THE HIGH COURT

COMMERCIAL

[2017 No. 6494 P]

BETWEEN

GILEAD SCIENCES INC. AND GILEAD BIOPHARMACEUTICS IRELAND UC

PLAINTIFFS

AND

TEVA B.V. AND NORTON (WATERFORD) LIMITED TRADING AS TEVA PHARMACEUTICALS IRELAND

DEFENDANTS

AND

THE HIGH COURT

COMMERCIAL

[2017 No. 2984 P]

BETWEEN

GILEAD SCIENCES INC. AND GILEAD BIOPHARMACEUTICS IRELAND UC

PLAINTIFFS

AND

MYLAN S.A.S., GENERICS (UK) LIMITED TRADING AS MYLAN AND McDERMOTT LABORATORIES LIMITED TRADING AS GERARD LABORATORIES TRADING AS MYLAN DUBLIN

DEFENDANTS

JUDGMENT of Mr. Justice Denis McDonald delivered on 11 October, 2019

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Introduction

1. In recent years, the full horrors of the AIDS crisis have faded from public consciousness. Yet, less than 30 years ago, AIDS was a major public health issue across the world provoking stark public health warnings and attracting widespread media coverage. Millions of people became infected with the HIV virus which causes AIDS. A HIV diagnosis was, in turn, perceived as an almost certain indication that the patient would, in time, succumb to AIDS and suffer an early death. Fatalities from the disease mounted across the world over the course of the 1980s and early 1990s.

2. The outlook for HIV positive patients remained very bleak until the mid-1990s when, thanks to intensive efforts by clinicians, pharmacologists and other experts, combination therapies (as described in more detail below) were developed which proved to be highly efficacious in stalling the progress of the HIV virus. By mid-1996, combination therapy had become the standard method of treatment for HIV infection. A number of different combination therapies were developed over the next number of years including a drug developed by the first named plaintiff in these proceedings which is sold under the brand name Truvada which contains two anti-retroviral agents namely tenofovir disoproxil *("TD")* and emtricitabine *("FTC")*. One significant practical advantage of Truvada is that the therapy can be administered to the patient in a single formulation taken orally. In that way, the number of individual medications to be taken by a patient can be minimised.

3. Truvada has the benefit of a Supplementary Protection Certificate *("SPC")* granted by the Controller of Patents Designs and Trade Marks *("the Controller")* under Co. Reg. EEC no. 1768/92 which has since been replaced by Co. Reg. (EC) No. 469/2009 *("the SPC Regulation")*. The SPC was granted on 11th August, 2009 and is due to expire on 20th February, 2020. The SPC is, in turn, based on Irish Patent No. EP 0915894 (*the 894 Patent")* which expired on 25th July, 2017. The priority date of the 894 Patent is 26th July, 1996.

4. The plaintiffs have commenced both of the above entitled proceedings against the Teva and Mylan defendants respectively claiming that it would be an infringement of the SPC for the defendants to put any product on the Irish market containing a combination of TD and FTC. In this context, it should be noted that the defendants are involved in the manufacture and supply of generic pharmaceuticals.

5. In both sets of proceedings, the defendants have mounted a counterclaim in which they contend that the SPC is invalid. In broad terms, the grounds on which it is claimed that the SPC is invalid is that the combination of TD and FTC is not protected by the 894 Patent. In particular, it is contended that FTC is not identified or specified

in the claims of the 894 Patent and, furthermore, that the combination is not part of the invention, the subject of the patent. As a consequence, the defendants both make the case that the combination of TD and FTC is not protected by the 894 Patent for the purposes of Article 3 (a) of the SPC Regulation.

6. The proceedings were originally listed for hearing in 2018. However, they were subsequently adjourned pending the outcome of a reference made to the Court of Justice *("CJEU")* by the High Court of England & Wales. That reference was made in proceedings taken by (among others) Teva UK Ltd and Generics (UK) Ltd trading as Mylan against Gilead challenging the validity of the UK equivalent to the SPC. The CJEU gave judgment on foot of that reference in July 2018 and thereafter these proceedings were listed for hearing on 30th April, 2019. The hearing was confined to the question of the validity of the SPC. It was agreed by all parties that the evidence in both sets of proceedings would be heard together and that the evidence in each set of proceedings would be admissible in both. The hearing ultimately concluded on 23rd May, 2019.

The development of therapies for HIV infection

7. Before addressing the legal issues which arise, it may be helpful at this point, to summarise the evidence available to the court in relation to the development of therapies to deal with HIV. The first AIDS cases were described in the United States in 1981. The US Centre for Disease Control *("CDC")* identified a number of opportunistic infections and malignancies that arose when a patient's immune system was significantly impaired and this list was used to define a disease which became known as Acquired Immunity Deficiency Syndrome or AIDS by way of acronym. The disease was characterised by a progressive loss of immune function and, in particular, a fall in the number of CD 4 + T cells. These are white blood cells that, when working normally, help the body to fight infections and diseases caused by viruses and bacteria. When a patient is infected with HIV, these T cells no longer work properly because they are slowly destroyed by the HIV infection.

8. After a short number of years, the relevant infectious agent was identified namely the human immunodeficiency virus which quickly became known as HIV. HIV is a retrovirus. As I understand it, a retrovirus 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 in question (which are critical to its replication) were identified as being in a class of enzymes known as DNA polymerases. As I understand it, a DNA polymerase is a type of enzyme that is responsible for forming new copies of DNA. According to Prof. William G. Powderly (who gave evidence on behalf of the plaintiffs) a class of compounds called nucleoside analogue reverse transcriptase inhibitors *("NRTIs")* were known to inhibit DNA polymerases and so these were tested *in vitro*

for their ability to inhibit HIV replication. These included an NRTI known as azidothymidine *("AZT")* a molecule which, as Dr. Graeme Moyle (who gave evidence on behalf of the Mylan defendants) explained was first synthesised in 1964 as a potential anti-cancer agent. AZT was the first NRTI that went forward into human studies and it was found to suppress HIV replication. It was approved as an anti-retroviral drug by the US Food & Drug Administration *("FDA")* in 1987 but it soon became clear that, when taken as a single agent (monotherapy) it had no long term clinical benefit. While it improved the immune function in patients for a period of time, the virus developed resistance to AZT (when used on its own). In the meantime, the early promise of AZT led to the development of additional NRTIs including didanosine *("ddI"),* zalcitabine (*"ddC"),* and stavudine *("d4T").* These received FDA approval in 1991, 1992 and 1994 respectively.

9. According to Prof. Powderly, during the course of 1993, a small clinical trial of combination therapy with AZT and ddI found improved immune responses in the patients receiving combination therapy, compared to those in a group of patients receiving AZT as a monotherapy. The results of further trials appeared in the autumn of 1995 and, according to Prof. Powderly, these dramatically affected the treatment landscape.

10. In the meantime, in 1991, Glaxo Wellcome (subsequently GlaxoSmithKline) commenced studies in respect of a further NRTI known as lamivudine *("3TC")*. When used as a monotherapy, HIV rapidly developed a resistance to 3TC. However, further research suggested that treatment involving a combination of AZT with 3TC delayed the emergence of the AZT resistant virus and also that the AZT resistant virus retained some susceptibility to 3TC. An additional advantage of 3TC as a combination agent was that it had minimal side-effects. Following further studies, the FDA approved 3TC in combination with AZT as a treatment for HIV. According to Prof. Powderly, this was the first FDA approval of specific combination therapy for HIV and he says that by early 1996 the combination became the most commonly prescribed NRTI combination. Prof. Powderly also drew attention to the fact that, even prior to FDA approval, the combination of AZT and 3TC had been used for approximately 30,000 patients in the United States through a compassionate use programme.

11. In the course of the hearing, it was agreed by all of the experts that, by the first half of 1996, combination therapy was accepted as the standard of care by HIV clinicians globally. This was recognised in the International AIDS Society-USA Guidelines published by Carpenter et al in July 1996 (but developed and written prior to that date). These guidelines were produced by a group of internationally recognised HIV expert physicians who had been involved in clinical research and drug development for several years. Prof. Powderly's evidence was to the effect that these guidelines clearly established combination NRTI therapy as the "*gold standard*" for the

treatment of HIV although ddI monotherapy remained as a possible monotherapy for patients who could not tolerate the side effects of other therapies.

12. The Carpenter paper promoted a combination involving two NRTIs and one protease inhibitor ("*PI*"). As I understand it, a PI interferes with the ability of HIV to replicate itself within the CD4 cells. A little earlier, in March, 1996, the FDA approved two PIs, namely Ritonavir and Indinavir for HIV treatment to be used either alone or in combination with NRTIs. In simple terms, the reason why a combination of NRTIs and a PI was found to be more effective is that the NRTIs and the PI respectively target different stages of the HIV replicative cycle. There are ten steps in that cycle, namely adsorption, fusion, uncoating, reverse transcription, integration, DNA replication, transcription, translation, maturation and, finally, budding (i.e. release). As I understand from the material available to the court, the NRTIs act at the reverse transcription stage of replication (i.e. the fourth step in the cycle). In contrast, a PI acts at the maturation stage (i.e. step 9). By combining agents which act at different stages of HIV replication, the agents act synergistically thereby increasing the inhibitory effect and stalling the progression of HIV infection. This did not cure the virus but it reduced the viral load to a level which ensured that many patients were asymptomatic.

13. For completeness, it should be noted that as Dr. Moyle said in his evidence, there was also a third PI trialled at this time, namely Saquinavir and also a non-nucleoside reverse transcriptase inhibitor ("*NNRTI*") nevirapine which it was considered could be used in combination with two NRTIs in place of a PI. Dr. Moyle identified the Vancouver World AIDS Conference of 9-12 July 1996 as the "*Watershed*" event for HIV management, establishing (a) three drug combinations as the standard of care and (b) viral load values below the limits of assay detection (i.e. undetectable) as the key surrogate of treatment response. Dr. Moyle also confirmed that since 1996, the approach of using combinations of two NRTIs plus a third agent from a different drug class has remained the preferred treatment approach. Since then, the main refinements have been less frequent dosing, fewer adverse events, fixed dose formulations (including one pill) which have led to better adherence by patients and the relative normalisation of life expectancy among people infected with HIV. All of the clinicians who gave evidence accepted that the "*backbone*" of combination therapy is the presence of two NRTIs.

FTC

14. As noted above, Truvada is a combination of TD and FTC. The latter is an NRTI first synthesised at Emory University in Atlanta in 1990. It is the same class as 3TC described above. Prof. Powderly explained that both 3TC and FTC are classified as oxathiolane-cytosine analogues which comprise a class of NRTIs that selectively block HIV and hepatitis B virus replication. 3TC was the first of this class to be

studied and approved for these indications. FTC was first described in a paper (authored by Schinazi and others) in 1992 as a potent inhibitor of the HIV virus. It is important, however, to note that the studies discussed by Schinazi and also in a paper subsequently published in 1993 authored by Mathez and others (to whom Prof. Powderly also referred) were *in vitro* investigations. Dr. Moyle emphasised that the translation of *in vitro* data to clinical data is imprecise and can be misleading. It should also be noted that both the Schinazi and Mathez papers were published in a journal called "*Antimicrobial Agents and Chemotherapy*" and there was significant debate in the course of the hearing before me as to whether this was a journal that would be read by clinicians. However, it is clear from the evidence of Prof. Roberts that this journal was on his reading list (Day 4 p. 43). He also confirmed that it was unlikely that he would have missed the Schinazi paper.

15. More importantly, it emerged during the course of the hearing, that only one study involving the administration of FTC to humans was conducted in the period prior to the priority date of the patent. This was a very small scale study which did not address long term use of FTC. The principal scientific material (providing any level of detail) on which the plaintiff relied was an abstract of a poster (in very terse terms) presented at the 35th Interscience Conference on Antimicrobial Agents and Chemotherapy held in September, 1995, in San Francisco, California. Both Dr. Moyle and Prof. Powderly attended that conference. Neither of them have any recollection of seeing the poster at the conference (although one would not realise this on reading Prof. Powderly's witness statements). Both witnesses explained that at a conference of this kind, there is an extensive display area in an exhibition hall where large numbers of posters are displayed in a series of temporary corridors assembled within the exhibition hall. In addition, abstracts from these posters are collected in booklets which are distributed to those attending the conference. Each booklet will identify the time at which one of the authors of the abstracts would be available to discuss the abstract with conference attendees. According to Dr. Moyle, this conference was predominantly attended by US physicians and more sparsely by Europeans. It was a very large conference with ten or more different "*tracks*" covering different infectious diseases along with pre-clinical and early phase drug development data. The HIV component of the conference was "*Track I*". The poster cited by Prof. Powderly was not part of Track I but instead was part of "*Track A*". It does not refer to FTC by name or by chemical structure. Instead it uses a development code F24W91 which was an internal Glaxo development code. No copy of the poster was available for the hearing of these proceedings. However, a very brief abstract of the poster was put in evidence by Prof. Powderly. The abstract of the poster refers to a number of authors, the lead author being L.H. Wang. For that reason, the poster has been described, throughout the hearing as the *"Wang abstract"*. The abstract describes 524W91 as a new "*pyrimidine-based nucleoside analogue RTI that has shown potent anti-HIV and anti-HBV activity in vitro and favorable safety profiles in*

monkeys and mice. A phase I--blind randomized, parallel placebo-control study was conducted to evaluate PK and safety of single oral doses of 100-1200mg… in HIV-infected (primarily non-AIDs) volunteers… 18 volunteers enrolled…". The abstract stated that 524W91 was well tolerated by all volunteers with no adverse events reported other than a mild rash in the case of one subject.

16. The abstract suggested that on the basis of a single ascending dose, and on the basis of this relatively small study of 18 volunteers, FTC was quite well tolerated. However, as the expert evidence at the hearing made clear, not only was FTC not identified by name in the abstract, but, even more importantly, the abstract provides no information in relation to potential toxicity that might arise from long term use of FTC. For that purpose, multiple ascending doses would have to be administered in the course of a phase one study. In this context, it is necessary to assess the impact of accumulation, over a period of time, of the agent in the human body which may give rise to increased toxicity and unwelcome side-effects.

17. Although the Wang abstract was the only publication identified in the course of the evidence that provided any level of detail in relation to the stage 1 clinical trials (however limited that detail may have been), the fact that such clinical trials had taken place was noted in a number of scientific journals. Thus, for example, in an article in *"Antimicrobial Agents and Chemotherapy"* published in December 1994 (authored by Lloyd W. Frick and others) it was noted (by reference to the chemical formula for what subsequently became known as FTC) that the pharmacokinetics of the nucleoside were then under investigation as part of a phase 1 clinical trial. The article concluded with the words:-

> *"The good bioavailability of 524W91 after oral dosing coupled with its simple metabolic profile, in vitro antiviral potency, and low toxicity in model species makes it a promising candidate for further evaluation as a therapy for infections with HIV and HBV".*

18. It will be noted that the compound is described as a promising candidate for further evaluation as a therapy not only for HIV but also Hepatitis B. The "*model species"* tests mentioned in the abstract were tests that had taken place in mice and cynomolgus monkeys (otherwise known as crab eating macaques). The Frick article in question was published in December 1994. Previously, in November 1993, an article by substantially the same authors had appeared in the same journal which specifically referred to the chemical formula as FTC and which described tests which had taken place in rats. However, Prof. Roberts in the course of his evidence, drew attention to the fact that the results of the tests in question (as described in this article) showed that the administration of FTC produced small amounts of fluorine in urine samples which the authors stated had been unexpected. Prof. Roberts

explained that the presence of fluorine raised toxicity concerns. The concern was that the fluorine could be converted *in vivo* into a toxic compound ("*5-FU").* Prof. Roberts accepted that there was only a small amount of fluorine present and that, going forward, while it would be necessary to *"keep an eye on it",* the level of concern was not such as to dissuade further investigation of the compound.

19. Prof. Powderly also introduced in evidence an article published by George R. Painter and others in a journal called *"Drugs of the Future"* in 1995, which was entitled *"524W91 – Anti-HIV, Anti-Hepatitis B Virus".* Prof. Powderly acknowledged that this was a journal that he did not himself read and had not previously been aware of. Dr. Moyle also gave evidence that he had not heard of this journal. He also said that he did not believe that the HIV clinician would have read it. However, he suggested that its target readership included medicinal chemists and pharmacologists involved in drug development. In this article, FTC was described as an *"extremely potent and selective inhibitor of HIV and HBV replication in vitro and in vivo".* And the article also stated that the compound is *"being pursued as a potential therapeutic agent for the treatment of HIV and HBV".* It described the phase 1 trial in the following terms:-

> *"In a phase 1 trial 12 HIV infected volunteers received 6 single oral doses of 100-1200 mg of 524W91 separated by at least a six-day interval. The compound was rapidly absorbed with peak plasma concentrations occurring within 3h. 524W91 was eliminated from the plasma, primarily via renal excretion, with a half-life of less than 4h. Food intake slightly decreased the rate of absorption but did not affect the extent of oral bioavailability. Overall, the disposition of 524W91 follows linear kinetics with small intersubject variability. The compound was well tolerated by all subjects in the dose range studied".*

20. Prof. Roberts (who was the only medicinal chemist to give evidence) explained that the journal *"Drugs of the Future"* is not a highly regarded journal. He also explained that the article in question was written by George Painter who was one of the scientists leading the FTC programme and that, as a consequence, the available data (such as it was) was deliberately framed in a positive light. He also highlighted that the article reports that FTC *"does not effectively cross the blood/brain barrier of monkeys"* which would have been a disappointing outcome for the researchers at the time since anti-HIV drugs with activity against HIV harboured in the brain were preferred.

21. It should be noted at this point, that in addition to questioning the extent to which material of this kind would be known to the skilled addressee, the expert witnesses on behalf of the defendants also stressed that, at most, the material indicated that FTC was in phase 1 clinical development. They noted that the phase 1 tests had not been completed (in that no multiple ascending doses had yet been administered) and

they suggested that the results of the phase 1 study that had taken place did not support the conclusion that FTC had excellent pharmacokinetics or confirm that it was a safe and convenient drug. According to their evidence, a great many more tests would have to be carried out before any conclusion could be reached about the safety or efficacy of FTC for long term use in humans. Nonetheless, Prof. Roberts (Day 4 at p. 129) accepted that FTC was a promising potential NRTI candidate, although, at a later point, he explained that it was in a group of 30 to 40 candidates that could possibly go forward for consideration. Prof. Powderly gave evidence that the number of potential candidates was somewhat lower.

22. Initially, FTC was licensed to Glaxo by Emory University but in early 1996 Glaxo returned the rights to Emory, having decided to concentrate on the development of 3TC. In turn, Emory University granted exclusive rights to commercialise a number of anti-HIV compounds including FTC to a company called Triangle Pharmaceuticals Inc, which was established by Dr. David Barry (formerly of Glaxo) who had been associated with the development of AZT as an AIDS therapy. Prof. Powderly says that he was aware of this development and his evidence was that the involvement of Dr. Barry was significant. In light of Dr. Barry's involvement, Prof. Powderly would have considered at the time that FTC was particularly well placed to do well in further clinical trials and go on to be approved for use in HIV therapy. However, it should be noted that the only material put forward by Prof. Powderly in support of this proposition was a press release which he says he remembers from the time although he was unable to identify where the press release might have been published. For the purposes of the hearing, Prof. Powderly simply put in evidence a copy of a press release which he found following an internet search in the course of his preparation for the hearing.

23. The press release stated that FTC had demonstrated potent activity against the viruses that causes AIDS as well as Hepatitis B and that it was *"highly synergistic when used in combination with AZT, ddC or ddI and is 4 to 10 times more active than 3TC against HIV in the test tube. In a Phase I dose ranging study in patients, FTC was well tolerated and exhibited excellent pharmacokinetics. FTC is as potent as 3TC against Hepatitis B and has shown potent activity in woodchuck hepatitis…".*

24. Quite apart from the lack of any evidence that this press release found its way into any publication, the evidence of each of the expert witnesses called on behalf of the defendants was that clinicians and medical chemists would be unlikely to have regard to an essentially promotional press release of this kind by a pharmaceutical company. For completeness, it should be noted that the Phase I study cited in the press release appears to relate to the rather limited study in eighteen human volunteers discussed in the Wang abstract.

TD

25. The other active ingredient in Truvada is TD. This is not an NRTI (a nucleoside reverse transcriptase inhibitor). It is a nucleotide reverse transcriptase inhibitor. As explained by Prof. Roberts a nucleotide is a compound consisting of a nitrogenous base, a 5-carbon sugar, and one or more phosphate group. As I understand it, a nucleoside, in contrast, lacks a phosphate group. Although a nucleotide reverse transcriptase inhibitor is chemically distinct from an NRTI, it targets the same stage of the life cycle of the HIV virus. TD is the subject of Claim 25 of the patent. It is also identified as compound 5(f) in Table 2 of Example 16. TD is part of a family of PMP compounds which also includes PMPA (described below). Prof. Roberts explained that the PMP series of compounds was found *in vitro* to be potentially useful in treating retroviruses including HIV. However, as explained in paras. 26-27 below, the compounds were found to have limited bioavailability. In addition, Prof. Roberts was of the view that, as of the priority date of the patent, no studies had been carried out in relation to the administration of PMPA to humans. He drew attention to a number of scientific articles which expressed concern about the possibility that PMPA might have unexpected toxicities and to the fact that a lot more work would require to be carried out before the potential of PMPA for human use could be established. Prof. Roberts also suggested that, because TD was a new drug, it was unlikely that the skilled person, as of the priority date of the patent, would envisage that it would be combined with another new drug such as FTC. His evidence was that the most obvious candidates for combination with a new entity would be one of the drugs which had already been approved by the FDA.

