THE HIGH COURT

COMMERCIAL

[2017 No. 9398 P.]

BETWEEN

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

PLAINTIFF

AND

MYLAN TEORANTA T/A MYLAN INSTITUTIONAL AND BY ORDER YEDA RESEARCH AND DEVELOPMENT COMPANY LIMITED

DEFENDANTS

JUDGMENT of Mr. Justice David Barniville delivered on the 5th day of June, 2018

Introduction

1. This is my judgment on the plaintiff's application for an interlocutory injunction restraining the first named defendant, its servant or agents, from directly or indirectly infringing Irish Patent No. EP (IE) 2 949 235 entitled "*Low Frequency glatiramer acetate therapy"* ("Patent" or EP (IE) 335, as appropriate). Without prejudice to the generality of that relief, the plaintiff also seeks an injunction restraining the first named defendant, its servants or agents, from making, offering, putting on the market and/or using any articles, products or other matter which directly or indirectly infringe the Patent and/or from importing or stocking any such articles, products or other matter together with various ancillary orders.

2. The application was made by a notice of motion dated 19th October, 2017 in the context of proceedings commenced that day. In the proceedings, the plaintiff claims that a generic drug for the treatment of multiple sclerosis ("MS") manufactured by the first named defendant at its facility in Inverin, Co. Galway infringes the Patent, of which the plaintiff is the exclusive licensee. The second named defendant is the registered owner of the Patent. It was joined as a co-defendant to the proceedings on consent of the parties at the end of the hearing of the interlocutory injunction application in order to address a technical objection to the proceedings made by the first named defendant.

Description of the parties

3. The following is a brief and hopefully non-controversial description of the parties based on the affidavit evidence adduced in this application.

4. The plaintiff, Teva Pharmaceutical Industries Ltd. ("Teva"), is an international pharmaceutical company incorporated in Israel which specialises in the development, manufacturing and marketing of generic and proprietor pharmaceuticals and active pharmaceutical ingredients. Copaxone is Teva's drug for the treatment of relapsing forms of MS, a chronic inflammatory demyelinating disease of the central nervous system. Another Teva entity, Teva Pharmaceuticals USA, Inc. ("Teva USA") is a subsidiary and licensee of Teva and is an authorised distributor of medicines including Copaxone in the United States on its behalf. Teva USA purchases Copaxone from Teva and then resells the product to third party customers in the United States. Teva USA is the holder of a marketing authorisation in the US (known as a New Drug Application authorisation) in respect of Copaxone 40mg/ml (which is the particular Copaxone drug, the market for which in the US Teva is seeking to protect in these proceedings) ("Copaxone 40mg"). For convenience, where appropriate, I will refer to the various companies in the Teva Group collectively as "Teva".

5. The second named defendant, Yeda Research and Development Co. Ltd. ("Yeda"), is also an Israeli corporation and is the registered owner of the Patent. It has granted an exclusive licensee in respect of the Patent to Teva.

6. The first named defendant, Mylan Teoranta trading as Mylan Institutional ("Mylan Teo"), is a company incorporated in Ireland. Its immediate parent company is Mylan Pharma Group Ltd., also incorporated in Ireland. The ultimate parent company in the Mylan Group is Mylan N.V.. Again, where appropriate I will refer to the various companies in the Mylan Group collectively as "Mylan". Mylan is another leading company in the global pharmaceutical industry. It develops, licenses, manufactures, markets and distributes generic, branded generic and speciality pharmaceuticals. In Ireland, Mylan has facilities in Dublin, Meath and Galway and a work force in Ireland of in excess of 1,000 employees. Mylan Teo operates a facility at Inverin, Co. Galway. At that facility, which was acquired by Mylan in 2010, Mylan Teo develops and manufactures high quality, sterile injectable pharmaceutical products, for a range of therapeutic categories.

The product at issue in the proceedings

7. At issue in these proceedings is Mylan's generic glatiramer acetate 40mg/ml drug (the "Mylan 40mg GA product") which is manufactured by Mylan Teo at its facility in Galway and which was launched by Mylan in the United States on 4th October, 2017 to compete with Copaxone 40mg, Teva's 40mg GA product. Teva alleges that the Mylan 40mg GA product infringes the Patent. While the Mylan 40mg GA product is manufactured in Ireland, it does not have a marketing authorisation and is not sold in Ireland. It is exported to the United States where it is supplied and prescribed to MS patients.

8. The active drug substance in Copaxone and in Mylan's competing products is glatiramer acetate ("GA"). Copaxone is administered as either a 20mg daily subcutaneous injection or (since 2014) as a 40mg subcutaneous injection administered three times per week with at least a day between injections (referred to as "TIW"). GA was first discovered and synthesised in the 1960s by a group of scientists at the Weizmann Institute of Science. In 1987, Yeda, an arm of the Weizmann Institute, entered into an agreement with Teva to commercially develop and seek regulatory approval for GA. In 1996, the US Food and Drug Administration (the "FDA") approved Copaxone 20mg/ml ("Copaxone 20mg") to be administered daily for treating relapsing forms of MS. Since approximately 2002, Copaxone 20mg has been commercially sold in the US in prefilled syringes.

9. In January 2014, Teva received FDA approval for a new dosing regimen for Copaxone. The approval was for a 40mg dosage administered three times per week ie, TIW. This is Copaxone 40mg. When the FDA approved Copaxone 40mg, it granted Teva a three year period of marketing exclusivity. This meant that the FDA would not grant approval under the US regulatory regimen for a generic version of the drug for three years following its approval. That period of exclusivity expired on 28th January, 2017.

10. The global revenues for Copaxone are very significant indeed. They were $4.283 billion in 2016. In the first two quarters of 2017,

global revenues of Copaxone (both the 20mg and 40mg products) were almost $2 billion. At the end of the second quarter 2017, Copaxone 40mg accounted for over 85% of total Copaxone prescriptions in the US.

11. In 2009, Mylan sought approval from the FDA for a high quality, substitutable, generic Copaxone equivalent. It did this by filing an Abbreviated New Drug Application ("ANDA") with the FDA. In February 2014, Mylan filed an ANDA with the FDA seeking specific approval for the Mylan GA 40mg product. On the expiry of the three year period of exclusivity for Copaxone 40mg on 28th January, 2017, it was open to the FDA to grant approval in respect of Mylan's 40mg GA product, barring any legal or regulatory impediments. As we shall see, it did so on 3rd October 2017.

US Regulatory Regime

12. The regulatory regime for generic drugs in the United States is governed by legislation enacted by the US Congress in 1984 called the Drug Price Competition and Patent Term Restoration Act of 1984, known informally as the Hatch-Waxman Act. Briefly explained, the holder of a New Drug Application ("NDA") approval for a branded pharmaceutical drug product is required to inform the FDA of the patents which it asserts cover the branded drug. Those patents are then listed by the FDA in an FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations", which is commonly referred to as the "Orange Book". When a company wishes to manufacture and sell a generic equivalent, it must file what is called an Abbreviated New Drug Application ("ANDA") with the FDA. The ANDA filer must also include a certification stating that any unexpired Orange Book patents are invalid or will not be infringed by the manufacture, use or sale of the generic product the subject of the ANDA, (this certification is known as "Paragraph IV certification") unless that company is not seeking FDA approval until the Orange Book patents expire. If the ANDA filer submits a Paragraph IV certification, then the patent holder/owner of the NDA, if it wishes to contest the approval, must bring an action for infringement of the patent that is the subject of the certification before the US District Court. The FDA will not generally approve the ANDA until infringement proceedings are resolved or thirty months past, whichever is the earlier. This procedure, therefore, allows the patent holder the opportunity to protect valid patents while at the same time not delaying the filing of the ANDA or its regulatory review. The idea is that the legislation allows ANDA filers to launch their competing generic products once the patents have been found invalid or not infringed or immediately upon the expiration of valid patents.

Delaware Proceedings

13. Mylan's filing of an ANDA in respect of its 40mg GA product led to the commencement of proceedings by Teva in the United States District Court for the District of Delaware (the "Delaware District Court") against Mylan and five other ANDA filers, Sandoz (in partnership with Momenta), Synthon (in partnership with Pfizer), Amnel, Dr. Reddy's Laboratories and Apotex (in partnership with Biocom). In those proceedings (the "Delaware Proceedings"), which I consider in later detail below, Teva alleged infringement of four US patents obtained by Teva in 2012 which were intended to cover the Copaxone 40mg TIW dosing regimen. Those patents all issued from the same priority applications as the Patent the subject of these proceedings and claim the same dosing regimen as that Patent. Mylan filed Paragraph IV certifications in respect of those patents following which Teva commenced proceedings in the Delaware District Court in 2014 asserting that Mylan's 40mg GA product would infringe four of the five relevant patents. Following a trial in September and October 2016, the Delaware District Court delivered its opinion on 30th January, 2017 holding all four of the patents invalid as obvious. Teva have appealed to the United States Court of Appeals for the Federal Circuit. Teva sought an injunction or stay preventing Mylan from launching the Mylan 40mg GA product pending the appeal but that application was refused by the Delaware District Court on 1st February, 2017. No application for an injunction or stay pending the determination of the appeal was made to the Court of Appeals.

Commencement of Proceedings

14. The FDA approved Mylan's ANDAs for the Mylan 40mg GA product and Mylan's 20mg GA product on 3rd October, 2017. Mylan issued press releases on 3rd October, 2017 and 4th October, 2017 in respect of those approvals. Teva, initially through its English solicitors, and then through Irish solicitors, corresponded with Mylan Teo and its Irish solicitors commencing on 11th October, 2017 and, ultimately issued these proceedings on 19th October, 2017. The proceedings were entered in the Commercial List on 6th November, 2017. By that stage a statement of claim had been delivered (on 3rd November, 2017) with particulars of infringement. Thereafter, particulars were sought and replies furnished.

15. Initially Teva claimed in the proceedings that Mylan's 40mg GA product infringed two patents, the Patent and another patent, Irish Patent No. EP (IE) 3 050 556 entitled *"Process for manufacturing a pharmaceutical preparation containing glatiramer acetate"* (the "556 Patent"). Interlocutory injunctive relief was initially sought in respect of both patents. However, the plaintiff withdrew its claim in respect of the 556 Patent and delivered an amended statement of claim and amended particulars of infringement on 20th December 2017 alleging infringement of the 335 Patent only. At the time of the hearing of the interlocutory injunction application in January, 2018 Mylan Teo had not yet delivered its defence and counterclaim. However, it was indicated that a defence and counterclaim would be delivered in which it would be asserted that the Patent was invalid. Mylan Teo had not sought revocation of the Patent prior to the launch of the Mylan 40mg GA product. This failure to "clear the way" by Mylan in advance of the launch of its product was relied on by Teva in the course of its application as being significant in the context of the balance of convenience.

The Patent/EP (IE) 335

16. Teva filed an application for a European patent, EP 2 949 335 ("EP 335") on 19th August, 2010 with the European Patent Office ("EPO") with Ireland as one of the designated contracting states. Priority was claimed to 20th August, 2009 from US Provisional Application US 274687 P. EP 335 was granted by the EPO on 4th January, 2017. It was subsequently validated in Ireland.

17. Under s. 119 of the Patents Act 1992 (as amended), a European patent designating Ireland as one of the contracting states is treated as if it were an Irish patent granted by the Irish Patents Office. It has the same rights as those conferred by an Irish patent granted by the Irish Patents Office. Any alleged infringement is dealt with under Irish law.

18. EP 335 is a divisional patent stemming from the parent patent, EP 2 405 749 ("EP 749"). EP 335 covers a method of using GA in treating patients with a relapsing form of MS or who have experienced a first clinical episode and have a high risk of developing MS in accordance with a specified dosing regimen, namely 40mg GA subcutaneous injections administered three times per week with at least one day between injections (ie TIW).

19. As noted, EP 335 Patent is a divisional patent stemming from EP 749. EP 749 also covered the 40mg TIW dosage regimen. It was the first patent issued in Europe which claimed the use of GA in that particular dosing regimen. It was granted by the EPO on 8th May, 2013. Mylan and others commenced opposition proceedings in respect of EP 749 before the EPO. An appeal hearing was scheduled for November 2017. However, on 7th February, 2017 the opposition proceedings were terminated because Yeda, the patent owner, requested that EP 749 be withdrawn. It was withdrawn and revoked by the EPO.

International Developments

20. Teva claims that the Mylan 40mg GA product infringes the Patent. Mylan contends in response that the Patent is invalid and will

counterclaim in the proceedings to that effect. Reliance is placed by Mylan on the fate of the equivalent to the Patent in other European states, including the United Kingdom and Germany, and on the fate of a number of US patents obtained by Teva which purportedly cover Copaxone's 40mg TIW dosing regimen which all issued from the same priority applications as the Patent and claim the same dosing regimen. Teva disputes the significance of those developments and contends that its application must be determined by reference to an Irish patent, which is presumed to be valid notwithstanding the fate of the equivalent patent in other European states and notwithstanding the fate of the US patents in respect of the same dosing regimen. An examination of what has happened in those other jurisdictions is, in my view, essential.

21. I commence with the position in the United States. In the period between 2009 and 2014 there was litigation in the United States in relation to the Copaxone 20mg product. Teva commenced proceedings in the United States District Court for the Southern District of New York in October 2009 (*Teva Pharms US Inc. v. Mylan Pharms Inc*. 09 Civ. 8824 BSJAJP) in relation to Mylan's generic equivalent of the product alleging infringement of a series of US patents (different to the US patents referred to in these proceedings). The New York District Court found for Teva, upheld the patents in issue as valid, found that Mylan's 20mg GA product would infringe those patents and granted an injunction restraining Mylan and others from launching competing generic products until the expiration of one of the patents in September 2015. Mylan appealed that decision to the United States Court of Appeals for the Federal Circuit. That court held some of the claims of the patents invalid but upheld the validity of certain other of the claims and reduced the duration of the injunction restraining the defendants, including Mylan, from entering the market with a 20mg GA product until May 2014. Teva appealed that decision to the United States Supreme Court. Teva requested the US Supreme Court to recall and stay the order shortening the injunction so that the generic competitors to Copaxone 20mg could not be launched while the appeal was pending. Teva alleged that it would suffer irreparable harm if the generic product could be launched while the appeal was pending. The US Supreme Court refused the stay. In a judgment delivered in April 2014, Roberts C.J., as the assigned Justice of the Supreme Court for the Federal Circuit, rejected the assertion that Teva would suffer irreparable harm if a stay were denied. He held that should Teva prevail and its patents be held valid it would be able to recover damages for past patent infringement. While not directly relevant to the substantive claims made in these proceedings, the refusal by the US Supreme Court of the stay on the grounds just summarised is relied upon by Mylan to resist the grant of interlocutory injunctive relief in respect of the Patent at issue in these proceedings.

22. Of more direct relevance to the patents at issue here are the proceedings in the US District Court for the District of Delaware (touched upon above) (the "Delaware Proceedings") and proceedings before the United States Patent Trial and Appeal Board (the "US PTAB").

23. In the period from 2012 Teva obtained a series of US Patents covering Copaxone's 40mg TIW dosing regimen. These patents issued from the same priority applications as the Patent and claim the same dosing regimen as that patent. Three of these patents were held to be unpatentable by the US PTAB in August and September 2016. These were US Patent Nos. 8, 232, 250 (the "250 Patent"), 8, 499, 413 (the "413 Patent"), and 8, 969, 302 (the "302 Patent"). The US PTAB found that the patents were unpatentable in light of the prior art and, in particular, Teva's US Patent application disclosing and claiming the use of Copaxone 40mg every other day. Teva requested that the US PTAB to reconsider its decisions in respect of these three patents. It did so and issued three modified final written decisions on 2nd December, 2016. In these modified decisions, the US PTAB again held that the relevant claims in the three patents were unpatentable. Teva has appealed these three decisions to the US Court of Appeals for the Federal Circuit. As of the date of the hearing of Teva's application for interlocutory injunctive relief in respect of the Patent, the parties were awaiting a date for the oral hearing of that appeal.

24. As noted earlier, Teva commenced the Delaware Proceedings asserting that Mylan's 40mg GA product infringed four of the five relevant US Patents held by Teva. The four patents at issue in those proceedings were the 250 Patent, the 413 Patent, the 302 Patent and a further patent, US Patent No. 9, 155, 776 (the "776 Patent"). Those proceedings were heard by the US District Court for the District of Delaware in September and October 2016. The Delaware District Court gave judgment on 30th January, 2017 finding that all the asserted claims of the patents in suit were invalid as obvious. As I touched on earlier, the Delaware proceedings were consolidated Hatch-Waxman patent infringement actions, and were brought by various Teva entities including Teva US and Teva itself as well as Yeda against a number of entities that had filed ANDAs seeking approval to market generic versions of Copaxone 40mg. It was alleged that those generic products (including Mylan's 40mg GA product) infringed the four US Patents referred to. The Delaware District Court held that the patents in suit were obvious over certain prior art publications including a US Patent application published by Teva which disclosed a 40mg GA every other day dosing regimen to treat MS (the "Pinchasi application"). The Delaware District Court expressed the view that the patents in suit were "*nothing more than 'life-cycle management' – an attempt to continue to monopolise a multi-billion dollar market for blockbuster drug*" (p. 47 of the judgment).

25. Teva has appealed this decision to the US Court of Appeals for the Federal Circuit. This appeal was, at the time of the hearing of the current application, awaiting a hearing date before that court. Thus, there are two appeals pending the US Court of Appeals in relation to a number of the relevant equivalent US Patents.

26. There have also been relevant developments in relation to equivalent patents to EP (IE) 335 in a number of European jurisdictions. Before turning to look at some of those, I should record what has occurred before the EPO. As noted earlier, EP 335 was granted by the EPO on 4th January, 2017 on the back of a parent patent EP 749. EP 749 was withdrawn by Teva in February 2017 and revoked by the EPO after opposition proceedings had been commenced against it by Mylan and others thereby obviating the need for the appeal hearing, scheduled for November 2017. Mylan and others have commenced opposition proceedings at the EPO in respect of EP 335. A preliminary assessment has not yet issued by the Opposition Division and hearings are not expected for some time.

27. EP 335 has, however, been considered by the courts in a number of European states. The parties have referred to these proceedings in evidence and each has sought to put its own gloss on the impact of those proceedings in other European states on Teva's present application.

28. I first consider the position in the UK. Mylan and Synthon BV ("Synthon") (a generic manufacturer) commenced proceedings in the High Court of England and Wales, (Chancery Division) (Patents Court) relating to EP (UK) 335 (being the UK patent granted on foot of EP 335) in February 2017 seeking revocation of that patent. Yeda, as the registered proprietor, was joined as the defendant and Teva, the exclusive licensee, was joined as a third party. They counterclaimed for infringement of the patent. Arnold J. heard the revocation proceedings in October 2017 and delivered judgment on 26th October, 2017. He held that the relevant claims of EP (UK) 335 were obvious in light of Pinchasi and, therefore, invalid. In the course of his judgment, Arnold J. observed that:-

> "*The sole difference between Pinchasi and claim 1 of the patent is that Pinchasi discloses a regimen of 40mg QOD [ie every second day] while claim 1 requires a regimen of 40mg TIW [ie three times per week]. As discussed above, the difference amounts to one dose every fortnight*". (para. 175).

Arnold J. refused permission to appeal. Yeda/Teva then sought permission to appeal from the Court of Appeal. That permission was refused in an order made on 9th January, 2018 by Lewison L.J. The order refusing permission noted that the appeal would have *"no real prospect of success".*

29. Recent developments also occurred in relation to EP 335 in the Netherlands. Synthon brought proceedings before the District Court of the Hague seeking the revocation of the Dutch version of EP 749, the parent patent from which EP 335 stemmed. However, as noted above, the EPO's Technical Board of Appeal revoked EP 749 in February 2017. Teva did not seek to validate EP 335 for the Netherlands. In those circumstances, Synthon confined its claim to certain declaratory relief, seeking a declaration equivalent to an "Arrow declaration" under the law of England and Wales (*Arrow Generics Ltd. v. Merck & Co. Inc.* [2007] EWHC 1900 (Pat)). The Netherlands court refused to grant that declaration on the basis that Synthon had no legitimate interest as there were no 40mg GA patent claims in force in the Netherlands.

