THE COURT OF APPEAL

UNAPPROVED

Neutral Citation Number [2021] IECA 22
Court of Appeal Record Nos. 2019/536
2019/537

Costello J.
Haughton J.
Murray J.

BETWEEN

GILEAD SCIENCES, INC.
AND
GILEAD BIOPHARMACEUTICS IRELAND UC

PLAINTIFFS/
APPELLANTS

- AND -

MYLAN S.A.S., GENERICS (U.K.) LIMITED T/A MYLAN
AND
MCDERMOTT LABORATORIES LIMITED T/A GERARD LABORATORIES T/A MYLAN DUBLIN

DEFENDANTS/
RESPONDENTS

BETWEEN

GILEAD SCIENCES INC AND GILEAD BIOPHARMACEUTICS IRELAND UC

PLAINTIFFS/
APPELLANTS

- AND -

TEVA B.V.
AND
NORTON (WATERFORD) LIMITED T/A TEVA PHARMACEUTICALS IRELAND

DEFENDANTS/
RESPONDENTS

JUDGMENT of Ms. Justice Costello delivered on the 02 day of February 2021

Introduction

1. This appeal arises from a challenge brought by the respondents in each of the above entitled proceedings ("Teva" and "Mylan" respectively) to the validity of a Supplementary Protection Certificate ("SPC") held by the appellants ("Gilead") since 2 September 2009 in respect of TRUVADA®, a combination of Tenofovir Disoproxil ("TD") and Emtricitabine ("FTC"). The validity of the SPC depends upon whether the TD + FTC combination is protected by Patent Number EP (IE) 0915894 ("the patent") within the meaning of Art. 3(a) of Regulation (EC) No. 469/2009 ("the SPC Regulation"). In his judgment, dated 11 October 2019 ([2019] IEHC 683), McDonald J. held that it was not so protected and by order dated 8 November 2019 declared the SPC to be invalid, ordering its revocation.

2. Gilead's case is that the TD + FTC combination is protected by the patent and in particular by Claim 27 which provides:-

> *"A pharmaceutical composition comprising a compound according to any one of claims 1-25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients."*

It says TD is one of claims in claims 1-25 and FTC is another therapeutic ingredient which is required to be combined with TD.

Background

3. The trial judge set out the background in considerable detail and this judgment should be read in conjunction with his judgment. In short, the product TRUVADA is a combination therapy for the treatment of HIV infection. The HIV virus causes AIDS. In the early 1980s and 1990s, there were no effective treatments available to many patients suffering from that disease, who went on to succumb to an early death. HIV is a retrovirus

which changes the genome of a host cell that it invades. Once inside the host cell, the virus uses its own reverse transcriptase enzyme to produce DNA which is then incorporated into the host cell genome. The viral enzymes are known as DNA polymerases. A class of compounds called nucleoside analogue reverse transcriptase inhibitors ("NRTIs") were known to inhibit DNA polymerases. Single agent (monotherapy) NRTIs had no long term clinical benefit for HIV patients. While improving the immune function in patients for a period of time, the virus rapidly develops resistance. During the course of 1993, a small clinical trial of combination therapy of two NRTIs found improved immune responses in patients receiving combination therapy, as compared to those in a group of patients receiving monotherapy. By the first half of 1996, combination therapy was accepted as the *"gold standard"* of care by HIV clinicians globally. Combination therapies might comprise two NRTIs or two NRTIs and one protease inhibitor ("PI"). It was also possible to combine two NRTIs with one non-nucleoside reverse transcriptase inhibitor ("NNRTI"). Since 1996, the preferred treatment for HIV patients has been to use a combination of two NRTIs plus a third agent from a different drug class, such as a PI or NNRTI.

4. FTC is an NRTI which was first synthesised in 1990 and is in a class of NRTIs that selectively block HIV and Hepatitis B virus replication. *In vitro* investigations had shown that it was a potent inhibitor of the HIV virus. At the priority date of the patent, 26 July 1996, a very small scale stage 1 study involving 18 patients had been conducted. The compound had been described as a *"promising candidate for further evaluation as a therapy for infections with HIV and [Hepatitis B]."*

5. As I have noted, the other active ingredient in TRUVADA is TD. It is not an NRTI. It is a nucleotide reverse transcriptase inhibitor. While it is chemically distinct from an NRTI, it targets the same stage of the life cycle of the HIV virus. In argument, it was referred to as an NRTI and, while technically this is inconsistent with the findings of the

trial judge, for the purposes of this judgment the shorthand of referring to it as an NRTI is adopted. TD is the subject of Claim 25 of the patent and it is also identified as compound 5(f) in Table 2 of Example 16. TD is part of a family of PMP compounds.

6. Nucleotides are "polar" *i.e.* they include oxygen atoms that are negatively charged in water at neutral pH. This means that they are not readily able to cross cell membranes. If taken orally, a nucleotide would have difficulty crossing the gastrointestinal membranes to enter the circulatory system of the patient. In addition, polar compounds are unable to cross the blood-brain barrier to give access to the brain. In the context of HIV, it is important to ensure that any anti-HIV compound can gain access to the brain in order to eliminate any virus harbouring in that region. The patent seeks to address the bioavailability problem thus arising from the fact that the nucleotide drug is polar and therefore cannot easily cross cell walls.

The patent

7. The patent is entitled "Nucleotide Analogs". Paragraph 0001 describes the invention in terms that it *"relates to intermediates for phosphonomethoxy nucleotide analogs, in particular intermediates suitable for use in the efficient oral delivery of such analogs."* The inventive concept of the patent is to improve the bioavailability of the compounds by providing "intermediates" in the form of prodrugs which would be suitable for oral deliveries and which would enable the intermediate to pass through the cell wall.

8. Paragraph 0044 describes a wide range of viral infections to which the compounds of the invention may be relevant. HIV is included in the list but it is only one of many, very serious viral infections affecting not only humans but also animals, and infections caused by DNA viruses and RNA viruses and other retroviruses thus identified. Prof. Stanley Roberts, a medicinal chemist, who gave evidence in the High Court on behalf of Teva, said that it would be clear to the medicinal chemist that the patent was claiming wide utility in

relation to a large range of common viruses in humans, as well as some viruses in animals. Similar evidence was given by Dr. David Hawkins, on behalf of Teva, and by Dr. Graeme Moyle, on behalf of Mylan. Dr. Moyle emphasised that the viruses listed in para. 0044 were very common and causative of many clinically important diseases in both humans and animals as at the priority date. Dr. Hawkins emphasised that Hepatitis B was *"a massive problem with maybe two billion people around the world infected and several hundred million with active infection and in fact 500,000 people a year dying of Hepatitis B".*

9. Prof. William Powderly, who gave evidence on behalf of Gilead, emphasised that the focus of the patent was on HIV. He did not dispute Dr. Hawkin's evidence but said that the scale and nature of HIV as of July 1996 was the greatest known threat in infectious diseases. Prof. Powderly conceded that para. 0044 covers all classes of viruses known to man, together with a range of infections in animals. He accepted that the problem relating to poor bioavailability of PMPA was solved by the patent. But he said that the focus of the patent was on anti-HIV drugs, which would have made sense in 1996 as, at that time, HIV was the major target for antiviral drugs development worldwide. The evidence of Prof. Roberts was that two-thirds of research conducted into antiviral drug development was directed to treatment for HIV.

10. Paragraph 0046 of the patent sets out the methods by which compounds of the invention can be administered. It describes as suitable routes *"oral, rectal, nasal, topical (including ocular, buccal and sublingual), vaginal and parenteral (including subcutaneous…and epidural)."* Prof. Powderly agreed that many of these routes of administration would not be relevant to the treatment of HIV and the trial judge held that the paragraph does not suggest that the focus is on one condition only, such as HIV.

11. Paragraph 0047 of the patent relates to Claim 27. It provides:-

"While it is possible for the active ingredients to be administered as pure compounds it is preferable to present them as pharmaceutical formulations. The formulations of the present invention comprise at least one active ingredient, as above defined, together with one or more acceptable carriers and optionally other therapeutic ingredients. The carrier(s) must be "acceptable" in the sense of being compatible with the other ingredients of the formulation and not deleterious to the patient."

12. The trial judge observed that there was no express guidance in the patent as to what the patentee meant by *"other therapeutic ingredients".* There is no specific reference to either FTC in particular, or to NRTIs in general. Under cross-examination, Prof. Powderly accepted that, in the context of para. 0047, there was nothing to suggest that the patent addresses only HIV or focusses on HIV. He also accepted that the preponderance of the contents of paras. 0044-0046 was irrelevant to HIV treatment.

13. Dr. Hawkins gave evidence that combination therapy was not confined to HIV and it might also be appropriate for the treatment of Hepatitis B and Cytomegalovirus. Even in the context of HIV, combination therapy was not limited to antiviral retroviral drugs.

14. Paragraphs 0068-0117 set out various examples. It was expressly stated that the examples are not to be construed as limiting the invention. Example 16 specifically refers to the activity of PMPA and certain PMA carbonates against HIV-1. This was relied upon by Prof. Powderly to support his view that the patent is focussed upon a treatment for HIV. Prof. Roberts' evidence was that the purpose of Example 16 was to show how easily the molecules pass through cell membranes in a HIV infected cell, and that the whole basis of the example was to understand which of the side chains worked best at killing the virus. While the example addressed the HIV virus, Prof. Roberts was of the view that the purpose of the example was to demonstrate the effect of the prodrugs and he said that could equally apply to the Herpes virus.

15. There are 29 claims in the patent. Claim 1 is to the formula (1a) compound and Claim 2 is to the formula (1) compound. Claims 3-23 are to particular examples of the compounds in Claims 1 or 2. At least one claim, Claim 22, is to a compound that has no role to play in the treatment of HIV. It is effectively directed to a broad range of herpes-type viruses including herpes simplex, shingles and cytomegalovirus. Claim 25 is to the nucleotide analogue which subsequently became known as TD. Claim 26 relates to the use of any of the compounds in Claims 1-25 for the treatment or prophylaxis of viral infections in humans or animals. Claim 27 is the only claim in the patent in respect of a pharmaceutical composition. It is also the only claim which envisages a combination. It provides:-

> *"A pharmaceutical composition comprising a compound according to any one of claims 1-25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients."*

16. The combination product, the subject of the SPC, was not expressly referred to in the claims of the patent. The patent refers to TD expressly in Claim 25. It makes no reference whatsoever to the other active ingredient in the combination product, FTC. At the heart of the case is the question of whether Claim 27 is focussed upon HIV. On Gilead's case, the reference to *"optionally other therapeutic ingredients"* must be to other drugs that were being used, or in the course of development, against HIV such as NRTIs or NNRTIs or PIs, and thus included FTC, a known NRTI.

