EIP

Patents Court affirms power to grant injunctions for pre-grant patents, but refuses injunction for Novartis

Swiss drug-maker, Novartis, sought a preliminary injunction to keep Teva and four other generics off the market for its prescription-only relapse remitting multiple sclerosis treatment, fingolimod, sold under the brand name "Gilenya". The Patents Court has affirmed, in Novartis AG v Teva UK Ltd & Ors [2022] EWHC 959 (Ch), its jurisdiction to issue injunctions for patents that are yet to go to grant, with a stern warning to patentees with respect to evergreening. Despite this, Novartis failed to secure an injunction against its generic competitors on the basis that there was no likely irrecoverable downward price spiral for Gilenya given there were no NHS regulatory drug tariffs for the product, and no loss which could not be adequately remedied in damages in the event the patent is found valid and infringed.

In a hearing before Lord Justice Birss on 25 May 2022, permission to appeal that decision was refused.

Background

Novartis had a pending European Patent Application 2,959,894 ("EP'894"), a secondary divisional from a previous application from 2007. Following refusal to grant the patent by the European Patent Office in November 2020, Novartis made an immediate appeal to the Technical Board of Appeal ("TBA"), which was not heard until February 2022. The TBA considered sufficiency and inventive step of EP'894 under the European Patent

Convention with respect to a number of observations submitted by objectors opposing its grant. The TBA decided to remit the application back to the Examining Division three days after the hearing, and it is now expected to be granted in mid-June 2022.

On 2 March 2022 Novartis filed proceedings in the UK and sought a preliminary injunction to prevent the entry of five generics onto the market. The hearing for that application was heard two weeks after it was made, and five days prior to the expiry of Novartis's regulatory and market exclusivity for Gilenya. The defendants to the application were Teva, Dr Reddy's, Glenmark, Tillomed, and Zentiva, each of whom received marketing authorisation for their fingolimod products in 2020 or 2021 and deemed likely to be able to seek to enter the UK market.

Jurisdiction

As the patent application EP'894 was (and remains) not yet granted, the Court had to consider whether it had jurisdiction to issue an interim injunction to restrain generic market entry. Dr Reddy's and Zentiva contended strongly that the Court had no such jurisdiction. The finding was, however, that although a prospective patentee is only entitled to bring patent infringement proceedings after a patent has been granted [1], there was no statutory bar on jurisdiction of the Court in the Patents Act 1977 to grant an interim (or indeed any) injunction for a pre-grant patent, citing Convoy Collateral Ltd v Broad Idea International Ltd [2] a decision of the Privy Council. The Court considered that because, following the decision of the TBA, the grant of EP'864 was held back for administrative reasons only, Novartis could seek interim relief for any loss suffered between generic entry and the date of grant. This came with a warning that such circumstances were exceptional, and that attempts by prospective patentees to seek interim relief on the basis that a patent has not yet but is very likely to go to grant will be rejected by the Patents Court.

Interim Injunction

Applying the principles in American Cyanamid [3], Mr Justice Roth found the following:

(i) Is there a serious question to be tried?

All parties agreed there was a serious question to be tried, particularly in light of the decision of the TBA.

(ii) Are damages an adequate remedy for Novartis?

p3

Unlike most other prescription medicines, fingolimod is prescribed in secondary care rather than by GPs and is therefore not determined by the NHS drug tariff. Under this arrangement, the NHS invites tender submissions in anticipation of generic launch. For pre-tender sales, the Court considered that although there would be a depression in the price of fingolimod, the overall effect of generic launch would not cause a downward price spiral often referred to in pharmaceutical interim injunction cases. Citing Floyd LJ in Neurim v Generics UK [4], whether a price spiral will occur in the period until trial is an intensely fact-sensitive question. Relevant factors were that the pre-tender period was very short, and that the generics that secured contracts would keep good record of sales volumes, which could be easily quantified with respect to damages if Novartis was successful at trial. In that event, the Court's determination of Novartis's financial loss suffered would need to take into account there being no downward price spiral during the tender period comprising the months leading up to the judgment, and that Novartis could compete for tenders through its own generic, Sandoz.

The Court did not find any basis that future sales of Gilenya would be materially affected by the temporary introduction of generic fingolimod for a short period, and that its monopoly prices could be restored. Similarly, it found that Novartis suffering any reputational damage following the refusal of an injunction was "unconvincing and inherently unlikely".

(iii) Are damages an adequate remedy for the generic defendants?

In case he was wrong about damages alone being an adequate remedy for Novartis, Roth J considered whether damage under the cross-undertaking would be an adequate remedy to the generic defendants if an injunction were granted. The volume and price of generic sales were relevant but difficult factors to quantify, particularly as several generics had obtained marketing authorisation. On that basis, Roth J considered it would be hard to adequately quantify damages for the generics individually as well as collectively.

(iv) The balance of convenience?

