

THE HIGH COURT

2014 No. 2 PAP

IN THE MATTER OF IRISH PATENT NUMBER EP (IE) 1379220 FILED ON THE 27TH DAY OF MAY 2002 AND REGISTERED IN THE NAME OF BOEHRINGER INGELHEIM PHARMA GMBH & CO KG IN RESPECT OF AN ALLEGED INVENTION FOR 'INHALATION CAPSULES'

AND

IN THE MATTER OF THE PATENTS ACT 1992

AND THE PATENTS (AMENDMENT) ACT 2006

JUDGMENT of Mr Justice Max Barrett delivered on 10th April, 2018

I

Introduction

1. This application follows on the judgment of the court in the above-titled proceedings delivered on 26th July last ('the principal judgment'). In that judgment the court explained why it would not accede to the application made by Norton (Waterford) Ltd t/a Teva Pharmaceuticals Ireland ('Teva'), which is also the applicant in the within application, to revoke the Irish designation of European Patent No (IE) 1379220 entitled 'Inhalation Capsules' which patent is owned by Boehringer Ingelheim Pharma GmbH & Co KG ('Boehringer'), the respondent to the within application. As the court mentioned in the opening paragraph of its principal judgment, application had also been made by Boehringer to amend its patent claims. However, the court had been asked in the first instance to address the revocation application on the basis of the proposed amended claims, with the application for amendment to be prosecuted at some future stage. In advance of that latter application coming on for hearing, Teva, in an abundance of caution, seeks an order pursuant to O.28, r.1 and/or O.63A, r.5 and/or O.94, r.16 of the Rules of the Superior Courts 1986, as amended ('RSC'), and/or the inherent jurisdiction of the court, granting Teva leave to amend the statement of opposition in the within proceedings and certain ancillary reliefs. (For the reasons identified hereafter, such an application is not in fact required). The detail of the proposed amended text is set out in the appendix hereto.

II

Certain General Observations

2. It may assist for the court to commence with a number of general observations concerning the nature of the within application and the relationship of the claims amendment application to the revocation application that was the subject of the principal judgment:

(1) *Distinct Application*. The claims amendment application sits separately from the invalidity claim. Whether it is provoked by the invalidity proceedings or not is irrelevant.

(2) *Burden*. The putative invalidities contended for in the revocation application do not define or limit the extent of the obligation on Boehringer as the applicant in the claims amendment application.

(3) *Issues*. The specific issues that Teva has raised and seeks to raise regarding lack of support and added matter concern issues that would in any event have to be considered by the court in the claims amendment application.

(4) *Findings*. Neither as a matter of general principle or patent law does a finding in an inter partes revocation application restrict the court in an associated patent claim application.

(5) *Pleadings*. Where, as here, there is an obligation on Boehringer to satisfy the court that the proposed amendments to the patent are appropriate and lawful, there is no place or provision for pleadings. (And, if one sits back for a moment, how could matters be otherwise? The obligation placed on Boehringer is not defined by a pleaded case but by its statutory obligation to satisfy the court that amendments are proper.) This is an aspect of matters that is considered in more detail hereafter.

III

Certain of the Affidavit Evidence

3. As mentioned, the detail of the proposed amendment to the statement of opposition is set out in the appendix hereto. In essence, the amendment involves (i) the bringing of a challenge on the grounds of lack of support in respect of the proposed amended Claim 6 and the claims dependent thereon, and (ii) a fresh added matter challenge in respect of the same claims. The proposed amendment is grounded on two pieces of evidence: (a) an expert report of Professor Buckton (whose evidence features prominently in the principal judgment); and (b) an expert report of an expert not previously encountered in the proceedings, being Dr Kelly, a European patent attorney and registered Irish patent agent.

4. As regards (a), the court's especial attention has been drawn to paras. 4.1-3 of same, in which Professor Buckton observes, *inter alia*, as follows:

"4.1 In my first Irish expert report I made reference to two letters from the UK IPO which are set out at Appendix 2 to my report.

4.2 In the letter dated 17 June 2015, the Comptroller states that 'there is not sufficient reference, explicit or implicit, to the special advantage obtained when hydroxypropylmethylcellulose that has a reduced moisture content as a TEWS or halogen drier moisture content of ≤5% is used as a capsule material as claimed in the proposed new claim 5'. New claim

5 in the UK is the equivalent of the proposed Amended Claim 6 in Ireland. The Comptroller notes that the specification states the moisture content for HPMC capsules is 'preferably less than 8%, particularly preferably less than 5%...most preferably...less than 4%, particularly preferably less than 2% before being filled with the inhalable powder...'. The Comptroller sees no support for why '5% which appears to be intermediate between the ranges discussed in the application as filed should be included into independent claim 5 [claim 6 in Ireland] as characterizing a feature of the invention'.

4.3 I understand the Comptroller to be questioning what the merit is in having a moisture content of less than or equal to 5% in the Irish Amended Claim 6..."

5. The above-quoted text touches on the 'lack of support' argument that Teva now wishes to introduce into the pleadings. It was an argument that was always present in the evidence of Professor Buckton and, as he mentions at para. 4.1, he made reference to the two letters from the United Kingdom's Intellectual Property Office in his original witness statement. There was no application made at the hearing of the invalidity application to strike out the just-referenced portion of Professor Buckton's witness statement; it is evidence that he was free to give and intended to give on one of the two fresh issues that Teva want to introduce into the statement of opposition (and also, frankly, issues that would engage the court even if there were no statement of opposition, amended or otherwise).

6. As regards (b), Dr Kelly identifies the principles to be applied in the context of patent amendments, treats, inter alia, with the amended Claim 6 and concludes that "the subject matter of Amended Claims 6, 7, 7(A), 7(B), 8, 8(A), and 8(B) of the Patent extends the subject matter disclosed in the Application as filed, contrary to the relevant principles applicable under the EPC and the Act."

7. The foregoing is the key evidence sustaining the fresh added matter contention that Teva wishes to lead in the context of Boehringer's amendment application.

IV

No Leave to Amend Required

(i) Section 38 and Order 94.

8. There is no rule that requires or lays down a mechanism for the amendment of a document setting forth the basis for an objection to the amendment of a patent.

9. Section 38 of the Patents Act 1992, as amended, provides as follows:

"(1) Subject to the following provisions of this section, the Controller may, on an application made in the prescribed manner by the proprietor of a patent, allow the specification of the patent to be amended, subject to such terms as to advertising the proposed amendment and such other conditions, if any, as he thinks fit; provided that no such amendment shall be allowed where there are pending before the Court or the Controller proceedings in which the validity of the patent has been or may be put in issue.