17. The application for the patent was filed on 25 July 1997, with a priority filing date of 26 July 1996 ("the priority date"). The patent was granted on 14 May 2003. The SPC at issue in these proceedings was applied for on 8 July 2005 in reliance upon the patent. The SPC was granted in respect of the product "Tenofovir disoproxil and salts, hydrates, tautomers and solvates thereof, in particular tenofovir disoproxil fumarate, in combination

with emtricitabine". It is referred to as TRUVADA. TRUVADA is used in the treatment of HIV. The patent expired on 25 July 2017 and the SPC expired on 23 August 2020.

18. It was not disputed that when in force the patent protected TD and therefore protected the combination product. The issue is whether the combination is protected by the SPC. As FTC is not expressly mentioned in the patent, it can only be protected by the SPC if the combination is within Claim 27 of the patent on the basis that it is captured by the words "*optionally other therapeutic ingredients*".

19. Before considering the SPC Regulation, and the extent of protection under national law and the European Patent Convention, it is necessary to refer to a second patent application made by Gilead, EP 1583542B1 ("the 542 patent"), on 13 January 2004. This was an application in respect of a pharmaceutical co-formulation in the form of a tablet containing a combination of TD and FTC. That combination was expressly claimed in Claim 1 of the 542 patent. However, the patent was revoked by the Opposition Division of the EPO on 14 February 2011. The appeal by Gilead was rejected by the Board of Appeal on 13 March 2017. The patent was revoked on the basis that prior to the priority date claimed (4 January 2003), the co-formulation had been disclosed in a journal read by biotechnology professionals which reported on the intention of Gilead to start developing a co-formulation of FTC and TD, to be dosed as one pill, once daily. However, there can be no doubt that the combination of TD and FTC was unambiguously claimed in the 542 patent and the combination was very clearly described in the summary of the invention contained in paras. 0011 to 0013 of the 542 patent. The implications if any, of this application by Gilead will be considered below.

The law

20. The question of whether the SPC is valid turns on whether the combination of TD and FTC is *"protected by a basic patent in force"* within the meaning of Art. 3(a) of the

SPC Regulation. This involves a consideration of EU law on the one hand and national patent law, based on the European Patent Convention ("EPC"), on the other. While the SPC Regulation is an EU law measure, and accordingly the proper interpretation of Art. 3(a) of the SPC Regulation is a matter of EU law, the EPC is not, and the extent of protection under national law and the EPC is a matter for the national courts, not for the Court of Justice of the European Union ("CJEU").

21. Section 18(2) of the Patents Act 1992 ("the 1992 Act") requires that every patent application shall contain (*inter alia*) a specification containing *"a description of the invention to which the application relates, one or more claims and any drawing referred to in the description or the claim or claims".* Section 19(1) of the 1992 Act requires that any application for a patent shall *"disclose the invention to which it relates in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art."* This is consistent with Art. 83 of the EPC. Article 84 of the EPC requires that the claim or claims *"define the matter for which protection is sought … be clear and concise and to be supported by the description."*

22. The patent must disclose the invention claimed in the patent in a <u>sufficiently</u> clear and complete manner, so that the person knowledgeable in the area of knowledge to which the patent relates - the person skilled in the art - may understand the invention claimed by the patent.

23. Section 45 of the 1992 Act governs the extent of protection conferred by a patent. It provides:-

> *"(1) The extent of the protection conferred by a patent or a patent application shall be determined by the claims; nevertheless, the description and drawings shall be used to interpret the claims.*
>
> *…*

(3) In the interpretation of this section, the Court shall have regard to the directions contained in the Protocol on the Interpretation of Article 69 of the European Patent Convention and set out in the Second Schedule to this Act."

24. Article 69(1) of the EPC provides:-

"The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims."

25. The Second Schedule to the 1992 Act essentially transposes Art. 1 of the Protocol of the Interpretation of Art. 69 of the EPC. It provides as follows:-

"Section 45 should not be interpreted in the sense that the extent of the protection conferred by a patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the descriptions and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of certainty for third parties."

26. The principles to be applied in construing the patent will be considered further later in this judgment.

The SPC Regulation

27. The SPC Regulation replaced an earlier regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate regime for medicinal products. The trial judge explained the genesis of the SPC Regulation and its

rationale, as set out in the recitals. The following recitals are relevant to the issues in this appeal:-

> *"(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.*
>
> *(4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.*
>
> *(5) This situation leads to a lack of protection which penalises pharmaceutical research.*
>
> *…*
>
> *(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product."*

Thus, the Regulation recognises two potentially competing interests. On the one hand, there is the need to encourage pharmaceutical research by extending the period of monopoly protection afforded in respect of medicinal products, while on the other, there are general interests of public health which benefit from fewer and shorter periods of monopoly protection for pharmaceutical products. The SPC Regulation seeks to balance these interests across the EU.

28. Article 3 provides that an SPC shall be granted if *"(a) the product is protected by a basic patent in force"*.

29. A *"product"* is defined in Art. 1 as meaning *"the active ingredient or combination of active ingredients of a medicinal product"*. A *"basic patent"* means *"a patent which protects a product as such …"*. Article 4 of the SPC Regulation makes clear that the protection conferred by an SPC extends only to the product covered by the relevant marketing authorisation for that medicinal product. It provides:-

> *"Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate."*

30. Article 5 provides that, subject to Art. 4, the SPC confers the same rights as the basic patent and is *"subject to the same limitations and the same obligations"*.

31. The validity of an SPC granted pursuant to the SPC Regulation involves an interaction between EU law and national law, including the EPC. This has led to a considerable number of references to the CJEU in relation to the interpretation of the SPC Regulation. These are discussed in detail in the judgment of the High Court.

32. The SPC at issue in these proceedings has been challenged in a number of jurisdictions. In the context of English proceedings in which a challenge was brought to the validity of the UK national equivalent to the SPC at issue in these proceedings, a reference was made to the CJEU by Arnold J. in the High Court of England and Wales ([2017] EWHC 13 (Pat)). The Grand Chamber of the CJEU handed down its decision on that reference: Case C-121/17 *Teva & Ors. v. Gilead Sciences Inc.* in 2018 (*"Teva"*). The court posited a test to be applied to determine whether a combination product is protected

by the basic patent in force where the combination is not expressly mentioned in the patent:-

> *"Article 3(a) of [the Regulation], must be interpreted as meaning that a product composed of several active ingredients with a combined effect is 'protected by a basic patent in force' within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basis patent:*
>
> - *the combination of those active ingredients must necessarily, in the light of the description and drawings of the patent, fall under the invention covered by that patent, and*
> - *each of those active ingredients must be specifically identifiable, in the light of all of the information disclosed by that patent."*

33. The application of this test to the SPC in respect of TRUVADA is the task of the national court. Both the *"necessarily"* and *"specifically"* components of the test must be satisfied. It is for the national court to *"verify"* whether this is so in respect of any SPC before it. This will require the national court to construe the patent in accordance with national law and by reference to the EPC and the Protocol, and then to verify whether, on the facts before the national court, the two limbs of the test have been met.

Principles of construction of a patent

34. Gilead's case is that the trial judge erred in construing the patent. As a result, it is claimed, he wrongly held that the SPC in respect of the combination product, TRUVADA, comprising TD + FTC, did not satisfy the test set out by the CJEU in *Teva* for a valid SPC.

Had he correctly construed the patent, Gilead says that it would have satisfied the test in *Teva* and established that the SPC is valid.

35. In *Ranbaxy Laboratories Limited v. Warner-Lambert Company* [2007] IEHC 256, [2009] 4 I.R. 584, the High Court (Clarke J., as he then was) identified the principles to be applied in construing a patent. Section 45(1) of the 1992 Act provides that the extent of protection conferred by a patent is to be determined by the terms of the claims as interpreted by the description and any drawings. Subsection (3) provides that the Protocol on the Interpretation of Art. 69 of the EPC shall apply for the purposes of s. 45(1). Article 69 of the EPC provides:-

> *"(1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.*
>
> *(2) For the period up to grant of the European patent, the extent of the protection conferred by the European patent application shall be determined by the claims contained in the application as published. However, the European patent as granted or as amended in opposition, limitation or revocation proceedings shall determine retroactively the protection conferred by the application, in so far as such protection is not thereby extended."*

36. The protocol requires the court to eschew an overly literal approach to the construction of the claims. The balance of the patent can properly be taken into account in construing the patent as a whole for the purpose of determining the extent of the claims.

37. Clarke J. referred to the other key concept involved in the construction of the patent in the following terms:-

> *"24. … [It]must be approached from the standpoint of what has been described in the authorities as the "skilled addressee". The skilled addressee is taken to be a*

person or persons with practical knowledge and experience of the kind of work to which the invention was intended to be used: see Catnic Components Ltd. v. Hill & Smith Ltd. [1982] R.P.C. 183 at pp. 242 to 243. It is common case that I should attempt to read the patent and construe it in the way in which the so called skilled addressee would have done so.

25. The knowledge which will be attributed to the notional skilled addressee is the knowledge that any worker in the area concerned would be expected to have as part of their general knowledge: see for example General Tire & Rubber Co. v. Firestone Tyre & Rubber Co. [1972] R.P.C. 457 at p. 482. The knowledge is that which a skilled addressee would have had as of the "priority date" which, for the purposes of this patent, it is common case, is the 30th May, 1986. It is, therefore, agreed between the parties that I should approach the construction of this patent on the basis of the common general knowledge that would have been available to a person working in the field ... as of that date.

…

26. The role of that expert evidence needs to be clearly defined. It is common case that it is not the function of experts, in proceedings such as this, to offer a view as to the proper construction of the patent. Rather, it is the function of such experts to enable the court to understand (and if necessary, in the case of dispute, to determine) the common general knowledge which would have been available to a skilled addressee as of the priority date: see for example Lubrizol Corp. v. Esso Petroleum Co. Ltd. [1998] R.P.C. 727 at p. 738."