26. Adenine *("PMPA")* is a nucleotide reverse transcriptase inhibitor which was shown in 1993 to have *in vitro* efficacy against HIV. However, as Prof. Roberts explained, phosphonomethoxy nucleotide analogues such as PMPA are quite *"polar"*. In other words, they possess oxygen atoms that are negatively charged in water at neutral pH. The effect of this polarity is that they are not readily able to cross cell membranes because such membranes are lipophilic (i.e. fat-loving). As a consequence, Prof. Roberts explained that the nucleotide cannot easily cross cell walls. His evidence was:-

> *"It's like – a cell wall is very fatty, and you imagine water and fat, it's polar water and fat; you try and clean the dishes, they don't mix, you can't get polar things across a cell membrane."*

27. Thus, 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. This is the background against which the patent needs to be understood. As explained in

more detail below, the 894 patent sought to address the bioavailability problem described above.

The 542 Patent

28. For completeness, it should be noted that, more recently, an application was made by the Plaintiffs for a European Patent (no. EP 1 583 542 B1) (*"the 542 patent")* 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, this patent was revoked by the Opposition Division of the EPO on 14th February, 2011 and its decision was in turn upheld by the decision of the Board of Appeal of 13th March, 2017. These decisions were based on the fact that, at some stage in advance of the priority date claimed, 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. There can be no doubt, however, 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 defendants in these proceedings have highlighted the very obvious differences between the manner in which the combination of TD and FTC was addressed in the 542 patent and the much more general way in which combinations are addressed in the 894 patent (as described below).

The 894 Patent

29. The 894 patent is entitled *"Nucleotide Analogs".* Paragraph 0001 describes the invention as relating to: *"intermediates for phosphonomethoxy nucleotide analogs, in particular intermediates suitable for use in the efficient oral delivery of such analogs".* According to Dr. David Hawkins (a consultant physician who gave evidence on behalf of Teva) this is the inventive concept of the patent, solving the problem of oral bioavailability described in paras. 26-27 above. As explained there, phosphonomethoxy nucleotide analogs are quite polar and therefore find it difficult to cross cell membranes. As a consequence, such compounds have very limited bioavailability. In the course of the hearing, Prof. Roberts explained that the invention is aimed at improving the bioavailability of the compounds by providing "*intermediates"* in the form of suitable prodrugs which would be suitable for oral delivery. This is done in the invention by adding a moiety to the tail of the phosphonate to create a more lipophilic compound which can cross the cell membrane more easily before the tail-end moiety falls off to release the phosphonate. Essentially, what the invention does is to attach to the phosphorus unit at the end of the molecule non-polar units which will allow that molecule (i.e. the intermediate) to go through the cell walls of the human or animal host. In simple terms, once the intermediate has gone through the cell wall, the additional units fall off to supply the warhead which then acts to inhibit the offending enzymes.

30. Intermediates are prodrugs. In other words, they are pharmacologically inactive outside the human or animal host. However, after administration, they are metabolised within the body into a pharmacologically active drug which acts (in broad terms) in the manner outlined in para. 29 above. Outside the body, they are inactive.

31. When Prof. Powderly was subsequently cross examined by counsel for Teva on Day 9 of the hearing, he confirmed that he did not disagree with the evidence of Prof. Roberts in relation to the scope of the invention. The evidence of Prof. Powderly is examined in more detail below.

32. Prof. Roberts explained that the *"Summary of the Invention"* at paras. 0003 to 0006 sets out various Markush formulae, including formula (1a) at para. 0003 and formula (1) at para. 0004. As I understand it, a Markush formula is a written chemical structure to indicate a group of related chemical compounds. These structures are depicted with multiple independently variable groups of varying structures. The formula assists in permitting a large class of compounds to be claimed without the necessity of writing out every single chemical entity. The formulae are described in more detail at paras. 0007 to 0036 (inclusive). In his evidence, Prof. Roberts explained that formula (1) and formula (1a) provide the structure for a range of different compounds falling under one or other of the formulae. He said that it was very difficult to accurately estimate the number of compounds in question but he thought that it was in the order of tens of millions if not hundreds of millions of compounds. According to Prof. Roberts, formula (1) is a phosphonate mimetic of a nucleotide analogue. Formula (1a) differs from formula (1) in the identity of the left hand unit. In addition, *"Z"* in formula (1a) is more diverse than the corresponding linkages in formula 1.

33. In paras. 0038 to 0043, the patent sets out synthetic methods for the preparation of the compounds. Paragraph 0044 then describes a wide range of viral infections in relation to which the compounds of the invention may be useful. While HIV is included in this list, it is just one of many viral infections affecting not only humans, but also animals. Some of these viral infections are very serious. They include hepatitis B, varicella-zoster and human cytomegalovirus, all of which, as Prof. Powderly acknowledged on Day 9 (p. 94), can be fatal. Paragraph 0044 is in the following terms:-

> *"The compounds of this invention are useful in the treating or prophylaxis of one or more viral infections in man or animals, including infections caused by DNA viruses, RNA viruses, Herpesviruses (CMV, HSV 1, HSV 2, VZV, and the like), retroviruses hepadnaviruses (e.g. HBV), papillomavirus, hantavirus, adenoviruses and HIV. Other infections to be treated with the compounds*

herein include MSV, RSV, SIV, FIV, MuLV, and other retroviral infections of rodents and other animals."

34. As Prof. Roberts observed in the course of the hearing, it would be clear to the medicinal chemist that the patent is 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. Hawkins. According to Dr. Moyle, a clinician would understand from para. 0044 that the compounds of the patent could be useful in the treatment or prophylaxis of a very wide range of viral infections in man and animals. Dr. Moyle emphasised that the viruses listed in para. 0044 were very common as at the priority date (July 1996) and were causative of many clinically important diseases in both humans and animals. According to the evidence of Dr. Hawkins (Day 5 p. 116) 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".* When he came to give his evidence, Prof. Powderly (Day 10 p. 29) did not dispute these figures although he expressed the view that:

"The scale and nature of HIV at that time was the greatest threat in infectious diseases that we knew of".

35. There was disagreement between Prof. Powderly, on the one hand, and the defendants' experts, on the other, as to the focus of the patent. As summarised in paras. 33-34 above, the experts who gave evidence on behalf of the defendants did not agree with Prof. Powderly that the focus of the patent was on anti-HIV drugs. Their evidence was that the previous problem relating to the poor bioavailability of PMPA was solved by the patent not only in relation to the treatment of HIV but also the broad range of other viruses and retroviruses described in para. 0044. Prof. Powderly disputed their view. His direct evidence was that a clinician, reading the patent in July 1996, would have understood that it was primarily directed to compounds for the treatment of HIV. However, on cross-examination (Day 9 pp. 124-127), Prof. Powderly conceded that para. 0044 covers all classes of virus known to man together with a range of infections in animals. For completeness, it should be noted that Prof. Powderly placed significant emphasis on Example 16 (addressed in more detail below) which demonstrates the effect of the compounds against a particular strain of HIV. He also stressed that PMPA, by July 1996, was already recognised as a potential development candidate having potent and long lasting activity against HIV and he referred to an article published in *Science* in November 1995 by Tsai which had specifically described PMPA as a *"promising candidate for anti-HIV treatment".* The article by Tsai and others described tests of PMPA against the simian immunodeficiency virus *("SIV")* in macaques as a model for HIV. In para. 7.2 of his second witness statement in the Mylan proceedings Prof. Powderly continued as follows:-

"However, PMPA was known to be unsuitable for oral administration because of poor bioavailability; in the monkey SIV study, it was given by … injection. As I explain below, this is a disadvantage for drugs that need to be taken by patients in the long term…and would have been a serious barrier to the widespread use of a drug in the treatment of HIV. This problem with PMPA is solved by the Patent. The focus of the Patent on anti-HIV drugs would also have made sense in 1996 as, at that time, HIV was the major target for antiviral drug development worldwide".

36. Prof. Roberts, in his evidence on behalf of Teva, rejected Prof. Powderly's observations concerning the focus of the patent. In the first place, he stressed that the patent describes a wide range of phosphonate prodrugs based on PME (claim 19), HPMP (Claim 22) as well as PMP (Claim 4). Prof. Roberts noted that HPMP derivatives have been shown to be active against DNA viruses other than HIV. Prof. Roberts also referred to an article by De Clercq which detailed a broad spectrum of DNA viruses inhibited by HPMPA and HPMPC (the relevant prodrugs being featured in claims 22 and 23).

37. Paragraph 0046 of the patent (under the heading *"Pharmaceutical Formulations"*) sets out the methods by which the compounds of the invention can be administered. This paragraph explains that administration can be effected through any route *"appropriate to the condition to be treated"*. The broad language of this paragraph should be noted. The paragraph does not suggest that the focus is on one condition only (such as HIV). Among the routes described as suitable in this context are: "*oral, rectal, nasal, topical (including ocular, buccal and sublingual), vaginal and parenteral (including subcutaneous … and epidural)".* In the course of his cross-examination, Prof. Powderly agreed that many of these routes of administration would not be relevant to the treatment of HIV.

38. For reasons which will become apparent, some significant emphasis is placed by the plaintiff on para. 0047 of the patent which is in the following terms: -

"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".

39. There is no express guidance in the patent as to what the patentee means by *"other therapeutic ingredients"*. In the particular context of the present case, it is noteworthy that no specific reference is made either to FTC in particular or to NRTIs more generally. It is also important to bear in mind that, when Prof. Powderly was cross-examined in relation to para. 0047, he accepted, in the context of para. 0047, that there is nothing to suggest that the patent addresses only HIV or focusses on HIV. He also accepted that the preponderance of the content of paras. 0044 to 0046 was irrelevant to HIV treatment. Dr. Hawkins also gave evidence that combination therapy was not confined to HIV. For example, on Day 6, he gave evidence that combination therapy might also be appropriate for Hepatitis B and also cytomegalovirus. He further expressed the view that, even in the context of HIV, combination therapy was not limited to antiviral retroviral drugs. He gave evidence that, for example, the combination of hydroxyurea and ddI was well recognised as a treatment for HIV. In that case, the hydroxyurea element made the NRTI (i.e. ddI) more effective.

40. Paragraph 0049 makes clear that formulations of the invention suitable for oral administration may be presented as capsules, cachets or tablets, as a powder or granules or as a solution or a suspension in a liquid. Paragraph 0051 and para. 0056 explain that, for infections of the eye or other external tissues such as the mouth or the skin, it is preferable to apply the formulations as a topical ointment or cream or, in the case of the eye, eye drops. Under cross-examination, Prof. Powderly confirmed that such routes of administration are not relevant to HIV. Similarly, para. 0063 and para. 0064 deal with veterinary use of the invention which again is not relevant to HIV.

41. Paragraphs 0068 – 0071 set out various examples. It is of some significance that para. 0067 makes clear that the examples: *"further illustrate the invention but are not to be construed as limiting the invention".* In the course of the hearing, the focus was on examples 15 and 16. Example 15 deals with oral bioavailability of PMPA and various PMPA carbonates in Beagle dogs. Prof. Powderly explained that example 15 is designed to show how effective the pro-drugs are using PMPA as a standard. The PMPA is kept constant but one changes the carbonates in order to see which one is best. Under cross-examination on Day 9 (at p. 142) Prof. Powderly accepted that, while PMPA is used in example 15 as a target example, this does not mean that the example could not apply to other compounds covered by the patent. Prof. Roberts was of the view that the *"whole emphasis"* of the example is to show how effective the carbonates are at getting the war head of PMPA into the blood stream of the dog. Under cross-examination, Prof. Roberts said:

"… it's all focussed on this pro-drug approach, as I think I might have mentioned before, the pro-drug has to have various properties of stability at different pHs and half-lives that are reasonable for where it has to get to and the amount of PMPA in the dog in this case has to reflect the fact that it is getting through the gastrointestinal wall …"

42. As noted above, Prof. Powderly placed some emphasis on example 16 since it is specifically referable to the activity of PMPA and certain PMPA carbonates against HIV-1. Prof. Roberts explained that the purpose of example 16 was to show how easily the molecules passed through cell membranes in a HIV infected cell; the end point being to show how much of the HIV is killed. The whole basis of the example is to understand which of the side chains work best at killing the virus. While the example addresses 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 one could equally set up a system with the herpes virus and have a read-out which would measure the knock down of that virus. Furthermore, as mentioned above and, as acknowledged by Prof. Powderly under cross-examination (Day 9 p. 136), the reader of the patent is specifically cautioned in para. 0067 that the examples are not to be construed as limiting the invention. Example 16 must be read in that light.

The claims of the 894 patent

43. Insofar as the claims of the patent are concerned, there are 29 in total. Claim 1 is to the formula (1a) compound. Claim 2 is to the formula (1) compound. Claims 3 to 23 are to particular examples of the compounds in claims 1 or 2 where particular groups within the formulae are specified. It should be noted that, in at least one case (namely Claim 22), the compound claimed has no role to play in relation to the treatment of HIV. According to the evidence, the compound in question *("HPMP")* is of little use against HIV. According to Dr. Hawkins (who gave evidence on behalf of Teva) HPMP has effect against a broad range of herpes-type viruses which include herpes simplex, varicella-zoster (i.e. shingles) and cytomegalovirus which can cause eye and gut infections. Prof. Powderly did not address Claim 22 in his direct evidence. However, in the course of his cross-examination on Day 9 (at p. 153) he was unable to recognise the compound described in Claim 22. Notably, when his cross-examination resumed on Day 10, he was still unable to establish the nature of the compound described in Claim 22.

44. Claim 25 is to the nucleotide analogue which subsequently became known as TD. According to Prof. Roberts, TD is also covered by the Markush formulae in claims 1 and 2. Prof. Powderly, in his evidence stressed the importance of Claim 25. On p. 152 of the transcript on Day 9, he explained that his reason for doing so was that the compound described in Claim 25 is an agent that has very significant activity against HIV. However, he was unable to explain why Claim 25 could be said to be

any more important than Claim 22 (which, as noted above, he was unable to recognise) and which, moreover, has little efficacy against HIV.

45. Claim 26 (which is in Swiss form) relates to the use of any of the compounds in Claims 1-25 for the treatment or prophylaxis or viral infections in humans or animals.

46. For present purposes, Claim 27 is important. It is the only claim in the patent in respect of a pharmaceutical composition. It is also the only claim which envisages a combination. Claim 27 is in the following terms:-

> *"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".*

47. The Plaintiff placed significant reliance on the terms of Claim 27. According to the evidence of Prof. Powderly, if he had seen Claim 27 in July 1996 he would have understood the reference to *"other therapeutic ingredients"* to relate to other drugs that were being used or were in the course of development against HIV – namely NRTIs or NNRTIs or PIs. According to his direct evidence, the NRTIs would have been the first to come to mind when reading Claim 27 in July 1996. However, under cross-examination on Day 10 (at p. 19), Prof. Powderly accepted that Claim 27 was not focussed on the treatment of HIV. He accepted that the claim makes no reference to the treatment of HIV and that it refers to any one of claims 1 to 25. Nonetheless, notwithstanding these concessions, the overall thrust of the evidence given by Prof. Powderly was that he would consider the focus of Claim 27 to be the treatment of HIV. His evidence on this issue is analysed in more detail in paras. 176-185 below.

48. In contrast, the evidence of the Teva and Mylan experts was that the skilled addressee would have understood the reference to *"optionally other therapeutic ingredients"* in Claim 27 to include potentially any other active ingredient used in the prophylaxis or treatment of patients or animals suffering from any of the viral infections listed in para. 0044 of the patent. Dr. Hawkins gave specific evidence on Day 6 (at p. 156) that patients were sometimes co-infected with HIV and other viruses and that often these other viruses were more aggressive such that they required combination anti-viral therapy. In the course of his cross-examination on Day 10, Prof. Powderly was cross-examined with regard to an article published in January 1996 in the International Journal of Ophthalmology which considered a form of combination therapy which had been studied for the treatment of relapsed cytomegalovirus retinitis. This article demonstrates that, as of the priority date of the 894 patent, combination therapy was not restricted to the treatment of HIV. Furthermore, Prof. Roberts, in the course of his evidence, expressed the view that,

even if Claim 27 was to be read as being confined to HIV, one would not restrict oneself to NRTIs. On Day 3 (at p. 121) he explained that there were: *"other opportunities working at different parts of the virus".* These included, for example, PIs (as described in para. 12 above).

49. In addition, the defendants' experts also suggested that, in the context of HIV treatment, the reference to *"other therapeutic ingredients"* would not necessarily relate to other active anti-HIV agents but could also have included other compounds such as, for example, hydroxyurea (which is not an anti-HIV therapy but, as described in para. 39 above, when used in conjunction with ddI makes the latter more effective). Prof. Roberts went so far as to suggest that the medicinal chemist, reading the patent in July 1996 might also have had in mind other therapies such as analgesics, anti-depressants or anti-fungals for secondary infection**.** Prof. Powderly rejected this suggestion. With regard to hydroxyurea, he stressed that, in 1996, it was only considered as a companion drug to ddI and not to other anti-retrovirals. With regard to Prof. Roberts' suggestion that the *"other therapeutic ingredients"* might have referred to a drug used to treat one of the various opportunistic infections associated with AIDS, Prof. Powderly said that a combination pill of that kind would be useful only for those with the particular opportunistic infection targeted by the other therapeutic ingredient in question. When it came to his oral evidence, Prof. Roberts, in the course of his direct examination, on Day 3 at p. 31 accepted that a single pill combining a combination of an anti-HIV compound with another therapeutic agent which is not an antiretroviral was unlikely unless it was found to be commercially feasible to combine such ingredients together based on the number of patients that required that particular treatment. However, he stressed that it was not unusual for patients to be prescribed many different compounds in combination with antiretrovirals for the treatment of the infections of patients with HIV. In the course of his cross examination on the same day, Prof. Roberts at p.p. 94-95, acknowledged that there had been no move as of 1996 to put components of this kind together in a single composition.

50. It will be necessary in due course, to make appropriate findings as to the meaning of Claim 27 and to resolve (to the extent necessary), any of the relevant conflicts of evidence arising as between the experts for the parties. The brief description of the evidence recorded above is intended to do no more than provide a general flavour of the respective positions of the parties.

51. For completeness, it should be noted that none of the remaining claims (which are essentially method claims) of the patent (running from Claim 28 to claim 33) is relevant for present purposes.

The contentions of the parties in relation to Claim 27

52. Insofar as the legal position is concerned, the defendants argue that Claim 27 does not reflect any further inventive advance or technical contribution and is not independently valid above Claims 1 to 25. They also maintain that the reference to *"other therapeutic ingredients"* would not have been understood by the skilled addressee to specifically identify FTC. They draw attention, in this context, to the fact that there is no mention of FTC in the patent and they say that there is no evidence to demonstrate that the skilled addressee would have had FTC in mind when reading the patent as of July 1996. This is particularly so in circumstances where very little was known about FTC as of that date. The defendants also say that the information in relation to FTC had not entered into common general knowledge as of July 1996. They also contend that any literature which did exist in relation to FTC was not sufficient to establish its therapeutic benefit or to demonstrate its safety for long term use in humans. They also emphasise that Claim 27 is capable of referring to a wide range of viruses and retroviruses which (so they contend) makes it even more unlikely that the skilled addressee would have had FTC in mind in the context of *"other therapeutic ingredients".* In addition, they draw attention to the use of the word "*optionally"* which they say is fatal to any suggestion that Claim 27 must necessarily include the combination product involving TD and FTC. They submit that the test laid down by the CJEU in Case C-121/17 *Teva UK Ltd v. Gilead Sciences Inc.* of 25th July, 2018 (in response to the reference made by Arnold J. in the English proceedings described in para. 6 above) is not satisfied in this case. They submit that, in the circumstances, the combination of TD and FTC is not protected by a basic patent in force within the meaning of Article 3 (a) of the SPC Regulation and they ask the court to reach a similar conclusion to that reached by Arnold J. in his judgment delivered in September 2018.

