# THE COURT OF APPEAL

**Neutral Citation Number [2023] IECA 111**

**APPROVED**

**NO REDACTION NEEDED**

**Record Number: 2023/17**

**High Court Record Number: 2022/4794P**

**Costello J.**

**Faherty J.**

**Haughton J.**

**BETWEEN/**

**MERCK SHARP & DOHME LLC**

**RESPONDENT/PLAINTIFF**

**-AND-**

**MYLAN IRE HEALTHCARE LIMITED, MYLAN IRELAND LIMITED and MCDERMOTT LABORATORIES LIMITED trading as GERARD LABORATORIES trading as MYLAN DUBLIN**

**APPELLANTS/ DEFENDANTS**

**JUDGMENT of Mr. Justice Haughton delivered *ex tempore* on the 14th day of March, 2023**

**1.** This is an appeal by the Appellant, Mylan, against the decision of the High Court of Sanfey J on 20 January 2023 to grant the Plaintiff/Respondent, Merck ("**MSD**") an interlocutory injunction restraining Mylan from offering, putting on the market or using products the subject of Supplementary Protection Certificate no. 2008/024 ("**the 024 SPC**"), in particular by 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 action, or if earlier, the expiry of the SPC on 7 April 2023.

**2.** It is Mylan's contention that 024 SPC is invalid and the MSD's combination product, Janumet, is no longer patent protected and it is free to launch a generic medicine. This judgment is being delivered ex tempore in light of the short time left to 7 April and the desirability that there be some certainty in the matter during that period.

**3.** Although there are several grounds of appeal, the issues have been narrowed considerably by the scope of Mylan's written and oral submissions.

**4.** The parties agreed in the High Court that the principles enunciated by O'Donnell J. (as he then was) in *MSD v. Clonmel Healthcare Limited* [2020] 2 IR 1 , govern the question of when an interlocutory injunction should be granted. In passing, it is of note that the facts of that case bear some similarity to the instant case and the Supreme Court granted an interlocutory injunction to MSD as the holder of a second SPC in respect of a combination medicine.

**5.** The trial judge in the present appeal found that there was a fair question to be tried, that damages would not be a full or adequate remedy to MSD if no interlocutory injunction was granted and would not be a full or adequate remedy for Mylan if it was granted due to the difficulty in ascertaining the extent of damage. He concluded that the balance of potential

irreparable harm in the present case favours neither party decisively. These findings are not contested in the appeal.

**6.** As the third limb of the test, the balance of justice, was finely balanced, the trial judge went on to consider other matters. He decided not to address, on a preliminary basis, the strength of the rival arguments. This is because the basis upon which an SPC may be granted or found to be invalid under Article 3 of Regulation EC number 469 of the European Parliament and of Council 6 May concerning the Supplementary Protection Certificate for Medicinal Products ("**the Regulation**") is the subject of two preliminary references to the CJEU which were heard by a Chamber of the Court last week, and where the Court's ruling is awaited. His reasoning was that there was no clarity as to the principles governing the issues that would arise at trial, One of the preliminary references has been made by the Supreme Court in *MSD v. Clonmel Healthcare Limited* [2022] IESC 11 , delivered on 21 February 2022, which I will refer to later.

**7.** At paragraph 100, the trial judge held that:

> "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."

**8.** At paragraph 103 he stated:

> "However, it is impossible to see the Supreme Court decision in *MSD v. Clonmel Healthcare Limited* 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."

**9.** Therefore, he was not bound by the Court of Appeal preference in *MSD v. Clonmel Healthcare Limited* for an invention based approach and rejected the argument based on the German Federal Patent Court decision as its views on the clarity issue were not shared by the Irish Supreme Court. He also held that there were not successive determinations in Europe such as to show a clear emerging view trending towards the applicable principles.

**10.** He therefore, relied on the presumption of validity enjoyed by the 024 SPC, a presumption that was not contested by Mylan. He found that the presumption was not rebutted and that Mylan had not cleared the way for launching a new product by moving to have the 024 declared a nullity and that the balance of justice favoured the granting of the interlocutory injunction.