Despite the Court's conclusion on the adequacy of damages, it sought to address, in obiter, the arguments by the generics concerning the balance of convenience. The Court considered it wrong to reach even a primary conclusion of the validity of Novartis's dosage patent (EP'894) given the position was unclear. The Court also warned patentees that an evergreening approach in an attempt to prolong the patenting process and resulting in inhibiting generics from effectively clearing the way would be a relevant factor in assessing the balance of convenience against the granting of a preliminary

injunction.

p4 Although Roth J refused permission to appeal, he put in place a brief injunction to "hold the ring" while the patentee sought permission from the Court of Appeal and until that was resolved.

Permission to Appeal

Novartis' application for permission to appeal was heard on 25 May 2022, submitted on paper just one week after filing its application, by a single judge in the Court of Appeal, Birss LJ. Novartis pleaded that Roth J erred in his application of the principles in American Cyanamid on the below grounds 1 to 5.

Ground 1:

Although the judge was right to find there would be a marked price depression following generic market entry, the judge was wrong (at paragraph [50]) to conclude that there would be no price spiral. On this ground, Birss LJ questioned counsel for Novartis what was "magic" about a price spiral that made damages more unquantifiable than a marked depression, and that in any event, the price would be restored in the time after the trial should Novartis be successful in the substantive proceedings. Counsel for Teva argued the judge gave clear reasons, namely the fact that there were limited contracts, that generics kept good records of sales, and the volume of Novartis's sales was known, as to why the pre-trial damages would be quantifiable.

Ground 2:

The judge failed to take into account the likely reduction in tender prices, which could be as low as 5% of the monopoly price based on the model of Mylan's reduced sales in Italy. The judge further ignored the fact that the tenders are blind giving the generic only one shot to win the tender.

Ground 3:

The judge applied a higher standard for Novartis to put to proof that the NHS will refuse to pay the full monopoly price. The NHS, being a sophisticated purchaser, would do what they can to resist higher prices. Teva argued that there is no reason the NHS would question the cost-effectiveness of the current monopoly price, which had already been approved, after only four months of generic fingolimod.

Ground 4:

The judge erred to consider the impact of uncertainties, which involves many factors including, but not limited, to generic entry, in the period following trial would result in the inability to quantify damage. Further, the generics cannot rely on the uncertainties in support of a case that their damages are unquantifiable in the pre-trial period and then seek to reduce those uncertainties in order to minimise a damages claim against them if unsuccessful at trial. Teva argued that it didn't matter if generic fingolimod was made available for a brief period because the market for fingolimod would reduce anyway as alternative drugs become available. Further, there was limited evidence regarding an alternative drug for which patients could be referred following fingolimod.

Ground 5:

The judge incorrectly considered (albeit obiter) the filing of a divisional, a mechanism available to all patentees under the European patent system, as a relevant factor in tipping the balance of convenience against the grant of an injunction. Teva argued that the judge considered the original parent application was prosecuted for a number of years since 2007 and had Novartis held a patent without being refused its grant three times by the Examining Division, they would have had a patent much earlier. Regarding the status quo, Teva further argued that the largeness of the patentee's losses compared with the generics' losses is not a relevant factor in assessing the status quo.

The decision to refuse permission to appeal

In an oral judgment delivered at the hearing, Birss LJ refused permission to appeal. Birss LJ considered that grounds 1-3 had no real prospect of success, and based on that decision, grounds 4 and 5 subsequently did not need consideration. The key finding was with respect to ground 3 in that Roth J did not apply the wrong standard when he decided that Novartis would be able to restore its sales at monopoly prices for Gilenya. The judge was found to have evaluated the likelihood of something happening in the future, and gave reasons for coming to his finding, which included that Novartis was not obligated to reduce its prices in the meantime, particularly given it could deploy its own generic via its subsidiary, Sandoz. Regarding ground 4, it followed from the finding with respect to ground 3 that damages would be an adequate remedy.

The substantive trial (with only validity in dispute) has been fixed for October of this year.

Refusal of preliminary injunctions since 2015

Since 2015, and prior to this case, only 30% of the applications for a preliminary injunction had been refused. Roth J's decision to refuse an injunction, and the Court of Appeal's decision to refuse permission to appeal that decision, enlarges that minority. The other pharmaceutical applications refusing an interim injunction since 2015 are Neurim & Flynn v Mylan [2020] EWHC 1362 (upheld by the Court of Appeal in Neurim & Flynn v Mylan [2020] EWCA Civ 793), Actavis v ICOS & Eli Lilly [2017] EWHC 2880, and Warner-Lambert v Actavis [2015] EWHC 72 (upheld by the Court of Appeal in Warner-Lambert v Actavis [2015] EWCA Civ 556).

Patents Court decision is here.

[1] Patents Act 1977 § 61(1)(a).

[2] [2021] UKPC 24.

[3] [1975] AC 396.

[4] [2020] EWCA Civ 793.