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ARTICLE

# Delay-and-Pay: Prolonging Pharmaceutical Patent Protection Without Paying the "Price"

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**Abstract** This article argues that actors use the patent system as part of a "delay-and-pay" strategy to preserve drug prices for as long as possible by delaying generic/biosimilar market entry – and that they have a significant financial incentive to do so. This strategy is based on the notion that it is much more profitable for patentees to delay generic/biosimilar market entry by way of a patent infringement claim and ensuing injunction, then pay damages to the enjoined party should the infringement claim be defeated. Indeed, patentees have much to gain and little to lose under "delay-and-pay". My analysis establishes that the money national health bodies spent purchasing the more expensive, patented drug whilst the interim injunction remained in effect is not usually compensated following a patent revocation and discharged injunction. That is neither just, nor fair: the losses of national health bodies ought to be recovered.

**Keywords** Delay-and-pay · Interim injunctions · Procedural rights · Medicines · Pharmaceutical patents

## 1 Introduction

Medicines are unaffordable around the world, even in high-income countries. In 2016, the Council of the EU expressed concern over the "increasing number of examples of market failure in a number of Member States, where patients' access to

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effective and affordable essential medicines is endangered by very high and unsustainable price levels".[1] Although high prices are attributable to an array of factors,[2] patents remain connected to this issue. Indeed, Ploumen and Schippers, two Dutch ministers, state that guaranteeing medicines for all cannot be achieved "without acknowledging that the current patent-based business model and the way we apply international patent rules need to change. The system is broken".[3]

This concern is not new. Much has been written about the tensions between access to medicines and patents. While this is an issue affecting health provision globally, current literature on this topic largely focuses on the US.[4] To the extent that there is European research, nascent scholarship explores solutions outside patent law. Suggestions largely range from reforming compulsory licenses,[5] to turning to competition law.[6] Each mechanism deserves attention. And each may represent a meaningful response. It depends on the concrete problem at hand. Common to these suggestions is a predominant focus on when the price is too high for society to bear. My focus is on another problem. I do not question the price itself or whether it is fair. This article centres on how actors use the patent system as part of a "delay-and-pay" strategy to *preserve* monopoly prices for as long as possible.[7]

Section 2 shows how actors can strategically delay generic/biosimilar market entry using large patent portfolios and interim injunctions. It then turns to the "why" by showing that, by using interim injunctions, pharmaceutical companies not only hinder generic/biosimilar market entry, but stand to gain a significant benefit, even if the infringement claim is eventually defeated. Once the patent protecting the pharmaceutical product (active ingredient) expires, generic/biosimilar companies who provide cheaper equivalent versions of brand drugs should enter the market. However, numerous subsidiary patents and interim injunctions are likely to stand in the way. This not only obstructs and delays generic/biosimilar market entry, but allows pharmaceutical companies to maintain their brand drug's monopoly price for longer than they were entitled to. The risk is then that pharmaceutical companies are overly incentivised to pursue patent delay strategies, in turn creating a disincentive for generic/biosimilar companies and disrupting the interests of key actors in the pharmaceutical sector. As Gurgula observes, "[w]hen the interests of these two players are kept in balance, benefits are maximised for society, which receives innovative and improved medicines, as well as timely access to generic

[1] Council of the EU (2016).

[2] For an overview, *see* Harris (2022).

[3] Ploumen and Schippers (2017).

[4] *See e.g.* Feldman (2018).

[5] Liddicoat and Parish (2021); The European Commission also recently proposed to reform compulsory licensing, though their focus is on public health emergencies, *see* European Commission (2023b).

[6] *See e.g.* Gurgula (2020); Akker and Sauter (2022).

[7] The "delay-and-pay" term is inspired by the "pay-for-delay" debate in competition law. "Pay-for-delay" occurs when an originator and generic company enter into an agreement, where the originator company pays the generic company to stay off the market, in exchange for the generic company agreeing to avoid or settle patent litigation. Such agreements may contravene competition law, *see* Case C-591/16 P, *Lundbeck v. Commission* EU:C:2021:243.

drugs".[8] The system needs both actors, and so the interests of both must be balanced to ensure they are incentivised to fulfil their role. Society relies on it.

There is, however, another actor that remains overlooked in academic literature, yet is significantly affected by patent delay tactics, namely the national health bodies,[9] who continue purchasing the more expensive, patented drug until generics/biosimilars launch. Considering their losses is crucial to capturing the gains made by delaying generic/biosimilar market entry. This is because the money that national health bodies spent purchasing the more expensive, patented drug whilst the interim injunction remained in effect is not usually compensated following a patent revocation and discharged injunction. Taken together this provides a financial incentive to delay generic/biosimilar market entry for as long as possible, even if patentees ultimately lose at trial. Drawing attention to how national health bodies are affected by patent litigation also opens a powerful route to countering the benefits resulting from delay-and-pay strategies.

Section 3 makes the case that national health bodies must not only be considered when pharmaceutical companies apply for interim injunctions, but that the financial loss they suffer whilst the interim injunction remained in effect must be compensated should the interim injunction be overturned following a finding of patent invalidity or non-infringement. This duty to compensate should apply for every discharged interim injunction, irrespective of any fault or wrongdoing, and it should be grounded in civil procedural law, not another cause of action, such as competition law. The UK has implemented this solution without legal reform – only a change in court practice – thus providing a helpful model for other national courts. Though this article focuses on Europe, particularly the UK, its findings are relevant outside Europe, where national health bodies are similarly pursuing claims against pharmaceutical companies to recover the loss they suffered whilst being forced to reimburse the more expensive, patented drug when the patent was later shown to have had no legal foundation.[10] And it is imperative that courts and governments across jurisdictions take action. It is only by neutralising any benefits gained from engaging in the delay-and-pay strategy that we can ensure that patentees are not rewarded for enforcing invalid rights and that undeserved wealth transfers are reversed.