53. In response, the plaintiff says that the decision of Arnold J. (which is subject to an appeal to the Court of Appeal of England & Wales) did not have the benefit of the evidence of Prof. Powderly heard by me in these proceedings. The plaintiff submits that, in any event, the decision of Arnold J. is wrong in law. The plaintiff argues, on the basis of the judgment of the CJEU in *Teva v. Gilead,* that it is not necessary that each ingredient in a combination product should be expressly referred to, as such, in the claims of a patent. The plaintiff stresses that, for the purposes of Article 3 (a) of the SPC Regulation, it is the extent of protection conferred by the claims of the patent which is crucial. The plaintiff submits that, on the basis of the CJEU judgment in *Teva v. Gilead,* the claims of the patent have primacy under the SPC Regulation. The plaintiff also emphasises that, in interpreting the claims, a narrow literal approach is not appropriate. It is not fatal if an active ingredient is not expressly mentioned in the basic patent if it is possible, on the basis of an interpretation of the claims of the patent in accordance with Article 69 of the European Patent Convention (*"EPC")* and the Protocol, to conclude that the claims relate implicitly but necessarily and specifically to the active ingredient in question. The plaintiff also submits that it is

not part of the test under Article 3 (a) to assess whether the product, the subject of an SPC, represents or reflects the core inventive advance or technical contribution of the patent. All that is required is that the product protected by the SPC be within the extent of the protection conferred by the patent. In assessing whether the claims of a patent relate implicitly but necessarily and specifically to the active ingredient in question, the test to be applied by the court (on the basis of the decision of the CJEU in *Teva v. Gilead)* is whether the product "*must be identifiable specifically by a person skilled in the art in the light of all the information disclosed by the basic patent and of the prior art at the filing date or priority date of that patent"* (to use the language of the CJEU at para. 51). The plaintiff submits that, on the basis of the evidence heard in this case, the skilled addressee of the patent would have understood the patent to be focussed on the treatment of HIV; that the established standard of care for HIV was combination treatment, that Claim 27 was referring to a co-formulation of TD with another therapeutic ingredient; that the reference to *"other therapeutic ingredients*" would have been understood by the skilled addressee to refer to a combination treatment involving at least two anti-retroviral drugs and that the most obvious candidate for combination with TD was another NRTI. The plaintiff submits that there was only a limited number of NRTIs (one of which was FTC), which were in clinical development as of the priority date. This was clear from the prior art that existed as of the priority date (which included the Wang abstract). The plaintiff also submits that the evidence establishes that the fact that FTC was in clinical development as of the priority date was a matter of common general knowledge. While the plaintiff accepts that FTC would not have been the most obvious combination therapy partner, it would have been on the shortlist of the skilled addressee and this is sufficient in order to meet the test laid down by the CJEU in *Teva v. Gilead* – namely that it was *"specifically identifiable"* and to the extent that *"necessarily"* is an additional requirement under the CJEU judgment, that this requirement is also met, on the basis of the evidence.

54. I stress that this outline of the respective contentions of the parties is, again, intended to give no more than a broad summary of the parties' respective positions. Before proceeding further, it is necessary, in the first place, to set out what I believe to be the correct legal position. Once that exercise has been completed, it will then become necessary to consider how the law is to be applied to the particular circumstances of this case.

The Law

55. The net legal issue which arises in these proceedings is whether the SPC is valid. The answer to that question turns on whether the combination of TD and FTC is *"protected by a basic patent in force"* within the meaning of Article 3 (a) of the SPC Regulation. This involves a consideration of EU law arising in relation to the SPC Regulation on the one hand and national patent law based on the EPC on the other.

It is important to bear in mind that the EPC is not an EU law measure. In Case C-493/12 *Eli Lilly & Co. Ltd v. Human Genome Sciences Inc.*, the CJEU held that in circumstances where the EU has not acceded to the EPC, it had no jurisdiction to interpret the provisions of the EPC and the CJEU could not therefore provide guidance to the national courts concerning the manner in which those courts should determine the extent of the claims of a European patent. Nonetheless, in more recent case law (in particular in the decision in *Teva v. Gilead* discussed in more detail below), it appears to me that the CJEU has gone some distance in the extent of the guidance which it has given to national courts.

56. On the other hand, it is equally important to bear in mind that the SPC Regulation is an EU law measure and accordingly the proper interpretation of Article 3 (a) of the SPC Regulation is a matter of EU law. Given the intersection between EU law in the SPC Regulation on the one hand and the principles which apply under the EPC on the other, it is unsurprising that the interpretation of the SPC Regulation has given rise to difficulty such that there has been a remarkably large number of references made by the national courts to the CJEU for preliminary rulings on the interpretation of the SPC Regulation (including the reference made by Arnold J. in the parallel proceedings in London described in para. 3 above). This court and the parties to these proceedings therefore have the benefit of specific guidance given by the CJEU in *Teva v. Gilead* on foot of the reference by Arnold J. in respect of identical patent.

57. Before attempting to analyse the judgment in *Teva v. Gilead*, it may be helpful to first consider relevant aspects of the EPC (and relevant national law) on the one hand and the SPC Regulation on the other.

The extent of protection under national law and the EPC

58. The extent of protection available to a patent under national law is governed by s. 45 of the Patents Act, 1992 (as amended) *("the 1992 Act"*) and the second schedule to that Act. In order to put those provisions in context, it may be helpful, in the first instance, to refer to some of the earlier sections of the 1992 Act which address what should be contained in an application for the grant of a patent. Consistent with Article 78 (1) of the EPC, s. 18 (2) of 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 claims".* It should be noted that, like the EPC itself, there is no definition, as such, of *"invention"* but, very clearly, the statutory provision and the EPC both proceed on the basis that a prospective patentee will be able to describe the invention claimed.

59. Consistent with Article 83 of the EPC, s. 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." Furthermore, in accordance with Article 84 of the EPC, the claim or claims are required to: *"define the matter for which protection is sought, be clear and concise and be supported by the description".*

60. As noted above, s. 45 and the second schedule deal expressly with the extent of protection. They are, in turn, consistent with Article 69 of the EPC and the Protocol on the interpretation of Article 69 EPC. Insofar as relevant, s. 45 provides as follows:-

> *"(1) The extent of the protection conferred by a patent … shall be determined by the terms of the claims; nevertheless, the description and drawings shall be used to interpret the claims.*
>
> *(2) … .*
>
> *(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 [EPC] and set out in the Second Schedule to this Act."*

61. In turn, the second schedule to the 1992 Act 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 script, literal meaning of the wording of the used in the claims, the description 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".

62. There is a plethora of authority on the manner in which the principles set out in the second schedule to the 1992 Act (and in the Protocol to the EPC) should be applied. In *Ranbaxy Laboratories Ltd v. Warner-Lambert Company* [2007] IEHC 256, Clarke J. (as he then was) drew attention to the observations made in the authorities that the protocol is designed to steer a middle course between the historical literal approach taken to a patent under common law principles (i.e. those in place prior to the decision of the House of Lords in *Catnic Components Ltd v. Gill & Smith Ltd* [1982] RPC 183) on the one hand and the more generalised approach to construction of the entire document taken under German law, on the other. At paras. 3.7-3.11, Clarke J. continued as follows:-

"3.7 The protocol needs to be seen in the context … that, typically, a patent document will set out in specific terms the claims made. It will also set out, by way of examples, descriptions and the like, further detailed specifications which will allow an understanding of the matters in respect of which the claims are made and will afford persons interested in the area a much greater understanding of the advance in knowledge which is said to form the basis of the invention at the heart of the patent itself. It does, of course, need to be recalled that the underlying basis for the grant of a patent … is that the patentee obtains his monopoly in return for disclosing to the public generally (and…the relevant sector of the scientific community in particular), the advance in scientific or technical knowledge that is claimed to be inventive.

3.8 As will be seen, the protocol requires a departure from an overly literal approach to the construction, in a semantic way, of … the claims. The balance of the patent document is not only to be used for the purposes of resolving any ambiguity in the claims but also can properly be taken into account in construing the patent document as a whole for the purposes of determining the extent of the claims.

3.9 The other key concept involved in the construction of the patent is that 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 in which the invention was intended to be used…. 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.

3.10 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. … 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. It is important in that context to define the role of expert witnesses.

…

3.11 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 … the common general knowledge which would have been available to a skilled addressee as of the priority date. …".

63. At a later point in the same judgment, Clarke J. also expressed approval for the approach taken in *Technip France SA's Patent* [2004] RPC 46 as approved and very slightly modified by Lord Hoffman in *Kirin-Amgen Inc. v. Hoechst Marion Roussell Ltd* [2005] RPC 9.

64. It is also necessary to consider how the national law approach outlined above intersects with the SPC Regulation. For that purpose, it will be necessary to consider in some detail, the relevant provisions of the SPC Regulation and the case law of the CJEU.

The SPC Regulation

65. The SPC Regulation is a successor regulation to Council Regulation (EPC) No. 1768-92 of 18 June, 1992 *("the 1992 Regulation"*) under which the SPC in issue was granted. By way of background, in the Commission proposal for the adoption of the 1992 Regulation, the EC Commission (as it then was) drew attention to the fact that, ordinarily, once a patent has been granted, the patent holder may, in principle, immediately make use of the invention concerned on the market. The proposal highlighted that this is not however, the case insofar as medicinal products are concerned. The holder of a patent in respect of a medicinal product must refrain from using it until a marketing authorisation has been obtained under the regime for the marketing of medicinal products for human use (now Directive 2001/83/EC). The proposal noted that under that regime, the makers of pharmaceutical products are required to demonstrate the quality, safety and efficacy of new medicinal products prior to their authorisation. The aim of the proposed regulation was described as follows, at para. 5:-

> *"More than in any other sector, research is particularly vital to the pharmaceutical industry itself and to society as a whole. There is no substitute for innovation in the case of medicinal products.*
>
> *European industry allocates between ten and fifteen per cent of its turnover for pharmaceutical research and is virtually self-financing. It is a high-risk activity in which investments are extremely costly and hazardous. Out of a total of about 10,000 substances synthesized by a research laboratory, a few hundred will be selected for the filing of patents out of which only one to three will actually be authorised to be placed on the market.*
>
> *The patent protection system is therefore essential to this innovating sector, in that investment in research is financed by means of returns obtained during a period of exclusive exploitation, thereby making it possible to ensure that self-funding continues and to guarantee further research in the future".*

66. The SPC Regulation (and the 1992 Regulation which preceded it), were clearly prompted by a concern that, because of the hurdles which pharmaceutical companies face in putting products on the market (and the significant time and expense incurred in preparing to do so) an appropriate regime needed to be put in place to effectively extend the life of a patent (at least insofar as the final medicinal product is concerned) beyond its lifetime under national law. This is reflected in, for example, Recital 4 to the SPC Regulation which is in the following terms:-

"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."

67. This is further developed in Recital 5 which provides that:-

"This situation leads to a lack of protection which penalises pharmaceutical research".

68. In turn, Recital 7 records that a uniform solution at EU level should be established, *"thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products…".*

69. Recital 9 records that the duration of the SPC should be such as to provide adequate effective protection. For this purpose, Recital 9 says that the holder of the patent on the SPC should be able to enjoy an overall maximum period of 15 years of exclusivity from the time the medicinal product first obtains authorisation.

70. It is important however, to keep in mind that, as Recital 10 makes clear, the SPC Regulation also addresses the interests of public health. As the more recent case-law of the CJEU highlights, the public interest in promoting pharmaceutical research has to be balanced against the interests of public health more generally. For example, there is a competing public interest in ensuring the availability of drugs at a reasonable price. Recital 10 is in the following terms:-

"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".

71. Article 3 sets out the conditions for obtaining an SPC. The only aspect of Article 3 which is relevant for present purposes is Article 3 (a) which requires that: *"the*

product is protected by a basic patent in force". No express guidance is given in the SPC Regulation as to what the Regulation intends by those words "*protected by a basic patent in force".*

72. 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. Article 4 provides as follows:-

> *"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 face 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."*

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

The case law of the CJEU prior to Teva v. Gilead

74. As noted above, the provisions of the SPC Regulation have given rise to a significant number of requests by national courts for preliminary rulings from the CJEU seeking guidance as to the meaning of the term *"the product is protected by a basic patent"* used in Article 3 (a). In some of the earlier rulings, the CJEU placed particular emphasis on the wording of the claims of the basic patent. For example, in Case C-322/10 *Medeva v. Comptroller General of Patents, Designs and Trade Marks* [2011] ECR I-12095, the CJEU said at paras. 25-28:-

> *"25. … it should be recalled that Article 5 … provides that any SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations. It follows that Article 3(a) … precludes the grant of a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent.*
>
> *26. Similarly, if a patent claims that a product is composed of two active ingredients but does not make any claim in relation to one of those active ingredients individually, a SPC cannot be granted on the basis of such a patent for the one active ingredient considered in isolation.*
>
> *27. That approach is also borne out by the second subparagraph of paragraph 20 of the explanatory memorandum to the proposal for Council Regulation (EEC) of 11 April 1990 …, which, in so far as concerns what is 'protected by the basic patent', refers expressly and solely to the wording of the claims of the basic patent. That interpretation also accords with that given in recital 14 in the preamble to Regulation (EC) No 1610/96 … concerning the creation of a supplementary protection certificate for plant protection products … which*

refers to the need for 'products' to be 'the subject of patents specifically covering them'.

28. The answer to the first five questions is, therefore, that Article 3(a) … must be interpreted as precluding … a Member State from granting a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent …"..

75. In the context of a European patent such as the 894 patent here, the claims would not, of course, be considered in isolation. They would be considered, in accordance with Article 69 of the EPC and the protocol, together with the description and drawings. This is very clearly explained in the extract from the judgment of Clarke J. in *Rambaxy* quoted in para. 62 above.

76. At an earlier point in its judgment, the CJEU, at paras. 21-23, had referred to its previous decision in Case C-392/97 *Farmitalia* [1999] ECR I-5553, where at para. 27, the CJEU stated that, in the absence of EU harmonisation of patent law, the extent of patent protection can be determined *"only in the light of the non-European Union rules governing patents".*

77. Nonetheless, in the immediately following para. (namely para. 24) the CJEU stressed that the SPC Regulation, as a measure of EU law, is designed to establish a uniform system of protection throughout the EU. The CJEU said:-

"24. It should be noted that Regulation No. 469/2009 establishes a uniform solution at European Union level by creating an SPC which may be obtained by the holder of a national or European patent under the same conditions in each Member State. It thus aims to prevent the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the European Union and thus correctly affect the establishment and functioning of the internal market…".

78. Similar observations were made by the CJEU in a judgment delivered on the same day in Case C-422/10 *Georgetown University* [2011] ECR I-12051. Those views were reiterated again by the CJEU in a series of reasoned orders made on 25th November, 2011 in Case C-518/10 *Yeda Research and Development Ltd* [2011] ECR I-12211, Case C-630/10 *University of Queensland* [2011] ECR I-12234 and in Case C-6/11 *Daiichi Sankyo Co*. [2011] ECR I-12257. It seems to me that the approach taken in para. 24 of the judgment in *Medeva* represents the beginning of a shift in emphasis by the CJEU from the approach previously taken by it in *Farmitalia*. In the latter, the Bundesgerichtshof, Germany had made a reference to the CJEU asking for clarity as to the criteria to be applied under Article 3 (a) for determining whether or not a product is protected by a basic patent. In reply, the CJEU had tersely responded

stating that, in the absence of harmonisation of patent law, the extent of protection could be determined only in the light of the non-EU rules which govern patents. As a consideration of the subsequent case law shows, the CJEU has now gone significantly further in the extent of the advice which it has provided to the national courts.

79. Subsequently, two judgments were delivered by the CJEU on 12th December, 2013 in Case C-443/12 *Actavis Group v. Sanofi* and in Case C-493/12 *Eli Lilly v. Human Genome Sciences Inc*. *Actavis Group v. Sanofi* was largely concerned with Article 3 (c) (which requires that the product, the subject of an application for an SPC, must not already have been the subject of a prior SPC). In the course of its judgment in that case, the CJEU used a phrase "*core inventive advance",* which has given rise to some debate in these proceedings. At para. 30 of its judgment, the CJEU stated:-

"30. However, … if the condition laid down in Article 3(a) … were satisfied, for the purpose of the application of Article 3(c) …, it cannot be accepted that the holder of a basic patent in force may obtain a new SPC, potentially for a longer period of protection, each time he places on the market in a Member State a medicinal product containing, on the one hand, the principle active ingredient, protected as such by the holder's basic patent and constituting, according to the statements of the referring court, the core inventive advance of that patent, and, on the other, another active ingredient which is not protected as such by that patent."

80. I do not believe that one could safely form the view, on the basis of this paragraph, that the CJEU intended to lay down a *"core inventive advance"* test. In the first place, para. 30 of the judgment is clearly concerned with Article 3 (c) rather than Article 3 (a). Secondly, as counsel for the plaintiff submitted in the course of the hearing, it is also clear that the reference to *"core inventive advance"* in that para. is a reference to language used by the referring court (namely Arnold J. in the London High Court). That said, as Arnold J. noted in his subsequent judgment in *Teva v. Gilead*, the same expression is also used in para. 41 of the judgment of the CJEU where it cannot be said that the CJEU was simply quoting the language of the referring court. Paragraph 41 of the judgment is also important for another reason. In that paragraph, the CJEU placed significant emphasis on the requirement to take into account all the interests at stake. In that paragraph, the CJEU said:-

> *"It should be recalled that the basic objective of [the SPC Regulation] is to compensate for the delay to the marketing of what constitutes the core inventive advance that is the subject of the basic patent, namely, …, irbesartan. In the light of the need, referred to in recital 10 in the preamble to that regulation, to take into account all the interests at stake, including those of public health, if it were accepted that all subsequent marketing of that active ingredient in conjunction with an unlimited number of other active ingredients, not protected as such by the basic patent but simply referred to in the wording*

of the claims of the patent in general terms, such as, in the case of the patent in the main proceedings, 'beta-blocking compound', 'calcium antagonist', 'diuretic', 'non-steroidal anti-inflammatory' or 'tranquilizer', conferred entitlement to multiple SPCs, that would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European Union by the use of SPCs."

81. The decision of the CJEU in *Eli Lilly* requires more extensive consideration. In that case, the defendant, Human Genome Sciences Inc. *("HGS")* was the holder of a European patent relating to the discovery of a new protein called Neutrokine Alpha. The patent disclosed and claimed (*inter alia*) that protein. The patent also related to antibodies that bind specifically to that protein. The protein in question acted as an intercellular mediator in inflammation and immune response. A surfeit of that protein is associated with diseases of the immune system. Thus, antibodies that bind specifically to the protein may inhibit its activity and be useful in the treatment of autoimmune diseases.

82. Claim 13 of the HGS patent included a claim in respect of what was described as "*an isolated antibody or portion thereof that binds specifically to…"* the protein. As Claim 14 explained, that antibody was to be selected from a group consisting of (*inter alia*) a monoclonal antibody. In turn, Claim 18 claimed a pharmaceutical composition comprising the antibody of any of Claims 13 – 17 and *"optionally, a pharmaceutically acceptable carrier".* As the CJEU observed in para. 19 of its judgment, the antibody was defined functionally in the patent *"thus covering an unknown number of unspecified antibodies. This is the broadest way of claiming an antibody".* In the same paragraph, the CJEU drew attention to the fact that the specification did not contain any example of an antibody having been made or tested and there was no structural description of antibodies which might function as therapeutic antibodies. At this point, it should be noted that, in the course of their submissions in the present case, counsel for the defendants emphasised that there was not even a functional definition of the *"other therapeutic ingredients"* in the 894 patent that might optionally be combined with TD for the purposes of Claim 27.

83. Eli Lilly proposed to market a pharmaceutical composition to be used in the treatment of autoimmune diseases containing as its active ingredient an antibody that binds to the protein. This later became known as Tabalumab. Eli Lilly was concerned that its plans to market Tabalumab could be thwarted in the event that HGS sought an SPC in respect of a product known as Benlysta in which a monoclonal antibody to the protein was an active ingredient.

84. Eli Lilly brought an action before the English High Court contending that any SPC would be invalid on the basis that the antibody was not protected by a basic patent within the meaning of Article 3 (a). It was specifically claimed that Claim 13 of the HGS patent was too broadly drafted for it to be possible for that antibody to be regarded as *"specified"* for the purposes of the test set out in *Medeva.* Eli Lilly contended that the patent would have to contain a structural definition of the active ingredients and the claims would have to be significantly more specific.

85. Following a reference by the English High Court, the CJEU stressed that, for the purposes of Article 3 (a), recourse could not be had to the rules governing infringement proceedings. The Court reemphasised what had been said in previous cases that the claims of the patent played a *"key role"* for the purposes of determining whether a product is protected by a basic patent within the meaning of Article 3 (a).

86. At paragraph 35, the CJEU highlighted that the importance of the claims of a patent was supported by a consideration of para. 20 of the Commission proposal (described in para. 65 above) which linked the ambit of protection given by a basic patent expressly and solely to the claims of that patent. On the face of it, this supports the case made by the plaintiff in these proceedings. However, for the reasons outlined in more detail below, it seems to me that in its subsequent case law, the CJEU has moved away from this concentration on the claims of a patent, while still acknowledging that they play a key role. In particular, the CJEU, in its more recent case law, has suggested that the claims must be construed in light of the *"limits of the invention"*.

87. At paras. 38 – 39, the CJEU gave the following guidance in relation to the issue as to whether it was necessary that an active ingredient should be identified in the claims of a patent by means of a structural formula or whether the protection extended to cases where the ingredient is covered by a functional formula in the claims: -

"*38. It should be recalled that, in accordance with the case-law cited at para. 34 above, an active ingredient which is not identified in the claims of a basic patent by means of a structural, or indeed a functional definition cannot, in any event, be considered to be protected within the meaning of Article 3 (a)…*

39. With regard to the question whether the use of a functional definition may alone be sufficient, it should be noted that Article 3 (a)… does not, in principle, preclude an active ingredient which is given a functional definition in the claims of a patent issued by the EPO being regarded as protected by the patent, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required

by Article 69 of the EPC Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question".

