Neutral Citation Number: [2021] EWHC 2692 (Pat)

Case No: HP-2019-000001

IN THE HIGH COURT OF JUSTICE

BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

Royal Courts of Justice, Rolls Building
Fetter Lane
London, EC4A 1NL

8 October 2021

Before :

HIS HONOUR JUDGE HACON
(Sitting as a Judge of the High Court)

- -

Between :

ROYALTY PHARMA COLLECTION TRUST	**Claimant**
- and -	
BOEHRINGER INGELHEIM GmbH	**Defendant**

- -

Andrew Lykiardopoulos QC and **James Segan QC** (instructed by **Powell Gilbert LLP**) for the **Claimant**
Adrian Speck QC and **James Whyte** (instructed by **Allen & Overy LLP**) for the **Defendant**

Hearing dates: 2, 4-6 and 9-10 November 2020 and 19-20 and 22 April 2021

- -

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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HIS HONOUR JUDGE HACON

Judge Hacon :

INTRODUCTION

1. On 10 May 2005 the Defendant ("Boehringer") entered into a written agreement with Prosidion Limited ("Prosidion"). Prosidion granted Boehringer a non-exclusive licence under patents and patent licences owned by Prosidion ("the Original Agreement").

2. Prosidion's benefit under the Original Agreement was assigned to the Claimant ("Royalty Pharma") pursuant to a written agreement, effective as of 29 July 2011.

3. Following negotiations between Royalty Pharma and Boehringer, the Original Agreement was amended by a written agreement effective as of 19 May 2015 ("the Amendment Agreement"). This gave rise to "the Amended Agreement".

4. The Original Agreement was governed by German law and provided that the courts of England and Wales have jurisdiction over any dispute. Both provisions were left unaltered by the Amendment Agreement.

5. Royalty Pharma claims about €23 million from Boehringer in outstanding royalties pursuant to the Amended Agreement. Boehringer counterclaims that it has overpaid royalties under both the Original and Amended Agreement, so that there is a sum owed by Royalty Pharma to Boehringer, although it has not been quantified. The counterclaim as it relates to the Original Agreement is admitted by Royalty Pharma, subject to quantification.

6. Andrew Lykiardopoulos QC and James Segan QC appeared for Royalty Pharma, Adrian Speck QC and James Whyte for Boehringer.

BACKGROUND

7. The products sold by Boehringer which generated royalties under the Agreements were pharmaceuticals authorised for the treatment of type 2 diabetes, sold under the names "Trajenta" ("Tradjenta" in the United States, but hereafter always referred to as "Trajenta"), "Jentadueto" and "Glyxambi" (collectively "the Products"). The active pharmaceutical ingredient ("API") of all three products is linagliptin, which is a dipeptidyl peptidase-IV ("DP-IV") inhibitor used to treat type 2 diabetes by blocking the enzyme DP-IV. All the linagliptin in the Products is manufactured by Boehringer in Germany. Some is formulated, labelled and packaged into Products in Germany and some linagliptin is exported by Boehringer to other countries.

8. One of the patents licensed by Royalty Pharma to Boehringer was the German designation of European Patent No. 1 084 705 ("EP 705"). EP 705 was granted on 25 June 2014.

THE OVERALL ARGUMENTS

9. Royalty Pharma argued that but for the licence under the Amended Agreement, Boehringer's manufacture of linagliptin in Germany would have infringed EP 705. From the date of the Amendment Agreement, 19 May 2015, royalties fell due on that

manufacture under the amended clause 3.3(a) until the date of expiry of EP 705 on 24 April 2017.

10. Boehringer advanced four arguments in response. First, royalties were generated in respect of Product. On a correct construction of the Amended Agreement "Product" meant a formulated product. Even if the manufacture of Product in Germany gave rise to the payment of royalties, the manufacture of the API linagliptin did not.

11. Secondly, in the Amended Agreement there was no change to the events which triggered the payment of royalties. Under the Original Agreement, as is now common ground, only the sale of a Product in a territory with a subsisting licensed claim covering the sale of the Product gave rise to an obligation to pay royalties; an act of manufacture did not. The Amendment Agreement did nothing to change that.

12. Thirdly, the manufacture of linagliptin in Germany would not in any event have constituted an infringement of EP 705 absent a licence. EP 705 has claims in EPC 2000 form. Under German law the manufacture of linagliptin would not directly infringe unless it was earmarked in Germany for use in the patented treatment, i.e. reducing blood glucose levels in the treatment of diabetes (I will return to the meaning of "earmarked"). It was not. Royalty Pharma does not allege that there would have been indirect infringement. Consequently EP 705 imposed no liability in respect of the manufacture of linagliptin in Germany.

13. Fourthly, no products made for export from Germany could have infringed EP 705 as a matter of law.

14. There was a fifth issue on the rate of interest, both in relation to payment due from Boehringer, if any, and separately on the reimbursement of royalties by Royalty Pharma to Boehringer.

THE WITNESSES

15. Royalty Pharma's witnesses of fact were George Lloyd and Molly Chiaramonte.

16. Mr Lloyd is the General Counsel of the Royalty Pharma group, of which Royalty Pharma forms part. He negotiated the Amendment Agreement with Boehringer and gave evidence about those negotiations. Such evidence is admissible as an aid to construction under German law. Mr Lloyd gave clear evidence and was a good witness.

17. Dr Chiaramonte is a Senior Vice President in the Research and Investments team of Royalty Pharma. She gave evidence about the acquisition of the benefit of the Original Agreement from Prosidion, the negotiation of the Amendment Agreement and Royalty Pharma's expectations regarding royalties that would accrue from the Original and Amended Agreements. Ms Chiaramonte gave clear and careful answers and like Mr Lloyd was a helpful witness.

18. Boehringer called Lutz Aye to give Boehringer's account of the negotiations which led to the Amendment Agreement. Dr Aye is Head of Legal, Animal Health Global Strategic Marketing and EUCAN (Europe, Canada, Australia and New Zealand). Although Dr Aye has fluent English, he gave his evidence by video link from a German court and therefore pursuant to German law his evidence was given in German with

interpretation into English. Dr Aye was a good witness giving well considered answers to all questions. However, Dr Aye could not speak to key issues in dispute because he was not involved in all the negotiations which led to the Amendment Agreement. They were largely conducted on Boehringer's behalf by Jürgen Beck who was then Corporate Director of Business Development and Licensing Strategy at Boehringer. Mr Beck still works for Boehringer in a different capacity and it was not suggested that he was unable or unwilling to give evidence. The failure to call a key witness did not assist Boehringer's case.

19. Both parties called expert evidence on German law. Royalty Pharma's expert was Maximilian Haedicke. He is a Professor of Civil Law and Intellectual Property at Albert-Ludwig University in Freiburg. Professor Haedicke has worked at the Max Planck Institute for Foreign and International Patent, Copyright and Competition law. He also worked in private practice as a patent litigator before becoming a full time academic where he specialises in intellectual property, competition and contract law. Professor Haedicke is the author of a leading German textbook on patent law: *Lehrbuch Patentrecht*, pub. Heymanns. From 2011 to 2017, in addition to tenure at Albert-Ludwig University, he was a judge at the Patent Division of the Düsseldorf Court of Appeal. Professor Haedicke was an excellent witness who gave helpful answers to the questions put to him.

20. Boehringer's expert was Professor Mary-Rose McGuire who since July 2015 has held the Chair for Private Law, Intellectual Property Law and German and European Civil Procedure at the University of Osnabrück. Professor McGuire previously held the Chair for Private Law and Intellectual Property at the University of Mannheim. Professor McGuire's research has focused on licence contract law. Her professorial thesis *Die Lizenz: Eine Einordnung in die Systemzusammenhange des BGB und des Zivilprocessrechts* (The License: An Integration into the Systems of the German Civil Code and Civil Procedural Law) was published in 2012 and she has participated in a published model for the recodification of German IP law. Professor McGuire has contributed a commentary to three sections of the German Patent Act and is currently contributing to a new edition of a handbook on patent and know-how contracts.

21. Professor McGuire said that her views on some of the issues on which she had been asked to give evidence came not from her own experience and knowledge but from research carried out in preparation for the case by two assistants supervised by her. I see no necessary objection to reliance on others' research. But on one potentially important subject I found her answers impossible to accept. For reasons I explain below, her opinion that EPC 2000 claims are treated in German law as process claims is to my mind plainly wrong. Yet in cross-examination Professor McGuire maintained the correctness of this view in the face of clear evidence to the contrary. In closing Boehringer downplayed the correct characterisation of EPC 2000 claims as being of no significance, but Professor McGuire seemed to think it mattered and it could have been of considerable significance. Her evidence on this to a minor degree undermined my confidence in the accuracy of her statements on German patent law. It may be that Professor McGuire was more comfortable discussing the German law of contract, about which she was extremely helpful.

THE OBLIGATION UNDER CLAUSE 3.3(a) OF THE AMENDED AGREEMENT

German law of contract

22. Contract law in Germany is governed by the German Civil Code, the *Bürgerliches Gesetzbuch* ("BGB").

The formation of a contract

23. There was common ground as to the principles underlying the formation of a contract in German law. It is analysed by reference to the parties' respective declarations of intent and begins where one party has declared an intent to enter into a binding agreement – communicated an offer. The offer may be accepted by the other party or a modification may be proposed. The decisive issue is whether there were successive declarations, one from each side, which correspond such that the parties agreed all the principal terms of the contract. Earlier declarations of intent are not binding but may be referred to in order to determine the parties' intentions at the time the contract was formed.

