

*Unapproved  
No redactions required*



**THE COURT OF APPEAL**

**CIVIL**

**Court of Appeal Record Nos 2017/544**

**Neutral Citation [2022] IECA 58**

**Noonan J**

**Haughton J**

**Collins J**

**IN THE MATTER OF IRISH PATENT NO EP (IE) 1379220 FILED ON 27 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**

**BETWEEN**

**NORTON (WATERFORD) LIMITED t/a TEVA PHARMACEUTICALS IRELAND**

*Petitioner/Appellant*

**AND**

**BOEHRINGER INGELHEIM PHARMA GMBH & CO KG**

*Respondent*

**JUDGMENT of Mr Justice Maurice Collins delivered on 14 March 2022**

## TABLE OF CONTENTS

<b>I - PRELIMINARY.....</b>	<b>4</b>
<b>II- THE HIGH COURT HEARING AND JUDGMENT.....</b>	<b>8</b>
<b>III - THE 220 PATENT AND THE AMENDED CLAIMS .....</b>	<b>14</b>
<b>IV - THE APPEAL .....</b>	<b>21</b>
<b>V – OGURA (1998) .....</b>	<b>24</b>
<b>VI - LITIGATION ELSEWHERE: ABOUT THE 220 PATENT AND THE ISSUE OF COMITY.....</b>	<b>26</b>
<b>The European Patent Convention .....</b>	<b>27</b>
<b>Other Litigation re the 220 Patent .....</b>	<b>30</b>
<b>Germany .....</b>	<b>30</b>
<b>Norway.....</b>	<b>31</b>
<b>The Netherlands.....</b>	<b>34</b>
<b>Spain.....</b>	<b>37</b>
<b>Comity.....</b>	<b>44</b>
<b>Ranbaxy .....</b>	<b>44</b>
<b>Gilead Sciences Ltd v Mylan SAS .....</b>	<b>46</b>
<b>Authority from England and Wales.....</b>	<b>48</b>
<b>The Judge’s Treatment of the Comity Issue.....</b>	<b>50</b>
<b>VII - THE JUDGE’S ASSESSMENT OF THE EVIDENCE .....</b>	<b>58</b>
<b>Did the Judge wrongly discount the evidence of Professor Buckton? .....</b>	<b>58</b>
<b>The Judgment.....</b>	<b>58</b>
<b>Experience “at the Coalface” – the evidence.....</b>	<b>64</b>
<b>Teva’s challenge to the Judge’s assessment.....</b>	<b>66</b>
<b>Professor Buckton’s inability to recall whether he had seen Ogura before the priority</b>	

date .....	71
Footnote 13 of Professor Buckton’s First Report .....	72
Assessment.....	74
<b>VIII – <i>AGREVO</i> OBVIOUSNESS/LACK OF PLAUSIBLE TECHNICAL CONTRIBUTION.....</b>	<b>83</b>
The Judge’s Reasoning.....	86
The Applicable Test .....	100
My Conclusions as to the Applicable Test .....	119
Applying the Test Here.....	122
<b>IX – PLAUSIBILITY AS TO SUFFICIENCY .....</b>	<b>141</b>
<b>X - CONCLUSIONS.....</b>	<b>142</b>

## I - PRELIMINARY

1. The Appellant (“*Teva*”) appeals from an Order of the High Court (Barrett J) dated 9 October 2017 (perfected on 3 November 2017) dismissing its claim for the revocation of the Irish designation of European Patent No (IE) 13799220 (“*the 220 Patent*” or “*the Patent*”). The reasons for the High Court’s decision are set out in the Judge’s comprehensive judgment of 26 July 2017 (“*the High Court Judgment*” or “*the Judgment*”).
2. As will appear, Ireland is but the latest stop in a litigation caravan concerning the 220 Patent that has already visited a large number of other jurisdictions within the European Patent Organisation. To date, all such litigation has arrived at a common conclusion, namely that the 220 Patent is invalid. The decision of the High Court is – so *Teva* says – a “*complete outlier*” and one of its grounds of appeal is that the Judge failed to have any adequate regard to the various decisions that upheld the same objections to the 220 Patent that *Teva* advanced unsuccessfully at trial here.
3. The 220 Patent is for “*Inhalation Capsules*”. The priority date of the Patent is 1 June 2001. The claimed invention relates to “*capsules for inhalation (inhalettes) consisting of specific materials with a reduced moisture content, which contain the active substance tiotropium in the form of powdered preparations and are characterised by*

*increased stability.*”<sup>1</sup> Tiotropium (as tiotropium bromide) is a bronchodilator used in the management of chronic obstructive pulmonary disease (COPD) and asthma. It is the subject of separate patent protection. The 220 Patent – which is owned by the Respondent (“Boehringer”) - protects the inhalation capsules rather than the active substance.

4. The 220 Patent is said to protect Boehringer’s SPIRIVA inhaler product. The SPIRIVA inhaler is a dry powder inhaler (DPI) that uses capsules made from gelatin<sup>2</sup>/polyethyleneglycol (PEG), containing a precise amount of tiotropium bromide formulated with a lactose excipient (an inactive substance that serves as the vehicle or medium for the active substance). The SPIRIVA product is, commercially, a highly valuable one.
  
5. Teva brought revocation proceedings in October 2014. In its Amended Particulars of Objection (dated 23 March 2015) Teva pleaded (1) that the subject-matter of the 220 Patent did not involve any inventive step and was obvious to a person skilled in the art having regard to the state of the art (what I shall refer to as “*conventional obviousness*”); (2) that, even if not obvious in the conventional sense, there was no disclosure in the Patent to suggest that that claimed capsules for invention possessed any technical benefit or solved any technical problem – the claims (it was said) represented an arbitrary selection and there was no data in the Patent to make it plausible that the claimed capsules solved the problems the Patent claimed they did (which, for reasons

---

<sup>1</sup> Patent, page 1.

<sup>2</sup> Gelatin is also referred to as gelatine. I shall use “*gelatin*” other than in quoted text.

that will become apparent, I shall refer to “*Agrevo obviousness*”) and (3) that the specification of the Patent was insufficient to allow the invention to be performed by a skilled person (*insufficiency*).

6. In the face of that challenge, and as it had done elsewhere, Boehringer sought to amend the 220 Patent, indicating that it did not intend to defend the Patent as granted. The proposed amendments concern only the claims in the Patent. The proposed amended claims are 13 in number. In its Statement of Opposition to the amendment application, Teva seeks to challenge claims 6 – 13 only. The common thread of these claims is that all involve the use of hydroxypropylmethylcellulose (frequently referred to as hypromellose) (HPMC) as the capsule material. Further reference is made below to the terms of the Patent, and the proposed amended claims (to which, for convenience, I shall refer as “*the amended claims*” even though the amendments have not actually been permitted and, accordingly, the claims have not yet actually been amended).
7. Teva’s generic Braltus inhaler product is also a DPI and also uses capsules containing a formulation of tiotropium bromide with a lactose excipient. However, the capsules are made from HPMC. While no infringement proceedings have been brought in this jurisdiction to date, Boehringer asserts that the Braltus product infringes the 220 Patent.
8. The High Court hearing here took 16 days. This Court heard Teva’s appeal over 3 hearing days. A great deal of material was provided to the Court, including lengthy and helpful written submissions and additional “*speaking notes*”. I should record the Court’s gratitude for the manner in which this material was organised and presented as well as

thanking all counsel for their written and oral submissions which were all of a very high standard.

## II- THE HIGH COURT HEARING AND JUDGMENT

9. The High Court was asked to determine the proceedings on the basis that the amended claims (and in particular claims 6 – 13) formed part of the Patent and those claims were the particular focus of the trial. The Judge characterised Teva’s challenge to amended claims 6 - 13 as a “*three-fold attack*” involving “(1) an *obviousness attack*, (2) an *insufficiency attack* and (3) an *Agrevo attack*” (Judgment, paragraph 8). He explained these “*attacks*” as follows:

- The “*obviousness attack*” was based on Teva’s contention that the protected invention was obvious in light of the prior art. The prior art relied on by Teva comprised Maesen *et al* “Tiotropium bromide, a new long-acting anti-muscarinic bronchodilator: pharmacodynamic study in patients with chronic obstructive pulmonary disease (COPD)” (1995) 8 *Eur Respir J* 1506 (“*Maesen*”); Ogura *et al*, “HPMC Capsules – An Alternative to Gelatin” (1998) 10 *Pharmaceutical Technology Europe* 31 (“*Ogura*”) and Barnes “Tiotropium bromide” (2001) 10 *Expert Opinion on Investigational Drugs* 733 (“*Barnes*”). The Judge also referred in this context to a further publication, Casaburi “The Spirometric Efficacy of Once-Daily Dosing with Tiotropium in Stable COPD: a 13-week multicentre trial” (2000) 118 *Chest* 129 (“*Casaburi*”) which, though not cited as part of the prior art here, had been relied on in other jurisdictions as the closest prior art (Judgment, paragraph 10)



- The “*insufficiency attack*” involved a claim that the specification of the 220 Patent does not disclose the invention clearly and completely enough for it to be performed by a person skilled in the art. (Judgment, paragraph 11).
  - The “*Agrevo attack*” was based on Teva’s claim that, insofar as the invention was not obvious in light of the prior art, it was obvious for lack of technical contribution to the art (Judgment, paragraph 12). As the Judge explained, this ground of challenge takes its name from the decision of the Board of Appeal of the European Patent Office (“*the EPO*”) in *Agrevo/Trizaoles* (Case No T939/92, 12 September 1995) and has been accepted as a ground of challenge in England and Wales (and, I would add, elsewhere). It “*applies where a development may not be obvious but where the elements of the development which distinguish it from what went before make no technical contribution to the subject-matter. These features are adjudged ‘arbitrary’ and incapable of contributing to inventiveness.*” (Judgment, paragraph 9).
10. Two witnesses were called by Teva (Professor Duncan Geddes and Professor Graham Buckton) and four witnesses gave evidence for Boehringer (Professor James Birchall, Graham C Higson, Hans-Joachim Delzeit and Professor Richard Costello). The principal witnesses on each side were Professor Buckton, an emeritus professor of the University College of London School of Pharmacy called by Teva and Professor Birchall, Professor of Pharmaceutical Sciences at Cardiff University, called by Boehringer. Their evidence is extensively referred to by the Judge in his Judgment. In all material respects, the Judge preferred the evidence of Professor Birchall. Teva says

that the Judge wrongly discounted the evidence of Professor Buckton, largely (so it is said) on the basis of a mistaken view that Professor Birchall had experience of “*working at the coalface*” of capsule-based DPI development that Professor Buckton lacked. That is one of Teva’s principal complaints on this appeal and it will be necessary to address it in more detail in due course.

11. In any event, based very significantly on his preference for the evidence of Professor Birchall, the Judge proceeded to make the following principal findings which led him to dismiss Teva’s claim:

- The notional skilled person to whom the 220 Patent was addressed was a pharmaceutical formulation scientist (also referred to as a formulator) (Judgment, paragraph 39). In so concluding, the Judge rejected Teva’s argument that the skilled person here would in fact comprise a skilled team that also included a clinician.
- As of the priority date (1 June 2001), gelatin capsules were perceived to be very useful for formulations for inhalation in DPIs and there was no “*hankering*” for any alternative capsule, whether by reference to concerns regarding moisture content or otherwise. Such capsules were “*not dried to get around notional problems.*” Equally, there was no moisture-related concern relating to the use of

tiotropium in DPIs. In any event, any such concerns would have been addressed by a process of “*equilibration*”<sup>3</sup> (Judgment, paragraph 68)

- As of the priority date, the use of HPMC capsules for inhalation purposes was not part of the common general knowledge of the notional pharmaceutical formulation scientist: the only capsule material for inhalation purposes that was part of common general knowledge at the priority date was gelatin (Judgment, paragraphs 95 and 96; also paragraph 129). The Judge’s conclusions on this point followed on a detailed discussion of the evidence of Professors Buckton and Birchall and of the documentary material referred to by them, including (but not limited to) *Ogura*.
- The invention here was not simply the use of HPMC capsules but the use of *reduced-moisture* HPMC capsules for a formulation of tiotropium powder for inhalation. The use of reduced-moisture HPMC capsules was “*one of the fundamental elements of the invention*” (Judgment, at paragraphs 99 and 100). “*Reduced-moisture*” here refers to capsules which have been dried so that their moisture content is lower than their natural moisture content in normal conditions.

---

<sup>3</sup> Explained at para 61 of the Judgment by reference to the first witness statement of Professor Birchall.

- As of the priority date, the notional skilled person would not have had concerns as to the sensitivity of tiotropium to moisture or about the suitability of gelatin capsules for use with tiotropium formulations (Judgment, paragraph 114)
- The development of a formulation of tiotropium powder for inhalation using reduced-moisture HPMC capsules was an inventive step which was not obvious over the prior art as of the priority date and, in particular, was not obvious over *Ogura* (Judgment, paragraph 126 and following, culminating in the conclusions set out at paragraphs 137-139). The steps necessary to take to arrive at the invention from *Ogura* (including as a final step deciding to lower the water content of the HPMC capsule material below specified thresholds) were such that they “*could not have been taken in connection with tiotropium without inventiveness*” (paragraph 135-136). The Judge considered that, if one applied the “*multi-factorial approach*” taken in *Generics (UK) Ltd v H Lundbeck A/S* [2007] EWHC 1040 (Pat), [2007] RPC 32 “*the invention of tiotropium preparations for inhalation in reduced-moisture HPMC capsules would not be obvious*” (para. 137). Even if (contrary to what the court had found) one assumed that the formulation of tiotropium in HPMC capsules was obvious over *Ogura* in 2001, “*there was nothing in Ogura or in the prior art more generally, however taken, that could lead to the formulation of tiotropium in reduced-moisture HPMC capsules without invention.*” (para 138)
- Taking the “*obvious to try*” approach, “*there would be no reason for the notional skilled person to try reducing the moisture content of HPMC capsules*

*and using them in a tiotropium formulation*” (para 139). (Earlier in his Judgment, the Judge identified the test for “*obvious to try*” as that identified by Kitchin J in *Generics (UK) Ltd v H Lundbeck A/s* [2007] RPC 32, at para 72: Judgment, para 37).

- The invention was not obvious over *Barnes* or *Maesen* (Judgment, paragraphs 183 – 189) or over *Casaburi* (Judgment, paragraph 190).
- The Judge addressed the “*insufficiency attack*” and the “*Agrevo attack*” under the general rubric of “*plausibility*” (Part XIV of the Judgment). In his view, the disclosure made by the 220 Patent was credible and not speculative and therefore satisfied the threshold test of plausibility (Judgment, paragraph 178; also at paragraph 181). The correctness of these conclusions is the central issue in the appeal and accordingly I will defer for the moment any more detailed account of the Judge’s reasoning.
- It followed from these findings that the Judge did not accept any of Teva’s grounds of challenge to the 220 Patent (Judgment, paragraph 192)

12. I should make it clear, in justice to the Judge, that the above are merely the headline findings made by him and his Judgment contains detailed discussion of the evidence and the authorities and includes by way of Appendix to the Judgment a further and detailed discussion of the “*Clinical Evidence*” heard by him.

### III - THE 220 PATENT AND THE AMENDED CLAIMS

13. The Patent identifies the invention in the terms set out in paragraph 3 above. The specification then sets out the background to the invention and gives a more detailed description of it. The aims of the invention are set out at page 2, namely, to prepare capsules for inhalation containing an inhalable powder containing tiotropium:

- which guarantee sufficient stability of the active substance
- which by virtue of its stability ensures release of the active substance with a high metering accuracy
- while enables the active substance to be administered while emptying the capsules completely
- which have good perforation qualities with good stability and low brittleness and which can therefore be used without any problems in inhalers designed for the administration of inhalettes

These statements identify the intended technical contribution of the invention. The issue of the technical contribution of the invention is one to which it will be necessary to return.

14. “*Surprisingly*” (so the description continues) these “*problems*” are solved by the use of capsules which contain, as an inhalable powder, tiotropium mixed with a physiologically acceptable excipient, “*characterised in that the capsule material has a*

*reduced moisture content*". The "concept of a reduced moisture content within the scope of the present invention" is then defined as being equivalent to a TEWS moisture level "of less than 15%" (my emphasis).<sup>4</sup> However, various other moisture content values are subsequently referred to in the description and in the examples and it may be useful to collect these references together at this point (the emphasis in all cases is mine):

- "*Preferred capsules for inhalation according to the invention have a TEWS or halogen drier moisture content of less than 12%, particularly preferably  $\leq 10\%$* " (page 3)
- "*In the case of gelatine-containing capsule materials, the capsules according to the invention preferably have a TEWS or halogen drier moisture content of less than 12%, particularly preferably  $\leq 10\%$* " (page 4)
- "*When cellulose derivatives are used as capsule materials the level of the TEWS or halogen drier moisture content is preferably less than 8%, particularly preferably less than 5%. 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%, before being filled with the inhalable powder containing tiotropium.*" (page 4)
- "*When synthetic plastics are used as the capsule materials the level of the TEWS or halogen drier moisture content is optionally less than 3%, optionally less than 1%*" (page 4)

---

<sup>4</sup> TEWS is a proprietary moisture measurement system.

- “When producing the capsules for inhalation according to the invention it is essential that, if the capsule material does not already have a suitably reduced moisture content as a result of its storage or production before being filled ... the empty capsules are dried. This drying is carried out until a moisture level of not more than 15% TEWS or halogen drier moisture content according to the invention.” (at page 5)
- “In another aspect the present invention relates to the use of capsules which are characterised by a TEWS or halogen drier content of less than 15%...” (at page 5)”
- “The capsules for inhalation according to the invention before filling with the tiotropium-containing inhalable powder until the maximum-permissible level of TEWS or halogen drier moisture content according to the invention is reached.” (page 8)
- Reference is also made, in what is referred to as “another preferred embodiment of the invention”, to the drying of the capsules *after* filling. This part of the description refers to various values for relative humidity, rather than moisture levels in the capsules, and does not distinguish between different capsule materials. (page 10).
- A number of the examples include values for moisture content. Examples 2 & 3 refers to a hard gelatin capsule with 9% TEWS moisture. Example 4 refers to an HPMC capsule of ≤ 2% TEWS moisture & examples 5 & 6 refer to a polyethylene capsule of ≤ 1% TEWS moisture. Example 7 refers hard gelatin capsules adjusted to a water content of “about 8.7%”. There is nothing in the examples to explain the significance (if any) of these moisture values.



15. As will be evident from the above, the 220 Patent encompasses a very wide variety of different capsule materials, including gelatin, cellulose derivatives, starch, starch derivatives, chitosan and synthetic plastics. Gelatin can be used with other additives, including – but not limited to – PEG. A number of cellulose derivatives, including HPMC, are identified. A range of synthetic plastics are also identified in the description. There appears to be nothing in the Patent as to the relative advantages and disadvantages of these various capsule materials.
  
16. As regards the composition of the inhalable powder, while crystalline tiotropium bromide monohydrate is identified as the “*most preferably used*” form of the active ingredient (page 6), other forms of the anion, such as tiotropium chloride may be used (page 5). As we shall see, the key amended claims refer only to “*tiotropium*”. Different levels of the active ingredient may be used. Various excipients are envisaged, though lactose is said to be “*the particularly preferred excipient*” and lactose monohydrate “*most particularly preferred.*” Amended claim 6 of the Patent does not refer to lactose in any form but only to “*a physiologically acceptable excipient*”
  
17. In light of the fact that Boehringer is not seeking to defend the 220 Patent as granted, it is not necessary to set out the original claims in detail but I should note that claim 1 is for capsules for inhalation containing tiotropium and an excipient “*characterised in that the capsule material had a reduced moisture content as a TEWS or halogen drier moisture content of less than 15%*” (my emphasis). The terms of this claim are such that it appears to apply whatever the capsule material may be. Claim 6 is for capsules

for inhalation where the capsule material was one of the cellulose derivatives (thus including HPMC but other such derivatives also) and claim 7 is for capsules for inhalation according to claim 6 “*characterised in that the capsule material has a TEWS or halogen drier moisture content of less than 8%, particularly preferably  $\leq 5\%$ .*”

18. The amended claims that are at issue are amended claims 6-13. Some of these include conditional claims within them: by agreement those claims were not considered by the High Court and accordingly it is not necessary to refer further to them. The key claims are claims 6 – 8. Claims 9-13 are dependent claims. Claims 9-11 relate to capsules for inhalation according to one of claims 6 – 8, with various characteristics in terms of the amount of active substance in the capsule (claim 9), the particle size of the excipient used (claim 10) and the salt form of the active substance (claim 11). Claims 12 and 13 are use claims, covering (*inter alia*) the use of capsules for inhalation according to claims 6 – 8. Amended claims 6 – 8 are in the following terms (again, in all cases the emphasis is mine):

*“6 Capsules for inhalation which contain as the inhalable powder tiotropium in admixture with a physiologically acceptable excipient, characterised in that the capsule material is the cellulose derivative hydroxypropylmethylcellulose and has a reduced moisture content as a TEWS or halogen drier moisture content of  $\leq 5\%$  and in that the physiologically acceptable excipient is lactose.*

*“7 Capsules for inhalation according to claim 6, characterised in that the capsule material has a TEWS or halogen drier moisture content of less than 4%.*

*“8 Capsules for inhalation according to claim 6, characterised in that the capsule material has a TEWS or halogen drier moisture content of less than 2%.”*

19. It is the terms of the claims that determine the extent of the protection conferred by a patent: section 45(1) of the Patents Act 1992 (as amended) (“*the 1992 Act*”). That is, however, subject to the directions contained in the Protocol on the Interpretation of Article 69 of the European Patent Convention: section 45(3). The effect of that Protocol – set out in the Second Schedule to the 1992 Act – was considered by the High Court (Clarke J, as he then was) in *Ranbaxy Laboratories Limited v Warner Lambert Company* [2007] IEHC 256, [2009] 4 IR 584 (“*Ranbaxy*”). As Clarke J explains, claims are not to be construed overly literally and the remainder of the patent may be taken into account in construing the claims. Expert evidence is not, as such, admissible for the purposes of the construction of a patent but such evidence is admissible – indeed it may be indispensable – in enabling a court to understand the common general knowledge that would have been available to the skilled addressee as of the priority date: *Ranbaxy*, at para 26.
  
20. It is notable that the amended claims of the Patent do not make any claim for HPMC capsules with a moisture content >5%. Also notable is the fact that the description in the Patent does not explain the significance and/or effect of using HPMC capsules with the particular levels of moisture content now specified in amended claims 6, 7 and 8. The ambient or natural moisture content of HPMC/HPMC capsules is not identified anywhere in the Patent.

21. The Judge identified the inventive concept of amended claims 6-8 in the following terms:

*“ ... the inventive concept of the impugned development is the formulation of tiotropium in prescribed reduced-moisture HPMC capsules, being HPMC capsules with  $\leq 5\%$  water content,  $\leq 4\%$  water content and  $\leq 2\%$  water content.”*

(Judgment, para 115)

That reflects *verbatim* the closing submissions of Boehringer.<sup>5</sup> Elsewhere in those submissions, Boehringer stated that *“the specific water content limits of the claims embody the inventive concept ... They are not separate from it.”*<sup>6</sup> At para 100 of the Judgment, the Judge stated that Teva had consistently sought to mischaracterise the invention as the use of capsules for inhalation purposes. In his view, Teva’s approach elided *“one of the fundamental elements of the invention, being that the capsules comprised in the invention are not only HPMC capsules but reduced-moisture HPMC capsules.”*

22. On appeal, Teva did not dispute the Judge’s finding as to the inventive concept of amended claims 6-8 and in fact relied on it for the purpose of the *Agrevo* obviousness challenge.

