THE HIGH COURT

COMMERCIAL

[2023] IEHC 24

[Record No. 2022/4794P]

BETWEEN

MERCK SHARP & DOHME LLC

PLAINTIFF

AND

MYLAN IRE HEALTHCARE LIMITED AND MYLAN IRELAND LIMITED AND MCDERMOTT LABORATORIES T/A AS GERARD LABORATORIES T/A AS MYLAN DUBLIN

DEFENDANTS

JUDGMENT of Mr Justice Mark Sanfey delivered on the 20th day of January 2023.

Introduction

1. In this application, the plaintiff seeks an interlocutory injunction restraining the defendants from offering, putting on the market or using products containing sitagliptin and metformin prior to the expiry on 7 April 2023 of supplementary protection certificate number 2008/024 ('the 024 SPC'). The 024 SPC in essence protects sitagliptin used in combination with metformin, the products of which combination are sold and marketed by the plaintiff ('MSD') under the brand name

"Janumet" in Ireland. Janumet is a medicine commonly used in treating type 2 diabetes.

2. The proceedings issued on 19 September 2022. The present motion was filed on 27 September 2022. The parties exchanged affidavits until early December 2022, and the matter was heard by this Court on 14-15 December 2022. Extensive written submissions were exchanged in advance of the hearing, and these were ably supplemented by helpful oral submissions from counsel at the hearing itself.

The parties

3. The plaintiff is a wholly owned subsidiary of Merck & Co Inc, the ultimate parent of the Merck group of companies which carry out research, development, production and sale of pharmaceutical treatments. The plaintiff – MSD – is the proprietor of the 024 following a merger of the plaintiff with Merck Sharpe & Dohme Corp, which was the registered owner of the SPC.

4. The defendant companies (collectively 'Mylan') were not differentiated as to function for the purpose of the present application. The lead affidavit on behalf of the defendants was sworn by Melissa Fisher, who describes herself as "General Manager of Viatris", and avers that she is "responsible for the commercial entity that is Mylan Ire Healthcare including sales, monitoring competitor activity, new product launches and for the Defendant's portfolio in Ireland…" [para. 2]. Ms Fisher goes on to aver at para. 4 of her affidavit that the defendants

> "…are part of the global Viatris group of companies which is one of the world's leading global pharmaceutical companies…Viatris is not a solely generics focused pharmaceutical company…we have one of the industry's broadest and most diverse portfolios and offer more than 1400 molecules

across more than ten major therapeutic areas. We employ over 1500 people in Ireland, and our global revenue in 2020 was US$11.496 billion…".

The nature of MSD's complaints

5. The plaintiff's grounding affidavit is sworn by Mairead McCaul, who avers that she is managing director of Merck Sharp and Dohme Ireland (Human Health) Limited ('MSD Ireland'), but has authority to swear the affidavit on behalf of the plaintiff.

6. Essentially, the plaintiff seeks injunctive relief to preserve the exclusivity conferred by the 024 SPC. The plaintiff is proprietor of European Patent 1 412 357 ('the 357 patent') "…which is for beta-amino tetrahydroimidazo (1,2-A) Pyrazines and tetrahydotriazolo (4,3-A) Pyrazines as dipeptidyl peptidase inhibitors for the treatment or prevention of diabetes, with a priority date of 6 July 2001" [written submissions, para. 2]. It appears to be accepted by the parties that the 357 patent discloses sitagliptin as an inventive treatment for diseases including diabetes. The plaintiff makes the point that the 357 patent discloses the sitagliptin/metformin combination, also for the treatment of diabetes although, as we shall see, there is an issue as regards the 024 SPC as to whether the mere disclosure of the combination suffices to satisfy the requirements for the grant of a supplementary protection certificate.

7. The 357 patent, which had a priority date of 6 July 2001, was filed on 5 July 2002. On 13 August 2007, the plaintiff filed for a supplementary protection certificate 2007/029 ('the 029 SPC') for a medicinal product identified as "sitagliptin, optionally in the form of a pharmaceutically acceptable salt". The 029 SPC was granted on 1 August 2012, and it expired on 22 September 2022.

8. On 14 August 2008, the plaintiff applied for a supplementary protection certificate 2008/024 for a medicinal product identified as "sitagliptin optionally in the form of a pharmaceutically acceptable salt, in particular the monophosphate, plus metformin optionally in the form of a pharmaceutically acceptable salt, in particular the hydrochloride". This SPC referred to the sitagliptin/metformin combination product, and was granted on 14 October 2009. It will expire on 7 April 2023. It was of some significance during the submissions that, while application was made first for the 029 SPC in respect of the sitagliptin product, the 024 SPC which related to the sitagliptin/metformin combination product was granted before the grant of the 029 SPC.

9. The plaintiff points to the rationale for SPCs articulated by O'Donnell J in *Merck Sharp & Dohme Corp v Clonmel Healthcare Limited* [2020] 2 IR 1 at para. 7 as follows: -

> "It is well known that the underlying objective justifying the grant of a patent is to provide a monopoly for a limited period in order to encourage invention and the dissemination of knowledge, which is beneficial to the wider community. However, the grant of a valid patent does not in itself lead inevitably to a commercially viable product. Because of the necessity to seek a patent at the earliest viable stage, claims are made at a point where it may not be clear how the invention may ultimately be marketed, if at all. Particularly in the medicinal and pharmaceutical field, the process of obtaining authorisation for the marketing of a product is lengthy and demanding. Accordingly, it may be some time before a commercial product can be launched to exploit the monopoly granted by the patent. Even then, there is no guarantee that the product will be successful, since other competing products may have been

launched in the intervening time. Furthermore, even if a product is successfully launched, the length of time in obtaining marketing authorisation has the effect of significantly reducing the period during which patent protection is of benefit. This difficulty was recognised by the European Union, which made provision for the grant of supplementary protection certificates by Regulation 469/2009 concerning the supplementary protection certificate for medicinal products ('the SPC Regulation')."

10. Much of the submissions concerned a consideration of the circumstances of the present dispute against the backdrop of the SPC Regulation. Both parties referred to Recital (10) of the Regulation which is as follows: -

"(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. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product".

11. Article 3 of the SPC Regulation was of central relevance to the dispute, and for that reason I reproduce it here in full: -

"Article 3

Conditions for obtaining a certificate.

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) The product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product."

12. The plaintiff argues that, on the grant of the SPC, the Irish Patent's Office (as it was then called) was satisfied that the combination product was protected by the 357 patent, had the relevant authorisations to be placed on the market, and had not been the subject of a previous certificate or authorisation. The defendant however disputes the validity of the SPC, and in particular whether the product the subject of the SPC is protected by the basic patent. A defence and counterclaim was delivered on 28 November 2022 by the defendants; the counterclaim seeks a declaration that the 024 SPC is invalid and an order revoking the SPC.

13. The plaintiff apprehends that the defendants will launch generic sitagliptin/metformin combination products in Ireland before 7 April 2023, and at a very considerable discount. This will have the effect of destroying the plaintiff's monopoly for the combination product. It is not disputed that the defendants have obtained marketing authorisations in Ireland for generic sitagliptin/metformin combination products as of February 2022, and have also obtained reimbursement prices from the Health Service Executive ('HSE') for their generic products. It is also not disputed that the defendant's products are bioequivalent copies of the plaintiff's Janumet products; the plaintiffs contend that marketing them prior to 7 April 2023 would therefore infringe the 024 SPC.

14. It appears that six other companies have also obtained marketing authorisations in Ireland for products which are a combination of sitagliptin and metformin. While some of these companies have indicated to the plaintiff that they will not enter the market until the expiry of the 024 SPC, the plaintiffs apprehend that this may change if a generic competitor such as Mylan gets an early foothold in the market.

15. The plaintiff maintains that the destruction of its monopoly prior to the expiry of the 024 SPC will result in a "massive reduction to the value of its Janumet products in a market with aggressive competitors…" [para. 15 written submissions]. It is suggested that the plaintiff would lose customers, income and the full control of its exclusive market. MSD maintains that it is entitled to plan on the basis that the SPC will be operative to protect its monopoly until the expiry date, and that it orders its affairs, and in particular its development of commercial and research strategies, on this basis.

16. In the aftermath of Mylan obtaining marketing authorisation for generic sitagliptin/metformin combination products, correspondence between the respective solicitors ensued. The plaintiff's solicitors wrote to the defendants seeking confirmation that the defendants would not market its generic combination product while the 024 SPC remained in force. Viatris responded by confirming that they would not launch a product until the expiry of the 357 patent and the 029 SPC – which was due to expire in September 2022 – but asserted that the 024 patent protecting the combination product was invalid. The 357 patent expired on 4 July 2022. After reimbursement prices for the combination products had been procured by the defendants from the HSE, the plaintiff's solicitors wrote to Viatris in early September seeking undertakings not to launch the generic combination products. By

letter of 9 September 2022, the defendants' solicitors wrote to the plaintiff's solicitors proffering an undertaking not to launch its sitagliptin/metformin combination products until the outcome of an application by the plaintiff for an interlocutory injunction in the commercial court.