General principles of contract interpretation

24. The experts agreed that the two most relevant provisions of the BGB in relation to the interpretation of a contract are sections 133 and 157. Section 133 provides:

> "*133 When a declaration of intent is interpreted, it is necessary to ascertain the true intention rather than adhering to the literal meaning of the declaration.*"

25. Section 157 provides:

> "*157 Contracts are to be interpreted as required by good faith, taking customary practice into consideration*."

26. Consequent upon the way that these provisions have been applied by the German courts, there are three approaches to the interpretation of a contract recognised in law: (1) subjective, (2) objective and (3) supplementary interpretation.

Subjective interpretation

27. Where the parties share a common subjective intention at the time the contract was made, they are bound by that common intention even if the objective meaning of the language of the contract differs from it. This seldom occurs in respect of commercial contracts. The party seeking to rely on subjective interpretation bears the burden of proving that there was a common subjective intention which differs from the meaning of the words of the contract.

28. There may be a loose parallel between the circumstances in which subjective interpretation applies in German law and those which an English lawyer would recognise as giving rise to the possibility of rectification.

Objective interpretation

29. The following principles of objective interpretation were explained by the experts.

30. Where there was no common subjective intention at the time the contract was concluded or if neither party seeks to rely on a subjective interpretation, objective interpretation is applied.

31. Objective interpretation involves a determination of how a party acting in good faith would have understood the other party's declaration of intent. The starting point is the language of the contract. The court will also take into account (a) the special skills and knowledge of the person who made the declaration, in so far as those matters were known or should have been known to the counterparty and (b) the shared business purpose of the parties.

32. Extrinsic evidence is admissible, including materials dating from both before and after the conclusion of the contract.

33. Applying the principles of objective interpretation, if there were consistent declarations of intent when each is viewed by the counterparty in good faith, there is what German law calls an "objective-normative consensus". The contract will be interpreted in line with that consensus where there were diverging subjective intentions.

34. Where the words of a written contract are clear and unambiguous and there is an inner coherence to the document, there is a presumption that the words reflect the complete and common intent of the parties unless the contrary is proved. A party seeking to show that the contract is to be interpreted in manner different from the clear and unambiguous meaning of its words bears the burden of proving facts which support an alternative meaning.

Supplementary interpretation

35. Where the court concludes that a term has been inadvertently omitted from the contract, the court may supplement the contract with a term enabling the contract to function as the parties intended.

Secondary obligations and good faith

36. Section 241 BGB provides:

> "*241 (1) By virtue of an obligation an obligee is entitled to claim performance from the obligor.*
>
> *(2) An obligation may also, depending on its contents, oblige each party to take account of the rights, legal interests and other interests of the other party.*"

37. Section 311(2) BGB provides:

> "*(2) An obligation with duties under section 241(2) also comes into existence by*
>
> *1. the commencement of contract negotiations*
>
> *2. the initiation of a contract where one party, with regard to a potential contractual relationship, gives the other party the possibility of affecting his rights, legal interests and other interests, or entrusts these to him, or*
>
> *3. similar business contacts*"

38. Section 241(2) in certain circumstances gives rise to what German law calls "secondary obligations" in relation to a contract. Pursuant to s.311(2) secondary obligations may arise in pre-contractual negotiations.

39. The experts explained that one category of secondary obligations is "information duties". A negotiating party may be under a duty to inform the other party of circumstances which may frustrate the purpose of the proposed agreement. Professor Haedicke said this will arise under three strict preconditions: (1) knowledge of the circumstances, (2) the ignorance of the circumstances on the part of the other party and (3) unfairness in the asymmetry of knowledge. The information gap may for instance be the product of expertise on one side but not the other, or one party's disability.

40. Notwithstanding any information duties, the experts were agreed that in German law there is no obligation on a negotiating or contracting party to give legal advice (unless of course that is the purpose of the contract). Nor is a party required to inform the other party how best to protect its rights.

41. Professor McGuire stated that information duties exist in two forms: (1) a formal aspect which requires drawing attention to the fact that there is a relevant change in a proposal and (2) a material aspect, i.e. drawing attention to the substance of an obligation such as telling the other party that signing the contract would be disadvantageous.

42. As to the formal aspect, I did not understand the experts to mean that in the context of draft changes to a contract being passed between the parties, each time there must be an express notice alerting the other party of a relevant change. Particularly as between sophisticated negotiating parties I have assumed that it will be sufficient if proposed changes appear in marked up form, or the fact that changes have been made is otherwise sufficiently clearly signalled in the text itself.

43. Professor Haedicke said that the material aspect of the information duty could not arise between two commercial parties dealing at arms' length. Professor McGuire agreed in cross-examination.

44. The experts both said that there could be no information duty to a party in respect of information which that party should know, such as information held within a company which has not reached an individual carrying out the contractual negotiations.

45. Professor Haedicke said that negotiating in a language other than German makes no difference where one is concerned with a sophisticated party.

46. Section 242 BGB provides:

> "*242 Performance in good faith: An obligor has a duty to perform according to the requirements of good faith taking customary practice into consideration.*"

47. The experts said that the obligation of good faith may overlap the secondary obligations under a contract, including information duties.

48. Professor Haedicke's evidence was that performance of a contract in good faith does not require the court to replace the terms of a contract with more equitable terms to ensure fairness. German contract law is based on the principle of freedom of contract, which is expected to ensure a correct agreement provided there is no inequality between

the parties. Every party is responsible for itself and there is no general duty on a party to consider or to take care of the needs of the other party. Professor McGuire did not dissent but qualified this by saying that s.242 BGB may require a party to take into account the interests of the other party.

49. The experts agreed that the principle of good faith will not assist a party where it has agreed terms disadvantageous to itself.

50. Professor Haedicke said that the obligations under ss.241(2) and 242 BGB do not affect the obligations arising under the contract. Professor McGuire agreed but said that those sections can affect the interpretation of contractual terms where they are ambiguous.

The negotiations leading to the Amendment Agreement

51. Part of Boehringer's case was that the negotiations which led to the Amendment Agreement were not conducted in good faith on the part of Royalty Pharma and that this has an effect on the correct construction of the Amended Agreement. I will therefore set out those negotiations in more detail.

52. Clause 3.3(a) of the Original Agreement stated:

> "In consideration of the rights granted by Prosidion to BI … BI shall make royalty payments as set forth in Exhibit C to Prosidion on Net Sales of Product in countries where a Valid Claim exists.
>
> …
>
> For the avoidance of doubt royalties will not by payable on Net Sales in a country where no Valid Claim exists."
>
> (original underlining)

53. "BI" was Boehringer. Exhibit C set out the timing and other mechanism of payment. "Valid Claim" so far as is relevant meant a valid and unexpired claim of a patent licensed under the Original Agreement as listed and defined in Exhibit A. "Net Sales" broadly meant the amount invoiced by Boehringer for sales of Product to its customers.

54. Mr Lloyd's evidence was that he found the Original Agreement unclear when he considered it in the period around the acquisition of DP-IV assets from Prosidion in June 2011. However, he continued, Royalty Pharma's assumption at that time was that royalties under clause 3(3)(a) would be paid only on sales, limited to sales in territories in which there was a Valid Claim. The primary focus was on the United States and the US patent did not cover manufacture. The only patent coverage in Europe was German national patent DE 19616486 ("DE 486"). Royalty Pharma did not know that DE 486 covered manufacturing at the time of the negotiations with Prosidion and Prosidion had warned Royalty Pharma that there was a risk that DE 486 would be revoked by the German Federal Patent Court.

55. Boehringer had launched Trajenta with Lilly Icos LLC in the US in May 2011. An issue arose regarding the possibility of German withholding tax being due on Boehringer's royalty payments under the Original Agreement. The tax would have to be deducted from royalties insofar as payment was attributable to acts done in Germany.

56. Mr Lloyd said that in November 2011 he received advice from German lawyers that DE 486 covered the manufacture of linagliptin in Germany for the therapeutic purpose claimed in the patent.

57. This was potentially relevant to the issue of withholding tax. Royalty Pharma took advice about its tax liability from the Berlin office of SJ Berwin LLP, informing them of the background to the acquisition of assets from Prosidion and the advice that DE 486 covered both the sale and manufacture of "a medicament for treating diabetes". SJ Berwin was also told that no more than 1% of the value of total royalties payable by Boehringer on sales of Trajenta were attributable to the right to manufacture inGermany because substantially all sales of Trajenta were in the United States and that even if DE 486 did not exist or if Boehringer moved its manufacturing activities outsideGermany, Royalty Pharma would still be entitled to the same amount of royalties in respect of sales of Trajenta in the United States because of the licence under the US patent.

58. In a memo dated 14 December 2011 SJ Berwin advised that Boehringer should not impose German withholding tax (on behalf of the tax authorities) on any of the royalties paid to Royalty Pharma, but for the sake of conservatism Boehringer should impose the tax at a level no more than 1% while DE 486 remained in force.

59. SJ Berwin's letter was sent to Boehringer on the same day, 14 December 2011. Mr Beck responded in an email dated 23 February 2012, informing Royalty Pharma that only 70% of 2011 sales of Trajenta were in the United States. Under the heading "Exploitation in Germany" he also said:

> "An exploitation within the meaning under German law is defined as the use or exercise of a right as part of the activities of the Licensee. Prosidion/RPCT granted medical use patents related to the use of DPP-IV inhibitors for the treatment of type 2 diabetes non-exclusive to BII. … The compound and subsequently Tradjenta™ is the result of [Boehringer's] own research and development activities. Thus, someone might argue that the rights have been exploited in Germany irrespective of the fact, that royalty payments are sales-related.
>
> In summary and contrary to RPCTs assumption we cannot completely exclude that the rights granted are exploited in Germany. As a consequence RPCT should be subject to limited taxation in Germany and BII is obliged to deduct German withholding tax due directly from all of the royalty payments made to RPCT."

