

COMPENSATING WRONGLY RESTRAINED DEFENDANTS IN PHARMACEUTICAL PATENT CASES: RECENT DEVELOPMENTS IN THE EU, ENGLAND AND AUSTRALIA

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Introduction

Provisional measures ('PMs') in intellectual property enforcement and, in particular, patent enforcement in the pharmaceutical industry have always required a careful balancing act between the interests of the rights-holder and

the interests of the alleged infringer. This is because, at an early stage in proceedings, the court is required to consider restraining an alleged infringer from certain conduct (and, in many cases, the launch of a new product or process) before it has had the opportunity to give careful consideration to the validity of the patent and whether such conduct actually infringes it.

In an effort to protect the alleged infringer subject to these restraints, many jurisdictions have a mechanism for compensating the defendant should it transpire that the patent is invalid or the relevant conduct would not have been infringing. The mechanism for providing such compensation throughout the EU (Article 9(7) of Directive 2004/48¹ ('the Directive')) was considered by the European Court of Justice in 2019 in Case C-688/17 *Bayer Pharma AG v Richter Gedeon Vegyészeti Gyár Nyrt. and Exeltis Magyarország Gyógyszerkereskedelmi Kft.* [2019] ('*Bayer*').² This article will look at this decision in detail, consider how it aligns with the legal position in England, and compare this with some recent, interesting trends in this area in Australia.

The Facts

In *Bayer*, the CJEU was required to consider whether Hungarian law, which had the potential to preclude a defendant's right to compensation for loss caused by a lapsed or revoked PM, was aligned with Article 9(7) of the Directive, which gave national courts authority to order such compensation. The case concerned Bayer's patent for a pharmaceutical product containing a contraceptive ingredient registered in the National Intellectual Property Office in Hungary ('the patent') and potentially infringing contraceptive products marketed by Richter Gedeon Vegyészeti Gyár Nyrt ('Richter') and Exeltis Magyarország Gyógyszerkereskedelmi Kft ('Exeltis') ('products in issue') prior to the grant of the patent.

During the proceedings Bayer obtained PMs restraining Richter and Exeltis for a number of months but these were later set aside due to procedural defects.³ Ultimately, the

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1) 'Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate

compensation for any injury caused by those measures'. Council Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L157/45.

2) Case C-688/17 *Bayer Pharma AG v Richter Gedeon Vegyészeti Gyár Nyrt. and Exeltis Magyarország Gyógyszerkereskedelmi Kft.* EU:C:2019:722 [2019].

3) The nature of these defects was not specified in the decision.

patent was declared invalid and Bayer's infringement claim against Richter and Exeltis was dismissed. Both Richter and Exeltis applied for compensation for the losses they suffered as a result of the PMs. Bayer argued that these claims should be rejected under the Hungarian rules of civil liability, as both Richter and Exeltis had caused themselves loss, having commenced marketing the products in issue at risk (that is, without first clearing the way).

The Budapest High Court referred two questions to the CJEU. In short, these were:

(1) Should Article 9(7) of the Directive be interpreted as requiring Member States to establish substantive rules of law on the liability of applicants of lapsed or revoked PMs (or where the court later finds there was no infringement or threat of infringement of the intellectual property right) and the amount and method of compensation to defendants who have been subject to such lapsed or revoked PMs?⁴

(2) If so, does Article 9(7) of the Directive preclude rules of a Member State that would operate to deny a defendant compensation for loss caused by lapsed or revoked PMs where:

- that loss was incurred as a result of the defendant's failure to act as would generally be expected in the circumstances in question;⁵ and/or
- the defendant was responsible for the loss for that reason; and
- the applicant acted as would be generally expected in those circumstances.⁶

The Opinion of the Advocate General

The Advocate General advised that:⁷

(1) Article 9(7) of the Directive allowed each Member State to establish its own rules governing a defendant's right to compensation for loss incurred as a result of PMs that were later revoked or lapsed. These rules should ensure that there

are effective legal remedies to allow defendants to obtain appropriate compensation for loss suffered and should not deter the holders of intellectual property rights from applying for PMs.

