THE COURT OF APPEAL

Neutral Citation Number: [2018] IECA 177

Court of Appeal No. 2018/166

Peart J.
Hogan J.
Whelan J.

BETWEEN

MERCK SHARP & DOHME CORPORATION

PLAINTIFF/

APPELLANT

AND

CLONMEL HEALTHCARE LIMITED

DEFENDANT/

RESPONDENT

JUDGMENT of Ms. Justice Máire Whelan delivered on the 12th day of June 2018

1. This is the appeal of Merck Sharp & Dohme Corp. (hereinafter MSD) from the refusal of Haughton J. to grant interlocutory injunctive relief on 27th April 2018 against the respondent (hereinafter Clonmel) in respect of an alleged patent infringement. MSD asserts that as the holder of patent rights extended by a valid Supplementary Protection Certificate ("the 001 SPC") it enjoys a monopoly in the manufacture and sale of the combi-drug product *Inegy* which will continue up to 1st April 2019. On 17th April 2018 Clonmel launched a competitor generic combi-drug on the Irish market. It is contended by MSD that Clonmel, by launching a generic version of *Inegy* during the lifetime of the 001 SPC, has infringed its intellectual property rights and that the trial judge erred in concluding that damages would be an adequate remedy for MSD and further that he erred in refusing to extend the terms of an interim injunction granted to MSD by McGovern J. in the High Court on 20th April 2018.

The Background

The patents

2. MSD is the registered proprietor of European patent number 0 720 599 ("the 599 patent"). The 599 patent covers the active ingredient ezetimibe. The 599 patent expired on 14th September 2014. Under Regulation EC no. 469/2009 the life of a patentee's monopoly may be extended by the grant of a Supplementary Protection Certificate. An SPC granted to MSD, Supplementary Protection Certificate 2003/014 (the 014 SPC), in respect of ezetimibe expired on 16th April 2018.

3. Simvastatin was separately protected by European patent number 0 033 538 ("the 538 patent"). This patent was filed on 2nd February 1981. The 538 patent for simvastatin is owned by MSD's parent company. A supplementary protection certificate for simvastatin based on the Irish parallel patent IE 51478 expired on 5th May 2003. Hence simvastatin was in the public domain at the time the 599 patent was sought and same did not confer MSD with any monopoly over simvastatin.

4. Ezetimibe and simvastatin have each been marketed separately by MSD as monotherapies. The 001 SPC in terms protects ezetimibe or a pharmaceutically acceptable salt thereof in combination with a cholesterol biosynthesis inhibitor. Simvastatin is one such cholesterol biosynthesis inhibitor.

Supplementary Protection Certificate- the EU SPC Regulation 469/2009

5. Supplementary protection certificates are granted pursuant to Regulation EC no. 469/2009 ("The SPC Regulation"). They are intended to provide protection in respect of a patented pharmaceutical product's active ingredients beyond the term afforded by the patent. Regulatory approval for pharmaceutical products can take several years to obtain and such delays erode the standard 20 year patent protection period. The SPC Regulation aims to compensate for the delay by extending the period of exclusivity for the active ingredient or ingredients protected by the basic patent.

6. Article 3, which governs the conditions for obtaining an SPC, requires that at the date of the application for the certificate the basic patent is in force and a marketing authorisation has been granted.

7. The explanatory memorandum for Regulation 1768/92 entitled "Proposal for a Council Regulation on the Creation of a Supplementary Protection Certificate for the Protection of Medicinal Products" dated 28th March 1990 states: "Only one certificate may be granted for any one product, a product being understood to mean an active substance in the strict sense."

The 001 SPC

8. Pursuant to the provisions of the SPC Regulation which entered into force on 6th May 2009, MSD's exclusive rights in respect of products containing ezetimibe in combination with, inter alia, simvastatin was extended until 1st April 2019 by virtue of the 001 SPC. The said combination therapy is marketed under the brand *Inegy*.

9. MSD asserts that the refusal by the High Court of interlocutory relief pending trial is not compatible with either domestic law or with the SPC Regulation and the EU Intellectual Property Enforcement Directive 2004/48. If at trial it is determined to be so then sale or supply of a generic product will be preventable by the patentee, MSD, as constituting an infringing act.

The Merck family of companies

10. Merck is a wholly-owned subsidiary of Merck & Co. Inc. and is the registered proprietor of the 001 SPC. The appellant company appears to have no function in regard to research, development, production, marketing or sales of the drugs in question. It seeks the interlocutory injunction for the purposes of maintaining its monopoly in accordance with the tenor of the 001 SPC and as the registered proprietor of same.

Clonmel
11. Clonmel is a pharmaceutical drugs company specialising in the generics market. It is a subsidiary of the German pharmaceutical company Stada Arzneimittel AG (hereinafter Stada). Clonmel has been granted marketing authorisations by the Health Products Regulatory Authority (HPRA) on 7th April 2018 for generic versions of *Inegy*. Clonmel contends that MSD's intellectual property rights and monopoly entitlements to exploit ezetimibe commercially came to an end on 16th April 2018 when the 014 SPC expired and that thereafter MSD ceased to have exclusivity rights in respect of its medicinal products which contained ezetimibe as an active ingredient notwithstanding the 2005/001 SPC continuing on its face to operate until 1st April 2019.

12. On 17th April 2018, Clonmel launched on the Irish market a generic version of the drug *Inegy*. Essentially, Clonmel contends that the 001 SPC procured by MSD in 2005 in respect of *Inegy* is invalid and of no legal effect. Clonmel, in supplying a generic version of *Inegy*, has undercut MSD from a pricing perspective by 92 %. The uncontested evidence before the High Court was that 15,000 patients in this jurisdiction use *Inegy* prescriptions on a monthly basis and this statistic appears to have remained substantially stable over the past three years.

13. MSD contends that the price differential of 92% has the effect in substance of blocking its *Inegy* product from the market. Further, MSD alleges that the discount price set by Clonmel is motivated by its desire to be competitive as against other generics whom it is anticipated will likely endeavour to enter the Irish market in early course. It asserts that if Clonmel is permitted to maintain its generic product on the market until the expiry of its the 001 SPC on 1st April 2019 MSD will have no alternative but to respond with very significant price reductions of its own in order to protect its market position. As such an interlocutory injunction is necessary in order to prevent such market erosion.

14. Further, MSD asserts that if it succeeds in obtaining a permanent injunction at the substantive trial of the action in the High Court such price reductions will not be easily reversed without significant reputational cost to MSD- particularly with pharmacists. MSD alleges that if an interlocutory injunction is refused the fall in demand for *Inegy* in this jurisdiction will impact on its staff employed to make the simvastatin ingredient at its plant in Ballydine and on the positions of ten individuals who are exclusively engaged for the purposes of promoting the sale of *Inegy*. It is asserted that if the injunction is refused there is a likelihood that parallel importers may purchase the generic product from Clonmel for importation into other EU countries and this in turn will cause loss to MSD in those markets.

15. As a result of the regime for the international reference pricing of pharmaceutical products, MSD claimed that in the event that the price of a medication fell in Ireland it is likely to impact on the price paid in the other referable countries. This would include the European mainland and the middle east.

16. MSD contends that by reason of the refusal of the High Court to grant interlocutory relief it will not enjoy the monopoly conferred by the 001 SPC for the full period granted by the EU legislature under the SPC Regulation. Further, its rights will be reduced to a damages payment should the SPC be found to be valid at the trial of the substantive action in the High Court.

17. Clonmel disputes all of the contentions advanced on behalf of MSD and asserts that the trial judge was correct at the interlocutory stage in refusing an injunction restraining it from making, offering, putting on the market or using products containing both ezetimibe and simvastatin as described in the 001 SPC or from importing or stocking such products for those purposes.