88. Although the CJEU, in para. 38, referred back to the case – law cited at para. 34 (which included *Medeva* and *Daiichi Sankyo*), it seems to me that the CJEU has significantly extended the ambit of the earlier case law which had stressed the importance that the active ingredient should be specified in the wording of the claims of the basic patent. In addition, it can be seen from what is said in para. 39 of the judgment in *Eli Lilly* that the CJEU has, notwithstanding its observations in earlier judgments about the EPC being outside its remit, nonetheless, emphasised that the claims are to be interpreted in light of the description of the invention as required by Article 69 of the EPC and the Protocol.

89. The next relevant decision of the CJEU is Case C – 577/13 *Actavis Group v. Boehringer Ingelheim* which was decided by a court comprising only three judges. However, the judge rapporteur, Judge Toader also acted as rapporteur in each of *Eli Lilly*, *Actavis v. Sanofi*, *Daiichi Sankyo*, *University of Queensland*, *Yeda Research* and in *Medeva*. The relevant facts of the case were that in 1992, Boehringer filed an application for a European patent which was granted in 1998. The patent disclosed and claimed numerous molecules, one of which was Telmisartan which is an active ingredient used to treat hypertension. Claim 5 of the patent related to Telmisartan alone. Claim 8 related to one of its salts. In 1998, Boehringer obtained a marketing authorisation for a medicinal product known as Micardis which contained Telmisartan as the sole active ingredient. In the following year, Boehringer obtained the first SPC for that active ingredient. Subsequently, in April 2002, a Boehringer company was granted a marketing authorisation for a combination of Telmisartan and hydrochlorothiazide which is a diuretic inhibiting the kidney's ability to retain water. Hydrochlorothiazide is a molecule that has been known to exist since 1958 and is in the public domain. The combination product was launched under the name MicardisPlus.

90. On 6th September 2002, Boehringer filed an application for an SPC for the combination of Telmisartan and hydrochlorothiazide. However, the UK Intellectual Property Office responded to say that the combination would have to be claimed in the patent, if an SPC were to be granted, and it suggested to Boehringer that an application should be made to amend the basic patent to insert a claim to a combination of Telmisartan and hydrochlorothiazide. Later that year, Boehringer applied to amend its basic patent and this was subsequently granted to include a new claim (Claim 12) relating to the combination. Thereafter an SPC was granted in respect of the combination. Actavis brought proceedings before the English Courts contending that the combination SPC was invalid on the ground that, at the date on which the application was originally made for the SPC in 2002, the product in question

was not specified in the wording of the claims of the basic patent. A reference was made to the CJEU for a preliminary ruling. In seeking that ruling, the English High Court drew attention to s. 27 of the Patents Act 1977 (UK) which provides that an amendment of a specification of a patent has effect (and is deemed always to have had effect) from the date of the grant of the patent. The questions referred by the English Court related to both Article 3 (a) and Article 3 (c) of the SPC Regulation.

91. In its judgment, the CJEU referred, in para. 26, to the fact that it was common ground in the English proceedings that Telmisartan (which was described by the CJEU as the "*innovative active ingredient of Boehringer's basic patent"*) was the sole subject matter of the invention. The Court continued: -

> *"Boehringer did not, in any event, contribute to the discovery of hydrochlorothiazide which is a molecule within the public domain, and the claim relating to that substance does not constitute the subject matter of the invention".*

92. Echoing the language used in para. 41 of *Actavis v. Sanofi*, the CJEU stated, at para. 36:-

> *"In the light of the need, referred to … in recital 10 in the preamble to Regulation No 469/2009, to take into account all the interests at stake, including those of public health, if it were accepted that all subsequent marketing of an active ingredient in conjunction with an unlimited number of other active ingredients which do not constitute the subject-matter of the invention covered by the basic patent would confer entitlement to multiple SPCs, that would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European Union by the use of SPCs …."*

93. The CJEU continued at para. 37-39 in the following terms:-

> *"37. Accordingly, in view of the interests referred to in recitals 4, 5, 9 and 10 in the preamble …, it cannot be accepted that the holder of a basic patent in force may obtain a new SPC, potentially for a longer period of protection, each time he places on the market in a Member State a medicinal product containing, on the one hand, an active ingredient, protected as such by the holder's basic patent and constituting the subject-matter of the invention covered by that patent, and, on the other, another substance which does not constitute the subject-matter of the invention covered by the basic patent …*
>
> *38. It follows that, in order for a basic patent to protect 'as such' an active ingredient within the meaning of Articles 1(c) and 3(a) of Regulation No 469/2009, that*

active ingredient must constitute the subject-matter of the invention covered by that patent.

39. In the light of the foregoing considerations, the answer to Questions 2 and 3 is that Article 3(a) and (c) … must be interpreted as meaning that, where a basic patent includes a claim to a product comprising an active ingredient which constitutes the sole subject-matter of the invention, for which the holder of that patent has already obtained an SPC, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, that provision precludes the holder from obtaining a second SPC for that combination."

94. It will be seen from the approach taken by the CJEU in the paragraphs just quoted, that the court did not focus solely on Article 3 (c). It applied the same principle to Article 3 (a). It also referred repeatedly to the requirement that, in order for a basic patent to protect *"as such"* an active ingredient, the ingredient in question must constitute the subject-matter of the invention covered by that patent. It was, however, argued on behalf of the plaintiff, in the course of the hearing before me, that the CJEU judgment must be seen in the particular context of the amendment of the claims of the patent and counsel for the plaintiff drew attention, in that context, to the specific language of the CJEU in para. 39 (which is repeated in the formal answer given by the CJEU to the questions raised by the English court) which expressly refers to the fact that the combination claim was subsequently added to the patent by way of amendment. Counsel for the plaintiff also stressed that, as noted in para. 91 above, it was common ground in that case that Telmisartan was the sole subject-matter of the invention covered by the patent in issue. Nonetheless, it seems to me that, in *Eli Lilly*, the CJEU went further than in previous cases in emphasising the importance of the subject-matter of the invention. This is particularly clear from what is said in para. 36 of the judgment (quoted above) in which the court invoked Recital 10 in the preamble to the SPC Regulation and emphasised the importance of balancing the interests of the pharmaceutical industry against the interests of public health. The CJEU was clearly concerned that pharmaceutical companies should only be rewarded (through the SPC regime), for the fruits of invention and that it would be contrary to the interests of the promotion of public health that a monopoly should be granted in respect of a product that was not truly within the ambit of the invention covered by a particular patent.

Teva v. Gilead

95. This is, obviously, the most relevant decision of the CJEU for present purposes. By way of background, the validity of the SPC issued to Gilead in the United Kingdom in respect of Truvada was challenged in the High Court of England and Wales by a number of companies including Teva UK and Mylan. That challenge was heard by Arnold J. in December 2016. In a judgment delivered in January 2017, Arnold J.

referred a question to the CJEU in similar terms to the question previously raised by him in *Actavis v. Sanofi* namely:-

> *"What are the criteria for deciding whether 'the product is protected by a basic patent in force' in Article 3(a) of SPC Regulation?".*

96. In referring that question to the CJEU, Arnold J. comprehensively analysed the earlier decisions of the CJEU in *Medeva, Yeda Research, Daiichi Sankwo, Eli Lilly, Actavis v. Sanofi and Actavis v. Boehringer*. In para. 71 of his judgment, Arnold J. drew attention to the language used by the CJEU in para. 41 of its judgment in *Actavis v. Sanofi* (quoted in para. 80 above), observing that the CJEU, in that paragraph of its judgment, drew a contrast (albeit in the context of Article 3 (c)) between an active ingredient which represents "*the core inventive advance that is the subject of a basic patent"* and *"other active ingredients, not protected as such by the basic patent but simply referred to in the wording of the claims of the patent in general terms".* At para. 88 of his judgment, Arnold J. having quoted paras. 36-38 of the subsequent judgment of the CJEU in *Actavis v. Boehringer,* commented as follows:-

> *"First, as in Actavis v. Sanofi, the Court places emphasis upon what is protected 'as such' by the basic patent. Secondly, the Court uses the expression 'the subject-matter of the invention covered by the basic patent', which is not an expression which it used in the cited paragraphs of Actavis v. Sanofi. Thirdly, despite this difference in language, it seems to me that this passage reinforces the message conveyed by Actavis v. Sanofi at [41] and that what matters is whether the product constitutes what is described here as 'the subject-matter of the invention covered by the basic patent'. Fourthly, it nevertheless remains unclear what is required in order for Article 3(a) to be satisfied."*

97. At an earlier point in his judgment, Arnold J. had sought to identify the applicable rules of patent law that are engaged in the context of the requirement, under Article 3 (a), that the product (the subject of the application for an SPC) must be "*protected by a basic patent in force".* He identified that, potentially, there were two sets of rules which might be relevant namely:-

(a) The national laws which implement Article 69 of the EPC which he called the *"Extent of Protection Rules";*
(b) The national laws which define what acts amount to an infringement of a patent which he called the '*Infringing Act Rules'*".

98. In light of the case law of the CJEU it is clear that what Arnold J. called the Infringing Act Rules are not applicable for the purposes of Article 3 (a). The rules which are applicable are those which apply under Article 69 of the EPC. Arnold J. was in doubt

however, as to whether satisfaction of the extent of protection test is sufficient in itself to establish that a product is protected by a basic patent for the purposes of the SPC Regulation or whether something more is required. Based on his review of the pre-existing case law of the CJEU, Arnold J. was of the view that something more than the extent of protection rules is required but that: *"It is not clear what more is required".* In those circumstances, Arnold J. referred the question identified at para. 95 above to the CJEU for consideration. He also, very helpfully, offered his own suggested answer to the question. In para. 97 of his judgment he said:-

> *"In my view, the answer is that the product must infringe because it contains an active ingredient, or a combination of active ingredients, which embodies the inventive advance (or technical contribution) of the basic patent. Where the product is a combination of active ingredients, the combination, as distinct from one of them, must embody the inventive advance of the basic patent."*

99. With regard to Truvada, Arnold J. was of the view that the active ingredient, TD, was protected by the patent within the meaning of Article 3 (a) because it embodied the inventive advance of the patent. However, he suggested that a medicinal product whose active ingredients are TD and another therapeutic agent such as FTC in combination is not protected *"because the combination, as distinct from TD does not embody the inventive advance of the Patent. This is not a question of the wording of the claims of the basic patent, which … can be manipulated by the patent attorney who drafts it, but of its substance. By contrast, if Gilead (or another inventor) were to obtain a patent for an invention consisting of a combination of TD and substance X which surprisingly had a synergistic effect in treating HIV, then a medicinal product whose active ingredients were TD and X would be protected by that patent since it would embody the inventive advance of that patent…."*

100. The reference from Arnold J. was heard by the Grand Chamber of the CJEU including the president and vice-president and six presidents of chambers. Judge Toader was also among the judges. However, the rapporteur on this occasion was Judge Jurimae. Advocate General Wathelat also participated.

101. The Advocate General, in his opinion, expressed the view that it was clear from the pre-existing case law of the CJEU that the only means of determining whether a basic patent protects an active ingredient within the meaning of Article 3 (a) is to be found *"only in the wording, or interpretation of the wording, of the claims of the patent granted, and nowhere else".* At para. 73 of his opinion, he expressly rejected the suggestion made by Arnold J. that there should be an additional criterion that the active ingredient embody *"the inventive advance of the patent".* He suggested that to incorporate such a test would give rise to confusion with the criteria for determining whether an invention is patentable. However, at para. 74, he

acknowledged that *"merely because a substance might fall within the protection of the claims of a patent under Article 69 of the EPC and the Protocol …does not necessarily imply that that substance is a product protected by a patent within the meaning of Article 3 (a) …".*

102. The Advocate General next considered what else was necessary for a product to be protected by a patent within the meaning of Article 3 (a). At para. 76, he suggested that the real question related to the degree of specificity required. At para. 77 he referred to *Eli Lilly* where the CJEU (as noted above) had held that it is not always necessary for the purposes of Article 3 (a) that the active ingredient be referred to literally by its name or chemical structure and that a functional definition in the claims of a patent could, in certain circumstances, be sufficient. On the other hand, he noted that the CJEU in *Actavis v. Boehringer* had suggested that the fact that a patent may contain a claim relating to a specifically named active ingredient may not always be sufficient. Like counsel for the plaintiff in the present case, he suggested that this decision should be read with caution given the "*singular facts"* (i.e. that one of the active ingredients at issue was not specified in the patent as initially granted).

103. At para. 80, the Advocate General noted that patent claims are often (deliberately and ingeniously) drafted in *"broad, vague, generic and stereotypical terms"* so that they cover multiple substances. In a footnote at this point, he suggested that this was exemplified by Claim 27 of the patent here. In that footnote he said:-

> *"Claims of this kind are drafted so broadly that they could potentially cover any combination of TD with another chemical substance …".*

104. Counsel for the plaintiff stressed that this observation by the Advocate General was made in the absence of detailed evidence as to what was known as of July 1996. Counsel drew attention to what was said later in the opinion (at para. 87) that the matter was *"subject to verification by the referring court…".*

105. At paras. 81-83 of his opinion, the Advocate General suggested the following approach:-

> *"81. To my mind, a product is protected by a patent within the meaning of Article 3 (a)… if, on the priority date of the patent, it would have been obvious to a person skilled in the art that the active ingredient in question was specifically and precisely identifiable in the wording of the patent claims. In the case of a combination of active ingredients, each active ingredient must be specifically, precisely and individually identifiable in the wording of the patent claim.*
>
> *82. The name of the active ingredient or its chemical composition does not need to be referred to expressly in the claims, provided that the active ingredient is specifically and precisely identifiable as at the priority date of the patent.*

> *83. If, for example, a substance claimed in a patent consists of several variants, the product protected by the patent within the meaning of Article 3(a) … does not necessarily encompass all those variants. As at the priority date …, a variant must be specifically and precisely identifiable in the wording of the patent claims in order for it to be 'a product protected by the patent' within the meaning of Article 3(a)…".*

106. Counsel for the plaintiff sought to place reliance on the opinion of the Advocate General in support of a submission that the opinion demonstrates that the *"inventive advance"* test proposed by Arnold J. was expressly rejected. However, I do not believe that there is any basis to form the view that the opinion expressed by the Advocate General can be said to have been adopted by the CJEU. It is noteworthy that, in the subsequent judgment delivered by the CJEU on 25th July, 2018, no significant reference is made, at any point, to any aspect of the opinion of the Advocate General. For that reason, I will confine myself, for present purposes, to a consideration of the judgment of the CJEU itself. In that judgment, the CJEU, at paras. 31-45 sought to summarise and explain the pre-existing case law. At para. 31, the CJEU reiterated what had been said in *Eli Lilly* at para. 31 that the extent of the protection conferred by a basic patent can be determined only in the light of the non-EU rules governing patents. At para. 32 the CJEU, again citing its earlier decision in *Eli Lilly*, restated that the rules for determining what is *"protected by a basic patent in force"* are *"those relating to the extent of the invention covered by such a patent, just as is provided… in Article 69 of the EPC and the Protocol …".* The court also repeated its earlier view that, for the purposes of Article 3 (a) no recourse may be had to the rules governing infringement proceedings.

107. In language that was emphasised by counsel for the plaintiff in this case, the CJEU continued at para. 34 of its judgment to say:-

> *"…the Court has repeatedly emphasised the key role played by the claims for the purpose of determining whether a product is protected by a basic patent within the meaning of [Article 3 (a)] …".*

108. In response, counsel for Teva said that this was an uncontroversial observation. He made the point that, while the claims may have a key role to play, it is clear from what follows in the judgment that they are not to be considered in isolation.

109. Counsel for the plaintiff also highlighted what is said by the CJEU in para. 35 of the judgment that, specifically with regard to European patents, Article 69 of the EPC envisages that the extent of the protection will be determined by the claims. In the same paragraph, the CJEU referred to Article 69 of the EPC, observing that the claims must ensure both a fair protection for the patent proprietor and a reasonable degree

of legal certainty for third parties. In para. 36, the CJEU, again referring to *Eli Lilly*, recorded that it had previously held that Article 3 (a) does not, in principle exclude from patent protection an active ingredient which is given no more than a functional definition in the claims where it is possible:-

> *"on the basis of those claims as interpreted inter alia in the light of the description of the invention, as required under Article 69 of the EPC and Protocol…to conclude that the claims relate implicitly but necessarily and specifically to the active ingredient in question."*

110. Counsel for each of the defendants sought to contrast the position where a functional definition of an active ingredient is given in the claims of a patent with the position here where they submitted the reference to "*other therapeutic ingredient"* in the 894 patent could not be said to constitute a functional definition. Ultimately, I do not believe that it is necessary to form any view in relation to that issue in circumstances where, as the balance of the judgment makes clear, the CJEU set out the very specific test to be applied in relation to the patent at issue here and it is that test that I must apply in these proceedings.

111. There was some debate between the parties as to what was intended by the CJEU in para. 37 of its judgment. In that para., the CJEU stated:-

> *"Therefore, a product cannot be considered to be protected by a basic patent in force within the meaning of Article 3 (a) … unless the product which is the subject of the SPC is either expressly mentioned in the claims of that patent or those claims relate to that product necessarily and specifically".*

112. Counsel for the plaintiff sought to suggest that the effect of this paragraph is that, if the product is expressly mentioned in the claims, that is the end of the inquiry and it is not necessary to address or apply the test set out in the balance of the judgment of the CJEU. In circumstances where the plaintiff expressly acknowledges (as it must) that FTC is not expressly mentioned in the claims of the patent here, I do not believe that it is appropriate to express any view on this issue. For present purposes, the balance of the judgment of the CJEU provides very comprehensive guidance as to how I should approach the interpretation of the 894 patent.

113. The guidance commences at para. 3, where the CJEU identifies that the description and drawings of the basic patent must be taken into account (as stipulated in Article 69 of the EPC read in light of the Protocol) in order to determine:-

(a) whether the claims of the basic patent relate to the product which is the subject of the SPC; and

(b) Whether that product in fact falls under the invention covered by that patent.

114. I believe this is clear from the language used in para. 38 where the CJEU says:-

> *"For that purpose, in accordance with the case-law cited in para. 36 …, the description and drawings of the basic patent must be taken into account, as stipulated in Article 69 … read in the light of the Protocol …, where that material shows whether the claims of the basic patent relate to the product which is the subject of the SPC* ***and*** *whether that product in fact falls under the invention covered by that patent."* (emphasis added).

115. At para. 39 of its judgment, the CJEU explains that the "*requirement*" set out in para. 38 of the judgment is in line with the objective of the SPC Regulation which is to re-establish a sufficient period of protection of the patent by permitting the patent holder to enjoy an additional period of exclusivity on the expiry of a patent in order to compensate the holder (at least in part) for the delay to the commercial exploitation of the invention as a consequence of the operation of the EU marketing authorisation regime. Nonetheless, in para. 40 of the judgment, the CJEU, in simple and straightforward language, makes clear that it is not the purpose of an SPC to extend the protection conferred by a patent beyond the invention covered by that patent. The CJEU stated:-

> *"40. However, it is not the purpose of the SPC to extend the protection conferred by that patent beyond the invention which the patent covers. It would be contrary to the objective of [the SPC Regulation] … to grant an SPC for a product which does not fall under the invention covered by the basic patent, inasmuch as such an SPC would not relate to the results of the research claimed under that patent."*

116. In para. 41 of the judgment, the CJEU explains (in language which mirrors what was said in para. 36 of its judgment in *Eli Lilly* and para. 41 of its judgment in *Actavis v. Sanofi*) that there are important public policy reasons why patent protection should be confined to the invention itself. Paragraph 41 is in the following terms:-

> *"In the light of the need, referred to … in recital 10 to [the SPC Regulation] to take into account all the interests at stake, including those of public health, to accept that an SPC could grant to the holder of the basic patent protection which goes beyond the protection guaranteed by that patent in connection with the invention it covers would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European union by the use of SPCs…".*

117. Notably, the CJEU does not use, here, the *"core inventive advance"* language which had been used in para. 41 of its judgement in *Actavis v. Sanofi*. Nonetheless, the repeated emphasis placed on the *"invention"* in those paragraphs is noteworthy. Similar language is used in para. 42. In para. 43, the CJEU makes clear that the claims of the patent must be construed in light of the limits of the invention covered by the patent. In that paragraph, the CJEU says:-

> *"43. Accordingly having regard to the objectives pursued by [the SPC 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)…,* ***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 drawings of that patent"* (emphasis added).

118. This is restated in somewhat different language in para. 46 of the judgment:-

> *"46. It follows from the above 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, such as claimed in that patent".*

119. Later, in para. 55 of the judgment, the CJEU explains that the approach to be taken by the national court in applying the "*rule"* identified in para. 46, is to be found in paras. 47-51 of the judgment. These are obviously key paragraphs for present purposes. In para. 47, the CJEU highlights that the national court is to approach the matter from the perspective of a person skilled in the art. In itself, this is an unsurprising observation. It is consistent with the approach taken under Article 69 of the EPC and the Protocol. However, para. 47, like paras. 40-43, again places some emphasis upon the *"invention".* Paragraph 47 is in the following terms:-

> *"47. With regard to the implementation of that rule, [i.e. the rule mentioned in para. 46], it must in the first place be stated that, in accordance with a principle shared by the patent laws of the Member States and reflected in Article 1 of the Protocol … on the Interpretation of Article 69 of the EPC, the claims of a patent are to be interpreted from the perspective of a person skilled in the art and, therefore,* ***the issue whether the product which is the subject of the SPC necessarily falls under the invention covered by that patent must be assessed from that perspective****."* (emphasis added)

The first limb of the Teva v Gilead test

120. In the following two paragraphs of the judgment the CJEU explains that there are essentially two steps involved in the process envisaged in para. 47. The first of these is set out in para 48 as follows:-

> *"48. To that end, it is necessary to ascertain whether a person skilled in the art can understand without any doubt, on the basis of their general knowledge and in the light of the description and drawings of the invention in the basic patent, that the product to which the claims of the basic patent relate is a specification required for the solution of the technical problem disclosed by that patent."*

It is quite clear from this paragraph that the CJEU had in mind that a patent is to be construed through the lens of a skilled person on the basis of the common general knowledge of that person and in light of the description and drawings of the invention. There is no suggestion in the language used by the CJEU that the patent is to be construed by reference to any part of the prior art that has not been assimilated into common general knowledge. This is of some importance for the purposes of the discussion which follows in paras. 126-135 below.