**11.** Mylan submits that the trial judge erred in failing to address the strength of the rival arguments and contends that there a strong case for nullity such that the balance of justice favoured refusal of interlocutory relief.

**12.** I will deal now with some of the factual background.

**13.** MSD is the holder of European Patent 1412357 ("**Patent 357**") with a priority date of 6 July 2001, filed on 5 July 2002, for a new class of anti-diabetics of Formula l, with sitagliptin as the main representative of the class, as an inventive treatment for type 2 diabetes and other diseases. It includes Basic Claims 1 to 15. This is a Basic Patent for the purposes of the two SPC's.

**14.** Patent 357 expired on 4 July 2022. It includes the following claims:

- Claim 20 a combination of sitagliptin with...

  (b) insulin sensitisers, including biguanides, which would include metformin.

- Claim 25, a pharmaceutical composition comprising sitagliptin and (b)(ii) biguanides, which would include metformin.
- And perhaps most relevant to MSD's claim for validity, Claim 30:

  "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, metformin, and a pharmaceutically accepted carrier."

**15.** The reference to metformin is clearly intended to refer to the active ingredient metformin which is a biguanide of the sort mentioned in Claims 20 and 25.

**16.** According to averments in the first affidavit sworn by Mairéad McCaul, who is not a chemist or a doctor, and which was sworn on behalf of MS]), the following emerges:

> "Sitagliptin inhibits the degradation of the incretins glucagon like peptide 1 ("**GLP 1**") and gastric inhibitory peptide ("**GIP**") by the enzyme dipeptidyl peptidase IV ("**DP IV**"). Metformin ensures that the new formation of glucose ("**gluconeogenesis**") in the liver is inhibited, increases GLP 1 and is also believed to inhibit the absorption of glucose in the intestine and reduces insulin resistance, thereby improving the absorption of insulin into muscle cells. This helps to lower blood sugar levels."

**17.** MSD asserts exceptional efficacy of the combination of sitagliptin and metformin, as metformin increases the total GLP l , the substrate for DPP IV, while sitagliptin inhibits the degradation of the same substrate.

**18.** MSD claims two inventions:

1. Sitagliptin (first in class in the class of gliptins), Sitagliptin in combination with a biguanide insulin sensitisers (preferably metformin).
2. MSD holds market authorisations for Januvia – ( a sitagliptin mono drug); and Janumet, tablets in two sizes, that is sitagliptin plus metformin.

**19.** MSD holds two SPCs, one in respect of each of these products. Firstly, the 024 SPC filed 14 August 2008 with a notification of grant published 14 October 2009. The date of expiry is 7 April 2023. This is for the product in controversy called Janumet, which is identified as sitagliptin plus metformin. 'Title of invention' refers to Patent 357 and DP IV for treatment for prevention of diabetes.

**20.** And, second in time, the 029 SPC, although filed first on 13 August 2007, with a notification of grant published 1 October 2012. 029 SPC expired on 22 September 2022. This SPC was for a sitagliptin mono product called Januvia, based on Patent 357.

**21.** Mylan's submissions are essentially twofold:

1. That the trial judge erred in effectively refusing to engage with Mylan's case that 024 SPC was invalid and;
2. That Mylan's case on invalidity possesses the requisite degree of strength to warrant the refusal of interlocutory relief.

**22.** Mylan obtained market authorisation for bioequivalent generics for Janumet in February 2022 and obtained reimbursement figures from the HSE which were 60% less than MSDs price for Janumet. Mylan undertook not to launch before 22 September 2022 (the expiry of SPC 029), but no further. There are six other companies with market authorisations. Mylan want "first mover" advantage and say SPC 024 is invalid and that on the balance of justice, an injunction should not have been granted.

**23.** Mylan argues that it has a strong case for invalidity because of a number of factors. It says it has a strong case based on findings at trial on similar facts in *MSD v. Clonmel Healthcare Limited* in the High Court and in this Court. And it says that this was not undermined by the fact that the Supreme Court decided to make a preliminary reference on how Article 3 is to be applied.