30. Proceedings were also commenced by Mylan and by Synthon in Italy seeking revocation of EP (IT) 335 in March 2017. Those proceedings are ongoing. Finally, proceedings were brought by Teva against a Mylan subsidiary in Germany seeking an interim injunction restraining the infringement of EP 335 in respect of a Mylan 40mg GA product which was about to be launched and marketed in Germany. In a judgment given on 14th December, 2017, the Regional Court of Munich rejected Teva's application. In doing so the Munich Court placed considerable reliance on the decision of Arnold J. in the UK proceedings.

Correspondence prior to proceedings
31. I now turn to the correspondence exchanged between the parties prior to the commencement of these proceedings. The correspondence is addressed in some detail in the affidavit sworn on behalf of the parties. The correspondence is detailed and extensive and many of the points made in the correspondence were pressed in submissions on the hearing of Teva's application.

32. It will be recalled that following FDA approval for Mylan's 40mg GA product on 3rd October, 2017 and the press releases issued by Mylan on that date and on 4th October, 2017, Teva and its English and, subsequently, Irish solicitors commenced corresponding with Mylan and its Irish solicitors. The first letter was sent on 11th October, 2017 by Teva's UK solicitors. There then followed an extensive exchange of correspondence between that date and 18th October, 2017. Many of the issues relied on by the parties on this application were ventilated in that correspondence. I will address those issues below.

The Proceedings
33. Proceedings were then commenced on 19th October, 2017 and the motion seeking interlocutory relief was issued on the same date. Teva's application was grounded on an affidavit sworn on 19th October, 2017 by Alan McBride of Teva Europe's Legal Department. It was also grounded on an affidavit sworn on 18th October, 2017 by John Hassler, the Senior Vice-President and General Manager for Teva USA's Central Nervous System Division and an affidavit sworn by Professor Jerry A. Hausman, McDonald Professor of Economics at the Massachusetts Institute of Technology (MIT). Replying affidavits were affirmed on behalf of Mylan by Jennifer Sunderland, Senior Patent Litigation Counsel at Generics (UK) Ltd. (trading as Mylan), which is part of the Mylan group on 9th November, 2017 and sworn on behalf of Mylan by Robert Tighe (Head of Mylan Pharmaceutical Inc. ("MPI") and Mylan Canada (and previously Chief Financial Officer of Mylan North America)) on 8th November, 2017 and by Professor Joel Hay, Professor and founding chair of Pharmaceutical Economics and Policy in the School of Pharmacy at the University of Southern California. Further affidavits were sworn on behalf of Teva on 20th November, 2017 by Dr. McBride, Mr. Hassler and Professor Hausman. Additional replying affidavits were affirmed by Ms. Sunderland on 4th December, 2017 and sworn by Mr. Tighe on 30th November, 2017 and by Professor Hay on 1st December, 2017.

34. In its notice of motion issued on 19th October, 2017 (as amended by an amended notice of motion dated 20th December, 2017), Mylan now seeks the following interlocutory injunctive relief:-

> *"4. An injunction restraining the defendant, its servants or agents, for directly or indirectly infringing Irish Patent No. EP (IE) 2 949 335 entitled 'low frequency glatimer acetate therapy' (the '335 Patent') pending the final determination of these proceedings or until further order of the court.*
>
> *5. Strictly without prejudice to the generality of the foregoing, an injunction restraining the defendant, its servants or agents, from making, offering, putting on the market and/or using any articles, products or other matter which directly or indirectly infringe the 335 Patent, 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.*
>
> *6. An order requiring the defendant to deliver up, or at the plaintiff's election, destroy all articles, products, or other matter in their possession or control which infringed the 335 Patent.*
>
> *7. An order for disclosure on oath of any and all persons to whom the defendant may have supplied or offered to supply any article, product or matter which infringed the 335 Patent.*
>
> *8. All appropriate relief pursuant to the European Communities (Enforcement of Intellectual Property) Regulations 2006."*

35. Teva's claim is appended in the amended statement of claim delivered on 20th December, 2017. The original statement of claim was delivered on 3rd November, 2017 but included claims in relation not only to EP (IE) 335 but also in relation to the EP (IE) 556. Teva subsequently dropped its claims in relation to the EP (IE) 556 Patent and now confines its claim to EP (IE) 335. Teva maintains its claim as the exclusive licensee from Yeda of the Patent. Yeda has since been joined as a co-defendant in the proceedings by agreement of the parties.

36. Teva's claim is that Mylan Teo and/or its servants or agents had done the acts specified in the particulars of infringement and have infringed the exclusive rights granted to Teva under s. 40 of the Patents Act 1992 (as amended). Teva further pleads that Mylan Teo threatens and intends to continue to infringe the Patent in the manner set out in those particulars. It further pleads that, without prejudice to the generality of the forgoing and from a date unknown pending discovery, Mylan Teo and/or its servants or agents have been making in the State products the subject matter of the Patent and/or have been importing and stocking such products for the purposes of shipping them to MPI for disposal on the US market in breach of Teva's rights under s. 40(1) of the 1992 Act.

37. In the amended particulars of infringement delivered on 20th December, 2017, Teva provided further particulars in respect of its claim. It asserts that MPI is authorised to market and sell the Mylan 40mg GA product in the United States and that it received its marketing authorisation from the FDA on 3rd October, 2017. It is further asserted that it recently came to Teva's attention that Mylan Teo had been manufacturing that product in the State for the purpose of shipping it to MPI for disposal on the US market. It is

pleaded that in so doing Mylan Teo is acting in breach of Teva's exclusive rights in the Patent. It is then alleged that Mylan Teo has infringed and is continuing to infringe the Patent by doing in the State without the consent of Teva certain acts namely:-

> *"Making the Mylan GA 40mg/ml generic product, which is a GA product in accordance with Claims 1 and 3 of the 335 Patent, and/or a medicament comprising GA in accordance with Claims 2 and 4 of the 335 Patent, or importing or stocking the product for those purposes." (para. 7 of the amended particulars of infringement)*

The particulars then refer to the press releases issued by Mylan on 3rd and 4th October, 2017 and to the link to the Patient Information Leaflet ("PIL") in respect of the Mylan 40mg GA product which confirms that the marketing authorisation holder for the product is MPI and that the product in question is manufactured by "Mylan Institutional, Galway, Ireland". Teva pleads that the name "Mylan Institutional" is a registered business name of Mylan Teo. The particulars then refer to certain publicly available shipping documentation concerning the importation into the US from Ireland of the Mylan 40mg GA product confirming a shipment of the product by Mylan Teo to MPI in the United States. The particulars then assert that the records show that the Mylan 40mg GA product is being manufactured in Ireland "*in part at least*" and shipped by Mylan Teo to the US to MPI for disposal on that market. The particulars refer to the correspondence between the parties' respective solicitors prior to the commencement of proceedings and to the confirmation in a letter from Whitney Moore (on behalf of Mylan) to Philip Lee (on behalf of Teva) dated 17th October, 2017 that Mylan Teo is manufacturing the Mylan 40mg GA product at its manufacturing site in Inverin, Galway for the US market and that the product "*has been made widely available to patients in the US*" since the FDA approval for the product was obtained on 3rd October, 2017. It is then pleaded (at para. 15 of the amended particulars) as follows:-

> *"This information, coupled with the information outlined at paras. 8 to 14 above, shows that the Mylan GA 40mg/ml generic product being manufactured by [Mylan Teo] is a fully-finished product, that is, that it is contained in its FDA-authorised packaging with the relevant PIL inserted into the packaging. From a US drugs-regulatory perspective, the concept of manufacture of a product includes the processes of packaging the product for final sale; and given that 'Mylan Teo' is the only listed manufacturer for the Mylan GA 40mg/ml generic product for the US market, this shows that the product is fully finished (vis-à-vis being packaged) in [Mylan Teo's] Irish facility ready for sale in the US market."* (para. 15 of the amended particulars)

38. The amended particulars then plead as follows:-

> *"The activities of [Mylan Teo] insofar as they relate to the importation, stocking and/or manufacturing of the [Mylan 40mg GA product] for use in treating patients with a relapsing form of MS or who have experienced a first clinical episode and have a high risk of developing MS and covers 40mg GA subcutaneous injection administered three times per week, with at least a day between injections amounts to infringement of the 335 Patent."* (para. 16)

39. The amended statement of claim pleads that Teva has sustained loss and damage by reason of the alleged wrongful acts of Mylan Teo as pleaded in the amended particulars of infringement. Among the particulars of loss and damage pleaded are allegations that Mylan Teo has deprived and continues to deprive Teva and/or its servants or agents of the benefit of the proceeds of sale of the inventions the subject matter of the Patent and has damaged Teva's ability commercially to exploit the monopoly rights conferred on it by the Patent in respect of its inventions. It is further pleaded that the activities of Mylan Teo constitute an interference with Teva's constitutionally protected property rights in the Patent and that the activities of Mylan Teo are likely to result in a significant reduction in Teva's market share in the US market as well as causing "*significant price erosion*" in respect of Teva's Copaxone 40mg product which it is alleged may be permanent and irreversible. Teva further pleads that as a result of the reduction in market share and significant price erosion in respect of Copaxone 40mg Teva is likely to have to reduce or withdraw certain patient support services which relate to and are funded from sales of that product in the US (namely, its "Shared Solutions" services) as a result of which it is said Teva is likely to suffer damage to its "Teva" and "Copaxone" brands and reputations. It is further pleaded that if Teva loses a significant percentage of its revenues from the Copaxone 40mg product, Teva would be likely to be forced to delay or eliminate Copaxone-related research as well as research and development into other new products currently in development and that this would in turn lead to significant lost opportunities in the future. It is in those circumstances that Teva seeks declarations in relation to the alleged infringement of EP (IE) 335, injunctions and other orders and damages or an account of profits as well as all necessary accounts and enquiries and other reliefs.

40. While, as noted earlier, no defence and counterclaim had been delivered at the time of the hearing of this application and was due to be delivered shortly thereafter, it is clear from the evidence adduced on behalf of Mylan on the interlocutory injunction application and from the submissions made on its behalf that Mylan intends defending the proceedings on various different grounds but principally on the grounds that the Patent is invalid and that even if it were not invalid the Mylan 40mg GA product does not infringe the Patent. Those two issues go to the first issue which I have to consider as part of the test to be applied in adjudicating on the application for interlocutory injunctive relief. It is also clear from the evidence and submissions adduced on behalf of Mylan on the hearing of the interlocutory injunction application that Mylan will also deny the loss and damage being alleged by Teva.

The test to be applied

41. Teva's application is required to be considered in accordance with the test identified by the Supreme Court in *Campus Oil Ltd. v. Minister for Industry and Energy (No. 2)* [1983] I.R. 88 ("*Campus Oil*"). As is well known, the Supreme Court in that case in turn accepted the test contained in the speech of Lord Diplock in *American Cyanamid & Co. v. Ethicon* [1975] AC 396 (a case involving an application for interlocutory injunctive relief in a patent infringement case). The test has been discussed and elaborated upon in various respects by the Irish courts in the years since *Campus Oil*, including by the High Court (McCracken J.) in *B&S Ltd. v. Irish Auto Trader Ltd*. [1995] 2 I.R. 142 ("*B&S*") (a passing off case) and was summarised by Clarke J. (as he then was) in his judgment for the Supreme Court in *Okunade v. Minister for Justice* [2012] 3 I.R. 152 ("*Okunade*") (an immigration case). In a passage approved of by McGovern J. in *Gilead Sciences Inc. & another v. Mylan S.A.S. Generics (UK) Ltd. & others* [2017] IEHC 666 ("*Gilead*") (the most recent judgment of the High Court on an application for interlocutory injunctive relief in a patent infringement case), Clarke J. summarised the test as follows:-

> "• *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."* (per Clarke J. at para. 70, [2012] 3 I.R. 152 at 180-181).

42. The test in *Campus Oil,* has been approved of and applied by the High Court in a number of cases in which interlocutory injunctions had been sought in patent infringement cases. The leading cases in this respect are the judgments of the Kelly J. (as he then was) in *Smithkline Beecham plc. & others v. Genthon B.V. and (by order) Synthon B.V.* [2003] IEHC 623 ("*Genthon*"), and, most recently, of McGovern J. in *Gilead*.

43. In summary, it is first necessary to consider whether the plaintiff seeking the interlocutory injunction has established a serious issue to be tried (there being no difference in substance between this formulation and the *"fair or bona fide or serious question to be tried"* referred to in some of cases). In the event that the plaintiff does establish a serious issue or issues to be tried, the plaintiff must then demonstrate that damages would not adequately compensate it in the event that the interlocutory injunction were ultimately to be refused but the plaintiff were to succeed at trial. If the plaintiff cannot establish this, then the application for the interlocutory injunction must be refused. If the plaintiff can establish that damages would not be an adequate remedy for it, the court moves to consider whether damages would adequately compensate the defendant in the event that the interlocutory injunction were granted but the defendant were ultimately to succeed at trial. If damages would adequately compensate the defendant, then the interlocutory injunction would normally be granted subject to the plaintiff being in a position to demonstrate that it could meet any liability on foot of its undertaking as to damages. It is normally only when damages would not adequately compensate the plaintiff or the defendant that it is necessary to go on to consider the question of the balance of convenience.

44. Some further legal principles do arise for consideration in the context of the application of each element of the *Campus Oil* test and I consider those as they arise in my application of the test later in this judgment. For present purposes, however, it may be helpful to refer to the following observations of Clarke J. in relation to the application of this test. In *Okunade*, Clarke J. described the test as follows:-

> *"It can be seen that the analysis of McCracken J. [in B&S] involves an application of the basic principle, under which the court is required to minimise the risk of injustice, to the sort of facts which normally arise in the context of commercial or property litigation. If a plaintiff does not establish a fair case or serious issue to be tried then interfering with the position of the defendant by means of imposing an interlocutory injunction on that defendant would create a serious and disproportionate risk of injustice. Where damages are adequate on either side and likely to be capable of being recovered in practice then there is no great risk of injustice for the plaintiff or defendant, as the case may be, will, if they win the case, be either awarded damages (in the case of a plaintiff) or be able to recover damages on the undertaking (in the case of a defendant). There is, of course, no real risk of injustice if such recovery would adequately compensate the relevant party."* (per Clarke J. at para. 71)

45. Clarke J. also observed in relation to the balance of convenience as follows:-

> *"The test of the balance of convenience is, of course, itself expressly directed to deciding where the least harm would be done by comparing the consequences for the plaintiff in the event that an interlocutory injunction is refused but the plaintiff succeeds at trial with the consequences for the defendant in the event that an interlocutory injunction is granted but the plaintiff fails at trial".* (per Clarke J. at para. 72).

Preliminary points raised by Mylan

46. Before considering Teva's application in light of this test, I should first deal with a number of preliminary points which have been raised on behalf of Mylan which it contends should lead to a refusal of Teva's application without even embarking upon a consideration of the *Campus Oil* test.

47. Mylan makes two such preliminary points. The first is that Teva's application is tainted by delay. The second is that I should decline to entertain Teva's application on the grounds that courts in the United States have already declined similar applications made by Teva.

48. I can deal very briefly with both of these points. On the issue of delay, Mylan contends that Teva has been guilty of very considerable delay in seeking the interlocutory injunction. Teva disputes that assertion. It seems to me that while the question of delay is very much live in this case, the appropriate stage at which to consider that issue is in the context of the balance of convenience when a whole range of factors will fall to be considered including the question of delay and the not unrelated contention by Teva that Mylan had failed to "clear the way" prior to embarking upon the manufacture and launch of the Mylan 40mg GA product. In my view, the appropriate stage at which to discuss these various issues is in the context of the balance of convenience in the event that it becomes necessary to consider that question as part of the *Campus Oil* test. I do not believe that I should refuse Teva's application on the grounds of alleged delay without considering that question in the context of the *Campus Oil* test.

49. I have reached a similar conclusion in relation to the second of the preliminary grounds of objection raised by Mylan. Mylan asserts that the US Supreme Court refused to grant a stay on an order of the Court of Appeals for the Federal Circuit (on appeal from the United States District Court for the Southern District of New York) which had shortened the duration of an injunction preventing Mylan from launching its generic 20mg GA product. Mylan contends that much of the evidence on which Teva relies on support of its application of these proceedings was raised in support of its request for that stay and makes particular reference to the evidence of Mr. Hassler adduced by Teva in the course of that application. Mylan relies on the order of Roberts C.J. dated 18th April, 2014 refusing the stay, where he stated:-

> *"I am not convinced, however, that it [i.e. Teva] has shown likelihood of irreparable harm from denial of a stay. Respondents [including Mylan] acknowledge that, should Teva prevail in this Court and its patent be held valid, Teva will*

be able to recover damages from respondents for past patent infringement … Given the availability of that remedy, the extraordinary relief that Teva seeks is unwarranted."

50. In addition to relying on these observations of Roberts C.J. in those proceedings, Mylan also relies on the refusal by the Delaware District Court on 1st February, 2017 to grant an injunction to Teva pending appeal from the judgment delivered on 30th January, 2017 in the Delaware proceedings brought by Teva against Mylan and others for infringement of the relevant US Patents. The Delaware District Court agreed with the position adopted by the defendants (including Mylan) that an injunction pending appeal was "*unwarranted*" and it denied Teva's request for such relief. Mylan relies on the fact that Teva did not make any application for a stay or injunction to the United States Court of Appeals for the Federal Circuit.

51. Mylan prays in aid these developments in the United States in support of its contention that as a matter of comity of courts, and having regard to the fact that a consideration of Teva's application involves an extensive analysis and consideration of the US market for pharmaceutical products, I should, as a matter of legal principle and in the exercise of my equitable jurisdiction, decline to entertain Teva's application.

52. Teva rejects those assertions, relies on the fact that its claim is one brought by an extensive licensee in respect of an Irish patent against an Irish defendant to prevent the manufacture in Ireland of a product which infringes an Irish patent. It does not accept that principles of comity of courts or otherwise should preclude me from considering its application in accordance with the well-established test for such applications in this jurisdiction.

53. I am satisfied that it would not be appropriate to decline to entertain Teva's application on this ground. I accept that the observations of Roberts C.J. in the US Supreme Court arose in the context of different litigation arising out of a different product (Copaxone 20mg) and in respect of different patents. While the arguments made by Mylan in relation to developments on the US market have considerable merit, and while principles of comity of courts undoubtedly arise for consideration, in my view, these are all factors to be considered in the context of the balance of convenience, in the event that the application of the earlier stages of the *Campus Oil* test leads me to a consideration of the balance of convenience. I do not believe that it would be appropriate for me to decline to entertain Teva's application on any of these grounds. In those circumstances, I will proceed to consider the application in the context of the *Campus Oil* test.

Application of *Campus Oil* test
(1) Serious Issue to be Tried

54. Mylan originally submitted that no serious issue to be tried could arise as the proceedings were not properly constituted. The basis for that submission was that Teva brought the proceedings in its capacity as exclusive licensee of the Patent from Yeda. Mylan contended that while s. 51(1) of the Patents Act 1992 entitled Teva to bring proceedings in its capacity as exclusive licensee, s. 51(2) requires that the proprietor of the relevant patent be a party to the proceedings either as plaintiff or defendant. Mylan submitted that as Yeda was neither a plaintiff nor a defendant to the proceedings, the proceedings were commenced and were being maintained in breach of the provisions of section 51(2).

55. It is not necessary for me to resolve this issue as it was agreed during the course of the hearing of this application that Teva would apply to join Yeda as a co-defendant to the proceedings. An order was made on consent on the third day of the application (16th January, 2018) joining Yeda as a co-defendant to the proceedings. This point, therefore, fell away and does not require to be further considered.

56. The next question which arises for consideration in the context of whether there is a serious issue to be tried is the issue of the alleged invalidity of the Patent, EP (IE) 335. Mylan initially contended that there was no serious issue to be tried on the question of the validity of the Patent. It contended that the Patent was clearly invalid. It relied in that regard on:-

> (1) The judgment of Arnold J. in the High Court of England and Wales delivered on 26th October, 2017 which found that Claims 1 and 3 of EP (UK) 335 were obvious having regarding to Pinchasi;
>
> (2) The decision of the Delaware District Court of 30th January, 2017 finding the 250, 413, 302 and 776 Patents invalid;
>
> (3) The decisions of the US PTAB of August, September and December 2016 finding the 250, 413 and 302 Patents to be unpatentable.

57. Teva maintained that it had established a serious issue to be tried on the question of validity and pointed to the fact that the Patent had not been revoked or even the subject of any counterclaim for revocation and that Mylan had not sought to "clear the way" before commencing the manufacture and supply of its generic product.

