Neutral Citation Number: [2019] EWHC 1520 (Pat)

Case No: HP-2017-000064

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

Royal Courts of Justice
The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: 20/06/2019

Before :

MR JUSTICE BIRSS

- -

Between :

PFIZER LIMITED	**Claimant**
- and -	
(1) F. HOFFMANN-LA ROCHE AG	
(2) ROCHE PRODUCTS LIMITED	**Defendants**

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Richard Meade QC, Thomas Raphael QC and **Thomas Jones** (instructed by **Taylor Wessing**) for the **Claimant**
Andrew Lykiardopoulos QC and **Mark Chacksfield QC** (instructed by **Herbert Smith Freehills**) for the **Defendants**

Hearing dates: 1st, 2nd, 4th April 2019

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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MR JUSTICE BIRSS

Mr Justice Birss :

Introduction

1. This is a claim by Pfizer for *Arrow* declarations in relation to its proposed launch in Europe, including the UK, of a biosimilar monoclonal antibody drug called bevacizumab, for the treatment of various cancers in combination with other drugs. Bevacizumab is an antibody against VEGF, a molecule in the signalling pathway that leads to the formation of blood vessels. The Defendants (Roche) already market a bevacizumab product under the brand name Avastin. Avastin is a successful product with a huge market. Roche's European sales of Avastin in 2018 were over £1 billion. Pfizer's biosimilar product will be branded Zirabev.

2. Genentech Inc (a member of the Roche group) held a patent for bevacizumab itself. As a result of a Supplementary Protection Certificate, including a paediatric extension, the protection conferred by the basic patent continues until June 2020. I refer to that date as SPC expiry. Pfizer wants to launch immediately after that. However Roche has what Pfizer calls a thicket of second-line patents and patent applications which hinder Pfizer in various ways and are causing uncertainty generally. Pfizer contends that causing this uncertainty is a deliberate policy of Roche.

3. The patents and patent applications all relate to combinations of bevacizumab with other known cancer drugs for use treating various types of cancers. The relevant types of cancer are the ones found in the Summary of Product Characteristics in the Marketing Authorisation for Avastin. The relevant types of cancer fall into three classes. The first class is a group consisting of colon, lung, renal and cervical cancers. These are free of patents and applications. Pfizer can obtain a marketing authorisation for its biosimilar bevacizumab product for those indications and can market the product after expiry of the SPC without fear of Roche patents. The other two classes are breast cancer and ovarian cancer. The patents and applications in this case relate to these two forms of cancer.

4. Roche's group of patents and applications include material (text and data) which would support claims to the use of bevacizumab in combination with certain other cancer drugs, for the treatment of particular instances of these two forms of cancer. One of the uncertainties which afflicts Pfizer is that a currently pending application might lead to

a patent being granted either before or after June 2020 and Roche might try to obtain an interlocutory injunction against Pfizer.

5. Pfizer's case is that given the state of the art at the earliest claimed priority date for a given patent or application, bevacizumab in combination with the relevant other cancer drugs for the treatment of the relevant indication lacked novelty and/or was obvious. To prove it Pfizer has put in evidence the relevant prior art, provided reports from experienced experts in breast cancer and ovarian cancer and set out cogent arguments in favour of its case. Assuming that fact is true then Pfizer would have a complete *Gillette* defence to any patent claim should Roche sue at any time after launch. The defence would be a good one regardless of when such a patent might be granted. An application for an *Arrow* declaration would allow the parties to resolve this dispute now and remove the uncertainty. If the declaration was granted it would be binding as between the parties in this jurisdiction. In addition says Pfizer, the declaration, along with a reasoned judgment on the issues would have a strong persuasive effect in other European contracting states to the EPC. One such state is Belgium. Pfizer plans to supply the UK market from Belgium and so a preliminary injunction application in Belgium would not only have effect in that country but would disrupt the UK market as well. Under Belgian law the courts apply a presumption of validity of patents at the preliminary stage but Pfizer contends that following a decision of the Belgian Cour de Cassation (***Syral v Roquette*** Cass 12 Sept 2014, Pas., 516 1861 IRDI 2014, 634) the judgment of a court of another contracting state of the EPC such as the UK must be at least taken into account, and when that happens it may be given weight and serve to help rebut the presumption of validity.

6. Roche disagrees with some important parts of this analysis. Roche does not accept that it has deliberately created uncertainty or that its conduct can be fairly characterised as "shielding" in the manner that term is used in the cases on *Arrow* declarations. Roche has led evidence to seek to show that its prosecution of this portfolio of patents and applications is commonplace in the field. Both sides called experienced patent attorneys as expert witnesses to comment on Roche's approach to patent prosecution. Roche also does not agree with Pfizer's analysis of Belgian law. Both sides called experienced Belgian lawyers as expert witnesses about that and I will need to consider this evidence further below.

7. Most importantly of all, today Roche has no relevant UK patent and furthermore Roche has now abandoned any prospect of obtaining such a UK patent in future. That "de-designation" of the UK from all relevant pending EP patent applications was complete in November 2017, a few weeks after this action for an *Arrow* declaration was commenced. There never will be a Roche UK patent for these indications arising from any of the relevant patent families. Roche contends that this means that the UK court ought not to grant an *Arrow* declaration in this case. The declarations would serve no legal purpose.

8. Roche has, save in one respect about priority, studiously avoided engaging with Pfizer's case on the question of the lack of novelty or obviousness of bevacizumab combinations for the relevant cancer indications. This refusal to engage is despite every opportunity to do so.

9. Pfizer contends as follows. The de-designation of the UK is a deliberate and transparent act of shielding by Roche. The UK is and will be in future a valuable market for

bevacizumab and the only rational reason for doing this must be to prolong the commercial uncertainty. Roche's case on novelty or obviousness is very weak and so this is all part of Roche's strategy to shield its patent applications from the scrutiny of the Patents Court. In some cases there can be rational reasons to de-designate a state like the UK, but none of them apply here. So, Pfizer argues, these submissions support the idea that the court should go ahead and consider the merits of an Arrow declaration and should grant one in this case despite the absence of UK rights. The real reason Roche says nothing about the merits in this case is because it has nothing to say which would withstand scrutiny.

10. Roche does not agree. While it does not engage with the issues of novelty or obviousness nor does it advance a positive case about its motives, Roche does take issue with one factual element of the reasoning in the previous paragraph. That is the significance of the UK market. Roche contends its future value is not so significant. Both sides called witnesses from their business teams to address that matter.

11. Finally Roche argues that if it is right that no *Arrow* declaration should be granted, then in this case it would be wrong and unfair for the court to conduct a fully reasoned analysis of the merits of the novelty and obviousness issues since that would be tantamount to giving Pfizer the relief which should not be given. At one stage there was a suggestion that the reasoned analysis could be part of a confidential annex in case the matter went on appeal, but Pfizer objected to that and Roche did not advance it in closing.

12. So this is a curious case to be tried in the Patents Court. The evidence about novelty and obviousness has not been cross-examined, because the patentee Roche chose not to do so. Nevertheless Roche has played a full part in these proceedings. Despite what seemed to be a suggestion to the contrary, these proceedings have been fully contested by Roche. No party who fully contests a case is obliged to disagree with every point raised by their opponent or to call evidence on every point. The fact a party has not done those things does not mean they have not fully contested the case. Roche has taken the opportunity to call detailed evidence on the topics it wishes to and to challenge the evidence from its opponent. Roche has had every opportunity to make submissions on the issues of novelty or obviousness, to call whatever evidence it wishes about them or to test the evidence before the court. At trial I asked Roche's representatives specifically if Roche would like the opportunity to have the case adjourned to give them another chance to call evidence on these topics. Roche declined to do so.

The issues

13. At a high level, there are two issues in this case: one is the technical issue about the novelty or obviousness of the use of the various bevacizumab combinations for the relevant cancer indications and the other is the declaration issue. The declaration issue is not simply whether the court should grant a declaration assuming the technical issue is established, the question is also whether the court should enter into the technical issue in any depth at all if it would not grant a declaration irrespective of the outcome on the technical issue.

The witnesses

14. Pfizer led factual evidence from Mr Daijin Kim and Mr Eddy Weygaerts. Mr Kim's evidence dealt with Pfizer's strategy for their intended global launch of Zirabev and the benefit to Pfizer of the declarations sought. Mr Kim has been an employee of Pfizer for over 15 years and is currently the Oncology Biosimilars Platform Lead. He is based in New York and is responsible for defining global commercial strategy and scenario plans for Pfizer's oncology biosimilars business. Mr Kim gave oral evidence and was challenged in cross-examination. Mr Kim gave his evidence fairly but did not have direct knowledge of the UK market and relied on information from others. I will take that into account.