The Reference to the CJEU in the Clonmel Healthcare case

17. The issues of the circumstances in which a court will restrain an apparent or purported infringement of an SPC, and the criteria which should govern the grant of an interlocutory injunction in that event, were the subject of comprehensive consideration by the Supreme Court in *Merck Sharp & Dohme Corp v Clonmel Healthcare Limited* [2020] 2 IR 1. In that case, the Supreme Court granted an interlocutory injunction in circumstances which bear a marked resemblance to those in the present case. However, the High Court on a subsequent hearing of the substantive matter held that the SPC in that case was in fact invalid, and this finding was upheld by the Court of Appeal.

18. The plaintiff in that case appealed to the Supreme Court (*Merck Sharp & Dohme Limited v. Clonmel Healthcare Limited* [2022] IESC 11) and sought a reference to the Court of Justice of the European Union as to the appropriate interpretation of Article 3(a) and 3(c) of the SPC Regulation as set out above. The Supreme Court, in a paragraph headed "Importance of the Issue", stated as follows: -

> "15. A brief consideration of the controversy on appeal before this Court indicates the nature of the uncertainty prevailing as to the interpretation of the regulation and as to whether it has imported into patent law new concepts or has required national intellectual property offices to consider: is something further required, beyond patent and marketing authorisation, before an SPC may be granted? Where there is a prior SPC for either a monotherapy of the

patented drug, or a different combination therapy SPC for the patented drug in an excipient with a public domain drug, what is the situation in European Union law? As a matter of national law, patented drug A in combination with public domain drugs B or C, or D, or any combination would prevent exploitation of any product containing patented drug A during the twenty-year life of the patent. By what measure of law could that situation be changed consequent upon the grant of an SPC? Or, is there a further test that the intellectual property offices of Member States must consider when granting an SPC? Is this step not limited to having a patent and to getting a marketing authorisation?"

19. The Supreme Court concluded that a reference was necessary; as the text of the request for a preliminary ruling states: -

"3. The Supreme Court considers that a reference under Article 267 of the TFEU is required in this case because the interpretation of Regulation EC469/2009 is unclear despite a number of decisions of the CJEU on the application and interpretation of the Regulation, particularly in circumstances where two or more SPCs have been granted in respect of products covered by a single national patent".

20. The plaintiff submits that the present application is on all fours with the decision of the Supreme Court in *Clonmel Healthcare* on the interlocutory injunction, and that the result should be the same. The defendants argue that this Court is bound by the Court of Appeal decision to consider, within the confines of the principles regarding interlocutory injunctions, whether, as it contends, there is a strong case that the product the subject of the 024 SPC does not fall under the protection of the 357

patent, and as such, the balance of justice to be considered on an interlocutory basis favours the refusal of the injunction sought by the plaintiff.

21. In the circumstances, it will be necessary to consider briefly the findings of the various courts in the *Clonmel Healthcare* case in order to determine the extent to which they may be applicable to the present application.

Merck Sharp & Dohme Corporation v Clonmel Healthcare Limited ('Merck v Clonmel')

The interlocutory injunction [2020] 2 IR 1

22. In *Merck v Clonmel*, the plaintiff ('Merck') held a patent ('the 538 patent') relating to simvastatin, a statin for the treatment of cholesterol. Merck was also the proprietor of a patent ('the 599 patent') which the parties agreed covered the active ingredient ezetimibe. SPCs were granted in respect of both products. While Merck marketed simvastatin and ezetimibe as monotherapies, they also marketed a combination of the products known as "Inegy", which was accepted as having greater therapeutic effect in the reduction of cholesterol. The parties agreed that Inegy was protected by the 599 patent and by the SPC ('the 014 SPC') obtained in respect of that patent, which expired on 16 April 2018. However, Merck obtained a separate SPC ('the 001 SPC') which covered a combination of the two active ingredients, and which was due to expire on 1 April 2019. The case related to the validity of the 001 SPC, in particular for the window period between 16 April 2018 and 1 April 2019. Clonmel argued that the 001 SPC was invalid, and that Clonmel was accordingly entitled to launch a generic competitor to Inegy, which it did on 17 April 2018, the day after expiry of the 014 SPC.

23. The High Court (McGovern J) granted an interim injunction on an *ex parte* application by Merck, but the court (Haughton J) subsequently refused the application

for an interlocutory injunction. That decision was subsequently upheld by a majority of the Court of Appeal (Peart and Whelan JJ; Hogan J dissenting): see [2018] IECA 177. Merck sought to appeal to the Supreme Court, and it was agreed in the course of case management hearings that, if Merck were successful in its appeal, Clonmel would not have injunctive relief imposed upon it prior to April 2019, when the 001 SPC would expire, and Clonmel would thus be free in any event to market its generic product. It was also agreed that the appeal would proceed on the issue of whether or not an interlocutory injunction should have been granted to Merck as of April 2018, thus avoiding the need to take account of developments subsequent to that date.

24. O'Donnell J (as he then was) considered the objectives addressed by the legal regime regarding patents and SPCs as follows: -

> "…the law in Ireland, as in many other countries, seeks in this regard to reconcile two competing public interests. Patent law and patent extension by SPC provide a monopoly as a reward and incentive for innovation and for the disclosure of the teaching involved, leading in this case to the development of beneficial products. However, once a monopoly comes to an end, whether by natural expiration, or by determination of invalidity, there is a strong competing public interest in encouraging entry to the market by generic alternatives, particularly since in Ireland, as in many European countries, the bulk of the cost of the drugs is met from the public purse. When a pharmacist substitutes a generic alternative for a branded product, the cost to the health budget is correspondingly reduced" [para. 13 - **NB references to paragraph numbers are to those in the Irish Reports version of the judgement**]

25. Clonmel argued that, if the injunction were refused but ultimately the SPC were found to be valid, damages would be readily quantifiable and would be an

adequate remedy for Merck. There was no issue about Clonmel's ability to meet any such award of damages. On the other hand, Clonmel would suffer harm which could not be compensated adequately by an award of damages should the injunction be granted and Clonmel succeed at trial, in that Clonmel would lose its "first mover advantage", *i.e.,* the entry into the market before other competitors seeking to sell generic equivalents, with the resultant ability to dictate the price of the product, establish market recognition ahead of its competitors, and so on.

26. Merck relied on authorities from UK courts which tended to favour granting injunctions to SPC holders seeking to restrain entry to the market by generic competitors. It was argued that the launch of a generic product in breach of a valid SPC would cause substantial and unquantifiable loss to the patentee because it would permanently depress the patentee's price. The authorities also suggested that an entrant to the market who anticipated a dispute over the validity of a patent or SPC should "clear the way" by invoking the appropriate procedures or, where necessary, embarking upon litigation to establish the alleged invalidity. A failure to do so might incline the court to regard the maintenance of the *status quo* as the appropriate course.

27. O'Donnell J commented at paragraph 25 on the approaches of the parties as follows: -

> "…the existence of these decisions creates a striking dichotomy between the arguments on either side. To some extent, the arguments are ships that pass in the night without engaging with each other. Merck rely heavily on the UK authorities and downplay the Irish cases, in particular the decision in *Curust Financial Services Limited v Loewe-Lack-Werk* [1994] 1 IR 450, which is treated as a case on a contractual issue alone and of little relevance in the field of patents. On the other hand, Clonmel rely heavily on the trend in the Irish

authorities and place particular emphasis on the *Curust* approach and tend to downplay the UK authorities. Indeed, they are sceptical of the factual basis of the arguments relating to a downward price spiral and the failure to clear the way. In addition, it was argued that Merck's claim here sought to superficially cut and paste the arguments which had succeeded in the UK, without regard to the facts of the case, and that there was in this case little if any evidence to support the arguments beyond mere assertion."

28. After a comprehensive survey of the case in relation to the adequacy of damages and the balance of convenience, O'Donnell J observed as follows: -

"43. There is a conundrum in any case in which an interlocutory injunction is sought. The parties at the interlocutory hearing vie with each other in arguing that they will suffer a loss or damages which cannot be compensated for by the award of monetary damages if they succeed at trial. Nevertheless, if the trial of the action proceeds then the plaintiff will put forward a claim for damages, and the defendant would be in a position to make a claim for damages under the plaintiff's undertaking, if the defendant succeeded in defeating the plaintiff's claim. In either case, a court will award damages and it cannot be suggested that the outcome is not to do justice to both parties. It is rarely, if ever, asserted by a successful plaintiff that it is simply impossible to award damages to compensate it for its loss, and rarer for any plaintiff to maintain that position at trial. On the other hand, the fact that it is possible to award damages does not preclude the grant of a permanent injunction, and should not be understood as an absolute bar to the grant of an interlocutory order…".

29. O'Donnell J went on to conclude as follows: -

> "…The fact that it is not completely impossible to assess damages should not preclude the grant of an injunction to the plaintiff in an appropriate case. Accordingly, I cannot agree that it is possible to resolve this case merely by determining that it is not completely impossible to assess the damages which the plaintiff might obtain, and therefore that it is not necessary to consider further any other aspects of the case. An injunction should not be granted merely because an applicant can tick the relevant boxes of arguable case, inadequacy of damages, and ability to provide an undertaking as to damages, and by the same token should not be refused merely because damages may be awarded at trial…" [para. 48].