**24.** It says secondly Metformin is not covered by Patent 357 at all, it was commonly used in Europe since the 1960s and until 2006 as standard treatment for type 2 diabetes.

**25.** Thirdly Mylan say, the description in Patent 357 of use of Formula 1 sitagliptin and other active ingredients, including metformin, does not equate to a second invention. There is no detailed teaching, disclosure or experimental data concerning the sitagliptin and metformin combination.

**26.** Fourthly, as of the priority date of Patent 357 the 6 July 2001 there was no public literature, studies or reports on benefits or efficacy of the combination sitagliptin and metformin. The evidence of Simon Heller on affidavit (a professor of clinical diabetes) in relation to publications and lack of awareness of the benefits or efficacy of sitagliptin and metformin as a treatment for type 2 diabetes at the priority date in 2001 and from 2001 to 2007 is relied on.

**27.** Fifthly, the combination of the two active ingredients was not in use until regulatory approvals for Janumet in the US in 2007 and the EU in 2008.

**28.** Sixthly, research and clinical trials after 6 July 2001 cannot be considered. Reliance is placed for this proposition on paragraphs 47 to 51 of the Grand Chamber decision in *Teva v. Gilead* C-121/17.

**29.** Seventhly, the Appellants rely particularly in their written submissions at page 17, and in oral submissions, on the decision of the Federal Patent Court ("**FPC**") in Germany in a judgment delivered on 23 June 2021, not as a precedent but as demonstrating the strength of its case. There, the FPC concluded that the combination of sitagliptin and metformin was not disclosed as a separate innovation separate from Formula 1, of which sitagliptin is an example.

**30.** Paraphrasing its findings at paragraph 1.3 of its judgment the FPC found: that Patent 357 only had general statements on active substance combinations; that Claims 20 and 25 and paragraphs 51 and 57 only indicate a variety of possible active substance combinations; that Claims 28 and 30 limit the number of these to the extent that Claim 28 reduces the active substance of Formula 1 to the DP IV inhibitor sitagliptin. Claim 30 identifies the insulin sensitiser, metformin, as a suitable second active substance component. The FPC stated:

> "However, since Patent Claim 30 refers neither directly nor indirectly to Patent Claim 28, it cannot be inferred from the Patent Claims that the disputed active substance combination sitagliptin/metformin is a product essential to the invention."

**31.** The FPC found that no information or data indicating any surprising pharmaceutical significance of the combination in the patent or description. It found examples 1 to 7 in paragraph 33 illustrate that the innovation lies in a Formula 1 compound such as sitagliptin. The Court found that no relevant specialist could derive any concrete indications from Patent 357 as to why a combination of sitagliptin and metformin should be considered particularly advantageous, surprising, tolerable or unexpected and thus regarded as an independent invention. It held that information and combined effect in later publications was irrelevant.

**32.** The FPC concluded that the combination does not constitute an independent innovation.

**33.** The FPC followed the innovation test indicated by the ECJ in *Actavis v. Boehringer* Case. So, as an SPC had in Germany already been granted for sitagliptin alone, the granting of the later SPC for the combination violated Article 3(c) of the Regulation.

**34.** The FPC refused to refer preliminary questions to the ECJ considering that it was bound by *Actavis v. Boehringer*.

**35.** Eighthly, Mylan acknowledge that the FPC decision is under appeal but submit that it is a particularly cogent analysis and asserts that the strength of Mylan's claim for nullity outweighs the presumption of validity of SPC 024.

**36.** Ninthly, it was also submitted that this Court should not, as did the trial judge, give weight in assessing the balance of justice to the presumption of validity of the 024 SPC, the retention of the status quo and the failure of Mylan to take action to clear the way for its generic launch, as these are matters that exist by definition in all such cases where interlocutory relief is sought and therefore are to be taken as a given before the balance of justice is considered.

**37.** In response, MSD contends that firstly, in *MSD v. Clonmel Healthcare Limited* the Supreme Court did not find the test under Article 3(a) or (c) *acte clair* and made a preliminary reference to the ECJ.

