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[approved]

Costello P.
Allen J.
O'Moore J.

IN THE MATTER OF IRISH PATENT NUMBER EUROPEAN PATENT (IE) 1 427 415 "LACTAM-CONTAINING COMPOUNDS AND DERIVATIVES THEREOF AS FACTOR XA INHIBITORS" AND REGISTERED IN THE NAME OF BRISTOL-MYERS SQUIBB HOLDINGS IRELAND UNLIMITED COMPANY

AND IN THE MATTER OF THE PATENTS ACT 1992 TO 2019

BETWEEN/

BRISTOL-MYERS SQUIBB HOLDINGS IRELAND UNLIMITED

RESPONDENT/APPELLANT

– AND –

NORTON (WATERFORD) LIMITED T/A TEVA PHARMACEUTICALS IRELAND

PETITIONER/RESPONDENT

JUDGMENT of Ms. Justice Costello delivered on the 28th day of November 2024

Introduction:

1. This is an appeal from the judgment of the High Court (Barrett J.) of 8 December 2023 ([2023] IEHC 744) and consequent order of 2 February 2024 declaring that Irish patent number EP (IE) 1 427 415 "Lactam – Containing Compounds and Derivatives Thereof as Factor Xa Inhibitors" *("the 415 patent")* and registered in the name of Bristol-Myers Squibb Holdings Ireland Unlimited Company *("BMS")* is, and at all times has been, invalid and should be revoked; and that Supplementary Protection Certificate *("SPC")* No. 2011/032 is, and at all times has been, invalid and should be revoked. The validity of the patent was challenged by the respondent, Norton (Waterford) Limited trading as Teva Pharmaceuticals Ireland, *("Teva")* on two bases; (1) on the grounds of priority, and (2) on the grounds of plausibility. The High Court rejected the case based on priority but held that the patent as filed failed the test for plausibility and accordingly was invalid. BMS appealed the finding of invalidity. There was no cross-appeal against the finding on priority.

Background:

2. This Court has concluded that, on critical matters, the High Court either made no findings of fact or failed to explain such findings that it did make. In those circumstances, it is difficult to set out in a completely satisfactory way the background to these proceedings. However, it is possible to understand the issues giving rise to the dispute on plausibility by reference to the undisputed facts (agreed between the parties), the first witness statement of Dr. Robert Young (a medicinal chemist called by BMS), and the second witness statement of Dr. Paul Edwards (a medicinal chemist called on behalf of Teva).

3. The patent which grounds the relevant asserted intellectual property rights on the part of BMS is, as already noted, the 415 patent. The patent is entitled: -

"Lactam containing compounds and derivatives thereof as factor Xa inhibitors."

4. As we shall shortly see, factor Xa is an oral drug which can prevent the formation of blood clots. The patent includes 140 embodiments, 110 of which are made in the laboratory. Example 18 in the patent is the production of 3.07g of apixaban. The SPC in respect of the patent has been granted in respect of the product apixaban *("ELIQUIS")*. The SPC has an expiry date of the 19 May 2026.

5. The agreed statement of Common General Knowledge *("CGK")* gives a very helpful background to the issues between the parties.

6. The parties agree about the significance of thrombosis as one of the leading causes of disability and death in the world. It was well known at the priority date (the date by reference to which the validity of the patent is assessed), that thrombotic / thromboembolic disorders could be treated by reducing blood clotting through inhibiting the coagulation cascade. There were two main pathways for triggering the coagulation cascade. These were the intrinsic (or contact) pathway and the extrinsic (or tissue factor) pathway. .

7. The intrinsic and extrinsic pathways converge in the common pathway with the activation of Factor X to Factor Xa. I will return to Factor Xa shortly.

8. The agreed CGK continues: -

> *"40. When patients are treated with anticoagulants, systemic hypocoagulation can occur where clots take too long to form. For this reason, anticoagulants are sometimes referred to as "blood thinners." However, anticoagulants do not make the blood "thinner," rather they prolong the time it takes for blood to form a clot. As a result, patients on anticoagulants can bleed easily and suffer spontaneous internal bleeding that can manifest as excessive bruising, gum bleeds, nose bleeds, and in serious cases, intracranial bleeding which can cause a stroke. These side effects are a direct result of the therapeutic action of anticoagulants and can*

outweigh the benefits of decreasing thrombotic risk. Weighing these risks is particularly important when considering preventative long-term treatment with anticoagulants."

9. For these reasons, it was well-established by 2001(the priority date) that an alternative oral anticoagulant was needed. In practice such an oral anticoagulant was to replace Warfarin (first approved for medical use in the 1950's) and Heparin (used as an anti-coagulant since the 1930's). The agreed CGK continues: -

"43. In particular, the clinical need in 2001 was for an oral antithrombotic that:

(a) Was effective at preventing thrombotic disease. It would be even more desirable if the drug was effective at preventing further growth of existing clots;

(b) Was safe and non-toxic;

(c) Had minimal side-effects, in particular with respect to bleeding;

(d) Could be given orally once, or at most twice, a day. This would make it convenient for patients outside of hospital settings who were taking the drug long term, and therefore would be expected to affect patient compliance;

(e) Had low interpatient variability, including low drug-drug and low drug-food interactions;

(f) Had no need for frequent patient monitoring."

10. The agreed CGK goes on: -

"50. Factor Xa was identified as a promising target for the development of new synthetic anticoagulants following the isolation and characterisation in the late 1980s of the first naturally occurring specific factor Xa inhibitor, antistasin, isolated

from leeches, and Tick Anticoagulant Peptide (TAP). TAP is a potent and specific inhibitor of factor Xa which inhibits thrombosis without causing excessive bleeding.

51. By 2001, essentially all the major pharmaceutical companies were attempting to discover novel factor Xa inhibitors … A variety of potent, selective, small molecule factor Xa inhibitors had been described in the scientific literature and some had been taken forward to clinical trials.

52. Factor Xa was considered to be a promising target with several potential advantages:

(a) Both the extrinsic and intrinsic pathways of coagulation culminate in factor Xa activation. Factor Xa then triggers thrombin generation and fibrin formation via the common pathway. Due to its position of convergence of the two separate pathways and because it catalyzes the conversion of prothrombin to thrombin, factor Xa was understood to play a central and crucial role in the coagulation cascade;

(b) Factor Xa inhibitors were predicted to have a lower risk of bleeding than heparin and VKAs and a much wider therapeutic window than direct thrombin inhibitors because they specifically inhibit coagulation without directly affecting platelet function;

(c) Unlike thrombin, factor Xa was not thought to have functions outside the coagulation cascade and therefore negative side-effects as a consequence of inhibition were hoped to be limited; and

(d) When the clotting process begins, many molecules of factor X are activated and each factor Xa molecule can activate more than one substrate molecule. In fact, it was known in 2001 that one molecule of factor Xa could generate many molecules of thrombin per minute.

It was therefore hypothesized that factor Xa inhibition could be a more effective and safer way to prevent blood clot formation than direct thrombin inhibitors as less drug would be needed."

11. This naturally led to the search for a potent and effective Xa inhibitor. At para. 102 of the agreed CGK, it is noted: -

"102. The ability of an inhibitor to inhibit the activity of an enzyme can be measured, and is termed 'potency'. In general, the more tightly an inhibitor binds to the active site, the more 'potent' it is said to be and, the more potent the inhibitor, the less of that compound that is needed to achieve a given level of inhibition."

12. There was also general agreement on the drug discovery process. Paragraph 110 of the agreed CGK reads: -

"110. In 2001, the drug discovery process typically encompassed a number of stages:

(a) The first stage, often referred to as "Target Discovery" (or "Target Identification"), involves the identification of a biological target or pathway that could potentially play a role in the disease. In the case of thrombosis, it was hypothesized that intervention within the blood coagulation pathway could lead to anticoagulant medicines. Early research identified thrombin as an initial target of interest and later factor Xa emerged as an additional target for intervention.

(b) it would be necessary to identify a compound (or class of compounds) that might be promising for further development based on in vitro potency and possibly selectivity against any of key off-target proteins. Preliminary results from in vitro DMPK assays could also be used if the data were available;

(c) if a promising compound/class of compounds was identified, the skilled medicinal chemist would then synthesise variations around the compound(s) and test their potency, selectivity and DMPK properties in the hope that it would be possible to build up an idea of SAR (Structure-Activity Relationships).

(d) using the SAR to narrow the choice of potential compounds to synthesise, the skilled team would synthesise and test compounds in the hope of identifying molecules with sufficiently good potency, selectivity and in vitro DMPK properties to be potentially useful as a drug;

(e) the most promising compounds would then be selected for in vivo testing. These tests would include in vivo DMPK studies on efficacy in an animal model of disease;

(f) the most promising compounds from the in vivo testing (if any) will then move on for further DMPK and toxicology screening; and

(g) if any compound was predicted to be sufficiently safe and effective in humans, the drug candidate would enter into clinical trials."

DMPK, in this context, stands for Drug Metabolism and Pharmacokinetics.

13. Under the heading *"Optimisation"* the CGK describes what the skilled medicinal chemist would do once a starting point had been identified in respect of a particular new drug discovery project. In particular, the following is agreed: -

"114. There are various strategies which can be used to improve the interactions between a drug and its target, including (i) variation of substituents; (ii) extension of the structure; (iii) chain extensions/contractions; (iv) ring

expansions/contractions; (v) ring variations; (vi) ring fusions; (vii) isosteres; (viii) simplification of the structure; and (ix) rigidification of the structure.