[Court Note: in the claims amendment application the court is effectively sitting in the place of the Controller, discharging the obligation that otherwise the Controller would have, and with all of the responsibilities that the Controller has for the adjudication on the appropriateness of allowing any amendments.]

(2) In any proceedings before the Court or the Controller in which the validity of a patent is put in issue, the Court or, as may be appropriate, the Controller may, subject to the following provisions of this section, allow the proprietor of the patent to amend the specification of the patent in such manner, and subject to such terms as to advertising the proposed amendment and as to costs, expenses or otherwise, as the Court or the Controller thinks fit.

(3) An amendment of a specification under this section shall be invalid to the extent that it extends the subject matter disclosed in the application as filed or the protection conferred by the patent.

[Court Note: This is the issue raised by Dr. Kelly in his witness statement, viz. that there is an extension of scope. So the very thing that the court is directed to address even in the absence of opposition is what Teva wants to bring to the court's attention.]

(4) An amendment of a specification under this section shall have effect and be deemed always to have had effect from the date of the grant of the patent.

(5) Where an application for leave to amend a specification has been advertised in accordance with subsection (1) or (2), any person may give within the prescribed period notice to the Court or the Controller, as may be appropriate, of his opposition to an amendment proposed by the proprietor of the patent, and if he does so shall notify the proprietor and the Court or the Controller shall consider the opposition in deciding whether the amendment, or any other amendment, should be allowed.

[Court Note: This is the provision that gives Teva its *locus standi* to speak and be heard in the claims amendment application.]

(6) Where an application for an order under this section is made to the Court, the applicant shall notify the Controller who shall be entitled to appear and be heard on the hearing of the application and shall so appear if so directed by the Court.

[Court Note: The court is not aware of a case in which the power of direction under sub-section (6) has been invoked. However, it may yet be, given that the patent in the within proceedings as proven to be so contentious, that this case might yet see the issuance of such a direction. Indeed, given the concerns that the Controller in the United Kingdom has manifested, it might, perhaps not unreasonably, be contended that the issuance of such a direction would be especially appropriate. However, before so proceeding (if it so proceeds) it will be appropriate and necessary for the court to hear further argument from the parties in this regard.]

(7) In considering whether or not to allow an amendment proposed under this section the Court or the Controller shall have regard to any relevant principles applicable under the European Patent Convention."

[Court Note: The court returns to the implications of sub-section in its consideration, later below, of the decision of the High Court of England and Wales in *Zipher Ltd v. Markem Systems Ltd* [2008] EWHC 1379 (Pat).]

10. Reference was made at hearing to Order 94 RSC, Part II ("*Actions for infringement of patent*"). Those provisions are an irrelevance in the context of a claims amendment application. The provisions of relevance appear in Part III ("*Amendment of specification*"), viz:

"15. An application by a patentee under section 32...for leave to amend his specification by way of disclaimer, correction or explanation shall be made by motion in the action or proceedings pending before the Court...."

16. On the hearing of such motion the Court shall decide whether and on what terms as to costs or otherwise the application shall be allowed to proceed..."

11. A couple of points can be made regarding O.94. First, the Rules prescribe that an application for an amendment of a patent be brought by motion in the action or proceedings pending before the court; that is what happened here, with the claims amendment motions being brought within the penumbra of the revocation proceedings. Second, O.94 does not require or even contemplate the delivery of pleadings in respect of a claims amendment application. What is contemplated is that a motion is brought, grounded on affidavit, and affidavits are then put in by reply. And if one sits back for a moment, one can see why this must be so: the obligation is on the patentee in a claims amendment application to satisfy the court of all matters in respect of the amendment and its appropriateness; that enquiry by the court (or indeed the contribution of a third party) could not be limited by a pleading point. Indeed, it would seem directly contrary to the public interest that it would be so limited in a situation where what is ultimately at play is the temporary monopoly rights that a patent confers.

(ii) *Zipher*.

12. *Zipher* was a case in which HHJ Fysh QC, sitting as a deputy High Court judge, was given an undertaking by Zipher as to what it would do with wider claims if it was successful in establishing its claim to be entitled to them. In fact, they failed at first instance, then succeeded on appeal and applied to amend a UK patent ('602'). At this point, Markem Corporation (which had been engaged in a sequence of associated disputes with Zipher) contended that the application to amend should not be entertained as it was not in conformity with the undertaking given to HHJ Fysh QC. So they opposed the amendments on statutory grounds and, in the just-described circumstances, maintained that the court should not exercise its discretion to allow the amendments, even if they were otherwise allowable. This latter point raised the question for the High Court of whether, under English patent law as it then stood, the court had any discretion to refuse to allow amendments which would not offend against the grounds of objection arising under statute (and, if so, on what principles such discretion fell to be exercised). In this regard, Floyd J., as he then was, observed as follows, at paras. 205-210:

"205 Section 75, as it now stands, requires the court to 'have regard to any relevant principles applicable under the European Patent Convention'. Accordingly, one should turn to the Convention to see what principles are applied to considering whether or not to allow amendments."

[Court Note: As can be seen, s.75 is materially identical to s.38(7) of the Act of 1992, as amended.]

206 There is very little by way of express guidance in the European Patent Convention. Amendments may be made both in the course of prosecuting the application and in the course of opposition proceedings. Article 123 in its original form provided:

'(1) The conditions under which a European patent application or a European patent may be amended by proceedings before the European Patent Office are laid down in the Implementing Regulations. In any case, an applicant shall be allowed at least one opportunity of amending the description, claims and drawings of his own volition.'

207 So there was one mandatory opportunity, followed by amendment under the conditions specified in the Rules. The first sentence has been amended to read:

'(2) A European patent application or European patent may be amended in proceedings before the European Patent Office in accordance with the Implementing Regulations.'

208 Rules 86(2) and (3) give effect to the right to amend once in the course of prosecution as follows:

'(2) After receiving the European search report and before receipt of the first communication from the Examining Division, the applicant may, of his own volition, amend the description, claims and drawings,

(3) After receipt of the first communication from the Examining Division the applicant may, of his own volition, amend once the description, claims and drawings provided that the amendment is filed at the same time as the reply to the communication. No further amendment may be made without the consent of the Examining Division.'