**38.** MSD say this Court is bound by that decision notwithstanding that in the subsequent appeal in *MSD v. Clonmel Healthcare Limited* it found that *Boehringer* required a qualitative test and that this was not displaced by *Teva v. Gilead* and *Royalty Pharma*.

**39.** Secondly, therefore MSD say that, Mylan cannot rely for its argument that it has a strong case on the High Court or Court of Appeal decisions in substantive decisions in *MSD v. Clonmel Healthcare Limited*.

**40.** Thirdly, for a number of reasons, Mylan cannot rely on the German FPC decision on sitagliptin and metformin for asserting a strong case.

**41.** Fourthly, that even on a qualitative test, the active substance composition of sitagliptin plus metformin in Janumet is a different product to the active substance of Januvia where only sitagliptin is active.

**42.** Fifthly, the combination of sitagliptin and metformin was not known or used at Patent 357 priority date, only metformin with other anti-diabetics having sub additive effect and as it was not obvious to the skilled technician it was a new invention.

**43.** Sixthly, pre patent priority date literature and test results are not required in law and cannot be expected as an invention cannot be patented if it is obvious, as testing and trials of their nature follow on the priority date and grant.

**44.** Seventhly, Prof. Flatt (Ulster University) gave evidence in the Finnish Market Court and this is exhibited in the present case that the combination of sitagliptin and metformin is exceptional and results in "*a unique and particularly powerful set of complementary glucose lowering effects.*"

**45.** Eighthly, studies of Janumet before the SPC filing in 2007 bear this out.

**46.** Ninthly, on the identificatory test, MSD relies on Claims 20, 25 and 30, and, in addition, descriptions in Patent 357 at paragraphs 52 and 53 which give examples of combination which include DP IV with biguanides such as metformin as expressly identifying sitagliptin and metformin as a combination.

**47.** Tenthly, under Article 3(a) the test is identificatory per the CJEU in *Teva v Gilead* and *Royalty Pharma* where the combination is necessarily and specifically covered and

protected by the patent, rather than requiring a qualitative assessment of the invention covered by the patent and requiring an inventive step per *Actavis v. Boehringer*.

**48.** Eleven, under Article 43(a) Janomet is covered by the Basic Patent in force, Patent 357, as the combination is expressly identified in Claims 20, 25 and 30.

**49.** Twelve, under Article 3(b) there was a valid marketing authorisation granted.

**50.** Thirteen, Article 3(c) is also satisfied as SPC 024 was the first in time at the date of the grant in 2018 so the product is not already the subject of a certificate. SPC 029 was for a different product the mono drug in which sitagliptin is the only active ingredient, and in any event was only granted subsequently.

**51.** Fourteen, there are multiple proceedings in being across Europe in relation to Janumet by generics seeking nullity of the SPC or in which MSD seek injunctions but there is no emerging pattern. In Sweden and in the Paris court, the courts have adopted an identificatory test and have decided cases on their merits where the equivalent SPC has been held to be valid.

**52.** Fifteen, in the Finnish Market Court, Teva brought nullity proceedings against MSD in respect of the Finnish Janumet SPC which are stayed pending the Article 267 reference to the ECJ on Article 3 of the Regulation. And on 9 September 2022, preliminary injunctions were granted to MSD against Mylan and Krka restraining entry to the market. The questions raised were whether the concepts of core inventive advance or subject matter of the invention are relevant to Article 3(c) and, in particular, whether the CJEU interpretation of Article 3(a) in *Teva v. Gilead* and *Royalty Pharma* have a bearing on the assessment of Article 3(c).

**53.** Sixteen, the Finnish and Irish references were heard together last week, and rulings are awaited.

**54.** Seventeen, in any event, Janumet satisfies the qualitative test as the combination is an inventive advance.

**55.** Eighteen, the presumption of validity and failure by Mylan to clear the path were valid considerations in the assessing of the balance of justice.

**Analysis**

**56.** O'Donnell J. in *MSD v. Clonmel Healthcare Limited* (the injunction proceedings) addresses the balance of justice at paragraphs 61 to 63 and I think all of these are relevant and the parties will forgive for reading them out.