115. One strategy the skilled medicinal chemist could try in an attempt to improve the activity of a given compound (which would result in the formation of a new compound with a different chemical structure to that of the original compound) and reduce its side-effects is "rigidification". One well-known method of rigidifying a flexible molecule is to incorporate the skeleton of the flexible molecule into a ring system (cyclisation). Flexible side chains can also be rigidified by incorporating a rigid functional group e.g., a double bond, alkyne, amide or aromatic ring."

14. The parties agreed that the drug optimisation process was an uncertain one, and there was no guarantee of success with any of the various optimisation strategies (including those which I have just set out).

15. Under the heading *"Structure–Activity Relationships"* the parties agreed on the following CGK: -

"118. As noted above, given the difficulty in predicting potency and selectivity based on structure alone, the skilled medicinal chemist would approach optimisation rationally by trying to generate SAR. To do this, the skilled medicinal chemist would make a series of small structural modifications to the initial compound, resulting in a number of different structural analogues. These analogues would be tested to determine how each of the modifications affects activity against the target. Often relatively small modifications can result in significant changes in activity against the target enzyme or against other enzymes. By measuring the activity of each analogue against the target enzyme (and its selectivity by measuring activity against other enzymes), the skilled medicinal chemist builds up an idea of which parts of the compounds are important for binding, and the size and nature of each of those parts

required for strong binding. However, this is very much an empirical process as it can take a large amount of trial and error experimentation.

119. SAR optimisation to improve potency and selectivity would typically be conducted by a medicinal chemist, working with a pharmacologist/biologist. By 2001, however, SAR optimisation work in pharmaceutical companies typically also monitored other drug properties (e.g. bioavailability, metabolism) in parallel with work to improve potency and selectivity, and would therefore also involve a DMPK scientist."

16. The agreed CGK then addressed specifically Factor Xa inhibitors, and what the relevant skilled person would have known of these at the priority date.

17. In addition to the CGK, the trial judge had available to him the evidence of the two medicinal chemists to whom I have already referred. Very importantly, at para. 77 of his first witness statement, Dr. Young set out the reasons why *"at the Priority Date and based on the Application and the skilled person's common general knowledge, it would have been plausible to the skilled person that Apixaban was an effective (and improved…) Factor Xa inhibitor."* Dr. Young gave six reasons why that would be so. This evidence is important because the patent by no means confines itself to apixaban as the preferred Factor Xa inhibitor. At page eight of the Application, a Markush Formula is set out describing the compounds which are the subject of the application. In the nature of such formulae, a very wide range of compounds are described in the Application. The evidence of Dr. Young, to the effect that it was plausible to the skilled person that apixaban was an improved and effective Factor Xa inhibitor, was therefore central to BMS' case on plausibility.

18. The evidence of Dr. Young was disputed by Dr. Edwards, notably in his second witness statement delivered in response to Dr. Young's report. At para. 1.47 (and following)

of his second witness statement Dr. Edwards disputes Dr. Young's conclusion (which I have quoted earlier) and instead offers the following view: -

> *"As I have explained, this conclusion would not be reached by the skilled medicinal chemist because there are no data to support the contention that Compound 18 was Apixaban, nor is there any biological data to suggest that this compound is effective as a Factor Xa inhibitor."*

19. Again, the evidence of Dr. Edwards was of central importance in the dispute before the trial judge. For the sake of completeness, I should note that Dr. Young delivered a second witness statement which addressed the second witness statement of Dr. Edwards.

20. One of the most important tasks of the trial judge in this case, therefore, was to decide on the differences between Dr. Young and Dr. Edwards and to make findings of fact on the relevant differences between them. As I will explain later in the judgment, this simply was not done.

The submissions of the parties.

21. The written and oral submissions of the parties, with considerable skill, isolated and addressed the essential differences between them. The BMS submissions were grouped under three headings, namely: -

> *"(a) the correct test for plausibility;*
>
> *(b) assessment of the technical evidence; and*
>
> *(c) the requirements of judicial comity."*

22. With regard to the first heading, it was submitted that there was a clear difference between the approach towards plausibility as set out by this Court in *Norton (Waterford) Limited t/a Teva Pharmaceuticals Ireland v. Boehringer Ingelheim Pharma GmbH & Co. KG* [2022] IECA 58 ("*Boehringer*") and subsequent decisions of the Enlarged Board of Appeal in Case G2/21 (*"Sumitomo"*) as applied by the European Patent Office *("the*

EPO")'s Technical Board of Appeal in its decision *T 0116/18* delivered on the 28 July 2023. For its part, Teva disputed that there was any real or relevant difference between these latter two decisions and the judgment of this Court in *Boehringer*. It also strongly challenged the entitlement of BMS to raise this issue on appeal. In particular, Teva placed significant reliance on its contention that BMS had defended the case in the High Court on the basis that it should succeed even if the approach described in *Boehringer* was applied.

23. On the second heading, BMS submitted that para. 1151 of the judgment constituted findings of fact in favour of BMS. On that basis, it was submitted that BMS should logically have succeeded in defeating the plausibility challenge. Teva, in response, submitted that para. 1151 (or relevant parts of it) could not and did not constitute findings in favour of BMS.

24. Apart altogether from whether some or all of para. 1151 of the judgment constituted findings of fact (as opposed to summaries of the submissions), a very important issue arising from BMS' submissions was whether or not the trial judge had fully and properly considered relevant evidence, and made findings on such evidence. I will obviously return to this later in the judgment, when I analyse the judgment in the court below.

25. The third and final heading advanced on behalf of BMS was the trial judge's approach to judicial comity. As has happened in other disputes, the invalidity claim in Ireland is just one theatre of operations in an international war. BMS had been unsuccessful in defending the patent in the United Kingdom, but had succeeded in Sweden, Norway, France and Switzerland. BMS challenged the approach taken by the trial judge towards judicial comity. Teva staunchly defended the position of the trial judge in that regard. Again, I will come to the detail of the dispute between the parties in the next sections of the judgment.

The patent bargain.

26. Ireland is a signatory to the European Patent Convention *("EPC")* and the Patents Act 1992 gives effect in national law to the EPC. Part II Chapter I 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 Patents Act 1992. Article 52 of the EPC stipulates that the invention must be new *("novelty")* and involve an inventive step. Article 54 provides that an invention shall be considered to be new if it does not form part of the state of the art. Article 56 provides that an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

27. The requirement that the technical contribution by the inventor be *"plausible"* to the person skilled in the art has been developed by the EPO when considering issues of patentability and validity. The concept was developed to deal with the problem of over broad claims in patent applications which could result in the grant of monopoly rights based upon mere assertion rather than an inventive step.

28. The test of plausibility in patent law was recently addressed by this Court in *Boehringer*. In a comprehensive judgment with which Noonan and Haughton JJ. agreed, Collins J. (at paras. 124 to 173) analysed the question of plausibility as to the technical contribution of the invention and at paras. 174 to 179 set out his conclusions as to the applicable test for plausibility in this jurisdiction.

29. As Collins J. observed in *Boehringer*, the EPO adopts the *"problem solution"* approach in assessing the question of inventive step. This 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. At para. 126 Collins J. observed:-

> *"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)".

30. Collins J. considered in detail the judgments of the UK Supreme Court in *Generics (UK) v. Warner-Lambert Co LLC* [2018] UKSC 56, [2019] 3 All E.R. 95. That case concerned a second medicinal 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 and claim one of the patent referred to the treatment of pain whereas claim three referred to treatment of neuropathic pain. The dispute between Generics, who sought the revocation of the patent, and Warner-Lambert, the patentee, turned on whether the patent was invalid on the ground of lack of inventive step and/or insufficiency. Lord Sumption, who gave the principal judgment in the Supreme Court, summarised the approach of the Board of Appeal of the EPO as importing *"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). At para. 160 of his judgment Collins J. set out the key passage from the judgment of Lord Sumption:

"[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."

31. Collins J. went on to consider the judgments of Lords Hodge and Mance who disagreed with Lord Sumption on the question of the applicable test. At para. 163 Collins J. concluded that the gap between the majority and minority positions as to the applicable threshold test was a narrow one and the difference was ultimately one of degree. He rejected the argument advanced by Boehringer, in the case before him, that mere assertion of efficacy was sufficient in this context.

32. At para. 166 Collins J. observed that *Generics (UK) v. Warner-Lambert* was concerned with 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 and 56 EPC (inventive step/ technical contribution) but accepted that the test was the same in both contexts and certainly it was not lower in the context of inventive step/ technical contribution.

33. Having analysed the argument advanced by Boehringer, Collins J. concluded as follows:-

"172. … 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 …*

…

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 [patent in suit].

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' …

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 …"

34. Thus *Boehringer* establishes that the applicable test is that in light of the teaching and specification and the CGK there must be a real reason for supposing that the claimed invention will indeed have the promised technical effect. There must be something that demonstrates that the claimed technical contribution is not speculative and that it 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. The skilled person must have a basis – "*a real reason*" or "*a real basis*" – for thinking that the claimed invention will indeed have the promised technical effect. Mere assertion will not suffice. The assessment of whether the patent or patent application provides the skilled person with a real reason or basis to believe that the claimed invention will have the promised technical effect or whether the application is no more than mere assertion is heavily context dependant and this will turn in each case on the CGK and the expert evidence adduced by the parties.