Thus the patent is to be construed through the eyes of the skilled addressee. He is – or as the case may be, they are – a hypothetical construct. The skilled addressee is thus a person

or persons with practical knowledge or experience of the kind of work in which the invention was intended to be used. They are deemed to have the knowledge which any worker in the area would be expected to have as part of their general knowledge which they would have had as of the priority date.

38. In *Re Glaxo Group Limited* [2009] IEHC 277, the High Court (Charleton J.) held that the common general knowledge attributed to the skilled person is any knowledge that a skilled person would acquire before he embarks on the problem to which the patent purports to be the solution. He acknowledged that frequently the person skilled in the art comprises a team. He described the members of the skilled team for the purposes of the 1992 Act at para. 45 as follows:-

> *"... The members of the skilled team are those who have a practical interest in the subject matter of the invention and it is to them that a patent is addressed. Since it is well settled that the skilled person can be a team, the kind of individuals with different skills and knowledge are proposed must be described in order to make a finding of fact as to the makeup of that skilled team."*

At para. 46, he accepted that he was obliged to *"take a realistic view"* as to what the make-up of the skilled but unimaginative team would be.

39. If a claim in a patent employs a word or phrase which is not a term of art, it is for the court to construe the meaning; it is not a matter for expert testimony (*Société Technique de Pulverisation STEP v. Emson Europe Ltd. & Ors.* [1993] R.P.L. 513) .

40. Thus, in conducting this exercise, the court hears the evidence of the expert witnesses as to the person skilled in the art and the prior art and general common knowledge. They help the court to understand the art and the problem to which the patent purports to be the solution. It is for the court to then determine who is the skilled addressee of the patent and to then construe the patent through the lens of the skilled addressee, applying the principles

outlined above. It is not the role of the expert witnesses to construe the patent, and any evidence they purport to give as to the construction of the words of the patent – other than terms of art – is inadmissible.

Trial Judge's "Skilled Team"

41. The trial judge considered the skilled person in paras. 147-153 of his judgment. He noted that Gilead and Teva both suggested that the skilled person would be comprised of a team made up of a medicinal chemist and a clinician, but that Mylan argued that the skilled person solely comprised a clinician. He explained in para. 147 why he rejected Mylan's position and accepted that the skilled person was a team comprising an appropriately qualified medicinal chemist and a clinician. This finding was not appealed.

42. He then considered what specific category of medicinal chemist and clinician should make-up the relevant notional team of the *"skilled person".* Over three pages, in paras. 148-149, he set out why he did not accept Gilead's case in this regard. He rejected Gilead's submissions as to the degree of expertise and interest in HIV to be attributed to the clinician on the basis that it:-

> *"... ignores the very plain terms of the patent itself which ... is very clearly concerned with a whole range of viruses. It is not focused purely on HIV... [i]n contrast, the 894 patent, by its own terms, expressly extends to a very wide range of viruses and retroviruses. As Prof. Powderly ultimately acknowledged, under cross-examination, para. 0044 of the 894 patent covers every virus known to man and extends to infections affecting both humans and animals".*

43. His essential findings are set out in paras. 150 and 151:-

> *"150. In these circumstances, I do not accept that the members of the team comprising the relevant "skilled person" would be focussed on HIV treatment to the extent suggested by the plaintiff. As Dr. Hawkins observed on Day 5 of the hearing, the*

approach taken by the plaintiff is unduly narrow. Given the wide terms of the patent, I fully agree with Dr. Hawkins. There is always a concern in these cases that specialist witnesses will inevitably look at a patent through the prism of their particular specialisation. I bear in mind, in this context, the observation of Barrett J. in Boehringer Ingelheim's Patent [2017] IEHC 495 at para. 38 where, in the context of considering the attributes of the notional person skilled in the art, Barrett J. observed:

> *"... the notional skilled person does not come to court: the court must make its own assessment of obviousness after hearing evidence from real-life witnesses who tend in practice to be rather more skilled than the notional person skilled in the art. ... No expert witness, however skilled, is proffered as the notional person made flesh. As the ... authors of Terrell on the Law of Patents (18th ed., 2016) observe, at para. 12-96:*
>
> > *'[E]xperts are not called as living embodiments of the unimaginative and uninventive skilled person…. [I]t is not a contest to see whose expert most closely represents the skilled person. As well as being over-qualified ... experts may come to the case with personal prejudices or preferences that must be discounted.'"*

151. It seems to me that Teva is correct in suggesting that the skilled person would comprise a team which would include both a medicinal chemist and a clinician. Insofar as the medicinal chemist is concerned, there was a substantial measure of agreement between the plaintiff and Teva that the medicinal chemist would be a pharmaceutical chemist with knowledge and experience in antiviral research activities. Insofar as the clinician is concerned, I cannot accept that the clinician would be solely focussed on HIV. It seems to me that, as Dr. Moyle suggested, that clinician would be involved in the management of a range of viral infections

including herpes, hepatitis B and HIV. The clinician would not have the same level of expertise in HIV as the witnesses who gave evidence before me, but would be a clinician who manages viral infections (including HIV) as part of his or her work. That seems to me to more accurately reflect the thrust of the patent itself. Obviously, if the patent had been focussed on the treatment of HIV (in the same way as the 542 patent), the relevant clinician would be correspondingly focussed on HIV treatment. I accept that the clinician and the medicinal chemist would be likely to attend conferences and that they would attempt to keep themselves up to date with developments in HIV, Hepatitis B and other viral infections. However, it would be a fallacy to suggest that they would be aware of every development mentioned in the scientific literature. This is demonstrated by the fact that, while Dr. Moyle and Prof. Powderly both attended the conference in San Francisco where the Wang abstract was published, neither of them noted the Wang publication, notwithstanding that both of them were HIV experts and were each particularly focussed on HIV treatment."

44. In arriving at his finding of *"the skilled person"* in these proceedings, the trial judge relied upon the evidence of Dr. Hawkins and Dr. Moyle, and on the wide terms of the patent. He had previously noted the concession of Prof. Powderly, under cross-examination, as to the scope of para. 0044 of the patent as covering every virus known to man. His decision was based upon the evidence of various expert witnesses and a reading of the patent, in light of that evidence. It is a finding of fact.

Scope of review of findings of fact by an appellate court

45. An appellate court is bound by the findings of fact made by the trial judge when they are supported by credible evidence (see *Hay v. O'Grady* [1992] 1 I.R. 210, pp. 217-218). Whether this rule is modified in the case of expert testimony is a matter which may arise in

another case in which the court is required to resolve a conflict between expert witnesses, but does not arise in this case as, ultimately, under cross-examination, Prof. Powderly accepted that it was a *"catch all patent"* and para. 0044 applied to all viruses known to man. Thus, the starting position is that this court is bound by the trial judge's finding of the person skilled in the art.

46. In this case, Gilead's complaint is that the trial judge failed to engage properly with some critical parts of its evidence or misdescribed its case and, therefore, erred in deriving the skilled team, and as a result he erred in construing the patent.

47. In *Leopardstown Club Limited v. Templeville Developments Limited* [2017] IESC 50, [2017] 3 I.R. 707, McMenamin J. set out (at paras. 109-111) the approach to be taken by an appellate court when reviewing the engagement of the trial judge with the evidence of the parties to the litigation:-

> *"109. Save where there is a clear non-engagement with* ***essential*** *parts of the evidence, therefore, an appeal court may not reverse the decision of a trial judge, by adverting to other evidence capable of being portrayed as inconsistent with the trial judge's primary findings of fact.*
>
> *110. "Non-engagement" with evidence must mean that there was something* ***truly glaring****, which the trial judge* ***simply did not deal with or advert to****, and* ***where what was omitted went to the very core, or the essential validity, of his findings****. There is, therefore, a* ***high threshold****. 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. This would arise* ***only in circumstances where findings of primary fact could not "in all reason" be held to be supported by the evidence*** *(see Henchy J. in V.C. v. J.M. and G.M. [1987] I.R. 510, at p. 523, quoting his earlier judgment in Northern Bank Finance v. Charlton [1979] I.R. 149). "Non-engagement" will not, therefore, be*

established by a process of identifying other parts of the evidence which might support a conclusion other than that of the trial judge, when there are primary facts, such as here. Each of the principles in Hay v. O'Grady [1992] 1 I.R. 210 is to be applied.

111. The task faced by the judges of our appeal courts is already too onerous. But the task would be made yet more onerous were appeals to be reduced to a piece-by-piece analysis of the evidence, in an effort to show, on appeal, that the trial judge might have laid more emphasis on, or attached more weight to, the evidence of one witness, or a number of witnesses, or one document, or a number of documents, rather than others on which he or she relied." (emphasis added)

48. The Supreme Court emphasised that this high threshold is only satisfied if a trial judge fails to deal with or advert to a matter which goes to the very core or essential validity of his or her findings. It is insufficient to identify other parts of the evidence which might support a conclusion other than that of the trial judge.

49. In *Morrissey v. HSE* [2020] IESC 6, Clarke C.J. quoted this passage with approval and said that the failure to engage with the evidence referred to *"the failure on the part of a trial judge to set out the reasons why central or important aspects of the case of one or other party on the facts were not accepted."*

50. He emphasised that it was *"far from sufficient"* to find some tangential or minor aspect of the case which is not expressly referred to in the judgment. He identified the question as:-

"… whether, taking that party's case as a whole, can it be fairly said that the trial judge has significantly failed to adequately address the reasons for rejecting the appellants' case on the facts?"

Bearing this threshold in mind, I have to consider Gilead's arguments that the trial judge failed to have regard to the uncontroverted evidence in the case regarding the significance

of the HIV/AIDS crises, the urgent unmet clinical need at the priority date and the fact that two-thirds of research into antiretroviral drugs at the time was directed towards treating HIV.