(2) Article 9(7) of the Directive did not preclude the application of a law that required the Member State to consider the relevant circumstances of the case in issue when determining the compensation to be awarded to the wrongly restrained defendant. Such circumstances could include whether or not a defendant launched a potentially infringing product before invalidating the relevant patent. However, Article 9(7) of the Directive did preclude the operation of a law under which a wrongly restrained defendant could not obtain compensation for their loss where they made the decision to launch potentially infringing products before clearing the way.

The CJEU

Despite the opinion of the Advocate General, the CJEU in many respects came to the opposite conclusion. Specifically, it held that Article 9(7) of the Directive *did not* preclude national legislation that prevented a party subject to a lapsed or revoked PM from obtaining compensation where that party had not acted as would generally be expected to avoid or mitigate its losses (such as failing to clear the way). This was the case provided that the national legislation allowed the court to consider all objective circumstances of the case to ensure that the applicant had not abused the process to obtain the original PMs. As an outsider reading the decision, it is not clear what specific abuse of process the CJEU was seeking to avoid.

Of particular interest, the CJEU said that:

(1) Given that Article 9(7) made no reference to the law of the Member States when referring to 'appropriate compensation', this concept needed to be given 'an independent and uniform interpretation without being able to come within the competence of different Member States'.⁸

4) Note 2 above, at paragraph 33.

5) We infer that what would have been expected is clearing the way before launch.

6) Note 2 above, at paragraph 33.

7) Ibid., Opinion of AG Pitruzzella, at paragraph 61.

8) Note 2 above, at paragraphs 40 to 44.

(2) Article 9(7) required the national courts to assess the specific circumstances in the case to decide whether it was appropriate to order a party to compensate another for losses incurred while lapsed or revoked PMs remained in force. Once this had been decided, such compensation needed to be ‘appropriate’ or justified given the circumstances of the case.⁹

(3) The fact that PMs were later repealed, lapsed or no longer applicable did not generate an automatic right to compensation for any loss caused by those measures.¹⁰

(4) In light of Recital 22 of the Directive, compensation for loss caused by PMs was only available where such measures were granted for an ‘unjustified’ request. A request for PMs would be ‘justified’ where ‘any delay would cause irreparable harm to the holder of an intellectual property right’. Where defendants market their potentially infringing products without clearing the way, ‘such conduct may, *prima facie*, be regarded as objectively indicative of the existence of a risk for the holder of the patent, of irreparable harm in the event of delay in the adoption of the measures sought by the patent holder’. An application for PMs in these circumstances ‘cannot be regarded *a priori* as “unjustified”’.¹¹

(5) Article 3(2) of the Directive required that, when facilitating the enforcement of intellectual property rights in line with the Directive, Member States and national courts should ‘avoid the creation of barriers to legitimate trade and ... provide for safeguards against their abuse’. This, therefore, required Member States to ensure that in each case, the applicant had not abused the measures and procedures in the Directive.¹²

(6) If the CJEU found that Article 9(7) precluded the operation of the Hungarian law, this would discourage patentees from seeking PMs and thus ‘run counter to the directive’s objective of ensuring a high level of protection of intellectual property’.¹³

General Comments

The CJEU’s decision does not seem to strike the balance required by Article 3(2) of the Directive which requires Member States to ‘avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse’. This is because, without the risk of compensating a wrongly restrained party, rights-holders may be encouraged to pursue PMs for weaker cases which may hinder the legitimate trade of non-infringing products and processes in the market.

The CJEU’s rationale that the opposite finding would discourage patentees from seeking PMs is not compelling. Patentees with a strong case for infringement have always sought PMs despite the risk that they would later need to compensate defendants. Any detriment caused by compensating defendants for loss of sales at a competitive price will not outweigh the benefit of a PM to the patentee who is able to continue profiting from an invention at a higher price, free from competition, for the duration of the PM. The profit from a wrongly ordered PM (with subsequent compensation to restrained defendants) will invariably be higher than where the defendant is allowed onto the market to compete with the patentee for that same period.

