \gamma C \\ &\geq D_1 + \pi(M_2 + \beta C) + (1-\pi)D_2 - \gamma C\end{aligned}$$

where the right-hand side is the expected profits from abstaining from a PI and using the patent instrument only. This reduces to the following version of E. (3) now modified to allow for litigation costs

$$\Gamma - \gamma \leq \rho \left[1 - \pi\beta - \frac{(1-\pi)\alpha}{\frac{C}{c}} \right] \tag{12}$$

If the Alleged Infringer plans to accept a PI request without any objections, the court will typically decide in favor of a PI, and the Patent Holder will therefore ask for a PI when

$$\begin{aligned}&M_1 + \pi M_2 + (1-\pi)(D_2 - \alpha c) - \Gamma C \\ &\geq D_1 + \pi(M_2 + \beta C) + (1-\pi)D_2 - \gamma C\end{aligned}$$

which reduces to the condtion

$$\Gamma - \gamma \leq 1 - \pi\beta - \frac{(1-\pi)\alpha}{\frac{C}{c}} \tag{13}$$

Equations (12, 13) are the new versions of Eq. (3) now modified to allow for litigation costs and formulated to support the graphical illustrations below. We see that

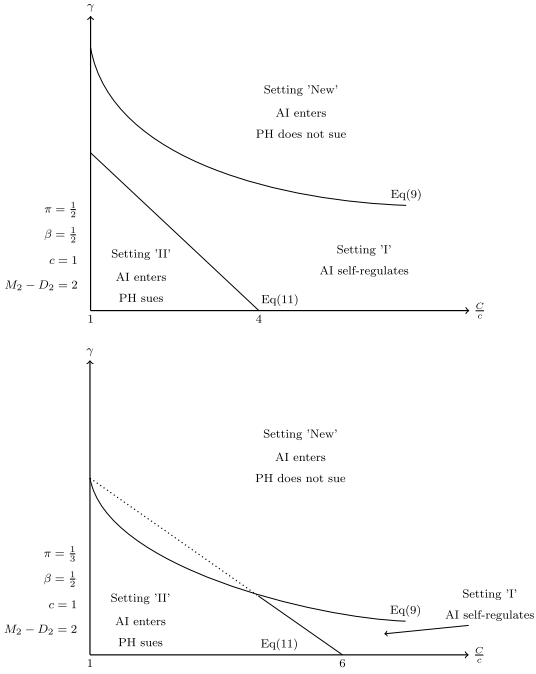

Fig. 15 Outcomes in patent only scenario with legal costs, γ

the PI instrument is more likely to be used the smaller is the extra costs of asking for a PI, $\Gamma - \gamma$, the larger is $\frac{C}{c}$, and the more willing the Alleged Infringer is to accept the PI.

Lastly let us consider when the Alleged Infringer will accept a PI request. This happens when

$$(1-\pi)\alpha c - \gamma c \geq \rho(1-\pi)\alpha c + (1-\rho)(d_1 - \pi\beta C) - \Gamma c$$

where we have used that accepting a request comes at negligible extra litigation costs. This condition reduces to

$$\frac{C}{c} \geq \frac{1-(1-\pi)\alpha - \frac{\Gamma-\gamma}{1-\rho}}{\pi\beta} \tag{14}$$

This corresponds to Eq. (6) except that we now have introduced legal costs. We note that the Alleged Infringer is willing to accept a PI request for smaller values of $\frac{C}{c}$ when legal costs are present since he prefers not to spend extra costs objecting to the PI. We can rewrite Eq. (14) as

$$\Gamma - \gamma \geq (1-\rho)\left[1-(1-\pi)\alpha - \pi\beta\frac{C}{c}\right] \tag{15}$$

We can summarize the above findings as in Fig. 16 below.