The function of an appeal court in an appeal from the grant or refusal of interim injunctions
18. In *Elan Digitals Systems Limited v. Elan Computers Limited* [1984] F.S.R. 373 at p. 384 the Master of the Rolls stated that:

> "… I think it should be said, and said with great volume and clarity, that this court does not exist to provide a second bite at each interim cherry in the sense that it is open to parties, having failed in front of the learned judge, simply to start again and have a *de novo* hearing in the hope that they will succeed in front of the Court of Appeal. We are a court of appeal, and particularly in the field of interim injunctions it is primarily the trial judge who is appointed to decide whether or not an injunction should be granted. This is not of course to say that there is no right of appeal, but there is a heavy burden on the appellant to show that the learned judge has erred in principle, and that in exercising his discretion there is either an error of principle or—which is the same thing in a different form—he exercised his discretion in a way which no reasonable judge properly directing himself as to the relevant considerations could have exercised it."

Decision of the High Court
19. The case proceeded with great expedition in the High Court6. The transcript records that the trial judge concluded that:

> "So far as the plaintiff is concerned, damages would be an adequate remedy, and there is no issue but that the undertaking that this defendant would give as to damages would be a good undertaking, indeed that is not challenged, and accordingly, I will refuse the application for interlocutory relief. I will give my more detailed reasons in relation to why the Court is of the view that damages are an adequate remedy at a later date."

20. To date no written judgment from the High Court is to hand. The trial judge further noted that he was not satisfied with the contentions advanced by Clonmel that the interlocutory injunction sought by MSD should be regarded as mandatory in nature. He considered that the first issue to be decided was whether there was a fair or serious issue to be determined as to whether or not the 001 SPC in relation to this combination drug of ezetimibe – simvastatin (*Inegy*) is still protected by the SPC which will not expire until 1st April 2019.

21. The trial judge was satisfied that there was a significant dispute between the parties with regard to the validity of the 001 SPC pertaining to the said drug combination. He assessed that MSD, as matters stood, was entitled to the benefit of the SPC and that accordingly a fair and serious question to be tried had been shown.

22. Given that MSD moved swiftly to appeal the refusal of interlocutory relief and that the appeal was heard on 11th May 2018 the substantive and reasoned judgment of the learned trial judge was not yet to hand at the hearing of this appeal. Nevertheless there was sufficient evidence before this Court from the transcript of the key essential reasoning, findings and determinations of the trial judge.

The appellant's arguments
23. MSD asserted infringement of its Irish 001 SPC by Clonmel arising from the latter's placing on the market generic products which contain ezetimibe in combination with simvastatin or importing or stocking such products for such purposes. The appellant argues that its entitlement to interlocutory relief should be determined by the application of the principles set out in the decision of the House of Lords in *American Cyanamid v. Ethicon Ltd*. [1975] A.C. 396 as adopted by the Supreme Court in *Campus Oil Limited v. Minister for Industry and Commerce (No. 2)* [1983] I.R. 88.

24. Clonmel disputes the appellant's contentions and denies its entitlement to seek interlocutory relief on a number of grounds. It contends that the Campus Oil guidelines and principles do not apply simpliciter in the current application, not least because, as they assert, in substance what is being sought is a mandatory interlocutory injunction. Hence it is argued that a far more stringent test should obtain. Further, Clonmel contends that the grant of an interlocutory injunction in the terms sought herein would effectively resolve the case in favour of the appellant it being unlikely that a trial of the action will ever take place having regard to the short time remaining until the 001 SPC expires. Separately, Clonmel argued that even if the patent suit went to trial it is unlikely that the substantive action and inevitable appeal could be disposed of prior to 1st April 2019.

Serious Question- novel and innovative
25. It is contended by MSD that a combination of the two drugs ezetimibe and simvastatin as contained in the *Inegy* product is novel and innovative over and above what was possible through treatment with statins alone as a monotherapy. In this regard reliance is placed on an opinion of Professor Assmann dated 24th August 2015.

26. MSD contends that the combination therapy of ezetimibe with a statin makes it possible to achieve a 10 to 20 % greater reduction in LDL cholesterol in the blood than is possible with a monotherapy treatment based on the maximum dose of a statin alone.

27. Whilst MSD does not appear to expressly contend for a synergy they characterise the combination therapy as a highly efficacious combination of active substances for which it received a drug approval and marketing authorisation under the name *Inegy* and continues to enjoy protection of an SPC granted pursuant to Article 4 the SPC Regulation in relation to that combination which will expire on 1st April 2019.

Clonmel's arguments
28. Clonmel acknowledges that the combination of ezetimibe with a statin such as simvastatin is superior to statin monotherapy. Nevertheless, Clonmel claims that there is nothing novel and innovative in the combination such as could be characterised as a synergy giving rise to a totally separate and distinct inventive concept. Each pharmaceutical ingredient is marketed and continues to be marketed as a monotherapy. It is contended that the 599 patent does not teach any advantage in taking simvastatin and ezetimibe in the same product as compared to administering simultaneously two separate pharmacological products, one containing simvastatin alone, the other ezetimibe. The claim relating to the combination discloses the core of the invention. Clonmel argues that the combination which purports to enjoy protection under the 001 SPC is not the core of the invention.

29. Clonmel contends that a basic patent is entitled to an extension once only through the mechanism of a Supplementary Protection Certificate. It argues that MSD availed of that entitlement previously by the 014 SPC which expired on 16th April 2018. Clonmel claims that the 001 SPC constitutes a second SPC based on the self-same basic patent which it argues was erroneously granted to MSD and is invalid and of no legal effect.

Engagement between the parties pre-litigation
30. Clonmel's parent company, Stada wrote to agents for MSD on 27th September 2016 and 31st May 2017 indicating it did not intend to launch a generic ezetimibe product prior to expiry of MSD's SPC for ezetimibe on 16th April 2018.

31. In my view a reasonable inference to be drawn from the tenor of that correspondence was that it was in the contemplation of Clonmel to launch a generic competitor to *Inegy* once the 16th April 2018 watershed had passed and the 014 SPC had expired.

32. On 4th April 2018 MSD learned that Clonmel had sought and obtained reimbursement prices for their proposed generic ezetimibe and simvastatin combi-tablets from the Health Services Executive (HSE).

33. On 6th April 2018 Whitney Moore, solicitors for MSD, wrote to Clonmel seeking signed undertakings including requiring Clonmel to inform the HSE that they would not market generic ezetimibe and simvastatin products in the Irish market until 1st April 2019 and calling upon Clonmel to change its reimbursable "effective date" with the HSE primary care reimbursement service scheme to 1st April 2019.

34. On 12th April 2018 William Fry Solicitors, on behalf of Clonmel, responded refusing to provide the undertakings sought. Further, they asserted; "our client contends that your client's SPC is invalid." On 17th April 2018 Whitney Moore corresponded, indicating that MSD had no option but to assume that Clonmel was about to launch generic ezetimibe and simvastatin combi-tablets onto the Irish market. "If we are incorrect in this assumption, we require written confirmation by 6.00 pm today, Tuesday 17 April 2018, otherwise our instructions are to immediately commence proceedings against your client for infringement of our client's SPC and to seek urgent injunctive relief."

35. On the same date William Fry on behalf of Clonmel responded refusing to provide the undertakings sought and confirming that two categories of generic combi-drugs, ezetimibe – simvastatin, had been released by Clonmel on the Irish market that day. It was further asserted as follows:

> "The balance of convenience clearly lies with our client and damages will fully compensate your client should an infringement be found to have occurred (which infringement is denied)."

Approach to be adopted
36. I now turn to consideration as to whether Haughton J erred in principle or exercised his equitable discretion unreasonably or contrary to established equitable principles in refusing an interlocutory injunction. In particular, it is necessary in this case in light of the facts to consider the extent to which the *Campus Oil* guidelines were required to be modified by the consideration of additional elements.