The skilled team and the construction of the patent

51. Gilead argues that the trial judge erred in finding that the relevant skilled clinician in the skilled team would not be focussed on HIV and would not have similar expertise to the expert witnesses who gave evidence in the case. Further, while he held that the skilled team would be likely to attend conferences and to be up-to-date with developments in HIV, it is contended that he erred in then finding that the skilled person would not have the same or similar expertise of the witnesses at the hearing. Gilead said that the trial judge erred in finding, at para. 148 of his judgment, that over the course of time it had sought increasingly to stress the level of expertise of the clinician in the treatment of HIV, whereas its case was consistently that the skilled clinician would be a person who was skilled and knowledgeable in relation to the development of drugs for the treatment of HIV. Finally, it argued that the trial judge failed to take into account the evidence presented at the hearing that the skilled clinician would be a person engaged in drug development and not just in clinical treatment.

52. Gilead argues that the trial judge misconstrued the evidence of Prof. Powderly. In his first witness statement, at para. 5.15 he said that the skilled clinician would be:-

> *"... a physician with several years of practical experience in the field of antiviral drugs and therapy, in particular in the treatment of HIV-1."*

In his second witness statement, he said at para. 4.1:-

> *"... in my opinion the skilled clinician to whom the patent is addressed, as part of the skilled team, would have been a specialist HIV clinician,* ***that is*** *a physician with particular experience and interest in HIV. His or her interest in other viral*

infections would primarily have been in the context of the various viral, fungal and bacterial opportunistic infections affecting HIV patients." (emphasis added)

53. He agreed with Dr. Moyle that *"HIV clinicians in July 1996 would likely have knowledge of other viral infection".*

54. The trial judge repeated these extracts virtually *verbatim* at para. 148 of his judgment, omitting only the words *"that is"* in relation to a specialist HIV clinician as being a person with particular experience and interest in HIV. At para. 149, the trial judge referred to the closing submissions of counsel on behalf of Gilead, in which some emphasis was placed on HIV treatment. Gilead said that it did not maintain in evidence that the clinician will be *solely* focussed on HIV, and, to that extent, the trial judge overstated the position adopted by Gilead at para. 151 of the judgment; but even if this is correct, it falls very far short of fundamentally undermining his conclusions.

55. In his submission to the High Court, counsel for Gilead maintained that the skilled team for the patent would be the same as the skilled team for the 542 patent. The 542 patent was emphatically focussed upon HIV: the first claim was for the combination TD + FTC. Claim 12 was:-

"Use of [FTC and TD] in the manufacture of a co-formulated tablet composition comprising one or more pharmaceutically acceptable carriers or excipients, wherein [TD and FTC] are present in a weight ratio … for the treatment or prevention of the symptoms or effects of an HIV infection …."

The combination of the two active ingredients is mandatory and the trial judge was entitled to take the view that the two patents were very different; the 542 patent was focussed upon HIV, whereas the patent in these proceedings was, to quote Prof. Powderly, *"a catch all"* patent. The difference between the two patents is properly reflected in a difference in the skilled teams in respect of them. In making this distinction, the trial judge relied upon the

evidence of expert witnesses whose role was to assist him in determining the identity of the skilled addressee.

56. He accepted the evidence of Dr. Moyle, and preferred it to that of Prof. Powderly. He was entitled to accept the evidence of Dr. Moyle and there is no suggestion that Dr. Moyle did not give the evidence which was attributed to him and accepted by the trial judge. It was open to him to conclude that the skilled team was not as focussed upon treatment of HIV as Gilead contended and, construing the patent through the lens of the person skilled in the art, to construe the patent as more broadly focussed and not primarily directed to HIV, in contrast to the 542 patent.

57. For these reasons, I am not satisfied that Gilead has met the high threshold set out in *Leopardstown* and *Morrissey*. The trial judge engaged with the essential evidence and arguments advanced by Gilead and the reasons why he rejected them are clearly set out in the judgment. It has not established a basis for this court to interfere with his findings on this ground of appeal.

58. Gilead submitted that the court should have determined the skilled team by (1) looking at the patent to get a sense of its technical field, which was the bioavailability of antiviral drugs; (2) it should then have heard evidence about who has a practical interest in patents in this field (two-thirds of antiviral research at the time was into HIV and there was an urgent unmet clinical need to treat these patients) and; (3) having heard that evidence, the trial judge should then, as a matter of fact, determine the composition of the skilled team, through whose eyes he would then construe the patent.

59. Gilead said that the trial judge should not read the patent himself and determine the scope of the patent and, in light of that determination, derive the skilled team. Gilead said that this is what the trial judge did when he referred to the terms of the patent and the breadth of the patent in deriving the *"skilled person"* in this case. In effect, it is argued, he

omitted step (2), and he failed to follow Charleton J. in *Glaxo*, and failed to have regard to the fact that members of the team have a practical interest in the subject matter of the invention, in this case the development of new antiviral drugs.

60. I do not agree with this criticism of the approach adopted by the trial judge. Prof. Roberts gave evidence that at the priority date two-thirds of research in antiviral drug development was directed towards developing treatments for HIV. It follows that one-third was not so directed. Gilead emphasised the urgent unmet clinical need in relation to HIV. Teva submitted that it was not accepted by Dr. Hawkins or Dr. Moyle, and ultimately not accepted by Prof. Powderly, that the skilled clinician for the purposes of this patent would be a HIV specialist interested in the development of drugs for HIV treatment.

61. Dr. Hawkins gave evidence (at Day 5, pp. 116-117 of the transcript) that HIV was an emerging clinical problem and there were maybe a million or so people affected around the world. He also said that maybe *"half the population"* had been infected with Herpes Type 1, and some with Type 2, and that Hepatitis B was a *"massive problem with maybe two billion people around the world infected and several hundred million with active infection and in fact 500,000 people a year dying of Hepatitis B."*

62. The trial judge was entitled to have regard to this evidence, as well as to the current clinical need in respect of approximately one million people suffering from HIV for whom an effective treatment was an urgent requirement. The patent was not exclusively directed toward HIV and this was never contended. The issue was the degree to which it was the focus of the patent. In assembling the skilled team, the trial judge was required to have regard to the terms of the patent in order to assess whether it was addressed to a specialised or wider cohort of addressees. Their evidence was that it was a *"catch all"* patent; that it could apply to all known viruses; that it included claims which had no application to the treatment of HIV (Claim 22); and that it included means of delivering the compounds

which had no application to the treatment of HIV. Based on the evidence as to the scope of the patent, he was entitled to conclude that the skilled clinician was not as specifically focussed upon HIV as Gilead contended.

63. Gilead argued that there was a serious flaw in the approach of the trial judge as he did not expressly address the evidence as to the urgent unmet clinical need to treat patients suffering from HIV. It further claimed that he had also failed to address the argument that the skilled clinician would have an interest in drug development. It also argued that the trial judge mischaracterised and misunderstood Prof. Powderly's evidence in relation to commercial considerations.

64. It is important to return to the high threshold referred to in *Leopardstown* and *Morrissey*. The judgment of the High Court in my opinion is exemplary. The trial judge carefully referred to the evidence of the expert witnesses at each stage of the judgment, frequently by reference to a page of a day of the transcript. He clearly set out the opposing views of the experts. It is abundantly clear that the trial judge understood the essential core of Gilead's case and addressed it in the context of the issues which fell for decision. Gilead's submission that the trial judge effectively ignored the evidence as to the urgent unmet clinical need to deal with HIV in 1996 is untenable in my view. He was clearly fully aware of the crisis and sets it out in some detail at the beginning of his judgment. Gilead's true complaint is that he also gave weight to the clinical need in relation to other viral infections including, in particular, Hepatitis B, but also Herpes and Cytomegalovirus, amongst others. Given the evidence of Dr. Hawkins, this approach was unimpeachable. It falls very, very far short of the threshold referred to in *Leopardstown* and *Morrissey.*

65. Similarly, his reference, in para. 182 of the judgment, to Prof. Powderly's evidence regarding commercial interests results in the conclusion that *"[i]n the context of the construction of a patent, I do not believe that evidence of this kind can be accepted."* In its

written submissions, Gilead says that *"as this appears to have been a significant aspect of the [learned trial judge's] reasons for rejecting Prof. Powderly's evidence, and Gilead's case, as to the focus of the Patent, this aspect of the decision is baseless and erroneous."*

66. I cannot agree that the trial judge's rejection of the admissibility of evidence regarding commercial interests when construing the patent was a significant aspect of the trial judge's decision. He had already made his decision in the preceding paragraphs and para. 182 is merely included *"[f]or completeness"*. Insofar as Gilead seeks to characterise this evidence of Prof. Powderly as, in fact, referring to the unmet medical need and public health emergency, that was clearly a matter to the forefront of the trial judge's mind, as I have already observed. I do not accept that the trial judge erred in the manner alleged by Gilead.

67. Gilead argued that the trial judge failed to take into account the evidence that the skilled clinician – as opposed to the medicinal chemist – would be a person engaged in drug development, and not just in clinical treatment. He concluded that the team would comprise an appropriately qualified medicinal chemist who would be a pharmaceutical chemist with knowledge and experience in antiviral research activities. This, of course, will cover drug development. The trial judge was entitled to take the view that it was not necessary that the clinician would also be a person engaged in drug development, bearing in mind that the skilled person is a hypothetical construct and that the knowledge of any one member of a skilled team is attributed to all members of the team. It is not as if the trial judge posited a clinician who took no interest in these areas of development. He expressly stated that the clinician and the medicinal chemist would be likely to attend conferences and they would attempt to keep themselves up-to-date with developments in HIV, Hepatitis B and other viral infections. This includes keeping up-to-date with the development of new drugs.

68. It is also important to recall that the claims of the patent are to be read in the light of the descriptions and the drawings. Paragraph 0044 describes compounds useful in respect of every known virus. Paragraph 0046 describes the variety of routes by which the compounds may be administered, many of which Prof. Powderly accepted, have no relevance to the treatment of HIV. While para. 0047 refers to the optional administration of one of the compounds in claims 1-25 in combination with *"other therapeutic ingredients"*, HIV is not referred to in this context, and other conditions were also treatable by combination therapy as of the priority date. There was nothing in the terms of the patent which limited Claim 27 to anti-retroviral drugs for the treatment of HIV. In light of the foregoing, the trial judge fairly concluded *"[g]iven the importance of Hepatitis B as a disease as of the priority date, and given the wide terms of the patent, I cannot accept that HIV is the principal or the most important focus"* of the patent.