121. At this point, it may also be useful to record that, when the matter was next considered by Arnold J. in the English High Court, he took this to mean that the product must be one that the skilled person would understand, on the basis of the description and drawings and their common general knowledge, as embodying the technical contribution made by the patent. Arnold J. was concerned that the CJEU was using terminology derived from patent law inaccurately. Counsel for each of the defendants submitted that the approach taken by Arnold J. is correct. I am not sure that it is necessary to express any view on the approach taken by Arnold J. because, when it came to the specific answer given in para. 57 of the judgment, the CJEU did not repeat the phrase *"a specification required for the solution of the technical problem disclosed by [the] … patent"* which appears in para. 48 of the judgment. Instead, it used somewhat different language, namely: *"the invention covered by [the] patent".* The same language is used in paras. 47, 49, 52, 55 and 56 of the judgment. It seems to me that I should attempt to decide the issue before me by reference to that language (as expressly used by the CJEU itself) rather than by reference to Arnold J.'s reformulation. The language of *"invention"* is, of course, consistent with Article 78 of the EPC which, as noted in para. 58 above, requires that every patent application must contain a specification containing "*a description of the invention".* It is also consistent with Article 83 of the EPC which, as noted in para. 59 above requires that any application for a patent must *"disclose the invention to which it relates".* The repeated emphasis on the *"invention"* strongly suggests that the CJEU had in mind similar considerations to those so clearly expressed by Laddie J. in *Merck & Co. v. Generics (UK) Ltd* [2004] RPC 31 at para. 38 where he said:-

> *"The purpose of a patent is to convey to the public what the patentee considers to be his invention and what monopoly he has chosen to obtain.* ***These are not necessarily the same. The former is primarily to be found in the specification and the latter is primarily to be found in the claims****. Although he is not deemed to be a patent lawyer, the patentee should be taken to be aware of the primary and rather different purposes of the specification and the claims when drafting his patent. So, the patentee must be taken to know the framework of form and purpose when he drafts his patent. It is his duty to communicate his invention and his assertion of monopoly to the public in language it will understand. …"* (emphasis added).

122. Notwithstanding the repeated emphasis in the judgment on the *"invention"*, the plaintiff submits that this first limb of the test laid down by the CJEU in para. 48 of its judgment, simply requires that the combination of TD and FTC should fall within Claim 27 when construed in accordance with s. 45 of the 1992 Act. It was argued on behalf of the plaintiff that it is *"universally understood that claims define the scope of monopoly claimed by a patent".* Insofar as the defendants have relied on the phrase *"falling under the invention covered by the patent"* used by the CJEU in its judgment, the plaintiff submits that this is: *"no more and no less than saying that the product must fall within the claims properly construed in accordance with the national rules that give effect to Article 69."* In support of this argument, the plaintiff has sought to rely on para. 43 of the judgment of the CJEU where (so the plaintiff argues) the CJEU equates *"the invention covered"* with the scope of the claims as normally construed. The plaintiff submits that there is no doubt but that the first limb of the test requires the national court to determine whether the combination of TD and FTC *"falls within Claim 27, properly construed, and no more".*

123. I do not accept the plaintiff's submissions as to the ambit of the first limb of the CJEU test. Had it been the intention of the CJEU to focus on the claims of the patent, it would have been a very straightforward matter for the CJEU to express itself in those terms in its judgment. However, that is not the way in which the judgment is expressed. On the contrary, the court has repeatedly used the phrase *"the invention covered by [the] patent".* In my view, para. 43 of the judgment provides no support for the argument advanced on behalf of the plaintiff. To the contrary, the language used by the CJEU in para. 43 of the judgment seems to me to undermine the case made by the plaintiff here. The full text of para. 43 is quoted in para. 117 above. That language clearly demonstrates that the CJEU was concerned that the monopoly claimed may go beyond the limits of the invention disclosed in the patent. For that reason, the CJEU emphasised that, for the purpose of the application of Article 3 (a), the claims must be construed *"in the light of the limits of [the] invention, as it appears from the description and the drawings of [the] patent".* While counsel for the plaintiff sought to argue that this was simply no more than a restatement of the

approach required under Article 69 of the EPC, I do not believe that this is borne out by a consideration of the terms of para. 43 as a whole. The opening words of the paragraph make very clear that the CJEU was concerned that claims *"cannot allow the holder of the … patent to enjoy, by obtaining an SPC, protection which goes beyond that granted for the invention covered by that patent*". This seems to me to require that the national court must form a view as to what are the limits of the invention disclosed in the patent. In turn, this requires an *"invention focussed"* approach rather than a *"claims focussed"* approach. In my view, this is borne out by the repeated references thereafter to the requirement that the combination must fall *"under the invention covered by [the] patent".*

124. For these reasons, I reject the suggestion that the CJEU, in the first limb of the test, was confining itself to the extent of protection approach which focusses on the claims of the patent (albeit that the claims are to be construed against the backdrop of the description and drawings).

The second limb of the Teva v Gilead test

125. The approach set out in para. 48 of the judgment in CJEU is only the first step in a two stage process. The second step is explained as follows in para. 49:-

> *"49. In the second place, having regard to the objective of Regulation No 469/2009, recalled in paragraph 39 above, for the purposes of assessing whether a product falls under the invention covered by a basic patent, account must be taken exclusively of the prior art at the filing date or priority date of that patent, such that the product must be specifically identifiable by a person skilled in the art in the light of all the information disclosed by that patent."*

126. The plaintiff places significant emphasis upon the reference by the CJEU, in this paragraph, to *"prior art".* Counsel for the plaintiff referred to the well-established distinction between prior art, on the one hand, and general knowledge, on the other. They submit that prior art is all that is relevant under this second limb of the CJEU test in *Gilead*. They further submit that the evidence shows that FTC was identifiable in the prior art as of July 1996, and that its promise as a combination therapy with another NRTI was also part of the prior art as of July 1996. They also argue that it is only in relation to the first limb of the *Gilead* test, that common general knowledge is relevant. This argument is clearly made with a view to being in a position to rely, for example, on the Wang abstract. The potential significance of the Wang abstract is that it is the first piece of scientific literature which suggests that FTC had been administered, in the course of a stage one clinical study, to humans (with no reported adverse effects other than a mild rash in the case of one volunteer). As noted above, none of the witnesses who gave evidence could say that they had seen the Wang abstract or that they were aware of its existence. This would raise an issue as to

whether it could be said to fall within *"common general knowledge".* However, the Wang abstract would form part of the prior art (as that term is classically understood), since it clearly existed before the priority date of the 894 patent and, in the context of prior art, there is no requirement that the information contained in the abstract had passed into common general knowledge. In this context, the plaintiffs draw attention to what was said by Lord Parker C.J. in *Bristol Myers Co's Application* [1969] RPC 146 at p. 155:-

> *"It seems to us that we are bound … to reject the contention that publication depends in some way … upon the degree of dissemination of the information alleged to have been published. On the contrary, if the information, whether in documentary form or in the form of the invention itself, has been communicated to a single member of the public without … fetter that is enough to amount to making available to the public".*

127. It is necessary to keep in mind that this observation by Lord Parker C.J. was made in a different context. It was not made in the context of the interpretation of a patent. Prior art is relevant where novelty and inventive step are assessed. In such circumstances, as counsel for Mylan argued, in his closing submissions, the fact that a piece of prior art is, to borrow a phrase, on a dusty shelf in a library on the other side of the world does not matter. However, prior art is not relevant *per se*, in the context of the interpretation of a patent.

128. More importantly, it appears to me to be clear from a consideration of the judgment of the CJEU, as a whole, that the CJEU did not have *"prior art"* in mind in the sense suggested by the plaintiffs here. It seems clear that the CJEU envisaged that, in assessing the state of general knowledge as at the priority date of a patent, one cannot have regard to any materials which only came into existence after the priority date. In this context, it is commonplace for experts in patent actions, to refer to scientific publications with a view to establishing the extent of common general knowledge as at a particular date. That is precisely what happened in the present case where each of the expert witnesses who gave evidence for the parties drew attention to articles in learned journals and other sources of information in order to bolster their respective evidence as to what was common general knowledge as of the priority date of the 894 patent. All that the CJEU has done in this case is to make it very clear that, in a case of this kind, in assessing common general knowledge, it is impermissible to have regard to material which post-dates the priority date of the patent.

129. It is also important, in the context of the construction of a patent, to recall that, as explained, for instance, by Clarke J. (as he then was) in *Rambaxy Laboratories Ltd v. Warner-Lambert Co.* [2007] IEHC 256 (quoted in para. 62 above) the knowledge

that will be imputed to the skilled addressee (i.e. the person skilled in the art) is the knowledge that any worker in the area concerned would be expected to have as part of their general knowledge. The person skilled in the art would not be deemed to be aware of a piece of prior art that had not entered into the common general knowledge of the relevant field of expertise involved. Accordingly, it would be a contradiction in terms for a court to impute to the person skilled in the art knowledge of some piece of art resting, unread, on the proverbial dusty bookshelf in a rarely visited library. I do not accept that, when the CJEU spoke of *"prior art",* the court intended to expand the process of construing a patent so as to embrace prior art in that sense. On the contrary, it seems to me that the CJEU was concerned to ensure that there should be a temporal limitation placed on the material that could be taken into account in determining what is comprised within the general knowledge of the skilled person. It is significant that, in para. 50 of the judgment (quoted in full below), the CJEU expressly rejected any suggestion that research which was not **known** as of the priority date could be taken into account. It seems to me, from a consideration of the judgment as a whole, that the CJEU was seeking to narrow the scope of the material which can be taken into account. In contrast, the approach advocated by the plaintiff would substantially broaden the extent of the material that could be taken into account in applying the second limb of the test. Under the approach proposed by the plaintiff, the skilled person would be required to have regard to arcane material which was not part of the general knowledge as at the filing date or priority date of a patent. I do not believe that there is any basis to conclude that the CJEU intended to broaden the range of material that could be taken into account. In my view, this is confirmed by what is said in paras. 50-51. It is worth quoting paras. 50-51 in full. I believe it is clear from those paragraphs that the references to *"prior art"* by the CJEU were intended to narrow the scope of what might be put in play by experts standing in the shoes of the *"person skilled in the art"* rather than to broaden that scope. At paras. 50-51, the CJEU said:-

"50. Were it to be accepted that such an assessment [i.e. the assessment as to whether a product falls under the invention covered by a basic patent] could be made taking into account results from research which took place after the filing date or priority date of the basic patent, an SPC could enable its holder unduly to enjoy protection for those results even though ***they were not yet known*** *at the priority date or filing date of that patent, … That would, as pointed out in paragraphs 40 and 41 …, run counter to the objective of [the SPC Regulation].*

51. Therefore, for the purposes of determining whether a product which is the subject of an SPC is protected by a basic patent…, that product must be identifiable specifically by a person skilled in the art in the light of all the information disclosed by the basic patent and of the prior art at the filing date or priority date of that patent." (emphasis added).

130. It seems to me that this conclusion is given added force by the answer given by the CJEU, in para. 57 of the judgment, to the question posed by Arnold J. In that para., the CJEU effectively summarises the test laid down in more detail in paras. 48-51 in the following terms:-

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

131. It will be seen from the language used in para. 57 that in fact, both the *"person skilled in the art"* and *"prior art"* are wrapped up together and are to be applied in relation to both limbs of the test. As noted in para. 120 above, the CJEU had previously explained in para. 48 of its judgment that, insofar as the first limb of the test is concerned, the understanding of the person skilled in the art of the patent is to be based on general knowledge. That is consistent with the approach which is classically taken in the construction of a patent. Accordingly, I believe it is clear that what the CJEU had in mind was that, for the purposes of assessing whether a product falls under the invention covered by a basic patent, the person skilled in the art is not entitled to rely, for the purposes of establishing what is comprised in the common general knowledge as of the priority date or filing date of a patent, on any item of the relevant art which only came into existence subsequent to those dates. I cannot see how the test laid down in para. 57 could have been intended to be applied by reference to prior art unknown to the person skilled in the art, as at the priority date. That would seem to me to entirely undermine the requirement to have regard to the general knowledge of the person skilled in the art as set out in para. 48 of the judgment (which is one of the paras. which the referring court is required, by virtue of para. 55 of the judgment of the CJEU, to apply in deciding the case).

132. Similar considerations arise in relation to what is said by the CJEU in para. 52 of its judgment where, the CJEU says:-

> *"52. Having regard to all the foregoing considerations, a product is 'protected by a basic patent in force' within the meaning of Article 3(a) … in so far as, if that product is not expressly mentioned in the claims of the basic patent, one of those claims relates to it necessarily and specifically. For that purpose, that product must, from the point of view of a person skilled in the art and in the light of the description and drawings of the basic patent, necessarily fall under*

the invention covered by that patent. 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 filing date or priority date of the patent concerned."

133. Again, it will be seen that the CJEU emphasises the role of the person skilled in the art. Such a person will approach the construction of a patent by reference to common general knowledge. As noted previously, the reference to prior art appears to be designed to place a temporal limitation on the material that can be relied upon for this purpose by the skilled person. This seems to me to be consistent with what is said in the preceding paragraphs running from para. 47 to para. 51.

134. It is also reinforced by a consideration of what is said by the CJEU in para. 55 of the 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."

135. It is clear from the language used in para. 55 that the court envisages that both limbs of the test would be assessed by reference to "*the point of view of a person skilled in the art".* I do not believe that the CJEU can have intended that the point of view of a person skilled in the art would be influenced by an item of art which was unknown to the general pool of such persons**.** I have already explained that, in my view, this would be inconsistent with the role of the person skilled in the art, in the context of the construction of a patent, who, as Lord Hoffman explained in *Kirin-Amgen* at para. 33, "*comes to a reading of the specification with common general knowledge of the art".* It is well settled that an item of art will not enter into common general knowledge in the absence of general acceptance. That requires that it should be known to a person skilled in the art. I therefore reiterate the view expressed above that the CJEU cannot have intended to expand the pool of knowledge available to the skilled person to include material that was not generally known. In expressing this view, I am acutely conscious that I am differing from the opinion very recently expressed by Advocate General Hogan in Joined Cases C-650/17 and C-114/18 *Royalty Pharma* at para. 71 which was brought to my attention while I was writing this judgment. I have enormous respect for the Advocate General. However, for all of the reasons discussed in paras. 126-134 above, on my reading of the judgment of the CJEU in *Teva v. Gilead*, I am driven to the conclusion which I have previously set out. Lest I am wrong in that conclusion, I will address the second limb of the

test both by reference to the prior art rubric (used in the sense suggested by the plaintiff) and by reference to common general knowledge. Ultimately, I believe that the result of the present case would be the same whether one follows the approach taken by Advocate General Hogan, or whether one applies the second limb of the *Teva v. Gilead* test by reference to the common general knowledge of the skilled person.

Other aspects of the CJEU judgment

136. Although, not technically part of the guidance given by the CJEU to the referring court, the CJEU made a number of observations about the UK equivalent of the 894 patent which, although leaving it to the ultimate determination of the referring court, went so far as to express considerable scepticism as to whether the test laid down by the court could be met on the facts. This is clear from paras. 54 and 56 of the judgment where the CJEU said:-

> *"54. Thus, as regards the issue whether a claim such as Claim 27 of the basic patent in fact covers a combination such as the TD/[FTC]… combination which is the subject of the SPC at issue, it falls to the referring court to determine whether the general expression 'other therapeutic ingredients', associated with the term 'optionally', satisfies the requirement that the claims of the basic patent must relate necessarily and specifically to the product….*
>
> *55. …*
>
> *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 [FTC]… 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 [FTC]…, 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 [FTC]… 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."*

137. Counsel for the plaintiffs trenchantly argued that these observations were made without the benefit of the evidence which I have heard in these proceedings. He made the same submission in relation to the ultimate decision of Arnold J. (who had refused an application made on behalf of Gilead to adduce the evidence of Prof. Powderly in the English proceedings). That said, the observations made by the CJEU are telling and they call into question whether the test laid down by the CJEU in that

case can be satisfied in circumstances where the reference in Claim 27 to *"other therapeutic ingredients"* is in such general terms. The defendants argue that the very broad terms of Claim 27 make it impossible to meet the requirement that FTC be specifically identifiable. This is thrown into sharp focus by the use of the adverb *"optionally"* immediately before those words. It will be necessary in due course, to consider the merits of the parties' respective contentions. These are addressed in para. 154 and the following paragraphs below. Before doing so, it is necessary to briefly address:-

(a) The final decision of Arnold J. following the preliminary ruling given by the CJEU;
(b) The arguments made by the plaintiff as to whether both limbs of the *Teva v. Gilead* test must be applied; and
(c) The nature of the *"skilled person"* for the purposes of construing the 894 patent.

The decision of Arnold J. in September 2018

138. When the matter returned to Arnold J. he expressed the view, at para. 15 of his judgment ([2018] EWHC 2416 (Pat)) that, contrary to the submission made by Gilead, the first limb of the CJEU test was not a "*pure extent of protection test".* He expressed the view that the CJEU has clearly gone further than that in its judgment in *Teva v. Gilead* and he suggested that it was *"tolerably clear"* that what is required is that the product is one that the skilled person would understand, on the basis of the description and drawings and their common general knowledge, to embody the technical contribution made by the patent. At para. 38, echoing the language of the CJEU at para. 56, he drew attention to the fact that FTC is not even mentioned in the specification and that there was no basis for the skilled person to understand that the combination of TD and FTC *"embodies the technical contribution of the patent".* In his view, it is TD alone that embodies the technical contribution of the patent.

139. Insofar as the second element of the test is concerned, he expressed the view that FTC is not specifically identifiable. He said:-

> *"Once again, it is not mentioned in the Patent. It is not even a member of a specific class of compounds mentioned in the Patent, whether by reference to their structure or activity, as being suitable for combination with the compounds of the invention. Furthermore, although [FTC] … was known at the priority date, there is no evidence that it was known that [FTC] 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…".*

Further issues raised by the plaintiff in relation to the Teva v Gilead test

140. It is next necessary to consider certain arguments advanced on behalf of the plaintiff as to whether both limbs of the *Teva v. Gilead* test must be applied.

141. I am in the fortunate position that, as a consequence of the preliminary reference made by Arnold J., the CJEU has given precise guidance in relation to the manner in which Article 3(a) of the SPC Regulation is to be interpreted in the specific context of the 894 patent. In paras. 106 to 137, above I have already set out my analysis of the relevant paras. of the judgment of the CJEU. In my view, the terms of the test laid down by the CJEU are clear. The test involves two limbs, under which, the national court is required, from the perspective of a person skilled in the art (limited to matters within the common general knowledge of such persons as at the filing date or priority date of the patent), to determine:

(a) Whether the combination of TD and FTC necessarily, in the light of the description and drawings of the patent, falls under the invention covered by the 894 patent; and

(b) Whether each of those active ingredients are specifically identifiable, in the light of all of the information disclosed by the patent.

142. In my view, it is quite clear from the judgment (read as a whole) and from the specific answer given by the CJEU in para. 57 of the judgment, that both limbs of that test must be satisfied. In the course of the hearing, counsel for the plaintiff sought to suggest that the second limb of the test is *"additive"* and that if the second limb of the test was met, it must necessarily follow that the first limb is also satisfied. In my view, the CJEU was careful to lay down two separate limbs of the test, both of which must be applied. The first limb is designed to address whether the relevant combination forms part of the invention covered by the patent. The second limb must be seen against the backdrop that, as the facts of this case demonstrate, not every element of a combination may be expressly mentioned in the claims of the basic patent. Here, Claim 27 simply refers to *"other therapeutic ingredients"*. The second limb is necessary in order to ensure that the use of such a general expression does not allow a patentee to claim an unlimited number of combinations with unnamed or undescribed chemical compounds. For that reason, protection will only be available where, from the point of view of a person skilled in the art, each of the active ingredients of the combination in question are specifically identifiable as of the filing date or priority date.