15. Mr Weygaerts' evidence explained Pfizer's supply chain for its Zirabev product and how Pfizer have planned to bring Zirabev to the UK market. He is the senior manager for logistics delivery at Pfizer and is responsible for Pfizer's external supply plants in Europe and APAC. He did not give oral evidence and his evidence was not challenged.

16. Roche led factual evidence from Mr Michael Kindell and Ms Elizabeth Capon. Mr Kindell is the Head of Antibody Value Management at Roche Products Limited, previously having held various senior roles in the wider Roche business. He is responsible for managing the commercial strategy for Roche's biologic medicines in the UK, including Avastin. His evidence responded to Mr Kim's, focussing mainly on the relevant UK market, the differences between "skinny" and "full" labels, and supply chains. He gave oral evidence and was challenged in cross-examination. He was a good witness and able to speak about the UK market. He was not in a position to answer questions about Roche's overall motivation.

17. Ms Capon is the Integrated Franchise Leader – Established Products at Roche Products Limited and is responsible for the UK sales and expenditure for Avastin (amongst other products). Her evidence addressed the value of Roche's sales of bevacizumab in the UK and the UK market in general. She did not give oral evidence and her evidence was unchallenged.

18. The expert evidence on the practice and procedure of patent prosecution before the European Patent Office was as follows. Pfizer called Dr Gordon Wright. Dr Wright is a retired patent attorney with approximately 30 years' experience at the time he retired. He held senior roles in-house in several large pharmaceutical companies before moving into private practice at patent attorneys Elkington and Fife LLP in 2000. He retired in 2014 but continued to consult for the firm until 2018. Since then he has been a visiting professor at Queen Mary, University of London. Broadly speaking, his evidence was led to support Pfizer's case that Roche had not been progressing their patent applications in an ordinary manner and that, therefore, their conduct could be subject to criticism. He gave oral evidence at trial. Roche criticised Dr Wright for giving long answers, which he did. In my judgment that was due to enthusiasm for his subject, that is all. Roche contended he gave the impression of wanting to advance a case. I disagree. Dr Wright was a good witness, seeking to help the court.

19. Roche called Mr Richard Bassett. Mr Bassett is a patent attorney and partner at Potter Clarkson LLP having been at the firm since 1986, a partner since 1990 and senior partner since 2013. From 1998 to 2018, he was a tutor at Queen Mary University of London. He has written various articles and edits a chapter in the European Patents Handbook. Mr Bassett's evidence was intended to respond to the matters raised by Dr Wright, focussing on his opinion on the manner in which Roche had prosecuted the

relevant patent applications. Like Dr Wright, Mr Bassett was a good witness, always seeking to help the court.

20. Pfizer's expert on Belgian law was Dr Vincent Cassiers. Dr Cassiers is a practising Belgian lawyer with the Belgian law firm Sybarius, specialising in intellectual property and business law. He qualified in 2001. He has a PhD in law and is a lecturer on intellectual property at a number of institutions: the Catholic University of Louvain, Belgium (since 2007); Katholieke Universiteit Leuven, Belgium (since 2009); and Universite de Lille, France (since 2013). He has co-authored or contributed to a number of intellectual property textbooks. He was criticised by Roche for the fact that he had not, in fact, had any practical involvement with a preliminary patent injunction case in the last five years. Dr Cassiers was a good witness. Roche suggested he lacked experience. As compared to Dr Buydens, Dr Cassiers had not conducted any preliminary injunctions in patent cases in the last five years. Nevertheless I reject the suggestion that this difference between the two experts in Belgian law would be any basis for preferring the opinions of one over the other where they conflict. I reject the submission that Dr Cassiers appeared to be unfamiliar with relevant cases. They were both well qualified experts.

21. Roche's Belgian law expert was Dr Mireille Buydens. Dr Buydens is a practising Belgian lawyer and is currently a partner in the intellectual property group at the Belgian law firm Janson Baugniet, having previously been a partner at Stibbe, Jones Day and Liedekerke (in the latter two as head of the intellectual property practice groups). She was a professor of IP Law at Universite Catholique de Louvain from 1995 to 2007 and has been a professor at the Free University of Brussels since 1995, teaching IP law. She is a member of the advisory committee to the Prof. Mr. E A. van Nieuwenhoven Helbach Foundation (which is composed of members of the Dutch Supreme Court) and a member of the Belgian Council for Industrial Property. She has authored or co-authored a large number of intellectual property textbooks and papers. Dr Buydens was a good witness.

22. Pfizer called Dr Paul DiSilvestro to address ovarian cancer. Dr DiSilvestro is a Gynaecologic Oncologist with over 20 years of experience. Dr DiSilvestro is also a professor of Obstetrics and Gynaecology at the Warren Alpert Medical School, of Brown University, an Examiner for the American Board of Obstetrics and Gynaecology and the co-Chair of the Gynaecologic Cancer Committee at NRG Oncology. His evidence firmly supported Pfizer's case that the relevant bevacizumab combination for the relevant ovarian cancer indications were obvious. Dr DiSilvestro was not cross-examined.

23. On breast cancer indications, Pfizer called Dr Alison Jones. Dr Jones is a Consultant Medical Oncologist who specialises in the treatment of breast cancer. She also has over 20 years of experience. Dr Jones has extensive experience of clinical trials in breast cancer care (including as a member of the Cancer Research UK Clinical Trials Advisory and Awards Committee between 2006 and 2013), and plays a major role in the introduction of new drugs at the private medical practice in which she is presently a member. Dr Jones has previously chaired and still sits on the steering committee of Cancer Physicians UK. Her evidence firmly supported Pfizer's case that the relevant bevacizumab combination for the relevant breast cancer indications lacked novelty or were obvious. Dr Jones was not cross-examined.

Background

24. The basic bevacizumab patent is EP 1 325 932 entitled "Anti-VEGF antibodies". It was filed on 3rd April 1998 claiming priority from US filings in 1997. SPC expiry based on this patent is in June 2020.

25. Bevacizumab under the brand name Avastin was first approved by the FDA in 2004 and by the EMEA in 2005. The first indication for which it was approved was metastatic colorectal cancer.

26. Today there are ten therapeutic indications set out in the SmPC for Avastin. As set out in Section 4 of the SmPC they are:

    (1) Bevacizumab in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of adult patients with metastatic carcinoma of the colon or rectum.

    (2) Bevacizumab in combination with paclitaxel is indicated for first-line treatment of adult patients with metastatic breast cancer. For further information as to human epidermal growth factor receptor 2 (HER2) status, please refer to section 5.1.

    (3) Bevacizumab in combination with capecitabine is indicated for first-line treatment of adult patients with metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate. Patients who have received taxane and anthracycline containing regimens in the adjuvant setting within the last 12 months should be excluded from treatment with Avastin in combination with capecitabine. For further information as to HER2 status, please refer to section 5.1.

    (4) Bevacizumab, in addition to platinum-based chemotherapy, is indicated for first-line treatment of adult patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology.

    (5) Bevacizumab, in combination with erlotinib, is indicated for first-line treatment of adult patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations (see Section 5.1).

    (6) Bevacizumab in combination with interferon alfa-2a is indicated for first line treatment of adult patients with advanced and/or metastatic renal cell cancer.

    (7) Bevacizumab, in combination with carboplatin and paclitaxel is indicated for the front-line treatment of adult patients with advanced (International Federation of Gynecology and Obstetrics (FIGO) stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. (See section 5.1).

    (8) Bevacizumab, in combination with carboplatin and gemcitabine or in combination with carboplatin and paclitaxel, is indicated for treatment of adult patients with first recurrence of platinum-sensitive epithelial ovarian, fallopian

tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents.

(9) Bevacizumab in combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin is indicated for the treatment of adult patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor–targeted agents (see Section 5.1).

(10) Bevacizumab, in combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, is indicated for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix (see Section 5.1).

27. The relevant indications are numbers (2) and (3) for breast cancer and numbers (7), (8) and (9) for ovarian cancer. Each of these indications relates to the use of bevacizumab in combination with other chemotherapeutic agents. In the relevant indications these chemotherapeutic agents are carboplatin, paclitaxel, gemcitabine, topotecan, pegylated liposomal doxorubicin (PLD) and capecitabine. For the purposes of this case indication (8) can be regarded as two indications, that is (8)(a) involving carboplatin and gemcitabine and (8)(b) involving carboplatin and paclitaxel. For the purposes of this case indication (9) can be regarded as three indications, that is (9)(a) involving paclitaxel, 9(b) involving topotecan and (9)(c) involving PLD. In the judgment below I will not repeat the full text of the indications when I refer to them because it is not necessary to do so. They will be referred to in shorthand.