The finding that compensation is not guaranteed appears at odds with a number of intellectual property enforcement regimes in EU Member States. For example, France, Austria and Germany all operate a strict liability regime for compensation where PMs are later lifted.¹⁴ The *Bayer* decision suggests that such strict liability regimes are not harmonised with the Directive, which requires something more than a lapsed, revoked or ceased PM before compensation will be granted to a wrongly restrained defendant.

On a strict reading of the CJEU’s interpretation of an ‘unjustified’ PM, defendants subject to PMs that are later repealed may only have a right to compensation for any loss caused by the PMs where an applicant was not in a position to

9) *Ibid.*, at paragraphs 49 to 51.

10) *Ibid.*, at paragraph 52.

11) *Ibid.*, at paragraphs 60 to 65.

12) *Ibid.*, at paragraphs 66 to 69.

13) *Ibid.*, at paragraph 67.

14) See, for example, Intellectual Property Code (France), L. 615-3; Cour de cassation, 96-18930, 1 July 1998 reported in (1998), Civ., 3ème; Enforcement Act (Exekutionsordnung) (Austria), § 394; Code of Civil Procedure (Germany), § 945.

prove that any delay to the grant of the PM would cause them irreparable harm. In England and Australia, this would mean that the applicant had failed to meet the burden of proof for establishing the need for such PMs in the first place. The very narrow set of circumstances that justify compensation to the defendant fails to acknowledge the potential harm to a defendant who has been unnecessarily restrained.

The consequences of this decision could go either way. On the one hand, provided it is within the ambit of a proportionality assessment in the relevant Member State, the fact that the defendant may only be compensated in a narrow set of circumstances may go against the grant of the PM in the first place, especially where the patentee has a weak *prima facie* case.

However, if PMs are routinely granted in response to a threat of infringement, defendants may be deterred from engaging in any conduct that might potentially infringe another party's intellectual property, even where the risk of infringement is low. In the pharmaceutical context, defendants will likely refrain from launching generic products until they have cleared the way. This delay could deprive consumers of any inevitable price reductions for many years, despite the fact that the generic products may not ultimately infringe the patent in suit or that the patent in suit may be found invalid.

The Current Position in England

In England, the defendant's right to damages for loss caused by an overturned PM is not a statutory right but stems from an undertaking provided to the court by the applicant for an interim injunction.¹⁵ While these undertakings are often granted and enforced, there are a number of discretionary stages such that the English system for compensating wrongly restrained defendants is not one of strict liability.

Under the Civil Procedure Rules Practice Direction 25A.5.1, 'unless the court orders otherwise', an order for an interim injunction must include 'an undertaking by the applicant to the court to pay any damages which the respondent sustains which the court considers the applicant should pay'. Although the grant of an undertaking with a preliminary injunction is discretionary, it is generally viewed as the price of the preliminary injunction.¹⁶ In fact, when granting a preliminary injunction, among other considerations (such as whether there is a *prima facie* case), the court is required to balance the interests of both parties and consider whether an undertaking would be an inadequate remedy for a wrongly restrained defendant.¹⁷

Once the final injunction is refused in the substantive proceedings, if the restrained party claims compensation, the court may (at its discretion) decide whether to enforce the undertaking in damages. A court may decide not to enforce the undertaking and initiate an inquiry as to damages where, for example, the defendant due to benefit from the undertaking has delayed making a claim for enforcement or where the damages claimed are trivial.¹⁸ Like the Hungarian Civil Code considered in *Bayer*, the common law requires the English courts to consider some aspects of the defendant's conduct before deciding whether the defendant is entitled to damages.

If an inquiry as to damages is ordered, the court will treat the undertaking as if it had been a contract between the parties where the applicant had promised not to prevent the defendant from doing that which the defendant was restrained from doing under the injunction.¹⁹ The damages are therefore assessed as damages for breach of contract, which requires consideration of causation, remoteness, and mitigation.²⁰ Again, like the Hungarian Civil Code, assessment of damages will require considering, among other things, whether the defendant mitigated their loss.²¹

15) Civil Procedure Rules Practice Direction 25A.5.1.