58. At the outset of the hearing of this application, however, it was confirmed on behalf of Mylan that while it would be asserting the invalidity of EP (IE) 335 in its counterclaim and that the validity of the Patent would very much be in issue in the proceedings, it did not propose to advance a submission that there was not a serious issue to be tried on this point. This was not withstanding that, some two days before the hearing commenced, the Court of Appeal of England and Wales had refused Teva/Yeda permission to appeal from the decision of Arnold J. on the ground *inter alia* that the appeal would have no reasonable prospect of success. Mylan's decision not to advance a submission that no serious issue to be tried on the question of validity arose was no doubt driven by a realistic acknowledgment of the relatively low threshold which has to be surmounted in order to satisfy this part of the *Campus Oil* test.

59. While Teva will undoubtedly have an uphill task on this issue at the trial, in light of developments elsewhere, and particularly in England and Wales, I am prepared to accept for the purpose of this application that a serious issue to be tried does arise in respect of the validity of EP (IE) 335.

60. The next question which requires to be considered at this first stage of the *Campus Oil* test under this heading is the question of infringement. Teva submits that it has established a serious issue to be tried on the question of infringement by Mylan Teo of EP (IE) 335. As noted earlier, in its amended statement of claim and amended particulars of infringement, Teva claims that the manufacture by Mylan Teo of the Mylan 40mg GA product at its manufacturing site in Inverin, Galway for the US market amounts to an infringement of EP (IE) 335. Teva seeks injunctive relief restraining Mylan Teo, its servants or agents from directly or indirectly infringing that patent. Although Teva relies on both alleged direct infringement under s. 40 of the 1992 Act and indirect infringement under s. 41 of that Act, it is fair to say that Teva relies principally and emphasises to a greater extent its claim for direct infringement under s. 40.

61. Teva submits that under s. 40, the proprietor of a patent (and its exclusive licensee) has a right to prevent third parties without their consent:-

> "from doing in the State all or any of the things following:-
>
> > *(a) making, offering, putting on the market or using a product which is the subject-matter of the patent, or importing or stocking the product for those purposes …."*

62. Teva asserts that Mylan Teo is "*making*" a product which is the subject matter of the patent and reserves its position on whether Mylan Teo is also "*offering*" such a product. Teva also relies on the fact that the Mylan product is manufactured, packaged and labelled in Ireland with the PIL being inserted here also. It submits that at that point, the Mylan 40mg GA product is complete and is not subject to any other process before its ultimate supply to the patient (in the United States). In those circumstances, Teva contends that an infringement occurs in Ireland and should be restrained. It cites a number of authorities in support of its contention that infringement occurs in Ireland. These include *Smithkline Corporation v. DDSA Pharmaceuticals Ltd*. [1978] FSR 109 (an English case arising under the pre-existing legislative regime) and *An Bord Trachtala v. Waterford Foods plc*. (Unreported, High Court, Keane J., 25th November, 1992) (a passing off case). It also relies on the judgment of Arnold J. in *Virgin Atlantic Airways Ltd. v. Delta Airways Inc* [2010] EWHC 3094 (Pat) ("*Virgin Atlantic*") (a case concerning "kits of parts") and on the discussion of that case in *Terrell on the Law of Patents* (18th ed., Sweet and Maxwell, 2016) (paras. 14-47 to 14-53, pp. 425 to 427). While noting that this is not a "kit of parts" case, Teva relies on the conclusion of Arnold J. that it is arguable that dealing in a complete "kit of parts" in the UK for assembly outside the UK constituted infringement. Teva submits that even without the *Virgin Atlantic* case, it is plain that it has established a serious issue to be tried on the question of infringement. It submits that the word "*making*" in s. 40 of the 1992 Act must mean something.

63. In response, Mylan contends that Teva has failed to establish even a stateable case on the question of infringement and that consequently there is no serious issue to be tried on that question. It points to the fact that there is no "*use*" of the Mylan 40mg GA product in Ireland. Its only "use" is in the United States. Mylan refers to Claims 1 to 4 of EP (IE) 335 and submits that the Patent does not cover GA or a GA 40mg product per se but rather it is a use specific product. It contends that this is clear from Claim 1 which refers to GA "*for use in a regimen of three subcutaneous injections of a 40mg dose of [GA] every seven days … for use in treating a patient …*", with a similar reference in Claim 2 to "*(a) medicament comprising [GA] for use in treating a patient …",* with Claim 3 being dependent on Claim 1 and Claim 4 being dependent on Claim 2. It submits that the only new and inventive technical contribution made by EP (IE) 335 was the manner of administration of the drug three times per week and that this was accepted by Teva in the proceedings before Arnold J. in relation to EP (UK) 335.

64. Mylan submits that s. 40 requires that the subject matter of the patent to be made in Ireland and that the subject matter of EP (IE) 335 and the invention contained therein is the "*use*" of GA in accordance with the regimen referred to in Claim 1 and that such use is not taking place in Ireland. Mylan notes that Teva accepts that GA and the administration of 40mg/ml of that substance every second day are part of the state of the art (and referred to in Pinchasi), and that the claims in the Patent are confined to use in a regimen of 40mg three times per week since GA is a long known and unpatented substance. It submits that as an Irish patent covering "*use*" as the sole inventive contribution, EP (IE) 335 is a patent claiming a monopoly in respect of use in Ireland rather than *use* somewhere else. Mylan submits that the patent is not extraterritorial and does not, therefore, cover use outside Ireland. It too relies on *Virgin Atlantic*.

65. Mylan further relies on *Warner-Lambert Co., LLC v. Actavis Group PTC EHF* & Ors [2015] EWCA Civ 556, [2015] RPC 25 (Court of Appeal of England and Wales) ("*Warner-Lambert*"). It submits that that case makes it clear that any liability on the part of a manufacturer can only arise if the manufacturer knows or foresees that the patented use will take place as a consequence of its manufacture. Mylan submits that the manufacturer here (Mylan Teo) anticipates or foresees use of the Mylan generic product in the US which is not the subject matter of the Irish patent. It submits that it is a novel proposition to suggest that manufacture for the purpose of deploying a patented use in a foreign country, where the patent is inapplicable, is an infringement of an Irish patent.

66. In response Teva reiterated its reliance on *Virgin Atlantic*, disputed the relevance of *Warner-Lambert* and stressed that the product is being manufactured in Ireland.

67. I have set out the respective contentions of the parties on the question as to whether a serious issue to be tried exists in respect of Teva's case on infringement in order to demonstrate the gulf between the parties on this issue. The question of infringement is going to be a very significant question in the case should it go to trial. In contesting the existence of a serious issue to be tried on the question of infringement, Mylan in effect asks me to conclude at this stage in the proceedings that Teva's claim for infringement must fail on the ground that the patent in suit protects use and nothing else and that such use takes place exclusively in the United States with no use taking place in Ireland. There may be force to that submission but it seems to me that it would not be appropriate for me to resolve that issue on this interlocutory application. I must bear in mind the relatively low threshold which has to be met by a plaintiff seeking to establish a serious issue to be tried. I consider that both Teva and Mylan have raised arguable points on the question of infringement and that it would not be appropriate for me to resolve this question against Teva at this stage in the proceedings. I also bear in mind the approach taken by Arnold J. in *Virgin Atlantic* where, notwithstanding his strongly expressed reservations in relation to the issue as to whether a claim for direct infringement under the English equivalent of s. 40 of the 1992 Act can be made in the case of the manufacture, disposal, offer for disposal or keeping within the relevant territory of a complete kit of parts for assembly into a product where the assembly is to be carried out outside that territory, nonetheless he accepted that it was arguable that dealing in a complete "kit of parts" is an infringement in such circumstances. While the parties both accept that this is not a "kit of parts" case, and while each seeks to rely on aspects of the judgment of Arnold J. in *Virgin Atlantic*, the decision does demonstrate (if demonstration be needed) that a point can be arguable notwithstanding that the judicial view may be that it is not a strong point. I do not find it particularly helpful to analyse *Virgin Atlantic* in any great detail as the facts of that case differ significantly from the present case. Nor is it appropriate that I express any concluded view on the potential application of *Warner-Lambert* to the facts of this case. Teva argues that that case was primarily directed to the question of the mental element or *mens rea* which must exist to establish infringement whereas Mylan views the case from an entirely different perspective. The respective views and contentions of the parties on the case may fall for consideration further at the trial of these proceedings but I do not consider it appropriate to offer a concluding view on the merits of the parties' respective contentions.

68. In light of the relatively low threshold which must be established, I am satisfied that Teva has raised a serious issue to be tried on the question of infringement. It is necessary therefore to proceed to consider the next stage of the *Campus Oil* test.

(2) Adequacy of Damages

(a) For Teva

69. Teva contends that damages could not adequately compensate it in the event that its application for an interlocutory injunction is refused but it subsequently succeeds at trial.

70. Much of the affidavit evidence on both sides is directed to this issue. It is a critical issue in that if Teva cannot persuade me as a matter of probability that damages would not adequately compensate it, then its application must be refused and it would not be necessary to proceed to consider the other parts of the *Campus Oil* test. In *Curust Financial Services Ltd. v. Loewe-Lack-Werk* [1994] 1 I.R. 450 ("*Curust*"), the Supreme Court held, first, that "*[d]ifficulty, as distinct from complete impossibility, in the assessment of … damages*" is not sufficient to establish that damages would be an inadequate remedy (per Finlay C.J. at 469); and second, that an applicant for an interlocutory injunction must establish inadequacy of damages "*as a matter of probability*" (per Finlay C.J. at 471). Many applications for interlocutory injunctions in patent infringement cases are refused on the grounds that it was not established that damages would be an inadequate remedy: see, for example, *Genthon* and *Gilead*.

71. In its written submissions, Teva relied as a ground for asserting that damages would not be an inadequate remedy on the fact that it possesses a property right in the Patent. However, it was clarified in oral submissions on its behalf that Teva was not submitting that merely because it was seeking to protect a property right (being its interest as exclusive licensee of EP (IE) 335) it necessarily followed that it was entitled to an interlocutory injunction. It now submits that this issue is best addressed in the context of the assessment of the balance of convenience (in the event that the court gets to that stage of the *Campus Oil* test). In my view, that is probably correct and I propose to take that approach.

72. I first set out the grounds advanced by Teva in support of its contention that damages are not an adequate remedy for it. Teva relies on the affidavit evidence of Alan McBride (who swore affidavits on 19th October, 2017 and 20th November, 2017), John Hassler (who swore affidavits on 18th October, 2017 and 20th November, 2017) and Professor Jerry A. Hausmann (who swore affidavits on 18th October, 2017 and 20th November, 2017). Teva's counsel helpfully boiled down the case advanced by Teva to demonstrate the inadequacy of damages to six main points, or propositions drawing on the affidavit evidence adduced on its behalf. Those six main points or propositions (in the order advanced on behalf of Teva) are as follows:-

1. Teva will suffer a loss of specialised staff in the event that the interlocutory injunction is refused.

2. Teva will cut back on investment in research and development which result in fewer potential new drug developments.

3. In light of the particular nature of the market for MS therapies, in the event that an interlocutory injunction is refused and the Mylan 40mg product is permitted to remain in the market, patients may well migrate from Copaxone 40mg to other products or indeed other types of therapies but not to the Mylan 40mg product.

4. Teva will suffer a diminution in its market share on the US market for Copaxone 40mg which will persist, with such diminution in market share being irreversible.

5. Teva will suffer a diminution in price for Copaxone 40mg which will persist beyond the date of the trial and is likely to be irreversible.

6. There will be a very difficult causation issue as to whether any loss of sales by Teva or diminution in the price of Copaxone 40mg is caused by the entry onto the market of the Mylan 40mg product or whether any such loss is caused by other factors. In other words, Teva will be faced with the argument that any loss which it may sustain as a result of the entry onto the market of the Mylan product was not caused by that entry but by other factors.

73. The principal affidavits relied upon by Teva in support of its contention that damages would not be an adequate remedy are those sworn by Mr. Hassler and by Professor Hausman. Having regard to their significance in the context of this application, I will set out the main contentions advanced by each of them on this point.

74. I will deal first with Mr. Hassler's evidence. He is the Senior Vice President and General Manager for Teva USA's Central Nervous System ("CNS") Division and is responsible for the sales and marketing of Teva products in the US including Copaxone 40mg. He describes the market in the US for relapsing MS ("RMS") therapies as being "*dynamic and highly competitive*". He notes that when Copaxone 40mg was launched in late January, 2014 there were eight other approved therapies for MS. They included oral therapies, injectable interferon therapies, an infused monoclonal antibody therapy and Teva's Copaxone 20mg product. Since then five other products for treatment of RMS have been approved in the US. Mr. Hassler explains that Copaxone 40mg has net annual sales of well over US$2.5 billion and the largest market share for any single therapy for the treatment of RMS. It is also Teva's largest single product by revenue as well as by employee head count. He further states that a significant portion of all sales, marketing and patient support efforts for Teva's CNS Division in the US is dedicated to Copaxone 40mg which he states generates over half of the revenue for that division. He also explains that Teva invests a significant portion of the revenue generated from Copaxone sales to provide a range of supports to MS patients through Teva's "Shared Solutions" services. Those services are funded by revenue from the sales of Copaxone 40mg. He states that the services provide significant reputational benefit to Teva and to the Copaxone brand.

75. In explaining the effect of a launch of a generic product, such as Mylan's 40mg GA product, to compete with Copaxone 40mg, Mr. Hassler outlines the complex system by which patients in the US are supplied with drugs such as Copaxone 40mg (and the competing Mylan product) through what are called Third Party Payors ("TPPs"). He says that the vast majority of patients taking Copaxone 40mg in the US rely on a TPP, such as an insurance company, to pay the bulk of the price of their prescriptions and that the impact of the entry of a generic product onto the market leads TPPs to reconsider the price which they charge patients for Copaxone 40mg as well as whether they will continue to offer patients reimbursement for that product. He states that decisions of TPPs could play a significant role in restricting demand for Copaxone 40mg by placing restrictions on coverage for patients. Mr. Hassler provides a detailed account of how TPPs in the US compile lists of drugs known as "*formularies*" which are divided into tiers based on factors such as the quality of the drug, the price relative to competitors and other similar factors. He explains that to secure a competitive formulary placement, a drug manufacturer is often required to make concessions on price to the TPP by way of rebates or discounts. While Copaxone 40mg has a preferred formulary position on the insurance plans of approximately half of US commercial and government insurance companies, now that a generic competing product has become available in the US (i.e. the Mylan 40mg GA product), there will be an incentive for TPPs to direct patients towards the cheaper product by placing Copaxone 40mg in a less favourable formulary position than Mylan's product and Teva's branded competitors that do not have any generic competition, unless Teva further discounts its price in order to compete with the generics. Mr. Hassler also explains that many US jurisdictions require TPPs to automatically substitute generic GA 40mg in place of Copaxone 40mg for existing and new Copaxone 40mg prescriptions and that TTPs may also attempt to demand "*burdensomely high*" co-payments for Copaxone 40mg or place other restrictions or conditions on physicians' ability to prescribe Teva's product. He states that if Teva does seek to compete on price that will result in a significant price erosion which is irreversible. Further, even if Teva had a contractual right to return to the prices it charged for Copaxone 40mg

prior to Mylan's entry on the market, he states that the practical aspects of doing so would be "*complicated*" and the success of doing so is "*less than certain*".

76. Mr. Hassler contends that changes in coverage by TPPs will cause Teva to lose a substantial portion of its market share not only to a generic entrant (such as Mylan) but also to other RMS therapies. He asserts that Copaxone 40mg will lose market share and revenue following the entry of the Mylan 40mg GA product onto the US market but that it is unclear how much of any such loss of market share or revenue will be due to the entry of Mylan's product or the availability of other new RMS therapies or a combination of factors, as a result of which the issue of causation will be "*difficult if not impossible*".

77. Mr. Hassler further asserts that in the event that there is a significant loss of market share for Copaxone 40mg, Teva will be required to reduce the time and effort put into marketing, medical education and outreach efforts for Copaxone 40mg. He further asserts that Teva "*may also be required*" to reduce patient support services through its "Shared Solutions" services. This in turn could lead to further losses in market share for Copaxone 40mg and loss of reputation for Teva. He states that such loss of market share "*may not be reversible*" in that it is difficult to rebuild the prescribing habits of physicians once they are lost and it is also unlikely that patients who chose other branded products would return to Copaxone 40mg should the generic 40mg GA product be withdrawn later from the market. He also states that because of the shelf life of the generic competing product, wholesalers may build up a large supply of stock of Mylan's 40mg GA product (to match the two year shelf life of Copaxone 40mg). He relies on the experience of Teva and its affiliates of irreversible impacts of even temporary loss of exclusivity in the past and gives the example of Cephalon's product Amrix (Cephalon is a Teva affiliate). He states that Teva was unable to recover its market share even after the generic product was withdrawn shortly after its launch.

78. Mr. Hassler also contends that the launch of a generic 40mg GA product will lead to significant price erosion for Copaxone 40mg which will be irreversible. He says that many TTPs will demand significant discounts, rebates and other economic incentives to ensure continued coverage for Copaxone 40mg. He understands that Mylan's 40mg GA product is priced well below that of Copaxone 40mg and if additional generics enter the market, the price of Copaxone 40mg is likely to fall even further. He also states that if it is necessary for Teva to offer rebates to compete with the Mylan product, it is unlikely that rebates could be subsequently withdrawn even if Mylan were restrained from selling its generic product. This is due to the involvement of TTPs. Even if Teva were able to negotiate increased prices after the withdrawal of the Mylan product, he states that Teva would suffer a loss of goodwill with those TTPs. Therefore, he says that it is highly unlikely that Teva could ever restore the price of Copaxone to the pre-Mylan entry price.

79. Mr. Hassler expands on the alleged inevitable reduction in Teva's patient support services through the "Shared Solutions" programme which he asserts will lead to patients not adhering to their therapies and cause damage to the reputation of Teva and the Copaxone brand which will be irreparable and not quantifiable in damages. He further expands on the contention that if Teva loses a significant percentage of its revenues from Copaxone 40mg (a substantial portion of which is invested in research and development), Teva "*would likely be forced to delay or eliminate*" Copaxone-related research as well as the research and development of new products currently in development which will lead to significant lost opportunities which, he says, are unquantifiable both for Teva and for patients.

80. Professor Hausman, an economic expert, supports the position advanced by Mr. Hassler. He notes that Copaxone 40mg is the leading MS therapy in the US. However, he states that it faces "*intense competition*" from a large number of branded therapies. Like Mr. Hassler, he describes the market for MS treatments as "*dynamic and competitive*" and asserts that the competitiveness and dynamism of the market is illustrated by changes in market shares (of the various MS therapies available on the US market) that occurred between 2011 and 2017. He agrees with Mr. Hassler that the market for MS therapies is "*highly promotionally competitive*". Professor Hausman also elaborates on the importance of TTPs and the placement of drugs on formularies and echoes what is stated by Mr Hassler.

81. Professor Hausman outlines in his affidavits the impacts of generic entry on the market for a drug and asserts that when a generic version of a prescription drug comes onto the market it can have severe economic impacts on the branded product. Those impacts include causing an immediate and significant erosion of market share of the branded product and significant price erosion which lead to substantial economic losses to the owner of the branded product which are irreversible and "*extremely difficult to quantify*".

82. Professor Hausman expresses the opinion that competition from Mylan's 40mg GA product would cause Teva to suffer "*immediate, substantial and long lasting harm to its financial position, reputation and human resources*" which he states could not be reversed or adequately compensated by way of damages. He expands on this in his affidavits.

83. In relation to loss of market share, Professor Hausman expresses the opinion that Teva will suffer an immediate and substantial loss of market share which will be irreversible and "*extremely difficult*" to quantify even where "*the generics are subsequently required to exit the market if Teva prevails after a final judgment*". I would observe in this context, however, that Professor Hausman's opinion in this regard must be confined to the situation where Mylan may be restrained from manufacturing and supplying the Mylan 40mg GA product as there can be no question of an Irish court requiring "*the generics*" to exit the US market. That scenario simply does not and cannot arise as a consequence of any order which may be made on Teva's application. Professor Hausman asserts that Teva will lose significant market share for Copaxone 40mg to Mylan's 40mg GA product as well as to other branded (non-GA products) due to the effects of TTP restrictions, the reduction in promotion and patient support services and wholesaler inventory stocking practices (echoing what Mr. Hassler says in his affidavits). He puts forward various reasons as to why such market share will be lost. These include loss of preferred coverage on formularies by TTPs; reductions in promotional efforts due to the presence of generic competition with the "*share of voice*" decreasing substantially in circumstances where competing therapies will be promoting the benefits of their products to physicians; the unlikelihood of Teva being in a position to regain its market share after the withdrawal of the generic product from the market because of "*inventory overhang*" (with bulk purchasers stockpiling lower priced generic product); and the unlikelihood of Teva being in a position to recover market share due to patients and physicians deciding to use different therapies who, he says, would be unlikely subsequently to switch back or return to Copaxone 40mg.