60. It appears that the rights exploited by Boehringer in Germany which Mr Beck had in mind were rights licensed under the Original Agreement. The only licensed patent in Germany was DE 486. It seems clear that Mr Beck thought it possible that the Original Agreement licensed acts done in Germany in relation to linagliptin. He also said that this was despite royalty payments being sales related. That remark could have meant that Mr Beck believed that acts in Germany were licensed acts although the mechanism for payment for such acts was sales related. It could also have meant that although such acts in Germany were licensed, they did not attract royalties. Mr Lloyd apparently took Mr Beck to have meant the former, which was consistent with Boehringer withholding the entirety of the withholding tax.

61. On 14 December 2011 Boehringer sent to Royalty Pharma its first royalty statement under the Original Agreement for the second and third quarters 2011. The royalties had been calculated by Boehringer on worldwide sales of Trajenta, including sales in territories in which there were no relevant patents.

62. Mr Lloyd's evidence was that there was a change in Royalty Pharma's perception of the effect of the Original Agreement at around this time, prompted by the advice that DE 486 covered manufacture in Germany, what Mr Beck had said about withholding tax, Boehringer's application of withholding tax to the entirety of royalty payments by Boehringer and Boehringer's calculation of royalties on a worldwide basis. A new possibility was considered by Mr Lloyd, namely that royalties were incurred not only by sales of Trajenta but also by the manufacture of linagliptin provided there was a Valid Claim which covered manufacture in the relevant territory, in this case Germany. Mr Lloyd said that he viewed this as being consistent with the standard practice in relation to IP licences, namely that royalties were due on all activities which, but for the licence, would infringe the IP rights licensed, even though the mechanism for payment may be solely in relation to sales.

63. There was no evidence from Boehringer about its reasoning and perspective at the end of 2011. Dr Aye had only recently joined Boehringer and was not in a position to know. Mr Beck, who would presumably have known, was not a witness and there were no documents from Boehringer which shone any light on the matter. The only clues as to Boehringer's understanding are the matters which influenced Mr Lloyd's view.

64. In 2013 Boehringer identified another patent family owned by Royalty Pharma, not licensed under the Original Agreement, referred to as the "GB Patent Family". These patents covered a combination treatment as a first-line therapy. A first-line therapy is the first treatment given to a patient suffering from a disease or condition. In this instance it consisted of a combination of a DP-IV inhibitor and metformin, another medication for the treatment of type 2 diabetes. One of Boehringer's products, Jentadueto, was a combination product covered by the GB Patent Family and although it had not yet been sanctioned by any regulatory authority for use as a first line therapy, Boehringer envisaged regulatory approval in the future and sought a licence from Royalty Pharma.

65. There was a difficulty: clause 3.3(a) did not distinguish first line therapy from other use. The GB Patent Family had a later expiry date than any of the patents licensed under the Original Agreement. Boehringer wanted to be sure that when the latter expired, royalties would be payable only on sales of combination products for use in first line therapy, which would be only a small proportion of sales of such combinationproducts.

66. In August 2013 Mr Beck approached Mr Lloyd asking whether Royalty Pharma would be prepared to amend the Original Agreement to add a licence under the GB Patent Family. In September 2013 Mr Lloyd indicated that Royalty Pharma was happy to do that. There were further discussions about the best way to approach this and on 1 April 2014 Mr Beck sent to Mr Lloyd a first draft of proposed amendments. The draft included the broadened licence and a mechanism to deal with the period after the existing licensed patents expired with the GB Patent Family still in force. In the covering email Mr Beck addressed another point. He said:

> "As you will see, while drafting the amendment we have noted an inconsistency on the basis for the royalty payment and, therefore, propose a modified wording."

67. The effect of Boehringer's proposed new wording was that the incurring of royalties by acts done in territories in which a Valid Claim existed was made subject to the proviso that such acts would, absent the licence from Royalty Pharma, infringe the Valid Claim. Mr Beck wrote this in a comment bubble next to his proposed amendment (it was common ground that "used" at the end of the second sentence meant "infringed"):

> "Note to Royalty Pharma. While drafting the amendment we noted that the current wording does not clearly reflect our joint understanding that royalties are only payable where valid claims are used. We suggest to include the highlighted wording (taken from Section 3.2) for clarification purposes."

68. Mr Lloyd's evidence was that he did not know what Mr Beck had meant by an "inconsistency" in his email of 1 April 2014, but it occurred to him that despite having paid royalties on the basis of worldwide sales, Boehringer may have taken the view that it need not have done. He asked Ms Chiaramonte to model the possibility of repayment to Boehringer. As it turned out, Mr Beck meant something else and Boehringer continued to pay on a worldwide basis for another year or so.

69. Mr Lloyd's reflections were not discussed with Mr Beck but on 27 May 2014 Mr Lloyd sent an email to Mr Beck with Royalty Pharma's proposed changes to Mr Beck's first draft. Clause 3.3(a) was significantly amended, as was Exhibit C. On 16 June 2014 Mr Beck replied with further proposals, although no changes were made to clause 3.3(a) or Exhibit C relevant to acts which would incur the payment of royalties. Mr Lloyd responded on 30 June 2014 with further proposals which included another change to clause 3.3(a).

70. Negotiations continued without further suggested changes to clause 3.3(a) or Exhibit C relating to the acts which would incur a payment of royalties. Mr Lloyd's proposal of 30 June 2014 became final in that regard.

DE 486 and EP 705

71. There were developments in respect of the patents licensed under the Original and then the Amended Agreement. After successive appeals and the remission by the Federal Court of Justice to the Federal Patent Court for further consideration, DE 486 was maintained by the Federal Patent Court on 25 November 2014. It expired on 25 April 2016.

72. On 25 June 2014 EP 705 was granted. Its designations included Germany.

The amendment to clause 3.3(a)

73. The amendment to clause 3.3(a) proposed by Royalty Pharma on 30 June 2014 was agreed and formalised in Clause 1.2 of the Amendment Agreement dated 19 May 2015. It reads:

> "1.2 Section 3.3(a) of the Agreement is amended as follows:

> 1.2.1 In the first sentence beginning 'In consideration of the rights […]', the words
>
> 'BI shall make royalty payments as set forth in Exhibit C to Prosidion on Net Sales of Product in countries where a valid claim exists.'
>
> are deleted and replaced by the following:
>
> 'subject to the provisions set forth in Exhibit C under the heading "Applicable Market Share", BI shall make royalty payments as set forth in Exhibit C to Prosidion on Net Sales of Product the development, manufacture, registration, use, import/export, marketing or offer to sell and/or sale of which, but for the Licence, would otherwise infringe a Valid Claim.'
>
> 1.2.2 The last sentence beginning with 'For the avoidance of doubt […]' is deleted and replaced with the following:
>
> 'For the avoidance of doubt royalties shall not be payable on Net Sales of Product the development, manufacture, registration, use, import/export, marketing, offer to sell and/or sale of which does not infringe a Valid Claim.'"
>
> (original ellipses, square brackets and underlining)

74. Clause 1.5 of the Amendment Agreement amended Exhibit C, primarily to include a provision which significantly reduced royalties due after the patents licensed under the Original Agreement had expired, so that only a licence under the GB Patent Family remained in effect. The amendments of paragraph 1.5 met Boehringer's objective that only sales of Jentadueto (or any other relevant combination product) for use as a first line therapy would attract royalty payments to Royalty Pharma.

75. I pause to consider here Mr Beck's reaction to, and acceptance of, Mr Lloyd's proposed changes to clause 3.3(a). Mr Beck was very experienced in the drafting and interpretation of patent licences. It is to be assumed that he gave close consideration to Mr Lloyd's proposals, that he believed them to be clear and that he understood them.

76. If he thought that the words to be deleted by clause 1.2.1 of the Amendment Agreement fully and accurately reflected the basis on which Boehringer paid royalties, he would surely have asked why such a deletion was appropriate. He would also have paid very close attention indeed to the words proposed for substitution in the same clause. On any view, they appear to indicate a change in the basis on which royalty payments were to fall due. Rather than being incurred solely by sales of a product in a country in which a Valid Claim existed which would have been infringed, royalties would be payable on any act of development, manufacture, registration, use, import/export, marketing or offer to sell and or sale of a Product, provided that such act would infringe a Valid Claim but for the licence.

77. I find it impossible to believe that Mr Beck accepted these changes without being of the view that the new proposal for the basis on which royalties fell due more accurately

reflected Boehringer's obligations. This view would have been consistent with the manner in which Boehringer had made payment thus far and would continue to make payments until the third quarter of 2015.