16) *Smithkline Beecham plc v Apotex Europe Ltd* [2006] EWCA Civ 658, at [24].

17) *American Cyanamid Co v Ethicon Ltd* [1975] AC 396, 406.

18) *Smith v Day* (1882) 21 Ch. D 421, 430.

19) *Hoffman-La Roche & Co AG v Secretary of State for Trade and Industry* [1975] AC 295, 361; *Les Laboratoires Servier v Apotex* [2008] EWHC 2347 at [9]; *AstraZeneca v KrKa* [2015] EWCA Civ 484, at [12] to [16].

20) *Fiona Trust & Holding Corporation v Yuri Privalov and Ors* [2016] EWHC 2163, at [47]; *Hone v Abbey Forwarding Ltd* [2014] EWCA Civ 711, at [38] to [44] and [63].

21) *Ibid.*

While a failure to clear the way is seen as a very compelling reason to grant an interim injunction, the English courts have not characterised this conduct as conduct that would preclude the defendant from recovering damages for a wrongly ordered interim injunction at the enforcement of undertaking or at the assessment of damages stage. In fact, under English law, the obligation to mitigate only arises once a wrong has been committed.²² In this case, the ‘wrong’ relevant to the enforcement of the undertaking would be the wrongly ordered interim injunction. Therefore, under English law, any actions taken prior to the interim injunction order would likely be irrelevant when considering whether the restrained party mitigated its loss.

Steps taken prior to the interim injunction could be relevant to quantifying the loss caused by the order. In this assessment, the claimant must first establish, on a balance of probabilities, that the chance of making a profit but for the injunction was real and not fanciful and once this threshold is met, the courts will assess damages based on particular hypotheses, adjusting the award by reference to the percentage chance of each hypothesis occurring.²³ While it will ultimately depend on the facts, it is likely that steps taken to launch at risk prior to an interim injunction will increase the percentage chance of profit from that launch but for the injunction, thereby increasing the wrongly restrained claimant’s award.

In *Les Laboratoires Servier v Apotex*,²⁴ evidence of the launch and sales at risk for six days prior to an injunction assisted the court in determining the probable state of affairs had the injunction not been granted, and arguably such evidence worked in the defendants’ favour. The court considered that evidence of the conduct of the applicant, defendants and other potential market participants increased the likelihood that, had the defendants not been restrained, there would have been a duopoly between the applicants’ originator and

the defendants’ generic product for a period of time.²⁵ The court rejected the argument that, but for the injunction, the defendants would have shared the market with other generics, as the threatened launch of other generics in the ‘at risk’ market (who had not in fact launched at the time) was considered speculative and uncommercial.²⁶ The value of the defendants’ sales prior to the injunction also informed the defendants’ likely price and sales during the period that they were restrained.²⁷ This evidence was far more compelling than evidence of what occurred after the injunction was lifted and a number of other generics had entered what was then an open market.²⁸

Therefore, unlike the Hungarian Civil Code, it would appear that launching at risk would not preclude a wrongly restrained defendant from compensation in England and may even assist in an assessment more favourable to the defendant (informed by actual sales and a favourable market share) than a situation where the defendant, like other generics, had decided not to launch at risk.

The Position in Australia: A Potential Model for England Following Brexit

As in England, in Australia the courts require the patentee to provide an undertaking as to damages when granting interlocutory injunctions against a potential infringer. Where such injunctions are revoked and wrongly restrained, and defendants seek to enforce the undertaking, the courts require the defendant/claimant to establish on a balance of probabilities that the interlocutory injunction caused a particular kind of loss. The award compensating this loss is then adjusted to reflect the chance that an alleged lost opportunity would have been pursued (or would have eventuated), resulting in an economic benefit to the particular claimant.²⁹

22) *Secretary of State for Health v Servier Laboratories Ltd* [2016] EWHC 2381, at [23] to [26].