84. Professor Hausman asserts that if the Mylan 40mg GA product were permitted to remain on the US market for a year or longer and if it were subsequently required to be withdrawn from that market, Copaxone 40mg would be unable to regain fully its pre-existing market share. He refers to Teva's prior experience with Amrix, where a competing product was launched by Mylan in May 2011 and was only the market for twelve days before being restrained yet Teva was and remains unable to return sales of Amrix to their pre-generic launch levels. Professor Hausman explains that from an economic perspective the long-term effects of a generic launch on market share are "*impossible to predict accurately*" with the calculation of further profits in the "*actual*" and "*but for*" worlds having to extend until at least 2030 with such a calculation being "*difficult to estimate*" in light of the "dynamic nature of the market" and that it will be "*extremely difficult*" accurately to calculate how much of the loss of sales of Copaxone 40mg is due to the entry of the Mylan product on the market as compared with other recent and expected future entrants or as a result of other market events. He further asserts that the economic and reputational harm to Teva by Mylan would be "*impossible to accurately calculate".*

85. As regards alleged price erosion, Professor Hausman asserts that the presence of the Mylan product on the US market would also be likely to lead to irreversible price erosion for Copaxone 40mg in light of what Mr. Hassler says about the need for Teva substantially to increase discounts and rebates on Copaxone 40mg to TTPs to preserve a competitive formulary position. He relies on what Mr. Hassler says about this. He asserts that it would be unlikely that TTPs would permit Teva to renegotiate prices back to their pre-Mylan levels and also relies on the strong bargaining position of TTPs. He also asserts that Teva would be prevented from being able to apply standard annual price increases to its product while the Mylan product is on the market. He opines that it would be "*extremely difficult, if not impossible*" for Teva to remedy any such price erosion without hurting its market, reputation and relationships with purchasers. He also refers to the difficulty (if not impossibility) of attempting to calculate damages by trying to predict the future price and sales of Copaxone 40mg up to 2030. He asserts that an economist could not estimate future damages with "*sufficient precision*" adequately to compensate Teva.

86. Professor Hausman then addresses the question of the alleged likely loss of qualified patient support staff and resulting future lost sales. He asserts that if the Mylan product remains on the market the loss of revenue which will be suffered by Teva will "*almost certainly*" require Teva to reduce the size of its "Shared Solutions" patient support staff and its nursing force (relying on Mr. Hassler in that regard) and that this will give rise to unquantifiable reputational harm to Teva in the eyes of prescribers and patients as well as the loss of "*such highly trained and experienced workers*" being likely to cause further economic harm. In that regard, he states that even if the Mylan competing product were withdrawn from the market, it is "*unlikely*" that Teva could remedy the harm (including reputational harm) associated with the reduction in its "Shared Solutions" services and also that the experience and expertise of Teva's staff, once lost, could not be quickly rebuilt. He states that the loss of goodwill and reputation associated with this would be likely to cause further separate loss of market share and sales and that it is unlikely that such losses could ever be regained. All of these factors, he asserts, represent irreparable harm to Teva.

87. Teva's position on the adequacy of damages issues is addressed further in supplemental affidavit sworn on his behalf by Dr. McBride, Mr. Hassler and Professor Hausman. Mr. Hassler helpfully summarises Teva's position on the alleged inadequacy of damages to it as follows:-

> "(a) He asserts that Teva has and will continue to suffer irreversible reduction in its market share for Copaxone 40mg not only to Mylan but to other competing branded MS therapies which will cause it to reduce marketing, medical education and outreach efforts resulting in damage to reputation and further damage in terms of loss of market presence;
>
> (b) He asserts that Teva already has and will continue to suffer irreversible price erosion for Copaxone 40mg due to the actions of TTPs requiring rebates from Teva to ensure Copaxone 40mg maintains a preferred status on their formularies which could not easily be reversed or prices increased while in the removal of the Mylan 40mg GA product and the continued demanding by TTPs of price rebates from Teva;
>
> (c) He asserts that the loss in market share and loss of profits as a result of irreversible price erosion may cause Teva to reduce its "Shared Solutions" services which will cause further unquantifiable damage to Teva in respect of the loss of trained and experienced staff and damage to its good-will and reputation in the eyes of patients who will no longer have access to those services; and
>
> (d) The loss in market share and loss of profits as a result of price erosion, he asserts, will cause Teva to reduce its investment in future research and development leading to significant lost opportunities for Teva in the future which are unquantifiable.

88. Mr. Hassler expands on these points in his supplemental affidavit. In support of his contention that the presence of the Mylan competing product on the market will cause "*real and concrete*" harm to Teva, which he says has already begun, Mr. Hassler refers to and exhibits an extract from a report dated 3rd November, 2017 (Teva's CNS MS Weekly Report) showing a reduction of 17% in Copaxone 40mg prescriptions for the week ending 3rd November, 2017 when compared with the week before the launch of the Mylan 40mg GA product and the new Mylan product representing 8% of prescriptions which had been filled by Copaxone 40mg prior to the Mylan launch. Mr. Hassler explains that data as indicating that Teva is potentially losing patients not only to Mylan but also to competing non-GA MS therapies and that there was a variation in the data from week to week due to the dynamic nature of the market. He also asserts that since the launch of the Mylan 40mg GA product there has already been significant erosion in the price of Copaxone 40mg which he says Teva will be unable to fully reverse. As regards the "Shared Solutions" service, Mr. Hassler states that significant losses to Teva's market share will "*inevitably*" lead Teva to reduce those services as investment in them is funded from sales of Copaxone. He states that while Teva will "*do its upmost*" to continue to promote and support Copaxone, Teva "*may*" have to reassess its level of investment in those services in circumstances where it is likely to suffer significant reduction in market share and loss of profits.

89. Professor Hausman, in responding to the evidence of Professor Hay on behalf of Mylan, stresses the problem of estimating post-trial damages and relies on the Teva's experience in the Amrix litigation as illustrating that future damages cannot be recovered. Therefore, he says that even though prescription data may be available from third parties such as Quintiles IMS, the existence of such information does not mean that the alleged harm to Teva is recoverable.

90. Professor Hausman rejects the suggestion that the impact of generic entry can be determined by pharmaceutical economists (as Professor Hay on behalf of Mylan contends) and asserts that forecasts such as those made by Teva of the effect of the launch of the Mylan product are necessarily imprecise as well as not being directly relevant to the calculation of damages.

91. As regards price erosion and loss of market share, Professor Hausman refers to evidence that Teva is reportedly offering a 30% discount on Copaxone 40mg in response to the entry of the Mylan product on the US market and also Mr. Hassler's evidence that Teva has had to substantially increase price rebates to TTPs. Professor Hausman further relies on the experience in the *Plavix* litigation in the United States (where Mylan contends that Plavix sales increased notwithstanding temporary generic entry) which he claims supports Teva's case on irreparable harm.

92. Professor Hausman rejects the suggestion that a reduction by Teva in marketing and provision of patient support services would be a voluntary choice (as contended by Mylan). He states that the issue is whether it would be economically rational for Teva to maintain such programmes in the face of generic competition and that it does not make economic sense to maintain such spending as the generic competitor "*free rides*" on the promotional effort by the branded entity. Professor Hausman repeats the assertion that Teva will suffer irreparable harm due to the loss of skilled employees and that it is unlikely that Teva would be able to rehire all of them as they would have sought other jobs in the interim period. He states, therefore, that Teva would face a long-term reduction in the human capital of its workforce which would affect its future profitability.

93. While accepting that the market share for Copaxone 40mg has been relatively stable over the previous five quarters, as Professor Hay points out, on behalf of Mylan, Professor Hausman asserts that this is no guarantee that its market share in the absence of the launch of the Mylan product would remain stable until trial and beyond. Further, he asserts the relative stability of Copaxone 40mg over the past two quarters does not make it any easier to predict how its pricing market share would change after the trial when the Mylan product was removed from the market.

94. Professor Hausman concludes his evidence by stating that in the absence of an interlocutory injunction, the continued presence of the Mylan 40mg GA product (on the US market) will cause irreparable harm to Teva due to factors including loss market share, price erosion and the loss of qualified patient support staff. He contends that this harm extends in the future and cannot be estimated with sufficient precision to enable Teva to be fully compensated in damages. He states that these types of harm are among those which US Courts have found to be irreparable.

95. It is on the basis of this evidence which, in oral submissions at the hearing, Teva advanced by reference to the six points or propositions referred to above. In support of its contention that damages would not be an adequate remedy to it, Teva relies on a number of cases in its written and oral submissions. Teva submits that it satisfies the test in *Curust* in that it would be impossible and not merely difficult to assess damages for the harm caused to it. Teva seeks to distinguish the outcome in *Curust* by reference to the fact that in that case the court was dealing with a "*stable and well established market"* in contrast to the market at issue in this case. As regards the duration of its damages claim, Teva relies on the fact that EP (IE) 335 expires on 2030 in contrast to the Supplementary Protection Certificate (SPC) at issue in *Gilead*. In *Gilead*, the SPC was to expire in February 2020 and the monopoly, therefore, only had a short time left to run.

96. As regards market related considerations, Teva relies on *Metro International v. Independent Newspapers* [2006] 1 ILRM 414 ("*Metro*") where, in a trademark case, Clarke J. observed that the in the context of the particular market at issue in that case (the market for free newspapers), the question of damages had to be assessed against a "*significantly speculative background*" in a market which was not an established one. Clarke J. further stated that even where the market is established there will always be difficult questions as to whether the business which the new entrant/alleged infringer has gained is the precise level of business which the incumbent is alleged to have lost.

97. Teva seeks to distinguish *Genthon* and *Gilead* on the basis that in those cases the market in question was a stable one with data and evidence readily available in relation to the market and no suggestion of a risk of multiple generic companies entering the market. Teva seeks to contrast the evidence in those cases with the present case where, it contends, the market for MS therapies in the United States is dynamic and highly competitive.

98. As regards irreversible price erosion, Teva seeks to distinguish *Gilead* where McGovern J. held that price reductions were unlikely and in any event, even if they occurred, it would not be difficult to work out any damages in light of the short period left in respect of the SPC.

99. Teva further relies on the English cases of *BASF v. Sipcam (UK) Ltd.* [2013] EWHC 2863 (Pat) ("*BASF*") and *Novartis AG v. Hospira UK Ltd.* [2013] EWHC 1285 (Pat) ("*Novartis*") as examples of cases where the English Courts have accepted arguments that an irreversible price reduction can render damages an inadequate remedy. Teva further relies on the decision of Jacob J. in *Smithkline Beecham plc. Apotex Europe Ltd.*, [2003] FSR 30 ("*Apotex*") to similar effect. As regards the irreparable loss which Teva alleges will arise due to the loss of skilled staff, Teva relies on the decision of Costello J. in *Powerteam Electrical Services Ltd. v. ESB* [2016] IEHC 87 ("*Powerteam*"). In that case, a public procurement case, the applicant (who was resisting an application by the respondent to lift the automatic suspension on the award of a contract) adduced evidence which was not controverted that there was likely to be a real issue retaining staff in the absence of work for the applicant and that it would be very difficult for the applicant to start again from scratch. On the basis of that uncontroverted evidence, Costello J. held that damages would not be an adequate remedy for the applicant were the automatic suspension lifted. Teva relies on this case in support of its contention that the loss of specialised staff gives rise to a loss which is not capable of being compensated in damages.

100. In response, Mylan contends that damages are an adequate remedy for Teva. It relies on the evidence adduced in affidavits affirmed by Ms Sunderland and sworn by Mr Tighe and Professor Hay.

101. Mr. Tighe, Head of MPI contends that the alleged potential losses put forward by Teva are speculative and hypothetical and have not materialised and may very well not materialise in the marketplace. Furthermore, he asserts that all of the alleged harm suffered by Teva relates to the market in the United States and that no alleged harm has been suffered by Teva in Ireland. He disputes the contention that the continued sale of Mylan's generic GA product in the United States will cause patients to switch from Copaxone 40mg to an alternative non-GA therapy and asserts that this would not be a standard market reaction. He further contends that insofar as it is suggested that Teva would stop providing services to patients or promoting its products, such would be an entirely voluntary choice on the part of Teva. He contends that any such a course by Teva would be inconsistent with the press release issued by Teva on 4th October, 2017 where it promised to "*continue to promote and support"* Copaxone. Mr. Tighe asserts that any alleged harm to Teva is readily quantifiable and that Mylan can meet any award as to damages. Further, Mylan undertakes to keep full and proper records and books of account in respect of the Mylan 40mg GA product sold in the United States.

102. Professor Hay, a pharmaceutical economist, contends that Teva has not identified any irreparable harm that it has or will suffer as a result of the continued presence on the US market of the Mylan 40mg GA product. He describes Copaxone 40mg as a "*mature product*" and that its "*branded lifestyle [is] nearing its end*". He further states that Copaxone 40mg was an extension of another product's lifecycle, Teva's Copaxone 20mg. He states that, in an apparent recognition that Copaxone is nearing the end of its lifecycle, Teva has steadily increased prices for Copaxone 40mg since its launch (in 2014). He notes that Teva increased the price of the product by more than 25% in that period.

103. Noting that, by the time he swore his first affidavit on 8th November, 2017, Mylan had launched and had already achieved a substantial presence in the US marketplace in respect of the Mylan 40mg GA product, he refers to evidence from Mylan that for the week ending 27th October, 2017, its share of new prescriptions was 16.2% and 8% of total prescriptions.

104. Professor Hay addresses Teva's claim of irreparable harm based on loss of market share, reduced prices and downstream lost sales based on losses of support services and investment in research and development. While disagreeing that Teva will suffer the alleged losses, Professor Hay contends that such losses can be quantified and calculated in monetary terms. He states that in the US, pharmaceutical economists and experts in damages routinely evaluate the impact of an infringing product and that this is well within the ability of a pharmaceutical economist. He gives the example of the *Amrix* litigation (relied on by Teva) where he says a damages claim was formulated in essentially identical circumstances to the present case. He further points to the public forecasts given by Teva of the impact of generic competition for Copaxone 40mg. He refers to the fact that prescription drug sales are highly

tracked and audited by third parties such as Quintiles IMS whose auditing includes prescription level data from more than 100,000 US data collection organisations. He states that data collected from Quintiles IMS can provide a measure of the amount of prescriptions lost as a result of a generic entry. He states that there are other similar organisations which provide similar data. He states that few other industries have such "*detailed and granular tracking of sales*" and that as such data is available, he disagrees that it would be difficult to determine the impact of Mylan's launch. Further, he states that since the Mylan product has already been launched, many of the supposedly unpredictable factors such as market shares for Copaxone 40mg and other GA 40mg products, rebates and discounts and quantities sold will be known and directly discoverable through data provided by Mylan, Teva and others, such as Quintiles IMS.

105. As regards alleged price erosion and loss of market share and revenue in respect of Copaxone 40mg, Professor Hay contends that neither Professor Hausmann nor Mr. Hassler has offered evidence of Teva's marketplace actions after the launch of the Mylan product. He gives the example of *Plavix* which she says, did not suffer irreparable harm following a generic launch and the subsequent removal of the generic from the market.

106. Professor Hay disputes the contention that Teva will respond to the launch of the Mylan product by lowering the price of Copaxone 40mg. He asserts that the literature does not support that response to generic competition. Further he asserts that Teva has provided no actual evidence that it made any price adjustments following the launch of the Mylan product.

107. Professor Hay further disputes the contention that Teva may be required to reduce its patient support services through "Shared Solutions". He asserts that Teva has failed to demonstrate why it would be forced to do so. In this regard, he makes three points. First, he says that Teva continued to maintain such patient support services for Copaxone 20mg despite the launch of a generic competitor, Glatopa. Second, he says that such a decision by Teva would be a voluntary choice made by Teva in order to preserve its profit margin. Third, he says that even if Teva were to cease such support services, patients would continue to receive support services (from Mylan). He also contends that the argument by Teva that the continued presence of the Mylan product on the US market will cause Teva to let staff go, leading to future loss sales is hypothetical and unsupported. As regards the cessation of marketing by Teva, Professor Hay contends that this would be entirely within Teva's control and that it has not been suggested that Teva cannot afford to maintain expenditure on such marketing, medical education and outreach efforts for Copaxone 40mg. Further, he contends that given its brand recognition, he would expect that Copaxone would be less sensitive to reduced marketing efforts compared to newer products or generic products. He further disputes the contention by Teva that a loss of operating profits in respect of Copaxone 40mg will affect its ongoing expenditure on research and development. Professor Hay believes that any such potential loss of operating profits would be unlikely to have any effect on ongoing research efforts for MS drugs or any other drugs. He notes that Teva, a global company with US$21.9 billion annual revenue in 2016 and gross profit of US$11.9 billion, would have access to the global debt and equity markets if it needed money to fund promising MS research.

108. In response to the argument made by Teva in relation to loss of market share, Professor Hay states that any such loss can be compensated for in damages. As regards the argument that Teva may lose market share not only to the Mylan product but also to non-GA products, Professor Hay argues that this is a recognition that Copaxone 40mg is in the late stage of its lifecycle and faces competition from a host of other MS therapies. It does not support an argument that the continued presence of the Mylan product on the US market will cause irreparable harm to Teva. He also disputes the assertion that patients will be reluctant to take a lower cost generic product (the Mylan product). He contends that it will be a straightforward matter to calculate any changes arising from market trends in Copaxone 40mg occurring during the period of alleged harm. He describes the market for branded Copaxone as being "*stable and established*" and refers to Teva's third quarter 2017 results which he says showed that the US market for Copaxone has remained stable over the last five quarters. Therefore, he contends that changes in sales trends can provide a direct measure of damages for Teva if it succeeds at trial. In those circumstances, he rejects the case made by Teva that price erosion, unpredictability of losses, irreversibility and difficulties of quantification give rise to irreparable harm. He concludes that Copaxone is a very long established product with a clear market track record and that the court would be in a position to quantify damages, if required.

109. Professor Hay further gives evidence in relation to the role of TTPs and the placement of the competing products on formularies. Teva could take action to prevent any worsening of its formulary status such as by matching generic price reductions through rebates and patient coupons (and he says that industry sources suggest that Teva is doing that already). He suggests that such rebates etc. could be done confidentially (although this is disputed by Teva). In any event he states that any such rebates or coupons would be clearly capable of being calculated in monetary terms. He also disputes the suggestion that this would give rise to irreversible price erosion.

110. In their supplemental affidavits, Mr. Tighe and Professor Hay respond on behalf of Mylan to the further evidence adduced by Teva on this issue. Mr. Tighe makes the point that the fact that Teva must now compete with Mylan does not result in irreparable harm. Mr. Tighe disputes the contention that Teva is losing market share not only to Mylan but to other MS therapies and he disagrees with Teva's interpretation of IMS data. He explains that the data relied upon by Teva demonstrates that prescriptions of all GA products for seven weeks prior to the launch of the Mylan product accounted for 31.1% of the total US MS market whereas for the five weeks after the Mylan launch, prescriptions of all GA products accounted for 29.9% of the total US MS market. Therefore, he says that the variance in prescriptions is just 1.2% as between the pre-Mylan launch and the post-Mylan launch. He further states that the data relied on by Teva shows that the US MS market has been "*fairly stable*". He disputes that the fact that there may be week-to-week variations in IMS data can prevent Teva from being in a position to calculate damages.

111. In his supplemental affidavit, Professor Hay contends that Professor Hausmann has advanced a new theory in his supplemental affidavit to the effect that while it may be possible to determine pre-trial damages, post-trial damages present more difficulty. Professor Hay disagrees with this argument on a number of grounds. First, he states that this type of analysis is exactly what economists such as Professor Hausmann and Professor Hay are trained to do. Second, he asserts that the "*relative stability*" of the Copaxone 40mg market makes the analysis comparatively straightforward. Third, he states that the market for MS products (in the US) is highly regulated requiring FDA approval in contrast to a non-regulated market where there are more competitive inputs impacting the market. This, he says, makes the post-trial damage analysis comparatively easier than in many other markets.