209 Article 102(3) of the Convention refers in passing to 'amendments made by the proprietor in the course of the opposition proceedings'. The relevant rules are rr.57 and 57A:

'57(1) The Opposition Division shall communicate the opposition to the proprietor of the patent and shall invite him to file his observations and to file amendments, where appropriate, to the description, claims and drawings within a period to be fixed by the Opposition Division.'

57A Without prejudice to Rule 87, the description, claims and drawings may be amended, provided that the amendments are occasioned by grounds for opposition specified in Article 100, even if the respective ground has

not been invoked by the opponent.'

210 It will be seen that r.57A restricts the discretion to amend to those amendments which are occasioned by grounds for opposition (including un-pleaded ones). Until the introduction of that rule, the EPO only permitted amendments under Arts 102(3) and 123 which were responsive to a validity attack actually raised by an opponent."

13. Admittedly, Floyd J. was not concerned with the question of the amendment of pleadings. Nonetheless what is clear from his judgment, especially paragraphs 209-210 of same, is that it is open to a party to seek to amend a patent or patent application if it is desirous of seeing off issues that it perceives could be a ground of opposition. That approach is consistent with the position that Teva takes in the within proceedings, which is that for the purpose of Boehringer's claims amendment application it has to meet every potential obstacle to amendment, whether opposed or not. Pleading, as counsel for Teva succinctly put it at hearing, 'is not the name of the game'. Boehringer is obliged to deal with all objections that are identified and put before the court and is not entitled to navigate around them by means of the approach that has led to the within application being brought by Teva in an abundance of caution.

V

Liberal Régime as Regards Amendment of Pleadings

(i) Introduction.

14. What if the court's analysis in Part IV of its judgment is wrong? The court does not consider that it is wrong; but if it is, Teva would in any event fall to succeed in the within application, thanks to the general, liberal regime that applies under Irish law as regards the amendment of pleadings. In dealing with this aspect of matters, it is useful, firstly, to consider a number of historical exchanges that have occurred between the parties and/or before this Court:

(ii) The Letter of 8th September, 2015.

15. In a letter of 8th September, 2015, from Boehringer's solicitors to Teva's solicitors, Boehringer's solicitors refer to an indication given to court on 20th July 2015 that alternative amendments to the 220 Patent might be proposed and then identify what is to be proposed. Then, over the page, Boehringer's solicitors state as follows:

"For the avoidance of any doubt, our client fully reserves the right to seek any further or alternative amendments to the 220 Patent as it deems necessary or appropriate in accordance with applicable law. However, in this regard our client confirms (as it has done before) that it would not seek to defend the 220 Patent as granted and that any amended claim set would only relate to gelatin or the HPMC capsules."

16. What is notable about this correspondence is that the patentee delivers no pleading in respect of the amendment of the patent. This in itself is unsurprising because that is how the system works. What is surprising is that in the within application, Boehringer, not without a certain audacity, has seen fit to take a pleading point against Teva in relation to Teva's amendment of its position.

17. Notable too about the letter is that Boehringer reserves its right to seek such further amendments as it considers appropriate on a rolling basis, yet seeks not to resist Teva's ability to seek a limited amendment at a given point in time based on evidence that Teva has produced.

(iii) Outline Legal Submissions (Revocation Application).

18. In its written outline legal submissions as part of the patent revocation application, Teva indicated as follows, under the heading "Amendment to the Patent":

"3.116 As mentioned in the introduction, Boehringer has made an unconditional application to amend the Patent. None of the proposed amendments result in the claims being validated. The Petitioner has addressed the impermissible nature of these amendments in its Statement of Opposition dated 23 April 2015 and as amended on 12 October 2015."

3.117 The UK Intellectual Property Office has also objected to all of the amendments in respect of the UK Patent, as set out in its letters of 17 June 2015 and 4 August 2015. These letters were exhibited to the Affidavit of Lucy O'Reilly sworn on 12 October 2015 in response to Boehringer's application to amend the Patent and the grounds of rejection are relied on in this jurisdiction. These letters are also referred to in the expert report of Graham Buckton in these proceedings."

19. So one of the issues that Teva now seeks to make, the 'lack of support' argument, was already before the court, without objection, in the original hearing, albeit the subject of notably truncated submissions, given that the focus of the argument at that time was the argument on the petition as to validity.

(iv) Revocation Hearing.

a. 7th February, 2017.

20. On Day 3 of the hearing of the revocation application, i.e. 7th February, 2017, counsel for Teva made the following observation:

"As I mentioned in opening...there is a question of an application, two motions in fact, to amend the patent in different ways, and there is some relevant evidence to be given by Professor Buckton about that, and I think it's anticipated that some evidence will be given by Professor Birchall, who is the formulator on the patentee side, about that same issue. Our submission to the court is that since the question of the amendment only arises in the event I fail in the challenge to the patent, if I win on the challenge to the patent then the amendment is pointless and won't be proceeded with, that in fact the court wouldn't require, at this stage, me to give my evidence from Professor Buckton or indeed hear evidence from Professor Birchall about the amendment issue and not hear any legal argument about the amendment issue, that the court would deal firstly with the validity of the patent. It would seem to be the most streamlined way of dealing with it. So, subject to the court, that is the way I intend to proceed."

21. There followed some to-ing and fro-ing between counsel, which ended with counsel for Teva responding to a query from the court

in the following terms:

"I am suggesting this: that in terms of the sequencing, I am putting up all my evidence in relation to validity first. That is the way it should be. [Counsel for Boehringer]...is going to call evidence on that. He is also going to call Professor Birchall on the issue of the amendment of the claim, and I would like to be able to call Professor Buckton then in response to what is said about that. I understood the court to have ruled that it would go that way..."

22. The court then indicated that *"that is the way we should proceed"*. So from an early point in the hearing there was an effective fragmenting of the revocation claim from the claims amendment application. Following on the court's ruling, Boehringer's solicitors, in a letter of 13th February, 2017, wrote in the following terms to their counterparts:

"As you know, in light of your application for the sequence of evidence in relation to the issue of the permissibility of the application to amend under section 38...our current cross examination of Professor Buckton extends only to the issue of alleged invalidity....We shall then call Professor Birchall to give his evidence in reply to the issue of alleged invalidity and he can then be cross examined by your counsel on that issue.

We shall then conduct direct examination of Professor Birchall on the issue of the permissibility of the application to amend under section 38, after which he can be cross examined on that issue by your counsel."