23) *Les Laboratoires Servier v Apotex* [2008] EWHC 2347, at [5]; *AstraZeneca v KrKa* [2015] EWCA Civ 484, at [12] to [13], [86]; *Fiona Trust & Holding Corp v Privalov (No 2)* [2016] EWHC 2163, at [55], [58], [91]; *SCF Takers Ltd (Formerly Fiona Trust and Holding Corp) v Privalov* [2017] EWCA Civ 1877, at [54] to [59].

24) *Les Laboratoires Servier v Apotex* [2008] EWHC 2347.

25) *Ibid.*, at [38] to [59].

26) *Ibid.*, at [37] to [43].

27) *Ibid.*, at [47] to [49].

28) *Ibid.*, at [33].

29) *Sigma v Wyeth* [2018] FCA 1556, at [215] to [216].

While compensation disputes between the patentee and a wrongly restrained defendant are often settled out of court, in a 2018 decision (*Sigma v Wyeth*) the Federal Court was required to determine the appropriate compensation for a number of generic pharmaceutical companies and their manufacturers who had been kept out of the market for a number of years due to interlocutory injunctions granted for a patent that was later found invalid on appeal.³⁰

Like the High Court of England and Wales in *Les Laboratoires Servier v Apotex*,³¹ the Australian Federal Court gave more weight to evidence of parties' actual conduct prior to the interlocutory injunction than later evidence of what the parties would have done had the injunction not been granted.³² For example, Jagot J held that potential manufacture or supply contracts that remained subject to negotiation at the time the interlocutory injunction was granted were too remote to be recoverable but awarded compensation on existing manufacturing contracts and where the manufacturers could prove that generics would have ordered additional products under those contracts (that is, where steps had been taken to launch at risk).³³ Similarly, in conjunction with other factors, a generic that had accumulated stock was more likely to have launched at the time than those generics that were not yet holding stock.³⁴ This increased likelihood benefited the damages assessment which was adjusted by reference to the percentage chance that each generic would have supplied its product had it not been restrained.³⁵

In contrast, parties who had taken steps to avoid infringement risks in anticipation of an interlocutory injunction against them, could not claim damages for loss resulting from taking such steps – the loss caused could not be characterised as

loss resulting from the injunction that subsequently transpired.³⁶

Following this logic, unlike the consequences considered in *Bayer*, in Australia, those who have taken steps to launch at risk and therefore have contemporaneous documents to assist the court could benefit in a compensation assessment over those who did not take such steps.

The difficult damages assessment that the court faced in *Sigma v Wyeth* has challenged previous assumptions on the balance of convenience when granting interlocutory injunctions in patent infringement cases. In the Australian courts up until this point, the balance of convenience generally favoured the grant of an interlocutory injunction to the rights-holder because of difficulties quantifying damages caused by the potential loss of market share and, in the case of pharmaceuticals on the Pharmaceutical Benefits Scheme, the threat of a practically irreversible regulatory price reduction. In *Sigma v Wyeth*, however, Jagot J concluded saying:

*Knowing what has occurred, it could never have been concluded, for example, that insofar as relevant to the balance of convenience it would be easier for the generics to prove their loss if the interlocutory injunctions were wrongly granted than for Wyeth to prove its loss if the interlocutory injunctions were withheld and the method patent was valid.*³⁷

As a consequence, the difficulty in calculating the loss caused by an interlocutory injunction has become more prominent in the balance of convenience assessment. In fact, a number of interlocutory applications have since been refused, acknowledging this difficulty among other relevant factors.³⁸

30) *Sigma v Wyeth* [2018] FCA 1556.

31) Note 24 above.

32) Note 30 above, at [273] to [286], [326].

33) *Ibid.*, at [216] to [227].

34) *Ibid.*, at [466], [633], [786], [792].

35) *Ibid.*, at [17] to [21].

36) *Ibid.*, at [13], [132], [230].