The 085 or "Fyfe" family

28. The first relevant Roche patent family in this case is the '085 or "Fyfe" family concerned with breast cancer. This family is based on an International Application filed under the PCT on 20th November 2009 (PCT/US2009/065381) and claiming its earliest priority from a US filing (US 117102 P) on 22nd November 2008. The application was published as WO 2010/059969.

29. The contents of the relevant patent application in the 085 family would support claims to bevacizumab in combination with capecitabine for use in the first line treatment of metastatic breast cancer. In other words the claims to indication (3). Favourable Phase III trial results for that indication were published in 2009 and indication (3) was added to the Avastin SmPC on 29th June 2011.

30. A divisional application in this family was filed on 22nd October 2013. It became European application EP 2 752 189 A.

31. The parent application of the 085 family had led earlier to European Patent EP 2 361 085, granted on 25th February 2015, but the claims of that patent are limited to combinations of bevacizumab with chemotherapeutic agents which are not approved on the Avastin SmPC. It is therefore irrelevant.

32. By the summer of 2016 application EP 2 752 189 A was proceeding to grant. Stripped of their verbiage the claims of this patent EP '189 cover indication (3). Shortly before

grant, on 2nd September 2016, Roche withdrew the UK designation for this patent. All the other designated states remain. Ten days later on 12th September 2016 Roche filed a divisional application in this same 085 family. That divisional became EP 3 178 478 A.

33. EP 189 was then granted on 26th October 2016, not including the UK. Nevertheless by then the second divisional EP 478 A was pending. It was published in June 2017. By mistake it purported to designate the UK but that was an error by the EPO and has now been corrected. That divisional remains as an application. It contains material which would support a claim to indication (3).

34. In fact EP 478 A also contains material which could support a claim to indication (2) as well. Nevertheless Pfizer are not worried about indication (2) in this case because that indication was in the SmPC before the earliest priority date in the 085 family. Therefore Pfizer does not regard the risk that it might have to contend with a claim to indication (2) as significant.

35. EP 189 was opposed in the EPO, including by Pfizer. On 7th January 2019 the Opposition Division issued a decision to revoke the patent for obviousness (Art 56 EPC). This concerned both the main request and 13 auxiliary requests advanced by Roche. Roche has appealed that decision to the Technical Boards of Appeal of the EPO.

36. In summary the position today is that Roche's 085 family consists of a revoked patent for indication (3) (EP 189), the revocation being stayed pending Roche's appeal to the TBA and a pending application (EP 478A). The pending application could lead to claims covering indication (3) and, since EP 478 A is still pending, Roche could file further divisionals in this family. However Roche cannot obtain patents in the UK from this family and Roche has not been able to do so since September 2016.

The '367 or "Dupont" family

37. The second relevant Roche patent family in this case is the '367 or "Dupont" family concerned with ovarian cancer. This family is based on an International Application filed under the PCT on 22nd February 2011 (PCT/US2011/025651) and claiming its earliest priority from a US filing (61/307,095) on 23rd February 2010. The application was published as WO 2011/106300.

38. The contents of the relevant patent application in the 367 family would support claims to bevacizumab combinations for use in the treatment of ovarian cancer for indications (7) and (8) in the SmPC. Put broadly indication (7) relates to using bevacizumab with carboplatin and paclitaxel for front line ovarian cancer treatment; while indication (8)(a) relates to using bevacizumab with carboplatin and gemcitabine, and indication (8)(b) relates to using bevacizumab with carboplatin and paclitaxel, in either case for platinum sensitive ovarian cancer treatment.

39. Favourable Phase III trial results for bevacizumab with carboplatin and paclitaxel for the treatment of front line ovarian cancer, which is indication (7) were published in June 2010. Favourable Phase III trial results for bevacizumab with carboplatin and gemcitabine for the treatment of platinum sensitive ovarian cancer, which is indication

(8)(a), were published in February 2011. Indication (7) was added to the Avastin SmPC on 19 December 2011 and indication (8)(a) was added on 24th October 2012.

40. By 2014 and following unity objections based on the inclusion of distinct drug combinations, the 367 application was limited to bevacizumab in combination with paclitaxel and carboplatin, covering indication (7).

41. Favourable Phase III trial results for bevacizumab with carboplatin and paclitaxel for the treatment of platinum sensitive ovarian cancer, which is indication (8)(b) were published in April 2015. Looking ahead in time, that indication was added to the Avastin SmPC on 2nd June 2017.

42. Meanwhile in 2015, the examining division summoned Roche to oral proceedings in a communication dated 12 June 2015. Such a summons is usually only issued in these circumstances if the examiner is expected to refuse the application. Roche filed written submissions, a new main request (which covered indication (7)) and two auxiliary requests. The examiner was not persuaded to cancel the oral proceedings and on 26th October 2015 Roche informed the examiner it had decided not to attend. By a communication of 5th February 2016 referring to proceedings held on 26th November 2015 the examining division refused the application. All three claims sets were found to lack inventive step (Art 56). Roche filed a notice of appeal on 14th March 2016 but did not file the grounds of appeal by the time they were due on 15th June 2016 and so the appeal lapsed. The 367 application therefore did not mature into a granted patent.

43. However on 8 March 2016 Roche filed a divisional application which became application EP 3 064 509 A. Like its parent application, that application EP 509 A would support claims to bevacizumab combinations for use in the treatment of ovarian cancer for indications (7) and (8)(a) and (b) in the SmPC. In 2017 the pending claims were limited to bevacizumab with carboplatin and gemcitabine for the treatment of platinum sensitive ovarian cancer, which is indication (8)(a). That application has yet to reach a conclusion. The examiner has raised objections on a number of grounds including lack of inventive step (Art 56), Pfizer has filed third party observations arguing that the patent should not be granted and in November 2018 Roche submitted arguments in favour of inventive step. The examiner has yet to respond.

44. In November 2017 Roche de-designated the UK (and only the UK) from application EP 509 A.

45. In summary the position today is that Roche's 367 family consists of a refused application for indication (7) (EP 367) for which the appeal has been abandoned so that that application is now terminated, and a pending application (EP 509A). The pending application could lead to claims covering indications (7), (8)(a) and (8)(b) and, since it is still pending, Roche could file further divisionals in this family. However Roche cannot obtain patents in the UK from this family and Roche has not been able to do so since November 2017.

*The '558 or "*Bernasconi*" family*

46. The third relevant Roche patent family in this case is the '558 or "Bernasconi" family concerned with platinum resistant ovarian cancer. This family is based on an International Application filed under the PCT on 11th March 2013

(PCT/EP2013/054818) and claiming its earliest priority from a US filing (61/610,128) on 13th March 2012. The application was published as WO 2013/135602.

47. The contents of the relevant patent application in the 558 family would support claims to bevacizumab combinations for use in the treatment of platinum resistant ovarian cancer for indications (9)(a), (b) and (c) in the SmPC.

48. Favourable Phase III trial results for three combinations, bevacizumab with topotecan, bevacizumab with PLD and bevacizumab with paclitaxel, each for the treatment of platinum sensitive ovarian cancer were published in June 2012. These are indications (9)(a) to (c). They were added to the Avastin SmPC on in June 2014.

49. Following predictable unity objections (which were first raised in 2013 by the International Search Authority and maintained by the EPO examiner in 2016), on 11th October 2016 the 558 application was limited to bevacizumab in combination with paclitaxel. It covers indication 9(a).

50. In November 2017 Roche de-designated the UK (and only the UK) from application EP 558 A.

51. Pfizer filed third party observations in November 2018 but the examiner held they were not relevant. On 28th November 2018 the EPO examining division gave a notice of intention to grant the application. It was granted on 15th May 2019.