23. Teva disagreed with the substance of this letter at the time. However, the letter is of interest because it shows the understanding of Boehringer's solicitors as to how matters lay. Having opposed the approach that eventually recommended itself to the court on 13th February, they were now making it fairly clear that there were now to be two slices of evidence, one in relation solely to the question of validity, the other in relation to the question of the amendment of the patent, with Professor Birchall going first (because he was Boehringer's witness and the onus was on them). Boehringer's solicitors then continue as follows:

"For the avoidance of any doubt Professor Buckton should not be questioned by your counsel or give any evidence on any matter relating to alleged invalidity at this stage as direct evidence on that is now complete and his cross examination on it is ongoing. We suggest that the examination of the amendment issue would take approximately a half to one day."

24. What does all of the foregoing show? That on foot of the court's ruling on 7th February, 2017, there was going to be a sequenced hearing of evidence on the two separate legal issues before the court: validity and amendment.

b. 10th February, 2017.

25. On 10th February, 2017, the court queried, following on an indication in the interim from counsel for Boehringer that the issue of amendment was effectively to be 'parked', whether the court in its judgment was to deal with the amendment claim at all, at which point the following exchange occurred between court and counsel (for Boehringer):

"COUNSEL – No, that is – you are assuming that the claims as amended are the claims that you have to construe.

JUDGE – Okay.

COUNSEL – If you make a decision on the basis that the claims as amended are not obvious...I have to bring an application in relation to amendment, and my friends have reserved their position in relation to that. There is no dispute between us on that. I am not for a moment suggesting my friends are shut out. That issue [i.e. the claims amendment application] obviously will then have to be addressed.

JUDGE – Very good. Thank you."

26. The understanding as expressed by Boehringer's counsel represented the common understanding between the parties.

(v) Recasting

27. Ms Scott, a solicitor for Boehringer, has sworn a number of affidavits in the context of the within application. In an affidavit of 16th March, 2018, she avers, inter alia, as follows:

"Mr. Kelly implies that Boehringer is resiling from its recognition of the directions of the court splitting the hearing of the added matter objection, generally identified as the ground relating to the amendment of the claims from the hearing of the remaining issues have now been heard and determined by the court. Mr. Kelly quotes again the assurance given on behalf of Boehringer subsequent to and in light of the court's directions to the separate hearing of the added matter challenge that Teva would not be 'shut out' from making its case in that regard. Boehringer stands by that assurance."

28. So far, so good. However, Ms Scott next avers as follows:

"Respectfully, however, it was an assurance that Teva should not be shut out making the remainder of its pleaded case. It was not nor could it reasonably be understood as being an acceptance by Boehringer that Teva could rethink its case and bring new challenges in addition to the outstanding pleaded added matter challenge in the second module of the case. My first affidavit deals with how the added challenges are indeed new challenges and in my respectful belief objectionable ones and not merely the expansion of existing challenges implied by Mr. Kelly. These matters will be dealt with in legal submission."

29. In other words, what Ms Scott contends, in an affidavit sworn a year after the above-quoted exchanges in court is that what had been intended (though not understood by Teva or indeed the court) was that Teva should not be 'shut out' of making the case that it had pleaded to 10th February, 2017, but that it should be and was entirely 'shut out' from varying in any way its opposition to the claims amendment application.

30. Ms Scott continues:

"Second, contrary to Mr. Kelly's averment, it is a fact that the implications that such a divided hearing would have for the evidence to be given in either module of the trial was not analysed or identified to the court at that stage. I do not make a criticism, I simply state the fact. As I averred in my first response, as matters transpired, it appeared to Boehringer that all necessary evidence of the outstanding issue of added matter had in fact been given in oral evidence

in the first module of the case. That was why as a practical matter my firm wrote to Mr. Kelly's firm to ask whether there was as a matter of fact anything that remained to be said by way of evidence and before the court was in a position to receive argument and determine the matter. There was no intention ever to 'shut Teva out' from giving evidence on their pleaded objection. The question posed was merely whether any now needed to be given."

31. With respect, this analysis does not stand up when viewed against the historical facts of what occurred: the court was told, and directed, that all evidence concerning the claims amendment application was to be dealt with separately. But what is now contended, in effect, is that through some mischance that no-one noticed during the course of the revocation hearing, all of the evidence concerning the claims amendment application was given. That contention is not accepted by the court as correct.

(vi) Letter of 23rd October, 2017.

32. Albeit slightly 'out of sync' with the chronology of events thus far, it is instructive to return to certain of the correspondence between the parties from late last year. A letter of 23rd October, 2017, from Boehringer's solicitors to Teva's solicitors states, *inter alia*, as follows:

"In its amended Statement of Opposition dated 12th October 2016...to our client's motion to amend, your client contested the validity of proposed amended Claims 6 to 13 on the same grounds set out in its Particulars of Objection in these proceedings. These validity issues have now been decided upon by the court in our client's favour by its judgment....Accordingly, the only issue remaining is your objection in respect of our client's amended claims under section 38. In that regard your client did not plead in the Statement of Opposition any objection under section 38 to the proposed amended claims."

33. In other words, what Boehringer's solicitors contend in effect is that the amended claims should now go through on foot of the court's judgment on invalidity. Boehringer's solicitors, having recounted certain of the evidence and findings of the court, then state *"In these circumstances having referred to Prof. Buckton's evidence can you please let us know what obstacle, if any, you maintain stands in the way to our client's application to amend Claims 7 and 8 as proposed."* It seems to the court, with respect, that the entire manner in which this letter is constructed rather ignores the obligation that sits with Boehringer, pursuant to the Act of 1992, to satisfy the court, in the course of Boehringer's claims amendment application, that there are no potential issues presenting in relating to the desired claim amendments.

(vii) Letter of 3rd November, 2017.

34. In their reply to the letter of 23rd October, Teva's solicitors, in a letter dated, 3rd November, 2017, refer to the exchange between the court and Boehringer's counsel on 10th February, 2017 (considered above). Teva's solicitors further noted that *"[e]arlier on in the hearing, [Boehringer's counsel] stated to the Court that the parties were standing over the amendment issue pending determination of the validity issue first"*. Notably, it is not suggested that the referenced submissions were taken out of context or that the mention of not being 'shut out' referred only to the pleaded case.

(viii) Letter of 21st November, 2017.

