THE HIGH COURT

COMMERCIAL

[2017 No. 5984 P.]

BETWEEN

GILEAD SCIENCES INC AND

GILEAD BIOPHARMACEUTICS IRELAND UC

PLAINTIFFS

AND

MYLAN S.A.S. GENERICS [UK] LIMITED T/A MYLAN AND MCDERMOTT LABORATORIES LIMITED T/A GERARD LABORATORIES T/A MYLAN DUBLIN

DEFENDANTS

THE HIGH COURT

COMMERCIAL

[2017 No. 6494 P.]

BETWEEN

GILEAD SCIENCES INC AND

GILEAD BIOPHARMACEUTICS IRELAND UC

PLAINTIFFS

AND

TEVA B.V. AND NORTON (WATERFORD) LIMITED T/A

TEVA PHARMACEUTICALS IRELAND

DEFENDANTS

JUDGMENT of Mr Justice Brian McGovern delivered on the 7th day of November, 2017

1. The plaintiff has brought an application for interlocutory injunctive relief and ancillary orders against the defendants in each of the above proceedings which shall be referred to throughout this judgment as "*the proceedings*" or the "*Mylan proceedings*" or the "*Teva proceedings*" as appropriate. The reliefs sought in the interlocutory application is the same in both proceedings as follows:-

> (a) an injunction restraining the defendants and each of them, their servants or agents or the servants or agents of either of them from directly or indirectly infringing Irish Supplementary Protection Certificate no. 2005/021 (the "*SPC*") pending the final determination of these proceedings or until further order of the Court;
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> (b) an injunction restraining the defendants and each of them, their servants or agents or the servants or agents of either of them from making, offering, putting on the market and/or using any articles, products or other matter which directly or indirectly infringed the SPC and/or importing or stocking any such articles, products or other matter for those purposes, pending the final determination of these proceedings or further order of the Court;
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> (c) an order requiring the defendants and each of them to deliver up to the plaintiff all articles, products or other matters in their possession or control which infringed the SPC;
>
> (d) an order for disclosure on oath of any and all persons to whom the defendants may have supplied or offered to supply any article, product or matter which infringes the SPC;
>
> (e) all appropriate relief pursuant to the European Communities (Enforcement of Intellectual Property) Regulations 2006 and, in particular, Regulation 3 thereof.

he defendant also seeks further or other relief and ancillary orders.

2. The first named plaintiff is a US based company and is the parent of a group of companies (hereinafter referred to as "*Gilead*") of which the second named plaintiff is a member. Gilead engages in research, innovation and the creation of drugs for the treatment of conditions such as the Human Immunodeficiency Virus ("*HIV*"). The injunctive relief sought in this application is in respect of an alleged infringement of the plaintiffs' rights in Supplementary Protection Certificate No. 2005/021 ("*the SPC*"), which rights derive from Irish registered patent no. EP(IE)0 915 894 (the "*894 patent*"). The product to which the SPC relates is Tenofovir Disoproxil ("*T.D.*") and its salts in combination with Emtricitabine ("*FTC*"). These are the active ingredients in the plaintiffs' medicinal product, marketed as Truvada®, which is used in the treatment of HIV.

3. The 894 patent expired on 25th July, 2017, and the SPC which derives from that patent will expire on 23rd February, 2020. The first named plaintiff is the registered owner of the 894 patent and the SPC. The second named plaintiff is the exclusive licensee from the first plaintiff in respect of the use of the invention, the subject of the 894 patent and the SPC in the EU and other countries. The SPC was granted by the Irish Patent Office on 2nd September, 2009, and it confers exclusivity on Gilead in respect of the combination of T.D. (or the salts thereof) in combination with FTC until 23rd February, 2020.

4. The SPC is an important form of protection that is intended to allow developers of an innovative medicinal product an additional period of protection to compensate for the fact that the effective period of protection of a patent is insufficient due to the time taken to get products on the market.