37. The principles set out in *American Cyanamid* and *Campus Oil* are important and helpful guidelines but are not to be treated as though written on a tablet of stone to be slavishly and blindly followed. These guidelines, though generally relevant and of assistance, in cases where the outcome at interlocutory stage is likely to be dispositive of the core of the action, must give way to an evaluation

of the balance of risk of doing an injustice. An important additional element is an assessment of the degree of likelihood that a plaintiff will have established an entitlement to a perpetual injunction if the action goes to trial. This is a significant added factor to be considered by the trial judge in such cases and is important in the assessment of the balance of convenience.

The issue
38. In this appeal at issue is whether the combination therapy involving simvastatin, the basic patent and supplementary protection certificate for which have expired, and ezetimibe, whose basic patent and supplementary protection certificate have also expired, when combined in a single therapy which *prima facie* enjoys effective protection under the 001 SPC, is "novel and innovative" as warrants the granting of an interlocutory injunction for its protection.

39. The validity and efficacy of the 001 SPC will ultimately be determined should a trial of this action take place.

Equitable nature of injunction remedy
40. The decision to grant or deny interlocutory injunctive relief is an exercise of equitable discretion by the High Court judge, reviewable on appeal for abuse of discretion. The equitable discretion over injunctions granted to protect rights under the Patent Act and relevant intellectual property law accords with the provisions of EU Intellectual Property Enforcement Directive 2004/48.

41. "Discretion is not whim, and limiting discretion according to legal standards helps promote the basic principle of justice that like cases should be decided alike." – Martin *v. Franklin Capital Corporation* 546 US 2005.

42. Such discretion must be exercised consistent with traditional principles of equity in patent disputes no less than in other cases governed by such standards. That principle rightly rests on the proposition that any major departure from the long tradition of equity practice should not be lightly implied. An injunction being an equitable remedy is not a remedy which issues as of course.

43. The existence of a monopolistic right to exclude does not per se dictate in equity the remedy for a violation of that right.

Risk of injustice
44. The decision of the House of Lords in *American Cyanamid Co. v. Ethicon Limited* [1975] A.C. 396 was accepted by the Supreme Court in *Campus Oil v. Minister for Industry & Energy (No. 2)* [1983] I.R. 88. It will be recalled that *American Cyanamid* concerned patent infringement alleged by the plaintiff in respect of absorbable surgical sutures. The plaintiff sought an interlocutory injunction and the defendant denied infringement and counter-claimed invalidity of the patent.

Temporary and discretionary
45. The first point to be borne in mind when considering the principles applicable to the determination of an application for an interlocutory injunction is that it is a remedy that is temporary and discretionary. In *Campus Oil*, O'Higgins C.J. prefaced his analysis of the relevant principles with the following observations at p. 105:

> "Interlocutory relief is granted to an applicant where what he complains of is continuing and is causing him harm or injury which may be irreparable in the sense that it may not be possible to compensate him fairly or properly by an award of damages. Such relief is given because a period must necessarily elapse before the action can come for trial and for the purpose of keeping matters in status quo until the hearing … The application for an interlocutory injunction is often treated by the parties as the trial of the action. When that happens, the rights of the parties are finally determined on the interlocutory motion. In cases where rights are disputed and challenged and where a significant period must elapse before the trial, the court must exercise its discretion (to grant interlocutory relief) with due regard to certain well-established principles."

Irreparable harm or injury
46. Though a plaintiff may have a weak case on the merits, this is not necessarily a bar *per se* to the grant of an interlocutory injunction provided the plaintiff can demonstrate some real prospect of succeeding at the trial of the suit.

47. It is clear from the jurisprudence in this jurisdiction that the aim of an interlocutory injunction is to protect a plaintiff against irreparable harm or injury ensuing from violation of his rights in the pre-trial period. This requires to be weighed against the defendant's need to be protected also against irreparable injury resulting from his having been prevented from exercising his own legal rights.

48. Ultimately it is necessary for the Court to engage in a balancing exercise having due regard to the affidavit evidence of the parties. "Irreparable injury" has been confined by the *Campus Oil* guidelines and subsequent jurisprudence to injury or loss that cannot be adequately compensated in damages recoverable at trial. The balancing exercise or test is thus based primarily on the extent of each party's potential irreparable loss.

49. Clarke J. in *Okunade v. Minister for Justice* [2012] 3 I.R. 152 outlined the operation of our distinct national jurisprudence in relation to the operation of equitable principles governing interlocutory relief succinctly stating:

> "It is fair to say that much of the detailed analysis of the *Campus Oil* test has occurred in the context of injunction proceedings which at least have a significant commercial contractual or property character. The basic rules for the grant or refusal of such injunctions at the interlocutory stage are well settled. The test perhaps finds its most detailed exposition in the judgment of McCracken J. in *B.&S. Ltd. v. Irish Auto Trader Ltd.* [1995] 2 I.R. 142, which has been approved by Laffoy J. in *Symonds Cider and English Wine Company v. Showerings (Ireland) Ltd.* [1997] 1 I.L.R.M. 481 and Quirke J. in *Clane Hospital Limited v. Voluntary Health Insurance Board* (Unreported, High Court, Quirke J., 22nd May 1998)." (para. 69)

50. He continued:

> "As formulated in *B.&S. Ltd. v. Irish Auto Trader Ltd.* the test can be summarised as follows:-
>
> (i) The party seeking the injunction must show that there is a fair or *bona fide* or serious question to be tried.
>
> (ii) 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.

(iii) 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.

(iv) If damages would not adequately compensate either party, then the court must consider where the balance of convenience lies.

(v) If all other matters are equally balanced the court should attempt to preserve the *status quo*." (para. 70)

51. It was further stated:

"It can be seen that the analysis of McCracken J. 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…"

"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."

"Finally, even that part of the test which suggests that maintaining the status quo might be determinative where all other factors are evenly balanced is in itself a recognition that, in order to interfere with the situation as it currently stands, the court requires a justification. Therefore the risk of injustice from not acting must be greater than that from acting in order that the court depart from the status quo."

"However it is clear that those detailed rules derive from the courts' regular experience of having to deal with the day to day issues which are thrown up in deciding whether to put in place interlocutory orders in the context of commercial or property litigation so as to minimise the risk of injustice. In that context it does also need to be noted that the courts have had to evolve variations on the test or [more] accurately the precise implementation of the test in order to deal with the specific types of problems which arise in particular types of litigation.

It is unnecessary for the purposes of this judgment to analyse in detail each of the types of cases where a refinement of what might be described as the "pure" *Campus Oil* test has evolved. However, some examples are illustrative of the fact that that such refinements and variations can be seen as a response to the need to minimise the risk of injustice in the context of the particular types of issues which are likely to arise in special cases." (paras. 71-75)

52. Over the past 35 years or so the practice has emerged in this jurisdiction whereby the determination of the court at the interlocutory stage generally favours the party who demonstrates that they stand to suffer the greater loss or injury. In general it is only where the extent of the irreparable injury to each party would not differ substantially that the court can proceed to have due regard to the relative strength of each party's claim.

Serious question to be tried

53. Accordingly, in the first instance it is necessary to consider the threshold question as to whether MSD has demonstrated a fair *bona fide* question to be tried.

54. In the instant case it has been demonstrated by MSD that they hold and enjoy rights on foot of the 001 SPC. It is clear that Clonmel has long been aware of the existence of that SPC. In order to obtain the 001 SPC, MSD had to comply with the basic proofs under the operative council regulation that then obtained. Although Clonmel asserts that they failed to validly do so that is an issue to be determined at plenary hearing.

55. As the holder of intellectual property rights MSD enjoys the ordinary incidents of title including the right to invoke equitable remedies to protect its monopoly from infringement. I am satisfied at the level of principle that, as the holder of the 001 SPC, MSD has demonstrated the existence of a serious issue for trial.