[8] Gurgula (2020), p. 1065.

[9] This article focuses on national health agencies because they are largely responsible for reimbursing medicines in England and other European countries. However, similar concerns apply to private providers, who would still lose out, even if state agencies are compensated. This can be remedied by applying the solution proposed herein to private providers.

[10] *See e.g. Commonwealth of Australia v. Sanofi-Aventis* [2015] FCA 384 and *Commonwealth of Australia v. Sanofi (No 5)* [2020] FCA 543. For a discussion, *see* Hacohen (2020), p. 553.

## 2 Strategic Patent Practices

To delay generic/biosimilar market entry, pharmaceutical companies now rely on large patent portfolios. While in the past medicines were "mainly" protected with one product patent claiming the compound,[11] this is no longer the case. In its 2009 Pharmaceutical Sector Inquiry Report, the European Commission found that the number of patents protecting each drug increased according to financial value, whereby:

> "blockbuster medicines can even be protected by up to nearly 100 INN [International Non-proprietary Name]-specific EPO patented bundles and applications (sometimes also referred to as patent families), which in one particular case lead to 1,300 patents and applications across all EU Member States".[12]

More recent empirical studies similarly show that top-selling drugs are protected with large patent portfolios in Europe.[13]

This increase is in some part due to medical advancements. As knowledge evolves there is more to patent. But it is in large part due to strategic patent filings. An empirical patent study published in 2022 found that:

> "[f]or approved drugs, patent fences contain between 149% and 106% more patents compared to drugs that fail in preclinical trials. This reflects the increasing effort of companies to delay generic entry by increasing the number of patents surrounding as approval becomes more likely".[14]

By filing further patents, patentees extend the patent life and market exclusivity of medicines – a practice known as "life cycle management" or "evergreening" depending on if you are for or against it.[15] Evergreening is not a formal legal concept *per se*. Definitions range from only looking at patent law – i.e. refreshing a monopoly period by slightly modifying individual drug attributes to qualify for another patent[16] – to describing all anti-competitive practices with this effect.[17] My focus is limited to patents and ensuing rights.

[11] Gurgula (2020), p. 1067.

[12] European Commission (2009), p. 188.

[13] *See e.g.* Moorkens et al. (2020); Storz (2014, 2016); In a 2020 report, I-MAK finds that Abbvie filed 76 patent applications relating to Humira in Europe, *see* I-MAK (2020), p. 4.

[14] Wagner et al. (2022), pp. 9–10.

[15] Gurgula (2020), p. 1068.

[16] Feldman (2018), pp. 601–602.

[17] For example, pay-for-delay agreements, extending regulatory exclusivities, and more. For an overview *see e.g.* Csiszár (2014).

While strategic patent practices increasingly garner academic attention, the focus largely remains on secondary patents in Europe.[18] As the European Commission observes, these patents are filed "[l]ater during the development phase and, … not uncommonly after the product launch, further patent applications will be made for other aspects of these active molecules … [s]uch patents … are often referred to as "secondary patents".[19] Examples of secondary patents include claims to formulations (e.g. tablets or intravenous injections), processes, dosages, therapeutic indications, and the like.[20] By limiting their scope of protection to the claimed property, secondary patents are narrower than product patents. But they can still confer wide protection. The claimed property may be the most relevant use of the medicine. And as secondary patents are filed after product patents, they can also extend a medicine's length of patent protection. Together these patents can further create a legal "minefield" of potential disputes.[21] As Hacohen observes, "by accumulating multiple probabilistic patents, brand-name manufacturers strategically raise the costs and risk associated with generic entry and maintain monopoly power".[22]

The 2009 European Commission report found that "the ratio of primary to secondary patents (and their applications) is 1:7".[23] More recent studies likewise observe that secondary patent filings and grants are high and rising.[24] In a 2021 empirical study, Aboy et al. show that "[t]he number of granted patents with independent EPC 2000 claims is increasing, and the total over the past two years is higher than it has ever been".[25]

Pharmaceutical companies claim secondary patents fulfil an important function, allowing drug repurposing and thus spreading research and development costs over a wider range of patents and encouraging the discovery of new, important uses for existing products.[26] But the trend also reflects companies' business strategy of simply maximising protection by whatever means. Indeed, "[d]evising patenting

[18] *See e.g.* Gurgula (2020). Note, however, that the Pharmaceutical Package presented by the European Commission in 2023 does not include measures aimed at targeting evergreening. Evergreening is only briefly mentioned in the Impact Assessment Report, *see* European Commission (2023a), p. 18 ("inquiries show that originator companies sometimes use various practices (such as "evergreening" or "killer acquisitions" early in the pipeline) to delay or prevent generic/biosimilar entry. These anti-competitive practices can be prosecuted by EU competition authorities. The evaluation confirms that further efforts can be made to fully exploit the savings generated by the generic and biosimilar competition; although measures in this regard are primarily outside the scope of the general pharmaceutical legislation, the revision can improve the conditions for generic and biosimilar authorisation and competition").

[19] European Commission (2009), p. 51.

[20] *Ibid.*; Gurgula (2020), p. 1067; Kapczynski et al. (2012); Feldman (2018), p. 602.

[21] Hacohen (2020), p. 498.

[22] Hacohen (2020), p. 492.

[23] European Commission (2009), p. 188.

[24] Mateo Aboy et al (2021); Gurgula (2020), p. 1063; For a US study, *see e.g.* Feldman (2018), pp. 590–597 ("78% of the drugs associated with new patents were not new drugs, but existing ones").

[25] Aboy et al (2021), p. 1342.

[26] European Commission (2009), p. 189; *See also* Holman (2017).

strategies to extend periods of protection is an essential aspect of 'life cycle management' in the pharmaceutical industry",[27] the extension being a goal in itself.