143. In principle, the second limb might well be capable of being satisfied even though the first limb is not. For example, a combination may be claimed in a patent of active ingredients which are specifically identifiable to a person skilled in the art, but which do not fall within the invention covered by the patent in question. This is the very point that seems to me to be made by the CJEU in para. 43 of the judgment (quoted in para.111 above), where the court (having previously outlined the objectives of the SPC Regulation) stresses that the claims cannot allow the holder of the patent to

enjoy protection which *"is beyond that granted for the invention covered by that patent".*

144. It was also argued on behalf of the plaintiff that, if the first limb requires that the combination forms part of the invention, the second limb will add nothing whatever to the test. While there may be cases where that may well be the result, on the particular facts, I do not believe that one could safely conclude that this would always be so. For example, there may be cases where the invention includes a combination of a particular compound with another unnamed ingredient which is to be taken from a *genus* or class of compounds but where, as of the filing date or priority date of the patent, a skilled person, by reference to common general knowledge, would not specifically identify the particular ingredient in question. The CJEU may have had such a situation in mind. Whether or not that is the case, it is clear that the CJEU has laid down a two-part test and I am therefore bound to apply both parts of the test to the facts as I find them here.

145. There is one further aspect of the plaintiff's submissions in relation to the *Teva v. Gilead* test that should be addressed at this point. In the course of his closing submissions, counsel for the plaintiff indicated that if I were to conclude that the first limb was something more than the *"extent of protection"* test, the plaintiff would accept that it does not satisfy that test. In light of the views which I have already expressed about the ambit of the first limb of the test, it might appear, therefore, that this concession by counsel means that the defendants must succeed. I do not, however, believe that I can safely proceed on that basis. What counsel said was quite specific. He said that if the first limb of the test involves the *"core inventive advance"* test proposed by Arnold J. (in his judgment seeking the preliminary ruling from the CJEU) or where if it involves *"the same animal but with a different label, the technical contribution of the patent"* (which is the language that Arnold J. used in his final judgment), the plaintiff would accept that it does not satisfy such a test. While I am not convinced that Arnold J., in his final judgment, was purporting to go any further than the approach ultimately taken by the CJEU in *Teva v. Gilead,* I do not believe that it would be appropriate for me to decide this case on the basis of a *"concession"* made in the terms outlined above. As I have already indicated, I propose to decide this case by reference to the language used more consistently in the CJEU judgment, i.e. by reference to the *"the invention covered by [the] patent".* There may ultimately be no difference, in substance, between this approach and that taken by Arnold J. in his final judgment but, nonetheless, I believe it is preferable to proceed in this way.

146. I will therefore proceed to make findings in relation to the application of both limbs of the *Teva v. Gilead* test on the basis of the evidence and arguments which I have

heard. In order to apply that test, it is next necessary to consider who is the "*skilled person"* for this purpose.

The skilled person

147. In applying the test laid down by the CJEU in *Teva v. Gilead*, the court is required to interpret the patent through the lens of the skilled person (with the benefit of the common general knowledge available to that skilled person as of the relevant filing or priority date, in this case, July 1996). It is therefore necessary to consider who is the skilled person for this purpose. The plaintiff and Teva both suggested that the skilled person here would, in fact, comprise a team made up of a medicinal chemist and a clinician. In contrast, Mylan sought to make the case that the skilled person solely comprised a clinician. In this context, Mylan placed considerable emphasis on para. 0044 of the 894 patent which refers to *"the clinician"* and Mylan submitted that this was the only part of the patent that identifies the skilled person to whom it is directed. In my view, this is an unduly restrictive approach to adopt. A large part of the patent is concerned with chemical formulae which, in my view, would not readily be digested by a clinician. This was demonstrated, in very graphic terms by the inability of Prof. Powderly to identify the compound claimed in Claim 22. Even when he was given an opportunity to consider the matter further overnight, he was unable to do so on his return to the witness box on Day 10 of the hearing. Given the level of technical detail contained in the patent relating to chemical matters, it is unsurprising that a clinician would not understand every line of a patent of this kind. As Charleton J. observed in *Re. Glaxo Group Ltd* [2009] IEHC 277 at p. 39, the person skilled in the art in almost all pharmaceutical cases will be a team. In my view, that observation very obviously applies to a patent such as the 894 patent under consideration here. Having regard to the nature of the 894 patent, it would be very difficult, in this case, to apply the first limb of the CJEU test (i.e. to identify the invention covered by the patent) if the court, with the assistance of relevant expert evidence, did not approach the matter from the perspective of a team comprising an appropriately qualified medicinal chemist and a clinician.

148. The next question to be considered is what type of medicinal chemist and clinician should make up the relevant notional team of the *"skilled person"* for this purpose. In this context, over the course of the evidence (and indeed the submissions), there has been a discernible shift in the contention advanced by the plaintiff as to the type of clinician that would be involved in the team. In particular, the plaintiff has, over the course of time, sought increasingly to stress the level of expertise of the clinician in the treatment of HIV. In his first witness statement, Prof. Powderly expressed the view that the relevant team included a chemist or a pharmaceutical chemist with a university degree and a PhD with knowledge and experience in antiviral research activities, including the antiviral activity of NRTIs, in cooperation with a physician with several years of practical experience in the field of antiviral drugs and therapy,

in particular in the treatment of HIV. However, in his second witness statement, he expressed the view that the clinician in question would be a specialist HIV clinician with particular experience and interest in HIV and that: *"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".*

149. This shift became even more pronounced in the plaintiff's closing submissions where the focus on HIV treatment was further elevated. In particular, very strong reliance was placed on the decision of the EPO Board of Appeal in respect of the 542 patent which, it was submitted, was of *"crucial relevance to the characterisation of the person skilled in the art in these proceedings, as well as the common general knowledge to be attributed to that person".* In that context, the submissions quoted the following observation made by the EPO Appeal Board in relation to the 542 patent:-

> "*A skilled person working in the field of antiviral therapy, especially HIV therapy using reverse transcriptase inhibitors, would consult all available literature dealing with this topic, including literature providing information on the research pipelines of company working in this field. Such information is essential in order to keep abreast of the latest developments".*

This shift in the plaintiff's approach is clearly designed to place the focus almost exclusively on HIV treatment and on research developments in relation to such treatment with a view to bolstering the case that the literature discussed in paras 14 to 23 above (in relation to FTC) and para. 35 (in relation to TD) and the other literature identified in the course of the hearing would have been read not only by the skilled person but also would have formed part of the relevant common general knowledge for that purpose. However, that ignores the very plain terms of the patent itself which, as discussed in paras. 33 to 34 above, is very clearly concerned with a whole range of viruses. It is not focused purely on HIV. Insofar as the plaintiff seeks to call in aid the Appeal Board decision, this seems to me to be inappropriate. As counsel for Teva submitted, the decision of the Appeal Board in respect of the 542 patent must be seen in the very specific context of that patent which, in the form ultimately considered by the Appeal Board, was narrowly focussed on HIV infection. The patent related to a combination of TD and FTC by name and the utility of the invention (as expressly described in the patent) was the treatment or prevention of the symptoms or effects of HIV infection. In 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.

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.

152. As noted at an earlier point in this judgment, there was significant disagreement between the witnesses as to the extent of the journals that would be read by the notional skilled person. Dr. Hawkins considered that the skilled clinician would not read *"Antimicrobial Agents and Chemotherapy"* which he suggested would be more relevant to a microbiologist. However, it is clear from Prof. Roberts' evidence that this journal was on his reading list and it might therefore be suggested that the knowledge of the chemist should be imputed to the clinician. In this context, it is well settled that the common general knowledge to be attributed to each member of a team will be regarded as pooled with the other members of the team. Nonetheless, it is equally important, in this context, to bear in mind that, merely because a particular disclosure is made in an article in a scientific journal, that makes the article part of common general knowledge. In *Bohringer Ingelheim's patent* [2017] IEHC 495, at para. 40, Barrett J. approved the explanation of common general knowledge given by Sachs LJ. in *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co.* [1972] RPC 457 at p. 483 where he said:

> *"As regards scientific papers generally, it was said by Luxmoore J. in British Acoustic Films:*
>
> > *'In my judgment it is not sufficient to prove common general knowledge that a particular disclosure is made in an article, or a series of articles, in a scientific journal, no matter how wide the circulation of that journal may be, in the absence of any evidence that the disclosure is accepted generally by those who are engaged in the art to which the disclosure relates. A piece of particular knowledge as disclosed in a scientific paper does not become common general knowledge merely because it is widely read, and still less because it is widely circulated. Such a piece of knowledge only becomes general knowledge when it is generally known and accepted without question by the bulk of those who are engaged in the particular art; in other words, when it becomes part of their common stock of knowledge relating to the art'.*
> >
> > *And a little later, distinguishing between what has been written and what has been used, he said:*
> >
> > > *'It is certainly difficult to appreciate how the use of something which has in fact never been used in a particular art can ever be held to be common general knowledge in the art'.*

Those passages have often been quoted, … We accept them as correctly stating in general the law on this point, though reserving for further consideration whether the words 'accepted without question' may not be putting the position rather high: for the purposes of this case we are disposed, without wishing to put forward any full definition, to substitute the words 'generally regarded as a good basis for further action'."

153. The mere fact, therefore, that one very highly qualified medicinal chemist such as Prof. Roberts has read the journal in which the Frick papers appeared does not establish that the material in question forms part of the common general knowledge of the skilled person here. It will be necessary, in due course, to consider whether the information contained in the particular publications on which the plaintiff relies can be said to have become part of the common general knowledge of the notional skilled person (i.e. the team which I have attempted to describe above).

Applying the First Limb of the Teva v. Gilead test

154. Under the first limb of the *Teva v. Gilead* test, I am required to consider, from the perspective of the person skilled in the art, whether, on the basis of the common general knowledge of such a skilled person as of the priority date of the 894 patent, the combination of TD & FTC *"**must** necessarily, in the light of the description and drawings of the patent, fall under the invention covered by that patent"* (emphasis added).

155. I bear in mind in this context, the observation made by the CJEU in para. 56 of its judgment, that the description of the patent contains no information as to the possibility that the invention could relate specifically to the combined effect of TD and FTC for the purposes of the treatment of HIV. The CJEU added that, as a consequence, it did not seem possible that a person skilled in the art would be able to understand that FTC in combination with TD necessarily falls under the invention covered by the patent. That observation is not, of course, binding on the national courts in relation to the 894 patent. As the CJEU made clear, the onus is on the national court to check whether *"such is indeed the case".* During the course of the hearing, counsel for the plaintiff forcefully argued that the observations made by the CJEU in para. 56 of its judgment were made without the benefit of the evidence which I have heard in these proceedings. In contrast, that evidence is available to me to assist in my determination of this issue through the lens of the skilled person.

156. I confirm that I have derived considerable assistance from all of the experts who have given evidence in this case. During the course of the hearing, an issue was raised by the defendants as to the weight to be given to the evidence of Prof. Powderly insofar as there is a conflict between his evidence and the evidence of the experts called on behalf of the defendants. The issue raised by the defendants in

relation to the weight to be given to Prof. Powderly's evidence was prompted by a number of factors. These included: (a) Prof. Powderly's previous association with the plaintiff in the United States; (b) his unfamiliarity with certain aspects of the patent (in particular Claim 22), discussed above, notwithstanding that Claim 22 had previously been explained in the evidence of Prof. Roberts in his second witness statement; and (c) the surprising fact that he did not reveal in his witness statements that he had never seen the Wang abstract prior to it being brought to his attention by the lawyers acting for the plaintiff in these proceedings. In relation to the last point, it is very difficult to understand why Prof. Powderly did not mention that fact in his witness statements given the extent of the reliance placed by him, in his witness statements, on the Wang abstract. For completeness, I should make clear that Prof. Powderly did mention this fact in his direct evidence. Subsequently, in the course of Prof. Powderly's cross-examination by counsel for Mylan, he acknowledged that the Wang abstract was the only *"published data in relation to putting FTC into humans"* that he was aware of and that it was provided to him for the purpose of his witness statement. That had not been stated in his witness statement. It should be recalled at this point, that both Prof. Powderly and Dr. Moyle attended the ICAAC conference at which the abstract was available but neither of them have any recollection of seeing it. Thus, in his witness statement, Dr. Moyle thanked Prof. Powderly for bringing the Wang abstract to his attention and he pointed out that, notwithstanding that he had presented a paper at the ICAAC conference, he was unaware of the Wang abstract. Although Prof. Powderly responded in detail to Dr. Moyle's witness statement, he never said that he had likewise been unaware of the Wang abstract. Nonetheless, Prof. Powderly went so far as to suggest, in para. 6.5 of his second witness statement that he had no doubt that a number of HIV clinicians in attendance at the conference would have viewed and been interested in the abstract. In the course of his cross-examination on Day 10, Dr. Powderly had no convincing explanation for his failure to disclose in his witness statement that he had not previously seen the Wang abstract prior to its being brought to his attention in the course of his preparation for giving evidence in these proceedings. This is particularly surprising in light of what was said by Dr. Moyle in para. 7.4 of his third witness statement where he referred to a number of reviews of the ICAAC conference including a paper co-authored by Prof. Powderly that did not refer to Wang. I should have thought that, at that point, Prof. Powderly would have drawn attention to the fact that he had not seen the abstract himself. Yet, when Prof. Powderly came to respond to this in para. 6.3 of his third witness statement, all he did was to explain that he did not write any part of the review of the conference and had no editorial input in the review in question. I have to say that it is incomprehensible that Prof. Powderly did not, at that point, explain that he had not himself seen the Wang abstract at the time. That said, I am not sure that anything turns on that issue insofar as the application of the first limb of the *Teva v. Gilead* test is concerned. It is an issue to which I may have to return when I consider the second limb of the

test. Insofar as the first limb of the test is concerned, there was ultimately very little disagreement between the experts in relation to the nature of the invention disclosed in the 894 patent. As discussed in more detail below, in the course of his cross-examination on this issue by counsel for *Teva*, Prof. Powderly was very honest and forthright in his answers. In the circumstances, I do not believe that it is necessary, in relation to this limb of the test, to adjudicate on the contention of the defendants that less weight should be given to the evidence of Prof. Powderly than to the other expert witnesses called on behalf of the defendants. For completeness, it should be noted that the case was made, without explanation, in the plaintiff's closing submissions, that Prof. Powderly's evidence should be preferred to that of the defendants' experts but no justification was ever offered for that proposition and I can see none.

157. As the only expert in medicinal chemistry called to give evidence, I found Prof. Roberts to be of very considerable assistance in understanding how the patent would be read by the skilled person. The medicinal chemist is the relevant member of the skilled team in relation to a substantial part of the patent. As noted in para. 29 above, he gave evidence to the effect that the invention is aimed at improving the bioavailability of polar compounds by providing intermediates which overcome the problem caused by the polarity. His evidence is confirmed by a consideration of the terms of the patent. As further noted in para. 29 above, the patent is entitled *"Nucleotide Analogs".* There is nothing in the description of the invention given in para. 0001 or 0002 which relates to the combination of TD and FTC or to any combination at all. Again, as noted in para. 29 above, the patent describes the invention as relating to: *"intermediates for phosphonomethoxy nucleotide analogs, in particular intermediates suitable for use in the efficient oral delivery of such analogs".*

158. Similarly, there is nothing in the summary of the invention given in paras. 0003 to 0004 which relates to a combination between TD and a second ingredient such as FTC. Paragraphs 0007 to 00117 all fall under the heading of "*Detailed description of the invention".* Only one of those paras. refers to a combination namely para. 0047. This occupies no more than four lines of the 43 pages of the patent running from para. 0007 to 0117. It is noteworthy that in para. 0036, the patent provides significant detail as to exemplary embodiments in relation to the compounds claimed but there is no equivalent detail provided in relation to any of the "*other therapeutic ingredients"* which are mentioned in para. 0047 and in Claim 27.

159. It is also of some significance that para. 0037 (which deals with the stability of the compounds of the invention) does not address the stability of any combination. Similarly, para. 0038 provides information as to how to make the compounds. There is no equivalent information provided in relation to the *"other therapeutic*

ingredients". Furthermore, as a matter of ordinary English, the phrase *"other therapeutic ingredients"* has a very broad meaning and there is nothing in the terms of the patent which confines those words to anti-retroviral drugs for the treatment of HIV. As noted in para. 40 above, paras. 0049, 0051 and 0056 describe a number of routes of administration of the invention which, as Prof. Powderly confirmed, in the course of his cross-examination, are not relevant to HIV. As observed in the Teva written closing submissions, the phrase *"other therapeutic ingredients"* could cover, for example (with reference to para. 0051 of the patent) an antiseptic to be administered in a co-formulation with a topical ointment.

160. Insofar as the examples are concerned, none of the examples addresses a combination involving one of the compounds of the invention and another *"therapeutic ingredient".* Although the plaintiff and Prof. Powderly have sought to place significant emphasis on example 16 (one of seventeen examples in total) this example focuses not on a combination including another *"therapeutic ingredient"* but on a monotherapy namely PMPA and its carbonates.

161. Insofar as para. 0047 is concerned, there is, of course, a reference (consistent with Claim 27) to *"other therapeutic ingredients"* which can be combined *"optionally"* with one of the active ingredients (defined earlier in the patent). However, no information whatever is provided anywhere in the patent in relation to any such optional therapeutic ingredient. The words *"other therapeutic ingredients"* are used in a very generic way. It might even be said that the term *"other therapeutic ingredients"* is used in the same generic way as *"one or more acceptable carriers"* which appears in the same sentence of para. 0047.

162. Ultimately, the proper construction of the patent is, of course, a matter for the court. However, as noted above, the court approaches this task through the lens of the skilled addressee. For that reason, the evidence of the expert witnesses is helpful. They have an understanding of the relevant science underlying the patent. For the purposes of para. 47 of the judgment of the CJEU, they are also in a position to assist the court insofar as common knowledge is concerned. In this context, as outlined in paras 26-27 above, Prof. Roberts, in his evidence, explained that, prior to the 894 patent, PMPA and a number of other compounds within the phosphonate group, such as PME (the prodrug for which is the subject of Claim 19 of the patent), HPMP (the prodrug for which is now the subject of Claim 22 of the patent) had been identified in a number of animal studies and *in vitro* as demonstrating good activity against a number of viruses and retroviruses. While PMPA had shown some promise (as noted, *inter alia,* in the article authored by Tsai discussed at para. 35 above) against HIV, a number of HPMP derivatives had been shown to be active against DNA viruses. However, the problem was that, as described in para. 26 above, phosphonomethoxy nucleotide analogues are quite "*polar"* such that they are not readily able to cross

cell membranes. This is a very important aspect of the factual background against which the patent falls to be construed.

163. The plaintiff also seeks to rely, as part of the relevant factual background, on the significance of the AIDS crisis in 1996 and on the fact that, as of the priority date of the 894 patent, combination therapy had become the standard of care for HIV patients. The plaintiff does so in the hope that that this element of the factual background can, in some way, overcome the difficulty thrown up by the very wide terms of the patent which it drafted. Ultimately, this is a question of greater relevance to the second limb of the *Teva v Gilead* test and is addressed in more detail in paras. 174-185 below. It is sufficient at this point to say that I agree that the AIDS crisis and the standard of care for HIV patients are part of the relevant background against which the patent falls to be construed. However, I do not believe that it is plausible to suggest that the patent is focussed on HIV treatment to the extent claimed by the plaintiff. Given the very significant public health concerns that arose in the years prior to 1996 in relation to HIV and the difficulty in finding a successful treatment for it. I accept that HIV is an important element of the background against which the patent is to be construed. That said, the patent very plainly extends to a very wide range of infections including, for example, Hepatitis B which was also a very significant concern as of the priority date of the patent with very large numbers of infected people around the world and a risk of mortality from the disease. Paragraph 0044 of the patent (quoted in para. 33 above) makes it very clear, as Prof. Roberts observed, that the patent is claiming wide utility in relation to a large range of common viruses in humans as well as some viruses in animals. Similarly, insofar as clinicians are concerned, Dr. Moyle gave evidence that a clinician would understand from para. 0044 that the compounds of the patent could be useful in the treatment or prophylaxis of a very wide range of viral infections in man and animals. As the author of the patent, the plaintiff must take responsibility for its terms. It is not for the court to rewrite the patent. Nor is there any reason to believe that no rational patentee would have intended to claim such a wide range of utility for its invention. Based on a reading of the patent, construed against the background I have briefly described, I cannot identify any basis on which to construe para. 0047 or Claim 27 as focussed solely or principally on HIV. Both para. 0047 and Claim 27 must be seen in the context of the patent as a whole. Both the terms of the patent and the factual background (where Hepatitis B was also a major worldwide health concern as of July 1996) strongly support the defendants' case that the patent cannot be construed in the manner suggested by the plaintiff. I appreciate that Example 16 is specifically referable to the activity of PMPA and certain PMPA carbonates against HIV-1. However, I accept Prof. Roberts' evidence that the purpose of Example 16 is to show how easily the molecules pass through cell membranes in a HIV infected cell, the end point being to show how much of the HIV is killed. I also accept his evidence that while the example addresses the HIV virus, the purpose of the example is simply to

demonstrate the effect of the prodrugs and the example could equally set up a system with the herpes virus. Furthermore, as noted in para. 42 above, Example 16 must be read in light of the opening words of para. 0067 which, in the plaintiff's own language, makes very clear that the examples are not to be construed as limiting the invention. Example 16 cannot therefore be given the level of importance attributed to it by Prof. Powderly and the plaintiff's legal team. During the course of the hearing, the plaintiff has sought to establish, through cross examination of the defendants' experts, that HIV is the primary focus of the patent. It was put to the defendants' experts that HIV was the most significant public health concern at the relevant time. It was also put to the defendants' experts that example 16 was focussed on HIV treatment and that TD was also perceived as a HIV treatment and was the most significant compound disclosed in the patent. In addition, in the course of the cross-examination of Dr. Hawkins, evidence that he had given to a court in Finland was drawn to his attention where he had appeared to support the statement that HIV is the most important of the diseases relevant to the patent. However, Dr. Hawkins carefully explained that, in his view, the patent is relevant to a number of important viruses. While HIV was important to him as of the priority date, there were other important infections that were also causing significant clinical morbidity at the time. He maintained the position that the skilled person would have an interest not only in HIV but in other viruses or retroviruses. On Day 6 at p. 55, he stressed:-

> "*But the patent is describing a very large number of compounds against a lot of medically important viral infections both in man and animals. So to dismiss those as not being important would be incorrect. They are all important. HIV was a very important problem at the time and if you ask me what was affecting me at the time, yes HIV was very important. But I have been asked to look at the patent and what that says…. HIV was an important part and for some people it would be the most important part, for others who were interested in other viruses and whatever then those would be important".*

It was put to Dr. Hawkins that TD was an anti-HIV compound. He confirmed that it was but he added that it also had very good activity against Hepatitis B. With regard to his evidence in the proceedings in Finland, Dr. Hawkins explained at pp. 74-75 on Day 6 that he certainly believed that HIV was the most important illness or disease at the time but he stressed that HIV was an important part of the patent rather than the sole focus of the patent. For a moment, he appeared to accept the proposition (put to him by counsel for the plaintiff) that HIV was the most important focus of the patent albeit not sole focus. However, he very quickly qualified his evidence in the following terms:-

> "*Yes, it was an important part. I mean, I think there's a debate about whether it's the most important part, because it's describing so many compounds".*

This evidence by Dr. Hawkins has to be seen against the backdrop that, for him personally, HIV was the most relevant disease. While Dr. Hawkins had a background in the treatment of sexually transmitted diseases generally and had also worked in the area of hepatitis treatment, it was clear from his evidence that, by 1996, his principal area of expertise was in HIV treatment. The same consideration arises in relation to Dr Moyle and Prof. Powderly. As noted in para. 150 above, there is always a concern in these cases that a specialist will look at a patent through the prism of his or her particular specialisation. I must bear in mind that a HIV expert will be inclined to look at the patent from the perspective of his or her particular expertise and experience. Given 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 most important focus of the 894 patent. For completeness, I examine the evidence in relation to this issue in more detail in paras. 176-185 below in the context of the second limb of the test. For the reasons discussed in those paragraphs, I believe that an examination of the evidence strongly supports this conclusion.