---

<sup>5</sup> Boehringer’s closing written submissions to the High Court (19 May 2017), para 195.

<sup>6</sup> *Ibid*, para 224

#### IV - THE APPEAL

23. Teva advances a number of grounds by way of appeal.

- First, it says that the Judge misunderstood and/or misapplied the principles of comity articulated by Clarke J in *Ranbaxy*. Specifically, it is said that the Judge wrongly considered that the principle of comity was concerned solely with “*shared legal principles*” whereas (so it is said) the principle required the Judge to have regard to the reasoning and ultimate decisions of those courts that previously considered the validity of the 220 Patent. While, at the hearing of the appeal, Counsel for Teva acknowledged that the “*real force*” of the comity point was “*on the Agrevo obviousness side*”, it was nonetheless important as a “*sense-check*” in respect of the findings made by the Judge which diverged from the findings made elsewhere, in particular the findings made by Morgan J in *Teva UK Limited v Boehringer Ingelheim Pharma GmbH* [2015] EWHC 2963 on the issue of obviousness over *Ogura*.
- Secondly, Teva says that the Judge misunderstood and/or misapplied the law regarding *Agrevo* obviousness. In this context, it is said that the Judge failed to apply the correct test, namely whether the invention claimed is rendered plausible as opposed to speculative by the contents of the patent specification alone (and, it is said, wrongly understood Teva’s case as being to the effect that the Patent had to provide data proving that the claimed invention was effective). The Judge (so Teva says), failed to consider whether the claims of the Patent

were plausible in terms of the particular technical effects of the alleged invention being shown within the claimed moisture boundaries. It is also said that the Judge erred in taking into account the post-filing experiments relied on by Boehringer (and also that the Judge misunderstood the evidence regarding the experiments). The Court is invited to reverse the High Court's findings on this aspect of the validity challenge and to proceed to revoke the 220 Patent. This issue of *Agrevo* obviousness/plausibility issue was the principal issue in the appeal.

- It is said that the Judge failed to properly consider and address the distinct plausibility claim (relating to sufficiency rather than obviousness) made by Teva to the effect that the Patent did not make it plausible that the claimed technical effects of the invention would be found for all salts and physical forms claimed, rather than the single form set out in the examples.
- As regards inventive step/obviousness, Teva says that the Judge erred in his assessment of the evidence of Professor Buckton and, in particular, in adopting “*a universal preference*” for the evidence of Professor Birchall over that of Professor Buckton. Complaint is also made that the Judge incorrectly/unfairly categorised a portion of Professor Buckton's witness statement as constituting a material change from the evidence given by him in the proceedings in Norway and England and Wales. It is also said (again in the context of the Judge's findings regarding obviousness/inventive steps) that the Judge erred in finding that the skilled addressee of the Patent was solely a formulator, that he was

wrong to conclude that, as of the priority date, a skilled formulator would not have been concerned with moisture issues affecting tiotropium and that he erred in failing to pay any or any sufficient regard to the teaching and/or status as prior art of *Ogura*. However, while these grounds were maintained at the hearing of the appeal, Counsel for Teva candidly acknowledged the difficulties presented by the *Hay v O'Grady* [1992] 1 IR 210 jurisprudence and made it clear that the Court was not being asked to substitute its findings for the findings made by the Judge. Rather, the focus of Teva's appeal in this regard was on what was said to have been "*significant and material errors in how the trial judge approached the assessment of the evidence and the witnesses*" and in particular what was said to have been the Judge's wrongful disregarding of Professor Buckton's evidence.

## V – OGURA (1998)

24. Though it was much less central in the submissions before this Court than in the evidence and argument before the High Court, it nonetheless appears appropriate to say something about *Ogura*.
25. As its title (“*HPMC Capsules – An Alternative to Gelatin*”) indicates, *Ogura* was concerned with the use of HPMC capsules as an alternative to gelatin capsules. The authors were connected to Shionogi & Co Ltd/Shionogi Qualicaps (“*Shionogi/Qualicaps*”). In his evidence, Professor Birchall explained that Shionogi/Qualicaps developed HPMC capsules, initially for oral use and (in 2003) for inhalation use.<sup>7</sup> In the summary section at the start of *Ogura* it is stated that “*HPMC capsules have a naturally low moisture content, maintain mechanical integrity under extremely low-moisture conditions and are, therefore, ideally suited for use with formulations containing water-unstable drugs*”. It refers to the fact that “*in recent years*” capsules had been adapted to contain “*even powders for inhalation*”. However, capsules had some drawbacks. Capsule shells made from gelatin – described as “*the main material*” used - generally contained 13%-15% water and therefore might not be suitable for use with readily hydrolysable drugs. For that and other reasons mentioned in the text, work was underway to develop capsules made from (*inter alia*) cellulose. After a brief description of how HPMC capsules could be manufactured, *Ogura* then addresses the physical characteristics of such capsules. In contrast to gelatin, which was

---

<sup>7</sup> Para 102 of Professor Birchall’s first statement, cited at Judgment, para 73.



prone to brittleness, *“no brittleness was observed in HPMC capsule shells even at moisture levels of only 2%”* (the lower end of the range of 2-5% moisture content given for HPMC capsules in Table 1). As a result of the lower moisture content of HPMC it permitted *“maintenance of a low humidity environment within the HPMC capsule shell”*. Ogura then went on to observe that, although HPMC capsules have a naturally low moisture content, the HPMC film did contain some adsorbed water (water held on the surface) that was readily released and suggested that for extremely moisture sensitive drugs, it might be desirable to add water absorbent excipients to the formulation and desiccants to the container to enhance stability. HPMC capsules, it was said, *“are particularly well suited to these situations because they resist becoming brittle under low humidity conditions”*. Ogura concludes by considering other applications (the previous discussion being focused on HPMC capsules for oral use), including dry powder inhalation;

*“Capsules have also been used as unit-dose containers to administer finely divided powders with specially designed inhalation devices. In the past, such delivery systems have encountered problems, including adherence of the powder to the gelatin capsule because of static electricity and capsule breakage that results from storage under very low humidity. The HPMC capsule avoids these problems and would be suitable for use in these situations.”*

## **VI - LITIGATION ELSEWHERE**

### **ABOUT THE 220 PATENT AND THE ISSUE OF COMITY**

26. One of the complaints made by Teva in this appeal – it is in fact its first ground of appeal - is that the Judge failed to pay any sufficient regard to the principle of comity and/or failed to apply that principle properly.
  
27. The context in which the issue arises in the proceedings is that the corresponding national iterations of the 220 Patent have been found to be invalid in various other European Patent Organisation jurisdictions. The Judge was referred to proceedings in England and Wales, Germany, Norway, the Netherlands and Spain and he in turn refers to those proceedings at paragraphs 14-20 of his Judgment. On appeal, the Court was furnished with English translations of decisions of the German Federal Supreme Court (Germany), the Oslo District Court and Borgarting Court of Appeal (Norway), the Commercial Division of the Hague District Court and the Hague Court of Appeal (the Netherlands) and of the Commercial Court of First Instance of Barcelona (Patent Division)(Spain), as well as the decisions of the Patents Court (Morgan J) and the Court of Appeal (England & Wales). Some of these decisions post-dated the High Court Judgment. In every instance, the 220 Patent was held to be invalid.

## **The European Patent Convention**

28. Before addressing these decisions further, it is necessary to say something about the European Patent Convention (EPC). The EPC is an international treaty adopted in 1973 which has been revised from time to time since then. It has a large number of Contracting parties, including (but not limited to) the Member States of the EU. The United Kingdom's status as a Contracting party is unaffected by its departure from the EU. The Preamble to the EPC refers to the desire of the Contracting States "*to strengthen co-operation between the States of Europe in respect of the protection of inventions*" and that "*such protection may be obtained in those States by a single procedure for the grant of patents and by the establishment of certain standard rules governing patents so granted*". To that end, the EPC established the European Patent Organisation and, as an organ of it, the European Patent Office ("*the EPO*") (including the Board of Appeals).
29. Patents granted pursuant to the EPC are referred to as "*European Patents*". In each of the Contracting States for which it is granted, a European patent has the effect of, and is subject to the same conditions as, a national patent granted by that State: Article 2(2) EPC. Applications for a European patent are made to the EPO and detailed provision is made in Parts III – VI EPC for the filing and examination of, and adjudication on, such applications (including opposition procedure and appeals to the Board of Appeals). The substantive conditions governing the grant or refusal of applications are set out in Part II EPC, particularly in chapter 1. Part II, chapter 3 is also significant, including as it does important provisions concerning the effect of a European patent (Article 64) and the extent of protection conferred by it (Article 69, now to be read with the Protocol on

the Interpretation of Article 69). The term of a European patent is 20 years from the filing date (Article 63(1)). When granted, a European patent may only be revoked on one or more of the grounds specified in Article 138 EPC.<sup>8</sup> One of those grounds is that the subject-matter of the patent is not patentable under Articles 52-57 EPC.<sup>9</sup> Inventions are not patentable under these Articles unless they are novel and involve an “*inventive step*”.<sup>10</sup> Insufficiency of disclosure is another ground for revocation: Article 138(1)(b) EPC.<sup>11</sup>

30. While the EPC lays down common rules (and a common procedure) for the grant of European patents, such a patent, once granted, is properly to be regarded as a bundle of national patents, the enforcement of which (and any issue regarding the validity of which) is a matter for the law of the relevant Contracting State. Thus, the CJEU has stated:

*“26. A European patent continues to be governed, as Articles 2(2) and 64(1) of the Munich Convention clearly show, by the national law of each of the Contracting States for which it has been granted. By the same token, any action for infringement of a European patent must, as is apparent from Article 64(3) of that convention, be examined in the light of the relevant national law in force in each of the States for which it has been granted (Roche Nederland and*

---

<sup>8</sup> Reflected in Section 58 of the 1992 Act.

<sup>9</sup> Section 58(a).

<sup>10</sup> Section 9(1) and 13 of the 1992 Act.

<sup>11</sup> Section 58(b). Section 19(1) is also relevant.

*Others, paragraphs 29 and 30).*” (Case C-616/10, *Solvay SA v Honeywell Flourine Products Europe BV*)

31. The establishment of the proposed Unified Patent Court (UPC) would significantly alter this position. The UPC is to be a specialist court (with courts of first instance and a court of appeal) with competence to hear disputes concerning the validity and enforcement of European patents, as well as disputes concerning a new category of European patents, European patents with unitary effect (also referred to as “*unitary patents*”), which will provide uniform protection with equal effect in all participating EU jurisdictions. As the Judge observed, the establishment of the UPC should avoid “*the protracted litigation that presently occurs in the various states of Europe*” in relation to European patents (Judgment, paragraph 23). The question of when the UPC will commence operations remains uncertain. The *Agreement on a Unified Patent Court* - the key element of the “*patent package*” agreed by EU Member States in 2012 – has not yet been ratified by a number of Member States. However, the Protocol on Provisional Application of the UPC Agreement recently came into operation and the expectation appears to be that the UPC will become a reality before the end of 2022. Ireland has yet to ratify the UPC Agreement and a constitutional amendment is required to permit it to do so.
  
32. No doubt the Judge was right to observe that – at least as regards European patents - the establishment of the UPC will make the issue of comity less significant than is now the case. However, the UPC will apply only to EU Member States, which constitute only a sub-set (though a significant sub-set) of the wider body of EPC Contracting

States. Equally, there is no doubt that the present European patent regime has significant potential for discrepancy and inconsistency. It is precisely *because* of such potential that the doctrine of comity is important in this context.

### **Other Litigation re the 220 Patent**

33. I propose to summarise briefly the position disclosed by the decisions opened to the Court. Aspects of some of those decisions will be discussed in greater detail in due course.

#### *Germany*

34. As the Judge noted, by the time that these proceedings came on for hearing in the High Court, the Federal Supreme Court had declared the 220 Patent null and void in proceedings brought by a third party. The Supreme Court's decision was given in January 2016 on appeal from a decision of the Federal Patent Court given in November 2013. The basis for that decision was that Court's view that the Patent did not disclose any inventive step and was obvious over the prior art (including *Maesen & Ogura*). The skilled person (which in the court's view would be a formulation scientist) would be aware of the sensitivity of inhaler powders to moisture. Whether the skilled person would have had reason to seek out capsules with an especially low moisture content (as the Federal Patent Court had found) was irrelevant as the skilled person would in any event have had reason to seek out information in the prior art on which capsules and

capsule materials had been considered for inhaler powder.<sup>12</sup> As regards the use of HPMC as the capsule material, the Supreme Court considered that a person skilled in the art could draw from *Ogura* “that HPMC is very well suited for capsule shells in addition to gelatin, and in particular that it offers a low moisture content with low brittleness and, therefore, good perforation capability.”<sup>13</sup> The skilled person would therefore have had reason to use HPMC as an alternative to gelatin (and the Court noted that the same conclusion had been reached by Morgan J). It does not appear from the Supreme Court’s decision that any issue of *Agrevo* obviousness was raised in Germany and it may be that no equivalent to amended claims 6-8 here were relied on in Germany.

35. As a matter of German law, the decision of the Federal Supreme Court is final.

*Norway*

36. The Judge noted that the District Court of Oslo, assisted by a panel of experts in pharmaceutical technology, found that the amended claims of the 220 Patent – which, he noted, corresponded to the amended claims relied on by Boehringer in the proceedings here – lacked any inventive step. He noted that an appeal was due to be heard in 2017.
37. The Borgarting Court of Appeal gave its decision on that appeal on 12 February 2018. In a detailed decision, it rejected Boehringer’s appeal from the decision of the District

---

<sup>12</sup> At paragraph 33 of the translation provided to this Court.

<sup>13</sup> At paragraph 34.

Court. Notably, the District Court had found that the moisture levels set out in the equivalent of amended claims 6-8 here lacked inventiveness and/or were arbitrary. The Court of Appeal agreed with the District Court that the skilled person would have been a team, including a clinician as well as a formulation scientist. The Court of Appeal concluded that the invention was obvious in view of the prior art, particularly *Ogura* and *Casaburi* (Teva had cited *Ogura* as the closest prior art whereas Boehringer cited *Casaburi*). *Ogura* undoubtedly formed part of the prior art and Boehringer's arguments that it had been published in a "low ranking journal", that it had not been peer-reviewed and none of the expert witnesses could remember reading it, did not affect that position. In any event, the Court noted, the article was based on common general knowledge at the time and the journal in which it was published appeared to have been widely distributed.<sup>14</sup> In the Court of Appeal's view, a skilled person instructed to look for an alternative to gelatin capsules, even if they started out from *Casaburi*, "would almost immediately have encountered the article of *Ogura*", not least because of its title. While *Ogura* was primarily concerned with capsules for oral use, that was not a "significant objection" as it also addressed the use of HPMC in capsules for inhalation.<sup>15</sup> Given that tiotropium was an ester and esters were known to be moisture sensitive long before the priority date, the skilled person would have looked for solutions for reducing the moisture content of the capsule material and, in light of *Ogura*, "would have noted the benefits from using HPMC as capsule material and would without any practical or technical challenges have been capable of formulating a powder tiotropium with

---

<sup>14</sup> At page 23 of the translation furnished to the Court.

<sup>15</sup> *Ibid*, at page 24.



*lactose as carrier in a capsule of HPMC*".<sup>16</sup>

38. The Court of Appeal went on to state that there was nothing in the disputed patent to suggest that the HPMC capsule material should be treated to achieve a specific moisture content and, consequently, the reduced moisture content of HPMC capsules appeared to the court to be an inherent property of the HPMC material and the 2%-5% range described in *Ogura* fell within the range of  $\leq 5\%$  claimed in claim 6 of the patent [amended claim 6 here].<sup>17</sup> The court agreed with the District Court that the lower moisture levels set out in the patent had been fixed arbitrarily and there was “*nothing in the patent itself to substantiate that anything would be achieved by using HPMC capsules with a moisture level of less than 2%, as compared to using capsules with a moisture level between just under 4% and 6%*” (which the Court regarded as the normal moisture level).<sup>18</sup> In any event, the Court was of the view that the specification of those levels had been “*fixed arbitrarily*”. Claims 6-8 were therefore invalid and the Court of Appeal agreed with the conclusion of the District Court that claims 9-13 lacked inventiveness and were invalid also. The Court of Appeal stated that it had found support for its reasoning in the proceedings regarding the 220 Patent in other jurisdictions, including the ruling of the Hague District Court and the judgment of Morgan J in the Patents Court.

39. The Court was told that the decision of the Borgarting Court of Appeal was final.

---

<sup>16</sup> *Ibid*, at page 25.

<sup>17</sup> Also at page 25.

<sup>18</sup> Also at page 25. See also page 27.

40. Before leaving the Norwegian proceedings, I note that, though they are not referred to specifically in the decisions of the District Court or the Court of Appeal, it is apparent from the evidence given in the High Court here that Professors Buckton and Birchall also gave evidence in Norway.

*The Netherlands*

41. The claims in dispute in the Netherlands were also in the same terms as the amended claims here. The District Court in the Hague concluded that the technical effects asserted in the specification (stability, high metering accuracy, good emptying characteristics and so on) were not made plausible – “*not even in the slightest*” – by the specification.<sup>19</sup> That was not changed by the results of the post-publication experiments submitted by Boehringer because the effect described in the patent had to be made plausible “*by itself without this post-published evidence.*”<sup>20</sup> It followed, in the court’s view, that the moisture level of  $\leq 5\%$  in claim 6 had to be disregarded and claim 6 had to be assessed as if the technical problem it was addressing was the provision of an alternative capsule material (to gelatin) that was suitable for tiotropium bromide in an inhalable powder form mixed with lactose.<sup>21</sup> The skilled person looking for an alternative to gelatin (and the judgment of the District Court records the agreement of the parties that the skilled person was in fact a team that included a clinician) would

---

<sup>19</sup> Para 4.13, at page 13 of the English translation furnished to the Court.

<sup>20</sup> Para 4.14.

<sup>21</sup> Para 4.15

have made their way, by way of *Casaburi*, to *Ogura* and would have been motivated to try HPMC as a capsule material. The court was not persuaded by the various arguments made by Boehringer as to why the skilled person would not have been motivated to find an alternative for gelatin or would have been deterred from trying HPMC. Claim 6 was thus invalid for lack of an inventive step. As regards claims 7 and 8, the moisture levels referred to in them were “*arbitrary parameter values*” and those claims lacked any inventive step and were invalid also. The court held claims 9-13 invalid also.

42. In a decision post-dating the High Court Judgment, the Hague Court of Appeal upheld the decision of the District Court. It rejected Boehringer’s argument that the skilled person, in light of the description, using their common general knowledge and with “*a mind willing to understand*”, would conclude that the core of the invention lay in the use of capsule material with lower-than-ambient levels of moisture content, thus implying the need for an active drying step.<sup>22</sup> Looking at the description, the skilled person would see that the patent referred to “*reduced moisture content*” as being equivalent to a moisture level of less than 15%. Even if that were to be read as referable only to gelatin capsules, and if an upper limit of 8% were read in for HPMC capsules, the skilled person would understand that HPMC with a moisture content of less than 8% (and the court noted that Boehringer’s own evidence was to the effect that it was “*generally accepted that the moisture content of HPMC under ambient conditions was between 5% and 7%*”<sup>23</sup>) already had a reduced moisture content and would understand that the advantages mentioned in the description were already achieved at that level and

---

<sup>22</sup> Paras 4.2 and 4.3 of the English translation furnished to the Court.

<sup>23</sup> At para 4.3.

would not deduce that, in order to obtain the advantages of the invention, an active drying step to reduce moisture levels to below ambient levels was required.<sup>24</sup> The patent did not “*show that and why the percentages of  $\leq 5\%$ ,  $\leq 4\%$  and  $\leq 2\%$  mentioned in modified claims 6-8 make any difference*” in the sense that something else or better is achieved than with a moisture level between 5% and 8%. Neither had Boehringer sufficiently substantiated its arguments that the average skilled person would assume on the basis of his common general knowledge that a reduction in moisture content to 5% or below would have any other or further advantages. “*On the contrary*”, the Court noted, “*Boehringer has expressly stated that the average skilled person would not assume that a drier capsule would necessarily be better, given the disadvantages associated with too dry capsules, such as problems with static electricity*”<sup>25</sup> These lower moisture levels did not disclose any technical effect and could only be regarded as “*arbitrary choices in which no contribution to the state of the art based on inventive activity can be recognised.*”<sup>26</sup> In arriving at that conclusion, the court specifically upheld the lower court’s rejection of the post-published data. The Court of Appeal also agreed with the lower court’s conclusion that the use of HPMC as a capsule material was obvious. In doing so, it placed significant reliance on *Ogura: Ogura* “*points [the skilled person] in the direction of HPMC as an alternative for gelatine as capsule material*”.<sup>27</sup> Bohringer had argued that according to the state of the art, gelatin capsules

---

<sup>24</sup> Para 4.4

<sup>25</sup> At para 4.6.

<sup>26</sup> At para 4.8.

<sup>27</sup> Para 4.22. The Court had noted earlier in its decision that Boehringer’s claimed invention lay in the use of an HPMC capsule with a reduced moisture content not the use of a HPMC capsule as such (under ambient conditions) (at para 4.9)

were seen as satisfactory and therefore the average skilled person would not have been motivated to investigate alternatives but the Court rejected that argument on the basis that, in principle, the average skilled person was always motivated to solve an existing problem (that being to provide an alternative capsule material suitable for the administration of tiotropium bromide in an inhalable dry powder form.<sup>28</sup>

43. Again, the Court was told that the Hague Court of Appeal's decision was final and not subject to further appeal.

*Spain*

44. The claims in the Spanish patent appear to differ from the 220 Patent either in its original form or on the basis of the amended claims. As here, Boehringer had sought to meet the validity claim by amending the claims in the patent as granted. One of those modified claims (claim 3) was similar in its terms to amended claim 6 here.<sup>29</sup> As the Judge noted, these amended claims were rejected on the basis of added subject-matter. However, the judgment of the Patent Division went on to express the view that new claim 3 lacked any inventive step. While the Judge stated that the prior art cited in the Spanish proceedings was different to the prior art cited here, *Ogura* was cited and relied on by the Patent Division,<sup>30</sup> the court noting that it described HPMC capsules as an alternative to gelatin, with a moisture value of 2%, less than the 5% value in claim 3.

---

<sup>28</sup> Pars 4.10-4.12.

<sup>29</sup> Pare 3.2 at page 8 of the translation furnished to the Court.

<sup>30</sup> Para 3.7.

The court also noted that *Ogura* described the advantages of HPMC as a gelatin alternative, including its naturally low moisture content.