30. Having examined some of the Irish cases in relation to the issue of adequacy of damages, O'Donnell J. concluded that: -

> "…It is, in my view, incorrect both to depreciate the 001 SPC as being no more than a right to an income stream, and at the same time elevate Clonmel's interest in becoming the incumbent generic to the key status of an interest which, if damaged, cannot be compensated by the award of monetary damages. The interest of the SPC holder and the interests of the generic challenger are both interests in acquiring a position in the market. The difference between them is that the SPC holder has a right conferred by a process of law which is presumptively valid: something which, if anything ought perhaps to favour Merck" [para 55].

31. At para. 60 of his judgment, O'Donnell J distilled the essence of the respective arguments. I quote in full what is an admittedly lengthy paragraph, but which nonetheless expresses eloquently and yet pithily the issues for consideration by the court, which in many respects mirror the issues which this Court has to decide: -

“60. Given the essential symmetry of the parties’ interests, I consider it appropriate to conclude that in neither case will damages be a fully adequate remedy, and, furthermore, the likelihood of some irreparable harm being occasioned to the successful party is also equally balanced between the parties. Both seek to maintain rights in respect of a stable market with 15,000 patients using a combination therapy of simvastatin and ezetimibe. In the real world, is it possible to rerun events like a laboratory experiment and consider what would or should have transpired had an injunction not been granted (if Merck succeeds at trial) or if an injunction is granted but it transpires that the 001 SPC was invalid? It is true that if Clonmel were restrained pending the trial and the 001 SPC is nevertheless determined to be invalid, Clonmel will never be able to gain the position of a first mover generic manufacturer which it sought to achieve by its launch in April 2018, and it will therefore be necessary to attempt a difficult estimation of both its likely profit if it had done so, and its position in the market, which would necessarily extend beyond the April 2019 expiry date. On the other hand, a similarly difficult calculation may have to be made if Merck succeed at the trial, but did not obtain an interlocutory injunction. Merck's right was not simply to recover income and profit pending the expiry of the 001 SPC. The rights of a valid SPC holder are to exclude all competitors with products covered by the SPC until the last day of the SPC. It follows that the SPC holder will know the precise date on which its rights will expire, and one of those rights, therefore, is to be able to plan for that eventuality so that it may maximise its position in the market both until that period and the period immediately after expiry. If Clonmel is held to have wrongfully launched its product and yet was not restrained by injunction, then

Merck would lose that significant benefit. The expiry of the SPC as a matter of fact, if not law, would be determined by the fact of entry by Clonmel: a circumstance for which Merck would not be able to plan or take defensive steps in advance. In the event that no injunction was granted, but the validity of the SPC was upheld, it would be necessary, therefore, to carry out essentially the same speculative calculation in reverse, and attempt to assess how Merck might have exploited its monopoly position pending expiry and defended its position in the market post-expiry, if it had not been deprived of the ability to control the date of expiry of the 001 SPC. In other words, it would be necessary to take the information in relation to the development of the market between April 2018 and 2019 and thereafter, and then hypothesise as to what would have occurred had Clonmel been restricted from entering until April 2019 when other generics might also have entered the market. Both parties must accept that this is not a case, as *Curust Financial Services Ltd. v. Loewe-Lack-Werk* [1994] 1 IR 450 was, where a market for a single product was shared between two parties. Instead the calculation is complicated further by the possibility of entry by up to four other generic producers".

32. The court considered that, in all the circumstances, damages could not be considered a full or adequate remedy for either party, and that the "balance of potential irreparable harm" did not favour either party decisively. The court however had regard to the fact that Merck "is the holder of an SPC granted pursuant to an authorisation process provided for by law and which involves the consideration both of the application for the 599 patent by the Controller of Patents, and the subsequent application for the SPC. As a matter of law, the SPC is valid and effective until

declared invalid by a court of competent jurisdiction" [paragraph 62]. As a result, O'Donnell J concluded as follows: -

> "63. In cases where the balance of convenience may be finely balanced, it may be appropriate to have regard, even on a preliminary basis, to the strength of the rival arguments as they may appear to the court. Certainly, if it was apparent that Clonmel's case for invalidity was strong, and/or if there had been successive determinations in Clonmel's favour of a similar challenge in other jurisdictions, then that might weigh against the grant of an injunction. In intellectual property matters where the same issue may have been addressed in other European countries, or the same issues adjudicated on in other comparable jurisdictions, it may be appropriate to take into account the outcome of such litigation…[c]ourts are correctly reluctant to express views on cases which are to come to trial. However, it would be absurd if this rule of abstention were to result in a court conducting an agonised and necessarily imperfect assessment of a number of variable factors in a field with which it has little familiarity and where the evidence is indirect, written, and untested, all the while averting its attention from the area (perhaps of pure law) in which it can justifiably claim expertise…"

33. The court acknowledged the "clearing the way" argument as a legitimate factor which the court could take into consideration, particularly where "…the only issue is validity and, moreover, that issue itself is to be determined within the limited confines of Article 3 of the 2009 Regulation…" [para. 62].

34. Finally, the court set out at para. 65 of its judgement the steps to be followed in considering interlocutory applications for injunctions "in a case such [as] this": -

"(1) First, the court should consider whether, if the plaintiff succeeded at the trial, a permanent injunction might be granted. If not, then it is extremely unlikely that an interlocutory injunction seeking the same relief pending the trial could be granted;

(2) The court should then consider if it has been established that there is a fair question to be tried, which may also involve a consideration of whether the case will probably go to trial. In many cases, the straightforward application of the approach in [American Cyanamid and Campus Oil] will yield the correct outcome. However, the qualification of that approach should be kept in mind. Even then, if the claim is of a nature that could be tried, the court, in considering the balance of convenience or balance of justice, should do so with an awareness that cases may not go to trial, and that the presence or absence of an injunction may be a significant tactical benefit;

(3) If there is a fair issue to be tried (and it probably will be tried), the court should consider how best the matter should be arranged pending the trial, which involves a consideration of the balance of convenience and the balance of justice;

(4) The most important element in that balance is, in most cases, the question of adequacy of damages;

(5) In commercial cases where a breach of contract is claimed, courts should be robustly sceptical of a claim that damages are not an adequate remedy;

(6) Nevertheless, difficulty in assessing damages may be a factor which can be taken account of and lead to the grant of an interlocutory injunction, particularly where the difficulty in calculation and assessment makes it more likely that any damages awarded will not be a precise and perfect remedy. In

such cases, it *may* be just and convenient to grant an interlocutory injunction, even though damages are an available remedy at trial;

(7) While the adequacy of damages is the most important component of any assessment of the balance of convenience or balance of justice, a number of other factors may come into play and may properly be considered and weighed in the balance in considering how matters are to be held most fairly pending a trial, and recognising the possibility that there may be no trial;

(8) While a structured approach facilitates analysis and, if necessary, review, any application should be approached with a recognition of the essential flexibility of the remedy and the fundamental objective in seeking to minimise injustice, in circumstances where the legal rights of the parties have yet to be determined".

35. In all the circumstances, the court claimed that "…Clonmel's case has not been shown to have that degree of strength which would outweigh the factors in favour of the grant of injunction…", and concluded that, if the case were to be considered as of April 2018, an interlocutory injunction ought to have been granted [see para. 63].

The substantive proceedings

36. The trial of the matter proceeded with commendable alacrity. The High Court (McDonald J) gave judgment on 29 November 2019, concluding *inter alia* that the defendant's claim that the SPC breached Article 3(a) of the SPC Regulation must succeed, and that the SPC must accordingly be revoked. The court found that the combination of ezetimibe and simvastatin was not an invention covered by the patent, and that "…the case made by the defendant that the combination was not an independent innovation itself is correct" [para. 95].

37. Merck appealed against the finding of the High Court that the SPC was invalid as it had breached Article 3(a) and (c) of the SPC Regulation. Clonmel appealed against the High Court's rejection of its claim that the SPC had been granted contrary to Article 3(d) of that Regulation.

38. The Court of Appeal (Costello J, Haughton and Murray JJ concurring) gave judgment on 24 February 2021: [2021] IECA 54, and rejected both appeals in affirming the decision of the High Court: [2019] IEHC 814. Heavy reliance is placed by the defendant on this judgment, going as far as to submit, at para. 6.10 of its written submissions, that this Court is bound by the decision, and "must reject MSD's arguments to the effect that what it calls the "identificatory approach" can be used in any consideration of the validity issue for the purpose of determining where the balance of justice lies".

The Supreme Court

39. MSD appealed the judgment of the Court of Appeal, and sought a reference to the Court of Justice of the European Union on what the Supreme Court termed "the core issue in this appeal, namely, the appropriate interpretation and application of Articles 3(a) and 3(c) of Regulation (EC) 469/2009…". Clonmel opposed the reference on the basis that the law was already clear.

40. The Supreme Court (Charleton J), in it sjudgment reported at [2022] IESC 11, addressed the criteria for a reference, noting the obligation on a court of final appeal to make a preliminary reference "…unless the CJEU has already ruled on the point and the existing CJEU case-law is clearly applicable, or unless the law is *acte clair*, meaning the interpretation is obvious…that obligation [*i.e.* to make a reference] only arises where a ruling of the Court of Justice is truly necessary for the court to reach its decision" [para. 10].

41. The court conducted a review of relevant cases. This review is at paras. 21-25 of the judgment; it is not necessary for the purposes of this interlocutory application to rehearse the Supreme Court's summary. The court went on in its judgment to set out the arguments made by the appellant and the respondent; it then set out the gist of what had occurred in the High Court and the Court of Appeal, and the respective rulings of those courts, and then briefly surveyed the position on the controversy in certain other Member States.