35. In their reply to the letter of 3rd November, Boehringer's solicitors state, *inter alia*, that *"It seems to us that the only objection expressed in that Amended Statement of Opposition in relation to added matter, namely that consisting in the sequence of drying of the capsules (and which applies only to proposed amended Claims 7 and 8), has been dealt with, both in evidence and by the Court."* In other words, what was being contended by Boehringer's solicitors was that the arrangement put in place by the court and agreed by the parties did not 'hold water' and that all of the relevant evidence on the amendment issue had been determined. Boehringer's solicitors continue: *"Clearly the application must be heard and determined by the court"* – to what substantive end, the court wonders, if all has been decided – *"Your letter confuses that step with a question we were asking which is what, if anything, remains the ground of opposition your client expressed in its Amended Statement of Opposition."* With respect, the claims amendment application does have to be heard and determined and it cannot be an application that the court (or indeed Teva) is 'bounced out of' by reference either to what Boehringer's solicitors claim was the import of the earlier evidence/decision (which it was agreed did not go to amendment at all) or, alternately, on the basis of the pleading point now raised.

(ix) Letter of 8th January, 2018.

36. If there is any letter in the correspondence between the parties that captures the truth of matters as they now pertain between them, it is a letter of 8th January last sent by Teva's solicitors to Boehringer's solicitors, and which captures as well as any words that the court might deploy how matters stand, stating, *inter alia*:

"We do not agree with the position set out in your letter and more particularly that our client is somehow shut out from raising a valid objection to your client's amendment application. There are a number of reasons for this.

First...[a]s you are aware, this application to amend the patent is your client's application. Despite this, our client is outlining its evidence first. This is a somewhat unusual approach....Our client has agreed to this approach so that it may set out precisely what is at issue. As indicated in our previous letter, the further objections were identified when marshalling the evidence in respect of the amendment application, after the [court's] directions were made, and we wrote to you as soon as the position crystallised. We do not accept that the changes are substantial in circumstances where added matter has always been a complaint in respect of your client's amended claims.

Second, there is simply no prejudice to your client in circumstances where it will be given an opportunity to respond to any evidence put forward. There is no requirement for your client to amend its pleadings and submissions are yet to be filed in relation to the application. Furthermore, no hearing has been fixed for the hearing of the application and it is open to your client to request further time to deal with its evidence, if required. The attempt to limit the objections is nothing more than a tactical manoeuvre that has no basis in the well-established jurisprudence regarding the amendment of pleadings.

Third, the amendment of the patent is a matter affecting the world at large rather than a conventional inter partes dispute. As a matter of public policy the Court is entitled to expect that all relevant issues would be canvassed before it in the determination of the appropriateness of any amended claims as sought by your client....

Finally, your client's objection to our client amending its objection to your client's amendment application (which is the second such application in these proceedings) rings somewhat hollow in circumstances where your client is at pains to point out in your letter of 23 October 2017 that your client reserves its right to seek to put forward further and/or alternative amendments to the claims at any time even after the Court may decide that the current amended claims

are inappropriate. There is no valid basis for your client to continue to assert that it can keep amending the claims to the patent at any time as it sees fit and yet seek to stop our client from raising a valid objection based on timing."

(x) Some Applicable Law.

a. *Kennedy v. Law Society of Ireland*

(Unreported, Kearns J., 14th February, 2003).

37. During the course of judicial review proceedings, after Kearns J. had made a determination on part of a case, application was made for a prolix set of amendments to Mr. Kennedy's pleadings. Objection was taken by the Law Society to these proposed amendments on the basis that: there had been a part-hearing of the action and Mr Kennedy was therefore precluded from amending the pleadings; Kearns J., as trial judge, had found facts that would prevent the applicant from amending the points of claim; the amendment/s introduced new causes of action which were statute-barred; and the applicant had sufficient knowledge to bring the actions at an earlier date. In the course of his judgment on the issue presenting, Kearns J. referred, *inter alia*, to *Doyle v. C&D Providers (Wexford) Ltd* [1994] 3 IR 57, which appeared to be the only case to that time in which an application to make amendments of substance was made after a judicial determination of the facts. (Oddly, the application in that case was to amend pleadings in the Circuit Court just before appeal to the High Court). In dismissing the appeal in *Doyle* and refusing the application to amend the endorsement of claim, O'Hanlon J. stated, *inter alia*, as follows, at 60:

"[T]he only basis upon which the plaintiff sought amendment of the civil bill at the very late stage when an appeal to the High Court was about to commence, was in reliance on evidence given on behalf of the defendant in the Circuit Court (which was by no means conclusive in deciding the issue in favour of the plaintiff)...[S]uch evidence could have been obtained at a much earlier stage by delivery of interrogatories, having regard to the plaintiff's anxiety to introduce the plea of fraud into his proceedings. In these circumstances, I concluded that the amendment sought should not be allowed, when the proceedings had been allowed to continue to a conclusion before the learned Circuit Court judge, and his decision on the claim had been given."

38. Notably, Kearns J. appears to have made his decision in large measure on the basis of lateness, i.e. that Mr Kennedy should have known about matters sooner, which is not now representative of the law as to whether and when to allow an amendment of pleadings (though, even had the point not been overtaken by later jurisprudence (and it has), it would not in any event be germane as it is not, unsurprisingly given the current lie of case-law, the basis of Boehringer's opposition to Teva's amendment to the statement of opposition). Of interest, in any event, are the following observations of Kearns J., at 15 *et seq*:

"[W]hen a case is heard in modules or consecutive parts, the findings produced at the conclusion of one part of the hearing cannot...without grave risk of injustice and uncertainty, be utilized and relied upon to seek amendments to pleadings for the next part. Amendment seeking on an incremental basis at each stage in the process would make the litigation process unworkable. Neither plaintiff nor defendants would ever know or be certain of the case he had to meet. Putting it simply, it seems to me basic that the findings of the court should not be a platform for further claims in the same proceedings. This is quite a different situation from one where new and previously undiscoverable information comes to light either prior to or during the course of a single gearing which may, event at a late stage, compel the court to exercise its discretion."