The Amended Agreement

78. There was no Amended Agreement in the sense of a document formally signed in that form but the parties generated a draft for this litigation. These are the relevant parts of that draft. The words added by the Amendment Agreement are shown in italics, those removed shown in strike-out:

> "**WHEREAS**, Prosidion is the holder of certain patent applications and patents and the licensee, with the right to sublicense, of certain patent applications and patents ("Patents", as more fully defined below);
>
> **WHEREAS,** BI wishes to obtain, and Prosidion is willing to grant to BI, a non-exclusive license in the Territory under the Patents for the development and commercialization of Product(s) based on BI Compound(s) (all such defined terms as hereinafter defined);
>
> **NOW THEREFORE,** in consideration of the mutual obligations and promises as set forth herein, the parties do hereby agree as follows:
>
> 1.0 **Definitions.** As used in this Agreement, the following terms shall have the following respective meanings:
>
> …
>
> 1.4 **"Compound(s)"** means inhibitors of dipeptidyl peptidase IV ('DP IV') developed and/or commercialized and/or acquired by BI and/or its Affiliates excluding (i) any inhibitor which has boronic acid as part of the DP IV inhibiting moiety under physiological conditions or (ii) any chemical compound which is defined by structural formula in a Valid Claim of the US provisional 60/073,409 family of patents and patent applications as set forth in Exhibit A or the German priority application DE 19823831 family of patents and patent applications as set forth in Exhibit B.
>
> …
>
> 1.9 **"Field"** shall mean Type II Diabetes and related indications covered by the Patents.
>
> 1.10 **"First Commercial Sale"** means the first commercial sale of Product in the Territory by BI, its Affiliates and/or Sublicensees to any unaffiliated third party as evidenced by the selling party's invoice or other relevant document to such third party. …
>
> …
>
> 1.13 **"Net Sales"** means the actual gross amount invoiced by BI, its Affiliates and Sublicensees for sales or other commercial disposition of

a Product to unaffiliated third parties, less the following deductions to the extent included in the gross invoiced sales price with respect to such sales: …

1.14 **"Patents"** means the patent applications and patents listed in Exhibit A hereto, …

1.15 **"Product"** means any pharmaceutical formulation containing at least one Compound as an active ingredient alone or in combination with any other active ingredient.

…

1.18 **"Royalty Period"** shall mean that time period beginning with the First Commercial Sale and continuing until the expiry date of the last-to-expire licensed Patent on a country-by-country basis.

…

1.21 **"Territory"** means the entire world.

1.22 **"Valid Claim"** shall mean any unexpired, issued claim of a Patent which has been maintained and which has not been held unenforceable or invalid by a court of competent jurisdiction from which an appeal has not been taken within the time period allowed or from which no appeal can be taken, A Valid Claim of a Patent which is unissued at the Effective Date but is issued thereafter, shall be deemed to be a Valid Claim as of the Effective Date for the purposes of royalties in Section 3.3 and Exhibit C provided that said Valid Claim is not identical in scope to a claim in a Patent in the same country which has been held unenforceable or invalid by a court of competent jurisdiction from which an appeal has not been taken within the time period allowed or from which no appeal can be taken.

*1.23 **"Additional Patents"** shall mean the GB 0526291.0 family of patents and patent Applications.*

…

2.0 **License Grant.**

2.1 **License Grant:** Prosidion hereby grants a non-exclusive right and license in the Territory under the Patents to BI to: (i) research, develop, non-clinically and clinically test, apply for and obtain Regulatory Approvals, all as may be required to manufacture or have manufactured and commercialize Product(s) in the Field; and (ii) make, have made, register, use, import/export, market, offer to sell and sell Product for use in the Field ("the License"). The License shall include the right of BI to grant sublicenses (a) to its Recognised Agents and (b) to its Sublicensees for Compounds and/or Products in the Field provided that such Compounds and/or Products have been developed and/or acquired by BI and/or its Affiliates. Any such sublicense granted by BI

shall be subject to the terms and conditions of this Agreement. For the avoidance of doubt, BI shall remain fully liable to Prosidion for all payments due under this Agreement even if its Sublicensees or Recognised Agents re in breach of its payment obligations. Any breach of the terms of this Agreement by a sublicensee and/or Recognised Agent shall be deemed a breach by BI, however, only any breach by a Sublicensee shall be subject to the indemnification provisions of section 5.4. However, any breach by a Sublicensee or Recognised Agent of their agreements with BI shall not entitle Prosidion to terminate this Agreement provided BI shall use reasonable endeavours to enforce any legal remedy available to BI against the breach of such Sublicensee and/or Recognised Agent and, where possible, to use reasonable endeavours to cure such breach.

…

3.0 **Execution Fee, Milestone Payments, Royalties and Documentation.**

3.1 **Execution Fee:** BI shall pay to Prosidion an upfront fee as set forth in Exhibit C.

3.2 **Milestone Payments:** During the term of this Agreement, BI shall make milestone payments in accordance with the provisions of Exhibit C for Products the development, manufacture, registration, use, import/export, marketing, offer to sell and/or sale of which, but for the License, would otherwise infringe a Valid Claim. BI shall advise Prosidion in writing within thirty (30) days after the milestone is achieved. BI shall make the payment in accordance with Exhibit C within thirty (30) days upon receipt of an invoice from Prosidion.

3.3 **Royalties:**

(a) **Payments.** In consideration of the rights granted by Prosidion toBI and its Affiliates hereunder, in particular the non-exclusive, sub-licenseable right and license in the Territory under the Patents to: (i) research, develop, non-clinically and clinically test, apply for and obtain Regulatory Approvals, all as may be required to manufacture or have manufactured and commercialize Product in the Field; and (ii) make, have made, register, use, import/export, market, offer to sell and sell Productfor use in the Field, ~~BI shall make royalty payments as set forth in Exhibit C to Prosidion on Net Sales of Product in countries where a Valid Claim exists.~~ *subject to the provisions set forth inExhibit C under the heading "Applicable Market Share", BI shall make royalty payments to Prosidion on Net Sales of Productthe development, manufacture, registration, use, import/export, marketing, offer to sell and/or sale of which, but for the License, would otherwise infringe a Valid Claim.* Upon the end of the Royalty Period on a country-by-country basis, BI shall have a fully paid-up, royalty-free, non-exclusive and perpetual license which is sub-licensable to its Recognized Agents and

> Sublicensees under the Patents in accordance with Section 2.1, without any further obligation to Prosidion. If a licensed Patent is held invalid by a court of competent jurisdiction from which an appeal has not been taken within the time period allowed or from which no appeal can be taken or abandoned by Prosidion the date of invalidity determined by such court or abandonment shall be deemed the date of expiration for purposes of calculating the Royalty Period as to such licensed Patent in the applicable country. ~~For the avoidance of doubt royalties will not be payable on Net Sales in a country where no Valid Claim exists.~~ *For the avoidance of doubt royalties shall not be payable on net Sales of Product the development, manufacture, registration, use, import/export, marketing, offer to sell and/or sale of which does not infringe a Valid Claim.*
>
> …
>
> (d) **Books and Records/Audit Rights.** BI shall keep books and records accurately showing all Products sold under the terms of this Agreement. Such books and records shall be open to inspection by an independent certified public accountant to be agreed upon by bothparties solely for the purposes of determining the correctness of the royalties paid under this Agreement. …
>
> …
>
> 7.5 BI may terminate this Agreement without cause, with respect to any country(ies) or all countries of the Territory, upon three (3) monthsprior written notice to Prosidion and, upon such termination Prosidion shall be entitled to retain for its own use all funds previously paid by BIand BI shall pay all payments, milestones or royalties which may have become due prior to the effective date of such termination. …"

79. This is the Amended Exhibit C:

> "**EXHIBIT C**
>
> **PAYMENTS**
>
> …
>
> **Royalty Payments.**
>
> In consideration of the rights granted by Prosidion to BI and its Affiliates hereunder, in particular the non-exclusive, sub-licenseable right and license in the Territory under the Patents to: (i) research, develop, non-clinically and clinically test, apply for and obtain Regulatory Approvals, all as may be required to manufacture or have manufactured and commercialize Product in the Field; and (ii) make, have made, register, use, import/export, market, offer to sell and sell Product for use in the Field, ~~BI shall make royalty payments to Prosidion on Net Sales of Product in countries where a Valid Claim exists:~~ *subject to the*

provisions set forth below under the heading "Applicable Market Share", BI shall make royalty payments to Prosidion on Net Sales of Product the development, manufacture, registration, use, import/export, marketing, offer to sell and/or sale of which, but for the License, would otherwise infringe a Valid Claim.

[The royalty rates are set out.]

Applicable Market Share

*On a country-by-country basis, during that part of the Royalty Period that begins after the expiration of all Valid Claims, which, but for the license would otherwise be infringed, under all of the Patents other than the Additional Patents, the aforementioned royalty rates shall be applied only to that portion of Net Sales of Product ("**Applicable Market Share")** as has been prescribed to patients for use in a manner which, but for the License, would infringe a Valid Claim under the Additional Patents ("**First Line Combination Use**").*

*The Applicable Market Share of Net Sales of Product for First Line Combination Use in each country in which there is a Valid Claim under the Additional Patents shall be determined every two years commencing with the expiration of all Valid Claims which, but for the license would otherwise be infringed, under all of the Patents other than the Additional Patents as follows: BI will provide Royalty Pharma with a written proposal (the "**BI Proposal")** for the Applicable Market Share based on market data, together with a written explanation in reasonable detail of the basis for its conclusions and the data sources relied upon in arriving at its conclusions.*

Royalty Pharma shall have thirty (30) days following the receipt of the BI Proposal in which to accept or object in writing to the BI Proposal. If Royalty Pharma shall so object, Royalty Pharma shall have thirty (30) days from the date it so objects in writing in which to make a written proposal (the "Royalty Pharma Proposal") to BI based on market data, together with a written explanation in reasonable detail of the basis for its conclusions and the data sources relied upon in arriving at its conclusion.