42. The Supreme Court concluded at para. 49 of its judgment that "a set of issues has arisen concerning the interpretation of Article 3 of the Regulation which cannot be said to be *acte clair.* Hence, this Court is compelled to make a reference". The court appended the terms of the reference to its judgment. The reference sets out the background, both factual and legal, and the differing interpretations of Articles 3(a) and 3(c), and in particular whether an "identificatory" test or an "inventive advance" test should be applied in determining whether the product "is protected by a basic patent in force". As the court put it at para. 41 of the reference:

> "There is a conflict on these interpretations. It is thus apparent that the High Court of England and Wales, the Court of Appeal of England and Wales and the Court of Appeal of Ireland have all taken differing views as to the interpretation of the judgment of the ECJ in *Teva v Gilead*. MSD contend that [57] of the judgment of *Teva*, read in the light of the entire judgment, means that Article 3(a) is satisfied in the case of a combination product where that product is expressly mentioned in the claims of the basic patent, or if not expressly mentioned, the claims relate necessarily and specifically to that combination. For that purpose, viz considering whether claims necessarily and specifically relate to a combination itself not expressly mentioned in the

> claims, it is necessary to establish that the combination of the active ingredients must necessarily in the light of the descriptions and drawings of the patent fall under the invention covered by that patent, and each of the active ingredients must be specifically identifiable in the light of all the information disclosed by that patent. Thus, on this interpretation, the reference to 'fall under the invention covered by that patent' does not involve any consideration of inventiveness but, rather, is merely a way of considering whether, if there is an application for an SPC, any combination of active ingredients not expressly mentioned in the claims is nevertheless necessarily and specifically covered and protected by the patent. On the other hand, Clonmel maintain that [57] establishes a general test requiring a court to consider in any case whether the combination product falls under the invention covered by the patent, which in turn requires an assessment of the invention covered by the patent."

The defendant's position

43. The plaintiff relies heavily on the decision of the Supreme Court in relation to the interlocutory injunction in *Merck v Clonmel*, contending that the analysis by the court in that case is of equal application to the present case, and should yield the same result. While I shall return to the plaintiff's submissions later in this judgment, it is appropriate to outline what the defendant says in response to this basic premise.

44. The defendant draws attention to the recognition by Supreme Court in the interlocutory application judgment that, where the balance of convenience is finely balanced, it "may be appropriate to have regard, even on a preliminary basis, to the strength of the rival arguments as they may appear to the court…" [para. 63 – see para. 32 above]. The defendant emphasises the Supreme Court's point in para. 63 of

its judgment that, if it were apparent "that Clonmel's case for validity was strong, and/or if there had been successive determinations in Clonmel's favour of a similar challenge in other jurisdictions, then that may weigh against the grant of an injunction". Counsel emphasised the use of "and/or" in that passage, contending that both of these factors, considered together, on the facts of the present case, warrant a finding by this Court that the balance of justice favours the defendant.

45. Counsel for the defendant submitted that there were indeed "strong grounds" supporting the defendant's case for the invalidity of the 024 SPC, and placed heavy emphasis on what he called the "merits-based" decision in the Court of Appeal in *Merck v Clonmel*, and suggested in both written (para. 6.10) and oral submissions that this Court is bound by that decision, although counsel submitted that the court "…could form the view…that it is sufficient for [the court] to make a decision that [the court] take it into account"… [day 2, p.15 lines, 7 to 17].

46. While I have dealt with the decisions of the High Court and Court of Appeal in the substantive matter in *Merck v Clonmel* somewhat cursorily above in the interests of brevity and concision – see paras. 36 to 38 above – it is important to emphasise that both courts were satisfied that, for the patent to protect the combination of ezetimibe and simvastatin, the combination must be an invention covered by the patent. As the court (Costello J) concluded in relation to the applicability of Article 3(a) of the SPC Regulation: -

> "82. The judgments of the CJEU require the national court to assess whether the product the subject of an SPC falls under the invention covered by the basic patent. In this case, ezetimibe falls under the invention covered by the patent as it is one of the novel compounds invented by the patent and is claimed in Claim 8. At the priority date, simvastatin was a known ingredient

and had been the subject of a different patent, and a different SPC, and so cannot be considered to fall under the invention covered by the basic patent. The combination of ezetimibe and simvastatin is expressly claimed in Claim 9 of MSD's basic patent. The trial judge rejected MSD's argument that it was sufficient for the purposes of Article 3(a) that the two ingredients were expressly mentioned in the claims of the patent and that no assessment of the invention of the patent was either required or permitted. At para. 89, McDonald J held that: -

> '…the addition of an existing compound to a novel compound cannot, without more, make the combination an invention in itself. If that was all that was required, it would mean that an SPC would automatically be available for any combination product containing a combination of a novel product disclosed in a patent and a pre-existing product available off the shelf'.

For this reason, he held that the product did not fall under the invention covered by the patent and therefore it was not protected by the basic patent, and he revoked the SPC. In my judgment, he was correct in his approach and his assessment, and I agree with his conclusion…".

47. In relation to Article 3(c) of the SPC Regulation, the Court of Appeal held that McDonald J was correct in holding that the product protected by the patent was ezetimibe, the mono-product, and not the combination of ezetimibe and simvastatin. As ezetimibe had been the subject of an earlier SPC, Merck's appeal under Article 3(c) failed [para. 83 of the judgment]. The court also rejected the appeal of *Clonmel* under Article 3(d) of the SPC Regulation: see paragraphs 84 to 101 in this regard.

48. These conclusions were preceded by a comprehensive consideration by the Court of Appeal of the decisions of the CJEU interpreting Article 3 of the SPC Regulation [paras. 25 to 81 of judgment], and counsel for the defendants placed particular emphasis on this analysis by the Court of Appeal. The court had, at para. 32 of its judgment, quoted paras. 36 to 39 of the judgment of the CJEU in Case C-577/13 *Actavis Group PTCEHF v Boehringer Ingelheim Pharma GMBH & Co*: -

> "36. In the light of the need, referred to, *inter alia*, in Recital 10 in the preamble to [the SPC Regulation], to take into account all the interests at stake, including those of public health, **if it were accepted that all subsequent marketing of an active ingredient in conjunction with an unlimited number of other active ingredients which do not constitute the subject-matter of the invention covered by the basic patent would confer entitlement to multiple SPCs, that would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health** as regard the encouragement of research within the European Union by the use of SPCs (see, to that effect, judgment in Actavis Group PTC and Actavis UK, EU:C:2013:833, paragraph 41).
>
> 37. Accordingly, in view of the interests referred to in Recitals 4, 5, 9 and 10 in the preamble to [the SPC Regulation], **it cannot be accepted that the holder of a basic patent in force may obtain a new SPC, potentially for a longer period of protection, each time he places on the market in a member state a medicinal product containing, on the one hand, an active ingredient, protected as such by the holder's basic patent and constituting the subject-matter of the invention covered by that patent, and, on the other, another substance which does not constitute the subject-matter of**

the invention covered by the basic patent (see, to that effect, judgment in Actavis Group PTC and Actavis UK, EU:C:2013:833, paragraph 30).

38. It follows that, in order for a basic patent to protect "as such" an active ingredient within the meaning of Articles 1(c) and 3(a) of [the SPC Regulation], **that active ingredient must constitute the subject-matter of the invention covered by that patent**.

39. In light of the foregoing considerations, the answer to questions two and three is that Article 3(a) and (c) of [the SPC Regulation] must be interpreted as meaning that, where a basic patent includes a claim to a product comprising an active ingredient which constitutes the sole subject-matter of the invention, for which the holder of that patent has already obtained an SPC, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, that provision precludes the holder from obtaining a second SPC for that combination". [Emphasis inserted in Court of Appeal judgment].

49. The Court of Appeal rejected the submission of Merck that the CJEU had effectively overruled the principles set out in *Boehringer* in Case C-121/17 *Teva UK Limited v Gilead Sciences Inc*., in which the CJEU met to consider "what are the criteria for deciding whether 'the product is protected by a basic patent in force' in Article 3(a) of [the SPC Regulation]?" In that case, Gilead had obtained an SPC based on a claim in the patent for a "pharmaceutical composition comprising a compound according to any one of the claims 1-25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients", and the marketing authorisation in respect of TRUVADA, a combination of two active ingredients which had a combined effect on treatment of persons infected with HIV. At para. 57 of its

judgment, the Court of Appeal pointed out that the CJEU in *Teva* expressly endorsed paras. 36 and 37 of *Boehringer*, and pointed out that "…the court in *Teva* reiterated that the holder of a basic patent in force may not obtain an SPC each time it places on the market a medicinal product containing two active ingredients, one of which is protected as such by the holder's basic patent and constituting the subject matter of the invention covered by the patent, and the other which does not constitute the subject matter of the invention covered by the basic patent".

50. The Court of Appeal went on to state as follows: -

> "59…. the protection granted by an SPC is limited to that granted for the invention covered by the patent. The court must make an assessment of what is the invention covered by the patent in order to ascertain whether or not the SPC at issue affords protection which goes beyond that granted for the invention covered by the patent, and thus is impermissible. The court emphasises that for the purposes of the application of Article 3(a), the claims of the basic patent must be construed in the light of the limits of the invention as it appears from the description and the drawings of the patent. It is therefore clear from para. 43 that the investigation to be undertaken by the court cannot be limited to the claims and cannot stop with the claims; the court must have regard to the description and the drawings of the patent in order to ascertain what are the limits of the invention in the basic patent."