56. The SPC Regulation establishes a mechanism for challenging the validity of SPC's, such a mechanism being available to any party seeking to impugn the validity of said measure pursuant to Article 15 of that regulation.

Has Clonmel raised a fair bona fide question

57. Whilst no revocation of the 001 SPC is being sought in the counterclaim, Clonmel asserts that same is invalid and was erroneously granted. In a defence delivered on 9th May 2018 Clonmel pleads:

"(a) It is admitted that the Plaintiff was the holder of Irish Patent Number 0 720 599 (the "599 Patent") which expired on 14 September 2014.

(b) It is admitted that the Plaintiff obtained Irish Supplementary Protection Certificate No. 2005/001 (the 001 SPC) on 3 August 2005 and that it purports to cover *"ezetimibe, or a pharmaceutically acceptable salt thereof, in combination with the cholesterol biosynthesis inhibitor such as simvastatin"*, but such grant was and remains invalid for the reasons pleaded in the Particulars of Objection delivered with the Counterclaim herein.

(c) It is admitted that the 001 SPC purports to identify the 599 Patent as "the basic patent", but this was and remains impermissible and thus invalid for the reasons pleaded in the Particulars of Objection delivered with the Counterclaim herein.

(d) It is denied that the 599 patent conferred rights on the Plaintiff in respect of products containing ezetimibe in combination with simvastatin, whether as alleged or at all.

(e) If the 599 patent conferred rights on the Plaintiff in respect of products containing ezetimibe in combination with simvastatin (which is denied), it is denied that the 001 SPC extended any such rights until 1 April 2019."

58. In the Particulars of Objection delivered by Clonmel on 9th May 2018 the following matters are pleaded:

- That the 014 SPC was applied for on or about the 30th October 2003 relying on the 599 patent.

- The 014 SPC was granted in respect of the product ezetimibe or a pharmaceutically acceptable salt thereof and expired on 16th April 2018.

- The plaintiff commercialises some additional product containing ezetimibe under the brand name *Ezetrol*.

- The 001 SPC was applied for on or about 21st January 2005 relying on the 599 patent.

- The 001 SPC was granted in respect of the product ezetimibe, or a pharmaceutically acceptable salt thereof, in combination with a cholesterol biosynthesis inhibitor such as simvastatin. The plaintiff commercialises a medicinal product containing a combination of ezetimibe plus simvastatin under the brand name *Inegy*.

- The 599 patent did not confer any rights in respect of simvastatin.

- The 001 SPC is invalid pursuant to Article 15 of Regulation (EC) no. 469/2009 of the European Parliament and of the Council of the 6th May 2009 (the SPC Regulation). This is so because it was granted contrary to the provisions of Article 3 of the SPC Regulation.

- Clonmel contends that Article 3 of the SPC Regulation was violated by MSD in the following manner:

  (a) In breach of Article 3(a), the combination of ezetimibe plus simvastatin was not protected by the 599 patent.

  (b) Ezetimibe plus simvastatin was not the core inventive advanced to which the 599 patent pertained.

  (c) In breach of Article 3(c), ezetimibe, the compound protected by the 599 patent, was already the subject matter of a prior SPC- SPC 014.

  (d) In breach of Article 3(d) of the SPC Regulation, the ezetimibe product *Ezetrol* was already available for the combined use of ezetimibe with a statin such as simvastatin for the same indications as *Inegy* and accordingly the market authorisation for *Inegy* was not the first authorisation for the combination.

59. I am satisfied that Clonmel in their Objection and Counterclaim also disclose a serious issue for trial as to whether the 001 SPC is invalid. Hence, I am satisfied that both parties have identified serious issues to be determined at the trial of the action.

Damages
60. The main thrust of Mr. Newman's argument on behalf of MSD is that the trial judge erred in his determination that damages would be an adequate remedy for MSD. He argued that damages would not be an adequate remedy for the following reasons:

- If Clonmel is permitted to stay in the market MSD will have to engage in very large price reductions of its own.

- In the event MSD succeeds at trial it is highly unlikely that such price reductions could be fully reversed.

- A reversal of prices back to current levels would damage MSD's relationship with pharmacists.

- There will be permanent damage to the 001 SPC.

- Parallel importers may acquire the generic product for resale in other EU states occasioning loss to MSD in those markets.

- The operation of price referencing means that if prices for the generic product falls in Ireland this will adversely impact prices in the relevant basket of countries to which Ireland belongs.

61. Clonmel asserts that the sands of time are running out on the disputed SPC itself. If the matter proceeds to full trial and a permanent injunction is refused then its first mover advantage will be rendered nugatory and other generic manufacturers will have had ample opportunity to advance their involvement in the Irish market ahead of 1st April 2019.

62. In *SmithKline Beecham plc v. Genthon* [2003] IEHC 623 Kelly J. (as he then was) considered the issue of damages and had regard to the principle that if damages for the alleged breach of rights in the measure recoverable at common law would be an adequate remedy and the defendant is in a position to pay them, no interlocutory injunction should normally be granted however strong the plaintiff's claim appears to be. The decision is of assistance in regard to the correct approach to the exercise of equitable jurisdiction at interlocutory stage, particularly in an intellectual property dispute.

63. The exercise by a judge at interlocutory stage as to whether to grant or deny interlocutory relief rests upon the equitable discretion of the High Court judge. That discretion must be exercised consistent with the principles of equity and having due regard to the guidelines of the Supreme Court in the *Campus Oil* decision.

Adequacy of damages and balance of convenience are separate and distinct considerations
64. The second step to be considered in light of the *Campus Oil* guidelines is whether damages would not be an adequate remedy in respect of the matters which the plaintiff now complains.

65. The approach to the issue of the adequacy of damages is wholly separate and distinct from the question of the balance of

convenience, as the Supreme Court has clarified in *Westman Holdings Limited v. McCormack* [1992] 1 I.R. 151. In that case Finlay C.J. stated at pp. 157-58:

> "I am satisfied that once a conclusion is reached that the plaintiff seeking an interlocutory injunction has raised a fair question to be tried at the hearing of the action in which, if he succeeded, he would be entitled to a permanent injunction that the Court should not express any view on the strength of the contending submissions leading to the raising of such a fair and *bona fide* question, but should proceed to consider the other matters which then arise in regard to the granting of an interlocutory injunction. They are, firstly, as to whether the plaintiff could, in the event of being refused an injunction and succeeding in the action, be adequately compensated by damages. That question raises two separate issues, potentially, in every case. The first is the question as to whether damages would be an adequate remedy, and the second is as to whether there is a defendant liable to pay such damages who is able to do so, and thus the appropriate compensation could actually be realised."

66. Once it is established that there is a serious question to be tried the Court must accordingly consider two aspects of the adequacy of damages. Firstly, whether, if it does not grant an interlocutory injunction and MSD succeeds at the trial of the substantive action, it will be adequately compensated by an award of damages for any loss suffered between the date of refusal and the trial of the action. If MSD would be adequately compensated by damages the interlocutory injunction should be refused. The evidence is that Clonmel would be in a position to discharge any damages likely to arise. Conversely, if damages would not be an adequate remedy for Clonmel then the Court must consider whether, if it does grant an injunction at the interlocutory stage, MSD's undertaking as to damages will adequately compensate Clonmel, should the latter be successful in its Objection & Counterclaim at the trial of the action, in respect of any loss suffered by it due to the interlocutory injunction being enforced pending the trial. If it is shown that Clonmel would be adequately compensated by damages, should it transpire at trial that the interlocutory injunction was erroneously granted, then the interlocutory injunction will normally be granted.

67. If at interlocutory stage the judge is satisfied that damages would be an adequate remedy then that is generally the end of the matter, and he or she should not proceed further to even consider the balance of convenience.

68. If damages would not adequately compensate either party, the Court must then proceed to consider where the balance of convenience lies.