> "61. One feature of this case, to which, in my view, weight should be given, can be viewed in three different, though related, ways. That is the fact that Merck is the holder of an S.P.C. 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 S.P.C. As a matter of law, the S.P.C is valid and effective until declared invalid by a court of competent jurisdiction. Just as in *Okunade v. Minister for Justice* [2012] IESC 49, [2012] 3 I.R. 152 it was recognised that it was appropriate to 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 S.P.C. is invalid. Another way of valuing this factor is that it represents the status quo ante. In this case, there was no unreasonable delay in the commencement of the proceedings, and the *status quo* must therefore be taken to be the position which existed prior to Clonmel's launch. Finally, the same factor comes

into play if consideration is given to the question of clearing the way. For the reasons discussed above, this cannot be treated as a single dispositive argument and, for example, in cases where the defendant might plausibly contend that his product did not infringe a patent, it might be of lesser weight. Here, however, the only issue is validity and, moreover, that issue itself is to be determined within the limited confines of Article 3 of the regulation. Since, by definition, any generic challenger will have to have taken preparatory steps both of a practical and regulatory nature it is, in my view, a legitimate factor to which weight should be given to consider that no steps have been taken to clarify the essential matters upon which Clonmel's right to launch the product depends: those concerning the question of the validity of the S.P.C.

62. 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. It is recognised in the decision in *American Cyanimid* that if the question of adequacy of damages is evenly balance, it may not be inappropriate to consider the relative strengths and merits of each party's case as it may appear at the interlocutory stage. Courts 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. For this reason, I consider that Hogan J, taking the view he did of the balance of convenience, was quite correct to form some tentative view of the merits. However, it is, in this case, sufficient to say 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, Accordingly, I consider that if the case was considered as of April 2018, then an interlocutory injunction ought to have been granted, subject to the Merck's undertaking in respect of damages, and direction for a speedy trial on the issue of validity."

and who in a paragraph that was not opened to the Court but which in my view is nonetheless significant. O'Donnell J. states:

> "63. I am conscious that, although expressed in perhaps a nuanced way emphasising the flexibility of the remedy, this decision is nevertheless capable of being read as suggesting that in every case in which an S.P.C. holder seeks an injunction against a threatened challenge by a generic competitor, then an interlocutory injunction ought to normally be granted. Given the fact that a number of the features are common to any such claim, this is inevitable. I would, however, emphasise that the balance is a fine one, and is capable of being affected by the circumstances of particular cases and by a range of factors, such as the outcome of similar litigation in other jurisdictions, which may lead to a different outcome."

**57.** Firstly, based on what is said in paragraph 61 by O'Donnell J., I cannot accept Mylan's submission that in addressing the balance of justice the Court should disregard the

presumption of validity. That presumption of validity, as a matter of law, was important in *Okunade*. It is there because, on its face, in the present case, the 024 SPC is valid. This is particularly important in the case of SPCs where the EU Regulation seeks to achieve a balance between the rights of an inventor who has invested heavily in the patent and in the patent disclosed the invention and bringing the product to the market, and the need to prevent creating excessive monopoly rights. Further, the SPC is not obtained without an application to a regulatory body and after rigorous trials for safety and efficacy. This Court, on appeal is also entitled to view the 024 SPC as enjoying a presumption of validity.

**58.** Secondly, O' Donnell J. does say in the same paragraph that it is legitimate to give weight to the failure to take steps to clear the path, notwithstanding that the failure to do so may feature in most of these cases. It would have been open to Mylan to do this at any point after the grant of SPC 024 in 2008 but the failure came more into focus after correspondence between the parties in 2020. This was undoubtedly a factor that the trial judge was entitled to take into account in assessing where, in his view, the balance of justice lay and, in my view, it was a factor that carried some weight.

**59.** I turn next to the argument that Mylan can rely on the substantive decisions of the High Court and Court of Appeal in *MSD v. Clonmel Healthcare Limited* notwithstanding the reference made by the Supreme Court to the CJEU to demonstrate the strength of their case for invalidity.