However, although secondary patents are important and deserving of further attention, an important piece in the puzzle is missing – namely, interim injunctions. Interim injunctions are not only used to enforce secondary patents,[28] thus playing a prominent role in pharmaceutical companies' strategic patent practices, they also provide an explanation for *why* companies pursue these patent strategies in the first place.

### 2.1 Interim Injunctions

Interim injunctions either prohibit or require a party to do something until a full trial is heard.[29] They are a legitimate tool, necessary to stop, say, imminent patent infringement – after all, patents afford the right to try to exclude.[30] Injunctions give effect to that right. They are therefore one of the most important measures provided for under the Agreement on Trade-Related Aspects of Intellectual Property Rights,[31] and the EU Intellectual Property (IP) Enforcement Directive.[32] The exact criteria the courts apply when deciding whether to grant an interim injunction differs depending on the country. However, a common feature across jurisdictions is that the injunction must be fair and equitable, and that the assessment usually centres around harm.[33] Indeed, the courts usually grant interim injunctions when financial damages are unlikely to remedy the harm a party may suffer should the alleged infringing act be allowed to continue until the case is adjudicated. As the courts have accepted that pharmaceutical companies may suffer irreparable harm following generic/biosimilar market entry, interim injunctions are not uncommon in these cases.[34]

This practice is understandable. Generic/biosimilar market entry will quickly reduce the originator's drug price. And if the courts do not grant an interim injunction and the patentee later wins at trial (thus forcing the generic/biosimilar off

[27] Sampat and Shadlen (2017).

[28] Interim injunctions can enforce any type of patent, but they are often granted based an infringement action concerning a secondary patent in pharmaceutical versus generic cases.

[29] An injunction can also be final following a full trial, but this article focuses on interim injunctions.

[30] That is, patents are probabilistic: they afford the right to try and exclude, rather than an actual right to exclude, *see* Lemley and Shapiro (2005).

[31] *See* Sec. 1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, Concluded as Annex 1C of the Marrakesh Agreement Establishing the WTO 15 April 1994.

[32] Article 9 of the Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L 157.

[33] *See e.g.* IP Enforcement Directive, Art. 3 and Recital 22; *See also* Case C-688/17, *Bayer Pharma AG* EU:C:2019:72 at [61]–[63].

[34] *See e.g.* Bently and Arnold (2022), p. 265; Birss et al. (2020), pp. 19–228; European Commission (2009), p. 409 ("According to the data submitted by respondent companies, hardly any interim injunctions were issued in litigation between originator companies. This is in contrast to the findings on litigation between originator and generic companies, where interim injunctions are more regularly sought"); For an overview of more recent data on injunctions in Germany, France and Denmark, *see* Bogetoft and Bogetoft (2022), p. 389.

the market until the patent expires), too much damage might already have been done. Patentees allege that restoring the brand drug price back to what it was is difficult, if not impossible.[35] Whether this is true is questionable,[36] but the purpose of injunctive relief is to alleviate the risk that a party suffers irreparable harm.

But interim injunctions may also present unappreciated risks for generic/biosimilar companies, as well as the public. As the European Commission observed in its 2009 Pharmaceutical Inquiry Report:

> "It goes without saying that interim injunctions can also be a necessary and legitimate tool allowing patent-holders to effectively enforce their patent rights. However, the grant of interim injunctions can become particularly relevant when examined in the light of originator companies' overall patent and life cycle strategies which are aimed at maximising profit and shielding their products from competition".[37]

For example, in the English case of *Servier*, a formulation patent filed in 2000 (EP1296947) threatened to help confer a 40-year monopoly on the drug Perindopril.[38] Being of the view that EP1296947 claimed no more than another process patent claiming priority from 1987 (EP0308341), Apotex launched at-risk in 2006. Servier successfully applied for an interim injunction. Pumfrey J then invalidated EP1296947 and discharged the injunction in 2007.[39] Servier nonetheless tried to prolong its monopoly after the courts revoked the patent (including the Court of Appeal), by re-applying to extend the injunction in the Patents Court and Court of Appeal.[40]

Not only did the injunction unduly delay Apotex's generic by one year, but when Apotex finally re-launched its generic competing generic manufacturers – supplied by Servier – were already on the market. As a result, post-injunction, Apotex sold 515,996 units at an average unit price of £7.20 (before the injunction it sold 529,751 units at an average unit price of £7.79) in July 2007, though both sales and prices drastically fell in August 2007, when Apotex achieved sales of 201,726 units at £6.59.[41] The injunction also gave other competitors time to catch up with their market preparations, which in turn influenced the price that the market was willing to bear. Although other competitors entered the market in February 2008, customers had already sought large discounts in July 2007 – "[o]ne major customer (Boots) sought such a significant discount that Apotex was unwilling to accept it".[42] By

[35] *See e.g. Les Laboratoires Servier & Anor v. Apotex Inc & Ors* [2008] EWHC 2347 at [2] and *Actavis Group PTC EHF v. ICOS Corporation* [2017] EWHC 2880 at [14].

[36] For an analysis, *see* Foss-Solbrekk (2025).

[37] European Commission (2009), p. 212.

[38] *Les Laboratoires Servier & Anor v. Apotex Inc & Ors* [2008] EWCA Civ 445. The product patent claimed priority from 1980.

[39] *Les Laboratoires Servier Ltd v. Apotex Inc & Ors* [2007] EWHC 1538 (Pat).

[40] As confirmed in *Les Laboratoires Servier & Anor v. Apotex Inc & Ors* [2008] EWCA Civ 445; *Les Laboratoires Servier & Anor v. Apotex Inc & Anor* [2007] EWCA Civ 783.

[41] *Les Laboratoires Servier & Anor v. Apotex Inc & Ors* [2008] EWHC 2347 at [29].

[42] *Les Laboratoires Servier & Anor v. Apotex Inc & Ors* [2008] EWHC 2347.