69. Regarding the standard of proof which requires to be satisfied on the question of the adequacy or otherwise of damages, Finlay C.J. in *Curust Financial Services Ltd. v. Loewe* [1994] 1 I.R. 450 stated:

> "The loss to be incurred by Curust if it succeeds in the action and no interlocutory injunction is granted to them, is clearly and exclusively a commercial loss, in what had been, apparently, a stable and well established market. 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 award of damages as an inadequate remedy." (at pp. 468-69)
>
> … 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 purposes of the interlocutory injunction that damages would not be an adequate remedy by reason of the real risk of the financial collapse of the Curust companies." (at p. 469)

70. The appellant must, as a matter of probability, demonstrate the likelihood that damages would be an inadequate remedy and identify the facts and issues being relied upon as being indicative of irreparable damage.

71. It is contended on behalf of Clonmel as promoters of the generic product that damages are almost always an adequate remedy for a claim for patent infringement and that an interlocutory injunction should not normally be made in favour of a patentee.

The relative positions of the parties

72. I accept the submissions on behalf of Clonmel that MSD's market has been demonstrated to be a stable and well-established one. The loss is pre-eminently a commercial loss and should be characterised as same in circumstances where the disputed 001 SPC is so close to expiration.

73. The adequacy of damages was considered by Clarke J. in *Okunade v. Minister for Justice* [2012] 3 I.R. 152 where he stated at p. 181:

> "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."

74. The undisputed evidence before the learned judge at the interlocutory hearing on 27th April 2018 was that four other companies have obtained market authorisation approval for a combination drug for ezetimibe and simvastatin. Should it transpire at the trial of the action that an interlocutory injunction ought not to have been granted to MSD it will present very significant and almost insuperable difficulties to Clonmel in proving the extent of the loss to it, particularly given the options available to Clonmel at this stage in regard to entry into parallel arrangements with importers and other EU markets. It would be virtually impossible to reliably evaluate any loss in retrospect based on how Clonmel's generic market share would or might have evolved.

75. This is particularly so in circumstances where Clonmel, with the benefit of first mover advantage, stands to become a market leader in the generic product in this jurisdiction at least in the crucial initial post monopoly stage. It being virtually impossible to confidently ascertain what Clonmel's loss would be in the context of first mover advantage, I am satisfied that damages would not be an adequate remedy for it.

The balance of convenience

76. In determining where the balance of convenience lies various issues may require consideration by a trial judge. These will vary from case to case and be case specific.

77. The recognized exception to the *Campus Oil* guidelines and approach is where the relief sought, should it be granted, would as a practical matter foreclose any further assessment of the true merits of the legal claim and bring to an end the action because such

relief would effectively decide the contest between the parties.

Dispositive of the substantive issue
78. A key question which arises, in this case, is whether the decision in regard to the application for interlocutory relief will be outcome-determinative on the central infringement aspect of MSD's claim. Thus, there is an issue as to the relevance and weight to be attached to that aspect of the interlocutory determinative process. Both sides are agreed that notwithstanding enthusiastic case management there is little prospect of the substantive action and any appeal being concluded before Michaelmas term which ends on 18th December 2018. All the indicators suggest that, on balance, it is not likely that a judgment will be delivered prior to the beginning of 2019. Thereafter MSD's 001 SPC is due to expire on 1st April 2019.

79. In the circumstances that obtain, I am satisfied that the granting or refusal of this interlocutory application will be dispositive of the substantive claim as between the parties. Accordingly, it is appropriate, to a limited extent, in the manner outlined below, as part of the assessment of the balance of convenience to consider the respective merits of the claim and counterclaim herein. This is warranted having regard to the principle that the object of an interlocutory injunction is the avoidance of irreparable injury to rights.

80. In the UK case *Lansing Linde Limited v. Kerr* [1991] W.L.R. 251 as in *NWL Limited v. Woods* [1979] 1 W.L.R. 1294, both cases where the interlocutory orders would be dispositive of the litigation, the applicant's prospects of success were not addressed at the "gateway" assessment of fair question to be tried. Rather the prospects of the parties were taken into account in determining the balance of convenience and only at that stage.

Balance of convenience where trial of the action is unlikely - evaluation of relative strength of the parties' claims
81. The fundamental principle is that an interlocutory injunction is never intended to constitute a decision as to final rights but rather a decision as to what seems to be the best for the time being, in light of competing exigencies which are identified to the judge, in order to maintain, as far as practicable, a proper balance between the parties until their rights are finally determined at a substantive trial.

82. Thus in *N.W.L. Ltd. v. Woods* [1979] 1 W.L.R. 1294, at p. 1306, Lord Diplock said that a judge ought to "give full weight to all the practical realities of the situation to which the injunction will apply" and that the *American Cyanamid* decision "was not dealing with a case in which the grant or refusal of an injunction at that stage would, in effect, dispose of the action finally in favour of whichever party was successful in the application, because there would be nothing left on which it was in the unsuccessful party's interest to proceed to trial."

83. Lord Diplock continued; "Cases of this kind are exceptional, but when they do occur they bring into the balance of convenience an important additional element."

84. In my view this reflects the correct approach to be adopted by the judge at the interlocutory stage in such cases and is supported by the jurisprudence in this jurisdiction including the Supreme Court decision in *Attorney General v Lee* [2000] 4 I.R. 298 which concerned an application for a mandatory interlocutory injunction where Keane C.J. noted at p. 305 that;

> "However, although in form the order appealed from is an interlocutory injunction, it is obvious that, if upheld, it will finally dispose of the proceedings. It is, accordingly, not entirely logical to resolve the issue as to whether the interlocutory injunction should or should not have been granted by reference to the usual test, i.e. as to whether the plaintiff has established that there is a fair question to be tried. If it should emerge at the plenary hearing of the proceedings, that, while there was a fair question to be tried, the defendant was entitled to succeed, it is difficult to see how justice could be done to the defendant where the interlocutory order has effectively disposed of the entire case."

85. It will be recalled that the principles in *Campus Oil* enjoy the status of guidelines in regard to the exercise of equitable discretion in determining whether to grant or refuse interlocutory relief pending trial. The jurisprudence over the past several decades indicates that the court generally seeks reassurance that a trial is likely to take place. The respondent asserts that the grant of interlocutory relief in the terms sought by the appellant would effectively resolve the case in favour of the appellant since the intellectual property rights contended for on behalf of the appellant as being derived from the SPC will determine automatically on 1st April 2019.

86. A key consideration is whether the interlocutory relief which the Court is requested to grant will have the effect in all practical likelihood of foreclosing a substantive trial. In my view, on the specific facts disclosed in this case, it more than likely will.

87. Where there is doubt as to the adequacy of the respective remedies in damages available to either party or to both the third stage of the inquiry is to assess where the balance of convenience lies. This modified approach has sometimes been characterised as evaluating "the balance of the risk of doing an injustice" (see per May L.J. in *Cayne v. Global Natural Resources plc* [1984] 1 All E.R. 225 at p. 237). This evaluation will depend upon an assessment of competing considerations which will vary from case to case though almost inevitably:

> "The decision to grant or to refuse an interlocutory injunction will cause to whichever party is unsuccessful on the application some disadvantages which his ultimate success at the trial may show he ought to have been spared and the disadvantages may be such that the recovery of damages to which he would then be entitled either in the action or under the plaintiff's [cross-] undertaking would not be sufficient to compensate him fully for all of them." (per Lord Diplock in *American Cyanamid* at pp. 408-9).

Irreparable injury
88. In calibrating the balance of convenience the Court should have regard to the extent to which either party will suffer irreparable injury. While both assert that they will suffer irreparable harm it is clear that MSD's market is finite, certain, stable and demonstrably established in terms of income stream. There is no evidence that it anticipates a dramatic variation in sales during the final 9 months or so of its monopoly.