**60.** It is undoubtedly the case that in light of the decision of the Supreme Court to make a preliminary reference to the CJEU, the substantive decision of this Court in *MSD v. Clonmel Healthcare Limited* was not binding on Sanfey J. at first instance. That is because if the CJEU gives as its opinion that the appropriate test under Article 3(a) is the identificatory approach; i.e. focused on whether the product necessarily falls within the claims in the Basic

Patent rather than a qualitative assessment, or whether the composite product is an invention covered by the patent, it may follow that the Supreme Court will in due course overrule the decision of this Court in *MSD v. Clonmel Healthcare Limited*. It follows, for the same reason, that this Court's decision in *MSD v. Clonmel Healthcare Limited* is not binding on this Court on this appeal.

**61.** But it goes further; it seems to me that in these circumstances, the decision of this Court that is under appeal, and which may be overturned by the Supreme Court, cannot be regarded as establishing a strong case as to the tests and principles to be applied under Article 3 when those very tests and principles both in respect of Article 3(a) and 3(c) will in due course be the subject of a preliminary ruling by the CJEU that will be binding on all courts within the EU.

**62.** I find this compelling. I simply do not see how this court or the trial judge could have embarked on a meaningful analysis of the strength of Mylan's case, even on a preliminary basis, without clarity in relation to the basic legal principles on which the issues will fall to be tried. Mylan says it has a strong case both in law and on the facts but it relies largely on a qualitative test such as enunciated by the CJEU in *Aciavis v. Boehringer* but that test is under scrutiny in the references. The Supreme Court here did not find the test under Article 3(a) or (c) *acte clair*.

**63.** At paragraph 3 of its judgment, under the heading 'necessity for reference' it stated:

> "The Supreme Court considers that a reference under Article 267 of the TFEU is required in this case because 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, particularly in circumstances where two or more SPCs have been granted in respect of products covered by a single national patent ."

And further in the judgment it is stated at paragraph 26:

> "Since the treatment of this decision [*And that is a reference to Boehringer*] is an important touchstone for the resolution of this case, some observations on that decision are merited. It is not clear whether the reference to a 'subsequent claim to a product comprising a combination' refers simply to a claim coming later in the patent (and, if so, what relevance this could have) or to the facts of that case where, as it happened, the combination claim was made later in time as a result of an amendment application. More importantly, it is not at all clear that, even if 'as such' is to be given an autonomous interpretation, it can support the quite elaborate edifice sought to be constructed on those two words."

And at paragraph 41 of the reference itself, the following appears:

> "There is a conflict on these interpretations…"

That is the interpretations Il have just outlined:

> "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 in 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."

**64.** This brings me back to paragraph 62 of the judgment of O'Donnell J. in *MSD v. Clonmel Healthcare Limited* in the injunction case. He is careful to say that it *may* be appropriate to have regard to the strength of rival arguments. It follows that it will not be appropriate in all cases, even where the balance of convenience is finely balanced.

**65.** He also refers to a preliminary basis and the tentative view of the merits of the sort taken by Hogan J. in his dissenting judgment in the Court below, Again, this displays the caution that a court should take in making any observation or coming to any view on the merits of the dispute at an interlocutory stage. Indeed, it is instructive to turn to the judgment of Hogan J. in this Court, which it will be recalled involved a basic patent for ezetimibe and an SPC For a combination drug of ezetimibe and simvastatin, another active ingredient. Hogan J. addressed the strength of Clonmel's case in paragraphs 27 to 32 of his judgment and, having observed that the interpretation of Article 3 has not been without its difficulties, he then states at paragraph 28:

"28. In the light of Professor Assmann's opinion there is, therefore, at least for the purposes of the present case, a strong case to be made on the evidence adduced before us that the SPC was granted in respect of a combination of active ingredients (namely, ezetimebe and simvastatin) which produces pharmacological, immunological or metabolic actions of their own.