112. While not disputing that the entry of the Mylan 40mg GA product onto the US market will result in a lower market share for Teva and lower prices for purchasers, Professor Hay contends that this does not amount to irreparable harm to Teva. The issue he says is whether economists will be able to quantify the loss of market share or decrease in price after the fact and his view is that they can.

113. As regards patient support services, Professor Hay contends that it is economically rational for Teva to continue such programmes. He contends that offering patient support services and marketing is rational even in the face of long expected generic competition. He cites Teva's press release of 4th October, 2017 in which Teva's CEO stated that Teva had planned for the eventual introduction of a generic competitor and that "*we remain confident in patient and physician loyalty to Teva's Copaxone due to its*

recognised efficacy, safety and tolerability profile, and we will continue to promote and support the product". Further, Professor Hay relies on the fact that notwithstanding that Mylan product was launched in October 2017 there is no evidence that Teva has discontinued marketing Copaxone or that it has or is likely to reduce patient services.

114. Professor Hay also contends that any renegotiation between Teva with TTPs would amount to routine commercial activity which is to be expected when facing generic competition and that whatever rebates or discounts Teva pays or gives to TTPs can be documented and serve as evidence in respect of its claim for damages. He disputes the existence of irreparable harm and points to the fact that Teva can rely on pre-Mylan launch and post-Mylan launch contracts and agreements with TTPs to determine damages.

115. In those circumstances, Professor Hay contends that while competition from the Mylan product may reduce Teva's sales and may lower prices for consumers, that alone does not create irreparable harm. He says that this is particularly so in the pharmaceutical industry where competition is limited by regulatory oversight, where the impact of generic competition is likely to be documented by internal documentation such as agreements with and rebates to TTPs and where there is a wealth of third party data containing sales information which demonstrate the marketplace impacts of generic competition.

116. In its submissions on this issue, Mylan contends that the market for Copaxone 40mg is stable and well-established. It relies on Teva's Q3 2017 results and on Professor Hay's evidence. It further relies on the three price increments in respect of Copaxone 40mg of more than 25% since 2015. It notes in its submissions Professor Hausmann's acceptance that the market for Copaxone 40mg was relatively stable over the previous five quarters (prior to the Mylan launch). Mylan further relies on the extent of the data available in respect of total weekly prescriptions of MS therapies as referred to by Mr. Hassler in his second affidavit and as exhibited by Mr. Hassler at exhibit "JH1" to that affidavit. Mylan refers to the "*extraordinary granularity*" of the data available. It also relies in submissions on the fact that it has undertaken on affidavit to keep full and proper records and books of account in respect of sales of the Mylan 40mg GA product. Further, Mylan relies on the estimates given by Teva of the impact on its revenues of the launch of the Mylan 40mg GA product on the US market and refers in this context to the press release issued by Teva on 4th October, 2017 which refers to the impact on its earnings of the Mylan launch. Mylan refers also to Teva's financial outlook for 2017 which predicts the impact of the Mylan launch on Teva's revenues.

117. As regards the six propositions relied on by Teva in support of its contention that damages would not be an adequate remedy for it, Mylan addresses each of these in turn. As regards the potential loss of specialised staff, Mylan notes that this was the last factor identified as a form of irreparable harm in the affidavits initially sworn on behalf of Teva and yet it was elevated to the first such ground in the submissions advanced on this issue by Teva. Mylan draws attention to the fact that in Teva's press release of 4th October, 2017, it was stated that Teva "*will continue to promote and support the product*" i.e. Copaxone 40mg. Mylan contends that any decision to reduce staff numbers would be a voluntary decision. Mylan seeks to distinguish the decision of Costello J. in *Powerteam* from the present case on the grounds that the evidence in that case was that the business was going to close and that the staff were, therefore, going to be lost. Further, Mylan contends that this alleged harm, if it is to be suffered, would be suffered by Teva US and not the plaintiff company. Finally, in this context, Mylan submits that if the point had merit, it would have been expected that it would have been raised by way of an application for injunctive relief in respect of the launch of the Mylan competing product in the United States and yet no such injunction was sought. It further states that the point was raised (albeit with less emphasis), in the application before the US Supreme Court which did not accept the point. Mylan further criticises the extent of the evidence put before the court on this issue referring to it as being extremely generalised and querying what staff it is suggested will be let go.

118. As regards the alleged irreversible diminution in market share and in price, Mylan relies on the decision of Kelly J. in *Genthon* (and it submits that the patent at issue in that case did have a long time to run). Further on that point, Mylan submits that the only basis on which an Irish court could assess the alleged harm to Teva on the basis of a legal monopoly in the United States up to 2030 would be if the US Courts reversed the position already taken by them and found Teva's US patents to be valid and then excluded all generic competitors from the market. Mylan further relies in this context on the apparent acceptance by Teva that the market position in respect of Copaxone 40mg has been relatively stable over the previous year prior to the Mylan launch.

119. As regards the harm consisting of the loss of potential new drug developments, Mylan submits that this was the very last factor identified by Mr. Hassler and not identified at all by Professor Hausman in his first affidavit. Further, it submits that on Teva's own evidence, it takes ten to fifteen years to develop a drug and that as a consequence this is a type of harm which is too remote to rely upon. Further, insofar as it is suggested that Copaxone related research and development will be affected, Mylan submits that this should be seen in a context of Copaxone being a relatively old and mature product and in circumstances where the US Patents have been invalidated.

120. As regards the contention that patients may choose MS therapies other than the Mylan 40 mg GA product and that this could create causation difficulties, Mylan refers to Professor Hausmann's acceptance that the market is relatively stable and submits that the effect of the entry of the Mylan product onto the market can be observed on a weekly basis on Teva's own evidence (referring again to the weekly prescription data exhibited by Teva). Mylan further submits that if Teva is correct and that it is only because of the entry of the Mylan product onto the market that sales will be diverted to Mylan and to other parties, then this would be readily objectively observable in the available data. Finally, notwithstanding Teva's evidence of a declining position on the formularies even prior to Mylan's entry, Mylan refers again to the acceptance by Professor Hausmann on behalf of Teva that the market was relatively stable prior to the entry on the market of the Mylan product.

121. Mylan relies on the decision of the Supreme Court in *Curust* and submits that Teva has not established that it would be impossible to assess damages and, having regard to the nature of the market, it would be possible for evidence to be adduced which would enable a judge to make a reasonable assessment of the effect of the Mylan launch. Mylan further relies on *Genthon* and on *Gilead*. On the point that the SPC in *Gilead* was to expire in 2020 whereas the EP (IE) 335 will not expire until 2030, Mylan submits that Teva exclusively relies on the harm which it alleges it will suffer in the US in circumstances where Teva can have no expectation of a monopoly on that market until 2030 or until any other date as there is no legal impediment to any company entering the market there (subject to FDA approval). Relying on *Gilead*, Mylan submits that the same arguments as regards irreversible price erosion were rejected by McGovern J. Mylan further notes that there are cases in which courts have had no apparent difficulty in assessing damages in patent infringement cases. In that context, Mylan refers to the judgment of Kitchin J. in *Ultraframe v. Eurocell* [2006] EWHC 1344 (Pat) ("*Ultraframe*").

122. Having carefully considered and assessed the evidence and submissions of the parties on this issue, I now set out my conclusions. There is no dispute between the parties that the test to be applied is that set out by Finlay C.J. in *Curust*. In that case, in describing the loss which would be incurred by the plaintiff if an interlocutory injunction were not granted but the plaintiff were to succeed in the action, Finlay C.J. described the loss as being:-

> "*Clearly and exclusively a commercial loss, in what had been, apparently, a stable and well-established market*" (per Finlay C.J. at 468).

Finlay C.J. continued:-

> *"In those circumstances, prima facie, it is a loss which should be capable of being assessed in damages both under the heading of loss actually suffered up to the date when such damages would fall to be assessed and also under the heading of probable future loss. 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*." (per Finlay C.J. at 468 – 469)

Further, in describing the approach which the court should take in determining the issue as to whether damages are or are not an adequate remedy, Finlay C.J. stated that:-

> *"… it is necessary that I should reach a conclusion on the affidavit evidence as to whether it has, as a matter of probability, been established at this stage for the purpose of the interlocutory injunction that damages would not be an adequate remedy …"* (per Finlay C.J. at 471)

123. These views were all expressly endorsed, in the context of similar applications to the present one, by Kelly J. in *Genthon* and by McGovern J in *Gilead*. I adopt and apply them in my analysis below.

124. Therefore, difficulty in measuring damages is not sufficient. It must be established as a matter of probability that the assessment of damages will be impossible by reason of the particular harm which may be suffered by the plaintiff. Having considered all of the affidavit evidence adduced, I am not satisfied that Teva has established that it would be impossible for a court to assess damages in the event that its application for an interlocutory injunction were refused but it was to succeed ultimately at trial. I am not satisfied that Teva has established as a matter of probability that it would be impossible for a court to assess such damages. I reach that conclusion for several reasons.

125. First, I am satisfied that notwithstanding the averments of Mr. Hassler and Professor Hausman that the market for MS treatments in the United States is dynamic and competitive, this does not mean that it will be impossible to assess damages at trial. I find the evidence advanced by Mylan on this issue much more compelling. I am particularly persuaded by the evidence of Professor Hay that the loss of market share, for example, is a classic type of loss which is compensatable in damages. I am further persuaded by Professor Hay that it will not be an impossible task for a court, assisted by expert economic and other financial and market evidence, to calculate damages on the basis of any change in the market position of Copaxone 40mg during the period of alleged harm. I attach considerable significance to the evidence of Professor Hay (which I accept for the purposes of this application) that the market for Copaxone 40mg is a stable and established one, particularly so over the five quarters prior to October 2017 as demonstrated by Teva's third quarter 2017 financial results. I attach further significance to the fact that Professor Hausman does not take issue with the description of the market for Copaxone 40mg as being relatively stable over those past five quarters although I do note Professor Hausman's qualification to that acceptance that merely because the market was stable for those five quarters there is no guarantee that it will remain stable until the time of trial and beyond. That may be so (although I note that no countervailing data were put before the Court), but I do not believe that this demonstrates that damages would be impossible to quantify on any of the grounds asserted by Teva. While it is true that five other companies filed ANDAs seeking approval to market generic GA 40mg products, as of the date of the hearing of this application, none of those ANDA filers have yet received approval for its generic product. On the evidence, therefore, there is no immediate risk of other generics entering the market, at least between the date of the determination of this application and the date of trial in circumstances where it should be possible for the trial to take place by the end of 2018/early 2019.

126. Second, while much reliance is placed by Teva on the fact that EP (IE) 335 does not expire until 2030 and while many of the arguments and much of the evidence on behalf of Teva on the alleged impossibility of assessing damages is based on that scenario, I believe that such reliance is misplaced in circumstances where, while the arrival of other generics on the market may not be immediate, once approval is obtained, there is no legal or regulatory bar to those generics entering the US market and proceeding to compete with Copaxone 40mg. No relief which an Irish court can grant will prevent that from happening. To the extent, therefore, that great reliance is placed by Teva on the monopoly given to 2030 under EP (IE) 335, that reliance is misplaced in circumstances where the monopoly on the US market is more apparent than real. While I have found that there is a serious issue to be tried on the question of validity, I cannot ignore the fate of Teva's US patents and the fate of EP 335 in the various European jurisdictions referred to above.

127. Third, I am not at all persuaded that the alleged potential irreversible loss of market share and price reductions for Copaxone 40mg creates an impossibility of assessing damages. The extent to which the market share for Copaxone 40mg may fall will likely depend on the actions of TTPs and the placement on formularies operated by those TTPs of Copaxone 40mg and of the Mylan 40mg GA product and in turn Teva's reaction to the actions of those TTPs. The affidavit evidence before me does not establish that Teva has in fact had to reduce its prices for Copaxone 40mg although that may well be a consequence of the arrival of Mylan's competing generic product. Further, Teva may have to offer discounts and rebates to TTPs and others purchasing Copaxone 40mg. However, I prefer the evidence adduced on behalf of Mylan and in particular the evidence of Professor Hay and Mr. Tighe that such losses, if they arise, are all capable of being calculated and ultimately assessed in terms of damages. As noted above, I accept the evidence that the market for Copaxone 40mg has been relatively stable for the five quarters prior to October 2017. I am also satisfied that the extent of the data available in respect of weekly prescriptions is such as to greatly assist in the assessment and calculation of damages. The extent of the available data is exemplified by the evidence of Mr. Hassler on behalf of Teva. As stated earlier, he exhibited, at "JH1" to his second affidavit, an extract from a Teva CNS MS weekly report dated 3rd November, 2017 containing data compiled by a third party, IMS. The available data clearly show the total number of weekly prescriptions not only for Copaxone 40mg but also Copaxone 20mg, the Mylan 40mg GA product, the generic GA 20mg product and non-GA MS therapies. The information is shown in very considerable detail and shows movement in the number and percentage of prescriptions on a weekly basis. This sort of information will be of great assistance to the experts and to the court in assessing damages. I should say that on the basis of that data, (admittedly for the period from August to October 2017), the US market for MS therapies was very stable both pre- and post-launch of the Mylan 40mg GA product. I note Mr. Tighe's evidence that the data show a variation in prescriptions of all GA products of just 1.2% pre- and post the launch of the Mylan 40mg GA product.

128. The evidence put by the parties before the court for the purpose of the interlocutory injunction application does not, in my view, support the contention that it would be impossible to assess damages because of the potential loss of market share by Teva for Copaxone 40mg not only to the competing Mylan product but also to non-GA therapies. That scenario does not appear to have arisen on the basis of the data put before the court by Teva (in exhibit "JH1"). In any event, as Mylan contends, the data will show any loss

of sales by Teva whether to competing GA or non-GA therapies, all of which losses Teva contends are due to the arrival of the Mylan product on the market. I do not accept, therefore, that the potential for patients to migrate from Copaxone 40mg to other non-GA products is borne out by the evidence before me. Even ifi it were, for the reasons advanced by Mylan, I am not satisfied that it would render damages impossible to assess.

129. Fourth, I do not accept that any reduction in price which Teva may have to implement for Copaxone 40mg is not capable of being compensated in damages. On the evidence, if any such reductions have to be given by Teva, whether by way of discounts or rebates to TTPs or others, they will be objectively ascertainable. There is no reason why Teva cannot put such evidence forward in support of its damages claim. Nor am I persuaded that Teva has established as a matter of probability that any difficulty of calculating post-trial damages means that damages are an inadequate remedy. The courts can assess such damages and are assisted by experts called by the parties in doing so. Damages are regularly claimed in patent infringement proceedings and, in my view, in circumstances where there will be objective evidence as to such price reductions (if any) caused by the arrival of the Mylan product on the market, there is no reason why the court conducting the trial of these proceedings will not be in a position to assess damages both up to and after the trial. While that may not necessarily be a simple exercise and may indeed be one of some difficulty, it does not, in my view, cross the threshold of impossibility.

130. Fifth, in my view it is possible to distinguish the English cases relied upon by Teva such as *BASF*, *Novartis* and *Apotex* on the basis of the evidence available on this application in relation to the US market. To the extent that there is any difference in principle between the approach taken in the English cases and that taken in the Irish cases such as *Genthon* and *Gilead*, and I do not believe there is, I would in any event prefer the approach taken in the Irish cases. Both Kelly J. in *Genthon* and McGovern J. in *Gilead* considered the particular evidence in respect of the market for the pharmaceutical product at issue and, on the basis of that evidence, concluded that damages would adequately compensate the plaintiff in each case. I have taken the same approach in this case and on the basis of the evidence available in relation to the US market and on the basis of the expert evidence adduced by the parties in relation to the operation of the US market, I am not persuaded that Teva has established as a matter of probability that it would be impossible to assess damages at a trial of these proceedings.

131. Sixth, I am not greatly assisted by the reliance on the cases involving *Amrix* and *Plavrix*, as I have very little evidence in relation to those cases. In any event, there is a clear dispute between the respective experts on the relevance of those cases and I am not satisfied that as a matter of probability they demonstrate that damages would be inadequate in this case.

132. Seventh, the interpretation of market data and the assessment of loss for the purposes of damages is quintessentially a task performed by economists and other experts engaged by the parties. I see no reason why the evidence of such economists and other experts would not be deployed by the parties in this case by way of assistance to the court in assessing damages. In this regard I note the evidence adduced before Kitchin J. in the English case of *Ultraframe* where the court had the assistance of forensic accountants in measuring damages in a patent case.

133. Eighth, as regards the alleged harm caused by the loss of specialised staff which has been put forward by Teva as a ground of loss which could not be compensated for in damages, I am not persuaded that the evidence supports the case made by Teva. While it is undoubtedly the case that in *Powerteam* Costello J. held that on the evidence before the court, which was not controverted, that there was a real issue retaining specialised staff in the absence of any work for the applicant company and that it would be very difficult to start up again from scratch at the end of the proceedings (without such staff), and that on that basis damages would not be an adequate remedy for the applicant, I am not persuaded by the evidence adduced by Teva on that issue in this case. I have referred earlier to the evidence put before the court by Teva in support of this ground of alleged uncompensatable loss. Both Mr. Hassler and Professor Hausman put forward this ground of loss in the context of patient support staff and nursing staff. Professor Hausman states that Teva's staff has "*over a decade of experience in supporting Copaxone and its users*" and that "once lost, that expertise and experience could not be rebuilt quickly". Unlike in Powerteam, Mylan has disputed this head of claim. For example, Professor Hay describes it has been "*hypothetical and unsupported*" and further queries why the launch of the Mylan product would force Teva to terminate or significantly scale back its patient services programme.

134. While linked to the alleged harm which Teva states will be caused as a result of the winding down of its support services in the event that an injunction is not granted (and I will deal with this point below), in my view, the evidence put forward by Teva in support of this ground of alleged irreparable harm is not convincing. Teva has put very little information before the court as to the staff involved apart from the fact that they are involved in patient support and nursing. There is very little detail on this. I am not told for example: what staff are involved? What are their qualifications? If they have to be taken off Copaxone duties, why can they not be deployed elsewhere in the Teva organisation? How would it be impossible for a company like Teva to source and recruit such staff at a later stage, if necessary? Further, I do not find it plausible that a global entity the size of Teva, being, on its own evidence, the world's largest generic pharmaceutical company and one of the top ten largest global pharmaceutical companies with sales of over US$21.9 billion in 2016 employing more than 46,000 people worldwide in more than sixty countries (with global revenues from Copaxone for 2016 of US$4.283 billion), would let go such support staff. It is much more likely that they would be deployed elsewhere within the organization. However, even if they did have to let such staff go, I am not persuaded that it would not be possible to re-engage them or other qualified staff in the event that an injunction was refused but Teva were to succeed at trial. I have not been provided with evidence that the staff involved are of such a degree of specialisation that a global entity of the size and strength of Teva would not be in a position either to keep on those staff or, if they had to let them go, could not re-engage them or other similarly qualified staff in the event that Teva were to succeed at trial.

135. Ninth, I do not find persuasive the evidence put forward by Teva to the effect that it would have to reduce the level of support provided to MS patients under its "Shared Solutions" service and that that this diminution in support available to MS patients would represent an irreparable loss which cannot be quantified in damages and also a loss to the reputation of Teva and to the Copaxone brand itself. I do not find persuasive the evidence put forward by Teva that it is likely to reduce these support services between now and the trial in the event that an injunction is refused. The comments made above in relation to the size and nature of the Teva organisation worldwide apply equally in this context. I believe that, on the basis of the evidence before the court, it is most unlikely that Teva will reduce such services in advance of the trial. I believe that this is clear from the news release issued by Teva on 4th October, 2017 following the anticipated launch by Mylan of the Mylan 40mg GA product. In that press release, Dr. Yitzhak Peterburg, Teva's Interim President and CEO stated:-

> *"We remain confident in patient and physician loyalty to Teva's Copaxone due to its recognised efficacy, safety and tolerability programme, and we will continue to promote and support the product. As we are closing the third quarter, it is too soon to officially comment on any change to our full year business outlook."*

In my view, the averments made on behalf of Teva in support of its application for the interlocutory injunction must be read in the context of, and are not consistent with, that statement by its CEO.