52. Roche has explained that it will file a divisional application before the grant takes place, as it is entitled to do. The parties' solicitors discussed the scope of this divisional in letters up to and during the trial. Roche's solicitors stated that Roche intends to file the divisional covering only the paclitaxel indication (9(a)). When pressed (since the material has basis for claims to the topotecan and PLD combinations too), Roche's solicitors stated that the divisional application "will not retain topotecan and PLD combinations as subject matter of the invention." Pfizer asked for a copy of the application itself. Roche stated it did not (yet) exist, which is reasonable since at the date of the trial an applicant in Roche's position would not need to have finalised the text. Pfizer contends that the assurance has no value because for technical reasons concerned with patent law, the only step Roche can take which would not jeopardise the future validity of any patent based on that divisional application (or any further divisional from it) would be one which does not rule out claims to the topotecan and PLD combinations in future. That is because deleting the relevant matter in the application would create a grave risk of invalidity under Art 123(2) EPC (added matter) whereas seeking to qualify the disclosure with words like "this is not the subject matter of the invention" do not rule out future claims to that subject matter. For present purposes I believe Pfizer is right at least to the extent that there remains a risk that claims to the topotecan and PLD combinations (i.e. indications 9(b) and 9(c)) could eventuate despite Roche's assurances. An undertaking by Roche to the court not to file such claims would be enforceable but is not offered.

53. In summary the position today is that Roche's 558 family consists of what is about to be a granted patent for indication 9(a). It does not designate the UK. Nine months after the grant, EPO opposition proceedings will very likely commence. There will be a pending divisional application whose purpose is to operate as a back up to try and cover indication 9(a) even if the granted patent is revoked in the opposition proceedings.

There is at least a risk that the pending application may allow for coverage of indications 9(b) and 9(c). While the soon to be filed divisional is still pending, Roche could file further divisionals in this family. However Roche cannot obtain patents in the UK from this family and Roche has not been able to do so since November 2017.

Summary of Roche's patent portfolio

54. Put shortly:

i) In the 085/Fyfe family directed at breast cancer, Roche has lost in the Opposition Division, is appealing to the TBA and has a pending divisional.

ii) In the 367/Dupont family directed at ovarian cancer, Roche's lead application was refused and the appeal was dropped. Roche has a pending divisional.

iii) In the 558/Bernasconi family directed at Pt resistant ovarian cancer, Roche's lead application is about to be granted. Roche has a pending divisional.

Pfizer's biosimilar product

55. On 18th December 2018 Pfizer was given a positive opinion by the relevant committee of the EMEA recommending approval of its biosimilar bevacizumab product Zirabev. As stated above, Pfizer plans to launch this in the UK and other EPO states in June 2020 at expiry of the bevacizumab SPC.

56. Unsurprisingly what Pfizer would like to do if it can is launch bevacizumab for all the indications for which bevacizumab is currently approved in Europe. That is all of indications (1) to (10). In the jargon that sort of marketing authorisation is called a full label. However in light of Mr Kim's evidence I find that the uncertainty caused by the Roche patent and application portfolio in this case led Pfizer to apply for a European marketing authorisation based on a skinny label for indications (1), (2), (4) (6) and (10) thereby excluding any which potentially fall within the scope of that portfolio. The exception is first line breast cancer with paclitaxel (indication (2)) because as explained above, Pfizer do not regard that risk as significant. With a skinny label there is always the possibility to add further indications in future. This is easier than taking indications off a full label.

57. Figures for the relative rates of prescriptions for bevacizumab in the five major European markets (UK, Germany, France, Italy and Spain) were set out by Mr Kim. I have added a (loose) cross-reference to the indication in the SmPC. The figures are:

(1)	Colorectal cancer	54%
(4) (5)	Non-small cell lung cancer	10%
(7) (8) (9)	Ovarian cancer	15%
	Glioblastoma	1%
(10)	Cervical cancer	0%
(2) (3)	Breast cancer	17%

(6)	Renal cell cancer	0%
	Others	4%

58. Thus although the largest indication is patent free, the ovarian and breast cancer indications do represent a substantial share of what is a very substantial market. Accordingly the skinny label is materially narrower in scope than the full label Pfizer would prefer. An alternative course would be to launch in different European states with different labels and so for example launch in the UK with a full label but use a skinny label elsewhere. Mr Kim's evidence was that this was not commercially practical. I accept his evidence. It makes sense.

59. Roche characterised Pfizer's case that the *Arrow* declaration might assist Pfizer in launching on a full label was a "lawyer's point" and cross-examined Mr Kim about when he received relevant advice. The issue was about whether the judgment might have an impact in other European states such that, if it lessens the likelihood of injunctive relief in foreign courts, then this makes it more likely Pfizer will decide to launch on a full label instead of a skinny label. I will come back to that.

The law

60. The topics to cover are declarations and Belgian law, albeit the latter is treated as an issue of fact.

Declarations

61. The court has the power to grant declarations, whether or not any other remedy is claimed (CPR Part 40 r40.20). Put broadly the factors that the court takes into account in deciding whether to do this are not disputed. They can be taken from ***FSA v Rourke*** [2002] CP Rep 14:

> "It seems to me that, when considering whether to grant a declaration or not, the court should take into account justice to the claimant, justice to the defendant, whether the declaration would serve a useful purpose and whether there are any other special reasons why or why not the court should grant the declaration."

62. Turning to *Arrow* declarations in particular, it is not disputed that this Court has the power to grant declarations of the type sought by Pfizer: namely a declaration that certain acts would have been obvious in light of the state of the art at a particular date. They are called *Arrow* declarations because the jurisdiction was established in ***Arrow Generics v Merck & Co Inc*** [2007] FSR 39. The jurisdiction was approved by the Court of Appeal in ***Fujifilm v AbbVie*** [2017] EWCA Civ 1. Moore-Bick LJ stated:

> "We have said enough to explain why we do not consider that there is any issue of principle which prevents the granting of *Arrow* declarations in appropriate cases. Drawing the threads together: (i) A declaration that a product, process or use was old or obvious at a particular date does not necessarily offend against section 74 of the 1977 Act. (ii) Such a declaration may offend

> against the 1977 Act where it is a disguised attack on the validity of a granted patent. (iii) Such declarations do not offend against the scheme of the EPC or the Act simply because the declaration is sought against the background of pending divisional applications by the counter-party. (iv) On the other hand the existence of pending applications cannot itself be a sufficient justification for granting a declaration. (v) Whether such a declaration is justified depends on whether a sufficient case can be made for the exercise of the court's discretion in accordance with established principles." [para 98]

63. Granting such a declaration is discretionary (sub-paragraph (v)) but while the existence of pending applications is necessary, it cannot itself be a sufficient justification for granting a declaration (sub-paragraph (iv)) – see ***Glaxo v Vectura*** [2018] EWCA Civ 1496 at para 25. The declaration still has to serve a useful purpose.

64. However, there the agreement between the parties about principles ends. The parties do not agree on how these principles are to be applied in this case. In summary counsel for Roche submitted that:

    i) The Court has no jurisdiction to grant declarations where there was no dispute about UK legal rights or disputes of facts that were relevant to UK legal rights.

    ii) In the alternative, if that argument fails, there was a "hard-edged" point of principle that precluded the Court from granting declarations in such circumstances. The "useful purpose" test (see ***FSA v Rourke***) therefore related to a purpose that was useful in the context of a UK legal dispute.

    iii) In the further alternative and in any event, the circumstances in this case do not justify granting a declaration for two reasons. First because in fact there is nothing in Roche's conduct to date which justifies exercising the jurisdiction as a matter of fact. Second because the only "useful purpose" relied on by Pfizer is the spin-off value of a UK judgment in foreign jurisdictions; and that is not enough.

65. In contrast, counsel for Pfizer argued that the discretion to grant declarations was wide – almost unfettered – and that "useful purpose" could be interpreted broadly to mean anything that was useful to the claimant. There was no point of principle to take about jurisdiction, hard-edged or otherwise. The lack of a dispute about UK legal rights was just one of the factors to take into account when the discretion is being exercised. In its submissions Pfizer placed weight on the criticisms of Roche's conduct and invited the Court to do the same.

66. Each side cited a lot of cases, many of which overlap. However these are decisions on the exercise of a discretion. Each turns on its own facts and has to be read in that context. There are few decisions which stand for any relevant overarching principles. Accordingly I will not go through all of the cited cases but focus only on what I believe are the most important ones.

67. I believe the most important case on the modern approach to declarations is ***Messier-Dowty v Sabena*** [2000] 1 WLR 2040. There the Court of Appeal held that when

determining the question of whether to grant a negative declaration the Court should decide "whether the declaration would serve a *useful* purpose". The court went on to hold that:

> "The approach is pragmatic. It is not a matter of jurisdiction. It is a matter of discretion." [p2050 G-H]

68. Pfizer relies on this for the proposition that there is no strict jurisdiction bar. Roche submits that the case was not concerned with a situation in which there was no dispute about UK legal rights at all and it is therefore very different from the present case.