March 2008, it was an open market, with an average unit price of £2.03. Instead of three or four years, the shift from a monopoly market to an open market took eight months,[43] resulting in a quick price erosion and Apotex losing a significant portion of its potential market share and expected profits.

*Servier* is not a standalone case, but it is an illustrative one. It reveals the two main consequences with "incorrect" injunctions,[44] as will now be discussed.

### 2.2 Disincentives to Generic/Biosimilars Manufacturers

Although pharmaceutical companies rely on interim injunctions to prevent the irreparable harm allegedly caused by a price spiral following generic/biosimilar market entry, they also use injunctions strategically to obstruct generics/biosimilars' route to market. This is achieved in three ways.

Firstly, actors file injunctions to intimidate generic/biosimilar companies. A pharmaceutical company elucidates that with an injunction they can "send a strong signal to the generics that we haven't softened which is important for possible IP issues with [name of second generation product] in beginning [year]".[45] Pharmaceutical companies can also use patent enforcement with the aim of "financially overburdening" smaller sized generic companies, "in particular where a big originator company obtains interim injunctions against the generic product being put on the market".[46] The European Commission observes that "this creates an uphill struggle for the generic firm, as its litigation costs rise without mirroring revenues from its generic pharmaceutical whereas the originator company will continue to collect revenues from its product".[47]

Overturning injunctions often involves several rounds of litigation, including appeals, and requires significant procedural costs and efforts because litigation is long and costly. This raises the stakes for generic/biosimilar manufactures. Not all generic/biosimilar companies can afford rounds of litigation, so an injunction not only prevents the enjoined generic/biosimilar from entering the market, but it may also dissuade non-enjoined generics/biosimilars from even trying. Expected litigation with pharmaceutical companies may therefore in itself deter market entry due to its associated costs.[48]

Secondly, after generics/biosimilars finally launch, their market opportunities may be vastly different than before the injunction because injunctions can erode the first mover advantage of generic/biosimilar manufacturers. Injunctions give competing companies time to catch up with their market preparations. This affects the market in two ways: (1) buyers, knowing that other generics/biosimilars are on the horizon, push for larger discounts before additional generics/biosimilars even

[43] *Les Laboratoires Servier & Anor v. Apotex Inc & Ors* [2008] EWHC 2347 at [14].

[44] This is not to say the court made an error. I use "incorrect" to mean that the injunction was later discharged because the patent was revoked or the infringement claim failed.

[45] European Commission (2009), p. 200.

[46] European Commission (2009), p. 200.

[47] European Commission (2009), p. 200.

[48] European Commission (2009), p. 200.

enter the market, as was the case in *Servier*; and (2) other generics will enter the market faster, causing the price to quickly decline, which in turn accelerates the shift from a monopoly to open market. Consequently, the first mover generic/biosimilar loses a large portion of expected market share and associated profits, reducing their incentive to provide cheaper substitutes in a timely manner.

Thirdly, when injunctions enforce invalid patent rights, they help to unduly delay generic/biosimilar market entry, give a market opportunity which the injunctor was not entitled to, and hinder competition. Sometimes they even extend the market protection of brand medicines because certain courts may grant injunctions after patents receive first instance revocations by the courts.[49] By so doing, injunctions can provide a 12-to-18-month patent extension, on top of the invalid patent extension that a secondary patent already offered.

Taken together, interim injunction may have significant financial consequences for generic/biosimilar companies. To remedy this harm, the courts therefore usually require patentees to pay damages to generic/biosimilar manufacturers for the loss they suffered whilst the interim injunction remained in effect, should the injunction later be discharged following a full trial on the merits.[50] This is otherwise known as a security, bond, or the cross-undertaking in damages.[51] The duty to compensate following a discharged interim injunction is sometimes referred to as the "price" applicants must pay for said interim injunction.[52] However, as will now be shown, pharmaceutical companies are not currently paying the full "price" of interim injunctions.

[49] Such as the English courts, *see e.g. Novartis AG v. Hospira UK Ltd* [2013] EWCA Civ 583.

[50] *See e.g.* IP Enforcement Directive, Art. 9(7). Note, however, that in Case C-688/17, *Bayer Pharma* (*supra* note 33), the CJEU notably held that the IP Enforcement Directive does not preclude national laws preventing a defendant from receiving compensation following a discharged injunction when the defendant fails to act "as may generally be expected in order to avoid or mitigate his loss". All factors must be considered, including the risk of irreparable harm to the patentee and the parties conduct. Consequently, as launching at risk, i.e. launching before one successfully revokes patents standing in the way of market entry, may increase the risk that patentees suffer irreparable harm, generic manufacturers may not be entitled to compensation under the IP Enforcement Directive, Art. 9(7) following an incorrect interim injunction if they launch at risk. For a discussion *see* Tilmann (2022). The *Bayer Pharma* ruling then raised questions of whether the IP Enforcement Directive precludes national law imposing strict liability for overturned injunctions, but the CJEU clarified that *Bayer Pharma* does not prevent strict liability in Case C-473/22, *Mylan* EU:C:2024:8. Rather, EU Member States have leeway to decide whether to impose strict liability or fault-based liability, and the courts must "assess the particular circumstances of the case before it in order to decide whether the applicant should be ordered to pay the defendant "appropriate" compensation, that is to say, compensation justified in the light of those circumstances", *see Mylan* [36]–[38].

[51] The English courts use the term the cross-undertaking in damages, which is a promise that the party seeking the interim injunction makes to the court, promising to hold the defendant harmless for losses sustained during the injunction, should they fail at trial, *see e.g. American Cyanamid* [1975] AC 396, 408.

[52] *Smithkline Beecham Plc & Ors v. Apotex Europe Ltd & Ors* [2005] EWHC 1655 (Ch) at [38].