37) *Ibid.*, at [1336].

38) See, for example, *Sanofi-Aventis Deutschland GmbH v Alphapharm Pty Ltd (No 3)* [2018] FCA 2060, at [163] (where, in significant *obiter*, Burley J considered that the calculation of the patentee's loss caused by the defendant's launch would be readily apparent, whereas the loss of a wrongly

restrained defendant would be 'highly speculative'. Special leave to appeal this decision was refused in *Sanofi-Aventis Deutschland GmbH v Alphapharm Pty Ltd* [2019] FCAFC 28, at [39] to [51], where a three-judge panel acknowledged that appropriate weight and consideration had been given to this issue); *Mylan Health Pty Ltd v Sun Pharma ANZ Pty Ltd (No 2)* [2019] FCA 505, at [137] to [139] (where an application for an interim injunction pending appeal of a patent invalidity decision was refused on the balance of convenience and the difficulty calculating the potential infringer's damages was referred to as 'the most compelling reason [for the refusal to grant the injunction]': [137]); *Redare Electronics Pty Ltd v B8 Systems Limited* [2019] FCA 3 (where the difficulty calculating damages was again acknowledged in relation to an application for an injunction that related to the launch of a brake control unit (although ultimately significant weight was placed on preserving the status quo where the alleged infringer had already launched the product in the Australian market)).

Unlike the distinctly pro-patentee direction taken in the EU in *Bayer*, in Australia the approach is more balanced and a trend is starting to emerge that arguably benefits the alleged infringer where PMs may not be granted in the first place.³⁹

The courts of England and Wales have also started refusing applications for interim injunctions and giving greater weight to the difficulty in quantifying the loss of wrongly restrained defendants.⁴⁰ However, thus far, this has only been where there are other circumstances unique to the case that warrant refusal (such as an imminent trial). Given the similarities between the Australian and English approach to interim injunctions, it is possible that the courts of England and Wales will follow Australia's emerging trends when they are no longer required to align with the EU following the end of the Brexit transition period.

Conclusions

The decision in *Bayer* on when compensation may be awarded to a wrongly restrained defendant under Article 9(7) of the Directive is at odds with a number of European strict liability regimes. Generics contemplating launching in the EU and risking an injunction should, therefore, proceed with caution.

There is a chance that, given limited availability of compensation, the courts may refrain from granting PMs as readily as they otherwise would have. However, where a PM is granted, a failure to clear the way before launch could preclude a wrongly restrained defendant from compensation.

The current position in England will consider both the applicant's and defendant's conduct when enforcing and quantifying compensation pursuant to an undertaking in damages when an interim injunction is overturned. While a defendant will be required to mitigate its loss, this requirement will not extend to the defendant's conduct prior to the grant of an interim injunction such as where a defendant has chosen to launch at risk. The wider set of circumstances in which compensation will be available to wrongly restrained defendants serves as a deterrent to patentees who may otherwise seek to enforce weak patents.

Rights-holders should also be aware of current trends in Australia that could be beneficial to the alleged infringer both at the stage of granting an interlocutory injunction and assessing damages to compensate loss caused to wrongfully restrained defendants. These trends may influence other common law jurisdictions, including England in future.

39) A recent case in Australia has suggested that losses incurred by the government who was deprived of significant reductions in subsidy payments made on the supply of an originator pharmaceutical are too remote to be recovered under the usual undertaking as to damages granted to a restrained generic. This case may further support the trend against the grant of interlocutory injunctions but we have yet to see this impact in practice: *Commonwealth v Sanofi (No 5)* [2020] FCA 543.

40) *Evalve Inc and Abbott v Edwards Lifesciences Ltd* [2019] EWHC 1158; *Neurim Pharmaceuticals (1991) Ltd & Another v Generics UK Ltd (t/a Mylan) & Another* [2020] EWHC 1362; *Neurim Pharmaceuticals (1991) Ltd & Another v Generics UK Ltd (t/a Mylan) & Another* [2020] EWCA Civ 793.