Developments in the jurisprudence of the Enlarged Board of Appeal of the EPO:

G2/21 Sumitomo.

35. Different boards of the EPO formulated the test of plausibility in different ways and ultimately in case *T 0116/18 Sumitomo*, the Technical Board of Appeal *("the TBA")* concluded that there were two lines of case law according to which post published evidence could be taken into account when considering the technical effect of the claimed invention. The first – identified by the TBA as type I case law – was whether, given the application as filed and the CGK at the filing date, the skilled person would have reason to assume the purported technical effect to be achieved (called *"ab initio plausibility"*). In such cases experimental data or scientific explanation in the application as filed commonly served as reasons which justified the assumption. The second line of case law – identified by the TBA as type II case law – asked whether, on the filing date of the patent, the skilled person would have had legitimate reasons to doubt that the purported technical effect would have been achieved. In such cases post published evidence could only be disregarded if the skilled person would have had legitimate reasons to doubt that the purported technical effect would have been achieved on the filing date of the patent (called *"ab initio implausibility"*) The TBA concluded that there was tension between the two lines of case law on the one hand and the principle of free evaluation of the evidence on the other and it decided to refer certain questions to the Enlarged Board of Appeal *("the EBA")* for decision under Article 112(1)(a) of the EPC. The referring board suggested that an answer from the EBA was needed both to ensure uniform application of the law and because points of law fundamental importance had arisen.

36. The EBA deemed the referral admissible. A referral was admissible either if a decision on the question was required in order to ensure uniform application of the law or if the point of law was of fundamental importance. In finding that the referral was

admissible, the EBA was satisfied both that the referred questions raised a point of law of fundamental importance and that a decision on the referred questions would serve to bring about a uniform application of the law.

37. In *G2/21 Sumitomo* the EBA considered the three questions referred by the referring board. The questions were:-

> "*If for acknowledgement of inventive step the patent proprietor relies on a technical effect and has submitted evidence, such as experimental data, to prove such an effect, this evidence not having been public before the filing date of the patent in suit and having been filed after that date (post-published evidence):*
>
> *1. Should an exception to the principle of free evaluation of evidence … be accepted in that post-published evidence must be disregarded on the ground that the proof of the effect rests* ***exclusively*** *on the post-published evidence?* [Emphasis original].
>
> *2. If the answer is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have considered the effect plausible (ab initio plausibility)?*
>
> *3. If the answer to the first question is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have seen no reason to consider the effect implausible (ab initio implausibility)?"*

38. Recognising that the referral potentially gave rise to issues of general importance, the EBA invited third party submissions. In addition to the submissions of the parties to the

proceedings before the TBA, the President of the EPO submitted comments in writing on the questions of law and 20 *amicus curiae* briefs were filed. It is clear that the EBA considered the question of proof of technical effect, free evaluation of evidence, and plausibility with a view to giving definitive guidance on the approach to such issues when considering patentability and the validity of patents. As such it is incumbent on the courts of the members of the EPC, including Ireland, to apply these guidelines, when resolving such issues. If the guidelines differ to the tests developed by national courts, then the test in *G2/21 Sumitomo* should be adopted henceforth.

39. The EBA first outlined the various submissions and arguments of the parties and in paras. 55-59 set out its intermediate conclusions on the first question. It observed at para. 57 that the gist of the matter underlying the referral extended beyond the literal wording of the first question and held:-

> "*58. The Enlarged Board considers the conceptional notion inherent in the term 'plausibility', which is often used as a generic catchword, as not being a distinct condition of patentability and patent validity, but a criterion for the reliance on a purported technical effect. In this sense, it is not a specific exception to the principle of free evaluation of evidence but rather an assertion of fact and something that a patent applicant or proprietor must demonstrate in order to validly rely on an asserted but contested technical effect. ...*
>
> *59. ... the Enlarged Board acknowledges a need to provide guidance on the application of the principle of free evaluation of evidence in respect of such post-published evidence for the reliance on a purported but contested technical effect*."

40. The EBA then proceeded to consider the EPO jurisprudence regarding the reliance on a technical effect for inventive step. It noted that the TBA in case *T 578/06* held that the EPC required no experimental proof for patentability and considered that the disclosure of

experimental data or results in the application as filed and/or post published evidence was not always required to establish that the claimed subject matter solved the objective technical problem. The EBA analysed the case law and observed that it was aware that the case law illustrated different approaches to the acceptance of a patent applicant's or patent proprietor's reliance on an asserted technical effect. In discussing case *T 31/18* the EBA noted in para. 65 that:-

> *"[T]he board of appeal held that the technical effect relied upon for inventive step according to the problem-solution approach must either be explicitly mentioned in the application as filed or at least be derivable therefrom, but not necessarily originally supported by experimental evidence".*

41. It is to be noted that the words *"derivable therefrom"* is the term used by the TBA in the case which the EBA was discussing, rather than a term it introduced. The EBA continued in its summary of the decision of the TBA in *T 31/18*:-

> "*It could not be expected from a patent applicant to include an extensive amount of experimental evidence corresponding to all technical features which could possibly be claimed in the application as filed and which could possibly constitute a future distinguishing feature over the closest prior art, since said closest prior art and its technical disclosure may not be known to the applicant at the filing date of the application.*"

42. Having considered the two lines of authority – type I case law and type II case law – the EBA reached intermediate conclusions in paras. 70 – 72 of its judgment:-

> "*71. However, when analysing the case law in more detail and irrespective of the conceptual terminologies for what questions 2 and 3 refer to as two distinct plausibility approaches, the Enlarged Board understands from the case law of the boards of appeal as common ground that the core issue rests with the question of*

what the skilled person, with the common general knowledge in mind, understands at the filing date from the application as originally filed as the technical teaching of the claimed invention.

72. Applying this understanding to the aforementioned decisions, not in reviewing them but in an attempt to test the Enlarged Board's understanding, the Enlarged Board is satisfied that the outcome in each particular case would not have been different from the actual finding of the respective board of appeal. Irrespective of the use of the terminological notion of plausibility, the cited decisions appear to show that the particular board of appeal focussed on the question whether or not the technical effect relied upon by the patent applicant or proprietor was derivable for the person skilled in the art from the technical teaching of the application documents." [Emphasis added].

In para. 71 the EBA refers to what the skilled person *"understands"* from the application as originally filed as the technical teaching of the claimed invention. The reference in para. 72 is to the focus of particular boards of appeal on the question whether or not the technical effect relied upon by the patent applicant or proprietor was *"derivable"* for the person skilled in the art from the technical teachings of the application documents. The focus is upon the technical teaching of the application and the word *"derivable"* must be understood in that context.

43. The judgment of the EBA in *G2/21 Sumitomo* continued under a subheading *"Considerations concerning the jurisprudence regarding sufficiency of disclosure"*. The EBA stated that the issues of sufficiency of disclosure (Article 83 EPC) and inventive step (Article 56 EPC) are to be treated separately. In para. 74 it noted that it was aware of the case law concerning second medical use claims. It observed that "*[f]or such claims, the*

issue of reliance on post-published evidence for a purported technical effect arises in particular in the context of sufficiency of disclosure." The judgment states that:-

> " *... because the subject-matter of second medicinal use claims is commonly limited to a known therapeutic agent for use in a new therapeutic application, it is necessary that the patent at the date of its filing renders it credible that the known therapeutic agent, i.e. the product, is suitable for the claimed therapeutic application*."

Thereafter, in paras. 74 - 76, the EBA addresses sufficiency of disclosure in the context of second medical use claims. It reaches an intermediate conclusion in para. 77 to the effect that:-

> " *... the scope of reliance on post published evidence is much narrower under sufficiency of disclosure (Article 83 EPC) compared to the situation under inventive step (Article 56 EPC). In order to meet the requirement that the disclosure of the invention be sufficiently clear and complete for it to be carried out by the person skilled in the art, the proof of a claimed therapeutic effect has to be provided in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the skilled person that the therapeutic effect is achieved. A lack in this respect cannot be remedied by post-published evidence*."

44. The EBA then considered the case law from Switzerland, Germany, France, the Netherlands and the United Kingdom with regard to the reliance on a technical effect for inventive step. At para. 86 it observed that, like the EPC, none of the legal systems of these Contracting States provide for an explicit patentability requirement of *"plausibility"*. At para. 87 the EBA noted that the decisions of the national courts turned on the facts of the cases in hand and the particular submissions of the parties but nonetheless:-

"*… recognises a certain degree of common ground that the courts of the EPC Contracting States, when confronted with the examination of an asserted technical effect in the assessment of inventive step and with the question whether a patent proprietor may rely on post-published evidence to confirm that technical effect, ponder on the technical teaching of the claimed subject-matter that the person skilled in the art, with the common general knowledge in mind, understands from the patent application*." [Emphasis added].

45. The EBA then gave its conclusions on the three questions referred by the referring board. It concluded that:-

"… evidence submitted by a patent applicant or proprietor to prove a purported technical effect relied upon for acknowledgment of inventive step of the claimed subject matter may not be disregarded solely on the ground that such evidence, on which the effect rests, had not been public before the filing date of the patent in suit and was filed after that date."