### 2.3 Cost to National Health Agencies

In *Servier*, Servier paid Apotex £17.5 million in damages for the "incorrect" injunction yet made at least £74 million during the injunction.[53] These profits significantly exceed damages because the UK National Health Service (NHS) was not a party to the damage assessment following the discharged interim injunction, making it much cheaper to delay-and-pay. Indeed, when the courts issue interim injunctions in pharmaceutical v. generic cases, it is not generic/biosimilar manufacturers who suffer the greatest financial loss. It is the national health bodies.

Under Europe's monopoly seller-monopoly buyer structure national health bodies must reimburse the more expensive, branded drug. There is no way to mitigate their loss. And their loss is significant. Pfizer's obstruction of generic market entry in the Lyrica (pregabalin) dispute cost the UK NHS an estimated £500 million.[54] With much to gain and little to lose, there is a distorted incentive to apply for patents and interim injunctions for the sake of delaying generic/biosimilar market entry for as long as possible, even if the patentee ultimately loses at trial.

The gain that pharmaceutical companies retain following discharged interim injunctions has not attracted significant scholarly attention. One exception is Hacohen, who proposes that "the monopoly proceeds secured by invalid follow-on patents would be disgorged and vested as a bounty in favor of the first successful patent invalidator".[55] This bounty would comprise of a sum reflecting the difference between the original monopoly price set without generic competition and the expected price had generics entered the market in a "timely manner".[56] Said generic invalidator would at a minimum have to prove that the secondary patent "served as the *sine qua non*" for hindering market entry.[57]

Though Hacohen's proposal would neutralise invalid gains, it would award generic/biosimilar manufacturers with damages far exceeding their loss. A large chunk of pharmaceutical companies' gain comprises national health bodies' loss, meaning the latter's loss should be recovered. Knowing this loss exists and overlooking it completely is unfair, and not in the public's interest. This causal gain and loss must be restored. Accordingly, the gains should be divided between generic/biosimilar manufactures and the national health bodies in a way that corresponds to their loss.

[53] *Les Laboratoires Servier & Anor v. Apotex Inc & Ors* [2008] EWHC 2347 at [60].

[54] Hawkes (2018), BMJ 363.

[55] Hacohen (2020), p. 483.

[56] Hacohen (2020), p. 533.

[57] Hacohen (2020), p. 533.

## 3 Interim Injunctions and Third Parties

Few national courts address the greatest harm and corresponding benefits created by interim injunctions in pharmaceutical v. generic cases.[58] Indeed, the European Commission's 2009 Pharmaceutical Inquiry report states that:

> "In their [generic companies] view, it remains, therefore, a relatively risk free operation for an originator company to ask for an interim injunction. This would change, however, if health insurers were legally able to – and actually did – claim damages in court from too high prices for patients resulting from unjustified legal protection from the originator product".[59]

Little has changed since 2009.[60] National health bodies largely remain overlooked and unaccounted for in proceedings concerning injunctive relief around Europe.

Keen to recover the financial damage they have suffered based on a patent that was later revoked, national health bodies have, however, pursued *other* legal claims against pharmaceutical companies in recent years. In a 2020 Dutch case, Menzis – a non-profit insurance company – turned *inter alia* to unjust enrichment law to recover its loss from an interim injunction (it was not covered by a cross-undertaking). Menzis claimed that AstraZeneca was unjustifiably enriched at its expense after AstraZeneca obtained an interim injunction, based on a secondary patent, forcing Sandoz off the market and deterring all other generics until the injunction was overturned.[61] Although the District Court of The Hague found that AstraZeneca was unjustifiably enriched, the Court of Appeal overturned this ruling in 2022.[62] The Court found that AstraZeneca had not acted unlawfully, nor had they been unjustly enriched.[63] Enforcing a patent which is later revoked is insufficient to assume liability; some form of culpability is required.[64]

Another example concerns the medicine Xalatan, where the Italian national competition authority found that Pfizer violated antitrust rules by using a "complex legal strategy", which included filing several divisional patent applications and Supplementary Protection Certificates[65] to delay generic versions of Xalatan (a

[58] Following legal reform, German law now mandates that third party interests may be taken into account in injunctive proceedings, but do not go so far as to require rightsholders to compensate their loss, *see* Stierle and Hofmann (2022) and Stief and Geller (2024); *see e.g. also Menzis Zorgverkzekeraar N.V v. AstraZeneca B.V* NL:RBDHA:2020:10160 which shows that the Dutch courts did not require AstraZeneca to compensate the relevant insurance provider should the injunction be overturned.

[59] European Commission (2009), p. 108 fn 201.

[60] The Pharmaceutical Package presented by the European Commission in 2023 also does not discuss this potential solution.

[61] *Menzis Zorgverkzekeraar N.V v. AstraZeneca B.V* NL:RBDHA:2020:10160.

[62] *AstraZeneca B.V v. Menzis Zorgverzekeraar N.V.* NL:GHDHA:2021:2535.

[63] *AstraZeneca B.V v. Menzis Zorgverzekeraar N.V.* NL:GHDHA:2021:2535.

[64] *AstraZeneca B.V v. Menzis Zorgverzekeraar N.V.* NL:GHDHA:2021:2535 [5.2].

[65] A divisional is a type of patent application that derives from an earlier patent application ("parent") and claims subject-matter contained in said parent, while a Supplementary protection certificate is a national, *sui generis* right offering a patent term extension of maximum five years, subject to a six-month extension if a Paediatric Investigation Plan is completed; For a discussion on how divisional patent applications may be used to obstruct generic/biosimilar market entry, *see* Foss-Solbrekk (2022).

glaucoma drug) from entering the market.[66] The Italian Finance Ministry and Health Ministry subsequently initiated civil proceedings against Pfizer, seeking damages since they had to reimburse the more expensive drug during the delay. Ruling that Pfizer had indeed abused its dominant position under competition law, the Italian Supreme Court upheld an order requiring Pfizer to pay around €13.4 million in damages to the Italian Finance Ministry and Health Ministry in January 2024.[67]