BI shall have thirty (30) days following the receipt of the Royalty Pharma Proposal in which to accept or object in writing to the Royalty PharmaProposal. If BI shall so object, an internationally recognized consulting firm with substantial experience in the pharmaceutical industry having no material prior relationship with either BI or Royalty Pharma shall be chosen by the Parties, and if the Parties cannot agree within thirty (30) days, by the London Court of International Arbitration, London, England. Such consulting firm shall be instructed (a) to review the BI Proposal and the Royalty Pharma Proposal and to conduct such additional research as such consulting firm determines is advisable, and then (b) to choose either the BI Proposal or the Royalty Pharma Proposal as the proposal containing conclusions that most closely approximate the conclusions that the consulting firm would have reached had it been asked to prepare its own proposal (which such consulting firm shall be explicitly instructed not to do). Upon such consulting firm's choice of either the BI Proposal or the Royalty Pharma Proposal, the proposal so chosen shall be

deemed to be the final proposal which shall apply for the applicable two year period. The fees of such consulting firm shall be paid by Royalty Pharma if the BI Proposal is chosen by such consulting firm and by BI if the Royalty Pharma Proposal is chosen by such consulting firm. For clarity, the Parties are at any stage of the process free to agree upon an amicably negotiated reduced royalty rate.

Notwithstanding the foregoing, in order to avoid unnecessary expense, the Applicable Market Share in all countries in the world other than the United States, Japan, Germany, France, the United Kingdom, Italy and Spain in which there exists a Valid Claim under the Additional Patents shall be deemed to be the Applicable Market Share determined for Germany, France, the United Kingdom, Italy and Spain on a weighted average basis.

No multiple royalties shall be payable because more than one Valid Claim exists in a country.

For the avoidance of doubt, where more than one Product exists, royalties shall be due and payable on each and every Product."

Subjective interpretation

80. To some degree Royalty Pharma and Boehringer shared a common subjective intent: to add the GB Patent Family to the patents licensed under the Original Agreement and to provide a mechanism for reducing royalty payments when the patents already licensed expired.

81. With regard to the nature of the acts done by Boehringer which would incur an obligation to pay royalties to Royalty Pharma, Mr Lloyd said that it was his intention that the status quo was to be maintained in the sense that royalties would continue to be paid on a worldwide basis, including sales in territories in which there was no licensed patent. The obligation to pay arose whenever Boehringer carried out an act which, but for the licence, would have infringed a licensed patent. In Mr Lloyd's view the manufacture of linagliptin in Germany was an act which, but for the licence, would have infringed the licensed patent in force in Germany, so this provided a rationale for payment on worldwide sales.

82. Mr Lloyd accepted that before around the end of 2011 it had been his belief that royalty payments only fell due if there were a sale in a territory in which there was a Valid Claim. As I have explained, events around this time collectively led Mr Lloyd to reconsider. He said he thought it possible that the Original Agreement had adopted the commonplace form of a patent licence in which royalties were due on all licensed acts but the mechanism for payment was related solely to sales. However, Mr Lloyd's evidence indicates that this was not a firm conviction because he continued to investigate the matter.

83. In cross-examination Dr Chiaramonte said that there was an appreciation at a particular time in Royalty Pharma that there was a probability that Boehringer had been mistakenly overpaying on worldwide sales. It was not made clear which time Dr Chiaramonte had in mind but it is not in dispute that at some point Royalty Pharma came around to that firm view. There was no formal concession by Royalty Pharma in

this regard until July 2020. Mr Lloyd said that it was only when he saw disclosure given by Boehringer in these proceedings, which included negotiation documents passed between Prosidion and Boehringer, that he understood the language of the Original Agreement and was able to conclude that royalties were triggered only by sales in countries with a Valid Claim.

84. I take the view that during the course of negotiating the Amendment Agreement Mr Lloyd wanted to believe that payment was due under the Original Agreement on worldwide sales and he had good reason to think that this was Boehringer's opinion. It was also possible for Mr Lloyd to rationalise such a belief, although I doubt that he was ever entirely convinced. Mr Lloyd did not ask Boehringer about it. I think it would be fair to say that in all likelihood he did not want to risk the possibility of provoking a change of heart on the part of Boehringer and an end to payment on worldwide sales. On the other hand, the Amendment Agreement provided a good opportunity to test Boehringer's view and if possible to make the obligation to pay on worldwide sales secure – based on the manufacture of all Boehringer's linagliptin in Germany.

85. Dr Aye claimed that during the negotiations it was clear to Boehringer that royalties would fall due only where there were sales in a country where there was valid claim of a licensed patent. Yet he did not know about Mr Beck's state of knowledge.

86. As to that, I was directed to an email dated 18 December 2013 from Mr Beck, at the early stages of discussions about amending the Original Agreement, in which he said:

> "We understand that royalty payments according to the existing agreement shall be made on net sales of a BI product in countries where a valid claim exist covering BI product's use."

87. I do not regard that remark as providing clear proof of Mr Beck's understanding of the Original Agreement in December 2013. In this email Mr Beck's mind was on how to achieve the addition of the GB Patent Family to the licence, not on a comprehensive statement of which acts gave rise to an obligation to pay royalties. Mr Beck's reaction to Mr Lloyd's proposed changes to clause 3.3(a), his acceptance of those changes, strongly suggest that he did not regard this as a full and accurate reflection of Boehringer's royalty obligations.

88. It must also be borne in mind that Boehringer continued to pay royalties on a worldwide basis for almost another two years. Dr Aye said he did not know about this. Someoneat Boehringer did. Whoever calculated and authorised the payments must have thoughtthat it was correct for Boehringer to make payment on sales in all countries.

89. There are two realistic possibilities regarding Mr Beck's state of mind. The first is that he did not know about the basis on which royalty payments under the Original Agreement were calculated. He believed that they should be, and that they were being, made on a country-by-country basis. In that event, neither he nor Dr Aye spotted the serious mistake made by the individuals in Boehringer who calculated and authorised payment. But if this were truly the case Boehringer could have provided evidence from those individuals. At least one of them could have explained how the mistake came about, who gave them instructions and why neither Mr Beck nor Dr Aye knew about the mistake for so long.

90. The second possibility is that Boehringer was in no position to file such evidence. Mr Beck was aware that Boehringer was paying on worldwide sales and believed that it was obliged to do so. Either Mr Beck calculated and authorised payment himself or, whoever did, acted on Mr Beck's guidance. There was no mistake made except by Mr Beck.

91. I find the second possibility much the more likely. It not only explains why Boehringer paid on a worldwide basis up to the third quarter of 2015, it also explains Mr Beck's acceptance of the amendments proposed by Mr Lloyd and the new basis on which royalties became payable.

92. I cannot know why Mr Beck made the mistake. His experience with patent licences would have made him familiar with the licence model of royalties being due all licensed acts but with a mechanism for payment attached only to sales. As I have said, Mr Beck apparently had in mind at least the possibility of acts done by Boehringer in Germany in relation to linagliptin which required a licence under the Original Agreement. That may have led him to think in terms of payment on all sales of Product made from linagliptin sourced in Germany.

93. With regard to clause 3.3(a) I think there was a meeting of minds between Mr Lloyd and Mr Beck to this extent: a common intention that the Amended Agreement should make Boehringer obliged to pay royalties if it carried out any act of development, manufacture, registration, use, import/export, marketing or offer to sell and/or sale of Product, which act, but for the Licence, would infringe a Valid Claim. Mr Lloyd was not sure whether this changed the scope of Boehringer's obligations. Mr Beck at the time either thought that it did not, or he thought that it did but that the change better reflected his understanding of Boehringer's obligations.

94. Notwithstanding the words of the Amendment Agreement, Dr Aye thought that under both the Original Agreement and the Amended Agreement Boehringer was obliged to pay only on acts of sale in a territory in which there was a Valid Claim. The added feature of the Amended Agreement was that the acts had also to infringe the Valid Claim.

95. The position in German law if there is a split in the subjective intention of individuals within a single corporate entity was not developed in evidence. But Royalty Pharma did not press its case of a common subjective intention, so I can turn to the objective interpretation of the Amended Agreement, in particular clause 3.3(a).

Objective interpretation

Secondary obligations and good faith

96. Boehringer argued that Royalty Pharma intended to change the Original Agreement with regard to the acts giving rise to an obligation to pay royalties, and failed to inform Boehringer of the proposed change. This was in breach of Royalty Pharma's obligation of good faith.

97. I disagree. Mr Lloyd had good reason to suppose that Boehringer believed that it should pay on a worldwide basis and it was possible to rationalise the belief. Royalty Pharma and Boehringer were two very sophisticated negotiating parties. That being so, there

was no bad faith on the part of Royalty Pharma in setting out proposed changes to the Original Agreement which, in its view, formalised payment on sales of all Product made from linagliptin sourced in Germany. From Mr Lloyd's perspective this may or may not have been an important change to Boehringer's obligations, but it was a means to bring matters to a head. If Boehringer agreed that the new wording more accurately reflected its obligations, so much the better. If not, presumably Mr Lloyd expected the negotiations to be more difficult than they were.