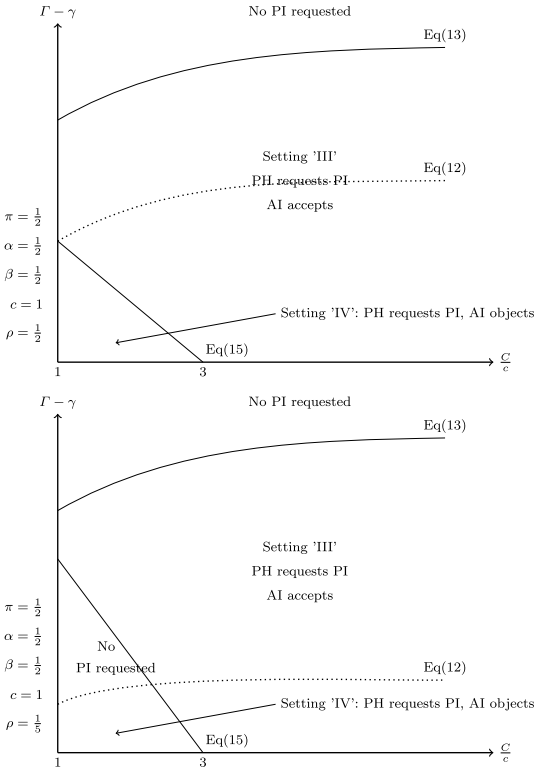

Fig. 16 Outcomes in PI setting with legal costs, Γ and γ

We see that for moderate extra costs of a PI case, the outcome is as before. The Patent Holder requests a PI, and the Alleged Infringer accepts when the potential damages to Patent Holder is large compared to the potential damages to Alleged Infringer (Setting 'III'). When the differences between potential damages are smaller, the AI objects to the PI request since the damage payments are downwards biased (Setting 'IV').

We see also that for high extra costs of a PI trial, the Patent Holder abstains from requesting a PI.

We note also that the Alleged Infringer is less interested in objecting to a PI when there are legal costs associated with fighting it. The $\frac{C}{c}$ value in Setting 'IV' is smaller the larger the extra legal cost of a PI objection.

Lastly, we see that for moderate extra litigation costs, there is also a possibility that the Patent Holder will abstain from requesting a PI since he can foresee that the Alleged Infringer will object. When at the same time the court is conservative in granting a PI, the moderate extra costs may not be worthwhile since they are not likely to lead to a PI. It is interesting to see how there are two separate sets in the lower illustration where the Patent Holder abstains from requesting a PI.

Over-compensation

In the main part of the paper, we have assumed that the parties on average are under-compensated, i.e. the damages paid are only a part β of C and α of c, respectively. Such fractions could be created by the court's downward bias in the damages estimations, cf. Sect. 3. Note that this does not exclude the possibility of over-compensation in specific cases as long as the parties do not know ahead of time that their particular case will lead to over-compensation.

In reality, it is of course possible that the court systematically over-compensates, i.e. uses $\alpha > 1$ and $\beta > 1$, as also discussed in Sect. 3, and we will therefore briefly discuss how this will impact our results.

Patent only scenario

In the patent only scenario, the Patent Holder's interest in suing is not affected by the possible over-compensations ($\alpha > 1$ and $\beta > 1$). This is clear since Inequality (1) does not depend on these parameters.

The Alleged Infringer's decision is, however, affected. We know from Inequality (2) that he stays out of the market when

$$C \geq \frac{c}{\pi\beta}$$

It follows that when β increases, so too will the Alleged Infringer's willingness to self-regulate. The Setting 'I' cases expand. In fact, when $\beta > \frac{1}{\pi}$, Inequality (2) always holds and the Alleged Infringer will always self-regulate, i.e. Setting 'I' will be the only Setting left. This is not surprising since when β increases, so does Alleged Infringer's expected damage payments and it may in the end not be worthwhile to enter in the first place. We can therefore say that expected over-compensation of the Patent Holder will tend to strongly reduce competition and may in extreme cases eliminate competition to begin with in a pure IP regime.