As the UK NHS trusts were not named in the cross-undertaking in the Perindopril dispute with Servier, as discussed in Sect. 2.1, they similarly pursued a claim to over £200 million in damages on other causes of action. Their claim, based on tort law, alleging Servier "intentionally caused loss to the appellants through their deceit (the unlawful means) of the EPO and the English courts (the third parties)", failed when the Supreme Court quashed their appeal in 2021.[68] Refusing to accept defeat, the NHS is now basing their claim solely on competition law.[69] The UK NHS is *inter alia* alleging that Les Laboratoires Servier (LLS):

> "obtained the grant of the 947 Patent, and further successfully defended it in opposition proceedings, by misleading or dishonest misrepresentations made to the EPO; and … further repeated or relied on those misrepresentations in obtaining interim relief in the English courts … Further and alternative grounds of abuse are alleged on the basis … they 'obtained, defended and enforced' the rights in relation to the 947 Patent was unreasonable or an abuse of process, and that Servier was 'not transparent in its provision of relevant information to the EPO and courts'".[70]

Servier notably tried to reduce damages by arguing that the UK NHS trusts failed to mitigate their own loss by not taking "reasonable steps to encourage switching to cheaper ACE Inhibitors".[71] In other words, their argument is that the UK NHS did not do enough to ensure that Servier's patented drug was not purchased when an interim injunction was in effect. Roth J rightly rejected this argument in 2022.[72]

The NHS' competition law claim may notably prove more successful due to developments at the EU level.[73] The CJEU recently upheld most of the European Commission's competition law findings against Servier. Firstly, agreeing with the European Commission, the CJEU held that Servier and several generic companies

[66] European Commission, (2019), p. 21.

[67] Decision No. 9, Italian Supreme Court, 2 January 2024; For an overview, *see* Marchesoni (2024).

[68] *Secretary of State for Health & Anor v. Servier Laboratories Ltd & Ors* [2021] UKSC 24 at [14].

[69] *The Secretary of State for Health & Anor v. Servier Laboratories Ltd & Ors* [2022] EWHC 369 (Ch) at [9]–[14].

[70] *The Secretary of State for Health & Anor v. Servier Laboratories Ltd & Ors* [2022] EWHC 369 (Ch) at [9].

[71] *The Secretary of State for Health & Anor v. Servier Laboratories Ltd & Ors* [2022] EWHC 369 (Ch) at [17].

[72] *The Secretary of State for Health & Anor v. Servier Laboratories Ltd & Ors* [2022] EWHC 369 (Ch). The Court of Appeal dismissed Servier's appeal in 2023, *see The Secretary of State for Health & Anor v. Servier Laboratories Ltd & Ors* [2023] EWCA Civ 763.

[73] *The Secretary of State for Health & Anor v. Servier Laboratories Ltd & Ors* [2022] EWHC 369 (Ch) at [9]–[14].

restricted competition by object (a competition law violation) by entering into agreements, where Servier paid generic companies to stay off the market in exchange for dropping their patent lawsuits.[74] Secondly, the CJEU annulled the General Court's decision that Servier did not hold a dominant position on the market. For a party to succeed with a claim alleging that another party has abused their dominant position by, say, misusing the patent system, the relevant authority must first find that said party holds a dominant position on the market, which is determined using a market definition.[75] The CJEU found the General Court had incorrectly defined the market, and referred the case back to the General Court, who will now reconsider the abuse of dominant position claim.[76] The General Court's upcoming ruling is of particular importance to the NHS as its dominance judgment must be reversed for the NHS to proceed with its abuse of dominant position claim in England.[77] This case should soon be finalised, but the UK NHS' potential damages would come 14 years after the Supreme Court upheld the generic manufacturer's damages under the cross-undertaking.[78] Clearly the UK NHS should have been named in the cross-undertaking from the beginning.

Although these legal actions constitute a step in the right direction, they should not *per se* be necessary. A simpler solution exists. Patentees should be required to agree to cover national health bodies' damages when applying for interim injunctions as a matter of procedural law. The duty should be anchored in the justification for awarding the interim injunction, and be separate from competition law. This is because the duty of pharmaceutical companies to compensate national health bodies should apply irrespective of a dominant position and without a competition law analysis. The duty to compensate should apply for every overturned injunction.

### 3.1 The UK's National Health Service

Governments and legislators should recognise the loss national health bodies suffer, and require patentees to compensate for that loss. As is discussed further below, this may be achieved by requiring patentees to compensate for national health bodies' loss when the courts evaluate whether to grant interim injunctions –

[74] Case C-176/19 P, *Commission v. Servier and Others* EU:C:2024:549 and Case C-201/19 P, *Servier and Others v. Commission* EU:C:2024:552. Such agreements are otherwise known as pay-for-delay agreements which have been held to contravene competition law, Case C-591/16 P, *Lundbeck v. Commission* EU:C:2021:243.

[75] *Ibid.*

[76] *Ibid.*

[77] As recognised in *The Secretary of State for Health & Anor v. Servier Laboratories Ltd & Ors* [2022] EWHC 369 (Ch) at [12].

[78] The UK Supreme Court upheld the damages after Servier successfully invoked the illegality defence in the Patents Court (2011), arguing that it should not be liable to pay damages under the cross-undertaking due to a Canadian Court ruling that Apotex infringed the Canadian patent, *see Les Laboratoires Servier & Anor v. Apotex Inc & Ors (Rev 1)* [2014] UKSC 55.

as certain courts require for generic/biosimilar manufacturers –[79] or by introducing a separate claim to damages in civil procedural law. Although this suggestion has not attracted significant scholarly attention,[80] it is not novel *per se*. Indeed, one country has acted already.