69. In all the circumstances, I do not accept that the judgment is not reasoned, whether as regards deriving the skilled person or then construing the patent. There has been no significant failure to adequately address the reasons for rejecting Gilead's case on the facts, as per the dicta in *Morrissey*. There was evidence to support the trial judge's findings of fact and he carefully both identified the evidence and explained why he accepted it throughout the judgment.

70. I, therefore, conclude that this court should not interfere with the trial judge's finding of the skilled team for the purposes of construing the patent and the patent should be construed through the lens of the skilled addressee of the patent in the manner found by the trial judge.

The test for construing Art. 3(a) of the SPC Regulation

71. In *Teva*, the CJEU stated the test to be applied to a combination product, one of whose active ingredients is not expressly referred to in the patent, as follows:-

"Article 3(a) of [the Regulation], must be interpreted as meaning that a product composed of several active ingredients with a combined effect is 'protected by a basic patent in force' within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

- *the combination of those active ingredients must necessarily, in the light of the description and drawings of the patent, fall under the invention covered by that patent, and*
- *each of those active ingredients must be specifically identifiable, in the light of all of the information disclosed by that patent."*

Limb 1 of *Teva*: "Necessarily"

72. From the point of view of the skilled addressee, as found by the trial judge, and on the basis of the prior art at 26 July 1996, the question for consideration is: does the combination of TD + FTC necessarily fall under the invention covered by the patent, in light of the descriptions and drawings of the patent. McDonald J. addressed this question at paras. 186 and 187 of his judgment:-

"186. I also bear in mind that, as noted in para 164 above, the terms of Claim 27 and para. 0047 of the patent do not appear, in any event, to be consistent with the case made by the plaintiff (and accepted by all sides) that, as of the priority date of the patent in July 1996, combination therapy was the standard treatment for HIV patients. In other words, it was necessary, if a treatment was to be effective that the patient should be prescribed a combination of anti-retroviral drugs. I fully accept that

combination therapy was the standard treatment as of July 1996. However, as previously noted, the addition of the "other therapeutic ingredients" envisaged by para. 0047 and Claim 27 is not stated to be mandatory but optional. I therefore, do not understand the basis upon which it could plausibly be suggested that Claim 27 had in mind the combination therapy that was required for HIV as of July 1996. In this context, I asked counsel for the plaintiff to address the meaning and effect of the word "optionally" in Claim 27. His response on Day 12 was as follows:-

> *"So what it means is that one doesn't have to, Claim 27 does not necessarily involve a combination and if that proposition is fatal to Gilead's case so be it, I don't believe it is, Judge. But we've never suggested that Claim 27 would be read only or could be read only as referable to products containing two active ingredients or more or two therapeutic ingredients ....*
>
> *Where therapeutically indicated or where a judgment is that it is going to be therapeutically beneficial then it provides for a product that contains more than one active ingredient and more than one therapeutic ingredient. The evidence clearly establishes that the combination of TD with something else, we say another NRTI such as FTC, was therapeutically indicated as of 1996 because that was the standard of care. And that's what we say about optionally, Judge."*

187. Counsel for the plaintiff therefore accepted that Claim 27 does not necessarily involve a combination. Given the language used in Claim 27, I believe that counsel for the plaintiff had no alternative but to make that concession. For the reasons already addressed in para. 164 above, I believe that this is a further basis to conclude that Claim 27 is not directed to HIV. Were it directed to HIV, as of July 1996, the claim would make it clear, in my view, that the addition of another therapeutic ingredient (in particular an NRTI or a PI) should be included in the

relevant composition. That was the accepted standard of care for HIV patients as of the priority date of the patent. There was nothing optional about the addition of the second NRTI. In the circumstances, I cannot see any basis on which I could form the view that a skilled person, construing a claim that refers to the inclusion of other therapeutic ingredients as optional, would consider the claim to refer to combination therapy for the treatment of HIV or that the skilled person would have in mind, as a therapeutic ingredient, an NRTI such as 3TC or, more particularly, FTC."

73. TD is mentioned expressly in Claim 25. FTC is not mentioned anywhere in the patent. If the combination TD + FTC necessarily falls under the invention covered by the patent, it can only do so under Claim 27 as properly construed. This, in turn, means that the combination of TD and *"optionally other therapeutic ingredients"* must be necessary, and the other necessary therapeutic ingredient must include FTC.

74. The foundation of Gilead's case is that the patent was primarily – though not solely – focussed upon treating HIV and thus, Claim 27 should be read as focussed primarily on treating HIV. It argues that the uncontroverted evidence in the High Court supports the conclusion that Claim 27 was really focussed upon treating HIV and not any other condition. Its case depends upon a construction of the patent which was rejected by the trial judge: that the patent was primarily focussed upon treating HIV.

75. Most unusually, there are persuasive authorities addressing SPCs issued in other jursidictions in respect of this very product and applying the test established by the CJEU in *Teva*. The first is the opinion of Advocate General Wathelet in *Teva*. At para. 87 and footnote 51 he expresses the following view:-

*"87. To my mind, **and subject to verification by the referring court**, as the active ingredient emtricitabine is claimed solely through the use of completely indeterminate expressions such as 'comprising' and 'optionally other therapeutic*

ingredients',[50] terms which may cover multiple substances that are not specifically and precisely identifiable on the priority date of the patent,[51] the combination containing the active ingredients TD and emtricitabine, that is to say, the medicinal product marketed under the name Truvada, is not protected by the basic patent within the meaning of Article 3(a) of Regulation No 469/2009, even though that combination may fall within the protection of claim 27 of the patent at issue in the main proceedings under Article 69 of the EPC and the Protocol on its interpretation and section 125 of the Patents Act 1977.

FN 51. Or even substances not yet invented on the priority date of the patent. The active ingredient emtricitabine is not specifically identifiable as such from claim 27 of the patent at issue in the main proceedings. See, to that effect, the judgment of 12 December 2013, Eli Lilly and Company (C-493/12, EU:C:2013:835, paragraph 36). In my view, an interpretation of Article 3(a) of Regulation No 469/2009 as including substances that are not specifically and precisely identifiable would undermine the objective of that regulation, which is to mitigate the insufficient period available to cover the investment put into research for new medicinal products (as referred to in recital 4 of that regulation), because it confers a benefit on the patent holder even though that patent holder had not made any investment in research relating to those substances. See, to that effect, paragraph 43 of the judgment of 12 December 2013, Eli Lilly and Company (C-493/12, EU:C:2013:835)." (emphasis added)

76. He was of the view that the product, the subject of the SPC, was not protected by the basic patent, while he accepted that this is subject to verification by the referring court.

77. The Grand Chamber held at paras. 55 and 56 of its judgment:-

"55. In particular, it is for the referring court to ascertain, in accordance with the considerations in paragraphs 47 to 51 above, whether, from the point of view of a person skilled in the art, the combination of active ingredients of which the product which is the subject of the SPC at issue consists necessarily falls under the invention covered by that patent, and whether each of those active ingredients is specifically identifiable on the basis of the prior art at the filing date or priority date of that patent.

56. In the present case it is apparent, first, ***from the information in the order for reference that the description of the basic patent at issue contains no information as to the possibility that the invention covered by that patent could relate specifically to a combined effect of TD and emtricitabine for the purposes of the treatment of HIV. Consequently, it does not seem possible that a person skilled in the art, on the basis of the prior art at the filing date or priority date of that patent, would be able to understand how emtricitabine, in combination with TD, necessarily falls under the invention covered by that patent.*** *The onus is nevertheless on the referring court to check whether such is indeed the case. Secondly, it is also for that court to establish whether emtricitabine is specifically identifiable by that person skilled in the art in the light of all the information contained in that patent, on the basis of the prior art at the filing date or priority date of the patent in question."* (emphasis added)

78. The court was of the view that it did not seem possible that a person skilled in the art would be able to understand how FTC in combination with TD necessarily fell under the invention covered by the patent, but it said it was a matter for the referring court *"to check whether such is indeed the case".*

79. The referring court in *Teva* was the High Court of England and Wales. Arnold J., applying the test articulated by the CJEU in *Teva*, held that the SPC must be revoked. Gilead appealed to the Court of Appeal; its judgment was delivered by Floyd L.J. He reviewed, in detail, the opinion of Advocate General Wathelet and the decision of the court. He also reviewed the opinion of Advocate General Hogan in *Royalty Pharma* (joined cases C-650/17 and C-114/18). In view of the fact that he was construing the patent, the subject of the SPC at issue in these proceedings, and applying the test set out in *Teva*, it is appropriate to set out his conclusions in some detail:-

> *"75. In my judgment, the first limb is simply a more elaborate exposition of the "necessarily" part of the test first advanced in Eli Lilly, namely that "the claims relate … necessarily … to the active ingredient in question". I agree with Mr Mitcheson that this limb means that a claim to "a formulation comprising compound A" does not protect a combination of A and B. That is because the presence of B is not a necessary part of the invention claimed. It follows that, to protect a combination product, a claim must require the presence of two compounds, not just one.*
>
> *76. This is not what a domestic patent lawyer would call a simple extent of protection test, applying Article 69 and the Protocol. Rather it is a test which examines whether each component of the combination product is required by the claim. A domestic extent of protection test would only ask whether that which is claimed is present anywhere in the product, which is quite a different question.*
>
> *77. I do not accept, however, that the first limb of the test, so understood, is met in the present case. The addition of "other therapeutic ingredients" to TD in claim 27 is expressly made optional. That is no different in principle to a claim which "comprises" TD, which we know is not good enough to protect a combination.*

...

78. ... As to the wording of the claim, it is not possible to understand claim 27 as requiring the presence of another therapeutic ingredient when it expressly states that it is optional. The fact that the claims might have been drafted differently does not assist. It is clear that claim drafting is of importance in this area, as cases such as C-577/13 Actavis (cited above) make clear. It did not assist Actavis to say that it could have had a claim to the combination. The claims which it had were all that mattered. The same applies here.

...

81. Finally, it is by a focus on the claims and the description that the skilled person (albeit with the benefit of his common general knowledge) decides what the claims necessarily relate to. Although the patent contains lengthy, standard form, material as to how the compounds of the invention can be formulated, there is nothing to suggest to the skilled person that claim 27 requires the presence of another ingredient. Everything points the other way. The skilled person might well know from the common general knowledge that other anti-viral agents would be useful in practice in the treatment of HIV, but he would not therefore assume that the presence of such an agent was required by the claim.