69. Roche relies on ***Rolls Royce v Unite the Union*** [2009] EWCA Civ 387 and in particular the summary of the bases on which declarations should be granted which was given in Aitken LJ's dissenting judgment at paragraph 120:

> "For the purposes of the present case, I think that the principles in the cases can be summarised as follows.
>
> (1) The power of the court to grant declaratory relief is discretionary.
>
> (2) There must, in general, be a real and present dispute between the parties before the court as to the existence or extent of a legal right between them. However, the claimant does not need to have a present cause of action against the defendant.
>
> (3) Each party must, in general, be affected by the court's determination of the issues concerning the legal right in question.
>
> (4) The fact that the claimant is not a party to the relevant contract in respect of which a declaration is sought is not fatal to an application for a declaration, provided that it is directly affected by the issue; (in this respect the cases have undoubtedly "moved on" from *Meadows*).
>
> (5) The court will be prepared to give declaratory relief in respect of a "friendly action" or where there is an "academic question" if all parties so wish, even on "private law" issues. This may particularly be so if it is a "test case", or it may affect a significant number of other cases, and it is in the public interest to decide the issue concerned.
>
> (6) However, the court must be satisfied that all sides of the argument will be fully and properly put. It must therefore ensure that all those affected are either before it or will have their arguments put before the court.
>
> (7) In all cases, assuming that the other tests are satisfied, the court must ask: is this the most effective way of resolving the issues raised? In answering that question it must consider the other options of resolving this issue."

70. Roche emphasises sub-paragraph (2), arguing that it precludes the grant of a declaration in this case because following de-designation there simply is no UK legal right to be disputed at all. Pfizer draw attention to the fact that Aitkens LJ was in the minority and, in the converse of Roche's argument on ***Messier-Dowty***, that the issue of whether or not there was a legal right was not in dispute.

71. Pfizer also submits that the declaratory jurisdiction is not limited to legal rights, it includes matters of fact. To support this Pfizer refers to another passage in ***FSA v Rourke*** in which Neuberger J stated that the Court has a very wide discretion whether to grant a declaration:

> "Accordingly, so far as the CPR is concerned, the power to make declarations appears to be unfettered. As between the parties in the section, it seems to me that the court can grant a declaration as to their rights, or as to the existence of facts, or as to a principle of law, where those rights, facts, or principles have been established to the court's satisfaction. The court should not, however, grant any declarations merely because the rights, facts or principles have been established and one party asks for the declaration. The court has to consider whether, in all the circumstances, it is appropriate to make such an order." (p.10)

72. Pfizer invited the Court to draw the inference that the Courts therefore have a completely unfettered discretion to grant declarations and that the Court should grant one where, in all the circumstances, doing so would serve a useful purpose and the Court believes that it is right to do so. However, as with ***Messier-Dowty***, Roche pointed out that this was another case in which there was plainly a dispute about a legal right. Although the case establishes that it is possible to grant a declaration relating to facts, there was a legal context to that factual dispute. Roche contended that it was not possible to extrapolate further to say that one could make a declaration about facts in a vacuum and absent the overarching context of a legal dispute.

73. On the point that Aitkens LJ's summary was in a dissenting judgment, Roche rightly pointed out that the passage had been approved by a subsequent Court of Appeal decision ***Milebush Properties v Tameside MBC*** [2011] EWCA Civ 270 at paragraph 46 of the judgment of Mummery LJ (agreed with by Jackson LJ). I agree with that submission. Nevertheless I also note that Moore Bick LJ at para 87 went out of his way to state that while he was generally in agreement with Aitkens LJ's paragraph 120, it was expressed somewhat too narrowly. The reasons Moore Bick LJ gave for saying the paragraph was too narrow were that the dispute could relate to rights which might come into existence in future (based on Lord Diplock in ***Gouriet*** [1978] AC 435) and that the dispute could involve the interpretation of a licence which was a matter of public law (based on ***Mercury*** [1996] 1 WLR 48).

74. In my judgment, the decisions above were all concerned with the existence or scope of legal rights, public or private. ***Milebush*** was about whether a party was legally obliged to grant a right of way. ***Rolls Royce*** was about whether certain steps relating to a pension scheme would be unlawful under the equality regulations. ***Messier Dowty*** was about liability for loss caused by an airline accident. ***Gouriet*** itself was about whether threatened industrial action was unlawful. Even ***FSA v Rourke***, in which Neuberger J

made the statement relied on which refers to facts, was about whether Mr Rourke had accepted various deposits in contravention of the Banking Act 1987 (see p8 and p9).

75. However the fact that a case is concerned with the existence or scope of a legal right is not the same thing as saying that the issue in dispute has to be an issue of law. It plainly does not. The difference is illustrated by ***FSA v Rourke*** itself. There was no dispute that Mr Rourke was not authorised to take deposits such that if he had done that he would be in breach of the legislation. What was in dispute in that case were purely matters of fact, i.e. whether Mr Rourke had accepted various deposits at all. Mr Rourke denied he had but the judge was satisfied that the factual basis for the declarations was made out (p12). So a declaration was made that Mr Rourke had indeed done those acts, which were unlawful. It was made because it would serve a useful purpose in helping existing and future depositors (p15-16).

76. To take another obvious example, in a boundary dispute the court might declare where exactly the boundary is between neighbouring properties. The dispute is often entirely factual. The application of the law and the effect in the neighbours' legal rights is not in dispute once the factual question of the location of the boundary has been decided. Nevertheless while that can be portrayed as a matter of fact, it comes to court because it is concerned with the existence or scope of a legal right.

77. It is worth repeating that the existence or scope of a legal right is not limited to the past or present, it also includes a legal right which someone claims might come into existence in future, as Moore-Bick J pointed out in ***Milebush***. After all one original basis for the declaratory jurisdiction was a claim of right (see ***Re Clay*** [1919] 1 Ch 66).

78. Of course, subject to a possible exception (below), the cases on the *Arrow* jurisdiction itself have all been concerned with the existence or scope of the legal right in just the same way as the previous cases. The disputes to be resolved about the existence of the *Gillette* defence, which may lead to an *Arrow* declaration, may be purely matters of fact (e.g. prior use) or mixed questions of fact and law (obviousness) but what is being declared is that the holder of a set of patent applications will have no legal right to rely on any patent arising from them to prevent the sale of a given product. The same is true of a declaration of essentiality (***Nokia v InterDigital*** [2005] EWCA Civ 614, [2007] EWHC 3077 (Pat)) and a FRAND declaration (***Unwired Planet*** [2018] EWCA Civ 2344).

79. The possible exception to this principle is the decision of Henry Carr J in ***FujiFilm v AbbVie*** [2017] EWHC 395 (Pat). This judgment came after the Court of Appeal's decision cited above, which had been decided at an interim stage and held that the claim for an *Arrow* declaration should go to trial. By the time the case came before Henry Carr J for trial, the patentee had abandoned UK patent protection and was offering undertakings that it would not obtain UK patent protection of the relevant scope. The judge held that nevertheless the declarations would serve a useful purpose and, having found that a *Gillette* defence was made out, granted an *Arrow* declaration. The relevant section of the judgment is from para 379 to 417.

80. Pfizer contends that this decision amounts to the grant of an *Arrow* declaration even when no UK legal rights existed because the judge accepted that even though the undertakings were not well drafted, they did mean that no relevant UK rights could ever exist (paragraph 398). However in my judgment it is not that simple. The judgment

makes plain that the judge was satisfied that the declarations would have a useful purpose in dispelling commercial uncertainty which did exist in the UK (and Europe) and which had been created by threats made by the patentee. The undertakings were complicated, long and included an avoidance of doubt provision. The judge took into account that "none of this is easy to understand, particularly for companies seeking to do business with the claimants in respect of their [products]" and see also paragraph 399 in which the judge held that clarity for third parties in the United Kingdom was not provided by the undertakings.

81. So the circumstances were that the patentee had claimed it had or would have certain legal rights in the UK, generated significant commercial uncertainty about the nature and scope of those legal rights which was damaging to the claimant, and was offering complicated and unclear undertakings supposedly to clarify the situation but which did anything but. In those circumstances it is not hard to see why a court was prepared to exercise the declaratory jurisdiction.

82. Standing back from the details of the *Arrow* jurisdiction, of course there is no general threshold jurisdictional requirement that the defendant must actually have some kind of legal right in the first place, before the court's wide declaratory jurisdiction can be exercised. After all the declaration sought can be one that the defendant has no right at all. The point arising here (and in ***FujiFilm*** before Henry Carr J) is more nuanced than that. This court could readily grant a simple declaration that Roche has no right arising from the defined patent family to prevent importation (etc.) into the United Kingdom of the relevant products. The reason that is true is because of de-designation. However that is not what Pfizer wants nor is it what Roche is resisting.