46. It addressed the question of plausibility in paras. 92 – 94 which are worth quoting in full:

"*92. The term 'plausibility' that is found in the case law of the boards of appeal and relied upon by the referring board in questions 2 and 3 of the referral and the reasons for it, does not amount to a distinctive legal concept or a specific patent law requirement under the EPC, in particular under Article 56 and 83 EPC. It rather describes a generic catchword seized in the jurisprudence of the boards of appeal, by some national courts and by users of the European patent system.*

93. The relevant standard for the reliance on a purported technical effect when assessing whether or not the claimed subject-matter involves an inventive step concerns the question of what the skilled person, with the common general

knowledge in mind, would understand at the filing date from the application as originally filed as the technical teaching of the claimed invention. The technical effect relied upon, even at a later stage, needs to be encompassed by that technical teaching and to embody the same invention, because such an effect does not change the nature of the claimed invention.

94. Hence, a patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would consider said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention."

47. The EBA emphatically states that plausibility is not a distinct legal concept or a specific patent law requirement under the EPC. It refers to it as a generic catchword and it does not use it (or indeed the word implausibility) in its formulation of the approach to be taken when considering issues of patentability or validity.

48. At para. 93, the EBA lays out the relevant standard to be applied when considering whether or not an application involves an inventive step. The examining board, board of appeal, or courts, must consider what the skilled person, with the CGK in mind, would understand at the filing date from the application as originally filed as the technical teaching of the claimed invention. The question is, what does the application teach? The question is to be answered by what the skilled person with the CGK in mind would understand to be the technical teaching of the claimed invention. The technical effect must be encompassed by the technical teaching and the technical effect must embody the claimed invention.

49. Notwithstanding the fact that the judgment of the EBA refers to what the skilled person would understand to be the technical teaching of the claimed invention, the order does not use the word *"understand"* but provides that:-

> "*2. A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention*."

While the order uses the word *"derive"* rather than *"understand"*, in light of the reasoning which I have analysed, I do not believe that the order in any way alters the terms of the judgment and I believe that in the order the word derive is used as a synonym for understand. I do not believe that the EBA in drawing its order intended to alter the conclusions set out in paras. 90 – 94, where it uses the word "*understand*" and I believe that there is greater clarity in employing the word *"understand"* from the judgment as opposed to the word *"derive"* from the order.

Can this Court apply the test in *G 2/21 Sumitomo* to the appeal?

50. The decision of the EBA in *G 2/21 Sumitomo* was delivered on 23 March 2023. BMS' written submissions in the High Court are dated 20 June 2023 and refer to the decision of the EBA. BMS suggested at the hearing in the High Court that *G 2/21 Sumitomo* had changed the legal test regarding plausibility but took the view that the High Court was bound by the decision of this Court in *Boehringer*. While referencing that decision, it ultimately invited the High Court to decide the question of the validity of the 415 patent on the basis of the test in *Boehringer*. The High Court judge refers to the decision of *G 2/21 Sumitomo* three times in the judgment but does not analyse whether it proposed a different test to that set out in *Boehringer* and the trial judge applied the test in *Boehringer* to the case before him. BMS did not invite the judge to find that the application

satisfied the test in *G 2/21 Sumitomo* notwithstanding the fact that the trial judge could not apply that test. It did not lead evidence to seek to establish that the 415 patent satisfied this test in addition – or in the alternative – to the test in *Boehringer* and it did not cross-examine Teva's witnesses in relation to the test in *G 2/21 Sumitomo*. Thus, Teva had no opportunity to rebut any proposition that the application satisfied the test in *G 2/21 Sumitomo*. In addition, the trial judge made no findings of any kind in relation to the application and whether or not it satisfied the test in *G 2/21 Sumitomo*.

51. BMS squarely advanced the appeal on the basis that the test was that set out in *G 2/21 Sumitomo* (as interpreted by the TBA in *T 0116/18 Sumitomo*). It thus invited this Court to determine the appeal on a point which was floated but was not actually engaged in the High Court. In my judgment it is not open to BMS to advance this case now. As was observed by Collins J. in *Boehringer* – in rejecting an argument advanced by Boehringer for the first time on appeal – the necessary implication of the argument was that the judge's approach to the issues of plausibility of technical contribution was fundamentally mistaken. As Collins J. observed:-

> *"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."*

The position of BMS is not as egregious as that of Boehringer. It did refer to *G 2/21 Sumitomo* and it accepted that the High Court was bound by *Boehringer* and could not apply *G 2/21 Sumitomo*. However, it did not take the necessary steps both by way of argument and adducing evidence to permit this Court to engage with the argument on

appeal. In circumstances where BMS has failed to lay the factual grounding for such a case, it cannot now be permitted to advance the argument on appeal to this Court.

52. In my judgment, for the reasons to which I will immediately come, the appeal against the decision of the High Court ought to be allowed and the matter remitted for rehearing by the High Court before a different judge. The judge will apply the test established by the EBA in *G 2/21 Sumitomo* as it is the definitive view of the highest authority on the interpretation of the EPC and it has recently given explicit guidance on this area of law in order to ensure uniformity across the Member States of the EPC.

53. It follows therefore that BMS will not be prejudiced by the fact that this Court will not permit it to advance its case based on the test in *G 2/21 Sumitomo* on this appeal. It will have the opportunity to present its case that the 415 patent is valid by reference to the test propounded by the EBA in *G 2/21 Sumitomo* when the challenge to the validity of the patent on grounds of plausibility is reheard by the High Court.

The obligation to engage with the core elements of the case made by the parties, to make findings of fact, and to give reasons.

54. The classic statement of the duty of a trial judge to give reasons for his or her decision is to be found in the judgment of the Supreme Court in *Doyle v. Banville* [2018] 1 I.R. 505, as follows:-

> *"10. ... Where, as here, a case turns on very minute questions of fact as to the precise way in which the accident in question occurred, then clearly the judgment must analyse the case made for the competing versions of those facts and come to a reasoned conclusion as to why one version of those facts is to be preferred. The obligation of the trial judge, as identified by McCarthy J. in Hay v. O'Grady [1992] 1 I.R. 210, to set out conclusions of fact in clear terms needs to be seen against that background."*

55. Clarke J. (as he then was) immediately went on to emphasise that while the court has a duty to analyse the arguments on both sides, it was not appropriate that the appellate court or the parties should *"engage in a rummaging through the undergrowth of the evidence tendered or arguments made in the trial court to find some tangential piece of evidence or argument which, it might be argued, was not adequately addressed in the court's ruling."* Rather, he said, *"[t]he obligation of the court is simply to address, in whatever terms may be appropriate on the facts and issues of the case in question, the competing arguments of both sides."* In a case in which there are competing accounts, the court must address at least the broad drift of the argument on both sides so that the parties may know why the court came to its conclusions.

56. In *Donegal Investment Group plc v. Danbywiske* [2017] IESC 14, [2017] 2 I.L.R.M. 1 the Supreme Court addressed the application of the principles in *Hay v. O'Grady* [1992] 1 I.R. 210 and *Doyle v. Banville* to expert evidence and to findings made by a trial judge on the basis of such evidence. Clarke J. held as follows:-

> *"8.8 It is, in my view, important to emphasise that the exercise which an appellate court has to carry out when scrutinising the judgment of a trial judge is not one to be conducted in a mechanical way so as to encourage parties to attempt to find some element of the findings of the trial judge which is said to be insufficiently explained. It must be recalled that a judgment is arrived at the end of a very open and transparent trial process. The case will have been fully pleaded, the evidence fully heard and submissions made on both sides. In many cases, and in particular in the Commercial Court, there will be further procedures including the exchange of witness statements and expert reports. Against that background it will often be possible readily to infer why a particular finding was made even if there is no express statement in the judgment. The parties will know how the case ran. An*

appellate court can read the record of the case. The judgment needs to be read in light of the case as made and defended before the trial judge.

8.9 But there can be cases where it is just not possible to ascertain, with any reasonable degree of confidence, the reasons why a trial judge adopted a particular approach in relation to an important part of the facts. Where a finding of fact is of significant materiality to the overall conclusion of the case and where the reasons of the trial judge are neither set out in the judgment or can safely be inferred from the run of the case and the structure of the judgment itself, then an appellate court is unable properly to carry out its task of scrutinising the judgment to see whether the findings of fact are sustainable in light of the principles set out in cases such as Hay v. O'Grady and Doyle v. Banville. In such circumstances an appellate court will have no option but to allow an appeal to the extent appropriate and take whatever further steps may be required in all the circumstances of the case in question."

57. In *Leopardstown Club Ltd. v. Templeville Developments Ltd.* [2017] 3 I.R. 707 MacMenamin J. (concurring with the judgment of Denham C.J.) cautioned that the duty to give reasons in a decision should not be used to circumvent the *Hay v. O'Grady* principles. As regards an allegation that the trial judge had not engaged with evidence, this was said to be a high threshold and *"in effect, an appeal court must conclude that the judge's conclusion is so flawed, to the extent that it is not properly 'reasoned' at all."*

58. The principles to be applied have also been addressed in a number of decisions of the Court of Appeal. Irvine J. (as she then was) in *O'Driscoll v. Hurley* [2015] IECA 158 (para. 19) said that:-

"The purpose of the judgment is to explain to the parties why a particular conclusion was reached so that they may properly understand why they won or lost and whether, in the circumstances, an appeal is or is not warranted."