*England and Wales*

45. Finally, I come to the position in England and Wales. In *Teva UK Limited v Boehringer Ingelheim Pharma GmbH* [2015] EWHC 2963 (Pat), Morgan J in the Patent Court upheld Teva's challenge to the validity of the 220 Patent. Again, Boehringer had sought to meet the challenge by seeking to amend the claims. The proposed amended claims were similar to though not identical to the amended claims here. New claims 5 and 6 (in EW) correspond to amended claims 6 and 8 here but, for reasons which are unclear, the amended claims in England and Wales did not include any claim corresponding to amended claim 7 here (which, it will be recalled, refers to HPMC capsule material having a moisture content of less than 4%).
46. Professors Buckton and Birchall also gave evidence before Morgan J (as did Professor Geddes). For the purposes of that litigation, it was agreed by the parties (in contrast to the position here) that the skilled person was in fact a skilled team consisting of a clinician as well as a formulation scientist (para 47).
47. On what he characterised as the "*principal challenge*" – that of conventional obviousness – Morgan J first found that the possible use of HPMC as a capsule material in a DPI was not part of the common general knowledge of a formulation scientist as of the priority date. The conventional material as at that date was gelatin and *Ogura*

would not have been sufficiently widely read so as to add to the common general knowledge of the formulation scientist (para 90). However, *Ogura* was part of the prior art as of the priority date and the reaction of the notional skilled formulation scientist to it had to be considered. It appeared from the evidence that many of the relevant statements in *Ogura* would have been known to be true by a skilled formulation scientist as part of his common knowledge, such as the brittleness of gelatin (para 92). Preferring the evidence of Professor Buckton over the evidence of Professor Birchall, Morgan J concluded that the desirability of a low moisture content for a capsule material for DPI use was also part of the common general knowledge as of the relevant time (paras 93-95). On that basis, a formulation scientist would have regarded the information in *Ogura* as “*particularly relevant and interesting in the context of formulating an active ingredient for delivery by a dry powder inhaler*” (para 95). Therefore, at least *prima facie*, “*a formulation scientist supplied with the Ogura article would be informed by it that the supplier of HPMC capsules was recommending them for use in dry powder inhalers and was stating that they were preferable to gelatine capsules whenever there was a concern about the moisture content of gelatine capsules*” (para 96) and “*the mere idea of using HPMC as the capsule material does not require innovation or imagination on the part of the formulation scientist*” (para 97).

48. Morgan J then considered and rejected a number of reasons advanced by Boehringer as to why the formulation scientist would not have followed up on the idea in *Ogura* to use HPMC as a capsule material. In his view, the formulation scientist would get out of *Ogura* that he had the option of choosing HPMC as the capsule material and he “*would show a great deal of interest in the content of Ogura in the present context*” (para 106).

The practical and technical reasons advanced by Boehringer as to why the formulation scientist would rule out the choice of HPMC as the capsule material did not persuade Morgan J. Having considered all of the evidence, he concluded that, in light of *Ogura* and in light of the common general knowledge about the general properties of HPMC, it was “*obvious to try*” HPMC as a potentially suitable capsule material (para 120).

49. On the premise that the claimed invention related to the use of HPMC as the capsule material for the use of tiotropium in a DPI, Morgan J considered that such did not require any degree of invention and was obvious (para 122). Applying the problem and solution approach favoured by the EPO, and taking the technical problem as being that of devising a treatment for COPD and asthma and/or to choose an appropriate capsule material, Morgan J again considered that the use of HPMC as the capsule material in that context was obvious (para 123).
50. However, Morgan J noted that the relevant claims described the use of HPMC as the capsule material “*in more closely defined terms.*” Having set out the relevant claims, and having brought together the various statements made in the patent about moisture content, Morgan J noted that it identified a wide range of capsule materials without discussing their relative merits and without referring to any tests of any of the materials. The patent defined “*reduced moisture content*” as being less than 15% but did not indicate what advantages, if any, might or would accrue if the moisture content was reduced to the other levels referred to in the patent. The patent did not “*attempt to justify the choice of different figures by describing, much less demonstrating, the consequences of making a product which conforms to such figures.*” (para 132 as well



as para 136)

51. Morgan J then referred to a number of authorities on the issue of arbitrariness/plausibility and summarised the principles established by them (with particular reference to *Generics (UK) Ltd t/a Mylan v Yeda Research and Development Co Ltd* [2012] EWHC 1848 (Pat)). I shall refer further to this part of Morgan J's judgment later when addressing the *Agrevo* obviousness issue. He then noted (in para 135) that the 220 Patent identified the suggested technical problem in fairly limited terms, stating that "*a capsule material with 'a reduced moisture content' helps to increase the stability of the active ingredient, tiotropium bromide.*" He further noted that the patent stated that the "*concept of a reduced moisture content within the scope of the present invention is defined as being equivalent to a TEWS moisture level of less than 15%.*" The next paragraph of his judgment is an important one and warrants citation in full:

*"136. It was well known as at 1 June 2001, that gelatine had an average moisture content of 13% to 15%. Therefore, the concept of a reduced moisture content to achieve sufficient stability of the active ingredient to create the allegedly invented product was achieved by the use of the conventional capsule material, gelatine. As earlier explained, the patent then proceeded to refer to a number of different moisture levels below 15%. It said that the lower moisture levels were "preferable". The patent specified a large number of alternative moisture levels. Amongst other things, it specified levels of less than 12% and less than 1% and a number of other figures between 12% and 1%. The patent*

*did not offer any explanation of what would be achieved by using a capsule material with those different moisture levels. As regards HPMC specifically, with an average moisture content of 2% to 5% (or possibly 4% to 6%), no explanation was offered as to what the technical advantage would be if one used HPMC capsules with their average moisture content instead of gelatine with a higher moisture content or what technical problem if any was created by using HPMC without drying it (apparently within amended claim 5) and what technical advantage would be achieved by drying it to less than 2% (within amended claim 6). Of course, it might be said that the teaching of the patent was the basic message that a drier capsule would be better than a more moist capsule. If that is the teaching of the patent, I have already held on the basis of Professor Buckton's evidence that that was common general knowledge. I referred earlier to Professor Birchall's attempt to qualify Professor Buckton's evidence by suggesting that one would not know precisely what the effect would be of using a capsule material (other than gelatine) with less moisture than gelatine. If I were to accept that evidence, it seems that it weakens further the Defendant's position in relation to the point that the moisture levels in the patent are purely arbitrary. If Professor Birchall were right, then the patent gives one no cause to think that the chosen moisture levels have been chosen for technical reasons. It is even more likely that they were chosen without a technical justification and were accordingly arbitrary.”*

52. As was clear from the authorities (Morgan J continued),*“if the moisture levels in the claims were arbitrary then the claims are obvious and invalid”* and, in such

circumstances, the results of later experiments, not referred to in the patent, could not save the claims (para 137). It was therefore not necessary to consider other arguments that had been made as to sufficiency or plausibility.

53. The Court of Appeal (Kitchin and Floyd LJJ) refused leave to appeal: [2016] EWCA Civ 1296, [2017] FSR 29. Two arguments were advanced by way of challenge to Morgan J's finding that, based on *Ogura*, the skilled person would follow up the idea of using HPMC. It was said, firstly, that the High Court judge had wrongly interpreted the evidence of Professor Buckton as meaning that the skilled person would regard drier capsules as inherently advantageous. Reliance was placed in that context on what Professor Buckton had said in a report prepared for these proceedings. Floyd LJ did not think that there was anything in that point as, faced with a material with a naturally lower water content (HPMC), the skilled person would see an immediate advantage over gelatin. The second argument was that the judge had wrongly dismissed the 2% moisture limit as arbitrary. Floyd LJ was equally dismissive of that argument, observing that "*there was no significance in the moisture level being below 2% as opposed to being above it.*"
54. As a result of the refusal of leave to appeal, the decision of Morgan J is final.

## *Comity*

### *Ranbaxy*

55. Before the High Court - and again before this Court - Teva relied on *Ranbaxy* as authority for the proposition that, in considering the validity of the 220 Patent, the Irish courts should not “*lightly depart*” from the decisions arrived at in the other EPO jurisdictions where the very same issue had been litigated.
56. The issue in *Ranbaxy* was the construction and scope of an Irish patent held by the defendant for a synthetic compound which was the active ingredient in Lipitor, an anti-cholesterol drug. Similar issues had arisen in the United Kingdom, as well as in the United States, Canada and Australia and decisions from those jurisdictions were opened to the High Court. Clarke J expressed the need for some caution in considering such decisions given that the patents at issue were not identical and that there were differences in the applicable statutory regimes (para 50). However, “*less caution*” was necessary in relation to decisions of the courts of the United Kingdom in this context given that both Ireland and the UK were signatories to and had ratified the European Patent Convention and that Irish Patent legislation was closely modelled on UK law (para 52). Having noted “*by way of caution*” that each case had to be determined on the basis of the evidence presented to the court (para 52), Clarke J explained the distinction between the persuasive effect of decisions from other common law jurisdictions – which is independent of any factual connection between the litigation in that jurisdiction and the litigation here – and the “*entirely separate*” issue of the status of “*foreign*

*litigation which touches upon the same actual matters”*. It was, in his view, important not to confuse the two concepts. As to the former, “[w]hat is afforded the status of persuasive authority are the legal principles to be derived from the decision rather than the decision itself” (para 53). As to the latter:

“[54] ... The principle of the comity of courts requires that the courts in one jurisdiction should not lightly depart from a decision on the same issue made by a court of competent jurisdiction in another country which had to deal with that issue as part of litigation properly under its consideration. Thus, for example, where the courts in one jurisdiction have interpreted a contract in an particular way and where the same contract comes to be interpreted, in a separate dispute between the same or similar parties, in the courts of another jurisdiction, then the comity of courts requires that the interpretation of the contract in the second proceedings should not lightly depart from the interpretation given to the same contract in the first proceedings.”

[55] This latter principle, it seems to me, ought also apply, though obviously to a more limited extent, where the issue, while not identical, is very similar. For those reasons it seems to me to be appropriate, subject to the caveats relating to differences in statutory law, jurisprudence, the patents themselves and the evidence which I have already identified, to pay appropriate regard to the international decisions in the related cases.”

In *Ranbaxy*, Clarke J applied the “*no rational patentee*” test that had been articulated by Jacob LJ for the Court of Appeal in *Ranbaxy U.K. Ltd v Warner-Lambert Co* [2006] All E.R. (D) 322 and reached the same conclusion as to the proper scope of the patent in issue as had been reached by the Court of Appeal. Accordingly, Ranbaxy’s claim failed, as it had in the other jurisdictions in which the issue had been litigated.

57. There appears to have been no dispute in the High Court that the applicable principles were as set out in *Ranbaxy*. The Judge was not invited to depart from that decision. On appeal, *Ranbaxy* was again accepted as correctly setting out the principles of comity.

*Gilead Sciences Ltd v Mylan SAS*

58. *Ranbaxy* was recently considered by this Court in *Gilead Sciences Ltd v Mylan SAS* [2021] IECA 22. That decision post-dates the hearing of this appeal. *Gilead* was concerned with the validity of a Supplementary Protection Certificate (SPC) held by Gilead for TRUVADA, a combination therapy for the treatment of HIV infection. SPCs are a creature of EU law, provided for under EU Regulation (Regulation (EC) 469/2009), that operate to extend the period of patent protection for pharmaceutical and plant protection products that are subject to regulatory authorisation. SPCs are, however, granted by individual Member States in respect of their particular territories. A number of successful challenges had been brought to the validity of SPCs issued in respect of TRUVADA elsewhere in the EU, including in England & Wales and the defendants relied on the decisions in those challenges in support of their claims that the

Irish-issued SPC was invalid and in particular contended that this Court should “*not lightly depart from*” the decision of the EW Court of Appeal. In her judgment (with which Haughton and Murray JJ agreed) Costello J stated:

*“90. It seems to me that, in these circumstances (but noting that neither party in this case canvassed the possibility of an issue estoppel arising from a final decision of the courts of another jurisdiction in proceedings between the same parties and applying the same EU law test to identical SPCs – see Rio Tinto Zinc Corp. v. Westinghouse Electric Corp., RTZ Services Ltd v. Westinghouse Electric Corp. [1978] 1 All ER 434; [1978] AC 547), this court should start from the proposition that it ought to follow the decision of a final court of a member state of the EU where it is applying an identical EU law test to the identical SPC. In this instance, the decision of the English Court of Appeal is final as leave to appeal was refused by the UK Supreme Court. It is for the party who asserts to the contrary to satisfy this court why it should not follow this precedent. It may do so by reference to material factual differences or if it can demonstrate that a decision was reached on a clearly erroneous application of EU law.”*

As Costello J noted, Gilead alleged that there were evidential differences which warranted a different outcome in this jurisdiction and also alleged that the Court of Appeal of England and Wales had erred in law in its application of the SPC Regulation. Costello J examined these arguments in some detail before rejecting them and concluded that the Court ought to follow the decision of the EW Court of Appeal.

59. Costello J went on to refer to the decisions made elsewhere in the EU on the validity of the SPC, noting that all had concluded that the SPC was invalid and that no judgment upholding the SPC had been cited to the Court. It is clear that the Court considered that those decisions weighed significantly against the position of Gilead.
60. As in *Gilead*, no question of issue estoppel was canvassed in argument here and, accordingly, it is not necessary to consider the decision of the House of Lords in *Rio Tinto Zinc Corp v Westinghouse Electric Corp*.

*Authority from England and Wales*

61. The issue of comity has also been considered in the specific context of EPC patent litigation by the UK Supreme Court. In *Generics UK Ltd (trading as Mylan) v Warner-Lambert Co* [2018] UKSC 56, [2019] 3 All ER 95 (referred to in detail below in the context of considering Teva's objections to amended claims 6, 7 and 8 on plausibility grounds) a particular claim of the patent (claim 3) was challenged as insufficient. Claim 3 had been upheld as sufficient in litigation in France, Germany and Sweden, a fact on which the patentee placed some reliance. Giving the leading judgment, Lord Sumption stated that this was:

*"[55] .... more than a forensic point. If courts in other jurisdictions have upheld Claim 3, that may serve as a reality check against my own, less favourable conclusions. Other things being equal, it would be unfortunate if different*



*jurisdictions party to the EPC arrived at different conclusions concerning the same patent. However, other things are rarely equal, and the force of this point depends entirely on how far the factual and technical evidence before the foreign court was the same as the material before Arnold J, and how far their domestic statutes were comparable”*

Lord Sumption then addressed the decisions of those other courts and explained why they did not cause him to doubt the conclusions he had reached as a matter of English law, in light of the evidence given and the facts found in the proceedings (at paras 56-60).

62. The issue was also addressed by the Supreme Court (per Lord Hodge) in *Actavis Group PTC v ICOS Corporation* [2019] UKSC 15, [2020] 1 All ER 213. The issue there was whether the claims in a dosage patent were obvious. The issue had been the subject of litigation in a significant number of EPC States, with different views being reached on the issue of obviousness. Lord Hodge began by observing that “*while consistency of approach between the domestic courts of the signatory states to the EPC on matters of principle is desirable, we are not bound by the judgments of other national courts and it is possible that national courts applying the same law may come to different conclusions for a various reasons*” (para 97). Lord Hodge then briefly addressed the decisions particularly relied on by the claimants and commented that one “*can draw some support from judicial decisions in other national courts which reach the same conclusions as one has come to. But it is necessary to recognise not only that the first instance decisions in the Netherlands and Germany are the subject of appeals but also*

*that the evidence led before the different courts may differ and, even when the same evidence is led, each court's findings of fact based on that evidence may not be the same*" (para 100). Having referred to some of the findings made in the Netherlands and Germany and how they differed from the findings made in the English proceedings, Lord Hodge concluded in the following terms:

*"[101] Because of the differences in the evidence led, the manner by which it is tested, and the differing findings to which that evidence gives rise, one may derive support from the approach to the question and the methods of reasoning of other national courts but should never rely uncritically on the outcome."*

### **The Judge's Treatment of the Comity Issue**

63. In the introductory section of his Judgment, the Judge noted that the proceedings before him did not represent the first time that *"the wider Teva and Boehringer families have tilted with each other in the courts of European states as regard the 220 Patent"*.<sup>31</sup> He then summarised the then current state of play in the jurisdictions to which I have referred.
64. Observing that the judgment of Morgan J in the Patents Court had been the subject of particular focus at the hearing, the Judge noted the submissions of Boehringer to the effect that Morgan J had erred in his assessment and, therefore (so it was urged) the

---

<sup>31</sup> Judgment, paragraph 14.

High Court should feel free to depart from his findings. In the Judge’s view, those contentions involved “*something of a misunderstanding as to the role of persuasive authority.*” The decisions to which the Court had been referred were persuasive “*as to their principles*”. The Court’s interest in the judgment of Morgan J was limited to any insight it offered into applicable legal principle and “*the court has no view and makes no comment on Morgan J’s interpretation or treatment of the evidence before him in Teva.*”<sup>32</sup>

65. The Judge considered that this followed from *Ranbaxy* and went on to set out a lengthy passage from the judgment of Clarke J, including the passages set out above. Having offered some observations regarding the UPC and also about Brexit (which in my view do not bear on any issue in these proceedings), the Judge noted that “*there is no material difference between the respective statutory regimes of Ireland and the United Kingdom, no material difference between the jurisprudence of the two jurisdictions, and many parallels, it seems, between the evidence tendered in both jurisdictions.*” That being so, the Judge stated that, for the reasons set out in *Ranbaxy*, the judgment of Morgan J “*so far as the legal principles to be derived from the decision are concerned, falls to be viewed as particularly persuasive.*”<sup>33</sup> As for the decisions from the other European jurisdictions, “*they likewise have a status, with regard to the legal principles to be derived therefrom, of persuasive authority, albeit, for the reasons stated by Clarke J, comparatively less persuasive authority at this time.*”<sup>34</sup>

---

<sup>32</sup> Judgment, paragraph 20.

<sup>33</sup> Judgment, paragraph 25.

<sup>34</sup> *Ibid.*

66. Teva says that these observations on the part of the Judge disclose a misunderstanding of *Ranbaxy*. It says that where – as here – a decision of a foreign court involves “*a decision on the same issue made by a court of competent jurisdiction in another country which had to deal with that issue as part of litigation properly under its consideration*”, the duty of an Irish court extends beyond giving persuasive weight to the *legal principles* to be derived from the foreign decision but rather requires weight to be given to the *decision* itself, such that an Irish court “*should not lightly depart from a decision on the same issue.*” For the reasons set out below, that submission is, in my view, correct. But I would observe that, in any event, far from viewing the principles to be derived from the decision of Morgan J as “*particularly persuasive*”, the Judge does not subsequently refer to any aspect of that decision – either as to its reasoning or its outcome<sup>35</sup> - or indeed to *any* of the other decisions on the 220 Patent to which he was referred in his Judgment. Having been referred to briefly at the start of the Judgment, those decisions effectively disappear from view as the Judge entered into his substantive consideration of the issues in the proceedings and did not feature again in the Judgment, at *any* level of analysis or discussion. Anyone reading the substantive analysis of the issues in the Judgment would be left wholly unaware of the fact that those issues had been litigated in other EPC jurisdictions and determined adversely to Boehringer in every case.

---

<sup>35</sup> The Judge does refer to an aspect of the evidence of Professor Buckton in the EW proceedings at pages 44-45 of the Judgment. That was the subject of specific submission by Teva and I will discuss it when I come to address Teva’s challenge to the Judge’s assessment of the evidence.

67. Like *Ranbaxy*, this is a patent action. Unlike *Ranbaxy*, all of the decisions from other jurisdictions relied on by Teva emanated from jurisdictions within the EPE. All concerned the 220 Patent. Neither the High Court nor this Court was referred to any decision from any jurisdiction outside the EPC. Such decisions might well fall to be treated differently.
68. This action differs from *Gilead* in that the IP right at issue there was a *sui generis* right (the SPC) created by EU law and, accordingly, its grant and revocation was subject to uniform rules throughout the EU, the interpretation of which was ultimately a matter for the CJEU (which had, in fact, given a decision concerning the equivalent EW SPC on an Article 234 reference from the Patent Court).
69. The Judge here was of course entitled – indeed obliged – to make his own assessment of the arguments and evidence heard by him. As *Ranbaxy* makes clear, the principle of comity did not require the High Court here to reach the same outcome as the other courts which had considered the validity of the Patent. In the language of Lord Hodge in *Actavis Group PTC v ICOS Corporation*, the Judge could not “*rely uncritically on the outcome*” of other challenges to the 220 Patent. But *Ranbaxy* required the Court to engage with the *decisions* made by those courts. That obligation went beyond merely giving a persuasive status to the legal principles applied in those decisions and it is clear that, in adopting that approach, the Judge fell into the confusion highlighted by Clarke J in *Ranbaxy*. The Judge was required to address the *decisions* made elsewhere and to give those *decisions* persuasive status.

70. There are, no doubt, many points of difference that can be identified as between the proceedings in this jurisdiction and the actions elsewhere. There are certain differences as between the precise terms of the amended claims sought to be relied on by Boehringer. In some jurisdictions, the skilled person was taken to be a team that included a clinician, whereas in others (including here) it was taken to be a formulator alone. *Agrevo* obviousness may not have been advanced as a ground of challenge in all jurisdictions. There were some differences in the cited prior art and, more generally, differences in the evidence (though it is notable that Professors Buckton and Birchall gave evidence in Norway and in England and Wales as well as in this jurisdiction). The experiments proffered by Boehringer also differed somewhat from jurisdiction to jurisdiction. These differences are unsurprising: no trial will exactly mirror another. Even where the witnesses are the same, there may be differences in the evidence they give, as Clarke J explained in *Ranbaxy* itself (at para 52). As O’ Donnell J aptly observed in *McDonagh v Sunday Newspapers Limited* [2017] IESC 59, [2018] 2 I.R. 79, trials are not repeatable in the manner of scientific experiments (at para 109).
71. While all of these differences are potentially material in assessing the weight (if any) to be given to the decisions of the various foreign courts regarding the 220 Patent, they certainly do not justify the Judge’s failure to engage with those decisions. Clearly, the injunction in *Ranbaxy* not to “*lightly depart*” from such decisions is not fulfilled by disregarding them entirely, as the Judge did here. Nor is it the case, as Boehringer suggested in argument, that, for the principle in *Ranbaxy* to be engaged, an Irish court must be “*presented with all of the material that was presented in the other jurisdictions to understand the nature and import of the decisions given there.*” Any such general

requirement would render the principle of comity practically inoperative.

72. All of the foreign decisions here concerned the revocation of the Patent at issue in these proceedings (albeit with amended claims that, in some cases, appear to differ, at least in their detail, from the amended claims here). The legal framework within which the issue arose – Article 138 EPC - was the same. The decisions set out in detail the reasoning of the various courts. In *every* jurisdiction – including but not limited to the two other jurisdictions in which Professors Buckton and Birchall had given evidence – the Patent was revoked for lack of inventive step/obviousness. In *every* jurisdiction in which the issue was addressed – including Norway and England and Wales, where Professors Buckton and Birchall gave evidence - the claims corresponding to amended claims 6-8 here were found to be arbitrary and implausible.
73. While all these jurisdictions are parties to the EPC, England and Wales is perhaps in a special position. As the Judge himself observed, “*there is no material difference between the respective statutory regimes of Ireland and the United Kingdom, no material difference between the jurisprudence of the two jurisdictions, and many parallels, it seems, between the evidence tendered in both jurisdictions.*” That being so, the conclusions reached by Morgan J in the Patent Court would appear to have particular resonance here.
74. In these circumstances, it is very striking that the Judge reached diametrically-opposed conclusions to those arrived at elsewhere, without any – or at least any express - explanation for doing so. It is suggested by Boehringer that it can be inferred from the

Judge's analysis why his conclusions depart so markedly from the conclusions reached elsewhere. But it ought not to be a matter of inference: the reasons for departure ought to have been sufficiently explained. None is provided here. Ultimately, it was said by Boehringer that there were significant differences between the evidence in England and Wales and the evidence given here. Even if that is so – and given that the experts were the same, the vague suggestion that there were significant differences in their evidence is surprising to say the least – it was incumbent on the Judge to give *some* indication that such was the case. It was also suggested by Counsel for Boehringer that courts elsewhere – with specific reference being made in this context to Morgan J – had fundamentally misunderstood the invention claimed by the Patent. Again, if that was the view taken by the Judge, one would expect that it would have been articulated by him (as will appear, I do not consider that there is any substance in this point in any event).