89. By contrast Clonmel's position is nascent, evolving, aimed at maximising first mover advantage through exploitation of public health purchasing arrangements, availing of freedom of movement of goods within EU markets and parallel imports mechanisms. It anticipates a long-term presence in the generic market with the product. Given the uncertainty of its position at this stage as to whether it will or could achieve its objective regarding market share, exportation and parallel imports, there are significant risks not readily resolvable that Clonmel will suffer losses not easily ascertainable or verifiable if the interlocutory injunction is granted. Future potential losses of a generic drug company denied first mover advantage in the market may not be amenable to probative proof. The risk to Clonmel if the injunction is granted is that it will suffer irreparable injury since the remedies available at law, such as pecuniary

damages, are inadequate to compensate for any injury.

Uncompensatable disadvantage
90. The factors to be considered will or may include:

> (a) the balance of uncompensatable disadvantage to either of the parties;
>
> (b) the extent to which such disadvantages might potentially be capable of being compensated;
>
> (c) where the balance is still uncertain, whether upon the facts disclosed by undisputed evidence, the strength of one party's case is disproportionate to that of the other party; and
>
> (d) any other special factors that the court considers impact on the risk of doing uncompensatable damage, including to innocent third parties;
>
> (e) finally, regard must be had to what is to be taken as the status quo, it being, if other factors appear to be evenly balanced, a counsel of prudence to take such measures as are calculated to preserve it.

91. The various factors outlined above are not prerequisites; rather, they must be balanced.

92. In this jurisdiction Laffoy J. in *Jacob v. Irish Amateur Rowing Union Ltd*. [2008] 4 I.R. 731 considered the relevant principles to be taken into account in modifying the Campus Oil guidelines and the balance of convenience test where interlocutory relief is sought which is likely to be dispositive of the core issues between the parties. She considered the appropriate calibration of the *Campus Oil* guidelines to address such circumstances. She noted that Lord Diplock in *N.W.L.* had addressed the scenario in which the grant or refusal of an interlocutory injunction would dispose of the action finally in favour of the successful party to the application.

Issues should be tried and not be pre-empted
93. Laffoy J noted that Lord Diplock had recognised "exceptional" cases which, when they occur, bring into the balance of convenience an important additional element and cited Lord Diplock in this regard in *N.W.L.* where he had stated at p. 1307:

> "Where, however, the grant or refusal of the interlocutory injunction will have the practical effect of putting an end to the action because the harm that will have been already caused to the losing party by its grant or its refusal is complete and of a kind for which money cannot constitute any worthwhile recompense, the degree of likelihood that the plaintiff would have succeeded in establishing his right to an injunction if the action had gone to trial, is a factor to be brought into the balance by the judge in weighing the risks that injustice may result from his deciding the application one way rather than the other."

Entitlement to have full rights determined at a full trial
94. Laffoy J cited with approval the English Court of Appeal decision in *Cayne v. Global Natural Resources plc* [1984] 1 All E.R. 225, where May L.J. offered authority for such an approach by stating at p. 238:

> "With those considerations in mind, I do not think that in cases such as the present, whatever the strengths on either side, where the decision on an interlocutory application for an injunction will effectively dispose of the claim, the court can legitimately, nor is it bound, to apply the Cyanamid guidelines, which as I have already said, I think are based on the proposition that there will be a proper trial at a later stage when the rights of the parties will be determined.
>
> It may well be that it is the same ultimate consideration which the court has in mind, namely the question whether it is likely to do an injustice. Where a plaintiff brings an action for an injunction, I think that it is, in general, an injustice to grant one at the interlocutory stage if this effectively precludes a defendant from the opportunity of having his rights determined in a full trial. There may be cases where the plaintiff's evidence is so strong that to refuse an injunction and to allow the case to go through to trial would be an unnecessary waste of time and expense and indeed do an overwhelming injustice to the plaintiff. But those cases would, in my judgment, be exceptional."

95. The question arises, has the respondent, Clonmel, as it contends, established that this approach is an exception to the usual rule; namely that it suffices to show that there is a fair, *bona fide* question for determination or is there a further burden on MSD to demonstrate an "overwhelming" case.

96. In *Cayne* there is the following passage in the judgment of Kerr L.J. at p. 236:

> "As was pointed out during the argument, if this position were viewed as an application for summary judgment under RSC, Order 14, then it would be clear beyond argument that the defendants must be given unconditional leave to defend, because they would obviously be entitled to a full trial. However, the grant of an injunction would preclude this, so far as can be foreseen at present, for the reasons already stated.
>
> In these circumstances it seems to me that it would be wholly wrong for this court, in effect, to decide the entire contest between the parties summarily in the plaintiffs' favour on the untested material before us. This does not present any overwhelming balance on the merits in the plaintiffs' favour, or any other overriding ground for an immediate injunction without a trial. There is only a triable issue whose outcome is doubtful; and that issue should be tried and not pre-empted."

The risk of doing injustice
97. In such circumstances May L.J. noted in *Cayne* at p. 237 regarding the "balance of convenience" that:

> "That is the phrase which, of course, is always used in this type of application. It is, if I may say so, a useful shorthand but in truth, and as Lord Diplock himself made clear in the *N.W.L.* case, the balance that one is seeking to make is more fundamental, more weighty, than mere "convenience". I think that it is quite clear from both cases that although the phrase may well be substantially less elegant, the "balance of the risk of doing an injustice" better describes the process involved."

98. May L.J. further stated at p. 238:

> "In general, as I say, where a plaintiff brings an action and in it seeks an interlocutory injunction on the basis that the defendant has breached the former's rights, then justice requires that the defendant should be entitled to dispute the plaintiff's claim at a trial, and if the grant of the injunction would preclude this, then it should not be granted on an interlocutory basis."

99. In the instant case the withholding of the injunction may lead to MSD suffering some damages which they are unable to recover; but I am far from persuaded that such damages are likely to be substantial. In *Jacob*, at p. 741, Laffoy J. was of the view that given the state of evidence in that case it was not possible to assess the relative strengths and weaknesses of the case put forward by the plaintiff and the defendant:

> "Obviously, one could form a view on a theoretical basis of the propositions of law advanced by counsel for the plaintiff as to the cause of actions (sic) which he asserts the plaintiff has against the defendant, but, in my view, that would be a meaningless exercise because the real problem in this case is the conflict on the evidence. The best one can do, it seems to me, is to consider the question suggested by May L.J. in *Cayne*… whether the plaintiff's case on the evidence is so strong that to refuse an injunction would constitute an injustice."

100. Laffoy J. continued:

> "It is not possible to conclude that the plaintiff's case on his own evidence, leaving aside the conflicts, bears that weight." (at p. 741)

101. MSD rely on the Opinion of the Advocate General in *Teva v. Gilead* (Case C-121/17) concerning Article 3(a) of the SPC Regulation in support of its contention that its claim is strong and that Clonmel has no *bona fide* defence in law or on the merits that will succeed at trial. I find the opinion of limited assistance to the matters at issue.

Teva v. Gilead (case C-121/17) concerning Article 3(a) of the SPC Regulation

102. A net question was referred by Arnold J. from the High Court of England & Wales to the CJEU as follows:

> "What are the criteria for deciding whether "the product is protected by a basic patent in force" in Article 3(a) of Regulation No 469/2009 [the SPC Regulation]?"

103. In his opinion in *Teva v. Gilead*, delivered in April 2018, Advocate General Wathelet stated:

> "Article 3(a) of Regulation (EC) No. 469/2009 of the European Parliament and of the Council of the 6th May 2009 concerning the supplementary protection certificate for medicinal products precludes the grant of a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent. The fact that a substance or combination of substances falls within the scope of protection of the basic patent is a necessary, but not sufficient, requirement for it to constitute a product protected by a patent within the meaning of Article 3(a) of Regulation No. 469/2009.
>
> A product is protected by a patent within the meaning of Article 3(a) of that regulation if, on the priority date of the patent, it would have been obvious to a person skilled in the art that the active ingredient in question was specifically and precisely identifiable in the wording of the claims of the basic patent. In the case of a combination of active ingredients, each active ingredient in that combination must be specifically, precisely and individually identifiable in the wording of the claims of the basic patent…"

104. In his opinion, the Advocate General agreed with Arnold J. that it is necessary but not sufficient that the product falls within at least one of the claims of the basic patent under the extent of protection rules as set out in Article 69 of the European Patent Convention.