59. In *McCormack v. Timlin* [2021] IECA 96 Collins J., speaking for the Court, stated (as he had previously done in *McDonald v. Conroy* [2020] IECA 239) that the appellate court self-restraint mandated by *Hay v. O'Grady* has an important *quid pro quo*, namely the requirement for *"a clear statement … by the trial judge of his findings of fact, the inferences to be drawn, and the conclusions to be drawn."* He said that appellate courts nonetheless must be astute not to permit *Doyle v. Banville*- inspired complaints of *"non-engagement"* with the evidence to be used a device to circumvent the principles in *Hay v. O'Grady*. At para. 59 he held:-

> *"What is required of a trial judge is that their judgment 'engages with the key elements of the case made by both sides and explains why one or other side is preferred': Doyle v Banville, at paragraph 10. Where a case turns on 'very minute questions of fact' as to how an accident or injury occurred – and this case is such a case par excellence – 'then clearly the judgement must analyse the case made for the competing versions of those facts and come to a reasoned conclusion as to why one version of those facts is to be preferred'."*

60. He then adopted with approval the statement of Irvine J. in *O'Driscoll* and noted the important observations of Clarke J. in *Donegal Investment Group*.

61. In *Kehoe v. Promontoria* [2023] IECA 72 Butler J., speaking for the Court, held that *"[w]here complaint is made that an issue is not addressed or adequately addressed in a judgment, the appellate court can examine the extent to which that issue was one of the key elements of the case which had been made by the complaining party."* In *Kadege v. Dunnes Stores* [2023] IECA 27 Noonan J. considered *Doyle v. Banville* and *Donegal Investment Group* and stated that where the evidence of one expert is preferred over another, particularly in cases which rely on complex evidence, the judge must engage in some analysis of that evidence and demonstrate why one side was preferred over another.

This is because the parties need to understand why they won or lost and *"[t]he same applies with equal force to an appellate court which cannot perform its functions if left in the dark by the court of trial as to the reasons for the outcome."*

62. In two decisions from 2024 (*Butler v. Regan* [2024] IECA 52 and *Action Alarms Limited v. O'Rafferty* [2024] IECA 117) Faherty J., speaking for the Court of Appeal, reiterated the duty arising from *Doyle v. Banville* to give reasons in a judgment and confirmed that the *quid pro quo* for an appellate court's self-restraint is that the trial judge must make a clear statement of his findings, the inferences to be drawn, and the conclusions to be drawn. It follows that if a judgment fails to make key findings of fact or fails to explain why the evidence of one witness is preferred over another and why the key or core elements of a party's case is rejected (and it thereby loses its case) it cannot stand and falls to be overturned on appeal.

Unsafe judgment.

63. The judgment of the High Court inclusive of appendices runs to in excess of 900 pages. It is undoubtedly the longest in the experience of any member of the Court. It is replete with very lengthy extracts from the evidence of all of the witnesses; set out either from their witness statements or the transcript of their evidence.

64. It is extremely regrettable that notwithstanding this conscientious and exhaustive exercise, the trial judge failed to a very large extent to make essential findings of fact. Indeed the parties could not even agree whether certain passages of the judgment represented findings of the trial judge or not. Furthermore, insofar as it may been inferred that he preferred the evidence of one witness over another, he failed to give any reasons, or any adequate reasons, why he rejected the evidence of one witness and preferred the evidence of another. Simply put, BMS does not know why it lost in the High Court and this Court cannot properly assess whether or not the High Court was correct to conclude

that the 415 patent was invalid. This means, in my view, that the judgment cannot stand and that the case must be remitted to the High Court for rehearing.

Findings of fact which the trial judge made or failed to make.

65. In para. 1151 of the judgment the trial judge said *"BMS has suggested that the following conclusions fall to be drawn (though as, as will be seen later below, there are, I respectfully observe, significant flaws in the position contented for by BMS)"*. He then sets out 18 points made by BMS. BMS argued that these amounted to findings of fact or, if they were not findings or fact, they represented findings which the trial judge ought to have made.

66. The first difficulty with BMS' contention that para. 1151 comprises the trial judge's findings of fact is that para. 1151 is not confined to facts. For example at 1151[8] the judgment recites the legal basis on which the patent application should be approached and dismisses a submission of Teva in this regard.

67. At 1151[10] r. the trial judge says-

> "*Dr Edwards suggested that it would require considerable work to convert the 74 listed names [in embodiment 8] into structures. Dr Young's evidence shows that to a medicinal chemist this task is straightforward and could be done relatively quickly*."

But the trial judge neither sets out BMS' suggested conclusions in relation to this evidence nor states which of the witnesses' evidence he prefers and why he prefers the evidence of one expert over another.

68. At 1151[11] s., under the heading *"Binding Potency",* the trial judge addresses p. 170 of the patent application in the following terms:-

> "*The application contains a brief section on p.170 setting out the binding potency (10μM) at which the molecules are considered to be active factor Xa inhibitors. Dr*

Edwards agreed that the said passage indicates that the research team were looking for nM binding efficacy. He also agreed that the difference between 10µM and nM potency is four orders of magnitude (10,000 times) which provides acceptable selectivity. At p.172, the specification indicates that some compounds have 10µM potency against thrombin. Taken together, these teachings indicate that the authors are looking for 4 orders of magnitude selectivity between factor Xa and thrombin binding. This would be suitable to make a molecule a candidate as an effective factor Xa inhibitor (per Dr Edwards)."

This passage – as contended by Teva – may amount to no more than the trial judge reproducing BMS' arguments, which in turn were based upon the evidence of Teva's expert medicinal chemist, Dr. Edwards, or – as contended by BMS – it may reflect the trial judge's acceptance of this evidence of Dr. Edwards. It is unclear from the judgment. It certainly is not a clear finding of fact.

69. On the other hand in 1151[14] v. the judge makes an express finding in the following terms:

"The skilled reader, I conclude, would recognise in the light of the CGK that paramethoxyphenyl was a potential binding group for the SI pocket and that the specification was indicating that it should be used."

Thus it is clear that para. 1151 is not simply a record of the submissions of BMS as is stated at the start of the paragraph. This in turn leaves it unclear which of the submissions of fact the trial judge accepts or rejects.

70. The parties were directed by the Court of Appeal list judge giving directions for the hearing of the appeal to provide a summary of the judgment to assist the Court hearing the appeal. The parties disagreed whether para. 1151 constituted findings of fact but they were agreed that findings of fact were not to be found outside paras. 1151 – 1153 of the

judgment. I have dealt with para. 1151. Paragraph 1152 sets out a submission by BMS as to the teaching of the specification and not a finding of fact. This effectively means that if there are no findings of fact clearly reasoned by the trial judge in para. 1153 then the judge has failed to carry out the basic task of making findings of fact, deciding which evidence he accepted and which he rejected, and explaining his reasons therefor. I shall consider para. 1153 later in this judgment.

The obligation to address the core elements of the parties' case.

71. In the sub-paras. x., y., aa. and bb. of para. 1151[14] and [15] the trial judge sets out the key elements of the case advanced by BMS:-

> *"'x. Dr Edwards accepted that the pattern of work identified from an analysis of the molecules in embodiment 8 and the worked examples led to certain conclusions. He recognised the pattern of work in embodiment 8. Whilst he indicated that the conclusions were theoretical he accepted that the scheme of work they showed would be pointless if the researchers had not discovered something useful.*
>
> *y. Dr Edwards agreed that the work described in the specification indicated that the workers were aiming to fine-tune the physicochemical properties of a molecule. The conclusion is theoretical because there was no data. However, theoretical conclusions based on sound scientific analysis are, in law, an acceptable means to demonstrate plausibility.*
>
> *aa. Dr Edwards accepted that if the specification said that testing had been done, he would accept that it had been done, even though the results are not given. He pointed out that the testing expressly noted was at low level of potency. However, taken with his agreement that the authors were looking for nM potency and his acceptance that the pattern of work shown by the examples would be pointless unless they had discovered reasonably potent (i.e. nM level) binding, the conclusion that a fair-*

minded skilled reader would reach was that some of the molecules in embodiment 8 and the worked examples had been found to be potent and selective inhibitors of factor Xa and that this was likely to be the case.

[15] Example 18

bb. Example 18, which is also the molecule listed at the bottom of page 69 of the specification in embodiment 8, is apixaban. It is amongst those molecules and has components which lie at the heart of the work identified in embodiment 8 and the worked examples."

72. At 1151[16] cc. the trial judge sets out an exchange between counsel and Dr. Edwards from Day 8 of the trial and says at 1151[16] dd. that:-

"*BMS has submitted that this exchange provides the answer to the question of whether or not apixaban is a plausible factor Xa inhibitor. Dr Edwards, BMS observes, accepts that apixaban's being a plausible factor Xa inhibitor is a theoretical conclusion that one can draw from the specification. Under the law as to plausibility, BMS observes, the test does not require prima facie proof. A reasonable scientific basis for believing that the promise may be true is sufficient. Dr Edwards, BMS posits, accepts in the above-quoted text that there is a sound theoretical basis for such a belief and that constitutes what is required to establish plausibility*."