29. That, however, in itself is not enough, since it is clear from the opinion of Advocate General Wathelet in *Teva v. Gilead* that the relevant active ingredients must be 'specifically and precisely identifiable on the priority date of the patent' It may be noted that in Teva the defendant company had obtained an SPC in respect of anti-viral medical product containing two active ingredients, namely, TD and emtricitabine, even though it was agreed that the latter active ingredient had not been expressly named in the claims of the basic patent. Wathelet AG noted that embricitabine had been claimed 'solely through the use of completely indeterminate expressions such as 'comprising' and 'optionally other therapeutic ingredients', terms which he thought 'may cover multiple expressions that are not specifically and precisely identifiable on the priority date of the patent'. The Advocate General accordingly concluded that 'it would not have been obvious to a person skilled in the art that the active ingredient emtricitabine was specifically and precisely identifiable in the wording; of the claims of the patent.

30. Can that be said here? The basic 599 patent contained a claim (claim 9) for ezetimibe in combination with cholesterol biosynthesis inhibitor in a pharmaceutically acceptable carrier'. Claims 16 and 1 7 provide:

> '16. A pharmaceutical composition of claims 9, 12 or 15 wherein the cholesterol biosynthesis inhibitor is selected from the group consisting HMG

> CoA reductase inhibitors, squalene synthesis inhibitors and squalene epoxidase inhibitors.
>
> 17. A pharmaceutical composition of claim 16 wherein the cholesterol biosynthesis inhibitor is selected from the group consisting of lovastatin, fluvastatin, simvastatin, CI 981 L 659, 869, squalestatin 1 and NB 598.'

31. In contrast, therefore, to the situation in Teva it is clear an active ingredient here simvastatin used in combination with ezetimibe was specifically and precisely identifiable in the original patent claim.

32. In these circumstances, unsatisfactory and all as it, I repeat that I believe that we have to choose based on the available evidence. Applying the Advocate General's text in Teva, I find myself obliged to conclude that as that evidence stands and I acknowledge that matters may change following further exploration of these complex and difficult matters at a full hearing Clonmel has not persuaded me that the SPC is invalid."

**66.** And that is s closing the quotation from Hogan J. That has some resonance with the instant appeal where metformin is expressly referenced in Patent 357 in Claim 30 and in the text at paragraph 53. However, it must be emphasised that the test posited by Advocate General Wathelet and whether the test is identificatory or qualitative remains unclear, as found by the Supreme Court, despite the CJEU jurisprudence, and remains to be clarified in the pending preliminary references rulings.

**67.** While I find the foregoing determinative, I will briefly deal with Mylan's argument that this Court should have regard to the reasoning, findings and conclusion of the German FPC in support of the strength of its case for invalidity. The decision there was based on a

qualitative test. There are number of difficulties with this, apart from the obvious point that the decision of that Court is not binding on the Irish Courts, albeit that it is one to which regard can be had.

**68.** Firstly, the German FPC decision is under appeal, which, to my mind, largely, if not entirely, deprives it of any current persuasive effect, even if it is ultimately upheld. The same could be said of the Swedish and Paris Court decisions, which adopted the identificatory test.

**69.** Secondly, while the FPC considered the test of validity under Article 3 to be clear, that is contradicted by the views of the Irish Supreme Court *in MSD v. Clonmel Healthcare Limited*, admittedly in the context of a different product, INEGY, but nevertheless in the context of a combination of drugs and active ingredients, and the Finnish Market Court in respect of Janumet in the case of *MSD v. Glenmark*, resulting in the two preliminary references to the CJEU.

**70.** Thirdly, the German Appellate Court will, just as the Irish Courts will, be guided by the ruling of the CJEU which could conceivably result in the FPC decision being overturned.

**71.** Fourthly, the FPC decision, while undoubtedly that of a specialist patent court, cannot be said to reflect an emerging trend across the EU. In particular, there are a number of courts that have taken the view that interlocutory orders should be granted to restrain the launch of Janumet generic products, or nullity proceedings have been suspended; for example, the Finnish Market Court which has granted interlocutory injunctions against a number of parties who might wish to launch generic products; the Paris First Instance Court which rejected Mylan's arguments based on the SPC Regulation and that Patent 357 was invalid; Hungary, where suspension of invalidity proceedings pending the CJEU ruling has been granted; Slovakia, where nullity actions have been suspended pending the CJEU ruling; and,

Sweden, where in Krka's nullity action, the Court refused the request to invalidate the SPC and held it to be valid.