82. In any event, Mr Mitcheson's argument appears to assume that claim 27 is limited to a pharmaceutical composition containing TD for the treatment of HIV. It is not so limited, and the phrase "other therapeutic ingredients" is not limited to anti-viral agents either. The breadth of the claim is a further reason for not reading it as requiring the presence of a second anti-viral agent known to have potential for HIV."

80. The English Court of Appeal thus emphatically rejected Gilead's claim to satisfy the first test on the grounds that other therapeutic ingredients which were optional could not be necessary, and where the breadth of the claim precluded reading it as requiring the presence of a second antiviral agent known to have potential for the treatment of HIV.

81. In *Royalty Pharma*, Advocate General Hogan held that the test *"is satisfied if the product to which the claims of the basic patent relate is a specification* ***required*** *for the solution of a technical problem disclosed by that patent"* and that if *"the claims in a patent in relation to a product are not required for the solution of the technical problem disclosed by a patent"* the first limb of the test is not met. He interpreted *"necessarily"* as meaning that the combination must be required. This is of some relevance in light of the submissions advanced by Gilead at the hearing of this appeal.

82. It is also worth observing that in footnote 35, the Advocate General expressed his belief that at para. 54 of the judgment in *Teva* the court:-

> *"... showed considerable scepticism as to whether a combination such as TD (which was specifically mentioned in the patent claims) and emtricitabine (which was allegedly covered by the general expression 'other therapeutic ingredients' and associated with the term 'optionally') satisfied the two-part test referred to in that judgment."*

83. In its decision in *Royalty Pharma Collection Trust v. Deutsches Patent- und Markenamt* (C-650/17), the CJEU referred to the test established in *Teva* and reiterated that the two cumulative conditions must be satisfied: first, the product must necessarily come under the invention covered by the patent and, second, the person skilled in the art must be able to identify that product *"specifically in the light of all the information disclosed by that patent, on the basis of the prior art at the ... priority date"*.

84. This court is, of course, bound by the decision of the CJEU in *Teva* (and in *Royalty Pharma*). We must, therefore, have regard to the observations of that court in relation to the claim at issue. As I have said, Advocate General Hogan was of the view that the court expressed *"considerable scepticism"* as to whether the product satisfied the two tests established in *Teva*. The CJEU, and the respective Advocates General, acknowledged that it is for the national court to verify whether, on the facts, the SPC satisfies the test laid down in *Teva.*

85. The decision of the Court of Appeal in England is persuasive authority. This is reinforced by the principle of comity of courts. The appropriate approach to these two principles was considered in *Ranbaxy*.

86. As regards reliance on the decisions of other common law courts as precedents, Clarke J. (as he then was) indicated that Irish courts should exercise *"some caution"* in relation to *"over reliance on judgments from other jurisdictions."* At para. 51, he said:-

> *"... it is important to note that, while the broad scope of patent law has many similarities from one common law country to the next, there are, undoubtedly, some differences in the established approach in the respective jurisdictions. In particular, the underlying statutory basis does differ. Ireland and the United Kingdom have, of course, the European Patent Convention in common and, as was pointed out by counsel for the plaintiffs, the Patents Act 1992 is in very similar terms to the equivalent United Kingdom legislation and is clearly closely modelled on the United Kingdom Patents Act 1977. This is hardly surprising as both the United Kingdom and Ireland are signatories to and have ratified the European Patent Convention. It is fair to state that less caution needs, therefore, to be exercised in considering the application of judgments of the courts of the United Kingdom than other common law countries. In those circumstances, it seems to me that, while it would not be*

appropriate to ignore the jurisprudence of other common law countries, it is the decisions of the United Kingdom courts that require most attention. … However, for the reasons I have set out, caution should be applied and it should not be assumed that all relevant factors are necessarily the same."

87. Noting that the court in *Ranbaxy* was not concerned with an SPC, or other instrument deriving from European Law, it is nonetheless important for the court here to ascertain whether there were material differences between the evidence before the Irish court and that before the foreign tribunals upon whose judgments parties sought to rely.

88. At para. 54, he addressed the separate consideration governed by the principle of comity. He stated as follows:-

"An entirely separate consideration has to be given to the result of foreign litigation which touches upon the same actual matters (rather than the same legal principles). The principle of the comity of courts requires that the courts in one jurisdiction should not lightly depart from a decision on the same issue made by a court of competent jurisdiction in another country which had to deal with that issue as part of litigation properly under its consideration. Thus, for example, where the courts in one jurisdiction have interpreted a contract in a particular way and where the same contract comes to be interpreted, in a separate dispute between the same or similar parties, in the courts of another jurisdiction, then the comity of courts requires that the interpretation of the contract in the second proceedings should not lightly depart from the interpretation given to the same contract in the first proceedings."

89. Counsel for Teva emphasised that the caution referred to by Clarke J. in para. 51 does not arise where, as here, the judgment is a judgment from a court of a member state applying an EU law test. While each member state granted Gilead a separate SPC in respect of TRUVADA, they were in identical terms and in respect of a patent in the

identical terms. In other words, the English Court of Appeal was required to apply the same legal principles to the essentially identical SPC, in respect of the identical patent. It was submitted that this court should *"not lightly depart from"* the decision of the English Court of Appeal in these circumstances.

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

91. Gilead alleges both. It says that the English Court of Appeal erred in construing the patent without reference to a skilled team or to expert evidence as to how the phrase *"optionally other therapeutic ingredients"* should be construed. Secondly, Gilead argues that there were differences between the evidence in the English courts and that adduced in the High Court which were of such materiality as would warrant this court in declining to follow the decision of the Court of Appeal in England.

92. Both Advocate General Wathelet and the CJEU in *Teva* say that it is for the national court to verify whether the SPC satisfies the two limbs of the test, *i.e.* in light of the

evidence before it, the court must determine whether or not the product satisfies the two-fold test established in *Teva*.

93. The first step is to look at the evidence before the English courts. This was limited as compared to that adduced before McDonald J. (and indeed an application by Gilead to adduce further evidence before the High Court in England was refused). Floyd L.J. summarised the evidence before the trial court in that jurisdiction at paras. 10-12 of his judgment:-

> *"10. At the claimed priority date of the patent a wide range of therapeutic agents was known for the treatment of viral infections including HIV. One known class was the class of anti-retroviral drugs known as nucleoside reverse transcriptase inhibitors or NRTIs. The judge found that, by that date, it was "increasingly common" to treat HIV using a combination of different NRTIs. Another approach was to combine a NRTI with a protease inhibitor or a non-nucleoside reverse transcriptase inhibitor (NNRTI), which are two other classes of anti-retroviral drugs.*
>
> *11. TD and emtricitabine are both NRTIs. Emtricitabine was first described in an article by Schinazi et al published in November 1992: Antimicrobial Agents and Chemotherapy, 36(11), 2423-2431. The article reported in vitro studies of emtricitabine against HIV. The judge found at [7] of the First Judgment:*
>
> > *'There is no evidence that it was known in July 1996 that emtricitabine was an effective agent for the treatment of HIV in humans, still less that this was common general knowledge to the person skilled in the art to whom the Patent is addressed. The European Medicines Agency first approved emtricitabine in October 2003, over seven years later.'*
>
> *12. Gilead does not seek to contradict this finding, but submits that emtricitabine was amongst a finite list of NRTIs known at the priority date as having potential for*

treating HIV. A non-exhaustive schedule compiled from journal articles available at the priority date was placed before the judge. It listed only 6 such NRTIs. Gilead asserts that emtricitabine was in clinical trials at the priority date, albeit that the result of those trials were not yet known. Clinical trials would not be permitted, Gilead infers, unless it had first been established that emtricitabine was tolerable by humans. It was to issues such as these that it wished to adduce further expert evidence."

94. Gilead says that there was evidence before the High Court that FTC had completed a small Phase 1 clinical trial and thus, that at the priority date there was evidence that it was an effective agent for the treatment of HIV in humans, contrary to the evidence in the English High Court. Gilead also says that there was evidence of two pieces of prior art, referred to as the Wang Abstract and the Triangle Press Release, respectively, in the decision of the trial judge, and thus the fact that FTC could be used as a treatment for HIV in humans formed part of the prior art. This contradicted the finding by Arnold J. at para. 7 of his first judgment. Furthermore, there was evidence before McDonald J. that two NRTIs (such as TD[1] and FTC) were the *"gold standard"* of treatment for HIV as of the priority date. Therefore, based on this evidence, according to Gilead, a skilled person would understand *"optionally"* to mean as depending on what was clinically indicated, and, where it was clinically indicated that it was mandatory, as in the treatment of HIV, then it would be understood to be mandatory and, therefore, it satisfied the *"necessarily"* test established in *Teva*. The existence of this evidence, which was not adduced in the English courts, was, accordingly, crucial and decisive.

95. I do not agree. I do not accept that the fact that FTC had undergone one small Phase 1 clinical trial changes the construction of the patent, because it still must be read

[1] Gilead treated TD as an NRTI for the purposes of the argument as it targets the same part of the life cycle of the HIV virus, though technically it is a nucleotide reverse transcriptase inhibitor.

with the assistance, or through the lens, of the skilled team. It cannot alter the extraordinary breadth of the claims of the patent. This evidence could only be crucial if the patent were indeed primarily focussed upon treating HIV. As the trial judge correctly construed the patent as being a broad patent which was not primarily focussed upon treating HIV, it follows that this difference between the evidence before McDonald J. and Arnold J. is not sufficiently material to justify this court in refusing to follow the decision of the Court of Appeal in England.

96. Separately, Gilead argued that the English Court of Appeal erred in construing the patent because it did not do so with the proper evidence assessed through the eyes of the skilled addressee, but rather the judges sought to read the patent themselves.

97. In the English proceedings, Gilead initially[2] took the approach that evidence was not required in relation to what became Limb 1 of the test established by the CJEU in *Teva*. Counsel for Mylan argued that this showed that Gilead did not believe that evidence was necessary to enable the court to construe the patent for the purposes of the first limb of the test. Accordingly, he contended, it was not open to Gilead in these proceedings to argue that the Court of Appeal in England erred in construing the patent for the purposes of the first limb of the test without reference to expert evidence. To my mind, this point is well made.