75. The Judge's failure to engage with these decisions (including but not limited to that of Morgan J) was, in my view, a significant departure from the approach mandated by *Ranbaxy*. The principle identified by Clarke J in *Ranbaxy* apply with arguably greater force here. Even if EPC rules governing the revocation of patents do not embody a uniform test in quite the same way or to the same degree as the test for the validity of SPCs at issue in *Gilead*, there is undoubtedly significant commonality between the regimes of the EPC Contracting States. That is also manifest from the decisions relied on here. While those decisions did not necessarily warrant precisely the same precedential status as decisions from other Member States regarding the validity of SPCs (as explained in *Gilead*), the fact is that the Judge failed to give *any* weight



whatsoever to *any* of those decisions.

76. The exercise of engaging with the decisions from the other EPC jurisdictions and explaining why the conclusions reached by the High Court differed so significantly from the conclusions that had been reached in those other jurisdictions would have served an important function. It would have compelled the Judge to critically interrogate the sufficiency of his reasoning and the soundness of his conclusions before reaching a final decision. That is, I think, what Lord Sumption had in mind when he referred in *Generics UK Ltd (trading as Mylan) v Warner-Lambert Co* to a “*reality check*”. The Judge failed to carry out any such reality check here.
77. The circumstances here are particular, perhaps exceptional. The Judge failed to have regard to the many EPO decisions opened to him, which considered in detail issues and arguments identical or near identical to the issues and arguments advanced in the High Court here. All of those decisions went the one way; in every case the 220 Patent was held to be invalid. *Ranbaxy* required the Judge to engage with those decisions. He failed to do so and instead proceeded as if those decisions simply did not exist. In the circumstances, the Judge’s failure to consider and engage with the EPO authority regarding the 220 Patent was a serious error.
78. I shall defer for the moment any further consideration of the question of the implications of that error for the disposition of the appeal.

## VII - THE JUDGE'S ASSESSMENT OF THE EVIDENCE

### **Did the Judge wrongly discount the evidence of Professor Buckton?**

79. The evidential findings made by the Judge were critical to the outcome of Teva's conventional obviousness challenge. Evidential issues played a far less significant role in the determination of the *Agrevo* challenge and the challenge to the sufficiency of the 220 Patent. The findings made by the Judge on the conventional obviousness claim involved, in every case, choosing to accept the evidence of Professor Birchall and reject the evidence of Professor Buckton. Whether the Judge assessed the evidence of Professor Buckton fairly is a critical issue in this appeal.

### *The Judgment*

80. The Judgment first refers to Professors Buckton and Birchall in the context of addressing the identity of the skilled addressee of the Patent. Having noted their differing views on that question, the Judge observes:

*“Both Professors Birchall and Buckton are distinguished professional gentlemen. However, the court's impression as to the degree and relevance of the respective expertise of each of the two professors when it comes to the issues at play in the within proceedings was significantly coloured by the fact that, under cross-examination, it emerged that Professor Buckton had himself done no dry powder inhaler (“DPI”)-related work before 2005 and thus no work*

*involving, let alone focusing on, capsules for inhalation medicines by or before the priority date. Additionally, he was never involved in any project or task at any time in which he formulated a capsule-based DPI using a gelatin capsule. He therefore had no personal experience of using gelatin or other capsules for inhalation products either at the priority date or in the period prior thereto, or of using gelatin capsules for such formulations. By contrast, from 1994 onwards Professor Birchall was working in a laboratory on the delivery of medicines to the lung using different types of inhaler devices and was working specifically on DPIs and propellant-driven metered dose inhalers from 2000. Thus, he brought additional "working at the coalface" experience to his expert evidence that Professor Buckton, with respect, did not."* (Para 39; at page 30)

81. The Judge next refers to the evidence of the two Professors at paragraph 42, in the context of considering the issue of common general knowledge. He indicates that aspects of the evidence "*rather coloured its impression generally in favour of Professor Birchall*" on this issue, namely the fact that Professor Buckton had been "*given up-front by Teva's solicitors all of the prior art cited in the within proceedings*". Having referred to the fact that Professor Buckton had stated in his evidence that he had consulted a textbook the name of which he could not remember, as well as his evidence that he could not recall whether he had seen *Ogura* before the priority date (a point to which he returns at paragraph 82), the Judge stated:

*"Having regard to all of the foregoing and to the observations made previously above as to Professor Buckton's want of 'coalface' experience in the DPI*

*capsule context, when compared with Professor Birchall, the court respectfully does not accept the contention of Teva, in its written submissions that, when it comes to the within proceedings and the issues here at play, Professor Buckton, though a distinguished professional, was, in the circumstances of this case, a witness 'well placed to address all of the formulation issues in the case'; certainly, he was not as well placed as Professor Birchall.*" (Para 43; page 39)

I would observe that, in this passage, the Judge appears to go further than simply indicating a view that Professor Buckton was not "*as well placed*" as Professor Birchall to give expert evidence on the "*formulation issues in the case*" and appears to doubt whether Professor Buckton was "*well-placed*" to give such evidence at all. The "*formulation issues*" effectively encompassed the entire field covered by the evidence given by Professors Buckton and Birchall.

82. At paragraph 45, the Judge makes the first of a significant number of references to the "*preferred*" evidence of Professor Birchall. At paragraph 60, in the context of addressing the standard practice of formulators in 2001, the Judge refers to such evidence being "*generally preferred for the reasons stated previously above*". At paragraph 62, there is a reference to Professor Birchall "*bringing to bear his practical experience as a professional working 'at the coalface of enterprise at the relevant time.*" It is clear from the context that the reference to "*relevant time*" here is to June 2001. Then at paragraphs 102 (common general knowledge re reduction of moisture/perceived issues re use of gelatin for DPI formulations), 119 (natural water content of HPMC), 183 (circulation/target audience of the journal in which *Barnes* was

published) and 185 (circulation/target audience of the journal in which *Maesen* was published) there are variations on the general theme of Professor Birchall's evidence being "*preferred*"/"*generally preferred*" by the court for the reasons outlined previously. Thus, for instance, it is said at paragraph 119 that Professor Birchall's "*evidence has generally been preferred throughout this judgment over that of Professor Buckton for the reasons stated elsewhere above*" - with an additional reference in paragraph 183 to "*the 'at the coalface' nature of [Professor Birchall's] experience*". As is evident from the statement from paragraph 119 just cited, the Judge's general preference for the evidence of Professor Birchall applied "*throughout*" the Judgment and thus appears to have been operative in relation to all issues in respect of which there was a conflict between that evidence and the evidence of Professor Buckton

83. A further aspect of the Judge's assessment of the evidence of Professor Buckton which Teva says is significant relates to what the Judge appears to have considered as a material change in his evidence on the issue of whether water would, as a matter of principle, be considered to be a "*general enemy in formulation*" and whether formulators would have taken the approach of "*the drier the better*". In his first report, Professor Buckton identified a number of respects in which the presence of water was a relevant consideration in formulating a DPI and where water could give rise to problems (para 2.32). "*Consequently*", he continued, "*a skilled formulator at the priority date would usually seek to keep the formulation dry enough to ensure physical and chemical stability*" (para 2.33). There was a footnote to that statement, in the following terms:

*“In my first report in the UK and Norwegian proceedings I wrote ‘as dry as reasonably possible’ in this sentence, that was taken to mean that I regarded the best approach to formulating DPIs to be the ‘the drier the better’. Despite the wording that was used, that was not what I intended to say. While it is always true that water will be an enemy in DPI formulation and as such it will always be necessary to set strict limits for water content, it is also true that using very low water contents is at the very least uncomfortable for operators and expensive to achieve. I clarified this point in cross-examination in London, but have adjusted the text here to make it clear from the outset. It is more accurate to say that the skilled formulator will use the driest conditions that are necessary to achieve physical and chemical stability, which means that the water content must be assessed and suitable control limits established.”<sup>36</sup>*

Having set out that footnote in full (at para 49; pages 44-45), the Judge then stated:

*“Professor Buckton could not be clearer in this re-wording of his written evidence, of which the court understands itself to be the unique beneficiary to this time. It represents, it seems, a significant re-wording of the written evidence that was before the Norwegian and United Kingdom courts.”*

84. In fairness to the Judge (and this point is forcefully made by Boehringer) it is not the case that the above represents the totality of the Judge’s engagement with Professor

---

<sup>36</sup> Footnote 13.

Buckton's evidence and/or his comparative assessment of that evidence *vis à vis* the contrary evidence given by Professor Birchall. By way of illustration, paragraphs 52-59 address aspects of the evidence given by Professor Buckton regarding the issue of whether the drying of capsules in DPI formulations was part of common general knowledge at the priority date, an issue to which the Judge returns at paragraphs 65-57 and again at paragraph 72, 82 (in the context of Professor Buckton's evidence that he could not recall whether he had seen *Ogura* prior to the priority date) and 83-85. Professor Buckton's evidence is also addressed in the context of inventive step//obviousness (though complaint is made by Teva that the Judge disregarded that evidence entirely in his ultimate analysis) and *Agrevo* obviousness/plausibility (referred to separately later in this judgment).

85. However, Teva says that the Judge's stated reasons for generally preferring the evidence of Professor Birchall over that of Professor Buckton in the manner that he did do not withstand scrutiny. In particular, it is said that the Judge's assessment of the relevant expertise and experience of the two witnesses is vitiated by clear errors on his part, leading him to wrongly discount Professor Buckton's evidence. While Teva accepts that, at various points in his Judgment, the Judge engaged with particular aspects of the evidence given by Professor Buckton, it says that his assessment of that evidence was significantly (and unfairly) affected by his frequently-stated (and, in Teva's submission, unfounded) general preference for the evidence of Professor Birchall. There was, it was suggested in oral argument, a "*fatal contamination*" of the Judge's approach to the evaluation of the evidence, including on the "*core issue*" of inventiveness/obviousness. There was, it was said, a "*kind of a priori relegation or dismissal of our expert and his*

*standing to give relevant evidence*". Teva also complains that, in addressing a number of issues in his Judgment the Judge refers only to the evidence of Professor Birchall and does not make reference to the evidence given by Professor Buckton.

*Experience "at the Coalface" – the evidence*

86. Professor Buckton furnished a detailed expert report to the High Court. It attached a number of exhibits, including his CV. Amongst the many publications authored or co-authored by Professor Buckton was a paper authored by him and published in the *Advanced Drug Development Review* (a peer reviewed journal) in 1997 on the subject of "Characterisation of small changes in the physical properties of powders of significance for dry powder inhaler formulations.". His CV also lists grants obtained by Professor Buckton and that list includes a grant (STG£69,000) in 1999 in respect of "Novartis studies of dry powder inhaler design". The Court's attention was also drawn to the fact that in June 2001 – contemporaneous with the priority date of the Patent here – Professor Buckton had given a talk on "Dry powder inhalers, powder properties".
87. In his witness statement, Professor Birchall stated that following the awarding of his PhD in 1998 he became a research associate at Cardiff University where he carried out research into nebulised lung delivery. He was awarded a Wellcome Trust grant in April 2000 in relation to the development of dry powder inhaler and metred dose inhaler formulations. He became a Lecturer in Drug Delivery in February 2001. He also provided a detailed CV.



88. In his oral evidence, Professor Buckton stated that throughout his career he had been working on capsules and on the science relating to formulation. He accepted that, as of June 2001, he was not involved in the commercial formulation or production of capsules.<sup>37</sup> He said that he had worked with gelatin capsules throughout his career, though, it seems, specifically with capsules for oral delivery rather than inhalation.<sup>38</sup> He had experience with HPMC capsules for inhalation but subsequent to the priority date. Parts of the evidence given by Professor Buckton in the Patent Court in London regarding his professional experience was then put to him and he agreed that he had no direct experience of the manufacture of capsule-based DPI formulations prior to 2005. However, his evidence was that he had been involved in that area of activity (including in relation to gelatin capsules) through collaborations with colleagues in the industry from much earlier than that. It was put to Professor Buckton that, unlike him, Professor Birchall was actually working “*in the lab*” with gelatin capsules as of the priority date. In response, Professor Buckton indicated that he had been working with gelatin capsules with students for decades.

89. In his oral evidence, Professor Birchall referred to the Wellcome Trust grant and said that he worked on that grant from 2000 into 2001. In those days, he said, he had been blessed to be in the lab still and was working with a novel metered dose inhalation formulation and a novel dry powder inhaler formulation. In cross-examination, Professor Birchall made it clear that he had not been involved in industry in 1998-

---

<sup>37</sup> Day 4, page 82.

<sup>38</sup> Day 4, pages 83-84

2000.<sup>39</sup> The Wellcome Trust grant did not involve collaboration with industry.

*Teva's challenge to the Judge's assessment*

90. Teva says that the Judge's assessment of the relative expertise and experience of Professors Buckton and Birchall was flawed. It points to what is said to be an error at page 39 of the Judgment where the Judge suggests that "*from 1994*" (my emphasis) Professor Birchall was working in a laboratory on the delivery of medicines to the lung using different types of inhaler devices. In fact, Professor Birchall had not completed his PhD until 1998. Teva also says that the Judge appears to have misunderstood the nature of Professor Birchall's involvement in 2001. He was not (as paragraph 62 of the Judgment says) "*bringing to bear his practical experience as a professional working 'at the coalface of enterprise'*" in June 2001. Rather, he was engaged in academic work in his laboratory in Cardiff. While in his other references to Professor Birchall having been "*at the coalface*", there is no reference to "*enterprise*", Teva suggests that the phrase was clearly understood in that same sense by the Judge. In reality, Professor Birchall's relevant experience as of the priority date was wholly academic and, it is said by Teva, the contrast drawn by the Judge between the relative experience of Professor Birchall and Professor Buckton is accordingly significantly over-stated. Accepting that Professor Buckton had no experience in manufacturing capsules for DPI use in 2001, Teva says that Professor Birchall equally had no such experience either. Teva further says that the Judge erred in stating that Professor Buckton had done no DPI-related

---

<sup>39</sup> Day 11, page 6.

work before 2005, pointing to the paper he had written in 1997 and to work he had carried out with Novartis in 1999. Professor Buckton, it is said, also had extensive experience of working with gelatin capsules. Reference was also made to the evidence given by him that he and his students had engaged in inhalation work in the university laboratory, involving the use of multi-dose inhalers.<sup>40</sup>

91. In response, Boehringer stands over the Judge's assessment, though it acknowledges that, the Judge's reference to Professor Birchall's experience "*at the coalface of enterprise*" was "*potentially an error*" as his relevant experience was in the laboratory rather than in industry/manufacturing. It says that it is apparent from the Judgment that the Judge was clearly aware of the correct position. Boehringer does not accept that the Judge's reference to Professor Birchall's experience running from 1994 was in error. Boehringer says that the Judge was entitled to conclude that Professor Birchall was better qualified to give reliable evidence on the issues in dispute and that the Judge's stated general preference for his evidence was justified. However, it also argues strongly that even if the Judge was in error in that respect, it does not affect his findings on the critical issues because those findings were made on the basis of the Judge's substantive assessment of the conflicting evidence given by Professors Buckton and Birchall, not merely on the basis of his general preference for the evidence of the latter.
92. I have carefully reviewed the evidence identified by the parties as bearing on this issue. In my view, on any fair analysis of that evidence any differences between the relevant

---

<sup>40</sup> Day 4, pages 83-84/

expertise and experience of Professor Buckton and Professor Birchall were far less stark and significant than was suggested by the Judge. Professor Buckton clearly had significant experience in the use of gelatin capsules prior to the priority date and, as is apparent from his CV, had also some involvement in DPI-related work (though perhaps not as much as Professor Birchall) prior to the priority date which the Judge seems to have overlooked. The Judge's statement that Professor Buckton had not done any DPI-related work prior to 2005 – a factor to which the Judge seems to have attached significant importance - was therefore inaccurate. While Professor Buckton had not been involved in the commercial manufacture of inhalation capsules prior to the priority date, that was true also of Professor Birchall, notwithstanding the Judge's references to his experience at "*the coalface*" and "*the coalface of enterprise.*" Professor Birchall had no experience at "*the coalface of enterprise*" – assuming that those words are to be given their ordinary meaning – at any point prior to the priority date. While perhaps not a point of the first significance, it also does not appear correct to suggest, at least without some qualification, that Professor Birchall's relevant laboratory experience began in 1994, given that he was engaged in his PhD from 1994 to 1998. As he explained in his evidence, that PhD was looking at developing a gene therapy complex for the purpose of treating cystic fibrosis<sup>41</sup> and, though he made passing reference in his evidence to the use of different types of inhaler devices in that context, there was no suggestion that this included DPI.

---

<sup>41</sup> Day 11, page 5

*The Judge's criticism of the fact that the prior art was provided to Professor Buckton*

93. In cross-examination Professor Buckton confirmed that copies of *Ogura*, *Maesen*, *Barnes* and *Casaburi* had been provided to him by Pinsent Mason, Teva's solicitors in the context of his retainer as expert in the 220 Patent litigation in England and Wales.<sup>42</sup> He had not seen *Masen* or *Barnes* previously. He could not remember whether he had seen *Ogura* before being sent it by Pinsent Mason.<sup>43</sup>
94. Teva relies on the judgment of Arnold J in *MedImmune Limited v Novartis Pharmaceuticals UK Limited* [2011] EWHC 1669 (Pat) as indicating that it was entirely appropriate for Teva's solicitors to have provided the relevant prior art to Professor Buckton. In the course of that judgment, Arnold J addressed the issue of the preparation of expert reports, and the presentation of expert evidence, in patent actions. The judge observed that expert witnesses in such actions require a high level of instruction by the lawyers and that the preparation of the expert's report will frequently involve an iterative process through a number of drafts, with much of the drafting being done by the lawyers (para 110). However, the judge went on, such a process involved an obvious risk of loss of objectivity on the part of the expert. One of the illustrative scenarios posited by Arnold J involved discussion of prior art and the risk that the expert's report will focus unduly on the parts of the prior art that support his or her opinion (para 112). The scenario assumed that the prior art was shown to the expert by the lawyers but that is not the subject of any criticism by Arnold J. He then went on to discuss the evidence

---

<sup>42</sup> Day 4, page 111.

<sup>43</sup> Day 4, page 106.

of one of the expert witnesses in the case before him, stating:

*“118. A separate point about Professor Brammar’s evidence is that he testified in cross-examination that, when he was instructed in this matter, he was first asked to consider the prior art, then the priority documents and then the Patents. That was the correct way for those instructing him to proceed, since it was calculated to enable Professor Brammar to form and express his opinions on the prior art without knowledge of the invention and on the priority documents without knowledge of the Patents.”*

95. No issue arises here regarding the priority documents and it is clear from the evidence given by Professor Buckton that he was asked to consider the prior art well before the 220 Patent was provided to him (in his words, he got it “*much later down the process*”).<sup>44</sup> That was, Teva says, the correct way to proceed in light of the decision in *MedImmune*.<sup>45</sup> Teva also emphasises that Professor Buckton was not challenged in the High Court on the basis that he was being partial in his evidence or that he was lacking in independence or not discharging his duty to the court.

96. In response, Boehringer accepts that it was “*perfectly normal*” for an expert in a patent action to be provided with the prior art. However, it says, the point it had made (and

---

<sup>44</sup> Day 4, page 113.

<sup>45</sup> In fact subsequent authority suggests that *MedImmune* should not be read as laying down any rigid rule: see *Terrell on the Law of Patents* (18<sup>th</sup> ed; 2016) at para 19-378. I do not think that this takes away from the point made by Teva in this context.

which appears to have been accepted by the Judge) was not about the giving of the prior art but rather about Professor Buckton's ability to give evidence on common general knowledge and the fact that his evidence on that issue depended in part on material provided to him, namely the Norwegian patents.

97. However, as counsel for Teva noted in reply, the Judge made no reference in this context to the provision of the Norwegian patents (though they are addressed elsewhere in his Judgment). Rather, his criticism was expressly in terms of the "*prior art cited in the within proceedings*" being given "*up-front*" by Teva's solicitors. It was that which "*rather coloured*" the Judge's "*impression generally in favour of Professor Birchall*" on the issue of common general knowledge (Judgment, para 42). But, given Boehringer's acceptance that it was "*perfectly normal*" for the cited prior art to be given to an expert witness such as Professor Buckton, it is difficult to understand the basis for the specific criticism made by the Judge and even more difficult to understand how it might justify a general preference for the evidence of Professor Birchall across all "*the issues .. at play*".

*Professor Buckton's inability to recall whether he had seen Ogura before the priority date*

98. A related point concerns Professor Buckton's inability to remember whether he had seen *Ogura* before the priority date. The Judge considered that surprising and, in my view, he was entitled to do so. The Judge's point is not met by the observation that common general knowledge is not "*a memory game*". Given that Professor Buckton

placed significant reliance on *Ogura* as demonstrating that the use of HPMC as a capsule material in a dry powder inhaler was common general knowledge as at 1 June 2001, it was perfectly legitimate for the Judge to attach significance to the fact that Professor Buckton could not say that he had read *Ogura* at the time (or was even aware of it). The Judge was entitled to view that evidence as undermining Professor Buckton's evidence, and Teva's case, in relation to common general knowledge. Ultimately, Counsel for Teva, Mr. Ferriter SC, accepted that that was so. However, as he observed, it does not follow - or at least does not necessarily follow - that this justified the Judge's stated general preference for the evidence of Professor Birchall.

*Footnote 13 of Professor Buckton's First Report*

99. According to Teva, the Judge wrongly took the view that Professor Buckton had materially changed his evidence on the issue of how dry a formulator would have sought to keep the formulation as of the priority date (footnote 13 is set out in full above; the change was from "*as dry as reasonably possible*" to "*the driest conditions that are necessary to achieve physical and chemical stability*"). Having noted that his understanding that the High Court was the "*unique beneficiary*" of this re-wording of Professor Buckton's written evidence, the Judge expressed the view that it represented "*a significant rewording of the written evidence that was before the Norwegian and United Kingdom courts*".
100. Teva says that Boehringer never put to Professor Buckton or suggested to the Judge that he had changed his evidence. In addition, it points to the fact that, in the action in



England and Wales, Boehringer had unsuccessfully relied on the contents of footnote 13 in seeking leave to appeal, arguing that it indicated that Morgan J had misunderstood the import of the evidence that had been given by Professor Buckton in London and undermined Morgan J's conclusion that the skilled person would have been motivated to use HPMC as a capsule material. However, Floyd LJ did not think that there was anything in that point ([2016] EWCA Civ 1296, [2017] FSR 29, at para 24).

101. Boehringer maintains that this was indeed a significant change of evidence on the part of Professor Buckton such as to undermine Professor Buckton's credibility. However, it accepts that no such suggestion was made to Professor Buckton in cross-examination, saying that there was no need to do so.
  