136. Tenth, nor do I accept that a refusal to grant an interlocutory injunction in circumstances where Teva ultimately succeeds at trial will cause irreparable harm to Teva in terms of a reduction or elimination of Copaxone-related research as well as research and development of other new products currently in development. I am not persuaded by the evidence put forward by Teva on this point. Further, I note that in a submission made on 6th October, 2017 to the United States House Committee on Oversight & Government Reform, Debra Barrett, Teva's Senior Vice-President, Global Government Affairs & Public Policy described the average time taken from drug discovery to approval has been ten to fifteen years at a cost of approximately €2.6 billion. In my view, even if there was any reduction in research and development undertaken by Teva in other drugs in the period between the date of the hearing and determination of this interlocutory injunction application and the date of trial, and I am not persuaded on the evidence that that is in any way likely, it is of such a short duration relative to the length of time it takes on average to develop a drug from discovery to approval as to be irrelevant and, in any event, too remote to be considered. Furthermore, insofar as Copaxone-related research is concerned, I am not at all persuaded that there will be any such reduction in research between now and the date of trial. Even if there were, I do not accept that that could not be compensated for in damages.

137. Eleventh, I have taken into account the undertaking offered to the court on behalf of Mylan by Mr Tighe to keep full and proper records and books of account of the Mylan 40mg GA product manufactured in Galway and sold in the United States.

138. Twelfth, there is no question but that Mylan is a mark for damages in the event that Teva succeeds at trial. That has not been put in issue on this application.

139. In conclusion, therefore, I am not persuaded by any of the grounds advanced by Teva in support of its contention that damages would not be an adequate remedy for it if the interlocutory injunction application is refused but Teva ultimately succeeds at trial. My conclusion on that issue is sufficient to dispose of Teva's application without the need to proceed to consider other aspects of the *Campus Oil* test. However, for completeness I will proceed to consider those other aspects as I have no doubt whatsoever that the balance of convenience favours the refusal of Teva's application, in any event, for the reasons I set out a little later.

(b) For Mylan

140. I now turn to consider the question of the adequacy of damages for Mylan in the event that an interlocutory injunction is granted to Teva but Mylan ultimately succeeds at trial. If I am wrong in my conclusion that damages would be an adequate remedy for Teva and damages would be an adequate remedy for Mylan on foot of Teva's undertaking as to damages, then it would be appropriate to grant Teva's application for an interlocutory injunction without moving to the balance of convenience stage. However, if I am wrong in my conclusions that damages would be an adequate remedy for Teva and if they are inadequate by reason of the various market dynamics and other considerations put forward by Teva, in relation to the US market then it is almost certain that damages would equally be an inadequate remedy for Mylan based on similar considerations. It would then be necessary to move to the balance of convenience. It is in that context that I consider this issue.

141. Teva contends that damages would be an adequate remedy for Mylan. It says that for a number of reasons. First, it contends that any damage caused as a result of the grant of an interlocutory injunction to Teva will not be suffered by the defendant, Mylan Teo, but rather by MPI or other Mylan-related entities in the US which, Teva submits, is not relevant in the context of this application. Teva submits that the affidavits filed on behalf of Mylan do not address any specific harm to Mylan Teo in the event that the injunction were granted. Second, and without prejudice to that position, Teva contends that if Mylan is entitled to rely on the potential loss to other Mylan entities then such loss is quantifiable and Mylan can be compensated in damages. In this context, Teva relies on *Gilead* where McGovern J. was satisfied that the product in question was only dispensed to a small cohort of patients through a limited number of centres as a result of which sales of the product together with sales of its generic competition in the event that an injunction was refused were readily traceable.

142. In this case, in support of its contention that damages would be an adequate remedy for Mylan, Teva relies on the evidence of Mr. Tighe on behalf of Mylan to the effect that the Mylan 40mg GA product is a unique product which is unlike a typical generic product market for various reasons. First he says that GA itself is a speciality drug distributed primarily to a smaller group of pharmacists (speciality pharmacies) across the US than the normal routes of supply of pharmaceutical drugs and as a result of the more limited distribution there are fewer customers for direct sales of the generic GA 40mg product compared with a typical generic.

143. Second, Mr Tighe states that the potential customer base for a generic GA 40mg product is also further limited by the rise of Pharmacy Benefit Management companies ("PBMs"), with three major PBMs comprising approximately 80% of the GA market covering more than 180 million people. Mr. Tighe contends that if Mylan were restrained from selling its 40mg GA product and from pursuing contracts with PBMs, it will have lost its opportunity and most of the markets. Third, Teva further refers to the assertion by Mr. Tighe that an injunction would harm Mylan by fuelling industry speculation as to Mylan's ability to bring a complex product to market and to maintain a presence on that market.

144. In response to all of this, Teva submits, primarily through the evidence of Professor Hausmann and also in submissions, that Mylan and, in particular, Mr. Tighe, fails to acknowledge that an interlocutory injunction in respect of Mylan's 40mg GA product will not remove its 20mg GA product launched at the same time, from the market. Therefore, it says that Mylan will still have a speciality product presence through which it can develop its relationships with speciality pharmacies and PBMs.

145. It is fair to say, I think, that much of Teva's response to the case made by Mylan that it would suffer irreparable loss if an interlocutory injunction were granted in respect of its 40mg GA product is centred on the fact that no injunction is sought by Teva in respect of Mylan's 20mg GA product which will remain on the US market.

146. Finally, in this context, Teva disputes the assertion that Mylan Teo., is the "first mover" on the 40mg GA generic market in the United States. At its height, Teva submits that another Mylan entity (MPI) may be.

147. For these reasons, Teva contends that damages would be an adequate remedy for Mylan in the event that the interlocutory injunction were granted but Mylan were ultimately to succeed at trial.

148. Mylan contends, however, that it would suffer irreparable harm if an interlocutory injunction were granted. In support of that position Mylan relies principally on the affidavits of Mr. Tighe and Professor Hay and on its written and oral submissions. It contends that the market for the Mylan 40mg GA product is immature and growing with Mylan benefiting from first generic mover advantage. It further contends that following its launch on 4th October, 2017 and in the absence of any application to or order from a US Court restraining the sale of that product, the product remains on the market and is being supplied to pharmacies, prescribed by physicians and taken by patients who benefit from the support services provided by Mylan.

149. Mylan relies on the "first mover" advantage gained by it and contends that the proceedings are an attempt to cause that advantage to stall and dissipate which will assist other generic producers to enter the US market in circumstances where there are at least five pending ANDAs seeking approval from the FDA in respect of a generic 40mg GA product in the United States. Mylan submits that it would be difficult, if not impossible, for it to re-establish itself in the face of such competition in the event that an interlocutory injunction was granted but that it was to succeed at trial.

150. It further relies on Mr. Tighe's evidence as to the unique nature of the market in the United States for 40mg GA products which, as noted above, Mr. Tighe states is unlike a typical generic product market. The first two reasons for this were set out above, namely, that GA is a speciality drug distributed to smaller groups of pharmacists (speciality pharmacies) across the US with limited distribution and fewer customers for direct sales of the generic product as well as the significance of PBM companies limiting the potential customer base for the generic 40mg GA product. Further reasons are also given by Mr. Tighe as to why patients and their prescribing doctors may be reluctant to switch GA products even if the Mylan 40mg GA product were permitted back on the market after trial. Mr. Tighe states that patients rely on 40mg GA products for long-term ongoing care and that there may be a reluctance to switch to a generic manufacturer of an injectable product from a branded injectable product and that, given those sensitivities, particularly where Mylan has already entered the market, patients and prescribing doctors who lose access to the Mylan product as a result of an interlocutory injunction may not switch back to the Mylan product after trial. Mr. Tighe describes this as an "*erosion of trust*" which he says would also spill over to Mylan's 20mg GA product. Further, he states that if an interlocutory injunction is granted to Teva which allows Mylan's competitors to enter and operate in the market ahead of Mylan, it would be extremely difficult to secure the return of customers who may have switched to the generic competitors.

151. Mylan relies significantly on its position as the "first mover" into the generic market for 40mg GA products in the United States as this allows Mylan to gain a significant customer base in the US and enables it to seek and secure long-term contracts for the 40mg GA product and for its 20mg GA product. It further suggests that such "first mover" advantage encourages companies like Mylan to invest in research and development. Mr. Tighe contends that loss of this "first mover" advantage will lead to a loss which cannot be compensated in damages in that multiple generic competitors may be permitted to enter on to the US market while an interlocutory injunction is in place which will enviably erode Mylan's market share and market price.

152. Mr. Tighe further relies on the impact of any injunction on Mylan's reputation in the US and states that it took more than eight years to bring the product to the market in circumstances where industry participants had doubted Mylan's ability to do so. Mylan contends that an injunction even for a short period would fuel such speculation as to Mylan's ability to bring a complex product to market and to maintain a presence on that market which would be extremely damaging to its reputation. He further submits that if speciality pharmacies in the US question Mylan's ability to bring a product such as this to the market and to maintain it there, they would be less likely to negotiate with Mylan for further complex products sold to the same channels or will at least demand more favourable terms from Mylan which may extend beyond Mylan's GA products and into other products in the speciality pharmacy sector. Finally, Mylan relies on the possibility of other generics entering the market in the meantime who would be able to benefit from unfair generic competition as they will be able to enjoy the advantage of entering the US market in a preferred situation where they do not have to compete with Mylan.

153. Finally, Mylan disputes the contention that it is appropriate only to look at the position of the defendant, Mylan Teo. It suggests that it would be inequitable to confine the examination to Mylan Teo only in circumstances where Teva has asked the court to look at the harm which will be caused to Teva entities in the United States. It submits that Teva's true complaint is in reality not the manufacture of the product in Ireland but rather its presence and sales in the US market and that the real attack is, therefore, on Mylan entities in the US. An approach which looks only at the position of Mylan Teo would, Mylan submits, facilitate the careful targeting of defendants. Finally, Mylan submits that it is open to the court to consider the effect of an interlocutory injunction on identified third parties and to cater for any harm to such third parties by requiring an appropriately tailored undertaking as to damages as a condition of granting the interlocutory injunction. Mylan relies on this context on the English case of *Allied Irish Bank plc. v. Ashford Hotels* [1997] 3 All ER 309.

154. I now set out my conclusions on this aspect of the test which, as noted above, are not strictly necessary in light of my conclusions on the adequacy of damages for Teva.

155. First, I am satisfied that it is appropriate for me to take into account the harm which may potentially be caused to Mylan entities other than the defendant, Mylan Teo, if an interlocutory injunction were granted but the defendant ultimately succeeds at trial. While it is correct that the only Mylan defendant in the case is Mylan Teo, the manufacturer of the Mylan 40mg GA product, the primary target for Teva in seeking the interlocutory injunction is the presence of the Mylan product on the US market. All of the harm relied upon by Teva in support of its application is harm caused in the US as a result of the launch and continued presence of the Mylan 40mg GA product on that market. While other Mylan entities are involved in the importation and supply of the product in the US, Teva has chosen only to sue Mylan Teo, the manufacturer. I agree with the submission advanced by Mylan that to confine consideration of the harm caused by the grant of the interlocutory injunction only to a defendant chosen by the plaintiff, in circumstances where other related or associated entities will suffer harm, would be inappropriate as it would encourage the selective targeting of defendants and the exclusion of defendants who would suffer harm by the grant of an interlocutory injunction to enable a plaintiff to make the point that no harm was suffered by the chosen defendant. I do not believe that this would be an appropriate approach to take as a matter of principle. It is particularly inappropriate in a case such as this where so much of the case being made by Teva is the harm which it says is being caused to it on the US market by Mylan entities operating in that market and not by the defendant Mylan entity. Teva did not refer to any authority on this point. Mylan referred to one, *AIB v. Ashford*, which is not directly on point. However, as a matter of principle, it seems to me that a court cannot blind itself or be blinkered in considering the harm that may be caused by the grant of an interlocutory injunction by reference only to the entity which a plaintiff has chosen to sue.

156. In my judgment, therefore, it is appropriate to consider the potential loss or harm not only to the defendant, Mylan Teo, but also to other Mylan entities in the United States. Indeed, it would be unfair and somewhat contradictory to do otherwise in circumstances where at least some of the loss and harm relied upon by Teva is loss and harm suffered not by the Teva entity which has brought the proceedings but by other Teva entities in the United States.

157. Having so concluded, however, I have to say that if I were required to consider the issue I would not be persuaded that the evidence would support a conclusion that damages would not adequately compensate Mylan if an interlocutory injunction were granted but Mylan were ultimately to succeed at trial. In my view, the potential loss and harm relied upon by Mylan would probably be capable of being compensated in damages. I agree with the submission made by Teva that the circumstances which led McGovern J. in *Gilead* to find that damages would adequately compensate the plaintiff seeking the interlocutory injunction in that case apply by analogy to the issue as to whether damages would adequately compensate Mylan. I am not persuaded that the fact that GA is a speciality market or the fact that a significant amount of the Mylan 40mg GA product is supplied through speciality pharmacies or indeed through PBMs would support a conclusion that damages would not be an adequate remedy for Mylan. Indeed, as Teva

suggests, they do demonstrate the relatively small number of supply points through which the Mylan product is being channelled i.e. through the speciality pharmacies most of which appear to be owned by PBMs. Further, the extent of the data available in terms of MS therapy products prescribed and supplied in the US as described earlier in relation to the supply of Copaxone 40mg and other MS drugs would similarly be available in the event that an interlocutory injunction was granted. Further, I am not persuaded by the argument that if an injunction were granted, other generic companies will enter the market and take patients who would otherwise use the Mylan generic product. As noted earlier, there is no evidence as to when other generic companies may enter the market for 40mg GA products while at least five have filed ANDAs, it is not clear whether and, if so, when the FDA will grant the requested arrivals and when the products of those ANDA filers will come on the US market. This is one of the reasons why I concluded that the sort of market disruption which Teva has relied on to show the damages would not adequately compensate it is somewhat realistic in terms of the time frame at issue here. There is no evidence that a launch by another generic or other generics is imminent. Nor is there any indication as to any expected timeframe for the launch by other generics of their competing product. There is no evidence to suggest, for example, that other generics will launch in the period between the determination of the interlocutory injunction application and the date of trial.

158. While an imminent risk of launch by another generic might well have persuaded me that the loss by Mylan of its "first mover" advantage in this market in the US would give rise to irreparable loss, two factors have lead me to conclude that it is not the case on the evidence. The first is, as I have noted, no launch by another generic is imminent. The second is that it is at least possible, as Teva pointed out in its closing oral submissions, that Mylan may obtain an exclusivity period of 180 days under the provisions of s. 505(j)(5)(B)(iv) of the Hatch-Waxman Act (see the FDA approval letter to Mylan dated 3rd October, 2017). While that letter referred to the possibility that Mylan may obtain such an exclusivity period (thereby precluding other generics from launching competing products before that period has expired), it appears that the FDA had not made any formal determination, at least at that stage, as to whether Mylan was entitled to the benefit of that exclusivity period. No further evidence was put before the court as to whether the FDA ever formally determined that issue. In any event, I am not satisfied that the "first mover" advantage here means that damages would not be an adequate remedy for Mylan. At best it may fall to be considered as part of the overall balance of convenience as McGovern J stated in *Gilead*.

159. As regards the other grounds relied upon such as the potential damage to its reputation in the event that an interlocutory injunction was granted as it would fuel industry speculation as to Mylan's ability to launch and keep its product on the market, I do not believe that this amounts to irreparable loss. The fact is that Mylan did launch its 40mg GA product and it has been on the market now for several months. In the event that an interlocutory injunction were granted, there are plenty of tools of communication for Mylan to explain to the market the basis of such an interlocutory injunction, arising as it does in the context of a hotly contested patent infringement suit, something not entirely unknown in the pharmaceutical sector. I believe that damages would, therefore, probably be an adequate remedy for Mylan.

160. In summary, therefore, I have concluded that damages would adequately compensate Teva in the event that an interlocutory injunction was not granted but Teva were to succeed at trial. I would also have concluded, were it necessary for me to reach that part of the *Campus Oil* test, that damages would also be an adequate remedy for Mylan. However, that conclusion is unnecessary in light of my first conclusion in relation to the adequacy of damages for Teva.

161. If, however, I am incorrect in my view that damages would be an adequate remedy for Teva by reason, for example, of the market dynamics and the potential entrance on the US market by other generic competitors, then almost by definition damages would not be an adequate remedy for Mylan and had I reached the conclusion that damages would not be an adequate remedy for Teva because of these market dynamics I would inevitably have formed the same view in relation to Mylan on the basis of the same market dynamics.

162. While not strictly speaking necessary in light of my earlier conclusions, for the sake of completeness and in the event that I am wrong in those conclusions I will proceed to consider the question of the balance of convenience. I do so on the assumption, contrary to the views I have just expressed, that damages would not be an adequate remedy for either Teva or Mylan.

(3) Balance of Convenience

163. If I am wrong in my conclusion in relation to the adequacy of damages for Teva (and for Mylan), it would then be necessary to move to consideration of the final stage in the *Campus Oil* test, namely, to consider where the balance of convenience lies. Essentially, as explained by Clarke J. in *Okunade*, the test of the balance of convenience is directed to an assessment of "*where the least harm would be done*" by comparing the consequences for the plaintiff in the event of a refusal of an interlocutory injunction where the plaintiff is ultimately successful at trial with the consequences for the defendant if an interlocutory injunction is granted but the plaintiff ultimately fails at trial (see para. 72 of *Okunade*). This stage of the *Campus Oil* test, therefore, involves the court considering which result would cause the least harm and avoid the greater risk of injustice.

164. It will be recalled that by reason of their conclusions that damages would adequately compensate the plaintiff in each case, Kelly J. and McGovern J. in the leading cases in this area, *Genthon* and *Gilead*, on which both Teva and Mylan relied in this application, did not find it necessary to consider the question of the balance of convenience.

165. It is in this context that I consider the question of the balance of convenience below under a number of different headings. Overall, my assessment is having considered the potential harm which may be caused to Teva by refusing to grant an interlocutory injunction and to Mylan by granting that application, that the greater harm would be caused to Mylan than to Teva and the greatest risk of injustice would be to grant Teva's application. In those circumstances, I conclude that the balance of convenience favours the refusal of Teva's application. I set out my reasons below.

(a) Property Rights

166. As noted earlier, while initially suggesting that one of the factors to be considered in the assessment of the adequacy of damages was whether the conduct sought to be restrained by means of the injunction sought involves the infringement of a property right, Teva accepted in oral submissions on its application that the proper place for consideration of this issue is probably at the balance of convenience stage of the *Campus Oil* test. Mylan agreed.

167. Teva submits that its interest in EP (IE) 335, as exclusive licensee, is a property right. Teva contends that significant weight should be given in the assessment of the balance of convenience to the fact that it seeks to protect a property right. It relies on the fact that EP (IE) 335 will not expire until 2030. Teva relies on the decision of Clarke J. in *Metro* (a trademark case). In that case, Clarke J. considered the relevance of the claim as being one alleging infringement of a property right under the heading of "Adequacy of Damages/Balance of Convenience" albeit that he considered the issue primarily from the perspective of the adequacy of damages in that case. Teva does not assert that there is a rule of law or a presumption that where a property right is in issue, an interlocutory

injunction should be granted almost as a matter of course.

168. Mylan submits that applications for an interlocutory injunction to protect property rights do not fall into a separate category of case. Mylan relies on the view of Kelly J. in *Genthon* that the test for the grant of an interlocutory injunction in a patent infringement case is the same as in any other case. It also relies on the decision of McGovern J. in *Gilead* that there is no rule or presumption that damages would not be an adequate remedy where infringement of an intellectual property right is alleged and that the fact that a property right is in issue is "*no more than a factor to be taken into account in applying the principles to be found in Campus Oil and Okunade*" (per McGovern J. at para. 22). Mylan also contends that it is not relevant that the patent at issue will not expire until 2030. It submits that Teva cannot expect that a monopoly on the US market will last until the expiry of the patent in 2030 in light of entitlement of others to enter the US market, subject to FDA approval. It further relies on the fact that in *Genthon* the patents at issue were in the relatively earlier stages of their respective terms. Finally, it relies on the decision of Murphy J. in *Falcon Travel v. Owners Abroad* [1991] 1 I.R. 175 where, notwithstanding his acknowledgment that the right which the plaintiff sought to protect in the passing off proceedings was "*a property right which would ordinarily be safe-guarded by the grant of an injunction*", Murphy J. refused to grant a perpetual injunction and awarded damages instead.