164. Moreover, I do not believe that the plaintiff improves its position by placing such emphasis on the importance of the standard of treatment for HIV patients as of the priority date of the patent. It is quite clear from all of the evidence that I have heard that, save in a very small minority of cases, combination therapy had become a necessity if there was to be any hope of controlling the progress of the disease in HIV patients. Neither para. 0047 nor Claim 27 give any indication that the compounds of the patent **must** be used in combination with other therapeutic ingredients (still less other anti-retroviral drugs) in the treatment of HIV. The co-formulation of one of the compounds disclosed in the patent with another therapeutic ingredient is described as optional. In the circumstances, I do not believe that it is plausible to construe para. 0047 and Claim 27 as referable to combination therapy for HIV patients. Neither para. 0047 nor Claim 27 use language which **requires** the compounds of the invention to be used in combination with *"other therapeutic ingredients"* such as an NRTI. In these circumstances, while I acknowledge that the standard of care for HIV patients as of the priority date of the patent is a factor to bear in mind as part of the backdrop to the patent, I do not believe that it assists the plaintiff insofar as the interpretation of the patent is concerned.

165. In my view, the evidence overwhelmingly supports the conclusion that the invention does not extend to the combination of TD and FTC. Each of the experts who gave evidence (including, ultimately, Prof. Powderly himself) perceived the invention to be the pro-drugs that enable bioavailability of the relevant compounds in man and animals, whether administered orally, or by any one of the other specified methods, for the treatment of the very wide range of viral infections covered by the patent. Prof. Roberts explained this very clearly on Day 2 at p. 127 where he said:-

"We have as the active ingredient the phosphonate, which … through its physical property, being polar, has difficulty getting into the bloodstream as an oral preparation. So the whole basis of the patent, in my view, is taking these phosphonates, making derivatives of them and then making them less polar, suitable for oral administration – in other words they can cross from the gastrointestinal system into the bloodstream and then either delivering the warhead to go into the cell with any of the prodrug remains, it can get into the cell effectively, very effectively and knock down the virus".

166. That evidence was given by Prof. Roberts with regard to viruses generally. It was not focussed solely on HIV. As noted previously, Prof. Roberts was the only medicinal chemist to give evidence in this case. In my view, his evidence in relation to this issue was entirely convincing and I fully accept it.

167. Furthermore, when Prof. Powderly came to be cross-examined by counsel for Teva, he did not disagree with the evidence of Prof. Roberts. On Day 9 at p. 117 he was asked, in very simple and straightforward terms, to summarise what he understood the scope of the invention to be. His answer was as follows:-

"It is a considerable series of derivations of and to the basic molecule to attempt to create more stable structures that might be suitable for administration in an oral form to humans".

168. Prof. Powderly was then asked whether he was familiar with Prof. Roberts' evidence. He confirmed that he was. He was then asked whether he disagreed with Prof. Roberts' evidence in relation to the scope of the invention and he confirmed that he did not have any major disagreement with it. At p. 118, he was pursued further in relation to the ambit of the invention. The relevant exchange between counsel for Teva and himself was in the following terms:-

"Q. I don't want to be nit-picking about this, the invention doesn't involve a combination of anything, does it?
A. I will accept that".

169. At that point, counsel for the plaintiff intervened to object to a specific question that the combination of TD and FTC does not fall within the invention. Counsel for the plaintiff contended that this was a question of law for the court. A debate then ensued as to whether counsel for Teva was entitled to ask Prof. Powderly about the limits of the invention. In circumstances where I am required to ultimately determine the issues through the lens of a notional skilled person, I ultimately allowed a question to be asked as to what the Prof.'s understanding was of the limits of the

invention. The following exchange then took place between counsel for Teva and Prof. Powderly at p. 120:-

"Q. … so, Prof., can you help in terms of defining for the court what … the skilled person in the art at the time would've felt to be the limits of the invention?

A. I think for the purposes of the invention, my understanding would be that we were looking at compounds that are oral equivalents, or oral preparations that would allow – how shall I put this – the creation of oral drugs or oral compounds from the primary PMPA product.

Q. The creation of an analogue?

A. Mm hmm.

Q. Yes? And an intermediate being the prodrug, yes?

A. Yes.

Q. … in a form suitable for use in the efficient oral delivery of those analogues, yes?

A. Yes.

Q. That's … the scope of the invention, isn't it? That's the invention. They've invented these analogues and these prodrugs?

A. (Witness Nods)."

170. This evidence on the part of Prof. Powderly is consistent with what he said in para. 7.2 of his second witness statement where he explained that the problem with PMPA was *"solved by the Patent".* I believe it is fair to say that the evidence of the experts on both sides ultimately arrived at the same view as to what the skilled person would regard as the invention covered by the patent to be. Their evidence coincides with my own reading of the patent which, for all of the reasons outlined in para. 157 to 162 above, seems to me to focus on the prodrugs and to treat the optional "*other therapeutic ingredients"* as incidental. This is reinforced by the use of the adverb *"optionally".* There is, in reality, nothing in the terms of the patent to suggest that the combination referred to in para. 0047 forms part of the invention. Of course, Claim 27 makes a claim in relation to such a combination but, for all of the reasons discussed above, it seems to me that the CJEU is careful to make a distinction between the monopoly claimed on the one hand and the limits of the invention on the other. While the plaintiff has claimed a monopoly over a combination comprising one of the compounds within any of Claims 1-25 and *"other therapeutic ingredients",* there is no basis on which to form the view that the combination of TD and FTC falls within the ambit of the invention described in the patent.

171. In these circumstances, I have come to the conclusion that, applying the first limb of the test in *Teva v. Gilead,* the combination of TD and FTC does not fall under the invention covered by the 894 patent. Accordingly, the Truvada product (comprising the combination of TD and FTC) cannot be said to be protected by a basic patent in

force under Article 3 (a) of the SPC Regulation. Strictly speaking, it is therefore unnecessary to consider the second limb of the test in *Teva v. Gilead*. Nonetheless, in the event that my decision in relation to the first limb is appealed by the plaintiff, I set out my views in relation to the second limb below.

The application of the second limb of the test in Teva v. Gilead

172. Under the second limb of the test in *Teva v. Gilead,* I must consider, from the point of view of a person skilled in the art (on the basis of a common general knowledge of such person as at the priority date of the 894 patent), whether each of TD and FTC can be said to be *"specifically identifiable"* in the light of all of the information disclosed by the patent. For this purpose, no one has contended that TD is not specifically identifiable. It is identified by name in the patent. The question is whether FTC can be said to be *"specifically identifiable"* to a person skilled in the art as of July 1996 as an *"other therapeutic ingredient"*.

173. In order to apply the second limb of the test, it is necessary to consider what was within the common general knowledge of the skilled person as of July 1996 in relation to FTC. This was an issue which gave rise to very considerable debate in the course of the hearing before me. As noted previously, the plaintiff took the position that the test requires the court to consider whether FTC could have been specifically identified by the skilled person from a document in the prior art. For the reasons discussed in paras. 120 to 129 above, I do not believe this argument is correct. However, the plaintiff submitted in the alternative, that the evidence here, goes well beyond establishing that FTC could have been identified by the skilled person by reference to a document available in the prior art. According to the plaintiff, the evidence demonstrates that FTC formed part of the common general knowledge and was identifiable not merely at a generic level but was identifiable specifically by name as a potential combination partner for TD. It was also submitted that the evidence establishes that FTC was one of only a limited number of combination partners for TD that were identifiable by the skilled person as of the priority date. As I have indicated in para. 135 above, I will address the second limb of the test both by reference to the *"prior art"* approach advocated by the plaintiff and now supported by Advocate General Hogan and also by reference to my own view that the second limb is to be assessed by reference to the common general knowledge of the skilled person. In both cases, it is important to bear in mind that, it is a foundation of the plaintiff's case that HIV is the focus of Claim 27.

The plaintiff's contention that HIV is the focus of Claim 27

174. It was confirmed by counsel for the plaintiff, in the course of his closing submissions on Day 12 of the hearing, that the plaintiff's case is founded on the proposition that Claim 27 will be read by a skilled person as focussed on the treatment of HIV and in the knowledge that the focus of HIV treatment, as of the priority date, was

combination therapy involving either a second NRTI or a second NRTI and a PI. Counsel submitted that the skilled clinician would, for the reasons articulated by Prof. Powderly, have read Claim 27 as being concerned with HIV and would have read that as being concerned with combination therapy in the sense of use of two NRTIs (or the use of those two agents together with a PI).

175. Counsel argued that, on the basis of the evidence, the skilled person reading Claim 27 would identify FTC as not just a promising partner of TD but as one of a relatively short list of agents that would be perceived as potential partners of TD. Counsel submitted that it did not matter how far down that shortlist FTC might be. The crucial factor was that it was on a relatively short list.

The evidence does not support the plaintiff's contention

176. In substance, I have already rejected this contention for all of the reasons discussed in para. 163 above. I will nonetheless address it here in the context of the second limb of the *Teva v Gilead* test. There are additional features of the evidence that are relevant in that context. At this point, it is important to draw attention to an element of Prof. Powderly's evidence in relation to Claim 27. Although Prof. Powderly had strongly put forward in his witness statements and in his direct evidence that Claim 27 would be construed by the skilled clinician as referable to HIV, he made a number of important concessions while under cross-examination. In the course of that cross-examination, Prof. Powderly was taken, very carefully, by counsel for Teva, through the patent. On Day 9 at p. 125 Prof. Powderly accepted that the utility of the patent is stated in terms that every skilled clinician would understand as being available for every form of virus. He also acknowledged that, insofar as HIV is concerned, it was simply one of the viruses on the list of viruses mentioned in para. 0044. He also acknowledged that several of the forms of administration addressed in para. 0046 and following paras. were inapplicable to HIV. At p.p. 129-130 of the transcript of Day 9, with reference to the terms of the patent up to and including para. 0047, it was put to Prof. Powderly that there is nothing to suggest that the patent addresses only HIV or focusses on HIV. His response was straightforward: *"that is correct".* Subsequently, at p. 131 on the same day, Prof. Powderly said:-

> *"As you have clearly pointed out, Mr. O'Moore, the patent is very broadly directed for antivirals, any possible antivirals. And certainly if one was developing a product out of this patent for the treatment of Herpes, one would want to have products that were oral or cream. I don't disagree with you that this is a very broad patent that has referenced many viruses".*

177. At p. 132 Prof. Powderly qualified what he said in the following terms:-

"I fully accept your point that this is a very broad patent. It is a catch all patent, to put it mildly. That said, it takes, I think, nothing away from a viewpoint that ultimately the primary purpose of this patent and the primary development purpose of this product, [TD] was to be HIV".

178. At p. 133 he explained that, given the fact that HIV was *"the most important virus infection of the time"* and given the fact that preliminary data for PMPA was in relation to HIV, the target of the patent was the treatment of HIV. Prof. Powderly was then taken by counsel through Example 15 and Example 16 and the evidence given by Prof. Roberts in relation to those examples. In particular, he was taken to the evidence of Prof. Roberts to the effect that it is the prodrug element of Example 16 that is important. Prof. Powderly confirmed that he agreed with the evidence given by Prof. Roberts and that the emphasis of Example 16 is on the antiviral activity of the prodrug. However, Prof. Powderly suggested that the example was chosen deliberately to demonstrate anti-HIV activity and it could not be used to demonstrate anti-herpes activity or anti-hepatitis activity. Prof. Powderly maintained that Example 16 demonstrated that the patent was focussed on HIV. He was then asked at p. 149 whether that means that the other viruses are somehow less important as a result of Example 16. His answer was that he believed this to be so. It was at this point that Prof. Powderly was cross examined about the claims of the patent. It was put to him that he laid some emphasis on Claim 25 (which is the claim relating specifically to TD). He said that Claim 25 was important because TD has significant activity against HIV. He was then asked why Claim 25 was more important than Claim 22. He was not in a position to answer that question. As noted above, he was still not in a position to answer that question on Day 10. On Day 10, at p. 5, he accepted that, not being a medicinal chemist, he could not say specifically what compounds are covered by Claim 22 and what their activity might be. The evidence of Prof. Roberts (which Prof. Powderly confirmed he had read) on the issue was then brought to his attention. Prof. Roberts' evidence was that the patent described a wide range of phosphonate prodrugs which included PME (Claim 19), HPMP (Claim 22) as well as PMP (Claim 4). He was then asked whether, armed with that information, he was in a position to venture a view that Claim 22 was less or more significant than Claim 25 or equally significant. His response was that: *"they both have significance. It would be difficult for me to say that I would say that one is more than the other".* He was then referred back to an article by De Clercq from 1993 which described HPMP compounds as being suitable for the treatment of herpes, hepatitis B and cytomegalovious virus. It was put to him that in those circumstances Claim 22 is significant and he accepted that it was. At that point, he was able to see from the material that was put to him by counsel for Teva that Claim 23 related to HPMPC which he acknowledged was a broadly active antiviral compound.

179. Prof. Powderly also confirmed that the compounds claimed at Claims 22 and 23 were either not effective against or of limited effect against retroviruses but that they were effective against DNA viruses. At that point, at p. 9 on Day 10 the following exchange took place between Prof. Powderly and counsel for Teva:-

"Q. Then it follows, therefore, that if Claims 22 and 23 are as important as we have agreed, that they would fall within the compounds claimed in Claim 27 because, as we discussed at the start of the cross examination, Claim 27 is not exclusive to the treatment of HIV. Isn't that right?

A. I don't disagree with you."

180. At p. 18 on Day 10 Prof. Powderly was asked about Claim 27 and in particular whether that claim was focussed on HIV. He confirmed that there was no reference to any particular virus in that claim. The following exchange then took place between counsel for Teva and Prof. Powderly at p. 19:-

"Q. … And Claim 27, in the light of the answer you have just given, given there's no reference to the treatment of HIV and it refers to any one of the Claims 1 to 25, is that focussed on the treatment of HIV?

A. No. I agree, Mr. O'Moore.

Q. Yes. So Claim 27 does exactly what it says on the tin…Prof.. It describes that the claim covers a composition, a pharmaceutical composition comprising of a compound according to any of the Claims 1 to 25, isn't that so?

A. That is correct."

181. This exchange between counsel for Teva and Prof. Powderly is important. I believe it shows very clearly that (understandably) Prof. Powderly had approached the patent from his very particular expertise as a HIV specialist and, as a consequence, he did not pay sufficient attention to the other aspects of the patent. This led him, in my view, to much too readily conclude that Claim 27 was focussed substantially on HIV. When he was taken through the patent, in the careful and comprehensive way in which counsel for Teva proceeded, Prof. Powderly very properly acknowledged that Claim 27 was not as narrowly focussed as he had previously suggested when looking at the patent from his perspective.

182. For completeness, I should record that, at p. 28 on Day 10, Prof. Powderly sought to bring commercial interests into play in relation to his understanding of the patent. He said that, given the importance of HIV, and the fact that TD (being within the PMPA family) had clear activity against HIV and that HIV was a public health emergency, it would be natural for a pharmaceutical company to focus on that element of activity that was likely to give a company its greatest commercial success which, as of 1996, he suggested would be HIV. In the context of the construction of

a patent, I do not believe that evidence of this kind can be accepted. In the context of the construction of a patent, there is very limited scope for commercial considerations. The correct legal position was explained as follows by Clarke J. in *Rambaxy Laboratories Ltd v. Warner-Lambert Co.* [2007] IEHC 256 at para. 3.30 as follows:-

> *"Just as it is no part of a court's function to rewrite a commercial contract because the commercial bargain may appear somewhat one sided, so equally it is no part of the role of a court in construing a patent to look at the commercial benefits that the patentee might obtain from it. I do not understand the Court of Appeal to have adopted a principle of that variety. It did not consider that the court should ask itself if the patentee might have done better commercially had he meant X rather than Y and thus assume that the patent should be construed as X because interpreted in that way it would be a 'better' patent from the commercial perspective of the patentee…."*

Clarke J. was there considering the decision of the Court of Appeal in England & Wales in parallel litigation in that jurisdiction. At para. 3.32 he continued as follows:-

> *"From paragraph 20 of the judgment of Jacob L.J. it is clear that the form of interpretation which should be leaned against is one which 'no rational patentee would have intended'. There is not, therefore, a principle of construction to the effect that the Court should lean in favour of an interpretation which might be perceived to be more commercially beneficial from the perspective of the patentee. There can, as a number of the authorities have pointed out, be all sorts of reasons why a patentee may choose to limit his claim in one fashion or another. I am, however, satisfied that, just as a court will lean against the construction of a commercial contract where it can be shown that the construction contended for would lead to a commercial nonsense, so also should a court in construing a patent adopt an analogous approach and lean against a construction for which there is no rational basis from the perspective of the patentee…."*

183. Crucially, there is nothing in the evidence which I have heard in the present case which would provide any proper basis to conclude that the construction of the 894 patent, in accordance with its express terms, would lead to an irrational or wholly uncommercial result. There was no evidence tendered by the plaintiff that it would have been commercially unviable in 1996 (or that this would have been known to the skilled person as of that date) to develop drugs aimed at Hepatitis B or Herpes for example. Furthermore, as noted in para. 48 above, the article in the January 1996 Journal of Ophthalmology dealing with combination therapy in the treatment of

those infected with cytomegalovious shows that combination therapy was not peculiar to the treatment of HIV.

184. The cross examination of Prof. Powderly then concluded on this issue in the following terms at p. 29 on Day 10:-

"*Q. … of course you have not disputed, I think, the evidence that was given by Dr. Hawkins about the scale of deaths caused by Hepatitis B, isn't that so?*

A. I have, however, also indicated that I believe that the scale and nature of HIV at that time was the greatest threat in infectious diseases that we knew of.

Q. Yes. So in terms then of where we are in respect of the patent, you maintain the position you said a moment ago that the focus of the patent was on HIV? Is that correct?

A. We may be slightly differing in our understanding or terminology. I would say that the focus of development from this patent was for HIV.

Q. … I disagree with you about that, Prof., as do my witnesses – but in terms of Claim 27, we do agree that that claim includes all compounds listed in Claims 1 to 25, and therefore it follows I think that the potential therapeutic ingredients referred to in that claim would be therapeutic ingredients which may be suitable for combination with those compounds; isn't that right?