102. In my opinion, had Boehringer wished to make the case that Professor Buckton had materially changed his evidence on this issue, such as to undermine his credibility, it should have put that criticism to Professor Buckton in cross-examination and given him an opportunity to address it: *McDonagh v Sunday Newspapers Limited* [2017] IESC 46; [2018] 2 IR 1. In fact, however, Boehringer expressly *disavowed* any suggestion that it was asserting that the evidence given by Professor Buckton in his statement differed from the evidence given in the action in London (no reference was made to the evidence given in the Norwegian proceedings). That is apparent both from its closing written<sup>46</sup> and oral submissions<sup>47</sup> in the High Court. Boehringer's point was, rather, that the terms of footnote 13 demonstrated that Morgan J had misunderstood the evidence that

---

<sup>46</sup> At para 60, footnote 8 (page 20))

<sup>47</sup> Day 14, at pages 157-158.

Professor Buckton had given (the same point dismissed by the Court of Appeal in refusing leave to appeal from Morgan J).

103. While the Judge's observations regarding footnote 13 refer only to the *written* evidence before the Norwegian and UK courts, the clear implication appears to be that there had been a significant change in Professor Buckton's evidence on this issue. That the Judge was bring critical of Professor Buckton was not disputed by Boehringer and that impression is rather reinforced by the reference to the High Court being the "*unique beneficiary*" of the re-worded evidence. In my view, any criticism of Professor Buckton on this point was unfounded.

#### *Assessment*

104. That the Judge generally preferred the evidence of Professor Birchall over the evidence of Professor Buckton is not in dispute: he said so explicitly and repeatedly. That this general preference affected his resolution of the many issues in dispute addressed in their evidence is also not in dispute: again, the Judge said so repeatedly and explicitly. In addition to reciting that general preference in the context of addressing various specific issues, the Judge made it clear that Professor Birchall's evidence had "*generally been preferred throughout this judgment for the reasons set out elsewhere*" (para 119). Those reasons, which appear to be those set out in para 39, footnote 1 and in para 43 of the Judgment, led the Judge to conclude that, "*though a distinguished professional*", Professor Buckton was not "*well-placed to address all of the formulation*

*issues in the case*” and “*certainly ... was not as well placed as Professor Birchall.*”<sup>48</sup>

The Judge also made it clear that his assessment of the respective expertise of the two professors “*when it comes to the issues at play in the ... proceedings*” was “*significantly coloured*” by Professor Buckton’s lack of “*working at the coalface experience*” (para 39, footnote 1).

105. Of course, the Judge had the opportunity of observing Professor Buckton and Professor Birchall giving evidence and insofar as the resolution of any particular conflict of evidence between them is concerned, this Court is bound to apply the well-known principles in *Hay v O’ Grady*: see the decision of the Supreme Court in *Donegal Investment Group plc v Danbywiske* [2017] IESC 14, [2017] 2 ILRM 1, per Clarke J at para 5.4. It follows that “*an appellate court should show significant deference to the views of a trial judge on the question of findings based on expert evidence because the trial judge will have had the opportunity to see the competing views challenged and scrutinised at the hearing*” (at para 5.7).

106. However, the complaint advanced by Teva here is not directed at the Judge’s resolution of any specific conflict of evidence. Rather, Teva says that the Judge discounted the evidence given by Professor Buckton generally and that this was not justified by the reasons given by the Judge for adopting that approach.

---

<sup>48</sup> The “*formulation issues in the case*” effectively encompassed all of the substantive issues in dispute with the possible exception of the identity of the skilled person (though the evidence of Professors Buckton and Birchall was also crucial to that issue) and the issue regarding the relevance (if any) of the need to obtain regulatory approval in assessing obviousness/willingness to try (the sole issue determined in favour of Teva by the Judge).

107. Professor Buckton and Professor Birchall gave conflicting evidence on many different issues. In respect of *every* such issue, without exception, the Judge preferred the evidence of Professor Birchall and large portions of Professor Birchall's witness statement were effectively adopted by the Judge as his own (see, for instance, pages 76-87; 119-124; 130-138 of the Judgment). Given the range of issues in dispute, it might seem surprising that the evidence of Professor Buckton was effectively rejected on every single one of them. There appears to have been no suggestion that Professor Buckton's evidence was untruthful in any way nor does it appear to have been suggested that he did not understand his duties as an expert witness or was under the sway of his client. The rejection of his evidence on all disputed issues is perhaps particularly surprising when one considers that his evidence was preferred to the evidence of Professor Birchall in relation to a number of crucial issues in the proceedings in England and Wales (including in relation to the issue of conventional obviousness). Furthermore, Morgan J considered that each of them "*was well-qualified to give the evidence which he gave*" (para 67). Professor Buckton's evidence appears to have been preferred in the Norwegian proceedings also. While the judgment of the Oslo District Court does not refer specifically to Professor Buckton and Professor Birchall or the evidence given by them, the court's substantive analysis of the issues in dispute (including the issue of conventional obviousness) and the conclusions reached by it clearly indicate that it preferred the evidence of Teva and thus of Professor Buckton.
108. I do not intend to suggest that the Judge here was bound by the assessments of the Patents Court in London and/or the District Court in Oslo. Clearly, the Judge was

required to make his own findings based on the evidence heard in Dublin. In my view, however, those assessments serve to bring into sharp focus the Judge's reasons for adopting the general – indeed universal - preference for the evidence of Professor Birchall that he did and for refusing to accept that Professor Buckton was “*well placed to address all of the formulation issues in the case*” (as is stated in express terms in para 42 of the Judgment), given that his assessment differed so significantly from the assessments in London and Oslo.

109. The approach adopted by the Judge – involving in effect the *a priori* discounting of the evidence of Professor Buckton – requires adequate justification. It is evident from the Judgment that it was a highly significant factor in the Judge's assessment of the evidence. That is not a matter of surmise or speculation: The Judgment says so repeatedly and in unambiguous terms. Of course, trial courts frequently express a preference for the evidence of one witness – whether expert witness or witness of fact – in respect of an issue or issues in dispute. That is an essential part of the function of a trial court. But, in my view, it is another matter for the trial court to say, as it did here, that it was generally preferring the evidence of one expert over the evidence of another in respect of all the issues in dispute and to state and restate that preference in the terms and with the frequency that the Judge did here. If and when a trial judge adopts such an approach, the basis for doing so needs to be explained and the reasons must be accurate and sufficient.

110. In my concurring judgment in *Morgan v ESB* [2021] IECA 29 (with which Noonan and Binchy JJ agreed) at paragraph 24 I expressed the view that:

*“A finding of credibility, whether in respect of a witness’s evidence generally, or some specific evidence given by them, ought generally to be the product of analysis and reasoning that is capable of explanation in a judgment. That does not mean that a lengthy or discursive analysis is necessary. The degree of explanation appropriate will depend on the nature, extent and significance of the relevant evidential conflict. Furthermore, there may be circumstances where a court must make its assessment based only on impression and demeanour, but such circumstances will be rare. As regards expert evidence, it is difficult to conceive of any circumstance in which it might be sufficient to resolve conflicts of evidence on the basis of a bare statement that the court “preferred” the evidence of expert A to the evidence of expert B. Of course, as Clarke CJ emphasised in Danbywiske, the choice “may not require a great deal of explanation in a judgment”. Again, the context will be key.”*

111. Here, the Judge has stated his reasons for the approach that he took to the evidence of Professor Buckton. The Court is entitled to review those stated reasons to see whether they are factually sustainable and/or whether they are capable of justifying the Judge’s approach. Doing so does not involve any departure from or evasion of the strictures of *Hay v O’ Grady*.
112. This was a long and complex hearing and the Judge’s Judgment is detailed and lengthy. As Mr Howard SC urged, “*considerable latitude*” is to be given to the Judge and his findings are not to be condemned on the basis of giving undue or unfair weight to

“*infelicitous phrasing*” or “*inelegance*” of expression. At the same time, however, the Judge’s stated approach to the assessment of the evidence is properly the subject of review by this Court on appeal.

113. I have already discussed in detail the criticisms made by Teva at paragraphs 79 - 92 above. As will be evident from that discussion, the Judge’s assessment was, in my view, significantly flawed. The suggestion that Professor Buckton had not done any DPI-related work prior to 2005 was inaccurate. The contrast repeatedly drawn between Professor Birchall and Professor Buckton on the basis that the former but not the latter had experience “*at the coalface*” and the “*coalface of enterprise*” was significantly over-stated if not wholly inaccurate. The other factors referred to by the Judge – the fact that the prior art was provided to Professor Buckton (which was in accordance with normal practice), his inability to recall whether he had seen *Ogura* at the time of its publication (a legitimate ground for criticism but not one capable of justifying discounting the evidence of Professor Buckton across the board) and the suggestion that there had been a significant change between the evidence given by Professor Buckton in London and the evidence given here (a suggestion expressly disavowed by Boehringer in their closing submissions) – are simply incapable of justifying the Judge’s approach.

114. The Judge was entitled to assess the evidence given by Professor Buckton and that given by Professor Birchall, but he was obliged to do so fairly. As is evident from the Judgment, the Judge discounted the evidence of Professor Buckton, to the point of appearing to question whether he was qualified to address the formulation issues

(effectively all of the issues in dispute) in the case at all (para 43). As I have explained, that was a significant factor in the Judge's resolution of those issues and in the conclusions that he reached. Treating the evidence of Professor Buckton in this way, in the absence of any adequate objective justification for doing so, did a significant unfairness to him and to Teva and, in my view, involved a significant error of assessment on the part of the Judge.

115. Boehringer argues that, even if there was any error by the Judge in this respect, it does not affect the findings made by the Judge. The Judge did not, Boehringer says, decide the issues in dispute on the basis of his stated general preference for the evidence of Professor Birchall but instead engaged with the substance of the evidence given by both experts and reached his findings on that basis. It is certainly the case that the Judge engaged with the substance of the expert evidence. However, his analysis of that evidence was clearly coloured by his stated general preference for the evidence of Professor Birchall. As I have said, that is not a matter of surmise or speculation: The Judgment says so repeatedly and unambiguously. There was, so to speak, a thumb on the scale which cannot be retrospectively removed. The Judge's assessment of the expert evidence materially miscarried in a manner that fatally undermines the reliability of all of the findings made by the Judge.

116. I also see force in Teva's complaint that, at various points in his analysis, the Judge addressed only the evidence given by Professor Birchall and effectively disregarded the evidence of Professor Buckton. Thus, no reference is made by the Judge to the evidence of Professor Buckton regarding *Barnes and Maesen* and *Casaburi* (see respectively,



paras 183-189 and para 190). Far more significant, however, is the absence of any reference to the evidence of Professor Buckton in the Judge's analysis of the issues of whether the use of HPMC capsules for inhalation purposes in connection with tiotropium preparations would have been obvious to the skilled person who was given *Ogura* to read and whether the use of reduced-moisture HPMC capsules for such an application was inventive. These issues were key to the determination of Teva's conventional obviousness challenge to the 220 Patent.

117. The Judge's discussion of this issue begins at para 126 and runs over some 13½ pages. Some 10½ pages consist of two extracts from Professor Birchall's first witness statement. No reference is made in this part of the Judgment to Professor Buckton or the evidence given by him concerning the question of whether the use of HPMC capsules, or reduced-moisture HPMC capsules, was obvious over *Ogura*. In an earlier part of his Judgment, the Judge had addressed *Ogura* in the context of what was common general knowledge as of the priority date and had considered the evidence of Professor Buckton in that context. But the issue of whether the amended claims were obvious over *Ogura* as a piece of prior art was a distinct issue. As one would expect, given its significance, Professor Buckton addressed that issue in his written and oral evidence. His evidence was to the effect that the skilled person would have been motivated by *Ogura* to try HPMC capsules for the delivery of tiotropium by inhalation and would then, if it seemed necessary, have looked at reducing the moisture content of the capsules. Teva was entitled to expect that the Judge would engage with that evidence and, if it was the case that the Judge did not accept Professor Buckton's evidence, to explain why that was so. Instead the Judge uncritically recited long extracts

from the witness statement of Professor Birchall, leaving Teva (and Professor Buckton) with entirely legitimate questions as to whether their evidence was properly or fairly assessed.

118. In my view, therefore, this ground of appeal also succeeds. It is a significant thing to set aside a trial judge's assessment of disputed expert evidence, particularly in a case that ran as long as this one did. But I am persuaded that the Judge here failed to assess Professor Buckton's evidence fairly. That is a fundamental flaw which this Court cannot overlook or dismiss.
119. For the reasons set out below, I have concluded that Teva's appeal on the ground of *Agrevo* obviousness/lack of plausible technical contribution must succeed. As a result, the amended claims 6 – 8 of the 220 Patent are invalid. But for that fact, I would have set out aside the Judgment of the High Court on the conventional obviousness ground and directed a retrial on that issue. However, in light of my conclusions on the *Agrevo* obviousness/lack of plausible technical contribution, no retrial is necessary.
120. I would add that my conclusion that, in principle, the Judgment should be set aside and a retrial ordered is reinforced by the Judge's clear disregard for the requirements of *Ranbaxy* and his failure to engage with the other decisions on the 220 Patent. It is not necessary to consider whether, if that issue stood alone, it would justify such an order. It is a further factor pointing to the conclusion that the Judge's assessment of the conventional obviousness issue was unsatisfactory.

## VIII – *AGREVO* OBVIOUSNESS/LACK OF PLAUSIBLE TECHNICAL CONTRIBUTION

121. This issue was the primary focus of Teva’s appeal.
122. In essence, Teva contends that the specific moisture levels in amended claims 6-8 are arbitrary and did not involve any inventive step(s). That contention was rejected by the Judge.
123. This ground of challenge to the 220 Patent stands on its own two feet and is not dependent on establishing conventional obviousness, as the following passage from *Terrell on the Law of Patents* (18<sup>th</sup> ed; 2016) makes clear:

*“12-40 An allegation of obviousness may sometimes succeed where the patent has made no ‘technical contribution’ to the art. This is a free-standing allegation in the sense that it may succeed even where a case of ‘conventional’ obviousness over the cited art has failed (as was the case in Eli Lilly v Human Genome Sciences).”*

124. As I have already noted, the Judge addressed both *Agrevo* obviousness and sufficiency under the rubric of “*plausibility*.” These are related but conceptually distinct grounds of challenge, reflecting different requirements of the EPC (and of the Patents Acts).
125. Part III, Chapter 2 of the EPC sets out the requirements for patentability. These are

reflected in this jurisdiction in the provisions of Part II, Chapter II of the 1992 Act. Article 52 EPC addresses novelty and Article 54 addresses inventive step.

126. The “*problem and solution*” approach long since adopted by the EPO in assessing the question of inventive step involves identifying from the relevant patent (or patent application) some technical contribution or effect which is said to solve the problem addressed by the patent. In the absence of any relevant technical contribution, the grant of monopoly rights will not be justified. According to the EPO, it follows from the definition of an invention as solving a technical problem (and not merely putting one forward) that it requires “*that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve*” (decision of the Board of Appeal of the EPO in T 1329/04 *Johns Hopkins University School of Medicine*, para 11). The requirement here is one of plausibility as to technical contribution in the context of assessing whether the invention involves an inventive step.
127. Article 138(1)(a) of the EPC provides that a European patent may be revoked on the ground that the subject matter of the patent is not patentable under Articles 52-57 EPC (i.e. Part II, Chapter 1). Section 58(a) of the 1992 Act is the equivalent provision in this jurisdiction. As a requirement for patentability under those Articles is (according to the EPO) plausibility as to the technical contribution/inventive step claimed by the patent, it follows that the revocation of a patent may be sought on the basis of the absence of any plausible technical contribution.

128. Sufficiency of disclosure – disclosure of the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art – is a separate requirement under Articles 83 & 84 EPC (and under section 19 of the 1992 Act) and Article 138(1)(b) recognises insufficiency of disclosure as a separate ground for revocation of a European patent (section 58(b) of the 1992 Act is the equivalent provision here). A threshold of test of plausibility has been held to apply in this context also: see the discussion in *Terrell on the Law of Patents* (18<sup>th</sup> ed, 2016) at para 13-54 and following. As Kitchin LJ explained in *Regeneron Pharmaceuticals v Genentech* [2013] EWCA Civ 93; [2013] RPC 28 at para 100 (in a passage cited at para 158 of the Judge’s Judgment) “*the assertion that the invention will work across the scope of the claim must be plausible or credible.*”
129. In this part of my judgment, I address only the issue of plausibility as to the technical contribution of the disputed invention(s) the subject of amended claims 6 – 8. I shall address separately the distinct argument made by Teva to the effect that those claims are invalid because they do not meet the threshold of plausibility as to the sufficiency.
130. In addressing this aspect of the appeal, I shall first address the Judge’s reasoning (including his evidential findings relevant to this issue). Second, I will then address in more detail than I have done already the submissions of the parties. Third, I will seek to identify the correct threshold test and, fourthly, applying that test, will state my conclusions on this issue.

## **The Judge's Reasoning**

131. The Judge makes some preliminary comments at paragraph 150 of his Judgment. He emphasised that plausibility was simply a “*threshold test*” in respect of the requirements of patentability such as technical contribution and sufficiency, one satisfied by a “*disclosure which is ‘credible’, as opposed to speculative*”. He noted that issues of plausibility mainly arose in cases involving early-stage science in high-technology fields with a potential for a large area of scientific research effectively to be cordoned off without proper basis by a single industry player at an early stage. That was far from the situation here, however, as the 220 Patent had a notably discrete subject-matter. The fourth and final preliminary comment was by way of endorsement of an observation of Birss J in *Merck Sharp & Dohme Ltd v Ono Pharmaceutical Co Ltd* [2016] RPC 10 (at para 137) to the effect that when one is considering plausibility “*it must be done in the context of the invention determined by properly construing the claim*”.
132. The Judge then addressed the authorities on plausibility and obviousness, including the decisions of the Court of Appeal of England and Wales in *Generics (UK) Limited t/a Mylan v Yeda Research and Development Co Limited* [2013] EWCA Civ 925 and *Idenix Pharmaceuticals Inc v Gilead Sciences* [2016] EWCA 1089. He cited the following passage from the judgment of Floyd LJ in *Generics (UK) Limited t/a Mylan v Yeda* which provides a helpful summary:

“[49] *I would summarise the position thus far in the following way:*

- i) Article 56 of the EPC is in part based on the underlying principle that the scope of the patent monopoly must be justified by the patentee's contribution to the art;*
- ii) If the alleged contribution is a technical effect which is not common to substantially everything covered by a claim, it cannot be used to formulate the question for the purposes of judging obviousness;*
- iii) In such circumstances the claim must either be restricted to the subject matter which makes good the technical contribution, or a different technical solution common to the whole claim must be found;*
- iv) A selection from the prior art which is purely arbitrary and cannot be justified by some useful technical property is likely to be held to be obvious because it does not make a real technical advance;*
- v) A technical effect which is not rendered plausible by the patent specification may not be taken into account in assessing inventive step;*
- vi) Later evidence may be adduced to support a technical effect made plausible by the specification;*
- vii) Provided the technical effect is made plausible, no further proof of the existence of the effect is to be demanded of the specification before judging obviousness by reference to the technical effect propounded.”*

133. In this context, the Judge emphasised, “*the specification is critical. It must provide*

*enough information to show that a technical contribution has been made and that there is an inventive step*” (Judgment, para 153). As it had been put by Arnold J in *Sandvik Intellectual Property AB v Kennametal UK Ltd* [2012] RPC 23, in a passage set out at para 153, the key question was whether the specification passed the threshold test of disclosing enough to make the invention plausible, that is to say “*to make it plausible that the selection has the technical significance claimed for it.*”

134. The Judge then cited a lengthy passage from the judgment of Kitchin LJ in *Idenix Pharmaceuticals Inc v Gilead Sciences Ltd* in which he addressed by reference to prior authority what is meant by plausible in this context. In the course of that passage Kitchin LJ referred to a passage from the judgment of Floyd LJ, in *Warner-Lambert LLC v Generics (UK) Ltd (trading as Mylan)* [2016] EWCA Civ 1006, in which he stated (at para 46) that the requirement of plausibility is “*a low threshold test .. designed to prohibit speculative claiming*”. Where (so Floyd LJ continued) “*the inventor provides a reasonably credible theory as to why the invention will or might work*” the claim will not easily be seen as speculative (also at Para 46). That was also true where the data in the specification is such that the reader is encouraged to try the invention (*ibid*). The test did not require the patentee to do more than show that the claim was not speculative; “*the specification does not need to provide the reader with any greater degree of confidence in the patentee’s prediction than that*” (para 47). The Judge attached particular importance to these statements by Floyd LJ, stating (*inter alia*) that he had stated the test for plausibility as “*merely that (para 46) ‘the reader is encouraged to try the invention.’*” (Judgment, para 155).