105. However he did not agree with Arnold J. that it is necessary to determine whether the product embodies the inventive advance of the patent, which is referred to in the CJEU's decision in *Actavis v. Sanofi* (Case C- 443/12), noting that the *Sanofi* case was only concerned with Article 3(c) and not 3(a) of the SPC Regulation and commenting that he had difficulty in understanding the difference between the "core inventive advance" and the invention disclosed by the claims.

106. The Advocate General considered it to be clear from CJEU case law that the sole means for determining whether the product is protected by the basic patent "is to be found only in the wording, or interpretation of the wording, of the claims of the patent … and nowhere else". The issue is with what degree of specificity or abstraction a product needs to be "specified" in the claims.

107. The Advocate General acknowledges that it is a matter for the national court to decide whether the patent in question "specifically and precisely" identified an active ingredient in a pharmaceutical composition as disclosed in the wording of the claims of the basic patent.

108. A novel element in the opinion of the Advocate General is the suggestion that the CJEU should take account of what would have been obvious to a person skilled in the art as having been identifiable in the claims of the patent at the priority date.

109. In his opinion, Advocate General Wathelet appears to reject both the "core inventive advance test" proposed by Arnold J., the referring English judge, and the "scope of protection test" which had been proposed by *Gilead* and non-parties interveners.

110. Instead, he sees the wording of the claims and the interpretation of that wording as the sole basis for determining whether an active ingredient is protected by the basic patent.

111. He considers that the decisive test should be whether at the priority date of the patent "it would have been obvious to a person skilled in the art that the active ingredient in question was specifically and precisely identifiable in the wording of the patent claims."

112. Ultimately this issue may be determined by the CJEU and its judgment is pending. Given the weight accorded by the appellant to the opinion I have cited it in some detail.

113. However, in my view there is no basis for adopting expansive principles suggesting that injunctive relief could or could not issue

where an interlocutory injunction is sought in the context of patents upon criteria other than those that normally apply under the rules of equity and its maxims and the relevant equitable jurisprudence as modified by the assessment of the balance of convenience where, as here, the trial of the action is unlikely.

Other aspects of the balance of convenience

The public interest
114. The SPC Regulation seeks to strike a balance between the competing and disparate interests at stake. It references in Recital 10 "All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account"

115. In analysing the appropriate approach to the interpretation of the predecessor to the SPC Regulation, the CJEU in *AHP Manufacturing BV v. Bureau voor de Industriële Eigendom* (Case C- 482/07) at p. 27 stated:

> "…the Court observes that the second sentence of Article 3(2) … must be interpreted not solely on the basis of its wording, but also in the light of the overall scheme and objectives of the system of which it is a part…"

Recital 10
116. Recital 10 is of importance in alluding to all the interests at stake. Hence these interests can be properly taken into account by a court in making equitable determinations. The jurisprudence suggests that the stakeholders in the field of patent rights include the patentee, producers of generic medicines, patients and members of the public who have an interest both in the introduction of new medicines and in same being marketed at a competitive price and finally public health authorities and health insurers for whom the welfare of the public and patients is a priority and who have an interest in ensuring that old and out-of-patent active ingredients ought not to be brought to the market in a slightly modified form under the protection of SPC's where there is a lack of genuine innovation in the product.

117. There is a significant public interest in having the issue determined. However, for the reasons stated above, it is in fact not likely that this particular issue will ever go to full trial.

The Medeva Decision
118. Clonmel seeks to rely on the *Medeva* decision (Case C-322/10) to support its contention that the 001 SPC is invalid. Medeva was the proprietor of a patent for the preparation of a combination of two antigens used in a vaccine against whooping cough. It was claimed that this combination produced a synergistic effect in vaccine potency. Medeva obtained marketing authorisations in respect of vaccines each of which was for immunisation against a number of diseases in addition to whooping cough. Medeva filed five applications for SPC's in respect of the medicinal products the subject of the marketing authorisations, all of which were refused by the UK Patent Office.

***Medeva* CJEU**
119. The Court of Justice in its judgment in *Medeva* stated at paras. 25-26:

> "Moreover, it should be recalled that Article 5 of Regulation No 469/2009 provides that any SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations. It follows that Article 3(a) of the regulation precludes the grant of a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent.
>
> Similarly, if a patent claims that a product is composed of two active ingredients but does not make any claim in relation to one of those active ingredients individually, an SPC cannot be granted on the basis of such a patent for the one active ingredient considered in isolation."

120. The Court must remain ever mindful of all of the interests at stake in the context of the interlocutory relief being sought particularly in a sector as complex and sensitive as pharmacology. Public health and welfare warrants that the threshold for the grant of interlocutory relief ought not to be lightly reduced. However, conduct, particularly if excessively egregious, on the part of a generic competitor may give rise to circumstances when same amounts to a "special factor" which may influence the exercise of discretion and the grant or refusal of the relief sought. Each application turns upon its own facts. There may well be cases where it will be considered important or indeed vital to scrutinize the generic operator's conduct and indeed where that conduct might well be outcome-determinative. This is not such a case. The principles of equity and its maxims have exhibited significant resilience over time in adapting to changing circumstances and the discretion enshrined in s. 28(8) of the Judicature (Ireland) Act 1877 ensures that a judge is entitled to grant equitable relief "whenever it is just and convenient to do so".

The *status quo*
121. There is a dispute in the instant case as to what constitutes the *status quo*. An essential aim of an interlocutory injunction is to preserve the *status quo* existing between the parties until the trial of the issues in dispute can take place. The rationale behind the grant of an interlocutory injunction is primarily the need to protect the rights of a plaintiff by preserving the circumstances which exist at the time he institutes proceedings to prevent him suffering irreparable prejudice by reason of the delay which must necessarily occur between the institution of the within proceedings and the trial of the action. The more time that has passed since the status quo was changed, the more likely it is that the result of the change will be considered the new status quo.

122. O'Higgins C.J. in *Campus Oil* stated at p. 105:

> "Such relief is given because a period must necessarily elapse before the action could come to trial and for the purpose of keeping matters in *status quo* until the hearing."

123. The respondent contends that the *status quo* involves a continued distribution of the generic pharmaceutical product by them as that represented the position which obtained at the date of the within proceedings.

124. In *Garden Cottage Foods Ltd v. Milk Marketing Board* [1984] A.C. 130 at p. 140, Lord Diplock discussed the meaning of *'status quo'* :

> 'The status quo is the existing state of affairs; but since states of affairs do not remain static this raises the query: existing when? In my opinion, the relevant status quo to which reference was made in *American Cyanamid* is the state of

affairs existing during the period immediately preceding the issue of the writ claiming the permanent injunction or, if there be unreasonable delay between the issue of the writ and the motion for an interlocutory injunction, the period immediately preceding the motion. The duration of that period since the state of affairs last changed must be more than minimal, having regard to the total length of the relationship between the parties in respect of which the injunction is granted; otherwise the state of affairs before the last change would be the relevant status quo.'

125. However, it is for the trial judge to determine what constitutes the status quo in any given case rather than adhering slavishly to pre determined formulae lacking the legal resilience that is a pre-requisite for a strict legal principle.