51. The Court of Appeal pointed out at para. 62 of its judgment that para. 47 of the CJEU judgment in *Teva* acknowledges: -

> "…that the claims of the patent are to be interpreted from the perspective of a person skilled in the art in accordance with Article 69 of the EPC and Article 1 of the Protocol, whether the product which is the subject of the SPC

necessarily 'falls under the invention covered by that patent' must be assessed from the perspective of a person skilled in the art in light of these principles".

52. Costello J concluded that: -

"63. In my judgment, the court requires the national court to make this assessment in light of the description and drawings, and not confine itself to the wording of the claims. It must assess the invention of the patent in order to determine whether a product, the subject of an SPC, is protected by the basic patent as such. The mention of a non-novel ingredient in the claims in conjunction with the novel active ingredient does not thereby mean that the combination of the novel active ingredient with the non-novel active ingredient falls under the invention covered by the basic patent."

53. Equally, the court did not regard the judgment of the CJEU Case C-650/17 *Royalty Pharma Collection Trust v. Deutsches Patent — und Markenamt* as altering the test set out in para. 42 of *Teva* – which endorsed that set out in para. 37 of *Boehringer* – or the *dispositif* of the judgment in *Teva*: -

72…. a court faced with a challenge to the validity of an SPC must ascertain whether the product, the subject of the SPC, falls under the invention of the basic patent, but not whether it is the core inventive advance of the patent…while ruling out a core inventive advance assessment, it still requires the national court to assess whether the product necessarily falls under the invention covered by the basic patent. As [Royalty Pharma] concerned a mono-product rather than a combination product, it did not address the issue of whether a listing or mention of a non-novel active ingredient in one of the claims of the basic patent sufficed for the purposes of Article 3(a) of the SPC Regulation".

54. The defendants in the present proceedings rely heavily on the view of the High Court and the Court of Appeal in *Merck v Clonmel* that the product the subject of the SPC must fall under the invention covered by the patent, and that if it is not "protected by the basic patent" – see para. 82 of the judgment of the Court of Appeal quoted at para. 46 above – the SPC must be regarded as invalid and should be revoked. At para. 6.10 of their written submissions, the defendants went as far as to contend that: -

> "…it is respectfully submitted that the for the purposes of the present application, this Court is bound by the decision of the Court of Appeal in *MSD v Clonmel*. Thus it must reject MSD's arguments to the effect that what it calls the '*identificatory approach*' can be used in any consideration of the validity issue for the purpose of determining where the balance of justice lies."

55. Counsel for the defendant was careful to emphasise that the court does not have to resolve, for the purpose of an interlocutory application, the issue of whether the combination of sitagliptin and metformin constitutes an "invention" which comes within the protection of the 357 patent. It was urged however that Mylan had, even on an interlocutory basis, strong grounds for suggesting that its case for invalidity of the 024 SPC was correct. It was submitted that this Court is bound by the decision of the Court of Appeal favouring a "qualitative" rather than an "identificatory" approach as to whether the combination product was covered by the 357 patent; counsel reviewed the terms of that patent at length with a view to submitting that, from the terms of the patent itself, the combination of sitagliptin and metformin could not be regarded as an "invention" protected by the patent: see transcript day 2, p.54 line 12 to p.69 line 18.

56. It was not disputed by the defendants that the 357 patent envisages "compounds of the present invention". Paragraph 52 of the patent states as follows: -

> "The compounds of the present invention may be used in combination with one or more other drugs in the treatment, prevention, suppression or amelioration of diseases or conditions for which compounds of formula I or the other drugs may have utility, where the combination of the drugs together are safer or more effective than either drug alone. Such other drug(s) may be administered, by a route and in an amount commonly used therefor, contemporaneously or sequentially with a compound of formula I. When a compound of formula I is used contemporaneously with one or more other drugs, a pharmaceutical composition in unit dosage form containing such other drugs and the compound of formula I is preferred. However, the combination therapy may also includes [sic] therapies in which the compound of formula I and one or more other drugs are administered on different overlapping schedules. It is also contemplated that when used in combination with one or more other active ingredients, the compounds of the present invention and the other active ingredients may be used in lower doses than when each is used singly. Accordingly, the pharmaceutical compositions of the present invention include those that contain one or more other active ingredients, in addition to a compound of formula I."

57. Paragraph 53 sets out examples of other active ingredients "that may be administered in combination with a compound of formula I, and either administered separately or in the same pharmaceutical composition…". These examples include "…(b) insulin sensitizers including…(ii) biguanides such as metformin and phenformin…". At para. 55, it is stated that "…the pharmaceutical compositions of the present invention include those that also contain one or more other active ingredients, in addition to a compound of the present invention". Paragraph 134 of the

patent concludes that "it is intended…that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable".

58. Claim 15 includes a diagram of the molecular structure of sitagliptin, and claim 25 includes: -

> "A pharmaceutical composition comprising
>
> (1) A compound of any one of claims 1 to 15 or a pharmaceutically acceptable salt thereof;
>
> (2) One or more compounds selected from the group consisting of:
>
> …(b)…(ii) biguanides…"

59. Claim 30 is as follows: -

> "A pharmaceutical composition as claimed in claim 25 comprising a compound of any one of claims 1 to 15 or a pharmaceutically acceptable salt thereof, netformin [sic], and a pharmaceutically acceptable carrier".

60. The "house style" – as counsel for the defendant put it – of drafting by MSD of patents so as to provide for a wide variety of possible combinations of active ingredients was trenchantly criticised by counsel, who argued that, whether or not the combination of sitagliptin and metformin could be identified in the patent, applying the qualitative "invention" test favoured by the High Court and Court of Appeal in *Merck v Clonmel*, the 024 SPC could not be said to cover an "invention" protected by the 357 patent.

61. The defendants proffer an affidavit from Robert Fitt, who is described as "Senior Patent Litigation Counsel" of a sister entity of the defendants in the Viatris group of companies. The purpose of the affidavit is to address averments by Ms McCaul on behalf of the plaintiff in identifying the "novel combination of active ingredients referred to in claim 30…". He avers at para. 16 of his affidavit that the

paragraphs of the specification on which the plaintiff relies "…support an interpretation that the 357 Patent concerns one invention and not two…".

62. There is also an affidavit from Professor Simon Heller, a Professor of Clinical Diabetes in the Department of Oncology and Metabolism at the Medical School of the University of Sheffield. It is suggested in this affidavit that the benefits or efficacy of a combined treatment regime of sitagliptin and metformin "only became apparent long after 2001…" [para. 29]. Mr Fitt expresses the view in his affidavit that Professor Heller's evidence "reinforces my view that the 357 patent discloses only one invention, namely the new class of antidiabetics of which the most prominent representative is sitagliptin…" [para. 18].

63. In a replying affidavit of 15 November 2022, Ms McCaul exhibited a report by Professor Peter R Flatt, Head of Diabetes Research Centre and Director of Biomedical Sciences Research Institute at Ulster University, Northern Ireland. This report was furnished in court proceedings in Sweden, where an SPC granted to MSD had been challenged. The SPC covered the combination of sitagliptin and metformin and was based on the 357 patent. Professor Flatt expressed the view that the combination of active ingredients sitagliptin and metformin had a "special, complementary mode of action…which was not appreciated at the Priority Date…", so that the subsequent combination could be regarded as an "inventive step" such as would attract the protection of the patent, even if a qualitative or "invention-based" approach were appropriate, as opposed to the "identificatory" approach for which MSD advocated.

64. Finally, heavy reliance was placed by the defendants on the decision of the Bundespatentgericht (Federal Patent Court, or 'FPC') of Germany on 23 June 2021 regarding an SPC registered on 11 September 2008 for a combination of sitagliptin

and metformin, expiring on 8 April 2023. Hexal AG had challenged the validity of the SPC in favour of MSD.

65. The FPC held that there was a "requirement that the disputed active substance composition of sitagliptin and metformin must prove to be another independent innovation compared to the innovative single active substance sitagliptin…" [para. 1.2, p.18]. The court held that "the basic patent contains no statements that the disputed active substance combination of sitagliptin/metformin should be assessed as an independent innovation compared to the single active substance sitagliptin…" [para. 1.3, p.19]. The FPC held that the preparation of DP-IV inhibitors such as sitagliptin were the only innovation of the basic patent, and as an SPC had already been issued for sitagliptin, the SPC was in violation of Article 3(c) of the SPC Regulation.

66. The FPC specifically held that the *Teva* and *Royalty Pharma* decisions did not call into question the principles set out in cases such as *Actavis v Boehringer, Actavis v Sanofi* [para. 2.2]. The court refused to refer the matter for a preliminary hearing "…since the present dispute does not raise any decision – relevant questions on the interpretation of European law that cannot be answered unequivocally from the legal sources and the case law of the Supreme Court…the correct application of Union law in the present case is sufficiently clarified".

67. In her supplemental affidavit, Ms McCaul states that this decision, which, as counsel for the defendants emphasised, was a decision of a specialised patent court of five judges, is presently under appeal. Ms McCaul sets out what she contends are defects in the approach of the German court, which give rise, in her opinion, to a "strong ground of appeal" in those proceedings.