98. Gilead criticised Floyd L.J. for construing the patent without receiving evidence as to the meaning of *"optionally"* in the context of Claim 27. It seems to me that this criticism is misplaced. In *Société Technique*, the Court of Appeal (Hoffmann L.J.) held that evidence from expert witnesses as to their understanding of non-technical words was inadmissible. He said:-

[2] After the decision of the CJEU on the reference by the High Court, it sought to adduce expert evidence but leave to do so was refused.

"The judge allowed counsel to ask the expert witnesses what they understood by words like "conduit means". These are not technical words having a special trade meaning and in my judgment the opinions of witnesses of their meaning were inadmissible. Construction was a matter for the judge. "Conduit" is in my view a word which expresses a function. It is not merely something through which liquid flows but of which at least one purpose is to convey liquid from one point to another, however close those points may be."

99. On the basis of this authority, not only was Floyd L.J. entitled but he was required to construe the word *"optionally"* without regard to the evidence of expert witnesses as to what they would have understood the word to mean in the context of the patent.

100. I am not persuaded by Gilead's arguments why this court should not follow the decision of the English Court of Appeal. It is the role of the court to construe the patent. The Court of Appeal did not err when Floyd L.J. said that it was *"not possible to understand claim 27 as requiring the presence of another therapeutic ingredient when it expressly states that it is optional."* It follows that there is no reason based on an egregious error of law not to follow the decision of the Court of Appeal. Likewise, there is no material difference between the facts before the High Court and the courts in England which should lead this court to decline to follow the decision of the Court of Appeal. For these reasons, this court ought to follow the decision of the Court of Appeal and I would reject the arguments of Gilead to the contrary.

Decisions of the courts of other member states

101. Gilead obtained SPCs in many of the member states of the European Union in respect of TRUVADA, based on the patent. Those SPCs have been challenged by, amongst others, Teva and Mylan, in a variety of courts throughout Europe. It is relevant to consider those decisions also. There is a striking uniformity in the decisions issued after

the ruling of the court in *Teva*: in every case cited to this court, the relevant SPC has been revoked. In Germany, France, Portugal, England and Wales, Belgium, Finland, The Netherlands and Italy, when the court applied the test established by the CJEU in *Teva*, the court in question held that the SPC did not meet the test. No judgment where a court upheld the validity of the relevant SPC, applying the test in *Teva*, was cited to us. Some courts held that the SPC failed both limbs of the test (Paris Court of Appeal, The Supreme Court of Germany, The Denmark Maritime & Commercial High Court, The Market Court in Finland, The Dutch Business Court of Brussels and the Court of Appeal in Milan). The Court of Appeal in Lisbon and the Court of The Hague held that emtricitabine (FTC) was not specifically identifiable and, therefore, the SPC was invalid, and neither court considered whether the SPC satisfied the first limb of the *Teva* test. Many of the courts found that the use of the word *"optionally"* was fatal to Gilead's claim that it satisfied the first limb in *Teva*, in line with the reasoning of the Court of Appeal in England.

102. The Supreme Court of Germany relied specifically on the decision of the Court of Appeal in England, to the effect that if emtricitabine is optional in Claim 27, it cannot satisfy the first limb of the test (para. 30 bb) and it is not necessary (para. 38). The Court of Appeal in Barcelona noted that the CJEU held that the relevant rules were *"those related to* ***the extent of the invention covered by such patent,*** *as is provided…in Article 69 of the EPC and the Protocol on the interpretation of that provision…"* and not those related to infringement (emphasis in the original). It then cited the dispositif of the court at paras. 55 and 56. At para. 24, the court in Barcelona summarised the issue to be determined as whether:-

> *"…[A]n expert skilled in the art must be able to conclude that the combination of these active ingredients, emtricitabine + tenofovir disoproxil, must* ***necessarily,*** *in*

the light of the description and drawings of that patent, fall under the invention covered by that patent…

[I]t is not sufficient that one of the combined active ingredients is given a functional definition (in this case, "therapeutic ingredients"), but it is necessary that, based on such claims, interpreted, in particular, in light of the description, a skilled person could conclude that such ingredient was necessarily included in claim 27 on the priority date…". (emphasis added)

103. It went on to conclude that as emtricitabine was not mentioned in either the claims or the description, the fact that the person skilled in the art *"could know that the active ingredient had anti-HIV activity and was being evaluated in phase 1 clinical trials"*, could not remedy this omission, as the active ingredient was not necessarily included in the claims. Thus, its analysis reinforces the case for this court following the decision of the English Court of Appeal.

104. It is also worth noting that the Court of Appeal in Barcelona and The Market Court in Finland each determined that the person skilled in the art comprised a skilled team equivalent to that found by McDonald J.

Does the SPC satisfy the first part of the test in *Teva*?

105. In any event, even if this court did not have the benefit of the decision of Floyd L.J., and the judgments of the courts of other member states, I consider that the SPC does not satisfy the first limb of the test.

106. Gilead's argument that it satisfies the test runs as follows: the skilled person would be able to identify a number of specific active ingredients which could be teamed up with TD, which is identified in Claim 25. The skilled person knows that *"therapeutic ingredient"* does not cover everything; it must be a relevant therapeutic ingredient. The standard of care for HIV in July 1996 was two NRTIs. Therefore, in 1996 the skilled

person would know that to treat HIV, two NRTIs were required. TD was an NRTI[3], and therefore its use in combination with a second NRTI was mandatory, not optional, for treating HIV. Thus, the combination is *"necessary"* and therefore, the SPC passes the first test possited by *Teva*.

107. I do not accept Gilead's submissions on this point. McDonald J. found that the skilled addressee is not focussed upon HIV treatments to the extent advocated by Gilead. The patent as read by such a skilled addressee is not, therefore, primarily addressed to the solution of the problem of treating HIV patients.

108. Secondly, the word optionally must be given its ordinary meaning, which precludes the conclusion that the other therapeutic ingredient is required by Claim 27. To my mind, Gilead is effectively rewriting Claim 27 in order to overcome this insuperable difficulty as two claims: 27A and 27B, where 27A is any one of claims 1-25 together with a pharmaceutically acceptable carrier, and Claim 27B is any one of claims 1-25 together with a pharmaceutically acceptable carrier and other therapeutic ingredients.

109. The court may not rewrite the claims when construing the patent and so may not do so when determining whether a product is protected by the basic patent in force, as required by Art. 3(a).

110. It is worth observing that Gilead applied for a patent in respect of the specific combination at issue in the 542 patent. It failed on the ground that it was not novel at the priority date, based on a prior publication. However, if Gilead is correct in the contention it advances in these proceedings, and the combination of TD + FTC is claimed in Claim 27 of the patent, then Gilead could not properly have obtained the 542 patent for TRUVADA, as that product could not have been novel, being already claimed in the earlier patent, and therefore was not patentable. This was accepted by counsel in his submissions to the court.

---

[3] See footnote 1.

It does not, of course, determine whether, in fact, TRUVADA is protected by Claim 27, but it is indicative, at the very least, of the fact that Gilead did not always make the case it advanced in the High Court and on appeal and, in fact, it advanced a claim contrary to it.

111. Furthermore, even if it may be argued that *"optionally"* in the context of Claim 27, is in fact a term of art in respect of which expert evidence may be received, the evidence adduced in the High Court does not support the position of Gilead. Prof. Powderly did not construe *"optionally"* as it was construed in argument before this court (Day 9, p. 35 of transcript):-

> *"Q. Mr. Justice McDonald: And do you place any meaning on the word "optionally" in that context?*
>
> *A. [Prof. Powderly]: I take it that what was being claimed or what was being proposed was that it would be an option in the sense that not every agent is combinable and therefore one would have to determine through further clinical testing whether or not another agent could actually be combined -*
>
> *Q. Mr. Justice McDonald: I see.*
>
> *A. [Prof. Powderly]: - with the tenofovir. So, I read it, Judge, as it was a composition with a carrier and optionally or potentially another agent but not limiting itself to doing that because you could have situations where you could not, you might not find anything that would actually be able to be combined."*

112. This interpretation of *"optionally"* in the context of Claim 27 is different to that advanced by Gilead, and is arguably inconsistent with it. It certainly does not support it.

113. Dr. Hawkins gave evidence that *"optionally"* clearly means that it is not necessary. In his witness statement, he said at para. 4.19:-

"The Clinician would understand the word "optionally" in claim 27 to mean that it is not necessary to have other therapeutic ingredients in all situations but that it may be a reasonable way forward in certain circumstances."

He said at Day 5, (p. 130 of the transcript):-

"Optionally clearly means it's not a necessary requirement."

And at Day 6 (p. 24 and pp.66-67 of the transcript respectively), he said the following:-

"Q: I now just want to ask you a question about the patent and claim 27 in particular, but the patent generally. Is it your view that the view of the person skilled in the art, the skilled clinician at the time as of the priority date would have come to the view that the combination of TD and FTC would or must necessarily fall under the invention covered by the patent?

A: [Dr. Hawkins] It is my view that there is nothing in the patent which would make me come to that conclusion.

...

A: [Dr. Hawkins] Claim 27 primarily states one therapeutic ingredient because the other is optional. So I don't see how you can say that it necessarily relates to combination therapy. One interpretation clearly would be that it does relate to combination therapy but that's not what Claim 27 says."

114. Prof. Roberts, the medicinal chemist, said in evidence on Day 4 (at pp. 26-27 of the transcript):-

"Q. ... I'm suggesting to you ... that claim 27 would've been read by the skilled practitioner, insofar as it refers to other therapeutic ingredients, as being directed to the combination therapy of HIV, combination therapy in the sense set out in the Carpenter paper, to antiretrovirals. Do you agree or disagree with that?

A: [Prof. Roberts] I don't read it that way. I think it could be considered to be any of the topics that we've covered in terms of other antivirals. I think in my – I think if you're a medicinal chemist, if you wanted to absolutely concentrate on HIV, you would've put it in claim 27 and have…

Q: Okay.

A: … optionally other HIV, anti-HIV ingredients.

Q: Well, if, as I said, if claim 27 is read as being directed at HIV, I'm suggesting to you that the first thing that one would understand as being referred to by "other therapeutic ingredients" is an antiretroviral.

A: They would be one of them. But in a way you would see the "optionally" then as redundant in that particular claim. Because if it was clear you needed a second anti-HIV component then it's not optional anymore."