A. That appears to be correct to me".

185. It will be seen from the exchange between counsel for Teva and Prof. Powderly quoted in para. 184 above that Prof. Powderly sought to maintain the position that the focus of the patent was on HIV. However, while Prof. Powderly valiantly sought to maintain that position, I do not believe that this is a credible position to adopt. Again, I believe it is likely that Prof. Powderly is, understandably, looking at the patent through his very specialised eyes as a dedicated and highly motivated HIV clinician. I wish to make it very clear that I do not criticise Prof. Powderly. I can well appreciate why his particular focus is on HIV. His long involvement in efforts to treat and combat this highly challenging disease provides an explanation for the viewpoint which he has sought to stand over. However, his cross-examination (which I have sought to summarise above) has demonstrated to me that, ultimately, his view on this issue does not withstand scrutiny. As a last resort, he was driven to rely on claimed commercial considerations to justify his position. For the reasons already explained in para. 182 above, I must reject that explanation. As outlined in more detail above, Prof. Powderly made a significant number of concessions during the course of his cross-examination as to the ambit of the patent. In my view, Prof. Powderly was absolutely correct to make those concessions. It was inevitable that those concessions would have to be made given the very clear and comprehensive terms of the 894 patent which, as I have already explained, are not focussed on HIV in particular. For these reasons, I am of opinion that the foundation for the plaintiff's

case - that Claim 27 is focussed on the treatment of HIV - collapses. As noted in para. 168 above, counsel for the plaintiff confirmed that this is the foundation of the plaintiff's defence to the counterclaim. It was on that basis that the plaintiff made its submission that, on the basis of the evidence, the skilled person would read Claim 27 as identifying FTC as not just a promising partner of TD but one of a relatively short list of agents that would be perceived as potential partners of TD in combination therapy. In light of the views expressed above, it must follow that the second limb of the *Teva v. Gilead* test cannot be satisfied in this case. As explained in more detail below, that is not, however, the only basis on which I have concluded that the second limb of the test is not satisfied.

The terms of Claim 27 are also inconsistent with the standard of care for HIV treatment

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.

FTC had not been established to be therapeutic as of the priority date

188. There is a further reason why I am of the view that the skilled person, reading the words *"other therapeutic ingredients"* would not have in mind FTC, as of the priority date of the patent. As of the priority date, FTC had not been established to be therapeutic. It could not therefore fall within the rubric of *"other therapeutic ingredients"* within the meaning of Claim 27. In reaching that view, I have considered the matter both by reference to what was part of the common general knowledge of the skilled person as of the priority date and by reference to the prior art in existence at that date. Thus, even if I were to follow the approach suggested by Advocate General Hogan, I would still be of the view that a skilled person, reading the 894 patent (and in particular para. 0047 and Claim 27 of the patent) would not come to the view, by reference to the prior art, that FTC was specifically identifiable, as of the priority date, as a *"therapeutic ingredient".* At best, as of the priority date, the prior art indicated that FTC was a promising candidate for further investigation. As of the priority date, there was no sufficient evidence available to show that it was therapeutic in humans. As discussed above, FTC had only been administered to a very small number of human volunteers in a Phase 1 study based on a single-ascending dose. The results of this study were insufficient to demonstrate that FTC was therapeutic in humans. One would need much more extensive tests (including tests involving multiple ascending doses) to form a view that the drug could be safely administered without causing an unacceptable level of toxicity. In a medical context, the ordinary meaning of the word *"therapeutic"* is curative or healing or health-giving. A therapeutic ingredient is therefore a compound which is administered to improve health or general wellbeing or to fight disease. I do not believe that *"other therapeutic ingredients"* can be read as extending to candidate therapeutic ingredients or promising ingredients for consideration as future therapies. Whether FTC would ultimately be found to be therapeutic was not known as of the priority date. As the judgment of the CJEU in *Teva v. Gilead* makes clear, one cannot have regard to items of art (such as further research) which have arisen subsequent to

the priority date. Thus, the fact that FTC was subsequently found to be very effective in the treatment of HIV in combination with TD cannot be taken into account. In this context, I fully accept that, as of the date of filing of a pharmaceutical patent application, the patentee will not necessarily know that the invention described in the application will actually work. Further testing will almost invariably be required. The patentee is not required to demonstrate that, as of the priority date, the invention can safely be used in humans or animals (as the case may be). That is largely why the SPC regime was put in place. Furthermore, as Arnold J. said in his first judgment (i.e. the judgment making the reference to the CJEU), if the plaintiff were to obtain a patent for an invention consisting of a combination of TD and substance X which surprisingly had a synergistic effect in treating HIV, then a medicinal product whose active ingredients were TD and X would be protected by the patent. However, that is not the way in which the plaintiff here chose to draft the 894 patent. The plaintiff, instead, expressly chose to refer both in para. 0047 and in Claim 27 to a generic term namely *"therapeutic ingredients".* The plaintiff did not refer to candidate therapies or to compounds which had a promising future. While I fully appreciate that a patent must be construed in a purposive way and not in an overly legalistic way, the language chosen by the plaintiff was straightforward. On the basis that the patent must be construed as of the priority date and by reference to material in the prior art that existed up to that date, it seems to me that it is only those ingredients which, as of the priority date, would be considered to be therapeutic, that can be said to fall within the ambit of para. 0047 and Claim 27. The evidence shows that, as of the priority date, there were several NRTIs which had been shown to have therapeutic activity in humans. These included 3TC. The evidence was that as of July 1996 there were nineteen antiviral drugs approved, nine of which were relevant to HIV. I accept that any drugs that were already approved for use in humans (or possibly drugs which had passed sufficiently comprehensive tests to demonstrate efficacy and safety for use in humans) would fall within the rubric of *"therapeutic ingredients".* However, FTC was not in that category as of the priority date. Thus, even if it were the case that Claim 27 were to be considered as focussed on HIV treatment, there were nine drugs approved by the FDA which qualified as *"therapeutic ingredients".* These included AZT, ddI, ddC, 3TC, d4T (all of which are NRTIs) together with three PIs namely saquinavir, indinavir and ritonavir and one NNRTI namely nevirapine.

189. I am reinforced in this view by a consideration of the evidence of the expert witnesses. It is true that, in answer to a question from me, Prof. Roberts accepted that FTC would be considered to be a *"therapeutic ingredient"* even though, as of July 1996, it was only at an early state of clinical development. However, when Dr. Hawkins came to give his evidence, he explained that there is, of course, a different emphasis between the clinical view and the non-clinical view. The evidence of Prof. Roberts was put to Dr. Hawkins, in the course of his cross examination on Day 6. In

response, he explained that a chemist and a clinician approach the issue from different viewpoints. His evidence, nonetheless was that there was insufficient information about the therapeutic effect of FTC at the priority date. In my view, Dr. Hawkins was entirely correct in his evidence. In terms of therapeutics, it seems to me that it is the view of the clinician which is key. It is also important to bear in mind that when Prof. Roberts was asked whether he regarded FTC as a therapeutic ingredient, he did so in the context that it had gone through the *"chemistry process research and development".* Critically, however, it had not gone through the necessary process to establish that it was a therapeutic ingredient safe for human use. As Prof. Powderly explained on Day 9 at p. 75 (in answer to questions from the plaintiff's counsel):-

"Q. … Would a skilled clinician in your opinion have distinguished between drugs and clinical development, depending on whether they were in phase 1, phase 2, phase 2(a), phase 2(b) or phase 3?

A. I think clinical development is a continuum, so you get more information with each phase of clinical development. And the more, the longer the drug is in clinical development the greater confidence you will have that it will ultimately progress to becoming a therapeutic agent that you can use in practice.

Q. Yes.

A. So in phase 1 you get a certain amount of information but it's quite limited. It gives you confidence to go to phase 2. In phase 2 you then have more information that often allows you to determine what is the appropriate dosing for human, large scale human trial.

Q. Thanks.

A. And in phase 3 you get the final definitive evidence that may lead to the approval of the product which then becomes a therapeutic agent because at that approval point it is when it can be prescribed and becomes a therapeutic".

In my view, this evidence of Prof. Powderly was illuminating. It summarises very clearly the process that must be undergone before a compound can be considered to be therapeutic and be approved by an appropriate regulator such as the FDA. Here, FTC had not gone beyond phase 1 and the study that had been carried out in respect of that phase was of a very limited nature. There was a lot more work to be done before FTC could be considered to be a therapeutic agent. That work did not take place until after the priority date. Thus, even if the second limb of the *Teva v. Gilead* test is to be assessed by reference to prior art, it seems to me that there is no basis on which to conclude that FTC satisfies the second limb of the CJEU test.

190. I should add that Prof. Powderly, in his evidence (Day 9 at p. 70) sought to give a more expansive meaning to the term *"therapeutic ingredients".* He suggested that Claim 27 should be read as referring to TD being combined with "*optionally other*

therapeutic ingredients at a time when that is possible to do so". However, that seems to me to go significantly beyond the ambit of Claim 27. The approach suggested by Prof. Powderly seems to me to go beyond a purposive interpretation of Claim 27 and to invest the claim with a level of elasticity which I do not believe is appropriate and for which no authority has been cited. It also seems to me to run directly counter to the requirement made very clear in *Teva v Gilead,* that it is only prior art in existence as at the priority date that can be taken into account.

191. Even if it were the case that Claim 27 were to be construed as focussed on HIV treatment, I do not believe that FTC could be considered to fall within the ambit of a *"therapeutic ingredient".* As noted above, there were, as of the priority date, at least nine HIV treatments which had been approved by the FDA. Each of those was a *"therapeutic ingredient"* which could potentially be used in combination with TD. In the course of his evidence, Prof. Powderly sought to downplay the extent to which these agents would be considered for inclusion in a combination therapy with TD. His evidence to that effect was largely contradicted by the evidence of the defendants' experts. Furthermore, all of the experts were agreed that 3TC was an obvious combination partner for TD. While there was disagreement about the remaining approved therapies, I accept the evidence of Prof. Roberts and Dr. Hawkins that AZT would also be considered as a potential combining agent with TD. I also accept the evidence of Prof. Roberts with regard to ddI to the same effect. Likewise, I agree with the evidence of Prof. Roberts in relation to ddC. I note that Dr. Hawkins would also have included ddC as a potential agent to combine with TD. Likewise, I accept the evidence of Prof. Roberts and Dr. Hawkins in relation to the potential use of d4T. While Prof. Powderly sought to suggest that it would not be feasible to combine TD with any of the PIs, he ultimately agreed that formulation science might have overcome some of the difficulties which he identified. Both Prof. Roberts and Dr. Hawkins suggested that there were practical ways to deal with the concerns expressed by Prof. Powderly in relation to the size of some of these drugs. Prof. Roberts gave evidence to the effect that while 600 mg is substantial, it is not unusual for a patient to take 500 mg of paracetamol quite regularly. Dr. Hawkins gave evidence that the doses could have been administered on a twice a day basis in order to address Prof. Powderly's concern. Ultimately, however, all of this debate seems to me to be somewhat academic in circumstances where, as Prof. Powderly acknowledged, TD had yet to undergo clinical development. As a consequence, the notion that it could be combined with anything was, as he acknowledged, *"rather hypothetical in the first place".* What is clear is that there were, as at the priority date, a number of anti-HIV compounds which had already been approved by the FDA and thus Claim 27 was well capable of being understood on that basis. There was no need, in the circumstances, to consider compounds that had not yet been demonstrated to be safe for use in humans such as FTC.

192. In the circumstances, I believe that, even if one takes account solely of the prior art in existence at the priority date (without considering whether that art had become common general knowledge) there is no plausible basis to suggest that FTC would have sprung to the mind of the skilled person as of the priority date as a therapeutic ingredient. As of that date, its efficacy and safety as a therapeutic agent had not been established. As noted above, it was at best a promising candidate.

Common general knowledge

193. For the reasons previously discussed in paras. 120-129 above, I am of the view that, in applying the second limb of the test, the CJEU considered that this requires the national court to address the issue by reference to the position of the skilled person possessing the common general knowledge of such a person as of the filing date or priority date of the patent. In light of the views which I have formed in relation to the ambit of *"other therapeutic ingredients"* in para. 0044 and Claim 27, it is, strictly speaking, unnecessary to consider this issue. Even if the information which existed in relation to FTC as at the priority date had entered into the common general knowledge of the skilled person, this would not avail the plaintiff if I am right in my conclusion that FTC would not be considered to be a therapeutic ingredient as of that date. However, for completeness, I will address the issue as to the extent to which the information in relation to FTC which existed as at the priority date had entered into common general knowledge.

194. In the closing submissions delivered on behalf of the plaintiff, the case was made that the evidence very clearly demonstrates that, as of the priority date, FTC formed part of the common general knowledge and was identifiable not merely at a general or generic level but was identifiable as FTC and could and would have been identified by name as a potential combination partner for TD.

195. In support of the plaintiff's submission that the evidence demonstrates that FTC forms part of common general knowledge as at the priority date, the plaintiff has sought to rely on a number of exchanges that took place between the plaintiff's counsel and the defendant's experts in the course of their respective cross-examination. The plaintiff relies, in particular, on what was said by Prof. Roberts on Day 4 and Day 5. Reliance is also placed on certain elements of the evidence of Dr. Hawkins on Day 6 and the evidence of Dr. Moyle on Day 8. I addition, the plaintiff relies on the evidence of Prof. Powderly on Day 9. However, in my view, it is important, when considering this evidence, to keep in mind the relevant test that applies in the context of common general knowledge namely the test applied by Sachs L.J. in the *General Tire & Rubber Co*. case (quoted in para. 152 above) and approved by Barrett J. in Ireland in *Bohringer Ingelheim's* patent [2017] IEHC 495. It is clear from the test that it is not sufficient to prove common general knowledge that a particular disclosure is made in an article or in a series of articles in a scientific

journal. A matter disclosed in a scientific paper does not become common general knowledge merely because it is widely read and widely circulated. It only becomes part of the general knowledge when it is generally known and accepted. Thus, for example, in the present case, the mere fact that Prof. Roberts read some of the articles that appeared in the journal *"Antimicrobial Agents and Chemotherapy"* does not establish that the information relating to FTC formed part of common general knowledge as of the priority date of the patent.

196. The cross examination of the defendants' experts elicited a number of concessions on which the plaintiff now seeks to rely to demonstrate the extent to which FTC formed part of the common general knowledge of the skilled person as of the priority date:-

(a) On Day 4, in the course of the cross-examination of Prof. Roberts, it was put to him that, as of July 1996, a person skilled in the art would know that FTC had been the subject of significant pre-clinical research in a successful phase 1 trial (albeit the phase 1 trial was limited in the manner previously outlined by Prof. Roberts and summarised in this judgment). The answer given by Prof. Roberts at p. 128 was that this was correct. At p. 129 on the same day, it was put to Prof. Roberts that: *"anybody skilled in the art aware of the material that was in the public domain that we have looked through would have been aware, I am suggesting to you, that FTC was a promising … potential NRTI treatment?"* to which Prof. Roberts answered that: "*I think it was a promising candidate".* Prof. Roberts also confirmed, in the course of his cross-examination that some of the journals in which information relating to FTC (albeit not always by reference to its name) had been on his reading list;

(b) In the case of Dr. Hawkins, it was put to him on Day 6 that the skilled person would have been aware that FTC was an NRTI in development and Dr. Hawkins confirmed at p. 86 that the skilled person *"would've probably heard about it over the previous two or three years, yes".* It was also put to him at p. 131 on the same day that FTC was part of common medical knowledge as of 1996 and part of the state of the art as of that date. Dr. Hawkins responded that: *"there was prior art about FTC, and I would also say it was, FTC as a compound was known as common general knowledge by skilled clinicians in the field. They may not have known about the alphanumeric number for the initial phase 1 study which we have been discussing".*

(c) In the case of Dr. Moyle, it was put to him that, if the skilled clinician had set about looking to identify what NRTIs were in clinical development in 1996, they would readily have been able to do that. Dr. Moyle confirmed that this was so. The purpose of this cross examination appeared to be to demonstrate that FTC would have come to the attention of a clinician undertaking such a search;

(d) The plaintiff also drew attention to the evidence of Prof. Powderly to the effect that the skilled clinician would have identified the drugs outlined by him in Appendix 27 to his witness statements where he listed all of the anti-HIV treatments which had either been authorised or were in development as of July 1996. The plaintiff also drew attention to what was said by Prof. Powderly in the course of his direct examination on Day 9 at p. 25 where the following exchange took place between him and counsel for the plaintiff:-

"Q. What did you know of FTC as of July 1996?

A. So as of July 1996 I knew that FTC was a drug that was in development for the treatment of HIV infection. I was aware of the fact that Glaxo had, which had the rights to FTC had HIV returned those rights to Emory University and I was aware that those rights had been acquired by Triangle Pharmaceuticals.

Q. Where you aware of the fact that it had entered into clinical development?

A. I was aware of the fact that it was entering clinical development, yes."

197. At this point, it is important to bear in mind who is the skilled person for the purposes of this exercise. I have already dealt with this issue in paras. 147-153 above. I have already held that the skilled person for this purpose comprises a team made up of a medicinal chemist and a clinician. For the reasons already discussed I do not believe that it is correct to suggest that the team would be focussed on HIV treatment in the manner suggested by the plaintiff. Given the breadth of the patent, this seems to me to be the correct approach to take. In those circumstances, the fact that highly specialised experts in HIV treatment such as those who gave evidence in these proceedings may have heard of FTC does not establish that it had become part of the common stock of knowledge of those involved in the management of a range of viral infections. For that reason, I do not believe that the plaintiff is correct in attributing such weight to the concessions made, in the course of their respective evidence, by the expert witnesses called on behalf of the defendants.

198. Quite apart from the considerations outlined in para. 197 above, the evidence in this case falls far short of demonstrating that the skilled team of the kind described above would be aware that FTC had reached the stage of a phase 1 trial or that the results of that phase 1 trial were promising. While several of the journals relied upon by the plaintiff appear to have been on Prof. Roberts' reading list, he was a highly specialised medicinal chemist. I do not believe that he can be treated as a proxy for the medicinal chemist member of the notional skilled team. Moreover, he had a particular interest in the development of FTC given his involvement in Glaxo. He was advising Glaxo in relation to 3TC which is in the same family as FTC. By reason of that very particular background, he was more likely than the typical medicinal

chemist to become aware of and to follow the development of (to the limited extent that he did) FTC.

199. Insofar as the clinician member of the team is concerned, I have already explained that I do not believe that the clinician in question would have the same level of expertise as the clinicians who gave evidence before me. Nor would such a clinician have the same focus on HIV as the clinicians who gave evidence before me. Furthermore, it is clear from all of the evidence that I have heard that there was in fact very little known about FTC by any of the medical expert witnesses prior to July 1996. This included Prof. Powderly himself. It emerged in the course of the direct evidence given by Prof. Powderly on Day 9 that his knowledge that FTC was in clinical development as of July 1996 was based purely on a press release which he said was issued by Triangle Pharmaceuticals after it had acquired FTC from Glaxo (the latter having decided to proceed with 3TC). This evidence emerged in answer to a question asked by me. There was no evidence as to the extent to which the press release generated publicity at the time. In fact, there was no evidence at all of its publication anywhere. However, Prof. Powderly gave evidence that he recalled seeing a press release and, in the course of his preparations for the trial of these proceedings, he unearthed a copy of the press release on the web. In that version of the press release, it was indicated that Triangle had acquired the rights to develop FTC and it was stated that a phase 1 study had taken place in patients which had shown that FTC was *"well tolerated and exhibited excellent pharmacokinetics. FTC is as potent as 3TC against hepatitis B and has shown potent activity in Woodshuck hepatitis, which is considered a valid and predictive model of human hepatitis B infection".*

200. A number of points arise in relation to the press release. In the first place, it will be noted that the press release highlighted the potential of FTC as a potential agent for use not only as against HIV but also Hepatitis B. Secondly, the press release provides little or no hard information about the phase 1 study. Thirdly, as noted above, there is no evidence about the extent to which the information contained in the press release was subsequently disseminated. Prof. Roberts gave evidence that a press release of this kind would not be regarded by the skilled person as material on which any reliance could be placed. A manufacturer is always likely to extol the merits of a product in its catalogue. In my view, the evidence in relation to the press releases fall far short of establishing that the information contained in it became part of the common stock of knowledge of the skilled person as at the priority date of the 894 patent.

201. I have, accordingly come to the conclusion that, even if the existence of FTC could be considered to fall within the common general knowledge of the skilled person as of July 1996, it was not part of that common general knowledge that FTC had successfully passed phase 1 trials. As noted previously, the Wang abstract (on which

the plaintiff places so much reliance) was not even seen by Prof. Powderly or Dr. Moyle notwithstanding that both had attended a conference in San Francisco where the Wang poster was presented.

202. I have come to the conclusion that there is no reliable evidence before the court to establish that the skilled person would have been aware that FTC had entered into clinical trials in humans as of July 1996. Thus, even if I am wrong in my conclusion that, in the absence of appropriate evidence from phase 1, 2 and 3 clinical trials, FTC could not be considered to be a therapeutic ingredient, I can see no basis on which one could form the view that, as of July 1996, FTC was even a promising candidate for consideration as a therapeutic ingredient. In my view, in the absence of evidence of knowledge that phase 1 trials had taken place, FTC would not spring to the mind of a skilled person as a potential combination partner for TD even if it would otherwise be correct to hold that a drug that had passed a small phase 1 clinical trial constituted a *"therapeutic ingredient"* for the purposes of Claim 27 of the 894 patent.

Conclusion

203. For all of the reasons outlined in paras. 154-171, I am of the view that the defendants succeed in relation to the first limb of the *Teva v Gilead* test. For all of the reasons discussed in paras. 172 -202, they also succeed in relation to the second limb. I have, accordingly, come to the conclusion that the counterclaims of the defendants must be allowed in both cases and that the SPC should accordingly be revoked.

204. In turn, it would appear to follow that the plaintiff's case in both sets of proceedings should be dismissed but I will, of course, hear counsel as to the precise form of the orders to be made.