135. The Judge did not specifically comment on the concluding paragraph in the passage from *Idenix Pharmaceuticals Inc v Gilead Sciences Ltd* set out by him out but it appears to me to be worth setting out at this point:

*“114. In my judgment the same approach should be adopted in considering obviousness and whether a technical effect is plausible in the light of the teaching in the specification and the common general knowledge. There must be a real reason for supposing that the claimed invention will indeed have the promised technical effect.” (my emphasis)*

136. The Judge then addressed the question whether post-published evidence can be relied upon to establish a claimed technical effect (Judgment, para 156). It was, he said, clear from *Generics (UK) Limited t/a Mylan v Yeda* that “*later evidence may be adduced to support a technical effect made plausible by the specification*”. Contrary to what had been argued by Teva, *Idenix Pharmaceuticals Inc v Gilead Sciences Ltd* was not authority for the exclusion of post-publication evidence. While Kitchin LJ had indeed stated that the “*claimed technical effect must ... be plausible in light of the teaching of the specification*” he had also stated that the “*claimed technical effect cannot be established solely by post-published evidence.*” Regard could therefore be had to such evidence, provided that it was not the sole evidence relied on. That was, in the Judge’s view, consistent with the judgment of Floyd LJ in *Warner-Lambert LLC v Generics (UK) Ltd (trading as Mylan)* where, after a review of the case-law, he had stated that post-publication data was not admissible “*if they alone render the invention plausible.*”

137. The Judge then addressed the substance of Teva's challenge. I summarise the principal points of his analysis:

- It was clear from the caselaw that there was no requirement in the EPC that a patent should contain data or experimental proof to support its claims (Judgment, para 165)
- It was clear from Professor Birchall's evidence that the benefits to be obtained at the water-content thresholds of the 220 Patent were plausible. (Judgment, para 166)
- Professor Buckton had accepted that the skilled person could readily do measurements to check the technical benefits from the patent (Judgment, para 168)
- Teva's argument as to plausibility was inconsistent with the experimental evidence. Such evidence could be adduced "*to support a technical effect made plausible by the specification, and the court accepts that the invention in issue was rendered plausible by the 220 Patent*" (Judgment, para 175)
- The 220 Patent identified the benefits to be obtained from the invention and gave the reader the information necessary to make the products claimed. Professor Birchall's evidence made it clear that the Patent provided the skilled person with everything needed to make the claimed capsules for use in a DPI and nothing in the Patent would have put the skilled person off doing so. (Judgment, para 176)

- The objection as to plausibility was misplaced in a challenge to a patent such as the 220 Patent. The 220 Patent had a notably discrete subject matter involving a new formulation approach to a medicine comprised of a single active substance (tiotropium) and its salts and forms for two identified conditions, namely asthma and COPD and as such the proceedings were “*starkly different*” from cases involving early-stage science in high-technology fields (Judgment, para 177).
- The test of plausibility was a threshold test which was satisfied by a disclosure that was credible rather than speculative. In the Judge’s view, there was “*ample in the 220 Patent by way of worked-out instructions as to the making of embodiments of the invention to demonstrate to the notional skilled person that it is not speculative.*” (Judgment, para 178)
- In truth, what Teva was seeking to achieve under the heading of plausibility was to establish a ground of challenge, unrecognised at law, whereby Boehringer would not be entitled to its patent if it did not provide proof of the effectiveness of the invention of the patent. Such a basis of challenge had been rejected by Lord Hoffman in *Conor Medsystems Inc v Angiotech Pharmaceuticals* [2008] UKHL 49, [2008] RPC 28 (Judgment, para 179)

In light of these points, Teva’s plausibility challenge had to fail (Judgment, para 181)

138. The specific evidence of Professor Birchall said to have established that the benefits to

be obtained at the water-content thresholds in the amended claims are plausible is identified at paras 166 and 167 of the Judgment. In the first passage, it was put to Professor Birchall that there was nothing in the patent that made it plausible that if one went below 5% (water content) the technical aims of the patent would be achieved whereas above 5% they would not. That promoted the following exchange:

*“A. Clearly that’s something you’re going to have to test, is to see*

*Q Sure*

*A – which is the best moisture content with regard to stability*

*Q Okay. But we don’t see that testing in the –*

*A The data isn’t there.*

*Q The data isn’t there. And even your assumptions on Boehringer having made the thing, you’re not assuming that they have done that test on that particular boundary, are you?*

*A Well, I would have thought they have done tests because they have come up with a boundary. And, as I explained before, you do your test first, you establish your boundary, you do your test and you demonstrate whether that boundary makes a difference or not. “<sup>49</sup>*

139. The second passage relied on by the Judge concerned claim 8 (where the water threshold is  $\leq 2\%$ ). It was put to Professor Birchall that the only additional information regarding that threshold in the patent was that one of the examples had a moisture

---

<sup>49</sup> Evidence given on Day 12, at pages 38-39.

content in that range. The following exchange then occurred:

*“A Right*

*A – so one would think, to have got down to that as an example though might be one of the ones that is working perfectly well. That is all you take from that.*

*Q But that would only work in that – you’re supporting that with the example, your inference from that example, that would only work in respect of tiotropium bromide monohydrate, which is the subject of the example –*

*A Yes*

*Q – not any of the multitudinous of other tiotropium things we have looked at?*

*A Yes, I think that in that particular sample it must be quite good, otherwise why would it be an example?”*

140. In this part of his Judgment (at para 160), the Judge also referred to Professor Birchall’s witness statement where he had stated that, while certain of the language used in the patent could be regarded as “*over-stated*”, “*the skilled person has no reason when reading the [220] patent to think that he or she would not see such benefits upon making (and then using) the capsules in accordance with the instructions set out therein.*” The Judge then noted (at para 161) that Professor Buckton had been asked whether he agreed with Professor Birchall. Professor Buckton had responded that, while one would expect benefits from reducing water content (that was, he said, “*a reasonable overarching concept*”) that didn’t lead you to “*the numbers which are in the Patent.*” As to whether it was plausible that for any one particular formulation that those numbers will have significance in relation to chemical and physical stability, Professor Buckton did not

think that there was “*any reason to believe those numbers have any significance. There is nothing here to convince me those numbers have significance.*”

141. The Judge went on to refer to other evidence given by Professor Buckton which he considered to be at odds with the evidence just cited and which indicated that “*there was real substance to the [220] Patent.*” As I shall explain, the Judge’s criticism of Professor Buckton’s evidence in this respect was, in my view, misdirected and unfair. It does not follow, of course, that the Judge’s conclusion on this issue was wrong.

### ***The Submissions***

142. Teva says that the test is “*that there must be some real reason based on the specification and CGK for supposing that the claimed technical effect is true*”. While a reasonable expectation of success was not required “*there must nonetheless be a credible reason contained in the specification (read in the light of the CGK) to think that the claim is true.*”<sup>50</sup> It was, Teva says, common ground between the parties that the relevant principles had been accurately summarised in *Generics (UK) Ltd (t/a Mylan) v Yeda*. The Judge had misread para 46 of the judgment of Floyd LJ in *Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan)* as stating “*that the test for plausibility is merely that ... ‘the reader is encouraged to try the invention’*” (Judgment, para 155). Floyd LJ was providing examples of how the test might be satisfied, not a substitute test. The technical effects claimed to be provided by the invention was as set out on

---

<sup>50</sup> Teva’s written submission on appeal, para 7.10

page 2, lines 1-16 of the 220 Patent (guaranteed sufficient stability of the active substance, both chemical and physical, release of the active substance with a high metering accuracy, complete emptying of the capsules and capsules having good perforation qualities with good stability and low brittleness). What had to be rendered plausible, therefore, was that use of HPMC capsules at the moisture levels specified in claims 6 – 8 would achieve those technical effects. According to Teva, the Judge had not properly addressed that question and instead appeared to have proceeded on the assumption that Boehringer would not have included the specific moisture levels in the claims unless it had a basis for them. The Judge had also been in error in appearing to attach importance to the fact that the skilled addressee could carry out tests to confirm whether or not the claimed technical effects were achieved. That was an entirely irrelevant consideration. Finally, the Judge was wrong to have regard to the experiments. The claims were not made plausible by the specification (read in light of CGK) and it was therefore clear that post-publication evidence was not admissible.

143. In its written submissions, Boehringer rejected the contention that the Judge had misunderstood or misapplied the applicable threshold test. The Judge had applied the correct question “*namely whether it would have been credible to the skilled person at the priority date that the Patent would deliver the invention – formulations of tiotropium with improved stability and performance.*”<sup>51</sup> Professor Buckton himself had accepted that one would expect that reducing the water content would have “*benefits in terms of less hydrolysis and better physical delivery.*”<sup>52</sup> It was, Boehringer suggested, difficult

---

<sup>51</sup> At para 150.

<sup>52</sup> Day 4, page 26 (cited at para 161 of Boehringer’s submissions).

for Teva to maintain a challenge to the findings of the Judge in circumstances where their own witness had accepted that the invention was plausible for formulations in reduced-moisture content HPMC capsules. In order to get away from that difficulty, Teva had asserted that Boehringer was required to demonstrate that it was plausible that the invention yielded “*boundary effects at each moisture content threshold*”. That had been rightly rejected by the Judge who correctly identified the relevant question as whether it was plausible that invention as claimed worked in the sense of leading to the benefits described. Given the Judge’s finding that the claims were plausible, post-publication evidence was admissible and the results of the experiments confirmed the effectiveness of the invention.

144. Boehringer’s written submissions referred to two decisions of the EPO Board of Appeal, *Ipsen* (T578/06) and *Arch* (T1642/07) which do not appear to have been referred to in the High Court and which were certainly not referred to by the Judge in his Judgment. Those decisions loomed large in Counsel’s oral submissions, as I shall shortly explain.

145. Prior to the hearing of the appeal, but after the exchange of the parties’ written submissions, the UK Supreme Court gave its decision in *Generics UK Ltd (trading as Mylan) v Warner-Lambert Co* [2018] UKSC 56, [2019] 3 All ER 94. That decision was referred to extensively in oral argument. According to Teva, the Supreme Court had taken the view that the threshold test formulated by Floyd LJ in the Court of Appeal (on which the Judge had placed such reliance) “*sets the bar too low*”. While *Generics UK Ltd (trading as Mylan) v Warner-Lambert* was a sufficiency case rather than an



*Agrevo* obviousness case, and while it involved a different form of patent (a Swiss form patent in respect of a second medical use), Teva relied on it as providing support for its fundamental contention that the applicable test was whether or not there was a “*real reason*” for believing that the invention as claimed will have the asserted technical effects i.e. that tiotropium in HPMC capsules at or below the claimed moisture limits will have increased stability. That was the position it had advanced in the High Court on the basis of *Generics (UK) Limited t/a Mylan and Idenix Pharmaceuticals Inc v Gilead Sciences* and that remained the position after the Supreme Court’s decision in *Generics (UK) v Warner-Lambert Co*. It was not sufficient to rely on bare assertion or apply a test of good faith. Even if *Generics (UK) v Warner-Lambert Co* could be interpreted as positing a modified and more exacting test (which Teva did not accept), Teva did not rely on, or need to rely on, any such test.

146. For its part, Boehringer sought to rely on the Supreme Court’s decision *Generics (UK) v Warner-Lambert Co* as a springboard for inviting the Court to review the EPO jurisprudence on plausibility. According to Boehringer, Lord Sumption (who gave the majority judgment in the appeal) had mischaracterised the EPO jurisprudence and in particular the decision of the Board of Appeal in *Ipsen*. As it was put in the Points of Rebuttal that Boehringer was permitted to deliver subsequent to the hearing of the appeal, *Ipsen* makes it clear “*that no issue of plausibility of inventive step can arise at all (let alone one that can be answered in the specification other than by experimental evidence) in the absence of a substantiated doubt (whether arising from the patent itself or the common general knowledge) as to the suitability of the claimed invention to solve*

*the technical problem addressed.*”<sup>53</sup> According to Boehringer, and contrary to the view of Lord Sumption in *Generics (UK) v Warner-Lambert Co*, mere assertion of efficacy *is* enough (at least absent a substantiated doubt).<sup>54</sup> That position is said to follow from a number of decisions of the EPO Board of Appeal, particularly *Ipsen* and *Arch* but also including *Supergen* (T1616/09) and *Novo Nordisk Health Care AG* (T872/13). It does not appear that the High Court Judge was referred to *Supergen*. The decision in *Novo Nordisk Health Care AG* post-dates the High Court Judgment.

147. While I will consider the substance of this argument in due course, I would observe immediately that it necessarily seems to imply that the Judge erred in his approach to the issue of *Agrevo* obviousness/plausibility of technical contribution. While Teva criticises the Judge for setting the bar too low, the Judge did not hold – and was not invited by Boehringer to hold – that the plausibility of the claimed technical contribution of the inventions was to be assumed in the absence of any “*substantiated doubt*” and/or that mere assertion of the claimed technical contribution might be sufficient in this context. Boehringer now maintains that that is the correct position. However, in circumstances where that case was not made in the High Court (and in the absence of any cross-appeal or application to vary brought by it), Boehringer would seem to face a significant difficulty in advancing that position on appeal.

148. In its oral and written submissions/further submissions, Boehringer makes a number of further arguments which it will be necessary to address:

---

<sup>53</sup> At para 5 (original emphasis)

<sup>54</sup> Day 2, page 120.

- The invention found to be inventive by the Judge was the formulation of tiotropium in reduced-moisture capsules (where the moisture content was 5% or less and where Boehringer’s Protocol 5 experiments had established that the “normal moisture content” of HPMC at normal manufacturing conditions was above 5%). The invention was not the use of HPMC capsules with tiotropium.
- Each of claims 6-8 are said to be “*embodiments*” of the inventive concept of formulation of tiotropium but claimed at reduced moisture levels. At one point in its Points of Rebuttal, it is said by Boehringer that the moisture content levels of claims 6 – 8 are embodiments of the inventive concept (the formulation of tiotropium in reduced-moisture HPMC capsules) “*expressed in dependent claims.*”<sup>55</sup> Elsewhere in that document, however, claim 6 is characterised as the “*main claim*” and the “*independent claim*” on which claims 7 and 8 are dependent.
- HPMC capsules within claims 6-8 delivered the stability and performance that comprised the claimed technical contribution of the invention, as Professor Buckton had accepted in his evidence.
- The decision of Morgan J in the Patents Court is to be distinguished in that he found (on the basis, it is said, of different evidence and of a misunderstanding of Professor Buckton’s evidence) the inventive concept obvious. It was only on that basis that

---

<sup>55</sup> At para 25.

the arbitrariness or otherwise of the moisture thresholds came into issue. While Boehringer disagreed with Morgan J’s reasoning, the point is that “*once the inventive concept is accepted as being the formulation of tiotropium in dried HPMC capsules – which it was by the High Court and which finding has not been appealed by Teva – the notion of arbitrariness of water content limits in the dependent claims representing dried formulations cannot be in issue.*”<sup>56</sup> That is, so it appears, because each of the water content limits “*represents dried HPMC*”.<sup>57</sup>

- The achievement of “*boundary effects*” at each of the water content thresholds in claims 6, 7 and 8 was no part of the technical contribution claimed by the invention.

Boehringer also stood over the Judge’s finding that evidence of the experiments it had carried out subsequent to the priority date was admissible and his view that this evidence confirmed that the claimed invention here was plausible.

### **The Applicable Test**

149. As Teva observed during the hearing, there appears to have been no, or no significant, dispute between the parties before the High Court as to what the applicable test was. In its closing written submissions to the High Court, Boehringer noted that plausibility was a “*threshold test*” in respect of the requirements of patentability – including the

---

<sup>56</sup> *Ibid*, at para 20.

<sup>57</sup> *Ibid*, para 26.

requirement of technical contribution – which required (and which was satisfied by) “*a disclosure which is ‘credible’ as opposed to speculative*”.<sup>58</sup> The principle that the technical contribution had to be made plausible by the patent – i.e. by its specification – read in the light of any relevant CGK was not in dispute. Rather, the issue was what precisely that test required in concrete terms and how it applied in the specific context of the 220 Patent.

150. Immediately after setting out the helpful summary offered by Floyd LJ in *Generics (UK) Ltd t/a Mylan v Yeda*, the Judge appears to offer his own formulation of the applicable threshold at para 153 of his Judgment when stating that that the specification is “*critical*” and “*must provide enough information to show that a technical contribution has been made and that there is an inventive step.*” That formulation of the test appears entirely consistent with what was said by Kitchin LJ at para 114 of *Idenix Pharmaceuticals v Gilead*, namely that “*in light of the teaching in the specification and the common general knowledge*” there “*must be a real reason for supposing that the claimed invention will indeed have the promised technical effect*”. That passage was cited by the Judge, without any suggestion that he differed from it.
151. Unaccountably, the Judge did not refer in this context to the decision of Morgan J in the Patents Court. At para 134 of his judgment, Morgan J set out his own summary of the principles established by the authorities, drawing largely from *Generics (UK) Ltd t/a Mylan v Yeda*:

---

<sup>58</sup> At para 249

*“(1) The following principles apply regardless of the field of invention, but the application of the principles can vary according to the circumstances, including the field of invention.*

*(2) An arbitrary selection from the prior art is not inventive, regardless of the field.*

*(3) Where it is suggested that the claimed invention is an arbitrary selection, the key question is whether the specification passes the threshold test of disclosing enough to make the invention plausible, that is, to make it plausible that the claimed invention has the technical significance claimed for it.*

*(4) “Plausible” conveys the sense that there is some real reason for supposing that the statement is true.*

*(5) If something is inherently unlikely, the burden of proof is on the party who wishes to persuade the court that it is indeed the case.*

*(6) When the disclosure of the patent, read in the light of the skilled person's common general knowledge, did not disclose enough to make the invention plausible, i.e. that it solved a technical problem, that was the end of the matter; it was not open to the patentee to rely on post-dated evidence to demonstrate the technical effect.*

(7) *When the disclosure of the patent, read in the light of the skilled person's common general knowledge, did disclose enough to make the invention plausible, i.e. that it solved a technical problem, it was not open to the party challenging the patent to rely on post-dated evidence to show that the invention was obvious.*

(8) *Post-dated evidence may be relied upon to confirm that the disclosure in the patent does or does not make it plausible by showing that it solved a technical problem.”*

152. Teva says that these are the applicable principles and that the specification of the patent (read in light of any relevant CGK) must provide a “*real reason for supposing that the claimed invention will indeed have the promised technical effect.*”

153. However, Teva says, the Judge adopted a different and less exacting test, pointing to para 155 of his Judgment to which I have referred in detail above. Although the Judge referred to the test as merely being “*that the reader is encouraged to try the invention*”, it is not clear that the Judge was intending there to formulate any different test in substitution for the approach that he himself had identified in para 153 or the test that was identified by Kitchen LJ in *Idenix*. There must a reason why the reader is encouraged to try. Where a patent fails to disclose a real reason for supposing that the claimed invention will have the promised technical effect, then it is difficult to see how the reader would be encouraged to try that invention. Conversely, where the patent

provides a real reason for supposing the claimed invention will have the promised effect – or, as the Judge put it, the patent provides “*enough information to show that a technical contribution has been made and that there is an inventive step*” - the reader will be encouraged to try the invention. As will appear, this approach is consistent with that taken by the Supreme Court in *Generics UK Ltd v Warner-Lambert* which I will next consider.

*The UK Supreme Court’s Decision in Generics (UK) v Warner-Lambert Co*

154. *Generics (UK) Ltd v Warner-Lambert Co* involved a second medical use /Swiss-form patent for Isobutylgaba and its derivatives for the treatment of pain. Pregabalin is a derivative of Isobutylgaba. The claims of the patent were all purpose-limited. Claim 1 of the patent referred to the treatment of pain whereas claim 3 referred to the treatment of neuropathic pain. Actavis marketed a generic pregabalin product. Both Actavis and Mylan sought the revocation of the patent on grounds of lack of inventive step and insufficiency. Warner-Lambert in turn claimed that Actavis’ product infringed claims 1 and 3 of the patent.
155. In the Patents Court, Arnold J rejected the arguments based on lack of inventive step and that issue did not feature subsequently. However, he held that claims 1 and 3 were invalid because in his opinion there was insufficient disclosure in the specification to support the claim that pregabalin was effective in the treatment of central neuropathic pain (though the disclosure was, in his view, sufficient to support the claim that it was effective in the treatment of inflammatory pain and peripheral neuropathic pain). As he



construed claim 1 to refer to *all* pain and claim 3 to refer to *all* neuropathic pain, those claims failed for insufficiency, by reference (*inter alia*) to *Regeneron Pharmaceuticals Inc v Genentech Inc*. Other claims of the patent were also held invalid, but those claims did not feature before the Supreme Court and need not be considered further here.

156. Arnold J's decision was upheld by the Court of Appeal. On Warner-Lambert's further appeal to the Supreme Court (and Actavis' and Mylan's cross-appeal against the finding that the specification was sufficient to support the claim that it was effective in the treatment of peripheral neuropathic pain), the only claim of the patent that was really in issue was claim 3 relating to the treatment of neuropathic pain. A significant additional issue arose as to the applicable test for infringement in a case where the monopoly conferred by the patent was confined to manufacture for a particular use, but no such issue arises here and accordingly nothing further need be said about it.
157. Lord Sumption gave the principal judgment in the Supreme Court. He began his analysis of the issue of sufficiency and plausibility by recalling the basis on which patents are granted, the so-called "*patent bargain*". The patent monopoly had to be justified by the actual technical contribution to the art. The principal conditions of validity, novelty, inventive step, industrial application and sufficiency were all, in one way or another, directed to satisfying that principle (para 17). Patent protection should not be granted on the basis of speculative or over-broad claims (para 22). Lord Sumption explained that the concept of plausibility had originated in the case law of the EPO as a response to over-broad claims. The Board of Appeal treats the condition of sufficiency under Article 83 EPC as satisfied if it is possible to work the invention

across the scope of the claim from the information in the specification, interpreted in light of the common general knowledge as of the priority date. It addresses the “*broader question*” of whether the disclosed contribution to the art is commensurate with the monopoly claimed under Article 56 EPC, in the context of inventive step. Its case-law “*imports a requirement that the patent should disclose not just what the invention is and how to replicate it, but some reason for expecting that it will work. Plausibility was the standard to which the patentee was expected to demonstrate this.*” (para 23). That approach was illustrated by the decision of the Board of Appeal in *Johns Hopkins*.

158. Lord Sumption then addressed a submission by Warner-Lambert to the effect that the Board of Appeal’s decision in *Salk Institute for Biological Studies* (T-609/02) - where in the context of a second medical-use patent, the Board had stated that Article 83 EPC required that the application must disclose the suitability of the product to obtain the claimed therapeutic effect unless that would already be known to the skilled person at the priority date – had to be read in light of subsequent EPO caselaw which indicated that the *Salk* principle applied only where the claimed therapeutic effect was inherently implausible. Lord Sumption allowed that the submission was consistent with “*some turns of phrases in the cases*”. But, he continued:

*“it would have been a strange thing for the Technical Board of Appeal to have meant. It would be inconsistent with the reason why plausibility of the claimed therapeutic effect is required, namely to support the implied claim to therapeutic efficacy and to justify the monopoly by reference to the patentee’s contribution to the art. If Warner-Lambert’s argument were sound, it would mean that if*

*nothing was known either for or against the claimed therapeutic effect, no disclosure need be made in support of it.” (para 30)*

159. Lord Sumption then addressed a number of decisions of the Board of Appeal relied on by Warner-Lambert, starting with *Ipsen*. In his view, *Ipsen* was authority for the proposition that plausibility can be demonstrated in the specification without experimental evidence, if there is no substantiated doubt about the theoretical case made for the efficacy of the invention. As the Board had observed in *Intervet* (T-716/08) – a decision cited in *Ipsen* – common general knowledge at the priority date may be used to interpret the teaching in a patent but, Lord Sumption added, “*there must be something in the patent to interpret*” (para 31). He then discussed the Board of Appeal’s decision in *Allergan* (T-1437/07) which was also, in his view, authority for the proposition that experimental data are not essential to sufficiency unless it is being positively alleged with convincing evidence that the invention does not work. In his view, *Allergan* was not:

*“authority for saying that the objector has the onus of showing that it is implausible. Sufficiency turns on what the patentee has disclosed. It must always be necessary for the patentee to demonstrate that he has included in the specification something that makes the claim to therapeutic efficacy plausible. Otherwise a mere assertion of efficacy would be enough.” (para 33)*

160. Having referred to one further decision of the Board of Appeal, *Bristol-Myers Squibb* (T-950/13), Lord Sumption expressed his understanding of the law in a passage that

warrants extensive citation:

*“[35] All of these judgments deal with highly fact-specific issues arising from objections or potential objections on the ground of insufficiency. When reading them, it is important not to miss the wood for the trees. The fundamental principle which they illustrate is that the patentee cannot claim a monopoly of a new use for an existing compound unless he not only makes but discloses a contribution to the art. None of them casts doubt on the proposition that the disclosure in the patent must demonstrate in the light of the common general knowledge at the priority date that the claimed therapeutic effect is plausible. On the contrary, they affirm it: see Allergan at paras 26, 37, and Bristol at para 3.2.*

*[36] The Court of Appeal's statement of the effect of the plausibility test has already been quoted (para 20 above). They considered that the threshold was not only low, but that the test could be satisfied by a “prediction ... based on the slimmest of evidence” or one based on material which was “manifestly incomplete”. Consistently with that approach, they considered (paras 40, 130) that the Board's observations in Salk laid down no general principle. I respectfully disagree. The principle is that the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true. Plausibility is not a distinct condition of validity with a life of its own, but a standard against which that must be demonstrated. Its adoption is a mitigation of the principle in favour of patentability. It reflects the practical difficulty of*

*demonstrating therapeutic efficacy to any higher standard at the stage when the patent application must in practice be made. The test is relatively undemanding. But it cannot be deprived of all meaning or reduced, as Floyd LJ's statement does, to little more than a test of good faith. Indeed, if the threshold were as low as he suggests, it would be unlikely to serve even the limited purpose that he assigns to it of barring speculative or armchair claims.*