169. My conclusion on this issue is as follows. It is clear that there is no rule of law or presumption that in a case where the plaintiff who seeks to protect a property right an interlocutory injunction should be granted as a matter of course. This is evident in the context of patent infringement proceedings from the decisions of Kelly J. in *Genthon* and McGovern J. in *Gilead*. It is quite clear that the test to be applied in considering an application for an interlocutory injunction in a patent infringement case is the same as that to be applied in other cases not involving the invocation of a property right. Indeed, it has not been contended otherwise by Teva. The fact that a property right is in issue is a factor to be taken into account as part of the balance of convenience assessment. However, it is only one such factor. The weight to be given to that factor in the overall consideration of where the greater risk of injustice lies will very much depend on the circumstances of the case.

170. In this case, I do not attach very significant weight to the property right factor for a number of reasons. Primarily, I must take into account the real possibility of entry onto the market in the United States of other generic manufacturers with their products to compete with Copaxone 40mg. The evidence does establish the possibility of entry onto the market of at least five other generic companies, being those who have filed ANDAs. While I recognise that no timeframe has been established in evidence as to the likely date of entry of those generics, the evidence does establish the possibility of such entry. I also take into account the fate of the similar US patents before the US Courts and the US PTAB and the fate of EP 335 in other European jurisdictions and, in particular, in the United Kingdom. I consider that these other factors serve as a counterweight to the property right factor. I am satisfied that I am entitled to have regard to these other factors as part of the balance of convenience assessment although I am clearly not deciding the merits of the case on validity, there being a serious issue to be tried on that point. In my view, therefore, the fact that Teva seeks to protect a property right is a factor to be considered as part of the balance of convenience assessment but it is not a particularly strong factor in light of the other factors to which I have referred.

(b) Delay

171. Mylan argues that Teva unreasonably delayed in making its application for an interlocutory injunction and that on that basis the application should be refused. Mylan alleges that Teva was aware for two and half years that Mylan intended to produce and launch a 40mg GA product on the US market to compete with Copaxone 40mg. It contends that the launch of the Mylan 40mg GA product on 3rd October, 2017 did not come as any surprise to Teva and refers in that regard to the Teva press release of 4th October, 2017 which referred to the anticipated launch of the Mylan product and stated that Teva had "*planned for such a launch*". Mylan points to a number of significant features to support its contention that Teva's application should be rejected on the grounds of delay.

172. Mylan relies primarily on events which occurred before the US PTAB and also on the disclosure process and events arising in the course of the proceedings before the Delaware District Court. As regards the US PTAB, Mylan notes that the defendant, Mylan Teo, was identified as a "*real party-in-interest*" in Mylan's petition before the US PTAB dated 6th February, 2015. Mylan Teo was identified as one of the "*real parties-in-interest*" along with MPI and Mylan Inc. Mylan submits that Teva ought to have made enquiries once it saw Mylan Teo identified in that capacity in the petition. It contends that Teva should have examined the Annual Report of Mylan Teo for 2014 which identified that entity as being engaged in the manufacture and distribution of speciality pharmaceutical injectables mainly in Europe and North America. It further refers to the Mylan website identifying Mylan Teo as manufacturing sterile injectables. It submits that Teva should also have made enquiries directly of Mylan as to the intentions of Mylan Teo.

173. As regards the disclosure in the Delaware Proceedings, Mylan notes that the Patient Information Leaflet (PIL) was a key document in those proceedings. A version of the PIL was disclosed in the proceedings. That version, which was dated January 2014, referred on the final page (p. 29) to the Mylan product being manufactured by "*Mylan Institutional*" of "*Galway, Ireland*". "Mylan Institutional" is a registered business name of Mylan Teo. The PIL was sent by Mylan's outside counsel, Perkins Cole, to Teva's outside counsel, Goodwin Proctor, on 13th April, 2015 along with other technical documents. Those documents were designated as "*external counsel only*" under Delaware Local Rule 26.2 and were being produced to Teva's counsel only. On 15th July, 2015, Perkins Cole sent a thumb drive containing documents including the PIL to Goodwin Proctor. The documents were marked "*outside counsel only*" and/or "*highly confidential*" under a protective order which had been made in the Delaware Proceedings. The protective order was entered by the Delaware District Court on 27th May, 2015. The PIL was also used as an exhibit by Teva in the proceedings (marked PTX 445.1-R) and was marked "*outside counsel only*". On 25th September, 2016 Perkins Cole sent a redacted version of the PIL "*for use in open court*" to Goodwin Proctor by email. The redacted version redacted the "*outside counsel only*" footer. The email noted that Mylan expected Teva to use the redacted version of the exhibit at the trial.

174. Mylan asserts that the final page of the PIL was displayed on the screen in the court room at the trial of the Delaware Proceedings on 27th September, 2016. The final page is the page referring to the manufacturer as "*Mylan Institution*" of "*Galway, Ireland*". Mylan asserts that Teva's in-house counsel and third party analysts were present in court on that occasion. Mylan submits that the protective order made by the Delaware Court in May 2015 no longer applied as no further precautions or protections were sought for the purposes of para. 21 of the order following the removal of the "*outside counsel only*" designation from the PIL exhibit. It submits that the protective order, therefore, did not preclude the PIL being shown to Teva by its outside counsel. Alternatively, Mylan contends that an application could have been made to the court to lift any restriction on the use of the PIL to enable it to be shown to Teva. Mylan states that Teva has made a similar application in previous proceedings brought by Teva against Mylan and others in the US District Court for the Southern District of New York in 2010. Finally, Mylan states that in June 2017, it produced documents as part of a disclosure made in proceedings which had been commenced in West Virginia but subsequently transferred to the Delaware District Court which disclosed manufacture by Mylan Teo. While those disclosures were marked "*external counsel only*" and "*confidential*", Mylan submits that an application could have been made by Teva's outside counsel to show the documents to their clients or for use in other proceedings. For these various reasons, Mylan submits that Teva was aware since 2015/2016 that Mylan Teo would be manufacturing the Mylan 40mg GA product and unreasonably delayed in commencing these proceedings and

seeking the interlocutory injunction.

175. In response, Teva rejects the allegations of unreasonable delay on its part. Teva submits that it commenced proceedings promptly on becoming aware of the launch of the Mylan 40mg GA product manufactured by Mylan Teo following the FDA announcement and the Mylan press releases on 3rd and 4th October, 2017. The first letter was sent on its behalf on 11th October, 2017, some eight days later, and proceedings were ultimately commenced on 19th October, 2017.

176. With regard to the identification of Mylan Teo as one of the "*real parties-in-interest*" in the Mylan petition to the US PTAB of 6th February, 2015, Teva submits that there was nothing in that petition (or in the subsequently amended version of the petition which added another Mylan entity later in 2015) which indicated that Mylan Teo would be manufacturing a competing generic product at its facility in Galway for supply to the US market. It submits that the US PTAB applies a very broad standard for the identification of "*real parties- in-interest*" being an entity which had an interest in the outcome of the petition proceedings. Teva submits that there was nothing to alert it to the fact that Mylan Teo would be manufacturing the competing product in Galway such that proceedings could or should have been issued at that stage.

177. As regards the allegations of delay in relation to the disclosure of the PIL in the Delaware Proceedings, Teva principally relies on the protective order entered by the Delaware Court on 27th May, 2015 and on the requirements of Rule 26 of the Delaware Local Rules as precluding Teva's outside counsel from disclosing the relevant document to Teva and using it in other proceedings. It also disputes Mylan's assertion that the relevant page of the PIL was displayed on the screen at the hearing in Delaware in September 2016. In this regard, Teva notes that the letter of 13th April, 2015 from Perkins Cole to Goodwin Proctor (which sent a copy of the PIL with other technical documents) expressly noted that the documents were designated as "*external counsel only*" under Delaware Local Rule 26 and were being produced to Teva's counsel only. Teva also relies on the provisions of paras. 6(a) and 21 of the protective order. Again it notes that when the thumb drive containing documents (including the PIL) was sent by Perkins Cole to Goodwin Proctor on 15th July, 2015, it was expressly stated that the documents were marked "*outside counsel only*" and/or "*highly confidential*" under the protective order. Teva disagrees with Mylan as to the effect of the email sent by Perkins Cole to Goodwin Proctor on 25th September, 2016 attaching a redacted version of the PIL "for use in open court" and removing the "outside counsel only" designation. It submits that the provisions of the protective order and, in particular, para. 21 continued to apply as did the provisions of Delaware Local Rule 26.

178. Teva further disputes the assertion that the PIL was displayed on the screen in open court. On the contrary, it submits that the particular witness whose attention was directed to the final page of the PIL on 27th September, 2016 looked at the document in a binder and not on the screen. Even if the document had been displayed on the screen, it could only have been on the screen for about twenty seconds. Further, Teva submits that it was not until final FDA approval was issued (on 3rd October, 2017) that the final version of the PIL could have become known.

179. As regards the reliance on other proceedings, Teva relies on the fact that the documents furnished in those other proceedings (the West Virginia proceedings which were transferred to Delaware) were also marked "*external counsel only*". Teva submits that the height of the complaint made by Mylan in relation to documents containing this designation and subject to protective orders or local rules is that external counsel ought to have applied to court to have that designation or those restrictions lifted. It submits that the failure to make such an application cannot tell against Teva in terms of delay in seeking interlocutory relief in these proceedings.

180. Teva also place significant reliance on the statements made on behalf of Mylan at an earnings call in respect of Mylan NV's second quarter 2017 results on 9th August, 2017 (of which a transcript is available and was exhibited). It submits that a reasonable interpretation from what was said on that call is that Mylan did not anticipate FDA approval for its 40mg GA product until sometime in 2018 and that it had removed the product from its 2017 financial guidelines and deferred it to 2018. In these circumstances, Teva submits that there was no unreasonable delay on its part and it moved expeditiously on becoming aware of the launch of the Mylan product and the identity of the manufacturer on 3rd October 2017.

181. I now set my conclusions on the question of delay. The relevant legal principles applicable to the issue of delay in the context of interlocutory injunction applications are well established and are not in dispute. If an applicant for an interlocutory injunction unreasonable delays in seeking that relief, the application should be refused. In the High Court in *Nolan Transport v. Halligan* (Unreported High Court Keane J., 22nd March, 1994), Keane J. summarised the position as follows:-

> *"In all cases of this nature, where interlocutory relief is sought, the courts expect the parties to move with reasonable expedition where they are seeking interlocutory relief, because it is the essence of such relief that if it turns out that it has been wrongly granted, one party has suffered an injustice. It is, therefore, a remedy that should not be lightly invoked; and, if invoked, it should be invoked rapidly, and where a party simply awaits events as they unfold, they cannot expect to find the court amenable to the granting of this relief, as it would where a party moves expeditiously to protect his rights."* (per Keane J at p.6)

182. To similar effect are the observations of Clarke J. in the Supreme Court in *Dowling v. the Minister for Finance* [2013] 4 I.R. 576 where he stated:

> *"The factors, … which come into play in assessing whether a party has moved with reasonable expedition in applying for an interim or an interlocutory injunction are different, and are governed by much stricter scrutiny, than those which apply when the court is considering whether a party has lost all entitlement to bring proceedings at all, as a result of laches or delay …"* (Per Clarke J. at para. 44 p. 599).

183. The question, therefore, is whether Teva moved with reasonable expedition in applying for the interlocutory injunction. Each of the parties rely on the decision of the High Court in *The Irish Times v. Times Newspapers* [2015] IEHC 490. In that case, Hedigan J. refused the plaintiff's application for an interlocutory injunction on the grounds that the plaintiff had not moved with reasonable expedition. He did not find it necessary to determine questions of arguability and adequacy of damages. Hedigan J. was satisfied on the evidence that the defendant's intention to launch a new digital Irish edition of its newspaper was common knowledge since September, 2014 and yet proceedings were not commenced until May, 2015. The court referred in particular to tweets evidencing the fact that senior members of the plaintiff's staff and others involved in Irish journalism were well aware of the defendant's intentions. The knowledge in question was actual rather than constructive knowledge. Teva argues that any alleged delay on its part (which it denies) was of the nature of constructive knowledge in the sense that the case really made by Mylan is that Teva ought to have been aware of the fact that the Mylan 40mg GA product would be manufactured by the defendant, Mylan Teo, in Ireland at an earlier stage than on the date of the announcement on 3rd October, 2017. Mylan disputes this and further submits that even if the knowledge in question is constructive knowledge rather than actual knowledge, such would be sufficient in order to support a delay objection. On that point, I agree with Mylan. If with reasonable diligence a plaintiff seeking an interlocutory injunction could have

found out the facts allegedly providing the basis for its cause of action at a much earlier stage but failed to exercise reasonable diligence, it would be open to the defendant in resisting the interlocutory injunction to rely on an unreasonable delay on the part of the plaintiff. Delay can arise not only in the case of actual knowledge of the facts providing the basis for the cause of action but also facts which could have been discovered had reasonable diligence being adopted. Such is inherent in the requirement that an applicant for an interlocutory injunction must move with "*reasonable expedition".*

184. I have considered each of the grounds relied upon by Mylan to support its allegation of unreasonable delay on the part of Teva. I am not satisfied that in themselves they would support a finding that Teva failed to move with reasonable expedition in seeking the interlocutory injunction. The inclusion of Mylan Teo as one of the "*real parties-in-interest*" in the petition presented to the US PTAB and the failure by Teva to make enquiries as to the precise role or status of that entity following the presentation of that petition in February 2015 would not support a finding of unreasonable delay in the part of Teva. There is no explicit statement contained in the petition that Mylan Teo would be the manufacturer of the Mylan 40mg GA product and that it would be manufacturing that product from its premises in Galway. The criteria for inclusion of a party as a "*real party-in-interest*" in a petition are very broad and merely require that the named party have an interest in the outcome.

185. I am also satisfied that the disclosure of Mylan to Teva of the PIL, which contained a reference (on its final page) to"*Mylan Institutional*" of "*Galway, Ireland*" in April, 2015 and July, 2015 in the course of the Delaware Proceedings, was done on the basis that the document was "*external counsel only*" and "*outside counsel only*" and was made in accordance with the provisions of protective order entered by the Delaware Court in May, 2015 and on foot of the Delaware Local Rules. I do not believe that the failure by Teva's external counsel to seek permission to inform their client of the information contained in the PIL can count against Teva in terms of any failure to act with reasonable exhibition in seeking the interlocutory injunction in this case.

186. The removal of the "*outside counsel only*" designation from the PIL in the email from Mylan's external counsel to Teva's external counsel on 25th September, 2016 to enable the document to be used in court and the significance of the removal of that designation in terms of the protective order and the Delaware Local Rules has given rise to a significant dispute between the parties. I do not believe that it would be appropriate for me to resolve that dispute and to offer my view as to the correct interpretation of the protective order or of the Delaware Local Rules in this interlocutory application. I do not have any expert evidence on the applicable rules and law in Delaware on these issues. Nor would it be appropriate to attempt to resolve the dispute between the parties as to whether the PIL was or was not displayed on the screen at the trial in Delaware on 27th September, 2016. This is particularly so as there was no affidavit evidence provided in the course of this application from any person who was actually in the Delaware District Court on that day. I do not propose, therefore, to resolve that dispute on this application.

187. There is something to be said for the fact, however, that an application could have been made by Teva's counsel for permission to show the PIL to its client and such an application was not made in this case. However, that in itself would not support a finding that Teva had unreasonably delayed in bringing the application. That this is so is supported by the statements made in the course of the earnings call on 9th August, 2017, a reasonable interpretation of which is that the prospect of a launch of the Mylan product was being deferred to 2018. I believe that Teva was entitled to take that meaning from the call. Finally, there is some force in the contention made on behalf of Teva that until the FDA issued its final approval in respect of the Mylan 40mg GA product, there could be no certainty as to the identity of the manufacturer of the product or the place of manufacture.

188. In all these circumstances, I do not believe that Teva was guilty of unreasonable delay in seeking the interlocutory injunction in this case and I would not refuse the application on the grounds of delay. Even if it could be said that there was any unreasonable delay (and I do not believe that there was), such delay as a factor would be cancelled out by the next factor I consider, namely, the alleged failure by Mylan to "clear the way" before launching its product.

(c) Clearing the Way

189. Teva contends that one of the factors to be considered in the context of the balance of convenience is the failure by Mylan to "clear the way" before launching its 40mg GA product. It contends that Mylan ought to have issued proceedings seeking the revocation of EP (IE) 335 and/or seeking a declaration of non-infringement before proceeding to launch. It relies, in particular, on a number of English cases including *Smithkline Beecham plc. v. Generics UK Ltd.* (Unreported, Jacob J., 23rd October, 2001) ("Generics"), *Apotex and Cephalon v. Orchid* [2010] EWHC 2945 (Pat) ("*Cephalon*"). It also relies on the observations of Kelly J. in *Genthon* and on the English decision of *BASF*.

190. While accepting that this is a factor to be considered as part of the balance of convenience, Mylan contends that no significant weight should be attached to it for several reasons. It contends that Mylan did "clear the way" in the relevant market, being the market in the US and proceeded as required under the provisions of the Hatch-Waxman Act. It further states that it cleared the way in England and Wales by seeking and obtaining revocation of EP (UK) 335 by means of the judgment delivered by Arnold J. on 26th October, 2017. In doing so it cleared the way for sale of the product in the UK. Further, it submits that there was no question in this case of Mylan proceeding fully in the knowledge that Teva would issue proceedings in Ireland alleging infringement of EP (IE) 335 having regard to what it submits is the novel and unprecedented nature of the claim being made by Teva. Mylan further refers to the history of developments in relation to EP 749 (the parent patent of EP 335) in respect of which Mylan did prosecute opposition proceedings before the EPO leading ultimately to the withdrawal and revocation of that patent in February 2017. It further refers to developments in other European jurisdictions such as the recent decisions in Munich. As regards any failure to progress opposition to EP 335 before the EPO, Mylan contends that it could not progress such opposition for a period of nine months from the grant of EP 335 but did so as soon as it was permitted to on 3rd October, 2017.

191. Mylan submits that while a failure to "clear the way" argument might have some force where there is a predictable claim of infringement based on a reasonably solid patent, if Mylan were required to complete its opposition to EP 335 and to clear the way by removing an improbable claim of infringement based on a patent found to be defective in the UK and in the US in unequivocal terms, it would leave Ireland as an extreme outlier. Mylan submits that such a conclusion would be inequitable. Mylan seeks to distinguish the English cases on their facts and relies on the decision of Kelly J. in *Genthon*.

192. In my view, this factor has little significance in the context of the overall assessment of the balance of convenience. It may at best serve as a counterweight to the allegations of delay made by Mylan against Teva. If so, in my view, one complaint would cancel out the other in the assessment of the balance of convenience.

193. I agree with the approach taken by Kelly J. with this issue in *Genthon*. While citing the comments of Jacob J. in *Generics* and *Apotex* to the effect that the defendants in those cases ought to have "cleared the way" before launching their competing products and stating that both Jacob J. and Aldous L.J. (in agreeing with Jacob J.in *Apotex*) had "much to recommend their views", Kelly J. stated that those views impacted principally on the issue of the balance of convenience. I have considered the issue in that context

as part of the balance of convenience. Kelly J. also regarded it as significant in that case that the defendants had been on the market with their products since September 2002 (a number of months prior to the commencement of the proceedings). So do I.

194. I agree that in an appropriate case the failure to "clear the way" could tilt the balance in favour of granting an interlocutory injunction application as it did in Generics and in Apotex. However, it was not determinative of the applications, for various reasons, in BASF and in Cephalon. In the latter case, while Floyd J. stated that he was taking into account the failure by the defendants to take steps to "clear the way", he did not give it such weight that it necessarily swamped all the other factors.

195. On the facts of this case, I do not believe that the failure by Mylan to "clear the way" is particularly significant in the overall assessment of the balance of convenience. It certainly does not persuade me that I should grant the interlocutory injunctions sought by Teva. I agree with Mylan that this case is not comparable to Generics or Apotex. I also agree that the various steps which Mylan took in other jurisdictions such as the US and UK and before the EPO are all relevant in the overall assessment of the relevance of this factor in the context of the balance of convenience. While it might be said that Mylan ought to have anticipated litigation by Teva once the product was launched, and while it could have issued revocation proceedings or proceedings seeking a declaration of non-infringement in Ireland, it was not unreasonable for Mylan to have relied on developments in the US and before the EPO and expected developments in the UK as a reason for not commencing and prosecuting those proceedings to conclusion before launching the product.