The plaintiff's position

68. The plaintiff has sought injunctive relief from the court, and the onus is accordingly on the plaintiff to persuade the court, in accordance with established principles, that it should be granted the orders it seeks. Perhaps somewhat counter-intuitively, I have dealt at some length with the position of the defendants before dealing with the standpoint of the plaintiff. This is because, to some extent, the position of the plaintiffs is self-evident; MSD is the beneficiary of an SPC which is the product of a statutory process, and which does not expire for months to come. The defendant proposes to enter the market in defiance of this statutory protection, and argues that it is entitled to do so. In the circumstances, it seemed to me more appropriate to begin by setting out the defendant's case, so that the defendant's challenge to the plaintiff's statutory rights might be seen in its proper context, and the justification for it properly understood.

69. It is appropriate to set out briefly the grounds on which the plaintiff contends that it is entitled to interlocutory relief, and that the defendant's actions are invalid and misconceived. They may be summarised as follows: -

(1) The plaintiff contends that the present application is not materially different from the application for interlocutory relief in the *Clonmel* case. It contends that the principles set out by the Supreme Court should be applied by this Court, and that the same result should ensue;

(2) damages are an adequate remedy for the defendant if the injunction is found to be wrongly granted and there are no concerns as to the substance of the plaintiff's undertaking in this regard;

(3) even if an award of damages in favour of either the plaintiffs or the defendants were not regarded as being adequate recompense – as the

Supreme Court concluded in *Merck v Clonmel* – there are no strong grounds for the contended invalidity of the SPC;

(4) neither have there been "successive determinations" in the defendant's favour of similar challenges in other jurisdictions";

(5) this Court is not bound by the Court of Appeal decision on the merits in *Merck v Clonmel*;

(6) the Supreme Court has decided in its judgment of 21 February 2022 that the position in law regarding the principles governing challenges to the validity of SPCs is not *acte clair*, and requires to be resolved by a reference to the CJEU;

(7) the finding by the Supreme Court that the law is unclear and requires clarification from the CJEU is binding on this Court, which accordingly should not consider itself bound by the decision of the Court of Appeal;

(8) as the Supreme Court recognised, the SPC is, as a matter of law, valid and effective until declared invalid by a court of competent jurisdiction;

(9) no steps have been taken by the defendants of a practical or regulatory nature to clarify matters as to the SPC's validity *i.e.,* the defendants have not "cleared the way".

Discussion

70. It needs to be emphasised that the court in the present application is only required to decide matters on an interlocutory basis. The court has not conducted a full trial of the issues, and has been presented only with affidavit evidence directed towards whether or not an injunction in the terms sought by the plaintiff should be

granted pending the trial of the action, at which both parties would have the opportunity to adduce oral testimony as they see fit.

71. The court has the benefit of a full analysis by the Supreme Court, in the context of a case with close similarity to the present case, of the principles which should govern the grant or refusal of an interlocutory injunction. Accordingly, this Court must assess the circumstances of the present case in the light of the principles set out by O'Donnell J (as he then was) in *Merck Sharp & Dohme Corporation v Clonmel Healthcare Limited* [2020] 2 IR 1.

72. The principles governing the consideration of whether or not to grant an interlocutory injunction "in a case such [as] this" are set out at para. 34 above. This Court must also take into account, where the balance of convenience is finely balanced, the approach suggested by O'Donnell J at para. 63 of the Supreme Court's judgment, quoted at para. 32 above.

Would a permanent injunction be granted at trial?

73. The court must firstly consider "whether, if the plaintiff succeeded at the trial, a permanent injunction might be granted". Assuming the obvious logistical difficulties in convening a trial of the plenary action in advance of 7 April 2023 could be overcome, and that such a trial could be held and concluded so that there was a significant period of the SPC still to run, the court would, if it considered the granting of an injunction appropriate, be likely to grant the order restraining breach until 7 April 2023, the date of expiry of the SPC. It might well be that, even where the remaining period until expiry of the SPC were not significant, an injunction until 7 April 2023 would in any event be granted; if the court on a full hearing came to a conclusion that the SPC, which as the Supreme Court pointed out is "a right conferred by a process of law which is presumptively valid", was in fact valid so that its

infringement by the defendant was unlawful and in breach of the rights granted in accordance with the SPC Regulation, the court might well consider it inappropriate to allow the defendant to benefit from its unlawful act by securing a "first mover advantage", even where damages could perhaps be regarded, for such a short period, as an adequate remedy for the plaintiff.

Fair question to be tried

74. The court must consider "if it has been established that there is a fair question to be tried, which may also involve a consideration of whether the case will probably go to trial". The central issue in the case is the validity or otherwise of the SPC, and the defendant certainly does not dispute that there is a fair question to be tried in this regard.

75. If it were apparent that, if the interlocutory injunction were granted, that would effectively be "a significant tactical benefit" – as the Supreme Court put it – as the grant of interlocutory relief would for whatever reason, whether of practicality or otherwise, be decisive, this is a factor which the court must take into account in considering the balance of convenience or the balance of justice. While it is not for this Court to speculate as to what the defendant might do if the interlocutory injunction were granted, clearly the defendant could either appeal the decision of this Court to the Court of Appeal – which would determine the grant or otherwise of the injunction, but only on an interlocutory basis – or seek to press on to trial, which would hopefully entail a hearing and determination in advance of the expiry of the SPC.

76. The defendant did not seek to argue before this Court that the case might not go to trial if an interlocutory injunction were granted to the plaintiff, and that therefore the "significant tactical benefit" of the grant of an interlocutory injunction in

circumstances where the case might not go to trial was a factor affecting the balance of justice. Indeed, I was gently and tactfully reminded by counsel for the defendant, as the application before me concluded, of the imminence of the expiry date of the SPC – see day 2, p.182, lines 18 to 21. The implication clearly was that a judgment would be required sooner rather than later to give the parties an opportunity to assess their options in the litigation in advance of 7 April 2023.

77. In the circumstances, I propose to deal with the matter on the basis that there is a fair question to be tried, and that there is no reason to believe that, if an interlocutory injunction were granted, the matter would not proceed to trial. There is certainly no reason to believe that, if interlocutory relief were granted and a plenary trial and determination of the issues could not be achieved prior to 7 April 2023, the defendant would not proceed to trial in respect of its counterclaim in any event and seek damages on the basis that it was prevented from entering the market at a time of its choosing by an invalid SPC.

The balance of convenience and the balance of justice: adequacy of damages

78. As we have seen, the Supreme Court expressed the view that the most important element in considering the balance of convenience and the balance of justice was the question of adequacy of damages. The court embarked on an extensive analysis of the principles emerging from the case law in this regard: see paras. 25 to 32 above.

79. The respective positions of the parties as regards damages are rehearsed in the affidavits submitted in the application. On behalf of the plaintiff, Ms McCaul avers in her grounding affidavit that: -

> "…117. Mylan has obtained a reimbursement price for its sitagliptin/metformin products of the order of 60% (the mandatory reduction

> under the IPHA agreement) of the present MSD price. The presence of Mylan alone on the market will lead to price erosion and loss of market share prior to expiry of the 024 SPC. Not only will this occasion financial loss to MSD, it will also be disruptive of MSD's business. As set out above, I believe that other generic suppliers will very rapidly enter the market if Mylan is permitted to remain on the market now and further price reductions may occur as generics compete for market share…"

80. Ms McCaul goes on to aver that "…if Mylan is permitted to enter the market, pharmacists can immediately substitute the cheap Mylan products (and the products of any other generic companies that follow suit), unless the doctor or patient raise objection" [para. 121]. She refers to the fact that other generics companies have already obtained marketing authorisations to sell generic Janumet, and states her concern "…that if Mylan were to be allowed to continue on the Irish market with its generic product prior to the expiry of the 024 SPC, some, if not all, of these companies would be likely to feel commercially compelled to launch their medicines to compete against MSD and Mylan" [para. 126]. She contends that the entry of several generics companies to the market would result in a "free for all" forcing MSD to reduce its price to compete, a reduction which she states is not likely to be reversible.

81. Ms McCaul contends that MSD may suffer additional harm through the impact of reference pricing in other countries if the Irish price for Janumet is reduced; she states that fourteen named European States "use the price of Janumet products as charged in Ireland to set the price for the same products in their own territories… [para. 139]". She also refers to the possibility of courts in Europe following the refusal of an injunction "without due regard to the local circumstances" [para. 140].

82. In relation to Janumet itself, Ms McCaul refers to it as "among the most important and valuable medicines in the MSD portfolio" [para. 103]. The total market in Ireland for Janumet was worth in excess of €9m for the years 2019, 2020 and 2021. At para. 102 of her affidavit, Ms McCaul avers as follows: -

> "I and the other senior officers of MSD who are directly concerned with the market in Ireland are firmly of the view that, for the reasons set out below, damages would not be an adequate remedy for the infringement of the 024 SPC. At the outset, I believe that it is important to note that MSD's protection in respect of its Janumet products is in the nature of an exclusive monopoly albeit one which will expire on 7 April 2023. I do not believe that exclusive right can be reduced to a mere right to receive a payment of damages. Patent and SPC rights are monopoly rights for a limited period for complex policy reasons which include the encouragement of research and development and those policy objectives are wholly undermined if that right cannot be maintained".