73. These passages clearly set out the essence of the argument advanced by BMS to support the contention that the application as filed rendered apixaban plausible. They are not findings of fact.

74. This is a key part of BMS' claim and one which the trial judge rejected in a manner which cannot be upheld by this Court. Nowhere in the judgment is the argument properly addressed and rejected. The reasons for its rejection are not properly explained and set out.

Simply put, neither the parties nor this Court can know why this case was rejected. The authorities make absolutely clear that in such circumstances the case should be remitted for rehearing: it cannot be upheld on appeal.

75. What is set out does not, in my judgment, suffice. At para. 1152 Barrett J. says that: "*All of the foregoing, BMS posits, leads inexorably to the logical conclusion that the teaching of the specification of the application makes Example 18, apixaban, a plausible factor Xa inhibitor*." He then rejects this in para. 1153, stating that while the sequence of logic is persuasive "*on closer examination of all that is before me and all the submissions that have been made, … BMS's reasoning is flawed for the following reasons (which reasons have the result that BMS's contentions as to plausibility must fail)*".

76. The trial judge speaks generally of all that is before him and all the submissions that have been made but makes no attempt at this point to identify the particular evidence or submissions he relies upon or to resolve the conflicts or to explain why he resolves conflicts of either evidence or submissions one way or the other.

77. The first reason for rejecting the case in favour of the patent which *"alone … suffice[d] to render the application invalid for lacking plausibility"* is set out in para. 1153[A] as follows: -

> "*nanomolar potencies were required for a compound to have a potential anticoagulant effect (and thus potential therapeutic usefulness). Taken at its highest, the patent application asserts no more than that some compounds had a Ki of ≤ 10 μM. Additionally, there is no biological data in the application concerning apixaban. (Thus, asked whether there was any data in the patent application that tells that any specific compound has been tested, Dr Young responded 'No, there is no data point associated with any specific compound'. Thus, if I might respectfully paraphrase Arnold L.J. in his judgment for the Court of Appeal in Sandoz Ltd. v.*

BMS Holdings Ireland Unlimited Company [2023] EWCA Civ. 472 (at para. 105) while apixaban may have been one of the compounds tested, it also may not. The application does not disclose expressly or impliedly that apixaban has been tested and found to have Ki of <10 μM (let alone nanomolar Ki). In the absence of any theory based on e.g. its structure or any data in the specification, there is simply nothing in the application to support the assertion that apixaban is a factor Xa inhibitor, let alone a factor Xa inhibitor of sufficient potency to be useful in therapy."

78. This paragraph fails properly to engage with BMS' case for a number of reasons.

79. It is not possible to discern from the passage from the judgment what evidence the trial judge accepted and what evidence he rejected. One cannot discern why he rejected the evidence that he rejected and conversely why he accepted the evidence he did accept.

80. The essence of BMS' case was set out in all of para. 1151 but in particular at subpara. x where the building blocks which BMS say establishes plausibility are assembled. The drug design process is central to BMS' case. It was set out in the CGK and the written evidence of Dr. Edwards. It is an iterative process. Each molecule is tested for potency and selectivity and the molecules are refined based on the results of the tests. In cross-examination Dr. Edwards agreed that the pattern of work shows that the changes were focussed to secure potency and/or optimal pharmacological and physiological properties. Dr. Edwards agreed that BMS would not have carried out the work if it was not worthwhile. Therefore – so BMS' argument went – the application showed that work had been carried out and the fact that work had been carried out meant that the team had found compounds which were reasonably potent. The trial judge does not discuss this and certainly does not expressly reject it or explain why he rejects this argument.

81. The trial judge fails to analyse the theoretical case advanced by BMS which it says satisfies the test in *Boehringer*, or to explain why he rejects it. In addition, he does not, as one would expect, address the six points set out in Dr. Young's first report at para. 77 and identify which of these he accepts and which of these he rejects. Neither does he explain why he rejects some of them (he presumably does not reject all of them as some of them are agreed CGK).

82. The judge's reference in para. 1153[A] to the evidence of Dr. Young clearly reflects a misunderstanding of the question the witness was answering. Dr. Young was being asked whether there was <u>any data published in the application</u> which related to any specific compound. He was not asked whether any specific compound <u>had been tested</u>. The answer Dr. Young gave relates to the publication of data, not to the issue whether all compounds were tested as part of the drug development process. The trial judge seems to have misunderstood, ignored, or not taken into consideration, Dr. Edward's acceptance that each of the molecules were tested as part of the drugs development process. If he did not accept this evidence, it was incumbent upon him to address it and explain why he rejected it, as it was central to BMS' defence of the challenge to the validity of the patent.

83. The reference to *Sandoz Ltd* and the judgment of Arnold L.J. that "*while apixaban may have been one of the compounds tested, it also may not*" is inconsistent with the evidence of Dr. Edwards. Thus, the trial judge appears to adopt a conclusion from the judgment of the Court of Appeal in England based upon a different case with different evidence and different arguments and which was contrary to the evidence of both medicinal chemists before him. If this is what occurred it is an error which goes to the heart of the judgment under appeal. What is undeniable is that it is an observation which is contrary to the evidence of both medicinal chemists without any apparent awareness of this fact. It casts serious doubt over the reasoning in para. 1153[A].

84. The statement in para. 1153[A] that "*taken at its highest, the patent application asserts no more than that some compounds had a Ki of ≤ 10 μM*" refers to pg. 170 of the application. However, this in my view, is an incomplete reading of the application. The application states that *"[c]ompounds tested in the above assay are considered to be active if they exhibit a Ki of ≤ 10 μM* ." It goes on to state that *"[p]referred compounds of the present invention have Ki's of ≤ 1 μM"*; that *"[m]ore preferred compounds … have Ki's of ≤ 0.1 μM"; that [e]ven more preferred compounds … have Ki's of ≤ 0.01 μM"*; and that *"[s]till more preferred compounds of the present invention have Ki s of ≤ 0.001 μM."* The question then is whether apixaban is one such *"still more preferred"* compound. If the trial judge was to conclude that the application did not implicitly disclose that apixaban had such potency, he was obliged to address and give reasons why he rejected BMS' argument that apixaban is the heart of the application and therefore must have been one of these *"still more preferred compounds"*. He does not do so; either in this passage or elsewhere.

85. The trial judge held that there was no theory to support the assertion that apixaban is a factor Xa inhibitor, let alone a factor Xa inhibitor of sufficient potency to be useful in therapy. But BMS' case was based upon theory which the trial judge had effectively set out in para. 1151. It was not based upon data. That theory was based upon the drug design process and the CGK and the disclosures in the application. On the case advanced by BMS, it was simply incorrect to state that there was no theory to support the assertion that apixaban is a factor Xa inhibitor. Again, most regrettably, there was a singular failure to explain why the trial judge rejected it.

86. The trial judge correctly identified the test set out in *Boehringer* as to plausibility and noted in particular that data was not necessary. At para. 819 of the judgment, the High Court adopted the following observations made by counsel for BMS:-

"[A]ll that the law requires to establish sufficiency [as is clear from Warner-Lambert] is that there must be something in the specification read in the light of the common general knowledge from which the reader is given reason to believe the claim of factor Xa inhibition may be correct. There is no requirement for proof or prediction. Nor is there a requirement that the result be probable. All that is necessary is that it is reasonable to think that it might be true….The threshold is a low one and is not met only where there is no reason to believe that the claim based on what is in the specification, read in the light of the common general knowledge, will work. In the case of claims to novel compounds, as opposed to second medical use patents, the threshold required to establish that the claim might be correct can and should be no more than [that] the compound appears on its face to be one which may have the requisite properties to be an effective factor Xa inhibitor. Data to support the claim are not necessary. Indeed, one sees from the authorities that data are one way, but scientific theory and principle are another."

At para. 825 he concludes:-

"*However one formulates the test in terms of the wording deployed in that formulation, all the test requires is a reasonable technical basis for concluding that the patented molecule might well have the claimed effect (per Lord Sumption as quoted by Collins J. at § 176 of Boehringer). This is the basis on which I have approached the facts on the basis of the evidence adduced by the parties in these proceedings*."

At para. 826, he reiterates his acceptance of BMS' submission that "*data to support a claim is not necessary*" and says that:-

"*It is sufficient to provide information which demonstrates that the molecule has a suitable structure to engage with factor Xa as ligands which have been shown to*

bind, or which it is clear from the specification the authors have found to bind and has an overall make up with [sicrecte. which?], in the light of the common general knowledge, may reasonably be expected to give it the appropriate binding selectivity and biological properties to make an effective inhibitor."

Notwithstanding this, the trial judge nevertheless emphasised the absence of biological data in the application and regarded this as fatal to the validity of the patent (given the supposed absence of any theory based on the structure of the novel compound). It is difficult to avoid the conclusion that, notwithstanding his statements as to the law on the question of data, the trial judge placed great weight on the absence of data in his reasoning in para. 1153 [A] and, as we shall see, 1153 [B]. In my view the reasons for rejecting BMS' case set out in para. 1153[A] do not withstand scrutiny, fail to address the core elements of that case, and cannot be upheld.