The UK Patents Court Guide specifically states that when parties apply for an interim injunction that will "affect dealings in a pharmaceutical product … purchased by the National Health Service … the Court will consider whether the applicant should give such an undertaking in favour of the NHS".[81] When applying for injunctions, actors must email the Department of Health, notifying them of the application and any order following the application "as soon as practicable".[82] The email serves as notice to the four NHS agencies in England, Northern Ireland, Scotland and Wales.[83]

This solution was utilised in the dispute concerning the drug Lyrica (pregabalin). Warner-Lambert notified the Department of Health of its application for an interim injunction, but the Department initially rejected the opportunity to appear before Arnold J (as he then was).[84] On the first day of the hearing, an email from the Treasury Solicitor further indicated that they would forego this opportunity altogether. Only after Arnold J "repeatedly made it clear" that their appearance would be of assistance did the Department's counsel appear on the third day of the hearing and request that Warner-Lambert's cross-undertaking cover the NHS, should relief be granted.[85] Most NHS trusts ultimately settled their claims, and their settlement fee remains unknown.[86]

More recently, in 2020, in *Neurim Pharmaceuticals*, Smith J received communication from lawyers of the Secretary of State for Health, writing on behalf of the NHS, saying:

> "If the injunction is granted and/or continued on an interim basis, but later discharged, the NHS may well suffer substantial losses as a consequence of the delayed generic entry (since in those circumstances, but for the interim

[79] This is, for instance, the case in England. Certain countries, such as Germany, have a separate legal basis for damages, whereby it is "rare" for generic companies to enforce such claims, *see* Stief and Geller (2024).

[80] With the exception of Stief and Geller (2024) who propose various ways German health bodies may seek damages, including under tort law, unjust enrichment and competition law.

[81] The Patents Court Guide Issued April (2019).

[82] The Patents Court Guide Issued April (2019).

[83] The Patents Court Guide Issued April (2019).

[84] *Warner -Lambert Company, LLC v. Actavis Group Ptc EHF & Ors (Rev 1)* [2015] EWHC 72 (Pat) at [8]. Note that in this case Arnold J dismissed Warner-Lambert's application for an interim injunction, but later proceeded to grant an order requiring the NHS to tell clinical commission groups to prescribe pregabalin under the brand name Lyrica for the treatment of pain, *see Warner-Lambert Company, LLC v. Actavis Group PTC EHF & Ors* [2015] EWHC 485 (Pat).

[85] *Warner -Lambert Company, LLC v. Actavis Group Ptc EHF & Ors (Rev 1)* [2015] EWHC 72 (Pat).

[86] *See Dr Reddy's Laboratories (UK) Ltd & Ors v. Warner-Lambert Company LLC* [2023] EWCA Civ 73 at [74]. According to this case, NHS Scotland remained in litigation and the damage inquiry trial was scheduled for November 2023; however, no damage inquiry has so far been published.

> injunction, generic entry would be achieved sooner and the prices for Circadin would likewise decrease sooner).
> It is for this reason that the Court of Appeal has accepted that it is current practice in the Patents Court when an application for an interim injunction in respect of a pharmaceutical is sought to require the patentee to give notice to the Department of Health of the application in case it too wishes to seek a cross-undertaking in damages in addition to the usual cross-undertaking provided in favour of the respondent … The same rationale is applicable in relation to the NHS in Wales, Scotland, and Northern Ireland. It is also for that reason that section 10 of the Patents Court Guide requires the applicant to provide notice to the Department of Health.
> The position of third parties, such as the NHS, is one that the Court can properly take account of in exercising its discretion when deciding whether or not to grant the injunction … The unique position of the NHS in such matters, recognised by the courts, is such that it is just and convenient for it to benefit from a cross-undertaking in damages, should the Court grant the Claimants' application.
> Accordingly, if the injunction is granted and/or continued at the hearing tomorrow, our clients respectfully request that the following cross-undertaking is provided …"[87]

Neurim and Flynn raised no objection to such an undertaking, but as Smith J refused the injunction, no such undertaking was given.[88] In 2025, the NHS again applied to join the cross-undertaking in *Astrazeneca v. Glenmark*, to which AstraZeneca agreed.[89]

As of now, no damage inquiry regarding the UK NHS has been published. Therefore, as per Birss et al, "the effect of such a cross-undertaking and its extent are not wholly clear", and that "as to date no inquiry on such a cross-undertaking has taken place. These issues therefore remain to be decided in a future case".[90] However, the first case calculating the damages owed to the UK NHS may soon be decided as the English courts recently invalidated AstraZeneca's Supplementary Protection Certificates.[91] Said damage inquiry may then serve as helpful guidance for other courts when calculating the damages owed to national health bodies.

[87] *Neurim Pharmaceuticals (1991) Ltd & Anor v. Generics UK Ltd (t/a Mylan) & Anor* [2020] EWHC 1362 (Pat) at [91].

[88] *Neurim Pharmaceuticals (1991) Ltd & Anor v. Generics UK Ltd (t/a Mylan) & Anor* [2020] EWHC 1362 (Pat).

[89] Tappin KC refused the injunction, but the Court of Appeal overturned Tappin's decision and granted the injunction, whereby the cross-undertaking covers the NHS, *see Astrazeneca AB & Anor v. Glenmark Pharmaceuticals Europe Ltd (Re Interim Injunction Application)* [2025] EWHC 748 (Pat) and *Astrazeneca AB & Anor v. Glenmark Pharmaceuticals Europe Ltd* [2025] EWCA Civ 480.

[90] Birss et al (2020), pp. 19–233.

[91] *Generics (UK) Ltd & Ors v. AstraZenica AB* [2025] EWCA Civ 903.