39. It is important to note that the objectionable behavior referenced by Kearns J. in the just-quoted text is not behavior of a type that is at play in the within proceedings. Boehringer knows the case it has to make in the claims amendment application: it has to make a case that the amendments are allowable. It has known that from the outset. It is a case that Boehringer must be prepared to meet even if Teva was out of the picture entirely. So the concern that Kearns J. identifies in the *inter partes* proceedings before him just does not arise in the circumstances before this Court.

b. *Croke v. Waterford Crystal Ltd*

[2005] 1 ILRM 321

40. This is a case where a defendant pleaded the Statute of Limitations. The plaintiff wanted to amend his statement of claim to plead fraud and this was opposed the whole way up to the Supreme Court. Of especial interest are the following observations of Geoghegan J. for the Supreme Court, at 331 *et seq*:

"The operation of the rule was considered by...Kinlen J. in Bell v. Pederson [1995] 3 IR 511....In that case an application to amend the pleadings in a substantial and important way was made on the morning of the trial....Kinlen J. allowed the respondents to amend their defence in the manner sought. In his judgment he approved the principles laid down by Keane J. in Krops v Irish Forestry Board Ltd [1995] 2 IR 113 and referred also to the dicta of Lynch J. in Director of Public Prosecutions v. Corbett [1992] ILRM 674 at 678:

'The day is long past when justice could be defeated by mere technicalities which did not materially prejudice the other party. While courts have a discretion as to amendment that discretion must be exercised judicially and where an amendment can be made without prejudice to the other party and thus enable the real issues to be tried the amendment should be made. If there might be prejudice which could be overcome by an adjournment then the amendment should be made and an adjournment also granted to overcome the possible prejudice and if the amendments might put the other party to extra expense that can be regulated by a suitable order as to costs or by the imposition of a condition that the amending party shall indemnify the other party against such expenses.'

Kinlen J. adopted this reasoning as part of the *ratio* of his judgment. It appears also to be an application of principle which is in accordance with justice.

Even if I was not bound to do so, I would have no hesitation in following that judgment. I entirely agree with the approach to the interpretation of the rule which it represents.

[Court Note: The court notes in passing that here no prejudice of any nature presents for Boehringer as regards the

amendment to be made, making this a case where, to borrow the phraseology of Lynch J. the desired amendments should be made in order that the focus of the court is brought to bear on alleged concerns presenting as regards the amended claims.]

...

There are, however, some other pertinent and useful quotations from English cases in the judgment of Flood J. [with which judgment Geoghegan J. does not otherwise agree]. He first cites at p.603 the well-known case of Cropper v Smith (1884) 26 Ch.D. 700 at 710–711 where Bowen L.J. said the following:

'[I]t is a well-established principle that the object of Courts is to decide the rights of the parties, and not to punish them for mistakes they make in the conduct of their cases by deciding otherwise than in accordance with their rights ... I know of no kind of error or mistake, which, if not fraudulent or intended to overreach, the Court ought not to correct, if it can be done without injustice to the other party. Courts do not exist for the sake of discipline, but for the sake of deciding matters in controversy, and I do not regard such amendment as a matter of favour or of grace ... it seems to me that as soon as it appears that the way in which the party has framed his case will not lead to a decision of the real matter in controversy, it is as much a matter of right on his part to have it corrected, if it can be done without injustice, as anything else in the case is a matter of right.'

[Court Note: Perhaps two points arise from the foregoing. First, even if there was some egregious error in how Teva had acted to this point (and there is not), that would not suffice to prevent the court from allowing the amendments Teva seeks, provided the court could (and it can) do so without injustice arising for the other parties; here, again, no prejudice of any sort presents for Boehringer in the amendments being allowed. Second, what is notable about the just-quoted text is that Geoghegan J. refers approvingly to text which goes beyond Lynch J.'s suggestion that an amendment should be allowed if there is no prejudice to Bowen L.J.'s reference to amendment as a matter of right, provided it can be effected without injustice. (And here, again, no prejudice of any nature presents for Boehringer as regards the amendment to be made).]

...

An important High Court decision is Krops...where Keane J...carefully considered the ambit of Ord.28, r.1 and held that the court has a wide jurisdiction to amend pleadings in such manner and on such terms as it considers just in the circumstances. He went on to hold that as a matter of principle, pleadings carry with them from the time they are issued or delivered the potentiality of being amended by the court and that since their issue the proceedings were always capable of amendment by the court in such manner as might be just and in order to allow the real question and controversy between the parties to be determined. The mere fact that if a new cause of action sought to be included in the statement of claim had been brought by separate action it would be statute barred does not prevent the amendment being granted...

[Court Note: Again, perhaps two points arise from the foregoing. First, Geoghegan J. (for the Supreme Court) is of the view that pleadings are always pregnant with the possibility of amendment; that seems doubly so where, as here, Teva (and the court) were and are confronted with the assurance of Boehringer's counsel on 10th February, 2017, as to Teva's not being 'shut out'. Second, the reference to "[t]he mere fact that if a new cause of action sought to be included in the Statement of Claim had been brought by separate action it would be statute barred does not prevent the amendment being granted" is perhaps significant in appearing to contemplate allowing even a prejudicial amendment that defines the real issues (though again, no prejudice of any nature presents for Boehringer as regards the amendment to be made)]."

c. *Cuttle v. ACC Bank plc t/a ACC Bank*

[2012] IEHC 105

41. *Cuttle* was a case in which a customer of ACC Bank brought suit concerning an investment made in a financial product known as the 'Solid World Bond'. Leave of the court was sought to amend a statement of claim. In his judgment, Kelly J., as he then was, refers, at para. 7, to Geoghegan J.'s reference in *Croke*, at 401, to O.28, r.1 of the Rules of the Superior Courts being a "liberal rule", and (ii) at para. 8, to the judgment in *Cornhill v. Minister for Agriculture* [1998] IEHC 47 where O'Sullivan J. indicated that an amendment of pleadings should be allowed if it would have been appropriate in the original pleadings and would have withstood an attack under O.19, r.28 of the Rules. (Indeed, in *Cuttle* – see para. 9 – the parties to the proceedings agreed that the approach of O'Sullivan J. was the approach that Kelly J. ought to adopt). Notably, when that case-law is brought to bear in the context of the within application, it is neither said nor suggested that any of the proposed amendments would have been inappropriate had they featured in the original pleadings. As to the reference to O.19, r.28, that is a reference to not allowing an amendment where the issue sought to be included in the amended pleading must fail. But it is not contended that one is in that territory when it comes to the proposed amendments here.

d. *Dormer v. AIB plc*

[2017] IECA 199

42. In this case, AIB sued two individuals on foot of a summary summons. While the summary summons was pending, there were negotiations and there was a settlement. The settlement involved an assurance that the relevant bank official would go to the bank's Credit Committee to get some form of recommendation about the settlement. Subsequent to that, the bank said the settlement had not been honoured by the Dormers and had judgment entered against them. The Dormers then, on foot of a Freedom of Information Act request, got information which led them to sue the bank, effectively for misrepresentation. They made an application for an interlocutory injunction before McGovern J., which failed. After that, they took a radically different approach to the case and sought to amend the pleadings to make a claim of fraud. This amendment was allowed with Ryan P., for the Court of Appeal, expressing the view that there was no reason why a party could not change track completely if it had run into a poor result in an earlier application in the same case. In his judgment, Ryan P. observes, *inter alia*, as follows:

"41. I think that in order to understand this case we have to go back to the beginning. The bank brought its summary summons proceedings against the Dormers. On 30th January 2014, the hearing of the application for judgment was adjourned to enable the parties to negotiate. They reached agreement, whereby the three bank officials dealing with the case were to apply to the Area Credit Committee of the bank for sanction of the facility in the October 2013, Terms of Offer and the Dormers agreed to take other steps which were dependent on the loan being available. At that point, there was no longer a summary summons application for judgment before the court; the settlement was a contract between the parties which superseded the proceedings. The summons, however, remained in existence but only for the purpose of the settlement and in accordance with its terms.