83. The declarations sought are all in substantially the same form. They are that importation (etc.) into the United Kingdom of the claimant's biosimilar bevacizumab product for use [in a particular indication] would have been anticipated or obvious at the earliest priority date for any member of [a particular patent family] which proceeded to grant in the UK. The declaration sought is not merely that no UK rights exist but brings in the reason why that is so. The true purpose of this is the impact of such a declaration, and the reasoned judgment leading up to it, in foreign jurisdictions. That is what Henry Carr J called the spin-off value of a judgment. It is what the present dispute is really about.

84. Henry Carr J dealt with this in paragraphs 372-377 and came back to it at 412. As the judge did in those passages, I agree that the use of a UK patent judgment in other contracting states of the EPC can be very valuable and that it is legitimate for parties to rely on a judgment in that way. However as the judge also said, and I also agree, this cannot be taken too far and one needs to take into account the risk of forum shopping – where a declaration is sought from a UK court in a case with no connection to this jurisdiction. Notably however, in paragraph 412, the judge expressly did not take into account the value of the judgment in other contracting states in his assessment of useful purpose.

85. Finally I was referred to the judgment of Cockerill J in ***Deutsche Bank v Bright Food*** [2017] EWHC 3543 (Comm). In that case the judge granted declarations, including negative declarations, relating to the effect of a 2002 ISDA Master Agreement and an associated trade document which were expressly subject to English law and had a non-exclusive English jurisdiction clause. The purpose of the declarations was for them to

be used in the courts in China. Henry Carr J's judgment in ***FujiFilm*** was cited to the judge however Cockerill J was not concerned about forum shopping given the choice of law and jurisdiction clauses.

86. Taking stock, in my judgment the position is the following. Roche's first submission (set out at paragraph 64(i) above) is wrong because it purports to place a limit on the court's power to grant a declaration even when it would serve a useful purpose. That is not right because the only relevant limitation is concerned with useful purpose. I would characterise Henry Carr J in ***FujiFilm*** as a case illustrating why the first point is wrong. The fact that analytically, by the time the question came to be decided, it was true that there was no longer a dispute before the court about the existence or scope of AbbVie's UK legal rights, did not mean the declaration would serve no useful purpose.

87. As for Roche's second submission (paragraph 64(ii) above), the first part of it is wrong for the same reasons as the first submission. The second part of the second submission is that the useful purpose test must be related to a purpose that is useful in the context of a UK legal dispute. The ***Deutsche Bank*** case shows why that is not correct. At least as long as one is not concerned with forum shopping, the fact that the purpose is useful in relation to a dispute in a foreign court may justify granting a declaration. On the other hand ***Deutsche Bank*** is a long way on the facts from the present case, because there the foreign court was going to have to decide issues arising under a contract governed by English law.

88. Roche's third point (paragraph 64(iii)) is not really a submission of law or principle. The true principle in my judgment is that in considering all the circumstances and the issue of useful purpose, the court will wish to identify what the real purpose of the declaration is. There may be more than one purpose. The court will look carefully at a case in which the only or predominant purpose of the declaration sought is to use the court's judgment in foreign jurisdictions.

Belgian Law

89. Both sides led expert evidence on Belgian law and practice and made elaborate submissions about it.

90. Roche's summary of the points arising (Roche Closing para 155) is as follows:

(1) Could Pfizer have cleared the way in Belgium, at least at first instance? It is not in dispute that a revocation case on the 189 Patent could have been brought in January 2017. The following sub-issues arise.

1.1.1. How long would such an action have taken?

1.1.2. What about a stay pending the EPO opposition?

1.1.3. What is the effect of a first instance Belgian decision on *granted* provisional measures?

1.1.4. What is the effect of a first instance Belgian decision on *future* applications for provisional measures?

(2) What would the likely impact of a UK decision in this action be upon a Belgian Court hearing a case for preliminary measures or on the merits. Five sub-issues arise:

1.2.2. The ***Roquette*** decision.

1.2.3. How is the ***Roquette*** decision applied in practice?

1.2.4. What is the impact of the fact that there are no UK patent rights, and of Roche's principled stance on the technical issues?

1.2.5. The 'balancing the interests' point.

(3) Is *Arrow* relief likely to be available in Belgium?

91. Pfizer puts its case on Belgian law in a different way, advancing four propositions in its closing submissions on Belgian law:

> Proposition 1:
>
> Reasoned judgments and declarations of the English court on obviousness and novelty will, in general, be given significant persuasive effect by the courts of Belgium when considering questions of the validity of a patent, at the trial on the merits and when considering whether or not to grant preliminary measures such as injunctions, in respect of which they can also give significant direct protection.
>
> Proposition 2:
>
> In particular, a reasoned judgment and declaration of the English court on obviousness and/or novelty can play an indispensable role in resisting preliminary measures such as preliminary injunctions or *saisies description*, as it can rebut the presumption of validity in interim proceedings which would otherwise apply and can lead to preliminary measures being refused or limited in effect.
>
> Proposition 3:
>
> This significant effect will exist (a) whether the English judgment/declaration(s) are reached in the context of an *Arrow* declaration claim or otherwise; (b) even if the English judgment and declaration are reached in a situation where the defendant did not contest the technical merits. It is not defeated merely because the English judgment and declaration are reached in the context of different evidential or procedural rules.
>
> Proposition 4:
>
> The effect of the English judgment and declaration is not defeated or materially lessened if the English court applies the

> *Pozzoli* approach rather than the problem/solution approach. The Belgian courts do not always use the problem/solution approach and even if they use the problem/solution approach, they would take into account the reasoned judgment of the English court under *Pozzoli*.

92. I will start with Roche's points, addressing the corresponding Pfizer propositions when relevant. However before going any further I note Roche's characterisation of its position as a "principled stance on the technical issues" in 1.2.4. This is nothing to do with Belgian law but it is worth addressing now. The characterisation is self-serving and hypocritical. Roche is entitled to choose not to challenge the technical evidence if it wishes and I make no criticism of that at all. However this approach is not based on some high principle. Roche is simply seeking to do everything it can to minimise the utility to Pfizer of any relief Pfizer can obtain in this jurisdiction. Part of that strategy is to characterise any technical decision here as uncontested. The hypocrisy is exposed because Roche does in fact engage with the technical issues if it thinks it can do it subtly and can get away with it. The proof is a point on the technical issue of priority. Roche has advanced a positive case that the relevant priority date for any UK *Arrow* declaration ought to be the filing date of the applications concerned and not their earlier claimed priorities. This is pleaded in its Defence and was maintained in Roche's closing submissions. However Roche does not really mean that the true priority date of any of these inventions is the filing date. Once exposed, it is obvious that the only purpose of this argument is to seek to limit the damage which might be done in a foreign court by any *Arrow* declaration here by allowing Roche to say in the foreign court that the true priority dates are the earlier claimed dates whereas the *Arrow* declaration was only concerned with a later date.

Roche point (1) – Pfizer's existing options in Belgium

93. To recap part of the background section above, EP 189 covers indication (3), which broadly relates to bevacizumab with capecitabine for certain forms of breast cancer. It was granted in 2016 and did not designate the UK. It did designate Belgium. Pfizer is one of the opponents in the pending EPO opposition proceedings on that patent. Currently Roche is appealing the opposition division's decision to revoke the patent entirely. As Roche submit, as a matter of Belgian law, once it was granted Pfizer could have commenced a national revocation action in Belgium to revoke the Belgian designation. It is common ground that subject to a stay pending the EPO opposition, the earliest this could typically be done is three months after grant because of local rules – so January 2017. Although there was some confusion in detail, by closing it was clear that such a claim could be completed at the first instance by the end of 2018 but could well take longer, e.g. if the court decided to appoint an expert. Exactly how long is impossible to predict. What is clear from the evidence is that it is fair to assume the first instance would be complete by June 2020.

94. As for the prospect of a stay pending the EPO opposition, the Belgian courts take what seems to me to be essentially the same pragmatic approach as the Patents Court here. If a stay was sought by Roche, it might or might not have been granted. I rather think a stay would be unlikely if Pfizer explained that it was seeking to clear the patent out of the way pending launch in June 2020.

95. If a preliminary injunction to restrain Pfizer from infringing the Belgian patent EP 189 had already been granted then, assuming the Belgian court hearing the revocation case found the patent was entirely invalid, the effect of that decision would be to automatically revoke the preliminary injunction. Pfizer would be free to sell bevacizumab for indication (3).