*[37] Plausibility is not a term of art, and its content is inevitably influenced by the legal context. In the present context, the following points should be made. First, the proposition that a product is efficacious for the treatment of a given condition must be plausible. Second, it is not made plausible by a bare assertion to that effect, and the disclosure of a mere possibility that it will work is no better than a bare assertion. As Lord Hoffmann observed in *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] RPC 28, para 28, “it is hard to see how the notion that something is worth trying or might have some effect can be described as an invention in respect of which anyone would be entitled to a monopoly”. But, third, the claimed therapeutic effect may well be rendered plausible by a specification showing that something was worth trying for a reason, ie not just because there was an abstract possibility that it would work but because reasonable scientific grounds were disclosed for expecting that it might well work. The disclosure of those grounds marks the difference between a speculation and a contribution to the art. This is in substance what the Technical Board of Appeal has held in the context of art 56, when addressing the sufficiency of disclosure made in support of claims extending beyond the*

*teaching of the patent. In my opinion, there is no reason to apply a lower standard of plausibility when the sufficiency of disclosure arises in the context of EPC articles 83 and 84 and their analogues in s 14 of the Patents Act. In both contexts, the test has the same purpose. Fourth, although the disclosure need not definitively prove the assertion that the product works for the designated purpose, there must be something that would cause the skilled person to think that there was a reasonable prospect that the assertion would prove to be true. Fifth, that reasonable prospect must be based on what the Technical Board of Appeal in Salk (para 9) called “a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se.” Sixth, in Salk, this point was made in the context of experimental data. But the effect on the disease process need not necessarily be demonstrated by experimental data. It can be demonstrated by a priori reasoning. For example, and it is no more than an example, the specification may point to some property of the product which would lead the skilled person to expect that it might well produce the claimed therapeutic effect; or to some unifying principle that relates the product or the proposed use to something else which would suggest as much to the skilled person. Seventh, sufficiency is a characteristic of the disclosure, and these matters must appear from the patent. The disclosure may be supplemented or explained by the common general knowledge of the skilled person. But it is not enough that the patentee can prove that the product can reasonably be expected to work in the designated use, if the skilled person would not derive this from the teaching of the patent.”*

161. Lord Reed agreed with the judgment of Lord Sumption and Lord Briggs agreed with it on the issue of sufficiency. Lord Hodge agreed with Lord Sumption that the EPO decisions relied on by Warner-Lambert do not place the onus on an objector to show that the implied assertion of therapeutic efficacy is implausible. He also agreed with his view “(a) that the patentee must disclose in the patent, when read in the light of the common general knowledge, the contribution to the art which justifies his monopoly and, to that end, (b) that the specification must disclose some scientific reason for thinking that the medicament might well have the claimed therapeutic effect” (para 179). However, where he differed from Lord Sumption (and agreed with Lord Mance) was that he did not interpret those principles as requiring the patentee to demonstrate a *prima facie* case of therapeutic efficacy within its patent (para 180). In his view, the recent decisions of the Board of Appeal:

“181 ... (a) require that the therapeutic effect of the medication appears plausible from the data in the patent interpreted in the light of the common general knowledge, (b) do not require that the patent discloses experimental evidence to demonstrate that plausibility unless there is an allegation, supported by sufficient evidence, that the invention does not work, but (c) allow the plausibility to be reinforced by considering evidence which post-dates the patent (although later-published data are not admissible if they alone render the therapeutic effect plausible), (d) take account of the ease with which the therapeutic effect can be ascertained using straightforward tests which are known in the prior art, and (e) where the data in the specification have made

*the claimed therapeutic effect plausible, place a burden on an objector to substantiate doubt that the desired effect can be achieved.”*

Adopting that “*lower standard of plausibility*”, he would have upheld some of the claims of the patent and dismissed the cross-appeal.

162. Lord Mance considered that Lord Sumption’s analysis imposed too high a threshold. Having examined *Allergan, Ipsen* and *Bristol-Myers Squibb*, he considered that it put the test too high to suggest that the “*the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true.*” That amounted to, or certainly risked being read as, “*a requirement that the plausibility of the claim must appear to be established prima facie through scientifically cogent reasoning or experimental evidence set out in the specification*” (para 195). He continued:

*“[195] .... Despite the use of phrases such as “reasonable prospect” and “might well produce”, there is a real risk that the test as described by Lord Sumption would amount to, or be understood as, involving a requirement to establish a prima facie case on the material contained in the specification. In my opinion, the authorities analysed above do not put the standard so high. They certainly reject speculative or wide-ranging unsubstantiated claims. But they accept as sufficient a tailored claim which appears scientifically possible, even though it cannot be said to be even prima facie established, without for example testing or assays according to the state of the art. Only if a person skilled in the*



*art would have significant doubts about the workability of the invention would it, in such a case, fail for insufficiency of disclosure.*

*[196] I therefore consider that Lord Sumption's judgment puts the test of sufficiency of disclosure too high. I agree with the way in which Lord Hodge puts the position in para 181 of his judgment...."*

163. Ultimately, it appears to me that the gap between the majority and minority positions in *Generics (UK) Ltd v Warner-Lambert Co* as to the applicable threshold test is a narrow one and, in practice, the circumstances in which they might lead to different outcomes are likely to be limited.
164. *Generics (UK) Ltd v Warner-Lambert Co* itself was, of course, such a case, though only to a limited extent. The sole difference between the majority and minority on the issue of sufficiency was whether the disclosure in the patent was sufficient to make plausible the claim that the pregabalin was effective for the treatment of peripheral neuropathic pain. Lord Hodge and Lord Mance would have upheld the view of Arnold J in the High Court that Warner-Lambert “*had done just enough to satisfy the plausibility test in relation to peripheral neuropathic pain*” (per Lord Hodge, at para 182). As is, however, apparent from Lord Hodge’s discussion of Arnold J’s judgment, there was material in the patent which, read in light of the common general knowledge, might suggest that pregabalin’s efficacy in treating pain extended beyond inflammatory pain. It was common general knowledge that central sensitisation was involved both in relation to inflammatory pain and in relation to peripheral neuropathic pain. The empirical data

disclosed in the patent (and in particular the test results of the “*rat paw formalin test*”) read in the light of the common general knowledge was sufficient, in the view of Arnold J, to make credible the claim of efficacy in respect of peripheral neuropathic pain. The majority of the Supreme Court disagreed, for the reasons set out in detail in the judgment of Lord Sumption. But the difference was ultimately one of degree.

165. None of the judgments appear to support Boehringer’s argument that the mere assertion that the invention makes the claimed technical contribution is sufficient, at least in the absence of material giving rise to a “*substantiated doubt*” or its related argument that the onus is on the objector to show that the claimed technical contribution is implausible. That clearly was not the view of Lord Sumption. It was not the view of Lord Hodge either. While there are statements in the judgment of Lord Mance which appear to come close to Boehringer’s position, he ultimately agreed with the position set out in para 181 of Lord Hodge’s judgment and his principal concern (and the reason for his disagreement with Lord Sumption) was the standard of plausibility required to be demonstrated and in particular his concern that the test as formulated by Lord Sumption was, or would be understood as, a test of *prima facie* efficacy. Significantly, the judgment of Arnold J on the issue of sufficiency, which Lords Hodge and Mance would have upheld, does not support (and is in fact clearly inconsistent with) the proposition that the mere assertion of efficacy is sufficient in this context.
166. *Generics (UK) Ltd v Warner-Lambert Co* involved plausibility as regards sufficiency of disclosure in the context of Articles 83 and 84 EPC (sufficiency) rather than sufficiency of disclosure in the context of Articles 54 & 56 EPC (inventive

step/technical contribution). But as Lord Sumption observed, the test has the same purpose in both contexts. Furthermore, there is no suggestion in *Generics (UK) v Warner-Lambert Co* - or indeed in any of the many other authorities cited to the Court on this appeal - that the standard of plausibility to be applied in the context of inventive step/technical contribution is *lower* than that applicable in the context of sufficiency.

*Boehringer's Case on the EPO jurisprudence*

167. I have set out above Boehringer's contentions regarding the effect of the EPO jurisprudence and in particular the decisions of the Board of Appeal in *Arch* and *Ipsen*. To recap, Boehringer argues that, in the case of a product patent such as the 220 Patent, the mere assertion of efficacy is enough. No issue arises *at all* (Boehringer's emphasis) in relation to plausibility of technical contribution in the absence of a substantiated doubt arising from the patent and/or the common general knowledge.
168. As I have already observed, this argument does not appear to have been advanced before the High Court and the Judge was not referred to *Arch*, *Ipsen* or *Supergen*. None of the authorities relied on by the parties before the High Court supported the argument now sought to be advanced by Boehringer. While there are issues as to the precise test applied by the Judge and the manner in which he applied it, it is clear that the Judge was of the view that plausibility of technical contribution indeed arose as an issue here and that (in his words) the specification had to "*provide enough information to show that a technical contribution has been made and that there is an inventive step*". Boehringer has not appealed from the Judgment or sought to vary it in any respect. The

necessary implication of the argument advanced by Boehringer for the first time in this appeal is that the Judge's approach to the issue of plausibility of technical contribution was fundamentally mistaken. It was open to Boehringer to make whatever arguments it considered appropriate in the High Court on the basis of *Arch*, *Ipsen* and *Supergen*. Not having done so in the High Court, it would in my view be fundamentally inconsistent with the appellate jurisdiction of this Court to permit Boehringer to make such a radically new case on this appeal. It was not flagged in any way in the Respondent's Notice filed by Boehringer. On the contrary, the Respondent's Notice maintained that the Judge correctly identified the applicable principles and applied them correctly to the facts and evidence and asserts that the "*essential test for plausibility is whether the claimed invention is credible on the basis of what the skilled person would take from the patent specification.*" It would be grossly unfair to Teva (and to the Judge) to allow Boehringer to alter its position now.

169. Boehringer's argument is not, in any event, a persuasive one. It is, in essence, the same argument that was considered and rejected by the Supreme Court in *Generics (UK) Ltd v Warner-Lambert Co*, albeit by reference to a differently selected sub-set of EPO decisions (notably, Boehringer did not seek to place any reliance on *Allergan* or *Bristol-Myers Squibb*). *Arch* is the first of the Board of Appeal decisions invoked by Boehringer. The application there was for a patent for "*methods and compositions for viral enhancement of cell killing*" involving the use of the herpes simplex virus in combination with a suitable chemotherapeutic agent, for use as an alternative anti-cancer therapy. The application was refused by the examining division, *inter alia*, because of the absence of experimental data showing the synergistic effect of proposed

combination therapy. The Board of Appeal observed that there was no requirement in the EPC that a patent application should include experimental evidence in support of patentability or a claimed technical effect. Hence, it continued, “*the fact that the disclosure in a patent application is merely theoretical and not supported by experimental data is in itself no bar to patentability or to the presence of a technical effect being acknowledged*” (para 18). In *Arch*, the “*theoretical statements*” in the patent application were clearly considered sufficient by the Board, particularly because, in its view, the technical problem to be solved was properly formulated in less demanding terms than it had been by the examining board. The patent application as filed addressed “*expressis verbis the claimed subject matter and potentiation (additive until synergistic killing effect on cells/cancer cells)*” (para 18) and the technical effect was announced “*albeit at a theoretical level*” in the application as filed (para 20). The Board’s statement at para 22 that it saw “*no grounds for doubting*” that the combination therapy would achieve an increase in the level of cell killing must be understood in the light of those earlier observations and cannot, in my view, be read as formulating any general principle that assertions as to technical contribution, however bare, must be taken at face value in the absence of substantiated doubts. I am fortified in that conclusion by the fact that, in the course of its decision in *Arch*, the Board refers to *John Hopkins* without any suggestion that it considered it to be incorrect (at para 21).

170. As for *Ibsen*, it was considered in detail by the Supreme Court in *Generics (UK) Ltd v Warner-Lambert*. I agree with the analysis of Lord Sumption. Again, the examining division had laid emphasis on the absence of experimental data supporting the claimed technical contribution (here improving the survival of transplanted cells). The Board

pointed out that that issue was addressed specifically in the application as filed “*albeit in a theoretical manner*”. On the basis of that “*disclosure*”, the Board noted that “*the application explicitly addresses the effect(s) claimed*” (para 11). The examining division had not produced arguments discrediting the plausibility of the claimed invention and the Board saw no reasons to doubt its usefulness (para 12). In other words (as I read the decision in *Ipsen*) there was no reason to doubt the theoretical justification offered in the application. That being so, there was no requirement to provide experimental data showing the claimed effect. That was “*not always required to establish that the claimed subject-matter solves the objective technical problem*” (para 13). The later statements in *Ipsen* relied on by Lord Mance must, in my opinion, all be read in light of this analysis.

171. *Supergen* and *Novo Nordisk* relate to Article 83 rather than Articles 54 and 56 and the references to the specification being sufficient if it enables the invention to be produced must be understood in that context.
  
172. None of these decisions (and this is true also of the additional EPO decisions considered by the Supreme Court in *Generics (UK) Limited v Warner-Lambert Co*) appear to cast any doubt on the key decisions of the Board of Appeal in *Agrevo* or *Johns Hopkins*. Doubtless, the issue of whether a claimed technical contribution is plausible is context-dependent. Much will depend on the nature of the invention, the nature and breadth of the claimed technical contribution, the disclosure in the specification and what is the relevant common general knowledge. As is evident from the EPO jurisprudence, experimental data is not required in all cases. However, there will be cases where such

data is required to establish plausibility of technical contribution. In other cases – such as *Arch* and *Ipsen* – a theoretical justification may suffice, at least in the absence of evidence tending to contradict that theoretical justification. In these circumstances, it is unsurprising that the language used by the Board in formulating and applying the test for plausibility of technical contribution should differ somewhat from one case to another case. Those differences in language – what Lord Sumption referred to as “*turns of phrase in the cases*” – simply do not bear the weight that Boehringer’s argument requires them to bear.

173. I would, lastly, observe that the argument advanced by Boehringer appears either not to have been made or, if made, not to have been accepted in any of the other EPC Contracting States where the 220 Patent has been litigated. No such argument was advanced in the Patents Court where – as here – it appears to have been accepted by all parties that the applicable principles were set out in authorities such as *Generics (UK) trading as Mylan v Yeda*. While *Agrevo and Johns Hopkins* were cited, *Arch*, *Ipsen* and *Supergen* do not appear to have been referred to.

*My Conclusions as to the Applicable Test*

174. In my view, the applicable test is as stated by Kitchin LJ at para 114 of *Idenix Pharmaceuticals v Gilead*, namely that “*in light of the teaching in the specification and the common general knowledge*” there “*must be a real reason for supposing that the claimed invention will indeed have the promised technical effect*”. That is also the test applied by Morgan J in the Patents Court in the challenge to the 220 Patent.

175. That test is consistent with the approach taken by the majority of the Supreme Court in *Generics (UK) v Warner-Lambert Co*. While that involved plausibility as regards sufficiency of disclosure rather than plausibility as to technical contribution, it is clear from the judgment of Lord Sumption that he considered that the test adopted by him was applicable to both. *Generics (UK)* involved a Swiss-form patent for a second medical use but the principles identified by the Court are not, in my view, limited to such patents, as is evident from authorities such as *Idenix* and *Generics (UK) Ltd t/a Mylan v Yeda*, neither of which involved a Swiss-form patent.
176. Whether a “*real reason*” is disclosed requires assessment on a case-by-case basis and cannot be the subject of any *a priori* rule. Proof of efficacy – even to a *prima facie* standard – is not required. I agree with Teva that Lord Sumption’s judgment in *Generics (UK) v Warner-Lambert Co* is not to be read as requiring *prima facie* proof. On the other hand, mere assertion will not suffice. There must be something that demonstrates that the claimed technical contribution is not speculative and that will cause the skilled person to think that there is a real basis for thinking that the claim is true and that “*the claimed invention will indeed have the promised technical effect*”. I do not think that this formulation differs in any material way either from the test formulated by Lord Sumption in *Generics (UK) v Warner-Lambert Co* at para 37 (“*there must be something that would cause the skilled person to think that there was a reasonable prospect that the assertion would prove to be true*”) or the test suggested by Lord Hodge at para 179 (“*the specification must disclose some scientific reason for thinking that the [invention] might well have the claimed ... effect*”). Insofar as there is a conceptual difference



between those two formulations of the applicable test, it has no practical significance here in any event, as I shall explain.

177. In my view, this test is applicable to all categories of patent, though its application will obviously depend on the nature of the patent and the claimed invention. It is not the case that its application is confined to Swiss-form patents or to patents involving early-stage science in high technology fields such as the identification of genes and proteins. No category of patent is *a priori* excluded from the requirement to demonstrate that its claimed technical contribution is plausible, though as a matter of common sense the narrower and more specific the claimed invention, the more readily that can be done.

178. As I have explained above, it is not evident to me that the Judge was, in paragraph 155 of his Judgment, intending to formulate a lower or less exacting test than the one I have just set out. However, if and to the extent that his reference to the skilled person being “*encouraged to try the invention*” was indeed intended to identify a lower threshold for plausibility than that I have articulated, I respectfully conclude that he was in error to that extent.

179. As regards the admissibility of later published data or the results of experiments carried out after the priority date, the position was not really in dispute before us. As Morgan J put it, where the invention is not made plausible by the disclosure of the patent (read in the light of any relevant common general knowledge) that is “*the end of the matter*” and in such circumstances it is “*not open to the patentee to rely on post-dated evidence to demonstrate the technical effect*” (at para 134(6)). Conversely, where the disclosure

is plausible, subsequent data may be admitted in order to confirm the efficacy of the invention and/or to refuse a challenger's contention that it does not work.

### **Applying the Test Here**

180. Does the 220 Patent, read in the light of the relevant common general knowledge, provide "*a real reason for supposing that the claimed invention will indeed have the promised technical effect*"?
181. The technical contribution/technical effect of the 220 Patent is set out at page 2 of the Patent and has already been set out in this judgment.
182. In common with all other judges who have addressed this issue, I am of the view that there is nothing in the teaching of the 220 Patent that provides any reason for supposing that the claimed invention here – the inventions within the scope of amended claims 6-8 of the Patent – would have the promised technical effects of stability of the active substance, high metering accuracy in the release of the active substance, complete emptying of the capsule and good perforation qualities with good stability and low brittleness.
183. As Boehringer itself emphasised in its submissions, the claimed invention here was not the use of HPMC capsules with tiotropium. It was, Boehringer says, for use of HPMC capsules with "*a reduced moisture content*". In fact, of course, the claims embody specific water content limits which cannot be disregarded. But, in any event, what is

the teaching of the 220 Patent as to the technical effect of using HPMC capsules with “*a reduced moisture content*”?

184. One must first ascertain what the 220 Patent means when it refers to “*a reduced moisture content*” in this context. Helpfully, that is expressly defined in the specification “*as being equivalent to a TEWS moisture level of less than 15%.*” There was no dispute here that the ambient or normal moisture content of HPMC capsules is in fact significantly lower than 15%. *Ogura* had suggested that the average normal moisture content for such capsules was between 2-5%. Boehringer says that the Protocol 5 experiments carried out by it established that the normal moisture content of HPMC at normal manufacturing conditions was “*above 5%*”.<sup>59</sup> Rather unhelpfully, Professor Birchall (whose evidence about those experiments was accepted by the Judge) does not appear to have identified any more specific value (or range of values) in his evidence and certainly the Judge made no clear finding on that issue. But it seems clear that the Judge was persuaded that the experiments disclosed a higher normal moisture content than that indicated in *Ogura* or in *Nagata*.<sup>60</sup> In this context, I note from the judgment of the Hague Court of Appeal that Boehringer’s evidence in those proceedings was to the effect that it was “*generally accepted that the moisture content*

---

<sup>59</sup> Speaking Note on Plausibility Grounds of Appeal, para 22.

<sup>60</sup> S. Nagata “Cellulose Capsules – An Alternative to Gelatin” in Chiellini (ed) *Biomedical Polymers and Polymer Therapeutics* (2001). *Nagata* postdates the priority date of the 220 Patent. *Nagata* indicated that the normal moisture content of HPMC was 4-6%. *Ogura* and *Nagata* appear to have constituted the only evidence before the High Court as to what the common general knowledge might have been as to the normal moisture level of HPMC as of or close to the priority date. It is not clear on what basis the Protocol 5 data was tendered or admitted in the High Court but it may be that it was understood to represent testing that the skilled person could have carried out as of the priority date.

*of HPMC under ambient conditions was between 5% and 7%”* and that appears to be consistent with the approach of Boehringer here. It would indeed be surprising, and disquieting, were it the case that Boehringer had adopted different positions on this issue in different jurisdictions.

185. In any event, the 220 Patent says nothing about the normal moisture content of HPMC and its definition of a “*reduced moisture content*” clearly indicates to the reader that the technical effects claimed for HPMC capsules could be achieved by the use of HPMC capsules with ambient or normal moisture levels. The reader would not deduce that the technical effects claimed could only be achieved by the use of HPMC capsules with reduced moisture content in the sense of lower than normal/ambient levels of moisture i.e. HPMC capsules that had been subjected to a drying process. That was the view taken by the Borgarting Court of Appeal in Norway and by the Hague Court of Appeal in the Netherlands, as is evident from the discussion of their judgments earlier in this judgment. The same point is made by Morgan J in his judgment.

186. The specification cannot be read as making a claim only to HPMC capsules that have been dried below normal or ambient moisture levels. Not alone is that not said anywhere in the specification (and it would have been an easy thing to say), what is said is wholly inconsistent with that construction. The specification can only be read as claiming that, provided only that they have “*a reduced moisture content*” as defined in the specification, all HPMC capsules come within the scope of the invention and their use will achieve the claimed technical effects of stability, dosage accuracy and so on. That is reflected in (original) claim 6 of the Patent. The use of capsules with a moisture

content of “*preferably less than 8%*” (which includes HPMC capsules with normal or ambient levels of moisture content) is then reflected in (original) claim 7 of the Patent.

187. I do not overlook the fact that the specification does refer to the drying of capsules (at page 5). However, there is no suggestion there that HPMC capsules had to be dried to below normal or ambient moisture level in order to achieve the technical effects claimed by the Patent. In fact, that part of the specification expressly states that the drying is carried out “*until a moisture level is reached which corresponds to the specification of not more than 15% TEWS or halogen moisture content according to the invention*” (my emphasis). HPMC capsules do not require drying to come below the 15% moisture content threshold. While there is a reference on page 4 of the specification to capsules consisting of cellulose derivatives “*most preferably*” being dried to a “*TEWS or halogen moisture content of less than 4%, particularly preferably less than 2%*” before being filled, that clearly does not limit the claimed invention in any way or indicate that the claimed technical effects would be achieved only at those levels or give any indication whatever of the functional or technical significance of those *preferred* thresholds.

188. While Boehringer has sought to rewrite the claims of the Patent insofar as they relate to the use of HPMC capsules in order to claim protection only for capsules dried below normal/ambient levels of moisture content, the specification said to support those claims and render them plausible does *not* confine the claimed technical effects to dried HPMC capsules. That appears to me to be a fundamental difficulty for Boehringer here. If, as it contends, amended claims 6 – 8 are “*embodiments*” of the inventive concept of the formulation of tiotropium in reduced-moisture capsules, not in the sense in which

“*reduced-moisture*” is used in the 220 Patent but in the quite different sense of being dried below the normal or ambient moisture content, how can it then be suggested that the specification makes those claims plausible in the absence even of any assertion in the specification that the technical effects claimed could be achieved only by the use of such capsules?