42. The Dormers' case is in essence a claim for relief for misrepresentation and breach of contract in respect of the settlement agreement of the 30th January 2014. Their case is that the bank officials did not make application to the credit committee in accordance with the terms of the agreement. When the matter came before the High Court on 4th March 2014, the bank's summary proceedings had now been superseded by the settlement. The only matter before the court was the settlement. The Dormers had agreed that if certain specified events had not occurred they would consent to judgment. On this occasion, they were not consenting to judgment but were seeking an adjournment of the proceedings so that they could pursue their investigation or complaint about the bank's compliance with its obligations under the settlement. The court was satisfied that the terms were clear and it was beyond dispute that the specified events had not happened and so in the circumstances the court held that the bank was entitled to judgment.

...

47. The High Court ruled that the Dormers were bound by the clear terms of the settlement as it related to their undertakings. It did not decide whether the bank was in breach of its obligations under the agreement, which is the very case which is made by the appellants in their proceedings. *Res judicata* arises in two modes, namely, cause of action estoppel which prevents the entire case proceeding in the latter action, and issue estoppel which prevents a particular question that has previously been decided from being re-litigated. Neither would apply by reason of that judgment.

...

49. The High Court did not determine any issue between the Dormers and the bank on 4th March 2014. Kelly J. refused an adjournment and proceeded to give judgment for the bank....

...

51. The Dormers' proceedings came before the High Court in February 2015 on their application for an interlocutory injunction to continue until trial the order that they had previously obtained to restrain execution of the judgment. The general rule that was applied by McGovern J. in his judgment on the interlocutory application is that it is not possible to revisit and reopen a decision of the High Court for the purpose of setting it aside, unless there is an allegation of fraud. What this means is that the judgment is final for all practical purposes and in almost all circumstances. Specifically, a party cannot go back to court because new evidence has come to light that would or might affect the original decision. There has to be finality to litigation. Even if apparently compelling new evidence emerges, that is not a basis for applying to the court for reconsideration of the decision. If such a situation arises, a party may apply to an appellate court for liberty to adduce additional evidence for consideration on the appeal, subject to the jurisprudence as to when that facility might be extended. The position is different if a party alleges that the judgment in the court below was obtained by reason of fraud. It is not a question whether the proceedings before the court include a claim for fraud because that does not make the action different. However, when a party asserts that the court was misled into giving judgment by dishonest behaviour, then that is obviously a different matter. A person making such a claim can go back to the court of trial.

52. When the Dormers issued their proceedings, they did not include a claim for fraud and the case was as stated above. I do not consider that the rule concerning the setting aside of a judgment, restricting it to the circumstance where fraud in obtaining the judgment is the claim applies in this case. The Dormers are not claiming that the bank misled the High Court into giving judgment; their case is, rather, that the bank did not comply with the agreement of settlement of the summary summons proceedings and, as a result, the bank was not entitled to obtain the judgment that was granted by Kelly J. In my judgment, if it is a term of a settlement that one party will consent to judgment on the happening or non-happening of events and judgment is duly given on a basis of fact, it is open to an aggrieved party to complain that the other engaged in conduct amounting to misrepresentation or breach of contract which vitiated that party's contractual entitlement to the judgment under the terms of the settlement agreement. Obviously, that will be a very unusual set of circumstances. But I do not understand how the aggrieved party is deprived of the entitlement to claim to have the judgment set aside unless fraud is pleaded. It would not be a satisfactory outcome for the innocent party to succeed in separate proceedings in which he claimed compensation or other orders but left the original judgment standing. That is not the rule in law, as I understand the position. I would not propose a new general rule but would rather merely declare that in the circumstances as they obtain in this case the Dormers were not shut out of the remedy they sought, namely, vacation of the High Court order. The fact that the Dormers did not allege fraud in the pleadings or did not make the case that the judgment was actually obtained by fraud does not in itself represent a bar to the relief they claimed in the very unusual and particular circumstances in which the judgment that was given by the court was a term of the contract between the parties. It was not that the court resolved a dispute and gave a judgment; the parties agreed between themselves that on the happening or non-happening of certain events judgment would ensue.

...

54. On the question of *res judicata* in respect of the decision by McGovern J., it is important to keep in mind the decision that the court had actually to make in February 2015. The order was to refuse to continue the injunction. It cannot be the case therefore that the court proceedings on that occasion, considered by reference to the matter that was in issue and the order actually made, could be a bar to the further progress of the claim. *Res judicata* applies in circumstances where the order previously made by the court is binding on the subsequent proceeding. The question then arises whether there was issue estoppel or whether the rule in *Henderson v Henderson* applies. In my view, neither of these principles governs the case.

[Court Note: Leaving aside the issue about the order made at trial and the arrangements the parties subsequently

entered into, the court respectfully does not see how it can be said that any determination of the *inter partes* issue on validity is something that binds the application to amend the patent. Even if that could be said, how could such a position credibly be maintained when one introduces into the equation the fact that the court ruled, and the parties accepted, that the evidence and submissions re. the claims amendment was to be dealt with as a separate hearing on another day? And that, the court notes, is before one gets to the assurance of counsel for Boehringer on 10th February, 2017, that Teva would not be “shut out” from contesting the amendment. If one accepts: (i) the natural meaning of the just-quoted words and does not afford them the artificial meaning that Boehringer now seeks to ascribe to them; and (ii) as the court must, the judgment of Geoghegan J. in *Croke* that every pleading is capable of amendment, then it is patently clear that any argument as to *res judicata* in respect of the principal judgment does not, to use a colloquialism, ‘get off the starting-blocks’.]

...