The effect of increasing β is illustrated in Fig. 17. We have here simplified Fig. 5 by taking advantage of the fact that it is really only the relative damages, i.e., the ratio $\frac{C}{c}$, that determines whether the Alleged Infringer will self-regulate.

PI setting

In settings with a preliminary injunction instrument, it is intuitively obvious that the parties' interest in using the instrument is affected by possible over-compensations.

The Patent Holder is less interested in using a preliminary injunction since she may now be forced to over-compensate the Alleged Infringer, should the Patent Holder fail in the final court decision.

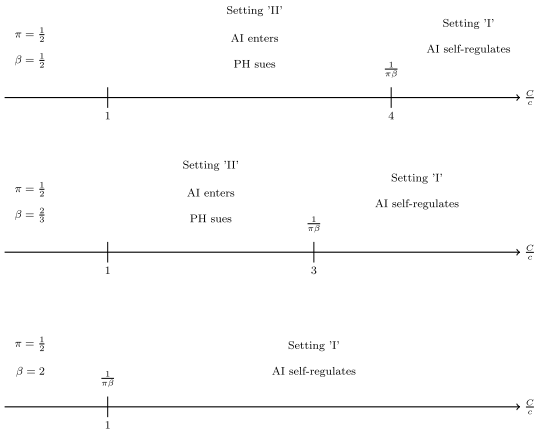

Fig. 17 Outcomes in patent only scenario with increasing β

On the other hand, the Alleged Infringer is more willing to accept a preliminary injunction since it reduces his exposure to the risk of having to over-compensate the Patent Holder.

When the Patent Holder does not ask for a preliminary injunction, we are back to the patent only scenario, and here we already know that the Alleged Infringer is more willing to self-regulate when over-compensation may occur. In sum, it seems intuitive therefore that over-compensation will make the preliminary instrument less attractive for the Alleged Infringer.

To see this more analytically, let us consider the case where the level of over-compensation is the same for the two parties, $\alpha = \beta = \kappa$. Also, let us assume for simplicity that there are limits to the over-compensation, $\pi\kappa < 1$.

We know from Inequality (3) that the Patent Holder will ask for a preliminary injunction only when

$$\frac{C}{c} \geq \frac{(1-\pi)\alpha}{1-\pi\beta} = \frac{(1-\pi)\kappa}{1-\pi\kappa}$$

When courts systematically over-compensate, $\kappa > 1$, the right hand side is now larger than 1. This means that the Patent Holder will sometimes not request a PI. When the court under-compensates, the Patent Holder always makes a request.

Also we know from Inequality (6) that the Alleged Infringer accepts a PI request whenever

$$\frac{C}{c} \geq \frac{1-(1-\pi)\alpha}{\pi\beta} = \frac{1-(1-\pi)\kappa}{\pi\kappa}$$

The right hand side here is less than one.[72] This means that the Alleged Infringer is now always willing to accept a PI request. In the case of over-compensation, we therefore have the outcomes summarized graphically in Fig. 18 below.

[72] To see this, note that for A and B between 0 and 1, $\frac{A}{B} > 1$ implies $\frac{1-A}{1-B} < 1$.

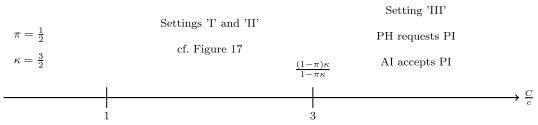

Fig. 18 Outcome in PI scenario with $\alpha = \beta = \kappa > 1$

With over-compensation, the Alleged Infringer is always willing to accept a PI request, but the Patent Holder does not always ask for it. This in turn means that in some situations, namely when $\frac{C}{c}$ is not too large, we are effectively back in the patent only setting. We know from our previous analysis, that this may lead the Alleged Infringe to self-regulate and stay out of the market entirely.

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Conflict of interest None.

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