5. Mylan is one of the largest generic pharmaceutical companies in the world which makes and sells a wide range of generic drugs. Teva is part of a large group of pharmaceutical companies that specialises in the manufacture and sale of generic pharmaceuticals. In the Mylan proceedings, the first defendant is a French company and is the holder of the centralised marketing authorisations *for Emtricitabine/Tenofovir Disoproxil Mylan*, the generic product to which the Mylan proceedings relate. The second defendant in those proceedings is the local representative in Ireland of those authorisations and the third defendant is an Irish registered company which manufactures the generic product.

6. Although asked to do so, Mylan failed to confirm its intentions with regard to the SPC in response to Gilead's request on dates between April and June 2017. On 29th June, 2017, Mylan confirmed that it has pricing approval for its generic T.D. + FTC product and stated that it would not launch the product prior to the expiry of the patent.

7. In the Teva proceedings, the first defendant is a Dutch company and a holder of a marketing authorisation ("*M.A.*") for a generic pharmaceutical product containing the combination of the active ingredients T.D. + FTC known as "*Emtricitabine/Tenofovir Disoproxil Teva"*. The second defendant in those proceedings is an Irish company which has confirmed that it intended to launch the product "*Emtricitabine/Tenofovir Disoproxil Teva*" on or after the expiration of the 894 patent on 25th July, 2017.

8. SPCs covering T.D. + FTC which were granted in several other jurisdictions are the subject of revocation proceedings by Mylan and Teva and other generics companies and there are also infringement proceedings by Gilead. Revocation proceedings are in being in the following countries: Finland, France, Germany, Italy, Portugal, Spain, Switzerland, and the United Kingdom.

9. In the United Kingdom proceedings (in which Mylan and Teva are plaintiffs) there is also a preliminary reference pending to the Court of Justice of the European Communities ("*CJEU*") concerning the criteria for deciding whether a SPC is protected by a basic patent. Gilead has filed written submissions with the CJEU. Injunctions have been granted in some jurisdictions and refused in others. On 14th September, 2017, an arbitral tribunal in Portugal considered that the Portuguese SPC was valid following an oral hearing involving expert evidence and ordered a generics company to refrain from marketing its generic T.D. + FTC product as long as the Portuguese SPC is in force. While the validity of the SPC has been challenged in many other jurisdictions, no proceedings have been initiated by Mylan or Teva to revoke or challenge the validity of the SPC granted by the Irish Patents Office.

10. Gilead has repeatedly asserted the SPC in correspondence with Mylan and Teva and has made it very clear that it would take all necessary steps to protect the SPC from infringement.

11. Although Mylan issued revocation proceedings in Italy, France, Germany, and the UK challenging the SPC and although it is a party to infringement proceedings in other jurisdictions, it has not issued any such proceedings against Gilead in Ireland and the plaintiffs complain that Mylan has decided to launch its generic product in Ireland without seeking to "*clear the way*" by seeking the revocation of the SPC or challenging its validity. Mylan has engaged in detailed planning and preparation including obtaining pricing approval to launch its generic T.D. + FTC product.

12. Teva did not respond to Gilead's correspondence asserting the SPC until 13th July, 2017, when it confirmed that it intended to launch a product that it is alleged to infringe the SPC on the expiry of the 894 patent on 25th July, 2017.

13. Teva has issued revocation proceedings in Finland, Germany, Italy, Portugal, Switzerland, and the UK challenging the equivalent SPCs in those jurisdictions and it is party to infringement proceedings in other jurisdictions. Like Mylan, Teva has made a decision to launch its generic product without seeking the revocation or challenging the validity of the SPC in Ireland. It is alleged by the plaintiffs that Teva decided to do so without seeking to "*clear the way*". It has engaged in planning and preparation for the launch of its T.D. + FTC product and only informed Gilead of these facts on 13th July, 2017.

14. The first issue which the Court has to decide is whether or not the plaintiffs have shown that there is a fair or *bona fide* or serious question to be tried. This is a pre-requisite for obtaining an interlocutory injunction. There is no doubt that the plaintiffs are the holder of an SPC and they rely on the protection afforded by the certificate to prevent the defendants from introducing generic versions of Truvada® into the Irish market before the SPC expires on 23rd February, 2020.