189. Furthermore, and in any event, there is nothing in the specification that explains why the use of HPMC capsules of any particular moisture-content will produce different effects in terms of stability etc. While Boehringer disputes any requirement to demonstrate “*boundary effects*” as between amended claims 6, 7 and 8, even on its case, there is one critical boundary, namely the boundary between HPMC capsules with a moisture content of above 5% (the use of which is no longer the subject of any claim to protection by Boehringer) and such capsules with a moisture content of 5% or less (which come within one or more of amended claims 6-8). However, there is nothing in the specification that suggests that this boundary or threshold has any functional or technical significance or which would lead the reader to expect that anything would be achieved by using HPMC capsules with a moisture level lower than 5% which would not be achieved by using capsules with a moisture content of 5% or higher. There is no data in the 220 Patent that supports that claim nor is there any theoretical disclosure that does so. That was also the view taken by the Bogarting Court of Appeal, the Hague Court of Appeal and by Morgan J in the Patents Court in London.
190. Boehringer says that it is only if the inventive concept (which it says is the use of “*dried HPMC*”) is obvious that the arbitrariness or otherwise of the moisture thresholds can

become an issue. I do not accept that that is so. I will come back to that issue when considering the extent (if any) to which the common general knowledge is relevant when considering the plausibility of amended claims 6- 8. But it appears to me that the plausibility challenge here is, as a matter of principle, independent of the conventional obviousness challenge. Even if the use of dried HPMC capsules (that is, according to Boehringer, capsules with a moisture level of 5% or less) was not obvious, there is still the issue of whether the claims are plausible. In terms of amended claim 6, the question is whether the specification discloses a real reason for supposing that the use of HPMC capsules with a moisture content of 5% or less will have the promised technical effects, whereas those effects are not (according to Boehringer) achieved by the use of capsules with a normal moisture content. In my opinion, the specification discloses no reason whatsoever for supposing that to be true. That is hardly surprising given that the hard cut-off that Boehringer now seeks to maintain between HPMC capsules with normal levels of moisture content and dried HPMC capsules finds no support whatever – indeed, is not even identified - in the teaching of the Patent.

191. Equally, the specification fails to disclose any basis for believing that the threshold moisture contents of 4% and 2% in amended claims 7 and 8 have any technical or functional significance whatever. That was also the view taken in Norway, the Netherlands and in England and Wales. Those numbers are entirely arbitrary.
192. Boehringer says that these courts misunderstood the relevant amended claims. They do not, Boehringer says, make any claim to “*boundary effects*” at all. That submission is difficult to credit. The amended claims 6, 7 and 8 – which, after all, were formulated

by Boehringer itself – appear on their face to assert that the thresholds of 5%, 4% and 2% have some significance and that inventions within the scope of those claims will achieve something different, one from the other. That appears to have been Professor Birchall’s view also, as is evident from the passage from his evidence which is set out by the Judge at para 166 of his Judgment and which I have set out at para [130] above.<sup>61</sup> There, Professor Birchall clearly characterises the 5% moisture content threshold in amended claim 6 as a “*boundary*”. Professor Birchall accepted that there was no data in the 220 Patent to indicate that the technical aims of the Patent would be achieved below, but not above, that 5% threshold but said that he “*would have thought they have done tests because they have come up with a boundary*” adding that “*you do your test first, you establish your boundary, you do your test and you demonstrate whether that boundary makes a difference or not*”. As regards claim 7, Professor Birchall also accepted that there was no data in the 220 Patent which suggested that different technical effects would be achieved either side of that threshold and that “*you would have to test it.*”<sup>62</sup> In respect of amended claim 8, Professor Birchall referred to the fact that one of the examples in the Patent had a moisture content in the range of under 2% and suggested that the reader might take from that example that “*this might one of the ones that is working particularly well.*” As a matter of fact, the example provides no information whatever, whether empirical or theoretical, as to the technical effects (if any) that could reasonably be expected to be achieved by the use of HPMC capsules with a moisture level of less than 2%. However, the main point here is that Professor Birchall seems clearly to have understood amended claims 6, 7 and 8 as involving a

---

<sup>61</sup> Evidence given on Day 12, pages 38-39.

<sup>62</sup> Day 12, page 41.



claim to boundary effects, albeit that the boundaries in those claims were not supported by any data in the Patent and would have to be tested.

193. It is also of relevance that Boehringer in fact presented experimental evidence at trial for the very purpose of demonstrating that the moisture content limits in amended claims 6, 7 and 8 were significant and Professor Birchall gave evidence to that end in his witness statement and supplemental witness statement (directed specifically to the Protocol 6 experiments). If (as Boehringer now appears to contend) there is no significance to be attached to the thresholds in amended claims 6, 7 and 8 (or, alternatively, the thresholds in amended claims 7 and 8, having regard to the key importance attached to the 5% threshold in amended claim 6) because they are all simply embodiments of the inventive concept of formulating tiotropium in reduced-moisture (in the sense of dried) HPMC capsules, one wonders what was the purpose of those experiments and that evidence.
194. It also appears to me that Boehringer's argument mischaracterises the inventive concept found by the Judge. The Judge did not find that the inventive concept was the formulation of tiotropium in reduced-moisture HPMC; rather, it was/is "*the formulation of tiotropium in prescribed reduced-moisture HPMC capsules, being HPMC capsules with  $\leq 5\%$  water content,  $\leq 4\%$  water content and  $\leq 2\%$  water content*" (Judgment, para 115; my emphasis). That was precisely the inventive concept that had been urged on the High Court by Boehringer who had submitted that "*the specific water content limits of the claims embody the inventive concept ... They are not separate from it.*" That was clearly accepted by the Judge, who found that "*each of the*

*moisture limits in the 220 Patent claims*” made “*a technical contribution to the art in itself*” as did the inventive concept that they embodied (Judgment, para 141(6)). These findings have not been challenged on appeal. In the circumstances, Boehringer cannot now be heard to suggest that those water content limits are to be regarded as having no significance.

195. In my view, the specification (and thus far I have been addressing the specification only) does not contain any teaching that would give the reader any reason – still less a real and credible reason – that the inventions within the scope of amended claims 6, 7 and 8 would have the claimed technical effects set out in the specification of the 220 Patent. The specification does not disclose “*any scientific reason*” for thinking that such inventions would have the claimed effects and there is nothing in the specification that would cause the skilled person to think that there was “*a reasonable prospect*” that the assertion that the inventions would achieve those effects was true.

196. I will now consider whether the common general knowledge might supply the deficiencies in the specification and make plausible amended claims 6, 7 and/or 8..

197. Notably, it was Boehringer’s case – and Professor Birchall’s evidence – that there was nothing in the common general knowledge that gave any reason for thinking that the technical effects claimed in the specification would be achieved by the use of HPMC capsules of the prescribed moisture levels. Boehringer’s case was, of course, that the use of HPMC capsules of the prescribed moisture levels – i.e. HPMC capsules dried to below normal moisture levels – was novel and inventive, solving a problem that had

not even been identified as of the priority date (the sensitivity of Tiotropium to moisture) in a manner that was in fact counter-intuitive (because, according to Boehringer, the skilled person would be concerned that reducing the moisture content of HPMC capsules would cause difficulties in terms of electrostatic charges/static electricity).

198. In any event, Professor Birchall gave clear evidence that, *“there is no information in the common general knowledge that reducing the moisture content would give you”* the benefit of stability.<sup>63</sup> Stability was, of course, only one of the asserted technical effects identified in the specification but at no point was it suggested by Boehringer that the common general knowledge suggested that the reducing the moisture content could plausibly deliver any of those other technical effects.
199. Professor Birchall did suggest in this evidence that anyone reading the 220 Patent would take comfort from the fact that the patentee was Boehringer. As he put it at one point during cross-examination: *“[t]hey’re looking at it, a big pharmaceutical company has come up with this idea and has got to the formula, so one would assume that they’ve done lots of testing.”*<sup>64</sup> In fairness to Professor Birchall, he did make it clear that it was not a *“major consideration”*. But, in my view, any suggestion that the claims of a patent might be made plausible on the basis of assumptions made arising from the identity of the patentee is wrong in principle. The law is clear – the technical contribution claimed by a patent must be plausible on the basis of the specification, read in light of any

---

<sup>63</sup> Day 12, page 40.

<sup>64</sup> Day 12, page 38.

relevant common general knowledge. The identity of the patentee is not relevant in this context. If it were, precisely the same claims could be considered plausible or not, depending on the identity of the patentee. That is not the law.

200. Accordingly, on Boehringer's case, common general knowledge does not assist in making amended claims 6, 7 and 8 plausible. The Judge accepted Boehringer's evidence as to what was common general knowledge, finding that "*HPMC capsules for inhalation were not part of the common general knowledge or the starting point for such a formulation, let alone reduced-moisture HPMC capsules*" (Judgment, para 129). Teva had, through the evidence of Professor Buckton, sought to make the case that the use of HPMC capsules, including use in inhalation devices, was common general knowledge as of the priority date of the 220 Patent. That claim was rejected by the Judge (as it had been by Morgan J in London). However, Teva did not contend that the use of reduced-moisture HPMC capsules (i.e. capsules dried to lower than normal moisture content) was common general knowledge. If that were the case, amended claims 6 would clearly have been obvious. Thus, even on Teva's version of what was common general knowledge as of the priority date (which the Judge rejected), it would not provide any basis for making plausible the claim that the use of reduced-moisture HPMC capsules (and only such reduced-moisture capsules) would achieve the technical effects claimed in the specification or make the technical contribution said to justify the monopoly sought in the form of the amended claims.
201. Teva did, of course, maintain that the use of HPMC capsules in inhalation devices was obvious as of the priority date. But a finding to that effect would not preclude a finding

that amended claims were invalid on grounds of *Agrevo* obviousness/lack of plausible technical contribution or that the moisture levels specified in those claims were arbitrary. That is demonstrated by the findings of Morgan J in the Patent Court and the contrary position was not argued by Boehringer. Far from arguing that a finding that the use of HPMC capsules was not inventive would foreclose Teva's *Agrevo* obviousness challenge, Boehringer in fact advanced the contrary argument – namely that the *Agrevo* obviousness challenge could succeed only in the event that the use of HPMC capsules was obvious and non-inventive. I have already explained why I consider that argument to be misplaced.

202. As I have noted above, in its submissions Boehringer relies on the evidence of Professor Buckton as accepting that the invention was plausible for formulations in reduced-moisture content HPMC capsules. He had, Boehringer emphasises, accepted that one would expect that reducing the water content of the capsules would have benefits in terms of less hydrolysis and better physical delivery. But the entire thrust of Professor Buckton's evidence to the effect that the skilled person would have expected benefits to follow from using capsules with lower normal moisture levels (such as HPMC capsules, with a normal moisture level significantly lower than the normal moisture level of gelatin) and/or capsules with reduced moisture levels (i.e. capsules that had been subject to a drying process) – and thus would have been motivated to try HPMC capsules for dpi use - was challenged by Boehringer, contradicted by Professor Birchall and roundly rejected by the Judge. It is opportunistic and wholly impermissible for Boehringer to pluck a statement from Professor Buckton's evidence simply because it suits it in this context. If it wants to rely on Professor Buckton's evidence, it would have

to accept the consequences of that evidence for the issue of conventional obviousness.

203. In the light of the above analysis, it appears appropriate to address the specific findings made by the Judge which led him to this ground of challenge to the 220 Patent. I will do so *seriatim*:

- *It was clear from the caselaw that there was no requirement in the EPC that a patent should contain data or experimental proof to support its claims (Judgment, para 165)*

That is correct as far as it goes. There must, nonetheless, be something in the specification of the patent, read in light of the common general knowledge, that gives a real reason for thinking that the claimed invention will make the claimed technical contribution/achieve the technical effects claimed.

- *It was clear from Professor Birchall's evidence that the benefits to be obtained at the water-content thresholds of the 220 Patent were plausible. (Judgment, para 166)*

The evidence of Professor Birchall did not add anything to Boehringer's case on plausibility of technical contribution. The essence of that evidence was that the skilled person had no reason to think that he or she would *not* see the claimed benefits if they made and used HPMC capsules in accordance with the 220 Patent. However, that is not the test. The test is whether the 220 Patent, read in light of

common general knowledge, gave the skilled person a real reason to think that the claimed benefits would be achieved. As already explained, Professor Birchall disavowed any reliance on common general knowledge and did not suggest that there was anything in the specification of the Patent itself that disclosed any such reason. He did suggest that the reader of the Patent would assume that Boehringer had carried out tests but, in the absence of any reference to any such tests in the Patent itself, that is not a relevant consideration for the reasons given above.

- *Professor Buckton had accepted that the skilled person could readily do measurements to check the technical benefits from the patent (Judgment, para 168)*

The fact that the claims of the Patent could be tested does not, of itself, render those claims plausible.

- *Teva's argument as to plausibility was inconsistent with the experimental evidence. Such evidence could be adduced "to support a technical effect made plausible by the specification, and the court accepts that the invention in issue was rendered plausible by the 220 Patent" (Judgment, para 175)*

The experimental evidence could only be admitted if the claimed technical effects were made plausible by the specification (read in the light of the common general knowledge). If the claimed technical effects are not plausible, they cannot be saved by the experimental evidence.

- *The 220 Patent identified the benefits to be obtained from the invention and gave the reader the information necessary to make the products claimed. Professor Birchall's evidence made it clear that the Patent provided the skilled person with everything needed to make the claimed capsules for use in a DPI and nothing in the Patent would have put the skilled person off doing so. (Judgment, para 176)*

The requirement that the asserted technical contribution be made plausible is not satisfied by showing that the Patent gave the information necessary to make the products claimed. Equally, the fact that the Patent does not “*put the skilled person off*” making the products is not the test.

- *The objection as to plausibility was misplaced in a challenge to a patent such as the 220 Patent. The 220 Patent had a notably discrete subject matter involving a new formulation approach to a medicine comprised of a single active substance (tiotropium) and its salts and forms for two identified conditions, namely asthma and COPD and as such the proceedings were “starkly different” from cases involving early-stage science in high-technology fields (Judgment, para 177).*

The fact that the 220 Patent may have been “*starkly different*” from patents involving early-stage science in high technology fields did not relieve the patentee from the requirement that the claimed technical contribution should be plausible (though, perhaps, it meant that the burden on the patentee might more readily be discharged). I note in this context that the courts of Norway, the Netherland and of England and Wales have all taken the view that the 220 Patent could be challenged



on grounds of plausibility and that those challenges were successful.

- *The test of plausibility was a threshold test which was satisfied by a disclosure that was credible rather than speculative. In the Judge's view, there was "ample in the 220 Patent by way of worked-out instructions as to the making of embodiments of the invention to demonstrate to the notional skilled person that it is not speculative." (Judgment, para 178)*

This is, with great respect, no more than assertion and there is no basis for it in the specification of the Patent or in the evidence.

- *In truth, what Teva was seeking to achieve under the heading of plausibility was to establish a ground of challenge, unrecognised at law, whereby Boehringer would not be entitled to its patent if it did not provide proof of the effectiveness of the invention of the patent. Such a basis of challenge had been rejected by Lord Hoffman in *Conor Medsystems Inc v Angiotech Pharmaceuticals* [2008] UKHL 49, [2008] RPC 28 (Judgment, para 179)*

I respectfully disagree with the Judge. Teva's challenge is not advanced on the basis that Boehringer was required to provide "*proof of the effectiveness of the invention of the patent*". Teva accepts that what is required by the law is not "*proof*" - even to a *prima facie* level - but the lower threshold of a real reason to think that the invention will make the claimed technical contribution. It is that lower threshold that Teva says has not been satisfied here.

204. The Judge also referred to the evidence of Professor Buckton in this context. Professor Buckton had, it will be recalled, explained in his evidence that while one would expect to see benefits from reducing water content (that was, he said, “*a reasonable overarching concept*”) that did not lead you to “*the numbers which are in the Patent*”. He noted that Teva had placed reliance on that evidence but commented that he would have found the evidence “*rather more persuasive*” had Professor Buckton not indicated in an answer “*but two minutes previously*” that there was real substance to the 220 Patent. The Judge also refers to evidence given later by Professor Buckton in which, in the Judge’s view, he had contradicted himself as to the significance of the absence of test results. As to the evidence given “*two minutes previously*”, the context was that Professor Buckton was asked to comment on a statement by Professor Birchall to the effect that the skilled person would draw comfort from the fact that the 220 Patent came from the Boehringer “*stable*”. He thought that no comfort could be drawn from the stable and that you could only draw comfort from the information in the Patent. Commenting on a specific statement by Professor Birchall that the skilled person would give weight to the fact that the Patent disclosed specific information about the tiotropium dosage/blend, Professor Buckton accepted that work would have been carried out on dosage in clinical studies (in relation to the active ingredient tiotropium which was the subject of a separate patent application which was pending as of the priority date of the 220 Patent). Professor Buckton accepted that some of the information on dose and blend would have come from the information produced by those clinical studies. However, he added – though this is not set out by the Judge in his Judgment– “[*t*]hat doesn’t mean there is a general position where this was applicable

*to everything across the Patent in terms of all of the options that exist.”*<sup>65</sup> There is nothing in this evidence that could properly be characterised as an acceptance by Professor Buckton that there was “*real substance*” in 220 Patent, as the Judge suggests, and certainly not that the claims in amended claims 6 – 8 had “*real substance*”. That is true also of the later evidence of Professor Buckton to which the Judge refers. There Professor Buckton maintained his criticism of the Patent on the basis of the absence of any testing, though he also accepted that if you already have a trial which is “*in late state, and phase 3*” you will have done a lot of testing “*on that particular product*”. That is clearly a reference to the active ingredient which was not the subject of the 220 Patent. Again, Professor Buckton was careful to add “*that doesn’t mean that you have tested any of the others that are put forward here*” The Judge’s criticisms of Professor Buckton’s evidence in this respect were unwarranted and unfair in my view.

205. In conclusion, I am persuaded that the Judge erred in rejecting Teva’s plausibility challenge to the 220 Patent. The specification of the Patent, read in light of the common general knowledge, does not provide any real reason to think that the assertion that the claimed invention within the scope of the amended claims in dispute will deliver the claimed technical contribution of the invention is correct. Nothing in the Patent suggests that the moisture-content limits set out in amended claims 6, 7 and 8 have any functional or technical significance or make plausible the assertion that the use of HPMC capsules with the prescribed moisture contents specified in those claims would achieve the claimed technical contribution of the Patent whereas use of HPMC capsules with a

---

<sup>65</sup> Day 4, page 24.

moisture content in excess of 5% would not. The Patent does not make plausible the assertion that the technical contribution of the Patent can be achieved by, and only by, the use of dried HPMC capsules. The moisture content levels in amended claims 6, 7 and 8 are arbitrary and make no plausible technical or inventive contribution. Once they are disregarded – as they must be – one is left with claims to the use of HPMC capsules *simpliciter*. However, Boehringer does not claim that the use of HPMC capsules was inventive and it does not assert that the claimed technical contribution set out in the specification can be achieved by the use of HPMC capsules *simpliciter*.

206. The experiments carried out by Boehringer cannot save the amended claims. It is clear that the claims must already be plausible if subsequent evidence is to be admissible. The claims here are not plausible and the experimental evidence is therefore not admissible.
207. It follows that this ground of objection to amended claims 6, 7 and 8 has been made out and those claims are invalid.

## **IX – PLAUSIBILITY AS TO SUFFICIENCY**

208. In view of the findings just made, it is not necessary to address this ground of objection further.

## X - CONCLUSIONS

209. I shall summarise my conclusions briefly:

- The Judge failed to assess the evidence of Professor Buckton properly or fairly. The Judge effectively discounted his evidence by adopting an across-the-board preference for the evidence of Professor Birchall which was not justified.
- While the Judge engaged with the substance of the evidence given by Professors Buckton and Birchall (with some significant exceptions), the Judge's unjustified general preference for the evidence of Professor Birchall – a general preference repeated time and again in the course of the Judgment – fatally undermines the reliability of the evidential findings made by the Judge.
- Had I not concluded that Teva's appeal on the ground of *Agrevo* obviousness/lack of plausible technical contribution must succeed, I would have set aside the Judgment of the High Court on the conventional obviousness ground and directed a retrial on that issue.
- The conclusion that, in principle, the Judgment should be set aside and a retrial ordered is reinforced by the Judge's disregard for the requirements of *Ranbaxy* and his failure to engage with the other decisions on the 220 Patent. It is not necessary to consider whether, if that issue stood alone, it would justify such an order. It is a further factor pointing to the conclusion that the Judge's assessment of the

conventional obviousness issue was unsatisfactory.

- The threshold test for *Agrevo* obviousness/lack of plausible technical contribution is that set out by Kitchin LJ at para 114 of *Idenix Pharmaceuticals v Gilead*, namely that “*in light of the teaching in the specification and the common general knowledge*” there “*must be a real reason for supposing that the claimed invention will indeed have the promised technical effect*”. That is also the test applied by Morgan J in the Patents Court in the challenge to the 220 Patent. A mere assertion of efficacy is not sufficient but proof of efficacy, even on a *prima facie* basis, is not required.
- In common with all other judges who have addressed this issue, I am of the view that there is nothing in the teaching of the 220 Patent which provides any reason for supposing that the claimed invention here – the inventions within the scope of amended claims 6-8 of the Patent – would have the promised technical effects of stability of the active substance, high metering accuracy in the release of the active substance, complete emptying of the capsule and good perforation qualities with good stability and low brittleness.
- The specification of the 220 Patent, read in light of the common general knowledge, does not provide any real reason to think that the assertion that the claimed invention within the scope of the amended claims in dispute would deliver the claimed technical contribution of the invention is correct. Nothing in the Patent suggests that the moisture-content limits set out in amended claims 6, 7 and 8 have

any functional or technical significance or make plausible the assertion that the use of HPMC capsules with the prescribed moisture contents specified in those claims would achieve the claimed technical contribution of the Patent whereas use of HPMC capsules with a moisture content in excess of 5% would not. The Patent does not make plausible the assertion that the technical contribution of the Patent can be achieved by, and only by, the use of dried HPMC capsules. The moisture content levels in amended claims 6, 7 and 8 are arbitrary and make no plausible technical or inventive contribution. Once they are disregarded – as they must be – one is left with claims to the use of HPMC capsules *simpliciter*. However, Boehringer does not claim that the use of HPMC capsules was inventive and it does not assert that the claimed technical contribution set out in the specification can be achieved by the use of HPMC capsules *simpliciter*.

- The experimental data sought to be relied on by Boehringer is therefore inadmissible.
- In the circumstances, it is not necessary to address the issue of plausibility as to sufficiency.

210. The parties should, if necessary, have an opportunity to be heard on the terms of the order or orders to be made to give effect to the conclusions of the Court. In its Respondent's Notice, Teva looks for an order revoking the 220 Patent but such an order may go beyond what is appropriate, given that not all the claims of the 220 Patent appear to have been the subject of challenge. The parties will also have an opportunity to



address the question of costs. Given that Teva appears to have been wholly successful in its appeal, it would seem to be entitled to its costs of the appeal. It would also seem to be entitled to the costs of the High Court. However, Boehringer will have an opportunity to contend for some different order if so advised. The parties will have a period of 2 weeks within which to try to agree the terms of the orders to be made (including as to costs). If agreement cannot be reached in that period, the Office should be notified and a further hearing will be scheduled at that stage.

*Noonan and Haughton JJ have read this judgment in draft and agree with it.*