87. In para. 1153 [B] the trial judge sets out three and a half pages of evidence to support a proposition which is not in dispute i.e., that selectivity over other serine proteases is an essential quality of a factor Xa inhibitor. At the end of para. 1153 [B], at p. 539 of the judgment, the trial judge concludes:-

"*So in truth it appears to be common ground in the case before me that selectivity is a primary essential characteristic of a potential factor Xa inhibitor. Yet no data is presented in the application regarding selectivity and no real reason offered to think that apixaban is a suitable therapeutic*."

For the reasons already discussed, the absence of data is not fatal and therefore not determinative. The test in *Boehringer* (which the trial judge was applying to the issue before him) is whether there is a real reason for supposing that the claimed invention will indeed have the promised technical effect. The trial judge simply stated that there is no such reason without analysing the evidence and the arguments of BMS to the effect that

there was a real reason to think that apixaban was plausible. As with point [A], the trial judge said that this alone sufficed to render the application invalid for lack of plausibility. In my view this ruling cannot stand as he fails to address the core argument in favour of validity and apparently misapplies the law which he earlier correctly set out.

88. In para. 1153 [C] the trial judge analysed the cross-examination of Dr. Edwards, which he had previously set out in 1151 [16] pp. 534 – 535. The trial judge noted that this was a discussion of the six points set out in para. 77 of Dr. Young's first report. The trial judge then refers to the statement in Dr. Edwards' written evidence to the effect that "*this conclusion would not be reached by the skilled medicinal chemist because there are no data to support the contention that compound 18 was apixaban, nor is there any biological data to suggest this compound is effective as a factor Xa inhibitor.*" When one reads Dr. Edwards' written evidence he is focussing upon the absence of data. It is already clear that the absence of data is not fatal.

89. The cross-examination moved to counsel's proposition that:-

> "*…when you take all these indicators together [Dr. Young's six points] a skilled medicinal chemist approaching the document with an open mind would reach the conclusion that these workers had done some work which gave one a reasonable basis for thinking it was likely that example 18 might be worthwhile.*"?

Dr. Edwards responded by saying that you needed to put these six matters together and he did not feel that an uninventive person (as the skilled reader is described) would be able to do this. It was pointed out to him by counsel that this was not a *creative or inventive* exercise but it was *analytical*. In response Dr. Edwards said:-

> "*Yes, but someone who is an uninventive scientist in the area I'm not sure would be able to come to the conclusion that each of these points is guesswork and that you combine them to come through. So, theoretically, if you were to believe each of the*

points and build one from the other, theoretically it's possible. But lots of things, in theory, are possible but in reality may not be the case.

Counsel: In theory it's possible?

Dr Edwards: In theory."

90. First, there was no question of there being any reason not to believe each of Dr. Young's six points. Second, Dr. Edwards used the word *"guesswork"* in contradistinction to the availability of data. Third, he accepted that theoretically it was possible to put the six points together. In my judgment this is contrary to what Dr. Edwards stated in this written evidence and which was relied upon by the trial judge. It is difficult therefore to understand why the trial judge held that Dr. Edwards had not resiled from his written position in his oral testimony. The trial judge's explanation for this was that:-

" It seems to me to be clear from the stance adopted by Dr Edwards in this regard that in his answer to counsel he is stating no more than the obvious truth that one can theorise as to anything – absolutely anything – and that he was not resiling from his express written disagreement with Dr Young, i.e. Dr Young's [sic.] answer highlights the <u>un</u>reality of what counsel was positing." [Emphasis original].

Taking the evidence as a whole, I think it is incorrect to state that Dr. Edwards was stating that one could theorise as to absolutely anything and that counsel for BMS was correct in stating that when he referred to guesswork, he was referring to the absence of data and therefore the fact that one was required to infer certain matters.

91. It would in the circumstances be unsafe, in my judgment, to uphold the judge's third reason for rejecting BMS' case on plausibility. It follows that the case must be remitted to the High Court for rehearing.

92. In the circumstances it is not necessary, in my view, to address the other reasons set out in para. 1153 in great detail. As Barrett J. noted, BMS did not rely on the ground he

identifies at 1153 [E] and he accepted that, unlike in England, the argument based on the quantity of apixaban which was synthesised (3g) (which he refers to as point [D]) was *"relegate[d] to a supporting role"* so his rejection of these arguments cannot be determinative of the question of the validity of the patent.

93. The last ground upon which the judge held that the patent was not plausible was set out in 1153 [F]. In this section he rejected a *"frequency of use"* analysis put forward by Dr. Young which differed subtly but significantly from BMS' central argument; which was based upon the pattern of work undertaken by the research team. This argument was that the skilled reader with the CGK in mind would know that when designing drugs each molecule would be tested for potency and selectivity, that the process was an iterative process which built upon the results of the earlier designs and moved forward in light of those results, and that the application showed that the team were achieving promising results, as otherwise they would not have persisted given the enormous costs involved. Para 1153 [F] of the judgment does not adequately address this argument. In view of the fact the matter will be reheard in the High Court I shall refrain from making any further observations on the balance of para.1153 [F].

94. For all of these reasons, in my judgment the appeal should be allowed and the challenge to the validity of the patent on grounds of plausibility remitted to the High Court for rehearing by a different judge.

The application of the principles of judicial comity.

95. The trial judge noted that Ireland was neither the first nor the only jurisdiction in which the validity of the 415 patent was challenged. He noted that Teva had failed in its challenges in France, Norway and Sweden, which were all signatories to the EPC but it had succeeded in the United Kingdom, also a signatory. At para. 18 of the judgment Barrett J. stated:

"For obvious reasons, weight and respect falls to be accorded by me to the decisions of the neighbouring jurisdiction, largely because the courts of that jurisdiction are applying the same system of patent law and both are common law jurisdictions. That said, I have an obligation to decide the case before me on the evidence presented to me and not on the evidence presented to any other court, whether in the United Kingdom or elsewhere. If the evidence is different, then the outcome may be different … where (as here) different experts give evidence it may well be that upon due consideration, a court will conclude that the relevant facts should be differently determined because the evidence is different."

96. The judge continued, suggesting that the French, Norwegian and Swedish judgments could be distinguished fairly readily *"leaving the English judgment as 'the last man standing'… my conclusion as to plausibility/validity is the same as the United Kingdom courts, so there is not just comity, but accord in this regard. There was discussion before me as to whether the evidence before me was entirely similar to the evidence which went before the London court. I do not know if it was and I do not know that the point needs to be explored in any detail in circumstances where my judgment accords in any event with that of the United Kingdom courts on plausibility/validity. I have decided this case on the evidence before me and I take comfort from the fact that (i) my judgment chimes with that of the United Kingdom courts in terms of plausibility, and (ii) the discordant French, Norwegian and Swedish judgments can be distinguished fairly readily."* [Emphasis added].

97. These observations were largely repeated in paras. 1162 – 1163. Barrett J. quoted extensively from the judgment of Clarke J. (as he then was) in *Ranbaxy Laboratories Limited v. Warner-Lambert Co* [2007] IEHC 256, [2009] 4 I.R. 584 and in particular his observation that evidence may evolve between cases as the issues become more focused.

He also referred to the English decision of *E Mishan & Sons Inc. v. Hozelock Limited* [2020] EWCA Civ. 871 where the court was considering a second challenge to the validity of the patent in suit. Arnold L.J., speaking for the court, observed that even where the validity and infringement of the patent had previously been litigated, strictly speaking the previous decisions were not admissible evidence on any question of fact arising in the subsequent proceedings. It was – he said – the function of the trial judge to decide the case on the evidence adduced by the parties in that case and where the evidence is materially different this can lead to a different outcome.

98. In this case, the High Court judge observed that the principle relevant to the proceedings before him was what he referred to as the second principle identified in *Ranbaxy* and *Boehringer*, namely, that:-

> *"[W]here a foreign court has determined an issue that is in dispute in litigation here the courts should not lightly depart from the decision of that foreign court."*

Barrett J. observed that the issues before him were the same as those that were before some or all of the other courts. At para. 1171 he said:

> *"No difficulty should typically arise in applying the second principle where there is only one foreign court decision or where all foreign courts have reached the same decision for the same reasons. Where, however, there are conflicting decisions of foreign courts, the position is otherwise. If this court is to apply the principle that it should not lightly depart from a corresponding decision of a foreign court, it can only do so by engaging with the conflicting foreign decisions and determine which is or are more persuasive. The conclusion resulting from that engagement may well be that the evidence in some cases was closer to that in the case before the Irish court than that in others and that the Irish court should therefore lean towards the*

decision/s from courts where the evidence was more aligned with that before the Irish court."

99. In para. 1174 Barrett J. identified 19 principles which can be gleaned from his consideration of the relevant case law. The points cited above formed some of those principles. At point 14 he observed that:

"Other things being equal, it would be unfortunate if the courts of different jurisdictions that are party to the European Patent Convention arrived at different conclusions concerning the same patent."

However, he then observed that other things are rarely equal and that the force of this principle *"depends entirely on how far the factual and technical evidence before the foreign court is the same as the material before the Irish court and how far their domestic statutes are comparable."* In this regard he expressly noted in passing that the Irish and British statutes are singularly comparable but cautioned that: *"regard it seems to me can also be had to whether a decision of the English courts represents something of an outlier in terms of the trend of decisions among the courts of successive European Patent Convention countries in a sequence of parallel proceedings"*.