15. It is true, of course, that the defendants intend to argue that the SPC is invalid, and that they have already challenged the validity of the SPC in other jurisdictions. In some cases, they have been successful. National patent offices in Austria, Greece, the Netherlands and Sweden refused to grant equivalent SPCs. In Germany, the Federal Patent Court has issued a preliminary opinion that the equivalent SPC in that jurisdiction is invalid and on that basis the District Court in Munich refused to grant a preliminary injunction against Mylan. A preliminary injunction has also been refused in France. In the proceedings before Arnold J. in the Courts of England and Wales, *Teva (UK) Ltd v Gilead Sciences Inc* [2017] EWHC 13 (Pat), the learned judge has made a reference to the CJEU namely, "*what are the criteria for deciding whether the 'product is protected by the basic patent in force' in Article 3(a) of the SPC Regulation?*". At para. 97 of his judgment, making the reference, Arnold J. stated:-

> A medicinal product whose active ingredients are T.D. and another therapeutic agent such as Emtricitabine in combination is not protected by the Patent within the meaning of Article 3(a) because the combination, as distinct from T.D. does not embody the inventive advance of the Patent."

he plaintiffs complain that the defendants have threatened to launch their generic products on the Irish market without "*clearing the way*" by challenging the validity of the SPC in this jurisdiction. The plaintiffs also raise issues around the preservation of the status quo and the adequacy of damages to the plaintiffs if no injunction is granted.

16. At a hearing for an interlocutory injunction, a court cannot reach a final decision on the principal issues in dispute between the parties. But it is very clear in this case that the plaintiffs have established that there is a fair or *bona fide* or serious question to be tried.

The Law

17. The test to be applied in an application for interlocutory injunction has been set out by the Supreme Court in *Campus Oil Limited v. Minister for Industry and Energy* (No. 2) [1983] I.R. 88. The judgments of both O'Higgins C.J. and Griffin J. show that the Supreme Court gave its approval to the principles enunciated in *American Cyanamid & Co. v. Ethicon* [1975] A.C. 396 and that has remained the position in this jurisdiction.

18. In more recent times, the test has been summarised by Clarke J. (as he then was) in *Okunade v. Minister for Justice* [2012] 3 I.R. 152 at 180 (para. [70]):-

> "• *The party seeking the injunction must show that there is a fair or bona fide or serious question to be tried.*
>
> • *If that be established, the court must then consider two aspects of the adequacy of damages. First, the court must consider whether, if it does not grant an injunction at the interlocutory stage, a plaintiff who succeeds at the trial of the substantive action will be adequately compensated by an award of damages for any loss suffered between the hearing of the interlocutory injunction and the trial of the action. If the plaintiff would be adequately compensated by damages the interlocutory injunction should be refused subject to the proviso that it appears likely that the relevant defendant would be able to discharge any damages likely to arise.*
>
> • *If damages would not be an adequate remedy for the plaintiff, then the court must consider whether, if it does grant an injunction at the interlocutory stage, a plaintiff's undertaking as to damages will adequately compensate the defendant, should the latter be successful at the trial of the action, in respect of any loss suffered by him due to the injunction being enforced pending the trial. If the defendant would be adequately compensated by damages, then the injunction will normally be granted. This last matter is also subject to the proviso that the plaintiff would be in a position to meet the undertaking as to damages in the event that it is called on.*
>
> • *If damages would not adequately compensate either party, then the court must consider where the balance of convenience lies.*
>
> • *If all other matters are equally balanced the court should attempt to preserve the status quo."*

19. The plaintiffs argue that the SPC is a property right protected by the Constitution and that this creates a presumption that an interlocutory injunction should be granted. I do not accept that argument. In *Glaxo Group Limited v. Rowex Limited* (Unreported, 19th May, 2015), Barrett J. analysed the judgment of Clarke J. in *Metro International S.A. v. Independent News and Media plc* [2005] IEHC 309, and stated:-

> *…even if there was no question of delay, an interlocutory injunction is not just there for the asking when the holder of an intellectual property right complains of alleged infringement." (p. 85, para. 120)*

20. In the Metro case, Clarke J. stated at para. 4.4 of his judgment:-

> *…in many cases where a plaintiff alleges an infringement of his property rights the court will intervene by injunction where those property rights have been established rather than compensate the plaintiff for the loss of those property rights."*