96. If a preliminary injunction was sought under the patent after it had been revoked at the first instance then under Belgian law the burden of proof is reversed. In other words, whereas normally under Belgian law the patentee holding a granted patent enjoys the benefit of a presumption of validity, when the burden of proof is reversed there is no longer such a presumption and the patentee would have to convincingly demonstrate that they were likely to succeed on appeal from the first instance decision.

Roche point (2) – likely impact of a UK decision in Belgium

97. This is the topic to which all four of Pfizer's propositions are addressed.

98. The key to this is the decision of the Cour de Cassation in ***Roquette***. The case was about an application for preliminary measures relating to alleged infringement of the Belgian designation of a European patent. The British designation of the patent had been revoked in the UK ([2010] EWCA Civ 1049). In France the national designation had been revoked at first instance but that was subject to appeal, and under French law the appeal has suspensive effect. The lower court in Belgium granted the preliminary measure relying on the presumed validity of the patent which was not displaced by the French decision because of the suspensive effect on appeal. On appeal the Cour de Cassation held (in translation):

> 8. Article 2(2) of the Convention on the Grant of European Patents concluded in Munich on 5 October 1973, approved by law of 8 July 1977, as amended by the Act revising the Convention on the Grant of European Patents of 29 November 2000, adopted by the decision of the Administrative Council of 28 June 2001 and approved by the law of 21 April 2007 provides that in each of the Contracting States for which it is granted, the European patent shall have the effect of and be subject to the same conditions as a national patent granted by that State, unless this Convention provides otherwise.
>
> By virtue of Article 138(1) of said Convention, the European patent may be revoked with effect for a Contracting State only on the grounds outlined by this Article, so that the validity of a European patent must be verified on the basis of the same criteria in each Contracting State for which it has been granted.
>
> It follows that even though the revocation of a European patent, granted for a Contracting State, only has an effect on the territory of that Contracting State and hence does not produce any legal effect in another Contracting State, such revocation, and the underlying reasons thereof, may be relevant when evaluating the apparent validity of a patent in a State different to the one it was granted for.

> 9. Article 1369bis/1, § 3, paragraph 1, 1), of the Judicial Code requires the President to assess the apparent validity of the patent on which the descriptive attachment order is based, taking into account all facts and circumstances invoked by the parties.
>
> 10. By ruling that the revocation of a particular section of a European patent only has territorial effect and by setting aside, on that ground, the final rulings of the English courts revoking the English section of the Belgian patent when assessing the apparent validity of the Belgian section of the European patent, the appellate court has not lawfully motivated its decision.

99. The court here was emphasising that although the individual national patents within a European patent are territorially distinct, there is a common system of law with the same basis for validity throughout the contracting states. Accordingly the lower court erred in not taking into account a decision in another contracting state which found that the patent was invalid.

100. Dr Cassiers explained that this decision represented a dramatic change in Belgian case law because hitherto the Belgian courts had applied the presumption of validity irrespective of the fact that courts of other contracting states to the EPC had held their national designations of an EP invalid. That had was been not enough to question the prima facie validity of a Belgian national designation of the same European patent. I accept his evidence. Dr Buydens' view was that while, following ***Roquette***, the Belgian courts cannot now ignore the invalidity decisions of courts in other jurisdictions, the case law showed that the mere fact a foreign patent had been revoked was not enough for the court to consider that a patent is prima facie invalid. In other words the presumption would not be automatically reversed. Stated at that level of generality, I accept Dr Buydens' evidence too. She identified various points which were relevant to this and I will consider them next in the context of how ***Roquette*** has been applied in practice.

101. Roche was keen to emphasise that it is not the legal effect of foreign decisions which matters but the reasons given for that decision. That makes sense. Roche also submitted that abandonment of a foreign right and its surrender without a reasoned decision would not affect the prima facie validity of the Belgian designation. That also makes sense, although I would have thought a patentee ought not to be surprised if questions come from any bench in those circumstances.

102. Unsurprisingly, the Belgian court will not follow a foreign decision blindly but will examine the extent to which it is relevant to the dispute and only take it into account insofar as it considers the foreign decision is relevant. That proposition derives from the decision of the Court of Appeal in ***Orion/Novartis v Eurogenerics*** on 20th September 2016 (Case 2015/KR/45). Relevance includes taking account of the factual and legal context. Nevertheless there is a pragmatic limit in that, again unsurprisingly, the Belgian court is not required to conduct an in depth analysis of a foreign decision. Overall the approach necessarily includes the possibility that it is open to a Belgian court in proper circumstances to decide to place no weight on a foreign decision after assessing its relevance. I accept all of this.

103. Dr Buydens said that in her opinion a Belgian court was very unlikely to be influenced in its determination of prima facie validity, or validity in a main action, by a judgment from another jurisdiction in which findings were made by the court but where one side played no part in the proceedings in relation to those findings and did not make any relevant admissions. This was clearly directed to a possible future situation arising from this case in which an *Arrow* declaration had been granted but Roche sought to characterise it as a finding in which they played no part. Dr Buydens maintained her opinion in cross-examination and denied it was speculation. Roche contend that Dr Cassiers agreed that presented with reasonable arguments to support the validity of the Belgian patent, a Belgian court would likely place little weight on the contrary foreign uncontested decision.

104. I did not understand Dr Cassiers to accept the point Roche sought to prove. What he was accepting in one passage in cross-examination (when he started a sentence with the word Yes) was that the Belgian court can make a different decision from the decision abroad. The scenario being put to him boiled down to an *Arrow* declaration being granted in this case but then in Belgium Roche advancing arguments in support of validity which it has chosen not to advance here. He did not agree with Roche's simple proposition that the Belgian court would then be likely to place the greatest weight on the arguments before it rather than on what Counsel for Roche called the uncontested decision. Dr Cassiers' point was that Roche would not be precluded in Belgium from advancing an argument just because it was not advanced here, but that overall the Belgian court would assess the relevance of the foreign decision.

105. In my judgment Dr Buydens' evidence about what a Belgian court would do was indeed speculative. I was not convinced by Dr Buydens' denial. In my judgment a Belgian court faced with a decision from this court will examine its relevance and take all the circumstances into account. That will include the fact that Roche has played a full part in as much of the case as it has chosen to and has had every opportunity to present arguments about validity and scope of the patents. It will include the fact that Roche de-designated the UK. If Roche, in Belgium, advanced arguments it had not advanced here, the Belgian court will consider them but it would be entirely open to the Belgian court to decide that nevertheless a judgment from this court was relevant and undermined the prima facie validity of a patent said to be infringed by Pfizer's bevacizumab and it would also be entirely open to the Belgian court to decide that a judgment from this court was not relevant and did not have that effect.

106. Turning to further Belgian law issues:

i) The fact that Roquette was decided relating to a *saisie description* rather than a preliminary injunction is not material. The principle is and will be applied in Belgium in relation to any provisional measures or preliminary injunctive procedure and on the merits.

ii) Even if an *Arrow* declaration as such is unavailable in Belgium, that does not mean a Belgian court would ignore the reasons in an English judgment deciding to grant an *Arrow* declaration. As to whether it is available at all (including in the same circumstances as in this case – with de-designation) the position is untested and uncertain.

iii) It is at least possible that a Belgian court might adopt an approach whereby it might refuse a preliminary injunction in a weak case but direct other lesser measures. However I am not satisfied that possibility is substantial enough to make a difference to any issue I have to decide.

iv) The fact that the judge of the English court did not apply the problem solution approach to obviousness is unlikely to be a material factor. The Belgian courts do not always use that approach.

107. Finally, focussing on Pfizer's first three propositions, I accept the following (with the changes from Pfizer's case shown):

> Proposition 1:
>
> Reasoned judgments giving rise to ~~and~~ declarations of the English court on obviousness and novelty will, in general, be taken into account ~~given significant persuasive effect~~ by the courts of Belgium when considering questions of the validity of a patent, at the trial on the merits and when considering whether or not to grant preliminary measures such as injunctions ~~in respect of which they can also give significant direct protection~~.
>
> Proposition 2:
>
> In particular, a reasoned judgment giving rise to a ~~and~~ declaration of the English court on obviousness and/or novelty can, if the Belgian court decides it is relevant play ~~an indispensable~~ a significant role in resisting preliminary measures such as preliminary injunctions or *saisies description*, as it can rebut the presumption of validity in interim proceedings which would otherwise apply and can lead to preliminary measures being refused or limited in effect. It is open to the Belgian court to decide it is irrelevant in which case it will have no role at all.
>
> Proposition 3:
>
> This ~~significant~~ effect will exist (a) whether the English judgment/declaration(s) are reached in the context of an *Arrow* declaration claim or otherwise; (b) even if the English judgment and declaration are reached in a situation where the defendant did not contest the technical merits. It is not defeated merely because the English judgment and declaration are reached in the context of different evidential or procedural rules.