100. The trial judge noted that at the time of writing, all final decisions rendered by the courts of contracting States to the European Patent Convention had been in favour of BMS with the sole exception of the decisions of the Patent Court and the Court of Appeal in the United Kingdom. He noted at para. 1177 that Teva had urged him to follow the decision of the courts of England and Wales and at para. 1178 he emphasised the following differences:

"• The evidence before me as to the teaching of the specification of the application differs from the evidence before Meade J. in the United Kingdom.

- *When one examines Meade J.'s judgment … it appears that the case advanced in London depended largely on the claims of efficacy made in the application, rather than the analysis which has been presented before me based on the molecules which are found in embodiment 8 and the synthesised examples.*
- *The evidence before Meade J. about what such structural analysis involved seems to have been different from the evidence before me. Here, Dr. Young (called by BMS) has explained that to a medicinal chemist the task of analysing the compounds in these groups is straightforward and Dr. Edwards (called by Teva) accepted that it could be done. This seems to be a key distinction from the evidence in London. …*
- *great emphasis was placed before Meade J. on the facts that 3g of Example 18 was made. Before me, the quantity made has been proffered by BMS (as I understand its closing submissions) as but an <u>additional</u> crutch on which to rest a finding of plausibility.* [emphasis original].
- *By contrast to the evidence before Meade J., the experts are agreed here that balancing the potency, selectivity and biological properties of a molecule is a key part of optimising its properties and that higher bioavailability may make up for lower potency as noted above. The evidence before Meade J., I understand, was to the opposite effect."*

101. Despite noting these differences, the trial judge observed in para. 1179 that:-

"[I]t sounded a little strange to me that when the same patent was in issue, the same issue (plausibility) was an in issue, and a similar legal system was being brought to bear in a fellow common law country in proceedings involving the same parties (albeit somewhat different independent expert witnesses) that the evidence would be wildly different."

He emphasised the fact that the CGK which was agreed before him was the same as that agreed in the proceedings before the UK courts.

102. In para. 1180 Barrett J. stated that just as he was of the view that BMS went *"somewhat overboard"* in emphasising the difference between the English case and the case before him, that likewise Teva *"went somewhat overboard"* in emphasising the similarities between the two cases. He then stated in para. 1181 that he had proceeded in his judgment:

> *"... solely by reference to the abundant evidence before me and arrived through my own reasoning at the conclusions that I have reached as to plausibility ... So the problem that presents for Teva is that even taking the most exclusionary approach to the London proceedings, I have arrived at the same (or much the same) conclusions when it comes to the various contentions of BMS as to plausibility (and fundamentally I have arrived at the conclusion that plausibility does not present). It is true that I have at points taken comfort from the fact that Meade J. and/or Arnold L.J. have brought similar reasoning to bear to that which I have applied. However, such comfort as arises to be drawn is an ancillary consequence of my reasoning through to certain conclusions; it has played no part in the reasoning itself."*

103. The trial judge then considered the decisions of the Norwegian, French and Swedish courts. First, he summarised aspects of the Oslo decision which *"might usefully be noted"* including the fact that the CGK document before the Oslo court was the same as that in Ireland (and England) and that Dr. Young had given evidence which he said *"appears ... to have been much the same evidence"*. Nonetheless he did not consider that the judgment *"can safely be followed"* as:

"... the judgment does not rely on Norwegian case-law but on a Norwegian text book on patent law in which plausibility is described by reference to case-law that precedes Warner-Lambert by seven years (and so also predates Boehringer)"

and

"... the court in Norway peremptorily dismisses the relevance of the decision of the English Court of Appeal in Sandoz Ltd v BMS Holdings Ireland Unlimited Co."

This approach, he suggested, *"sits askew with the approach adopted by the courts of Ireland when it comes to comity with decisions of the courts of England and Wales." (*See para. 1183 of the judgment). He rejected what he characterised as the unexpected proposition in the closing submission of counsel for Teva that Norway does not have the same law of plausibility as Ireland and the UK.

104. With regard to the decision from Paris, Barrett J. considered that it could not be safely followed because it *"is expressly premised on data which is not contained within the Application"* which *"is at odds with the understanding of plausibility in Ireland"* and concerns *"classical (in)sufficiency"*, an allegation that had not been pursued in the proceedings before him. He expressly noted that, as with the Oslo court, the Paris court had identified that the most preferred compounds of the application had nanomolar potency and each had taken heed of the amount of apixaban which was synthesised (3g).

105. In para. 1187 and 1188 the judge considered the decision of the trial court in Stockholm. He noted that *"a reading of the judgment suggests that the Stockholm court had before it technical evidence similar, at least in some respects"* to that before him. Nonetheless he concluded that the judgment could not *"safely be followed"* because (i) *"some of the Swedish judgment is concerned with classical obviousness"*; (ii) the Swedish court identifies no authority or case law when determining the standard of plausibility but suggests that *"... the technical effect must be possible to derive from the patent application*

either directly or via the skilled person's general knowledge". Barrett J. stated that being *"possible to derive' is not the Boehringer test which requires real reason to be shown"*; and (iii) *"at a later operative stage of its judgment the Swedish court refers to there being 'no reason to doubt' the invention, so neither in the test as to plausibility nor in the application of that test does the court proceed in a manner similar to that which the courts of Ireland adopt."*

106. Finally, the judge considered the judgment of the Court of Appeal of the Hague, reversing a decision of the District Court refusing relief in preliminary court proceedings. He noted that the Dutch Court of Appeal stated that it *"does not see any reason on the basis of Sandoz et al.'s arguments to assume in advance that the outcome of the French and Norwegian proceedings on the merits would be incorrect"*. He noted that the Dutch Court of Appeal also took issue with the legal test applied by the High Court and Court of Appeal in England and Wales based upon the decision in *Warner-Lambert*. At para. 1191 of the judgment, Barrett J. noted that he had already considered the position of the French, Norwegian and Swedish decisions and the English decisions and noted that he *"also had due regard amongst other matters to the decision of the Irish Court of Appeal in Boehringer, a decision that is of course a binding on [him]."*

107. In my judgment there are evident errors in the trial judge's approach to the question of comity in light of the decisions of other courts in relation to the 415 patent. In the first instance, while the trial judge noted the differences between the evidence adduced before him and that adduced before Meade J. in England, he did not advert to the different arguments which were advanced by BMS: in particular, the argument that the drug design process and the pattern of work undertaken by the research team involved synthesising and testing molecules in an iterative process which led to the conclusion that the researchers had developed a molecule or molecules of interest with the necessary potency and

selectivity was not an argument upon which Meade J. ruled. The difference in the evidence was critical to the different argument for plausibility and, in my judgment, the trial judge erred in failing to have regard to the manifest differences between the technical evidence and argument before him and that before the trial judge in England. While the trial judge reiterated that he reached his own judgment based on the evidence before him, he had recourse to the decisions of Meade J. and the Court of Appeal as a *"reality check"*. It is also concerning that in para. 18 of the judgment he referred to the English judgment as *"the last man standing"*. This clearly has no role to play in the application of the doctrine of comity where there are conflicting decisions from different foreign courts. The concern is underscored by the question posed by Barrett J. to counsel for BMS on Day 16, p. 117 of the Transcript when counsel commenced his closing submissions. The trial judge asked him:

> *"Is it your job to show that you're right or are you going to show Judge Meade was wrong? Because in a sense what I'm being presented with by the other side is 'we never quite got there, but you're all but bound by what Judge Meade decided in the United Kingdom."*

The answer from counsel was that it was neither; and to reiterate that BMS' case was that the evidence and therefore the case before the High Court was not the same as the case that Meade J. tried.

108. Given the frequency of the references throughout the judgment to the decisions of both Meade J. and the Court of Appeal, it is hard to avoid the conclusion that they to some extent guided the judge's conclusions. Despite the fact that the trial judge was aware that the agreed statement of CGK which was used in both England and Ireland had been submitted in all European jurisdictions, it was an error in principle to rely upon the use of the same statement of agreed CGK in Ireland and England as a reason to prefer the

decisions of the English courts over those of the other foreign courts. The trial judge ought to have appreciated that the agreed CGK could be of no significance when considering the comparability of foreign court decisions with the dispute before this court as it was no more than the agreed technical backdrop to the dispute. As was submitted by BMS, *"[r]eliance upon it as an indication of commonality of issues was an error of principle."* I agree.

109. It is important to note that since the High Court delivered judgment there have been several further judgments handed down by first instance courts and appellate courts from other Contracting States, both on interlocutory applications and on the substantive issue of validity. All of these will have to be considered in due course by the judge rehearing the case in the High Court. It will be for that judge to assess whether the evidence adduced and the arguments advanced in the case before him or her are sufficiently similar or dissimilar and to allow the application of the doctrine of comity as set out in *Ranbaxy* and *Boehringer*. In the circumstances it is not necessary for me to address the issue of what regard, if any, this Court should show to these judgments, and accordingly I refrain from so doing.

Conclusions

110. The appeal should be allowed and the case remitted for rehearing to be heard by a different judge of the High Court.

111. The case will be confined to a challenge to the validity of the patent on grounds of plausibility.

112. The test of plausibility to be applied is that set out in the judgment of the EBA in *G 2/21 Sumitomo*.

113. Allen and O'Moore JJ. have authorised me to indicate their agreement to this judgment.