21. But, there are cases where an injunction will not be appropriate even where it is alleged a property right is being infringed. In *Sony Music Entertainment Ireland Limited v. UPC Communications Ireland Limited* [2016] IECA 231, Hogan J. stated:-

> *The protection of the right to intellectual property is indeed enshrined in Article 17(2) of the Charter of Fundamental Rights of the European Union ('the Charter'). There is, however, nothing whatsoever in the wording of that provision or in the Court's case-law to suggest that that right is inviolable and must for that reason be absolutely protected."*

22. It follows, therefore, that even if the SPC in this case involves a property right vesting in the plaintiffs it is not determinative of whether or not an injunction should be granted. It is no more than a factor to be taken into account in applying the principles to be found in *Campus Oil and Okunade*.

23. In *Smithkline Beecham plc v. Genthon B.V*. [2003] IEHC 623, Kelly J. (as he then was) refused to grant an interlocutory injunction restraining the sale of a pharmaceutical product alleged to be infringing a patent. He did so on the basis that any commercial loss suffered by the plaintiff by the refusal of the injunction is compensable in damages. In the course of his judgment, Kelly J. stated:-

> *I wish to state that there is no hostility, inherent or otherwise, to the grant of interlocutory injunctions in patent infringement proceedings**. The tests for the grant of such an injunction are the same as in any other case.** No better exemplar of this is the decision of the House of Lords in American Cyanamid which set forth those guidelines of wide and general application in what was itself a patent infringement suit."(Emphasis added)*

here is no rule or presumption that damages are not an adequate remedy where infringement of an intellectual property right is alleged.

24. In para. 18 above, I referred to the remarks of Clarke J. in *Okunade* in which he said that if the plaintiff would be adequately compensated by damages, an interlocutory injunction should be refused provided the defendant would be able to discharge any damages likely to arise. This reflects the views of Lord Diplock in *American Cyanamid* where he stated at 408:-

> *If damages in the measure recoverable at common law would be adequate remedy and the defendant would be in a financial position to pay them, no interlocutory injunction should normally be granted, **however strong the plaintiff's claim appeared to be at that stage.**" (Emphasis added)*

25. It follows, therefore, that once the court is satisfied that the plaintiffs have shown there is a fair or *bona fide* or serious issue to be tried, the next question to be considered is whether or not damages would be an adequate remedy for the plaintiffs. It is only if damages are not an adequate remedy for the plaintiffs that the court must go on to consider the plaintiffs' undertaking as to damages and whether the defendants would be adequately compensated by damages, and then, if damages would not adequately compensate either party, the court must consider where the balance of convenience lies and how best to preserve the status quo.

26. The onus is on the plaintiffs to establish, as a matter of probability, that damages would not be an adequate remedy. See *Curust Financial Services Limited v. Loewe-Lack-Werk* [1994] 1 I.R. 450. At 469, Finlay C.J. said:-

> *Difficulty, as distinct from complete impossibility, in the assessment of such damages should not, in my view, be a ground for characterising the awarding of damages as an inadequate remedy."*

27. In that case, Finlay C.J. took into consideration the probable date on which the case was likely to come for hearing after it was sent back to the High Court and that the matter should be given an early trial date.

Are Damages an Adequate Remedy for the Plaintiff?
28. This question took up a lot of time over the three day hearing of the motion. The capacity of the defendants to meet any award of damages to the plaintiffs has not been challenged. They are both major pharmaceutical companies with substantial revenues.

29. If the defendants launch their products, these generic products have as their active ingredient T.D. + FTC and will infringe the plaintiffs' SPC if it is valid.

30. The plaintiffs maintain that damages would not be an adequate remedy as it would result in the deprivation of property rights and that to refuse the injunction would amount to a compulsory revocation of the plaintiffs' SPC despite the fact that no challenge has been mounted against the certificate in this jurisdiction by the defendants. The plaintiffs also argue that the issue of adequacy of damages requires an assessment as to whether or not those damages are, in fact, capable of calculation in order that they can be recovered. The plaintiffs say that any damages suffered by them as a result of the refusal to grant an injunction would be impossible to predict for the following reasons:-

> (i) the damages would result from losses in a market which is currently unstable and unpredictable;
>
> (ii) the losses to the plaintiffs would extend to markets that have not yet come into being namely the market for Pre-Exposure Prophylaxis (PrEP) and to different products and could not be computed or recovered;
>
> (iii) losses would include irreversible price reductions to the plaintiffs' products for which they could not be compensated; and
>
> (iv) the losses to the plaintiffs would be the result of the launch of infringing products by several different generic companies and conflicting issues of attribution of liability and recovery of damages would arise which would not be capable of calculation.