196. Accordingly, while Mylan's failure to "clear the way" is a factor to take into account, I do not believe that much significance should be attached to that factor in the circumstances of this case. I am not persuaded that it tilts the balance of convenience in favour of Teva. At most, it may cancel out any suggestion of delay on the part of Teva in seeking the interlocutory injunction.

(d) Relevance of United States market considerations

197. Mylan submits that a factor to be taken into account as part of the assessment of the balance of convenience is the fact that the real battleground for the dispute between the parties is the US. It notes that Teva has failed to obtain injunctive relief from any US Court in relation to the Mylan 40mg GA product in the very market in which it is said that Teva will suffer harm whereas it seeks an interlocutory injunction in Ireland where the product is not on the market and cannot be placed on the market since it does not have a marketing authorisation. It relies very much on the fact that almost all the relevant events at issue between the parties are taking place in the United States. In that context, Mylan relies on the decision of McCracken J. in *R. Griggs Group Ltd. v. Dunne Stores Ireland Co.* (Unreported, High Court, McCracken J., 4th October, 1996) ("*Griggs*").

198. Teva disputes this and contends that it is seeking to enforce an Irish patent to restrain an Irish defendant manufacturing a product in Ireland which it is says infringes that patent. It submits that *Griggs* has no application in the present case.

199. In my view, this factor overwhelming demonstrates that the balance of convenience favours the refusal rather than the grant of the interlocutory injunction sought by Teva. While it is undoubtedly the case that the product at issue is being manufactured by an Irish defendant in Ireland and while Teva seeks to restrain that manufacture on the grounds that it allegedly infringes an Irish patent, almost all of the evidence before me for the purpose of this interlocutory injunction application is evidence in respect of the operation and regulation of the US market for prescription pharmaceutical products. All of the evidence of loss put forward by Teva is in respect of loss which it has or will allegedly suffer as a result of loss of market share, reductions in price, damage to reputation, loss of staff, loss to patients in respect of services provided. All of these events relate to matters taking place in the US. A significant portion of the evidence put forward by Teva (and responded to by Mylan) concerns the US market including the role of TTPs and formularies operated by them, the operation of the Hatch-Waxman Act, the approval by the FDA of Mylan's ANDA and the filing by at least five other generic companies of ANDAs with the FDA and so on. The evidence even includes reference to a Congressional inquiry in relation to the pricing of prescription medicines which is being conducted by the Committee on Oversight and Government Reform of the House of Representatives. All of this is taking place in the US. All of the losses being alleged by Teva and indeed the losses being put forward by Mylan, in the event that the interlocutory injunction is granted, are or will allegedly take place in the US (excluding, of course, any direct financial losses to Mylan caused by the requirement to cease manufacturing in Ireland).

200. All of this has been alleged in circumstances where there is no injunction in place in the US to prevent the Mylan 40mg GA product being supplied, prescribed and used by patients in the US. Teva's application for a stay or injunction pending appeal from the decision of the Delaware District Court was refused and no application was made to the US Court of Appeals for a stay or injunction pending the determination of that appeal. As things stand, therefore, there is no bar to the supply and prescription of the Mylan 40mg GA product in the United States. Nor is there any bar to any other generic which has filed an ANDA with the FDA from entering the market for 40mg GA products once FDA approval is granted. While there is no evidence of immediate entry by other generics, there is certainly a possibility that such generics will enter the market at some stage and there is no bar to them doing so. The fact that the Mylan 40mg GA product can be and has lawfully been sold on the US market without restraint since early October 2017 in circumstances where the alleged losses being sustained by Teva as a result are all said to arise in the US, persuades me that the balance of convenience clearly favours the refusal of Teva's application. In my view, the greatest risk of injustice in balancing the interest of Teva and Mylan would lie in granting Teva's application.

201. Mylan relies on the judgment of McCracken J. in *Griggs*. Teva disputes its relevance and submits that the present case is entirely different. While Teva is undoubtedly correct that the factual situation at issue in *Griggs* is quite different to the present situation, I have derived at some assistance from the judgment of McCracken J. in that case. In *Griggs*, the plaintiffs were the manufacturers and owners of rights in respect of Dr. Martens boots. They sought an interlocutory injunction restraining the defendants, Dunnes Stores, from passing off a range of boots sold by them as and for the plaintiff's boots. Having held that the plaintiff had just about established an arguable case and having held that damages would not be an adequate remedy for either the plaintiffs or the defendant, McCracken J. went on to consider other aspects of the balance of convenience. In holding that it would be inequitable to grant the interlocutory injunction sought in the particular circumstances, McCracken J. stated:-

> *"What influences me more is that this is part of a world-wide campaign by the plaintiffs to establish a monopoly in a certain design of footwear. While the outcome of the action eventually will depend only on the reputation of the plaintiffs in this jurisdiction, nevertheless I am entitled to take into account the fact that this is a small battlefield in a world war, and that the attack in this battle is against what I might call a secondary target – namely a retailer – while no real attack is mounted against the primary target, namely, the manufacturers.*
>
> *The granting of an injunction is an equitable remedy, and the concept of balance of convenience is an equitable concept. It seems to me inherently inequitable in this case that the proceedings should be brought against a retailer which, on the evidence before me, bona fide purchased these goods from two manufacturers … while no action is taken against the manufacturers*". (per McCracken J. at pp. 7-8)

202. There is no doubt that there are differences between *Griggs* and this case. Here, the Mylan defendant is the manufacturer of the product at issue. In *Griggs*, it was the retailer which is being pursued. However, I do see some resonance with the case in the statement by McCracken J. that the proceedings in this jurisdiction were *"a small battlefield in a world war".* That could be said of the present case. Battles in relation to EP 335 and the corresponding US patents have been waged in several parts of the world as part of a world war. Ireland is but a small battlefield in that overall war. It is undoubtedly a significant one given that this is where the product is manufactured. However, the primary battlefield, it seems to me, is in the US with secondary battlefields in other jurisdictions including Ireland as well as the UK, Germany, the Netherlands and Italy and at the EPO itself. Therefore, adopting by analogy the observations of McCracken J. in *Griggs*, the concept of the balance of convenience is an equitable concept and, in my view, it would be inherently inequitable to grant the relief sought against Mylan in this jurisdiction in circumstances where the entirety of the losses and virtually all of the relevant evidence in relation to those losses are alleged to arise in and emanate from the US in circumstances where there is no legal or regulatory restraint on the supply and prescription of the Mylan product on that market.

203. In my view, therefore, were it necessary to proceed to an assessment of the balance of convenience, this factor would overwhelmingly persuade me that the balance of convenience favours the refusal of Teva's application.

(e) Other Jurisdictions

204. Another relevant factor in the assessment of the balance of convenience is the fate of EP 335 in other European jurisdictions. While Mylan has accepted that there is a serious issue to be tried on the question of validity, I am satisfied that I am entitled to take account as part of the assessment of the balance of convenience the fact that EP 335 has not fared well in other jurisdictions such as in the UK (where it was revoked by Arnold J. and an appeal was not permitted by the Court of Appeal) and other European jurisdictions such as Germany (where the Munich Court recently refused to grant injunctive relief for the reasons outlined earlier). I believe that I am also entitled to take into account the developments before the EPO in relation to EP 749, the parent patent of EP 335, where the patent was withdrawn and revoked by the EPO in February 2017 after the commencement of opposition proceedings. While it would not be appropriate for me to express a view on the merits of the case on validity, I am satisfied that I am entitled to take into account the fate of EP 335 (and its parent patent, EP 749) in other European jurisdictions. In this context, I agree with the observations of Barrett J. in *Glaxo Group Limited v Rowex Limited* (Unreported, High Court, Barrett J, 19th May 2015) (a trademark case) where he stated as follows:-

> *"150. … The sale of pharmaceuticals is an international trade and both parties have mentioned before the court certain international realities that pertain in this case, specifically that [the allegedly offending product] …, is already competing with [the plaintiff's product] on various markets, both within the European Union and elsewhere, and that Glaxo has failed to be granted preliminary injunctive relief in other jurisdictions, albeit that such relief may have been sought on different grounds and in places where the law and procedure is different to that which pertains in Ireland.*
>
> *151. … Glaxo is effectively asking the court in this application to impose an interlocutory injunction that would set Ireland apart from much of the rest of Europe as regards free trade in [the allegedly offending product] and free competition between it and [the plaintiff's product] … For the court to grant an injunction that would replace this status quo ante with its very opposite in Ireland, even for the few months before trial, seems to the court an absurdity …"*

205. To grant the interlocutory injunction sought by Teva would set Ireland apart from a number of other European jurisdictions (as well as setting it apart from the US which has not granted such interlocutory relief). This is a factor which I am entitled to take into account. I believe that it is a significant factor in assessing the balance of convenience. To my mind, it is another factor which points strongly against the grant of the relief sought by Teva and in favour of refusing the application. It is, I believe, another indication that the greater injustice would be to grant rather than refuse the application.

(g) Comity of Courts

206. The issue of comity of courts was raised by Mylan as a basis for refusing Teva's application. Teva disputes the application of the principle to the facts of this case. In any event, it submits that even if the question of comity of courts does arise, very little weight should be given to it.

207. It seems to me that this issue really informs part of the balance of convenience assessment and is very much related to the factors addressed at (e) and (f) above. I do not believe that the application of the principle of the comity of courts is determinative one way or the other of this application.

208. Both parties are agreed that the principle was correctly described and analysed by Clark J. in *Ranbaxy Laboratories v. Warner-Lambert Company* [2009] 4 I.R. 584. In that case, where the plaintiffs sought a declaration that a particular product would not infringe the defendant's Irish patent, Clarke J. had to consider the relevance of proceedings determined in other jurisdictions including the UK, Australia, the United States (United States District Court for the District of Delaware and the United States Court of Appeals for the Federal Circuit) and Canada. In most of the major common law jurisdictions the analogous issue had been determined against the plaintiffs. In that context, Clarke J. had to consider the question of the status of the proceedings in those other jurisdictions. The principle of the comity of courts was raised in that regard. In addressing that issue, Clarke J. stated as follows:-

> *"[53] Finally, it is important that I deal with the question of the status of other litigation. It is important not to confuse two different concepts. Appropriate decisions from other common law countries are, of course, afforded persuasive status by the courts in this jurisdiction and, indeed, by the courts in many common law countries. That status is wholly independent of any connection between the litigation in which the decision was handed down on the one hand and the litigation under consideration on the other hand. What is afforded the status of persuasive authority are the legal principles to be derived from the decision rather than the decision itself.*
>
> *[54] An entirely separate consideration has to be given to the result of foreign litigation which touches upon the same actual matters (rather than the same legal principles). The principle of the comity of courts requires that the courts in one jurisdiction should not lightly depart from a decision on the same issue made by a court of competent jurisdiction in another country which had to deal with that issue as part of litigation properly under its consideration. Thus, for example, where the courts in one jurisdiction have interpreted a contract in a particular way and where the same contract comes to be interpreted, in a separate dispute between the same or similar parties, in the courts of another jurisdiction, then the comity of courts requires that the interpretation of the contract in the second proceedings should not lightly depart from the interpretation given to the same contract in the first proceedings.*
>
> *[55] This latter principle, it seems to me, ought also to apply, though obviously to a more limited extent, where the*

issue, while not identical, is very similar. For those reasons it seems to me to be appropriate, subject to the caveats relating to differences in statutory law, jurisprudence, the patents themselves and the evidence which I have already identified, to pay appropriate regard to the international decisions in the related cases.

[56] However, it is also important not to lose sight of the fact that the international decisions in this case (and in particular the decisions taken by the courts of the United Kingdom which derive from an almost identical statutory regime and analogous jurisprudence) have also the status, as to their principles, of persuasive authority. …" (per Clarke J. at pp. 606-607).

209. In this context, Mylan relies, as an aspect of the comity of courts, on the decision of the US Supreme Court in April 2014 which refused the stay sought by Teva on the grounds that Teva had not shown a likelihood of irreparable harm and that it would be in a position to recover damages and on the rejection by the Delaware District Court of the stay pending appeal following its judgment of 30th January, 2017. Teva, however, submits that the principle of comity does not apply at all insofar as the US cases are concerned. It submits that the question decided by the US Supreme Court was not an identical one and concerned an entirely different product (Copaxone 20mg). It submits that it is not even a similar situation. It further submits that there was a significant difference in the evidence adduced before that court and the evidence adduced on this application. Further, Teva submits that the US decisions relied on do not contain any reasoned analysis or detailed explanation for the decisions reached.

210. In my view, the decisions reached in the US cases relied on by Teva do not engage the principle of the comity of courts, at least in the context of the application which I have to decide. I broadly accept that the arguments advanced by Teva in that regard. They are not reasoned decisions which set out in detail the evidence on which they are based. Indeed, the test to be applied in the two decisions in question are somewhat different to the test to be applied on the application for an interlocutory injunction in this jurisdiction. Further, in the case of the decision of the US Supreme Court, the case did not concern the same product with which these proceedings are concerned. I do not think that it can be said that either the US Supreme Court decision or the decision by the Delaware District Court amounts to a decision on the same issue which arises on this application nor, can it be said that the issues are "*very similar*" so as to attract the application of the doctrine of the comity of courts and so as to require me to afford a degree of judicial deference to those cases such that I should not lightly depart from them. Therefore, I do not believe the principle of the comity of courts really applies in this context.

211. Of much more relevance to the question of the balance of convenience, in my view, is the outcome, in particular, of those cases and the refusal by the Delaware District Court to grant the stay requested and by Teva and the subsequent failure by Teva to seek any stay or injunction from the US Court of Appeals. That has led to a situation where the Mylan 40mg GA product has been launched and has been available on the US market since early October 2017 in full compliance with US law. That is a factor which I consider of great relevance in the context of the balance of convenience in my earlier assessment. It is not, however, in my view, a comity of courts issue.

(h) Status Quo

212. In the event that all other matters are equally balanced in the consideration of where the balance of convenience lies, the court should attempt to preserve the status quo (see: *B&S Ltd. v. Irish Auto Trader Ltd.* [1995] 2 I.R. 142, summarised in *Okunade*, per Clarke J. at 180-181). In this case, however, I do not believe that all other matters are equally balanced, for the reasons I have mentioned. First, I have concluded that damages would be an adequate remedy for Teva. Second, I have identified various factors as part of the assessment of the balance of convenience which have persuaded me that overwhelmingly the balance lies in favour of refusing Teva's application on the ground that the greater risk of injustice would arise if the application were granted. However, if I am wrong in my earlier assessments, I will briefly consider the question of the status quo.

213. Teva submits that the fact that the Mylan product was already on the market by the time the proceedings were commenced does not mean that the court should treat that position as the status quo and should feel obliged to maintain that position. It relies on the fact that the product was launched in October 2017 in circumstances where it was stated on behalf of Mylan at the earnings call in August 2017 that the launch was being deferred to 2018. It also relies on the fact that it commenced correspondence and issued proceedings very shortly after the launch. In that context, Teva relies on the observation by Barrett J. in *Rowex* that the maintenance of the status quo "*is not a fixed rule*" (per Barrett J. at para. 150) (the origin for that comment being the judgment of McCracken J in B&S). Teva also relies on the decision of Finlay Geoghegan J. in *Contech Building Products Ltd. v. James Walsh, Contech (Northern Ireland)* [2006] IEHC 45 ("*Contech*") which was approved of and applied by Keane J. in *Tennant v. McGinley* [2016] IEHC 325 ("*Tennant*").

214. *Contech* involved an application for an interlocutory injunction to restrain passing off in circumstances where the allegedly offending product had already been placed on the market. It was argued by the defendant that as a result the status quo involved the product being on the market and, therefore, the preservation of that status quo meant that the application for the interlocutory injunction should be refused. Finlay Geoghegan J. granted the injunction. She held that the court was not confined to looking at the position at the date of the hearing and that where a plaintiff moved speedily after learning of the fact that the product had been launched, and where there was no delay, the status quo to which the court must primarily have regard was the position which prevailed before the commencement of the alleged wrongful acts. This approach was applied by Keane J. in *Tennant*.

215. Mylan contends that the preservation of the status quo must lead to the refusal of Teva's application. It submits that the status quo is that in the US market there is no legal impediment to any company entering the market, subject to FDA approval. It further refers to McCracken J's observation in B&S that the preservation of the status quo is "*not a fixed rule*". In that case the court found that the balance of convenience lay in favour of refusing an interlocutory injunction even where such refusal altered the status quo by allowing the allegedly offending magazine onto the market. Mylan places great stress on the fact that the Mylan 40mg GA product has been on the market since early October 2017.

216. In my view, if it were necessary to get to the question of the preservation of the status quo, and, for reasons outlined earlier, I do not believe that one gets to that stage, the preservation of the status quo would probably tilt the balance of convenience in favour of refusing Teva's application. There is in my view much to be said for the fact that the Mylan product has been on the US market since early October 2017. By the time Teva first commenced corresponding with Mylan in relation to the product, it had been on the market for about one week. By the time Teva's application for interlocutory relief was issued, the product had been on the market for almost two weeks. By the time the application was heard, it had been on the market for more than three months. While I accept that it may sometimes be the case that a plaintiff only becomes aware of the alleged infringing product after that product is placed on the market and such awareness may be a matter of "happenstance" as explained by Finlay Geoghegan J. in *Contech* and by Keane J. in *Tenant*, that is not the position here. Teva was clearly aware that Mylan was going to launch its 40mg GA product and anticipated and planned for that launch, albeit that it expected that it would occur in 2018 rather than 2017. The fact of the matter

is that by the time the application for the interlocutory injunction was heard, the Mylan product was on the market in the US for a number of months on foot of the FDA approval it received. As a matter of US law, it is entitled to be on that market and is not the subject of any restraining order in that jurisdiction. I agree that I must also consider as part of the status quo the position in the US where there is no prohibition on other generics entering the market to compete with Copaxone 40mg, subject to obtaining FDA approval and five other generics have applied for such approval. There is nothing to prevent those other generics from entering that market. I am satisfied that I can take this into account in considering the status quo.

217. I do not believe that there is anything in the judgment of Finlay Geoghegan J. Contech or in the judgment of Keane J. in *Tennant* which would preclude me from taking these factors into account in the context of my assessment of the status quo. The facts of those cases were entirely different. Of particular relevance in this context is the fact that in *Genthon*, the allegedly infringing product had been on the market for a number of months prior to the hearing of the interlocutory injunction application. This was regarded as significant by Kelly J. as representing the position at the time of the hearing although he considered this not in the context of an assessment of the status quo but rather as part of his consideration as to whether damages would be an adequate remedy for the plaintiff in that case. The fact is, however, that Kelly J considered it to be a relevant factor. As do I, albeit in the context of the balance of convenience.

218. Were it necessary to decide the issue, I would conclude that the preservation of the status quo would lead to a refusal of Teva's application.

Conclusion

219. In summary, I have reached the conclusion that I must refuse Teva's application for an interlocutory injunction and for the other reliefs it seeks in the notice of motion issued on 19th October, 2017. I have done so on the basis that I have not been persuaded that damages would be an inadequate remedy for Teva in the event that an interlocutory injunction is refused but Teva subsequently succeeds at trial. On the contrary, I am satisfied that damages would be an adequate remedy for Teva. That is sufficient to dispose of Teva's application. I would also have concluded that damages would be an adequate remedy for Mylan in the event that an interlocutory injunction were granted but Teva fails at trial (although if damages are an inadequate remedy for Teva, they are also likely, for similar reasons, to be inadequate for Mylan).

220. If I were wrong in those conclusions, and if damages were an inadequate remedy for Teva and for Mylan, and if it was, therefore, necessary for me to consider the balance of convenience, I would have concluded that the balance of convenience clearly favours the refusal of Teva's application. For completeness, I have considered the question of the balance of convenience by reference to a number of factors. I am satisfied that several of those factors clearly tilt the balance of convenience in favour of refusing Teva's application. I have been persuaded that the greatest risk of injustice would lie in granting rather than refusing Teva's application.

221. In conclusion, therefore, I refuse Teva's application. I assume that the pleadings have been closed and I will hear counsel as to whether it is now appropriate for the proceedings to be listed for further directions in the Commercial List to enable the proceedings to be listed for hearing later in 2018 or in early 2019.