98. Professor McGuire pointed to just one authority in support of Boehringer's contention of a lack of good faith, namely the judgment of the German Federal Court of Justice (*Bundesgerichtshof*) ("BGH") in *Irrelevance of hidden changes in a declaration of acceptance* (Case VII ZR 334/12, NJW 2014, 2100). The facts were these. In the course of negotiations about a building contract the claimant sent an offer setting out the work to be performed. The defendant sent an order to be signed by the claimant with payment terms. The claimant returned two signed copies of the order, one for countersignature. The claimant had changed the payment terms but did not inform the defendant that a change had been made. The alteration was done in the font of the original text in a manner which, as the BGH explained, was very difficult to identify. Other amendments were then agreed, but the defendant did not notice the change to the payment terms and countersigned the order. The BGH referred to s.150(2) BGB:

> "*(2) An acceptance with expansions, restrictions or other alterations is deemed to be a rejection combined with a new offer.*"

99. The BGH ruled that the principle of good faith applied to that subsection. It requires the recipient of an offer, if it wishes to deviate from the intent of the party making the offer, to express this wish clearly and unambiguously. If it does not, the contract is concluded on the terms of the offer. The terms of the contract were therefore those of the defendant's offer, subject to the subsequent agreed modifications.

100. Boehringer did not rely directly on s.150(2) BGB. By inference the argument was that the same principles would be applied under s.242 BGB. I will assume that is correct. There are two important differences between the case cited and the present facts. First, the claimant simply signed and returned the order sent by the defendant so that, absent any notice from the claimant, the defendant was probably entitled to assume that no change had been made. Secondly, the claimant went out of its way to disguise the alteration to the payment terms that had been made. There was a deliberate intent to deceive. By contrast, when Mr Lloyd made proposed changes to clause 3.3(a) and Exhibit C there is no doubt that Boehringer was made aware that changes had been proposed, nor any doubt that Boehringer knew fully what the changes were. Armed with that knowledge, Boehringer was free to make a commercial decision to accept or reject the proposal.

101. In my judgment, there was no breach of information duties or lack of good faith on the part of Royalty Pharma during the course of negotiating the Amendment Agreement. Nothing in that regard changes the objective interpretation of the Amended Agreement to be reached under other principles of German contract law.

First interpretation issue: the distinction between Product and Compound

102. In order to determine which acts gave rise to an obligation on Boehringer to pay royalties, the starting point is the language of the contract.

103. Boehringer argued that clause 3.3(a) was clear: although the manufacture of Product gave rise to the payment of royalties, the manufacture of Compound did not. Even if the formulation of linagliptin API into Product could have been a royalty-incurring act, the manufacture of the API itself could not.

104. Boehringer's difficulty, it seems to me, is the similarity of the language used to define the licence granted under the Amended Agreement and that used to define a royalty-incurring act. The licence granted to Boehringer under clause 2.1 was to:

> "(i) research, develop, non-clinically and clinically test, apply for and obtain Regulatory Approvals, all as may be required to manufacture or have manufactured and commercialize Product(s) in the Field; and (ii) make, have made, register, use, import/export, market, offer to sell and sell Product for use in the Field ("the License")."

105. If Boehringer was licensed to manufacture linagliptin API in Germany, as was common ground (on the assumption that such manufacture would otherwise have infringed EP 705), that licence must have been covered by those words.

106. The acts by Boehringer which incurred an obligation to pay royalties under clause 3.3 were:

> "the development, manufacture, registration, use, import/export, marketing, offer to sell and/or sale of [Product] which, but for the License, would otherwise infringe a Valid Claim."

107. Either the manufacture of Compound was licensed because it fell within the licence granted to manufacture Product or alternatively because it fell within Boehringer's licence to "develop" as required to manufacture or have manufactured Product in the Field. Either way, the manufacture of linagliptin was also a royalty-incurring act under clause 3.3(a), subject to Boehringer's second argument on the interpretation of the Amended Agreement.

Second interpretation issue: whether royalties could be incurred by an act of manufacture

108. As explained by the experts, where the words of a written contract are clear and unambiguous and there is an inner coherence to the document, there is a presumption under German law that the words reflect the common intent of the parties. The presumption may be rebutted by the establishment of facts which show that the parties had some other intent.

109. On a straightforward reading of the words of clause 3.3(a), the clause requires royalty payments by Boehringer on sales of Product the development or manufacture of which would have infringed a Valid Claim absent the licence granted. As I have said, this encompasses a requirement to pay royalties on the manufacture of linagliptin where such manufacture would infringe a Valid Claim but for the licence. In other words, acts of manufacture, not just sales, could incur an obligation to pay royalties. But this straightforward reading is subject to maintaining the inner coherence of the Amended

Agreement and is also subject to any facts which establish that the parties intended some other meaning.

110. Boehringer argued that parts of the Amended Agreement were inconsistent with manufacture creating an obligation to pay royalties. I consider below whether the manufacture of linagliptin was covered by EP 705, but Boehringer's arguments necessarily went forward on the assumption that it did.

111. Boehringer's first point was directed to this provision in clause 3.3(a) itself, carried over from the Original Agreement:

> "Upon the end of the Royalty Period on a country-by-country basis, BI shall have a fully paid-up, royalty-free, non-exclusive and perpetual license which is sub-licensable to its Recognized Agents and Sublicensees under the Patents in accordance with Section 2.1, without any further obligation to Prosidion."

112. As Mr Lloyd agreed in cross-examination, the expiry of patents and the end of the royalty period may happen at different times in different countries. He said that nonetheless, if Boehringer manufactured the API in Germany and this created an obligation to pay a royalty on Product sold, that obligation would remain even if the Product were sold in a country in which the Royalty Period had expired. Boehringer argued that this made a nonsense of the fully-paid up etc. licence (for brevity I will call it a "Perpetual Licence") in that country and that therefore, viewed objectively, the obligation to pay arose solely on the act of sale, on a country-by-country basis.

113. I am not sure that Mr Lloyd was right about the effect of clause 3.3(a) in the event that (i) royalties were triggered by the act of manufacture of linagliptin in Germany, (ii) there remained at least one Valid Claim in Germany which covered such manufacture and (iii) the Royalty Period has expired in the country of sale. It may be that the Perpetual Licence in the country of sale would cover a licence to manufacture anywhere. Alternatively, if Mr Lloyd was right, Perpetual Licences coming into force in various territories would be of little value unless and until patent coverage in Germany ended. The parties would have known that at the latest this would be in April 2017, subject to the grant of a supplementary protection certificate (SPC). But on either construction of clause 3.3(a), the clause was workable, by which I mean that there remains an inner coherence to the document. I did not understand the experts' evidence to be that the notion of inner coherence in the German law of contract means that the totality of a written agreement must be entirely satisfactory from the standpoint of one party or both or, for that matter, an objective observer with hindsight.

114. Boehringer's second point was that royalties are calculated on the Net Sales of Product, not the manufacture of Compound.

115. That is true, but I do not see why that is inconsistent with an obligation to pay royalties on Net Sales of Product made from Compound the manufacture of which required a licence under the Amended Agreement.

116. The third point was that the Amended Agreement required records to be kept about sales of Product, but not the manufacture of Compound. There was not even a requirement on Boehringer to record where Compound was made.

117. That is also true. But Boehringer knew that all Product sold by Boehringer was made from Compound manufactured in Germany and it was not made clear that Prosidion did not also know. Royalty Pharma came to know. Payment was on sales. There was no need to measure how much linagliptin was made because it made no direct difference to the royalties due. If some of the linagliptin manufactured in Germany werediscarded, the discarded portion would not have attracted royalty payments.

118. The fourth point was that clause 7.5 allows for country-by-country termination and that this did not make sense if Boehringer was paying royalties because of manufacture in Germany.

119. There may or may not have been much incentive to terminate the Amended Agreement in any particular country while EP 705 remained force. Once it expired that would have changed. It did not render the Amended Agreement unworkable.

120. The fifth point was that the Applicable Market Share mechanism of Exhibit C was completely incompatible with any interpretation other than that royalties were due only in respect of sales, not manufacture.

121. This part of Exhibit C required the calculation of the proportion of Net Sales of Product which would infringe a Valid Claim under the GB Patent Family, defined as the Net Sales which were for "First Line Combination Use". That proportion was called the "Applicable Market Share". The calculation of Applicable Market Share was to be done on a country-by-country basis, subject to a short cut, a weighted average, for countries other than the principal seven.

122. If EP 705 expired in the usual way at the end of its term, by the time the new mechanism came into force Boehringer was not going to require a licence for manufacture in Germany. Only if Royalty Pharma were granted an SPC would the issue arise (as it turned out, no SPC was granted in Germany). In that event and assuming further that SPCs were to be treated as a patent term extension under the terms of Exhibit C, in any country in which all Valid Claims of the original patents had expired, the reduced royalty on sales would have applied, notwithstanding the licence for manufacture in Germany. I see nothing incompatible in that.

123. The sixth point was that royalty payment under clause 3.3(a) was still on a country-by-country basis.

124. Clause 3.3(a) and Exhibit C required payment on those acts defined as incurring royalty, such payment to be on Net Sales of Product according to the percentages set out in Exhibit C. That was consistent with payment being incurred by the manufacture of linagliptin, with the mechanism for payment being solely linked to the sales of Product made from that linagliptin.

125. Taken cumulatively, I am not persuaded that the points made by Boehringer lead to the conclusion that despite the words of clause 3.3(a) there was no shared common intent for royalties to fall due on acts of manufacture.

Conclusion on objective interpretation

126. On the assumption that the manufacture of linagliptin API in Germany would have infringed EP 705 and subject to the issue of export, both discussed below, clause 3.3(a) of the Amended Agreement required payment of royalties on the manufacture of linagliptin in Germany. Payment was to be made by reference to sales of Product made from that linagliptin according to the percentages set out in Exhibit C.