115. Taking the evidence in support of the case advanced by Gilead at its height, it amounts to the following: *provided* Claim 27 is read as being directed at HIV (something which the trial judge has rejected), then the word *"optionally"* is redundant because the use of another therapeutic ingredient is mandatory. This evidence requires the court to ignore a crucial word in a claim if it is to construe the patent in the manner contended by Gilead.

116. In summary, I am not satisfied that Gilead has pointed to evidence adduced in the High Court which was so different to that adduced in the parallel case in England as to justify this court in rejecting the decision of the English Court of Appeal and finding that the combination product of TD + FTC satisfied the first of the two conditions established by the CJEU in *Teva*. On the contrary, in my judgment, the evidence adduced in the High Court and the findings of the trial judge support the conclusion that the patent is not primarily focussed upon HIV and, therefore, the trial judge was correct to conclude that

Claim 27 was not focussed upon combination therapy to treat HIV, but could encompass monotherapies and combination therapies for a variety of viruses. It necessarily followed, as was accepted by counsel for Gilead in the High Court, that the combination of TD + FTC was not required by Claim 27. That being the case, it was not "necessary" within the meaning of the first limb of the *Teva* test and, as Floyd L.J. said, that being so, it followed that the SPC was invalid.

Extent of protection test?

117. Separately, Gilead argued that the trial judge incorrectly applied a variant of the core inventive advance test when applying the first limb of the *Teva* test. It said that the CJEU established *"an extent of protection test"* and the trial judge erred in saying that the test was *"invention focussed"* rather than *"claims focussed"*.

118. Having correctly construed the patent in accordance with domestic law and the EPC, the trial judge was required to determine whether, as a matter of EU law, the SPC complied with the requirements of the SPC Regulation. This required him to determine whether the medicinal product was protected by the basic patent in force, in accordance with Art. 3(a). The answer to this was to be found by applying the test in *Teva*. It is a matter of EU law whether the test in Limb 1 is an extent of protection test, as Gilead contends, or some other test.

119. It is clear from *Royalty Pharma* that the core inventive advance approach is not relevant to the assessment under Art. 3(a) (see opinion of Advocate General Hogan para. 53, and para. 32 of the judgment of the court). But neither is it simply a domestic extent of protection test, as suggested by Gilead. This is clear from the opinion of Advocate General Wathelet in *Teva*. At para. 74, he said that merely because a substance might fall within the protection of the claims of a patent under Art. 69 of the EPC and the Protocol on its interpretation, and the provisions of relevant national law, it does not necessarily imply

that the substance is a product protected by a patent within the meaning of Art. 3(a). At para. 80, he said:-

> *"... it is not sufficient merely that a product falls within the scope of protection of a patent for it to be regarded as a protected product within the meaning of Article 3(a) of [the Regulation]. It is common knowledge that claims are often (deliberately and ingeniously) drafted in broad, vague, generic and stereotypical terms so that they cover multiple substances."*

120. The court at para. 43 of its judgment in *Teva* stated:-

> *"Accordingly, having regard to the objectives pursued by [the Regulation] the claims cannot allow the holder of the basic patent to enjoy, by obtaining an SPC, protection which goes beyond that granted for the invention covered by that patent. Thus for the purposes of the application of Article 3(a) of that regulation, the claims of the basic patent must be construed in the light of the limits of that invention, as it appears from the description and the drawings of that patent."*

121. Given that Art. 69 of the EPC provides that the extent of the protection conferred by a European patent shall be determined by the claims, the court could not at this point have been establishing a simple extent of protection test. The court was clearly positing a tighter test. At para. 46 it says *"that the subject matter of the protection conferred by an SPC must be restricted to the technical specifications of the invention covered by the basic patent"*. At para. 50 it rules out considering *"results from research which took place after the filing date or priority date of the basic patent"*.

122. This is underlined by the decision in *Royalty Pharma* at para. 46:-

> *"The Court has stated that it is not the purpose of the SPC to extend the protection conferred by the basic patent beyond the invention which that patent covers. It would be contrary to the objective of [the Regulation], according to which the grant of the*

additional period of exclusivity by the use of SPCs is intended to encourage research and, to that end, to ensure that the investments made in such research are covered, to grant an SPC for a product which is not covered by the invention which is the subject of the basic patent, inasmuch as such an SPC would not relate to the results of the research claimed under that patent (see, to that effect, judgment of 25 July 2018, Teva UK and Others, C-121/17, EU:C:2018:585, paragraphs 39 and 40)."

123. In *Royalty Pharma*, the court held that a product which is the subject of an SPC and which was developed after the priority date of the basic patent *"following an independent inventive step, cannot be regarded as coming within the scope of the subject matter of the protection conferred by that patent",* though applying domestic law to the patent, the newly discovered substance came within the functional definition of the patent and thus, within the extent of protection. Thus, even though it might come within the scope of the extent of protection of the patent as a matter of national law, where a patent is functionally defined, nonetheless, it is not regarded as been protected by the basic patent in force for the purposes of Art. 3(a).

124. Gilead says that the court is required to construe the claims in accordance with Art. 69 of the EPC and the Protocol. But this involves looking at the descriptions as well as the claims. The court must establish what is protected by the basic patent. It does this by looking at the claims and the descriptions. The court must identify what is the invention claimed in the patent. It is clear from *Royalty Pharma* that the third test in that case could not be applied if the referring court did not make an assessment of the invention claimed in the patent. It follows that the test under the first limb in *Teva* does not preclude an assessment of the invention claimed in the patent and, therefore, it is not limited to an extent of protection test.

125. For this reason, I agree with the views of Floyd L.J., in para. 76 of the judgment, and I also agree with the submissions of *Teva* and *Mylan*, that it is an EU test and not a domestic extent of protection test: it is neither as simple, nor as expansive as a domestic extent of protection test.

126. I do not agree that the trial judge erred and applied the core inventive advance test which was subsequently, definitely, ruled to be irrelevant to an Art. 3(a) assessment in *Royalty Pharma*. McDonald J. expressly said he was not applying such a test. The trial judge was correct to reject an extent of protection test also. As neither of those possible tests reflects the test laid down in *Teva*, he correctly focussed upon the language used by the court in its judgment in *Teva*. The court emphasised that the question was whether the product fell under an invention covered by the patent. This involves interpreting the claims having regard to the descriptions and the drawings, and this is precisely what the trial judge did. While he referred to the fact that the judgment of the CJEU was *"invention focussed"* rather than *"claims focussed"*, this does not mean that he applied a core inventive advance test, as contended by Gilead. In my judgment, he did no more than construe the patent by reference to the claims and the descriptions as required by Art. 69 of the EPC and Art. 1 of the Protocol. He did not apply an extent of protection test. I do not accept that he erred in applying a core inventive advance test or some unnamed equivalent, to the first limb of the test in *Teva.*

Decision on the first limb of *Teva*

127. I consider that the trial judge approached the construction of the patent correctly. He construed it through the lens of the skilled team and he did so by reference to the claims and the descriptions as he is required to do by Art. 69 of the EPC and s. 45 of the 1992 Act, *i.e.* as a matter of domestic law. He had regard to the evidence as to how it would be read by the person skilled in the art and he determined, in the light of all of these relevant

factors, how it was to be construed. He did not independently seek to ascertain the core inventive advance of the patent, as alleged by Gilead. He considered the argument whether *"optionally other therapeutic ingredients"* could satisfy the *"necessarily"* test established in the first limb of *Teva*. The experts understood that *"optionally"* did not mean necessary, mandatory or required. As a matter of plain language, optionally means that something is not necessary. In my opinion, the trial judge correctly construed Claim 27 in light of the evidence and then verified that the combination, TD + FTC, was not "necessary" within the meaning of the test provided for in the CJEU judgment in *Teva*. In my judgment, the trial judge was correct so to hold and I would reject this ground of appeal.

The second Limb of the *Teva* test

128. The *Teva* test requires that each limb be met for an SPC to be valid. Therefore, this conclusion disposes of the appeal. It follows that it is not necessary to consider the other grounds of appeal which concerned the second limb of the test. I shall refrain from addressing them and leave the decision on those points to a case in which their resolution is required.

Conclusions

129. The trial judge correctly identified that the person skilled in the art to whom the patent was addressed comprised a skilled team of a medicinal chemist and a clinician who would be involved in the management of a range of viral infections including Herpes, Hepatitis B and HIV. The clinician would not have the same level of expertise in HIV as the witnesses who gave evidence in the High Court, but would be a clinician who manages viral infections (including HIV) as part of his or her work. The clinician and the medicinal chemist would be likely to attend conferences and they would attempt to keep themselves

up-to-date with developments in HIV, Hepatitis B and other viral infections, but they would not be aware of every development mentioned in the scientific literature.

130. The trial judge construed the patent through the lens of the skilled team and concluded that the patent was not primarily focussed upon developing treatment for HIV. It was a broad patent and was concerned with developing treatments for other viral infections such as Herpes, Hepatitis B and Cytomegalovirus, all of which were of significant clinical concern at the priority date, 26 July 1996.

131. Claim 27 was not directed solely towards treating HIV. The word *"optionally"* could not be read as *"mandatory"* by reference to the fact that the *"gold standard"* for treating HIV at the priority date required combination therapy comprising two NRTIs and thus, would be read by the person skilled in the art, as referring to TD + FTC.

132. The word *"optionally"* is not a term of art and is a matter for the court to construe. As a matter of English, it does not mean necessarily.

133. In order for a product to be protected by the basic patent in force in accordance with the SPC Regulation, it is necessary that each of the active ingredients either be expressly identified or, implicitly, each are necessarily and specifically identifiable. By reason of the fact that FTC is not expressly claimed in the patent and is not necessarily identifiable, the trial judge was correct to hold that the SPC was not protected by the basic patent in force and accordingly, the SPC was properly revoked.

134. For these reasons, I would refuse the appeal.

135. This judgment is being delivered electronically. Haughton and Murray JJ. have indicated their agreement with this judgment.

136. As Teva and Mylan have succeeded on the appeal, the court is provisionally of the opinion that they are entitled to their costs of the appeal against Gilead, to be adjudicated in default of agreement. If Gilead wishes to contend that a different order as to costs

should be made, it has 10 days in which to contact the Court of Appeal Office to request a short hearing on the issue of costs.