31. The plaintiffs concede in their written submissions that the market for T.D. + FTC is an established market but argue that there will be difficult and insuperable obstacles to quantifying the loss inflicted by new entrants. The plaintiffs argue that the entry into the market of several generic companies (including the defendants) together with the existing instability in the market would make it exceedingly difficult to ascertain how the market would theoretically have developed in their absence. Therefore, it will be impossible to calculate the loss suffered by the plaintiffs, were an injunction to be refused. The defendants argue that Truvada® is not a mainstream drug which is widely distributed. It is dispensed to a small cohort of patients. The market is settled and consistent. They argue that all that is protected by the SPC is Truvada® and the plaintiffs are not entitled to claim losses in respect of any other products.

32. Ms Sandra Gannon, the General Manager at Teva Pharmaceuticals Ireland swore an affidavit on 7th September, 2017, in which she set out in great detail the issues in dispute between the parties and provided a significant amount of statistical information relevant to the issue of the adequacy of damages. In particular, she informed the Court that IMS Health (IMS) is an international company that supplies the pharmaceutical industry with accurate and timely sales data in more than one hundred countries including Ireland. IMS collects pharmaceutical sales and prescription data from wholesalers and supplies updated sales data on a monthly basis to its customers. This facilitates the tracking of accurate absolute sales value and volume and market share index. This information was not disputed.

33. She avers that in order to calculate the plaintiffs' losses (assuming they succeed in defending the SPC), it would simply be a matter of taking the IMS unit sales of the plaintiffs' product and multiplying that quantity by the loss in profit per unit. The plaintiffs and the defendants both contribute to IMS data which will give the relevant volume for the plaintiffs and the defendants' products on a monthly basis for the whole market. I am satisfied from the evidence in the affidavit of Ms Gannon and also an affidavit sworn by Dr James Keating that Truvada® is dispensed solely through a small number of specialised clinics based in hospitals in Ireland. There are seven such centres namely at: St. James's Hospital, Cork University Hospital, Mater Misericordiae Hospital, Galway University Hospital, Beaumont Hospital, Limerick Regional Hospital and Merlin Park Hospital. These centres supply a small cohort of patients. There are 1,200 HIV patients prescribed with Truvada®. The defendants have agreed that they will make available all their sales figures up to the trial of the action if no injunction is granted to the plaintiffs.

34. The affidavit of Dr James Keating sworn on 7th September, 2017, in the *Mylan* proceedings is of some significance. Dr Keating is a general practitioner with a particular speciality in treating HIV patients and he can be seen as an independent voice of someone working "*at the coalface*". His evidence is that the plaintiffs' T.D. based STR (Single Tablet Regimen) medicines are fast being replaced by the next generation of drugs, namely TAF (*Tenofovir Alafenamide*). He says that STR treatments are now "*the gold standard*" in the treatment of HIV patients. He prescribes TAF based STR treatments in preference to T.D. based STR treatments. His affidavit sets out the benefits of the emerging TAF based STR treatments and states that even if a generic version of Truvada® became available at a cheaper price, he could not justify switching a patient on a TAF based drug back to a T.D. based drug.

35. The evidence before the Court suggests that existing HIV patients on Truvada® who do not suffer side effects will probably be kept on that regime but all new patients will most likely be prescribed a TAF based STR treatment. Generic medicines will not undermine the developing market in TAF based STR but the competition will most likely be confined to the T.D. based STR market.

36. I am satisfied on the affidavit evidence that because Truvada® is not widely dispensed and is delivered to patients through only seven centres in the State, this facilitates the traceability of not only Truvada® sales but any sales of generics if an injunction is refused. I do not accept that the market for Truvada® is currently unstable or unpredictable.