83. In her replying affidavit of 28 October 2022 on behalf of the defendants, Ms Fisher states her belief that "…any damage or loss suffered by the plaintiff as a result of my company's launch of a generic sitagliptin-metformin product onto the Irish market is quantifiable and can be remedied in damages…the reality is that the remaining lifetime of the plaintiff's monopoly rights in its Janumet product is so short that it cannot argue that, as a result of a generic product launch, its product price will be negatively affected by price erosion for years to come or that the reputation attaching to its product will suffer irremediable harm…" [paras. 15 to 16].

84. At para. 35 of her affidavit, Ms Fisher refers to what the parties have termed the "first mover advantage": -

"It is clear that regardless of these proceedings, a generic form of sitagliptin/metformin will be available across the EU from early/mid next year onwards. The reality is, as set out at para. 9 above that both the plaintiff and other companies are getting ready to launch generic versions of Janumet. It is crucial from a generic drug company's viewpoint to be the first to launch. This is because the first company to launch will have the opportunity to set the price for pharmacies and will generally be able to set the tone and approach for a launch. Pharmacies tend to move supplier only once in respect of each specific generic drug type simply because of the sheer number of different types of generic drugs that they have to stock each year".

85. Ms Fisher develops the theme of the harm to the defendant being irreparable: -

"36. Unlike the position of the plaintiff who has a stable and predictable market from which any financial loss can be easily calculated, the position of the defendants is entirely different. If they are prevented by injunction from launching their product it will be impossible for them, or for the court, to calculate what sales they could have secured between now and the trial. If at trial it is determined that no injunction should have been granted how would the defendants demonstrate the level of sales which they would have secured in the interim had the injunction not been granted? That scenario is highly likely to occur here bearing in mind that the 024 SPC is likely invalid and therefore, should that finding be made at trial, the plaintiffs ought not to have been granted any injunctive relief."

86. In her replying affidavit of 15 November 2022, Ms McCaul responds to Ms Fisher's contention regarding the loss of "first mover advantage", averring that "…Mylan's aim appears to be to steal a march on the other generic companies who

Ms Fisher identifies as likely to enter the market on the expiry of the 024 SPC on 7 April 2023. However, this loss is predicated on trespassing on territory which is currently protected by the 024 SPC and which MSD (and the other generic companies) are entitled to presume to be valid…" [para. 33]. Ms McCaul also makes it clear that the plaintiff does not accept that Mylan's losses would be unquantifiable; the exercise which would have to be conducted by the court of quantifying damage "is familiar to the courts, being a confined sum of money for a relatively short period of time" [para. 34].

87. The respective themes of the parties in relation to the adequacy or otherwise of damages for either of them are fully rehearsed in the affidavits both written and oral, all of which I have considered and taken into account. While each of the parties adopts an aggressive stance regarding the other's position on adequacy of damages in the affidavits, it becomes clear on going through the submissions that there is no significant difference between the parties on this point. MSD emphasises heavily the similarity between the circumstances of the present case and *Merck v Clonmel*, and counsel for the plaintiffs essentially argued that the reasoning of the court in relation to how the principles regarding interlocutory relief should be applied to the facts of that case is of equal application to the facts of the present case. While not abandoning its assertion that damages would be an adequate remedy for Mylan, MSD is essentially of the view that, even if they were not, neither are damages an adequate remedy for the plaintiff for the same reasons set out by O'Donnell J at para. 60 of the Supreme Court judgment and quoted at para. 31 above.

88. Equally, counsel for Mylan deprecated the suggestion by Ms McCaul that damages would adequately compensate Mylan, pointing out that this ignored the loss by Mylan of "first mover advantage", and suggesting that an exercise of simulating

what market share might have accrued to Mylan had the injunction not been granted was "completely unrealistic". On being asked squarely by the court whether he contended that the analysis of O'Donnell J at paras. 60 to 61 of the Supreme Court judgment applied equally to the present case, counsel replied emphatically that he did: see day 2 p.43 lines 7 to p.44 line 28.

89. In *Merck v Clonmel*, O'Donnell J concluded in relation to the issue of adequacy of damages as follows: -

> "61. I consider that this is a case where damages, while available, cannot be considered to be said to be a full or adequate remedy for Merck so as to exclude the necessity to seek an injunction. I also consider that damages will not be an adequate or full remedy for Clonmel if an interlocutory injunction is granted and it is then determined that the SPC was invalid. Furthermore, it is plain that both parties have sufficient resources to pay any damages awarded. I do not consider, therefore, that the balance of potential irreparable harm favours either party decisively…"

90. In my view, these conclusions are equally applicable to the present case. I also conclude that the balance of potential irreparable harm in the present case favours neither party decisively. Accordingly, the court must have regard to other factors.

Strength of the rival arguments

91. As we have seen, the Supreme Court suggested that, where the balance of convenience is finely balanced "…it may be appropriate to have regard, on a preliminary basis, to the strength of the rival arguments as they may appear to the court…" [para.63]: see para. 32 above. Counsel for Mylan argued that, on the evidence before the court, its case for invalidity of the SPC was strong, and that there had been successive and, it was argued, persuasive determinations of similar

challenges in courts in other jurisdictions. Heavy emphasis was placed by counsel on the decisions of the High Court and in particular the Court of Appeal in *Merck v Clonmel*, to which I have made extensive reference above. It was submitted that the firm view of the High Court and the Court of Appeal that an "invention-based" test rather than an "identificatory" test governed whether or not the product in question was protected by the original patent should persuade the court that Mylan must be said to have "strong grounds" that it would ultimately succeed in the action.

92. Counsel for Mylan also relied on the affidavit evidence of Mr Fitt and Professor Heller as supporting the proposition that, as Mr Fitt put it, "…the 357 patent concerns one invention and not two…" [see para. 61 above]. Counsel for MSD on the other hand submitted that "…the analysis of a patent can't be addressed without evidence from the skilled addressee of the patent…" [day 2 p.171 lines 22 to 24]. It was pointed out that Mr Fitt is a solicitor, without any expressed relevant pharmacological or scientific qualifications or expertise, that there was no indication that Professor Heller had seen the patent [day 2 p.173 line 29 to p.174 line 1], and that "…this is an area of expert testimony from a skilled person and none has been proffered [to the court] … "[day 2 p.174 lines 10 to 12].

93. As regards determinations in other countries, this was the subject of much affidavit evidence and submissions. We have seen – at paras. 64 to 67 above – the decision of the FPC in Germany, which held that an equivalent SPC was in violation of Article 3(c) of the SPC Regulation, although that decision appears to be under appeal. In her second affidavit sworn on 15 November 2022, Ms McCaul summarised the position in foreign jurisdictions as follows: -

> "75. A very broad synopsis of the position is that in three countries' courts (the Czech Republic, France and Sweden) the validity of the Janumet SPC has

been upheld. In two countries' courts it has been held invalid (Romania and Germany). The Croatian application for a Janumet SPC was refused. Appeals have, or will be filed in each country in which the SPC has been found valid or invalid by the relevant court or office save for Poland where the Janumet SPC application has been finally refused. In sixteen countries there are ongoing proceedings in which the validity of the Janumet SPC is in issue (Finland, Austria, Belgium, Bulgaria, the Czech Republic, Estonia, France, Germany, Hungary, Italy, Portugal, Romania, Slovenia, Slovakia and Sweden). In Poland the basic patent has been challenged … and these proceedings are pending. In Greece preliminary injunction proceedings are pending but the validity of the SPC has not been challenged. Of these, three have stayed proceedings pending the outcome of the Finnish preliminary reference to the CJEU, and/or the outcome of the Irish reference in the Inegy matter (Finland, Hungary and Slovakia)".

94. Since that affidavit was sworn, a further affidavit was sworn by Aoife Murphy, a solicitor acting for the plaintiff, on 6 December 2022 which updated the situation; it appeared that the Finnish Market Court had granted an *ex parte* application to MSD in comparable proceedings involving sitagliptin/metformin. A Greek court of first instance had on the other hand refused an interlocutory injunction in a comparable case.

"Clearing the way"

95. The existence of other litigation in Europe in relation to the ambit of the patent and the validity of SPCs in the various jurisdictions is relevant to the criticism by MSD of Mylan that it has not "cleared the way". While Mylan has not taken steps to establish in this jurisdiction the alleged invalidity of the SPC, the point is made that

the litigation challenging MSD's position is a Europe-wide endeavour; in essence, the present dispute is a "battle in the war", and Mylan is entitled to rely on successes elsewhere in Europe which suggest that its view of how the SPC Regulation should be interpreted is correct.

96. Counsel for MSD on the other hand is heavily critical of Mylan's failure to clear the way, commenting that the defendants have "never actually put their money where their mouth is by commencing proceedings saying the patent is invalid" [day 2 p.179 lines 11 to 20].