WHETHER EP 705 WOULD HAVE BEEN INFRINGED ABSENT A LICENCE

127. The third and fourth overall arguments advanced by Boehringer in defence to Royalty Pharma's claim for payment turn on questions of German patent law and whether EP 705 would have been infringed by Boehringer's manufacture of linagliptin in Germany, absent a licence.

The Patent

128. The title of the invention of EP 705 is "Method for lowering the blood glucose in mammals". Despite the title, the claims are in EPC 2000 form. They are not process claims.

129. DP-IV is a naturally occurring protease, secreted by endothelial cells in mammals. The specification of EP 705 states that it is involved in signal transmission during the immune response. The invention claimed in EP 705 is summarised in the specification:

> "[0012] The invention is based on the surprising finding that a reduction of the DP-IV enzymatic activity acting in the bloodstream has a causal influence on the blood glucose level. It has been found that
>
> 1. the reduction of DP-IV activity results in a relative stability increase of the glucose-stimulated or externally introduced incretins, i.e. the incretin degradation in the blood can be controlled by the application of activity-reducing effectors of DP IV.
>
> 2. increased biological stability in the degradation of the incretins results in a modification of the effect of endogenous insulin.
>
> 3. The stability increase of the incretins in the blood achieved by the reduction of the DP IV activity results in a subsequent modification of the glucose-induced insulin effect and thus in a modulation of the blood glucose level which is controllable by means of activity-reducing DP IV effectors.
>
> [0013] The invention therefore relates to activity-reducing effectors of dipeptidyl peptidase IV (DP IV) enzymatic activity for use in lowering the blood glucose level below the glucose concentration characteristic of hyperglycaemia in the serum of a mammalian organism to alleviate diabetes mellitus."

130. The inventive concept is a new use of effectors which lower the activity of DP-IV. The new use is to reduce blood glucose levels in the treatment of type 2 diabetes.

131. These are claims 1 and 2 of EP 705:

> "1. Activity-lowering effector of dipeptidylpeptidase IV (DP IV)-enzymatic activity for use in lowering the blood glucose level below the glucose concentration in the serum of a mammalian organism characteristic of hyperglycemia for alleviation of diabetes mellitus, wherein said effector results in the reduced degradation of the endogenous insulinotropic peptides GIP_{1-42} and $GLP\text{-}1_{7-36}$ by DP IV.
>
> 2. Activity-lowering effector for use according to claim 1, wherein said effector is a DP IV-inhibitor."

Boehringer's admissions on technical matters

132. The claims of EP 705 cover the use of a class of products. The class of claim 1 is wider than the DP-IV inhibitors of claim 2 but for brevity I will refer to the entire class as "DP-IV inhibitors" since it makes no difference to this case. Linagliptin is a DP-IV inhibitor (in the strict sense).

133. The parties seem to have appreciated at an early stage of the proceedings that the issues to be resolved at the trial would turn on questions of construction under German contract law and on German patent law. Sensibly, requests for admissions were made to clear away any technical issues. By the time of the Re-Re-Re Amended Particulars of Claim Royalty Pharma pleaded its case in relation to Boehringer's linagliptin in this way:

> "23A. The linagliptin API manufactured in Germany:
>
> (i) is an activity-lowering effector of DP-IV enzymatic activity;
>
> (ii) results in the reduced degradation of the endogenous insulinotropic peptides GIP_{1-42} and $GLP\text{-}1_{7-36}$ by DP IV;
>
> (iii) is a DP-IV inhibitor; and
>
> (iv) is for use in lowering the blood glucose level below the glucose concentration in the serum of a mammalian organism characteristic of hyperglycaemia for alleviation of diabetes mellitus.
>
> …
>
> 23B. The linagliptin API is manufactured in Germany to produce medicinal products (the Linagliptin Products) to achieve the specific therapeutic purpose set out in paragraph 23A(iv) above. That therapeutic purpose (and the fact that the API was manufactured exclusively for the purpose of producing medicinal products for that therapeutic purpose) was at all material times known to the Defendant and/or was (and remains) a foreseeable result of the said manufacture. The Claimant relies on the Defendant's solicitors' letter dated 3 July 2020. Further, linagliptin is solely authorised for use in a medicinal product or products for that therapeutic purpose and that fact was at all material times known to the Defendant. In the premises, the manufacture of the linagliptin API in Germany infringes under 9(1) German Patents Act 1980 ("PatG"). The

> Claimant relies on the further particulars of German law set out in paragraphs 12-16 of the Claimant's Statement of Case on German Law."

134. Boehringer responded in its Re-Re-Re-Amended Defence and Counterclaim:

> "29A. As to paragraph 23A, it is denied that the linagliptin API manufactured in Germany is for the use specified in paragraph 23A(iv). The linagliptin API manufactured in Germany does not satisfy the purpose limitation of claims 1 and 2 of EP 705 construed under German law. It is further denied that paragraph 15 of this Re-Re-Re-Amended Defence and Counterclaim or the Defendant's solicitors' letter dated 3 July 2020 admits that the linagliptin API manufactured in Germany is 'for use' as specified in paragraph 23A(iv). Paragraph 23A is otherwise admitted.
>
> 29B. As to the first and second sentences of paragraph 23B, it is admitted that the linagliptin API manufactured in Germany is subsequently used in the manufacture of the Linagliptin Products and that such Linagliptin Products are for the use specified in paragraph 23A(iv) and that this was at all material times known to the Defendant. As to the fourth sentence of paragraph 23B, it is denied that linagliptin is authorised for use in a medicinal product as alleged. Medicinal products which contain linagliptin, appropriately formulated and in dosage forms suitable for patient use, along with appropriate labelling and patient information specifying their authorised mode of use, are authorised for use according to their authorised mode of use. The only authorised medicinal products manufactured and sold by the Defendant and/or its affiliates which contain linagliptin are the Linagliptin Products, and this fact was at all material times known to the Defendant. The third and sixth sentences of paragraph 23B are noted. Otherwise, paragraph 23B is denied. It is in particular denied that the manufacture of the linagliptin API in Germany infringes under s9(1) PatG. The Defendant relies on the further particulars of German law set out in paragraphs 16 to 24 of the Defendant's Statement of Case in Reply to the Claimant's Statement of Case on German Law."

135. The only qualification that Boehringer had to the allegations in paragraph 23A of Royalty Pharma's pleading related to subparagraph (iv). As explained in paragraphs 29A and B of Boehringer's pleading, its position was that the linagliptin API manufactured by Boehringer was used in the manufacture of Products which were for the use specified in paragraph 23A of Royalty Pharma's pleading – in brief, for treating diabetes. However, linagliptin API was not by itself for use in treating diabetes. Products containing linagliptin were authorised for use – if they were appropriately formulated and in dosage forms suitable for patient use, along with appropriate labelling and patient information. Linagliptin API was not so authorised.

136. Boehringer's assertion that linagliptin API was not authorised for the treatment of diabetes was accurate. Its position that the manufacture of linagliptin did not infringe EP 705 was a position it was entitled to take.

137. However, on a reasonable reading of the pleadings, the soundness of this position would turn on issues of German law, not on any technical issue. In fact, before the final round

of re-re-re-amended pleadings the parties' solicitors had corresponded in late June and early July 2020 in an attempt by Royalty Pharma to ensure that the trial would not require technical evidence. In its letter of 23 June 2020 Royalty Pharma's solicitors sought confirmation as to technical points in relation to the linagliptin API and said:

> "If your client is not prepared to give this confirmation, then our client will seek further directions for permission to adduce evidence from an appropriate technical expert."

138. In their letter in response of 3 July 2020 Boehringer's solicitors stated Boehringer's acceptance of the technical matters later set out in paragraphs 23A (i)-(iii) of the Re-Re-Re-Amended Particulars of Claim (see above). The letter also said that Boehringer did not accept that linagliptin API was (in summary) for use in the treatment of diabetes. The letter continued by saying that the issue between the parties was whether the manufacture of linagliptin API infringed EP 705 under a doctrine of German patent law: *sinnfällige Herrichtung*. The letter added:

> "We do not therefore understand there to be a technical dispute requiring technical expert evidence, but a legal dispute under German infringement law."

139. The admissions in the letter of 3 July 2020 became formalised in the Re-Re-Re-Amended pleadings which I have quoted. The proceedings went forward on the basis that there was no technical issue in dispute. This continued until the final day of the trial dealing with this aspect of the case when a technical argument emerged in Boehringer's case. In the course of a closing submission that linagliptin API is not suitable for the treatment of diabetes, counsel for Boehringer made two points. One was it would be dangerous and unethical to administer the API to a patient. The otherwas that in any event it was not possible to say that the API would have any effect in the treatment of diabetes.

140. As to the first, it would no doubt be unethical to administer the API to a patient because it is not authorised for such administration. Whether it would be dangerous would depend, I imagine, on the dose. But the purpose specified in claim 1 of EP 705 is not for use in the safe and ethical administration to a human patient. It is for use (in summary) in lowering the blood glucose level of mammals for the alleviation of diabetes. If linagliptin administered to a diabetic mammal would have the effect of reducing the mammal's blood glucose level and alleviating the diabetes, it is suitable for that purpose.

141. I found the second technical argument surprising. Boehringer had admitted that linagliptin inhibits the enzymatic activity of DP-IV and reduces the degradation of the endogenous insulinotropic peptides. One would assume that linagliptin API would therefore reduce the level of blood glucose given the role of insulinotropic peptides as explained, apparently not controversially, in EP 705. Yet Boehringer's counsel submitted in closing that I could not be sure of that. He speculated that the excipients in the Products may be necessary to make the linagliptin bioavailable.