37. The plaintiffs claim that they cannot be adequately compensated in damages for the losses in the market for PrEP. The evidence establishes that there is no current market in PrEP. Dr Keating in his affidavit avers that it is likely that any assessment for Truvada® for PrEP will not take place until the end of 2020. When any such scheme is funded, it is likely to be for a TAF rather than a T.D. based regime. I am not satisfied that the plaintiffs have established the existence of such a market so that it should be taken into account in determining whether damages could be adequately assessed.

38. The plaintiffs assert that if the generics were permitted to enter the market, they would suffer irreversible price reductions for which they could not be compensated. Ms Sandra Gannon in her affidavit offers detailed evidence of a number of cases where the HSE has not enforced price reductions for a considerable period after the generic entry into the Irish market and there are no

examples of the HSE imposing price reductions where patent litigation is ongoing between pharmaceutical companies. As pharmaceutical prices in Ireland are part of the data used to set prices in eleven other EU markets and as many as 37 worldwide markets, voluntary price reductions by the plaintiffs would seem unlikely and would not make commercial sense. While the plaintiffs do not go so far as to say that they would voluntary reduce their price, it seems unlikely they would do so. But even if they did, (or for that matter, were forced to do so) it would not be difficult to work out any damages to which they might be entitled in respect of a market that is very mature with only a short time left to run as a monopoly. I reject that argument as a basis for contending that the plaintiffs' damages could not be assessed.

39. The final element in the plaintiffs' claim of impossibility to ascertain damages arises out of the fact that infringing products by several different generic companies would arise posing issues of attribution of liability. I do not accept that as valid argument in the context of a pharmaceutical industry which is so well regulated in terms of traceability. The IMS has a sophisticated tracking system of both pharmaceutical sales and prescription data covering over one million pharmaceutical products from over three thousand companies including the plaintiffs and the defendants. In any event, the market for Truvada® and other T.D. + FTC products is, at best, likely to remain static and will, in time diminish as new patients are put on TAF based STR treatments and there is only a small cohort of patients involved who are being treated through seven centres.

40. In reaching a conclusion on the issue of adequacy of damages, it is relevant to consider the purpose of a SPC which is to ensure that the holder of a patent has sufficient opportunity to recoup the expenses incurred in developing and bringing the product to market and the delay in getting the product to market after the grant of the patent. In an affidavit sworn on behalf of the plaintiffs on 19th July, 2017, Mr Stylianos Karagiannoglou stated that the cost of bringing a product to market in 2016 was estimated to be in the region of US$2.87bn. Truvada® was launched in 2004 and it is reasonable to assume that the costs were probably lower at that time although this is not particularised. Ms Sandra Gannon in her affidavit deposes to the fact that the global revenue created by the plaintiffs from the sale of Truvada® in the past four years totalled over US$13.8bn. Regulation 469/2009/EC (The SPC Regulation), is intended to strike a balance between the interests of the patent holder and the generic manufacturer. The figures deposed to by Ms Gannon have not been disputed; however, even allowing a wide degree of latitude in respect of those figures, it appears that without the SPC (whether it be valid or not), the plaintiffs had obtained an ample reward for the cost of developing and distributing Truvada®. I take the view that it is reasonable to take these figures as one factor to be taken into account in determining the adequacy of damages issue.

Conclusions

41. I am satisfied that in this case damages are an adequate remedy for the plaintiffs if an injunction is refused and that those damages are capable of assessment. I am also satisfied that the defendants are in a position to meet any award of damages that might be made.

42. It follows from the case law which I have already set out earlier in this judgment that the application for interlocutory injunction should be refused. It is not necessary for the Court to consider other issues such as the adequacy of damages to the defendants, or the loss of "*first mover advantage*" claimed by Teva as these go to the balance of convenience. Neither is it necessary for the Court to consider the preservation of the status quo. As this case has been admitted to the Commercial List, it will be heavily case managed and there is no reason why it cannot proceed to a relatively early trial date. This is another factor to be taken into account in determining whether or not to grant an injunction in this case.

43. The plaintiffs' applications for interlocutory relief are refused.