Whether the injunction being sought is mandatory in nature
126. The respondent contends that in substance the interlocutory relief being sought by the appellant is mandatory in nature. To comply with such an injunction, it is argued, Clonmel will have to take positive steps to remove its product from the market, take it down from the shelves and withdraw it from circulation and from being marketed *inter alia* on the websites of various pharmacies. The granting of a mandatory injunction on an interlocutory application Clonmel contends is rare and exceptional though of course not unknown.

127. As was identified by Kelly J. (as he then was) in *Shelbourne Hotel Holdings Limited v. Torriam Hotel Operating Company* [2010] 2 I.R. 52 there is an inconsistency of approach in this jurisdiction on the standard that must be met by an applicant in order to obtain a mandatory interlocutory injunction: on one view, it requires the demonstration of a fair case or serious issue for trial, on the other a higher standard is required, described as a strong case likely to succeed at the hearing or a strong and clear case. In my view the approach of Kelly J. (as he then was) commends itself; that a court should adopt whatever course would carry the lower risk of injustice should it turn out to have been the "wrong decision".

128. However, I am satisfied that in substance the interlocutory relief being sought by the appellant is prohibitory and not mandatory in nature.

Relevance of decision of the hearing officer, Dr. Michael Lydon, on 3rd August 2017 in respect of a request by MSD for the grant of a supplementary protection certificate no. 2014/050
129. Clonmel argues that this decision is of relevance.

130. In this application the basic patent cited in support of the request was European patent 599. The SPC was sought in respect of a combination of ezetimibe with viazat.

131. On 26th November 2014 the examiner communicated with MSD, stating that the SPC request did not comply with Article 3(a) of the SPC Regulation on the grounds that "an SPC has already been granted (to the same applicant) for "ezetimibe or a pharmaceutically acceptable salt thereof", based on the same basic patent. (see SPC 2003/014)"

132. Whilst noting the weight which Clonmel attaches to this decision, on balance, it is likely to be of greater significance at any substantive trial rather than in the context of a limited review of the exercise of equitable judicial discretion.

133. It appears to follow from the *Georgetown* case (Case C 422/10) decision of the CJEU that Article 3(c) of the SPC Regulation should be interpreted as authority for the proposition that it is possible to have multiple SPC's based on the same patent if they concern a different "product".

134. The evidence suggests that MSD markets a combination of simvastatin in respect of which a basic patent expired on 2nd February 1981 and in respect of which an SPC expired on 5th May 2003 in combination with ezetimibe in respect of which a basic patent expired on 14th September 2014 and of which the original SPC expired on 16th April 2018.

135. It is for the trial judge to determine the relevance, if any, of these facts at the full trial in the context of the claims and counterclaims that are being pursued by the parties.

Conclusions
136. An interlocutory injunction is an equitable remedy. It is not a remedy which issues as of course.

137. The High Court exercising its equitable functions enjoys considerable discretion in determining whether the facts disclosed before it render it just and equitable to grant an interlocutory injunction.

138. The question arises whether the judge properly applied the traditional equitable framework that governs the award of interlocutory injunctive relief. The decision whether to grant or deny injunctive relief rests within the equitable discretion of the High Court judge and such discretion must be exercised consistent with traditional principles of equity in patent disputes as in other cases governed by such standards.

139. As outlined above, the patent for ezetimibe expired on 14th September 2014, whilst the SPC for *Ezetrol* expired on 16th April 2018. It is clear from the 599 patent and SPC 014 that statin combination therapies i.e. the concomitant administration of a statin with ezetimibe was in contemplation and governed by SPC 014. The said certificate expired on 16th April 2018 thereby demonstrating that *prima facie* Clonmel has a valid Objection, Defence and Counterclaim to the proceedings.

140. MSD does not appear to suggest any chemical modification of either of the active ingredients, each of which is already the subject of an expired SPC.

141. MSD does not appear to contend for a synergy nor does the report of Dr. Assmann.

142. There does not appear to be any assertion on the part of MSD that the combi-drug includes an excipient which changes the behaviour of either of the two ingredients or gives rise to or constitutes "a major change in the active ingredient."

143. Some jurisprudence regarding interpretation of the SPC Regulation suggests that the patentee must elect which patent to select for SPC protection. Only one patent can be selected as the "basic patent".

144. Under the provisions of the SPC Regulation, the ultimate issue of whether MSD was entitled to a further SPC for the combi-drug *Inegy* falls to be decided by the domestic civil courts at the substantive hearing.

145. The SPC Regulation, in keeping with all prior relevant regulations from Council Regulation 1768/92 of 18th June 1992 onward, suggests that only one SPC may issue if, at the time of filing the second application for a certificate, the first certificate for the product was already granted on the first application for an SPC. This is reflected in Article 3(a) of the SPC Regulation.

146. A substantive hearing will involve an inquiry pursuant to Article 3 and Article 15 of the SPC Regulation. It will be a matter for the trial judge to evaluate whether the combination of simvastatin and ezetimibe constitutes a "major change" compared with the medicinal products and the respective active ingredients in light of the relevant jurisprudence.

147. This Court should not replace traditional equitable considerations with a rule that an injunction automatically follows a determination that a patent or its SPC has been infringed.

148. There is no basis for adopting expansive principles suggesting that injunctive relief could or could not issue in the context of alleged patent infringement upon criteria other than those that normally apply under the rules of equity or as adumbrated in the Campus Oil guidelines where an interlocutory injunction is sought.

149. In the instant case Clonmel contends that the combi-SPC is invalid on a number of bases referable to Article 3 of the SPC Regulation and falls foul of the concerns identified in the jurisprudence of the CJEU including *Georgetown University* and *Actavis Group v. Sanofi*.

150. Contrary to the contentions of the respondent I do not accept that on its true construction the interlocutory relief being sought by MSD is mandatory in nature.

151. I do accept Clonmel's contention that the decision at interlocutory stage is likely to be dispositive of the substantive action in the instant case.

152. In my view it is appropriate that this Court disregards proceedings before the Paris Court of First Instance in circumstances where there are issues around the jurisdiction of the judge who made the order and undoubtedly, irrespective of the outcome, there is likely to be an appeal. Hence I do not attach any weight to the said proceedings or orders made.

153. The respondent is a newcomer to the market for this generic combination asserting first mover advantage. If it wrongfully makes inroads into the appellant's market that will be readily discernible both by reference in the fall of the appellant's stable and certain market share and the records which the respondents will, pursuant to their undertaking, be obliged to maintain.

154. An issue at this appeal hearing centred on the conduct of the respondent in marketing the generic product at 92 % cheaper than the appellant's *Inegy*. It is said that this may result in the appellant having to reduce its price. If that is so, and should it later transpire that the appellant's were wrongly deprived of an additional profit that is clearly recoverable as an item of monetary damage against the respondents. This does not give rise to an irreparable loss.

155. By contrast the potential loss to the respondent being substantially prospective in nature is unascertainable with any degree of certitude.

156. In my view the appellant has not, by reference to its objections, demonstrated that damages would not be an adequate remedy. I am satisfied on the evidence, that in the event of the appellant being correct and succeeding at trial it can be adequately compensated by an award in damages in respect of any losses which it may suffer by reason of the respondent's alleged wrongful marketing of the generic product.

157. In my view, on the particular facts disclosed, damages are an adequate remedy for the appellant.

158. I am satisfied, on the basis of the affidavit evidence adduced that the respondent is likely to suffer the greater uncompensatable damage and disadvantage if the interlocutory order is made.

159. The appellant has failed to discharge the heavy burden upon it to demonstrate that the refusal of the judge to grant the interlocutory relief sought is consistent only with either the learned trial judge having erred or having exercised his discretion in a way which no reasonable judge, properly directing himself as to the relevant considerations, and in light of s. 28(8) of the Judicature (Ireland) Act 1877 could have exercised it.

160. Accordingly, I find no basis established in law or equity to interfere with the refusal of the learned judge to grant an interlocutory injunction and I would dismiss this appeal.