The presumption of validity

97. At para. 62 of the Supreme Court judgment in *Merck v Clonmel*, O'Donnell J stated that weight should be given, in considering the balance of convenience and the balance of justice, to "…the fact that Merck is the holder of an SPC granted pursuant to an authorisation process provided for by law and which involves the consideration both of the application for the 599 patent by the Controller of Patents, and the subsequent application for the SPC". He held that "…as a matter of law, the SPC is valid and effective until declared invalid by a court of competent jurisdiction…", and referred to the decision of the Supreme Court in *Okunade v Minister for Justice* [2012] 3 IR 152 as recognising that the court should take into account: -

> "… the fact that an order had been made in accordance with law, by a body established and authorised by law to do so, and which must be treated as valid unless and until determined otherwise by a court or body, it is, in my view, not unreasonable to give this greater weight in the balance than the interests of Clonmel which only arise after it is determined that the SPC is invalid. Another way of valuing this factor is that it represents the *status quo ante*…"

98. In *Biogen MA Inc. & Biogen International GMBH v Laboratorios Lesvi SL & Neuraxpharm Ireland Ltd.* [2022] IEHC 592, decided by the High Court on 26 October 2022, an interlocutory injunction was sought in a patent dispute concerning a drug used to treat multiple sclerosis. Twomey J referred to the decision of the CJEU in case C-44/21 *Phoenix Contact GmbH & Co KG v Harting Deutschland GmbH & Co KG*, in which the court stated that "…it must be borne in mind that filed European patents enjoy a presumption of validity from the date of publication of their grant…" [para. 41]. Accordingly, Twomey J expressed the view that "…were it not for the unusual factors in this case, this Court would have to treat this decision of the examining division as granting the 873 patent a presumption of validity, which would be dispositive in favour of the grant of the injunction". Notwithstanding this view, the court refused the injunction, as "…the decisive factor in the balance of justice is the fact that *Biogen has benefitted* from an unlawful monopoly created by an invalid Parent Patent and it is now seeking to benefit from a monopoly from a patent that is derived from that invalid Parent Patent … [para. 86: emphasis in original]."

99. In the present case, the defendants do not argue that there is no presumption of validity as regards the 024 SPC; they argue that the presumption is outweighed by the strength of the defendant's case for invalidity of the SPC, which they say is borne out by the High Court and Court of Appeal decision on the substantive issues in *Merck v. Clonmel*, and by the determinations in other jurisdictions, particularly that of the FPC in Germany referred to above: see day 2 p.149 line 23 to p.151 line 19.

Conclusions on balance of convenience and balance of justice

100. In order for this court to assess, even on a preliminary basis, the respective strengths of the parties' cases for and against the validity of the 024 SPC, there has to be clarity as to what principles would govern the determination of the issues at trial.

The High Court and Court of Appeal in *Merck v Clonmel* were very clear as to what those principles are, and applied them to the facts of that case as established by the evidence at a full trial.

101. The Supreme Court on the other hand did not accept Clonmel's case that the principles were clear "…despite a number of decisions of the CJEU on the application and interpretation of the [SPC] Regulation…".

102. In the normal course, this Court would be bound by a decision of the Court of Appeal as to the appropriate principles of law to be applied in a case where the facts and circumstances of the matter were not materially different to those in respect of which the Court of Appeal's decision was made. In the present case, Mylan argues that this Court is either bound by the decision of the Court of Appeal in *Merck v Clonmel*, or that the strength of that decision, combined with the decision of McDonald J in the High Court and various decisions in other jurisdictions, should cause this Court to conclude that the balance of justice favours refusing the injunction.

103. However, it is impossible to see the Supreme Court decision in *Merck v Clonmel* as being other than at odds with the Court of Appeal decision; not in the sense of suggesting that the Court of Appeal's decision was incorrect, but rather that the principles were regarded by the Supreme Court as so unclear that, as a court of final appeal, it is obliged to seek clarification by way of reference to the CJEU, and should not decide the issues of EU law without such a reference.

104. In these circumstances, it does not seem to me that I must consider this Court to be bound by the Court of Appeal's preference in *Merck v Clonmel* for an "invention-based" approach rather than an "identificatory" approach, so that the strengths of the respective cases of the parties must be judged by this standard, in

circumstances where the Supreme Court is of the view that a ruling of the CJEU is necessary for the court to reach its decision on the appeal in that case.

105. Mylan seeks to argue that the correctness of the Court of Appeal decision is supported by the closely reasoned decision of the FPC in Germany: see paras. 64 to 67 above. However, as the quotation from that decision at para. 66 above shows, the FPC refused to refer the matter for preliminary hearing as "the correct application of Union law…" was "…sufficiently clarified". This view is directly at odds with the views expressed by the Supreme Court in this jurisdiction, which considers that it is obliged to refer the matter to the CJEU in circumstances where "… the interpretation of Regulation EC 469/2009 is unclear despite a number of decisions of the CJEU on the application and interpretation of the Regulation…" [para. 3 of the reference to the CJEU in *Merck v. Clonmel*].

106. The Supreme Court, in the interlocutory application in *Merck*, was of the view that it might weigh against the grant of an injunction if there had been "successive determinations in Clonmel's favour of a similar challenge in other jurisdictions…". In my view, the phrase "successive determinations" is significant. One can well envisage that, in a situation where courts in Europe had made a number of "successive" decisions which indicated a clear emerging view trending towards a consensus as to the appropriate principles, it might be possible to conclude that those principles had a strong chance of being recognised in Irish proceedings. However, Mylan has not produced evidence of "successive determinations". As we have seen, the results in courts across Europe have been varied. Some are on an interlocutory basis. Many are under appeal. It does not seem to me that it can be said that there is a definitive trend in those decisions one way or the other, much less "successive determinations" in favour of Mylan's interpretation of the SPC Regulation.

107. As O'Donnell J pointed out in *Merck* "…the SPC holder has a right conferred by a process of law which is presumptively valid…". While – as I was on more than one occasion reminded by counsel for Mylan – it is MSD which seeks injunctive relief, and thus must satisfy the court that the criteria for the grant of such relief are present, it is for the party resisting the injunction to show that the circumstances of its case are such that the presumption should be rebutted.

108. As we have seen, my view is that damages are not an adequate remedy for either party, and neither does the balance of potential irreparable harm favour either party decisively. It also seems to me that, particularly given the uncertainty in relation to the legal principles to be applied, it cannot be said, on a preliminary basis, that the strength of the defendant's case in relation to the invalidity of the 024 SPC is such that the presumption of validity must be set aside. In the absence of strong grounds for doing so, I accept that the plaintiff is entitled to develop its business and marketing strategies on the basis of certainty as to the period for which its products are protected as a statutory monopoly. Indeed, as the plaintiff submits, if the presumption of validity were to be unduly eroded, the end period of an SPC "will become open season".

109. Also, while the defendants may have had their own reasons for not initiating procedures in this jurisdiction, through litigation or otherwise, to have the SPC revoked as invalid, they have failed to "clear the way". The Supreme Court acknowledges that this is not "a single dispositive argument"; however, the only argument being made by the defendants is that, having regard to Article 3 of the SPC Regulation, the 024 SPC is invalid. No case is made by Mylan as to why it was not proactive in challenging the SPC in this jurisdiction, and chose to argue for its invalidity only by way of counterclaim in the present proceedings. In my view, the

failure of Mylan to take steps to "clear the way" is a factor in support of the court preserving the *status quo ante* by granting injunctive relief.

Orders

110. For the reasons set out above, I am of the view that the balance of convenience and the balance of justice favour the granting of injunctive relief. I propose to make an order in terms of para. 1 of the notice of motion as follows: -

> "An interlocutory injunction restraining the defendants, whether acting by themselves, their directors, officers, servants or agents, or any company or entity under the direction or control of the defendants, from offering, putting on the market or using products subject of supplementary protection certificate number 2008/024 (the '024 SPC'), in particular, by the offering, putting on the market or using products containing sitagliptin and metformin, or importing or stocking such products for those purposes until judgment in the substantive cause of action between the plaintiff and the defendants or, if earlier, the expiry of the SPC on 7 April 2023 or until further order of this Honourable Court".

111. In view of the parties' wish for expedition, I will list the matter for 10.30am on Tuesday 24 January 2023 for hearing in relation to any matters relating to the form of the order to be made.

Postscript

112. After completion but before delivery of this judgment, the plaintiff's solicitors, with the agreement of the solicitors for the defendants, wrote to the court's registrar with an update in relation to some decisions of courts in Europe handed down subsequent to the hearing before me and which touch upon the present application. The information imparted may be summarised as follows:

- The Market Court in Finland, which had previously referred issues to the CJEU in early 2022 in relation to the sitagliptin/metformin SPC, has granted four inter partes preliminary injunctions against four separate defendants prohibiting those parties, including the second-named defendant in the present proceedings, from entering the market with a generic product prior to the expiry of the SPC; the orders apply "… until a judgement is issued in the principal matter or until otherwise directed…";
- Mylan applied on 11 January 2023 to the Finnish Supreme Court for permission to appeal the decision against it;
- In the Czech Republic, 2 ex-parte applications have been granted restraining breach of the Janumet SPC. One further ex-parte application was refused;
- In Portugal, 3 ex-parte applications seeking to restrain breach of the Janumet SPC have been refused;
- In Switzerland, 2 ex-parte applications seeking to restrain breach of the Janumet SPC were refused, and one application was granted;

113. This court was provided with a certified translation of the judgement of the Finnish Court against Mylan, to which I have referred above. The court was not provided with copies of judgements or orders in relation to any of the foregoing proceedings in the Czech Republic, Portugal or Switzerland.

114. I refer to the information set out above only for completeness. I do not consider that the information furnished to me alters or affects the views or conclusions which I express in this judgement, and at para. 106 in particular.