**72.** As with the FPC decision, many of the decisions, including those that have gone against MSD, are under appeal, also many of them arc interlocutory only. I agree with the trial judge that Mylan did not establish that there are successive determinations in the sense meant by O'Donnell J. that could safely be regarding as establishing a trend, suggesting that it has a strong case and indeed counsel for Mylan did not try to make such a case before us today.

**73.** Fifthly, this Court is invited to look with granular detail at the assessment and analysis of the claims and descriptions in Patent 357 undertaken by the FPC. This raises an issue as to precisely what evidence was before the FPC and how that compares to the evidence that is presently before this Court at an interlocutory stage. Although Prof. Heller swore an affidavit, he did not look at Patent 357 and it was left to counsel for Mylan to suggest how the patent should be interpreted. Counsel for MSD, with some force, argue that had there was a gap in the evidence and in particular no evidence from a skilled person at the priority date as to how they would have read the patent.

**74.** More particularly, Mylan asked the Court to undertake at an interlocutory stage the sort of detailed analysis of the wording in the content of the patent that would normally be reserved to a full trial. In my view, the sort of assessment of the relative strengths of the parties that is appropriate to a wider assessment of where the balance of justice lies is one that should be relatively limited and should not cause the Court to engage with competing interpretations of a patent or expert views as to its true inventive reach where there may fairly be said to be arguments on both sides, and/or where the issues may be said to be complex. The Court should not embark on a mini-trial at the interlocutory stage. Where it

can reasonably be concluded that there is scope for differing interpretations of the patent, or the matter is complex and not capable of being fairly decided at an interlocutory hearing, the Court should fall back on the presumption of validity and the weight to be afforded the same per O'Donnell J. in *MSD v. Clonmel Healthcare Limited*, and leave to the trial of the action the issue of which interpretation should prevail. I find support for this approach in paragraph 62 of his judgment.

**75.** I am quite satisfied, that if, as contended for by MSD, an identificatory test is adopted, the claims and descriptions in Patent 357 are complex and its proper interpretation is not straightforward. MSD relies on Claims 20 and 25 and I think it is fair to say in particular the claim at 30, but it also relies on the earlier text in the patent that refers expressly to metformin.

**76.** On the other side, Mylan rely on the arguments apparent from the reasoning in the FPC, particularly at paragraph 1.3 where it addressed precisely the same claims and text and reached the conclusion that the sitagliptin and metformin combination could not be regarded as an independent invention.

**77.** This demonstrates the importance highlighted by the trial judge of establishing the principles that should be deployed in addressing Article 3(a) and (c). In my view, he was correct and because of the uncertainty of the core principles when applying Article 3, this is not one of those cases where the Court can or should attempt to express even a tentative view as to the strength or otherwise of Mylan's case or MSD's response. Had it not been for the pending references then it might have been possible to form a tentative view of the strength or otherwise of the argument on each side. However, I am not convinced that even if there was no pending reference that this is an occasion where the Court could have usefully embarked on that enquiry or that it could have worked in Mylan's favour.

**78.** In the circumstances, the trial judge correctly concluded that MSD was entitled to rely on the presumption of validity. This is sufficient to resolve this appeal because, in my view, the trial judge cannot be faulted for not making any finding as to the strength, other otherwise of Mylan's case and for the same reasons, this Court should not embark on the same exercise.

The trial judge was entitled to find as he did, that the balance of justice tilted in favour of MSD because of the presumption of validity, and the failure of Mylan to take steps to clear the path, the factors set out in *MSD v. Clomnel Healthcare Limited* at paragraph 61 by O'Donnell J. As no other ground of appeal has been pursued, I would dismiss this appeal,

*Costello and Faherty JJ have indicated that they agree with this judgment.*