### 3.2 Applicability Across Europe

A procedure, similar to the one laid down in the UK Patents Court Guide, could be implemented across jurisdictions. If national court practice cannot be changed without an explicit statutory basis allowing national health bodies' claim to damages, then national legislation should be enacted or changed, or EU legislation should be amended. As suggested in the 2009 European Commission report:

> "Stakeholders representing generic companies also argue that the balance of litigation risks, where interim injunctions are concerned, should be more equally spread by introducing European legislation that would allow the award of damages to national health care systems and insurers. This idea is based on their perception that the balance of risk in the area of interim injunctions is overwhelmingly in favour of originator companies which are able to easily compensate generic companies if the case is eventually lost (and the granted injunctions revoked) through the additional revenues gained during the injunction period".[92]

Implementing this change through EU legislation would be particularly helpful as it would harmonise national health bodies' right to seek damages, rather than waiting for individual countries to act. This may, for instance, be achieved by amending the EU IP Enforcement Directive, removing the need for an entirely new piece of legislation.

It is worth noting that the Agreement on the Unified Patent Court (UPC) represents a missed chance in this regard.[93] Although Art. 60(9) allows the Court to "order the applicant, at the defendant's request, to provide the defendant with appropriate compensation for any damage suffered" from measures, including interim injunctions, the Agreement makes no mention of any third-party rights to damages in such cases. These claims also appear to be outside the Court's competence,[94] so it is highly unlikely that the Court would allow such third-party claims. National or EU legislation must therefore ensure that national bodies may claim damages for losses suffered as a result of interim injunctions granted by the UPC.

As above, national health bodies should not need to rely on a separate legal claim where wrongdoing or fault must be proven to recover the damage they suffered whilst an "incorrect" interim injunction remained in effect. The duty to compensate national health bodies should be connected to the interim injunction and be grounded in procedural law. This is important for three main reasons. First, it ensures that the duty to compensate applies to every discharged interim injunction, and is not reliant on any type of wrongdoing or abuse of dominant position, as is, for example, required for competition law to intervene. Second, it simplifies the legal process as national health bodies' loss will be calculated once interim injunctions are discharged, alongside the losses of generic/biosimilar companies, not years later

[92] European Commission (2009), p. 518.

[93] Agreement on a Unified Patent Court OJ C 175, 20.6.2013, pp. 1–40.

[94] Agreement on a Unified Patent Court, Art. 32.

in a separate damage inquiry based on a different cause of action. Third, connecting their loss to the interim injunction will ensure that the courts will consider their loss when evaluating whether to grant injunctive relief. This is crucial. Without accounting for the harm suffered by national health bodies, the courts will continue to fail to consider the true effects of interim injunctions, as well as all key interests in the injunctive process. Nor can they ensure that the interim injunction is balanced and proportionate. Indeed, how can an interim injunction be fair if the greatest harm of all is overlooked?

Recovering national health bodies' loss may, however, encounter certain difficulties in practice, irrespective of what solution is used. National health providers are, for instance, organised differently across Europe (and beyond). Some countries have a "pure" public health system, such as Norway, while other countries may have a mix between public and private health providers, such as Germany.[95] With a mix, it may become more difficult to implement this change in practice. Pharmaceutical companies would have to notify several different providers to ensure they are aware of the interim injunction and can request to be covered by the cross-undertaking or a similar financial security mechanism in court. This hurdle can, however, be overcome in several different ways. One option is to list the email address of each provider in a court document or guide. Another solution is to create a centralised email which serves as notice to all relevant public bodies, like the UK. As there may be more than four relevant bodies in certain European countries, it may then further prove useful to create an automated function or email that would automatically notify each provider once the injunction has been registered, saving the body monitoring the centralised email address from having to notify each provider manually. Alternatively, the providers may have been notified already because they are subject to the injunction. Either way, it must be feasible to notify relevant providers.

Calculating national health bodies' losses will also be challenging. Damage calculations will have to estimate how many generics/biosimilars would have launched, when, at what price, and how much of the market each would have captured, which may in turn change depending on how many national health bodies comprise the market. However, helpful data to inform some of these estimates does exist. Due to the interim injunction, national health bodies will have purchased the drug exclusively from the originator, meaning the full information on price and quantity will be detailed in the national health bodies' purchase orders. The courts should thus order bodies to supply such purchase orders for the purpose of calculating their damages, in addition to any forecast data that generic/biosimilar companies may hold. Should the calculations be riddled with too much uncertainty, whereby the loss of national health bodies cannot be estimated accurately, then the courts should recognise that damages are not an adequate remedy for national health bodies and refuse to grant injunctive relief.

Although country-specific adjustments must be made when implementing this solution in each jurisdiction, the crucial point is that governments and the courts must address this failing in the near future. If they do not the state and ultimately the

[95] For an overview, *see* Table 4.2 in World Health Organisation (2018), pp. 14–15.

taxpayer will continue to pay the additional cost, seemingly without redress. This cannot be right. Nor does it meet the aims of interim injunctions. Undeserved wealth transfers must be reversed so patentees are not rewarded for enforcing invalid rights and so patentees are not incentivised to engage in the delay-and-pay strategy which harms both the public and generic/biosimilar manufacturers.

## 4 Conclusion

This article has shown that actors can use the patent system as part of a "delay-and-pay" strategy to preserve drug prices for as long as possible by delaying generic/biosimilar market entry – and that they have a significant incentive to do so. This strategy is based on the notion that it is much more profitable for patentees to delay generic/biosimilar market entry by way of a patent infringement claim and ensuing interim injunction, then pay damages to the enjoined party should the infringement claim be defeated. Patentees have much to gain and little to lose under "delay-and-pay". This is because the courts usually do not consider the national health bodies in the injunctive process, meaning the loss they suffer from paying for the more expensive, patented drug during the interim injunction is not remedied with damages following a patent revocation and discharged injunction. Patentees keep such gains.

That, in turn, creates an undue incentive to enforce patents via injunctive relief just to delay generic/biosimilar market entry, which consequently creates a disincentive for generic/biosimilar manufacturers and harms the public. Legislators and national courts must therefore consider the benefits that pharmaceutical companies gain from an interim injunction, at whose expense, and require patentees to compensate the harmed parties accordingly. Doing so represents one of the most powerful and effective ways to respond to the harmful delay-and-pay strategy.

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