56. *On an application to strike out proceedings, the court considers not only the case as pleaded but also on the basis of any amendments that might reasonably be anticipated. It is true that the amended claim is different and inconsistent with the submissions made by counsel for the Dormers at the interlocutory injunction hearing. Clearly, they have changed their minds and wish to make this case now. It may well be that they were disappointed that the outcome of the injunction application and the reasoning in the court’s judgment, specifically the reliance on the fact that fraud was not pleaded. Instead of proceeding with their appeal, they may have calculated that a more fruitful approach would simply be to introduce and supply what was missing by pleading fraud. That essentially is what the High Court inferred when saying that the application was attempting to overcome a legal impediment. However that may be, the question remains as to whether these parties are entitled to the amendment they seek. In other words, I am not of the view that because the amendment can legitimately be seen as something of a stratagem it follows that it is to be disallowed. Neither is it fatal in my view that the claim is inconsistent with previous submissions or, should I say, it is not necessarily fatal that it is totally at variance. It is in fact just the opposite of what counsel told the court was the case, which was undoubtedly a correct observation having regard to the case as pleaded that that point. And that was no doubt in accordance with the instructions given by the clients. So there was a volte face but it does not seem to me to be fatal to the application to amend. Obviously, it calls for explanation unless the circumstances establish some reasonable ground for the alteration of position.*

[Court Note: The ultra-liberality of the position adopted by the Court of Appeal in the last-quoted paragraph is striking: it is not necessarily fatal that what is afoot is “something of a stratagem”, “that the claim is inconsistent with previous submissions...that it is totally at variance”; this is sweeping wording that rebounds, in the context of the within application, to the favour of Teva which could not reasonably (and would not rightly) be contended to be engaged in, e.g., some form of stratagem; Mr Kelly, in his affidavit evidence, has given the reasons why the amendments are being sought (and one of those reasons concerns material put in evidence in Professor Buckton’s first witness statement)].

...

58. *The Dormers based their application on the new material that they obtained under the Data Protection Acts in relation to the application made by the three bank officials to the Area Credit Committee in February 2014. The High Court held that they were aware of that material at a time prior to the injunction application in February 2015. It would appear that they knew about it in January 2015, but nevertheless proceeded with the interlocutory injunction application on the basis of the case as it then stood. For my part, I am not clear as to why that should necessarily exclude the proposed amendment.*

[Court Note: Para. 58 in effect addresses the Kennedy-style ‘You should have known earlier’ or ‘You knew all along’ argument. What the Court of Appeal makes clear is that even if all had been known to the Dormers before they made their application, it was not at all clear why this would yield the result (and in point of fact it did not, in *Dormer*, yield the result) that the Dormers were ‘shut out’ from proceeding as they sought.]

59. *The courts generally adopt a generous approach to applications for amendment, following a policy that it is proper and indeed necessary to have all the relevant issues in dispute between the parties brought before the court. In this respect, it seems to me that the rule in Henderson v. Henderson actually supports the Dormers’ motion to amend. It would be practically a Catch-22 situation if they were to be defeated on a basis that they had not brought forward their whole case while being denied the means of doing just that. It is not satisfactory to have a claim defeated on a rule of technical pleading. It is also the case that the courts are sympathetic to amendment in circumstances where it will save the proceedings from premature elimination.*

[Court Note: Just as it is not satisfactory to have a claim defeated on a rule of technical pleading, it cannot be in the public interest, in the context of the monopolistic benefits conferred by a live patent, for a claims amendment application to succeed (in effect go through ‘on the nod’) because of a technical rule of pleading.]”

60. *Rather than acting as an obstacle for the Dormers’ application, the rule in Henderson v. Henderson [1843] 3 Hare 100 supports the proposition that the suit at hand should be amended to reflect the full exposition of the plaintiffs’ claim.*

[Court Note: That there should be a full and proper claims amendment process is, of course, precisely the proper ideal that Teva contends for in the context of the within application.]”

VI

Conclusion

43. The within leave application was brought by Teva in an understandable abundance of caution in all the circumstances presenting. For the reasons identified previously above the court considers that:

(i) its jurisdiction to permit the amendment of a patent cannot be equated with the adjudication of conventional *inter partes* disputes requiring pleadings,

(ii) the two previous statements of opposition delivered on behalf of Teva (a) are not pleadings envisioned by the Rules of the Superior Courts 1986, as amended, and (b) were not furnished by way of response to any pleadings emanating from Boehringer,

(iii) even if the court is wrong as to points (i) and (ii) (and it does not consider that it is), leave to deliver the further amended statement of opposition would in any event fall to be granted when one has regards to the law and rules applicable to the amendment of pleadings.

44. It follows that the leave sought is not required. For what it is worth, given the just-stated conclusion (and without prejudice to that conclusion), such leave can in any event be granted, if it continues to be desired by Teva.

Appendix

Proposed Amendments to Statement of Opposition

(The proposed amendments are double underlined)

"...SECOND AMENDED STATEMENT OF OPPOSITION

...PARTICULARS

...5A Proposed amended claim 6 (and the proposed claims dependent thereon) has no basis in the application for the Patent as filed and is comprised of added matter. In this regard:

(a) There is no reference (or no sufficient reference), whether explicit or implicit, to the special advantage obtained when hydroxypropylmethylcellulose ('HPMC') that has a reduced moisture content as a TEWS or halogen drier moisture content of $\leq 5\%$ is used as capsule material as claimed in proposed amended claim 6. When cellulose derivatives are discussed as capsule materials, it is indicated that the level of TEWS or halogen drier moisture content is preferably less than 8%, particularly less than 5%. It is also stated that most preferably, capsules for inhalation consisting of cellulose derivatives are dried to a TEWS or halogen drier moisture content of less than 4%, particularly preferably less than 2% being filled with the inhalable powder content of 5%, which appears to be intermediate between the ranges disclosed in the application as filed, should be included in proposed amended claim 6 (an independent claim) as a supposed characterising feature of the invention; and /or

(b) Proposed amended claim 6 consist of and/or results in an intermediate generalization, which is not directly and unambiguously derivable from the information previously presentation in the application as filed. The application as filed does not contain any explicit disclosure of the combination of lactose and the capsule material being HMC, with the capsule material having a reduced moisture content of $\leq 5\%$. In particular, and without prejudice to the generality of the foregoing, no preferred capsule material is disclosed in the application as filed (the material is to be selected from among gelatin, cellulose derivatives, starch, starch derivatives, chitosan and synthetic plastics).

...Re-served this 8th day of January 2018...".