The declaration on the facts

108. Having dealt with the law I turn to consider whether to grant an *Arrow* declaration, focussing on whether it would serve a useful purpose.

The prima facie merits of the technical case

109. I have read the (lengthy) reports of Dr DiSilvestro and Dr Jones. I have looked at the prior art relied on. They show the following. By the relevant earliest priority date for the relevant patent family, there were various standard chemotherapy treatments and combinations used for treating breast cancer and ovarian cancer. Bevacizumab was known and was known to be a treatment with a different mechanism of action from the other standard drugs. The result of clinical trials were public and they showed that bevacizumab was effective in combination with other standard drugs to treat other cancers. Further clinical trials were under way or, in some cases, had already reported on the efficacy of using bevacizumab with some established standard chemotherapy combinations to treat breast cancer and ovarian cancer. Given that bevacizumab was an established agent with a different mechanism of action, there is an apparently strong case that it would be obvious to combine it with the other standard chemotherapy combinations and an apparently strong case that a skilled person would have reasonable prospects of success in providing improved efficacy that way. Aside from the question of reasonable prospect of success, in some cases there might be a point on features such as dosing, but these appear to be trivial distinctions in this case. The evidence as a whole makes a compelling case in favour of a *Gillette* defence. However I will not at this stage in the reasoning go further and decide the various issues. That would require me to go into the detail much more closely. Nevertheless in my judgment it is relevant to examine the apparent merit of the technical case in this way because it may help to explain the motives of the patentee. A patentee with faith in its case on the merits would be unlikely to engage in shielding.

Roche's conduct and shielding

110. There was an argument about the numerical value of the future UK market. Mr Kindell addressed this for Roche. Mr Kim addressed it to some extent for Pfizer. I decline to get drawn into the numbers because they do not help. I find that the potential value to Roche of the future UK market for Avastin is very substantial. The value if Pfizer's bevacizumab could be kept out of all the indications in issue in this case in the UK is itself very substantial. It is far more than the cost of this sort of litigation. Keeping the contested indications of Pfizer's bevacizumab out of the UK market by using patents would be a prize worth fighting this litigation for. On the other hand, looking at the market protected by these European patents as a whole, the future UK market is only a fraction of it. The value of the rest of the European market is much larger than the UK market. The same goes for the value of the market relating to the contested indications.

111. I infer the Roche's motive for de-designating the UK is to shield its portfolio from the risk of an adverse decision in this court. There is no other rational explanation.

112. What of the arguments about the specifics of Roche's patent prosecution practice? I accept Mr Bassett's overall view that the way in which Roche approached this portfolio has been standard industry practice and not unusual. Dr Wright's view was not so much that what Roche had done was unusual, his view was that patentees ought not to do the sorts of things which were being done. That is not necessarily inconsistent with Mr Bassett's evidence. The focus on the minutiae of patent prosecution risks getting out of hand and it is worth keeping in mind what it is all directed to. Pfizer says it sheds light on Roche's intentions. Pfizer argues that viewed properly it supports the allegation of shielding, of Roche trying to avoid adverse decisions and maintaining uncertainty for as long as possible to its commercial benefit and to the disadvantage of its competitors.

113. The only aspect of the prosecution practice which stands out is the way Roche behaved in relation to the 367 application, the abortive appeal from the refusal by the examining division and the timing of the filing of the divisional. The natural thing to do if the examining division reject an application you believe is well founded is to file an appeal. Roche did that. Having got that far, the natural thing to do would be to pursue the appeal and vindicate your case. Roche dropped the appeal. I infer that the reason Roche did that was to avoid the risk of an adverse decision on appeal which would carry more weight than a refusal by the examining division. It was shielding. The fact that an appeal would not come on for a number of years is true but no answer. The newly pending divisional filed instead will take even longer to come to a conclusion.

114. Apart from the point on the 376 application, I am not convinced the detail of how Roche has conducted itself in the course of prosecuting these applications tells one anything beyond what is apparent from looking overall. That includes Pfizer's clinical trials point. Overall Roche applied for patents to cover all the relevant indications. It has used the ability to file divisionals to maintain pending applications of as wide a scope as possible (save possibly in relation to indications 9(b) and 9(c)). Nothing Roche has done is unlawful. Objectively this conduct gives rise to significant uncertainty for Roche's competitors. Roche knows that perfectly well. On the other hand Roche would no doubt like to get a valid patent for one of these indications if it can. It is entitled to try. None of this means that Roche does not have a bona fide belief that despite the obvious weakness of this portfolio, it might manage to get or hold on to some kind of valid patent claim relating to perhaps some of the relevant indications. Something might turn up. However the fact that Roche has that state of mind (I will assume in its favour) should not prevent the court from making an *Arrow* declaration when, as here, Roche has taken steps to shield the patents from scrutiny.

Real commercial value of a declaration?

115. An *Arrow* declaration would be of real commercial value for Pfizer. It would reduce the uncertainty which Pfizer faces in relation to its launch of bevacizumab all over Europe.

116. A concrete illustration of the value of the declaration is the decision which Pfizer has to make about launching bevacizumab on a skinny label or a full label. I reject Roche's attempt to play down this so called lawyer's point. Pfizer has not yet decided what course it will take and, depending on the circumstances, it may opt for a full label or a skinny label. The outcome of this case, as well as advice on what impact the outcome of this case may have in other jurisdictions, will be some of the factors Pfizer will consider when the time comes. None of this means that the *Arrow* declaration has no value. The judgments of courts of countries which are members of the EPC do play a role in influencing the decisions of courts of other EPC states considering the local designations of the same European patent. The outcome of this case will materially assist Pfizer in making its decision about full and skinny labels when the time comes. That is of real commercial value to Pfizer.

117. Another example of real commercial value is that a judgment would be taken into account in Belgium and, assuming it was favourable to Pfizer, could help Pfizer resist a patent case brought by Roche in that country.

Useful purpose – overall

118. If today there were pending UK applications in any of the families, this would be a plain case for an *Arrow* declaration and I would go on to examine the merits of the *Gillette* defences in detail. However given the complete absence of the possibility of UK rights in future, the reality is that the commercial value of an *Arrow* declaration to Pfizer is the utility it might have (along with a reasoned judgment) in helping Pfizer defend itself against suits brought by Roche in other European countries. This case is unlike ***FujiFilm*** in that in relation to bevacizumab there is no outstanding uncertainty at all relating to UK rights. Pfizer does not need the Patents Court to tell it or anyone else that it can freely sell bevacizumab in this country without risk from the Roche patent families.

119. There is uncertainty relating to the UK market but that derives from the fact that the goods are to be supplied from a separate jurisdiction (Belgium) in which the uncertainty remains. Now what Pfizer really wants is a UK judgment so as to use it in Belgium. In ***Deutsche Bank*** the issue which was to come before the foreign court was about a UK contract and UK law and so the UK court was naturally in a better position than a foreign court to rule on such a point, and so obtaining a ruling here to use abroad was not forum shopping. However the position here is different because the issue which will come before the Belgian court (if it ever does) will be about a Belgian patent and Belgian law. The fact that a Belgian court would take a judgment of this court into account does not alter the fact that the UK courts are in no better position to rule on those points of the patent law. It is true that under the EPC we apply the same law in Belgium and in the UK but that is not a sufficient justification for embarking on the exercise of deciding the technical issues.

120. What will happen in Belgium is likely to affect the UK market but that is only because of the local effect in Belgium of a Belgian designation of the European patent. It is nothing to do with any UK legal right.

121. Another way a declaration could be useful would be to assist settlement. That can often be a useful factor, and I think it probably applies in this case, but on these facts it is not enough to make a difference.

122. When the action began it was not forum shopping at all. There were pending UK applications which provided a basis for considering an *Arrow* declaration. However now they have gone. There might have been other factors which justified *Arrow* relief such as arose in ***Fujifilm*** but on examination in this case, there are not. There is no evidence of uncertainty about UK patent rights. The true purpose of an *Arrow* declaration in this case would be for it to be used in foreign courts. I am not persuaded that that is enough.

Conclusion

123. Irrespective of the merits of the *Gillette* defence claimed by Pfizer in this case, I would not grant an *Arrow* declaration. Accordingly I will not examine the merits of the *Gillette* defence in any detail because to do so would be tantamount to doing the very thing I have decided not to do.