142. I can leave to one side the question whether there is likely to be any sound foundation in that speculation. I do not allow Boehringer to raise that technical issue at the last minute. If it was in Boehringer's mind by the time the final amendments to the principal pleadings in August 2020, Boehringer was under an obligation to raise the point clearly

so that technical evidence could be exchanged in relation to it. The procedure in this court is not trial by ambush. If, as is likely, the point did not occur to Boehringer until very late and therefore had not been pleaded, it was not a point Boehringer could take.

143. Boehringer admitted that the linagliptin API it manufactured in Germany between May 2015 and April 2017 satisfied the technical requirements of claims 1 and 2 of EP 705. Specifically, the linagliptin was:

(i) an activity-lowering effector of DP-IV enzymatic activity;

(ii) which results in the reduced degradation of the endogenous insulinotropic peptides GIP_{1-42} and $GLP\text{-}1_{7-36}$ by DP-IV;

(iii) a DP-IV inhibitor.

144. Boehringer's defence to the allegation of infringement of claims 1 and 2 had two limbs. First, German law requires that in an EPC 2000 claim the purpose limitation is satisfied only if there is the necessary *sinnfällige Herrichtung* in relation to the product. On the facts of the present case there was not. Secondly, even assuming the first requirement had been satisfied, product destined for export from Germany could in no circumstances infringe. The defence thus rested solely on issues of German law.

The German statute

145. Sections 9 and 10 of the German Patent Act, the *Patentgesetz* ("PatG") set out the scope of protection afforded by a patent. Like the equivalent sections of the UK Patents Act 1977, these sections are derived from the Community Patent Convention and are therefore similar to their UK counterparts. They provide (in official translation):

> "***Section 9***
>
> *The patent shall have the effect that the proprietor of the patent alone shall be entitled to use the patented invention within the scope of the law in force. In the absence of the consent of the proprietor of the patent, any third party shall be prohibited from*
>
> *1. producing, offering, putting on the market or using a product which is the subject-matter of the patent, or from either importing or possessing such a product for the purposes referred to;*
>
> *2. using a process which is the subject-matter of the patent or, if the third party knows or if it is obvious from the circumstances that use of the process is prohibited in the absence of the consent of the proprietor of the patent, from offering the process for use within the territorial scope of this Act;*
>
> *3. offering, placing on the market or using a product which is produced directly by a process which is the subject-matter of the patent, or from either importing or possessing such a product for the purposes referred to.*
>
> ***Section 10***

> *(1) The patent shall further have the effect that any third party shall be prohibited, in the absence of the consent of the proprietor of the patent, from supplying or offering to supply, within the territorial scope of this Act, persons other than those entitled to exploit the patented invention with means relating to an essential element of the invention for use within the territorial scope of this Act if the third party knows or if it is obvious from the circumstances that those means are suitable and intended for using that invention.*
>
> *(2) Subsection (1) shall not apply if the means are generally available commercial products, except where the third party induces the person supplied to perform any of the acts prohibited under section 9, second sentence.*
>
> *(3) Persons performing the acts referred to in section 11 nos 1 to 3 shall be deemed, within the meaning of subsection (1), not to be persons entitled to exploit the invention.*"

146. Royalty Pharma alleged only direct infringement under s.9(1), although s.10 was discussed during argument and cross-examination and it had some comparative relevance.

German case law and EPC 2000 claims

147. Like the courts in England, German courts have dealt with the prohibition on the patenting of methods for treatment of the human body, and with the formulation of claims by patentees to circumvent that prohibition. The prohibition stems from the European Patent Convention ("the EPC"), formerly contained in art.52(4) and now found in art.53(c) of the EPC currently in force ("EPC 2000").

148. There have been three formulations of pharmaceutical use claims which have successively been recognised. In chronological order they are:

(i) Original second medical use claims: "Use of substance X for the treatment of indication Y".

(ii) Swiss-form claims: "Use of X for the manufacture of a medicament for the treatment of indication Y".

(iii) EPC 2000 claims: "Compound X for use in the treatment of indication Y".

The alleged infringement of EP 705

149. There is an unusual feature of the alleged infringement of EP 705 in the present case. In the general run of pharmaceutical use claims, the patentee has found a new use for an old product. The issue is whether the alleged infringer is exploiting that new use. In the present case the product in issue was new. Boehringer developed linagliptin afterthe priority date of EP 705.

150. EP 705 has EPC 2000 claims. The scope of such claims under German law is better appreciated by considering how German courts have approached the three successive forms of pharmaceutical use claims.

German case law

151. Before the enactment of the PatG 1967, patents for pharmaceuticals were not available in Germany. In January 1977 the BGH ruled that even if a pharmaceutical product was known, a new use for the product could be given patent protection, see *Benzolsulfonylharnstoff* (Case X ZB 13/75, NJW 1977, 1104). These were the original second medical use claims.

152. The judgment of the BGH a few years later in *Sitosterylglykoside* (Case X ZB 21/81, GRUR 1982, 548) concerned a patent application claiming a pharmaceutical product consisting of β-sitosterol glycosides for treating benign prostate hypertrophy and rheumatoid diseases. β-sitosterol glycosides had been part of the art since the 1930s and were known to have other purposes. The BGH reversed in part a decision of the Federal Patent Court, remitting the application to that Court for further consideration of the claim. The BGH said:

> "[10] The note included in the patent claim [i.e. the limitation in the claim] thata product is to be used for a certain purpose (here: pharmaceutical product for treating illness A with active substance X) conveys the teaching for the expert that they must treat the substance such that it attains a form or state which is suitable for achieving the stated purpose. In the case of pharmaceutical products for treating a certain illness witha certain active substance this generally means that the expert must treat the active substance that is in a certain state (gaseous, liquid or solid) such that it, either on its own or in combination with carrier substances,attains a form which is suitable for treating the illness, i.e. to formulate it as a pharmaceutical product.
>
> …
>
> [13] d) Based on the present application, the applicant claims a pharmaceutical product consisting of β sitosterol glycosides for treatingbenign prostate hypertrophy and rheumatoid diseases. The applicant derives patentability of the subject matter of this application exclusivelyfrom the surprising effectiveness of this active substance in treating the specified illnesses. According to this reasoning, the patentability of the subject matter of this application essentially depends on the novelty, theprogress and the inventive step involved in using the specified compounds for treating these illnesses. The protection of its patent claim, too, does not differ, at least not in material respects, from the protection of a correspondingly formulated use claim which does not directly coverthe manufacture and distribution (offering for sale and marketing) of thesaid compounds, but rather the evident orientation of the active substance for use in the therapeutic treatment of said diseases (BGHZ 68, 156, 181 - *Benzolsulfonylharnstoff* (benzene sulfonyl urea)). The essence of the invention claimed and the protection of any patent granted in respect thereof thus require, for reasons of legal clarity, that the 'composition claim' is rejected and the applicant is referred to the use claim."

153. This was before the BGH had fully developed its doctrine of *sinnfällige Herrichtung*, discussed below. The expression "evident orientation" in paragraph 13(d) is a

translation of *augenfällige Ausrichtung* which, as Professor McGuire said, is a narrower term, though nothing much turns on the difference.

154. As appears from the paragraphs I have quoted, the BGH was at pains to emphasise that the claims it remitted to the Federal Patent Court did not cover the manufacture and distribution of β-sitosterol glycosides – that would have protected an old group of compounds. Rather, a use claim was allowed to go forward which protected the subject-matter of the invention, namely the surprising effectiveness of those compounds in treating the specified illnesses.

155. In 1981 the PatG was revised to bring it into line with the EPC. The BGH reiterated that the grant of second medical use claims was possible and ruled that infringement of such claims could be direct (as opposed to contributory), see *Hydropyridin* (Case X ZB 4/83, GRUR 1983, 730, translation taken from IIC 1984, 215, at 219):

> "… this Court has regarded inventions providing chemical substances formulated for treatment of the human body by therapy and the application of such substances for use on the human organism in order to maintain or restore its health as being susceptible of industrial exploitation, which amounts to being susceptible of industrial application. In so doing, this Court has made possible appropriate protection for inventions of this type. It has regarded the displayed formulation of a chemical substance for use in treatment by therapy being covered by the subject-matter of the use claim, thus ensuring that this 'industrial' part of the claimed use is also covered directly by the exclusive right of the patent proprietor."

156. The BGH continued by explaining the protection afforded by a second medical use claim, which includes the export of the therapeutic substance:

> "The patent proprietor thus enjoys effective protection against a third party in Germany industrially preparing the therapeutic substance for therapeutic use, offering it for sale or bringing it onto the market, or in Germany offering for sale or bringing onto the market a substance formulated abroad for such use. He can also take effective action against export of the substance; this would be impossible if his sole recourse were against an indirect infringement of his patent."

157. Swiss-form claims were recognised by the Enlarged Board of Appeal of the European Patent Office in Case G5/83 *Second medical indication/Eisai* (OJEPO 1985, 64). These were subsequently replaced by EPC 2000 claims, introduced by art.54(5) EPC 2000.

158. EPC 2000 claims were made permissible in Germany by the revision of the PatG in 2007 to comply with EPC 2000, which included the introduction of a new s.3(4) PatG.

159. In *Kollagenase I* (Case X ZB 5/13, GRUR 2014, 461) the BGH considered a claim for collagenase for use in the treatment of Dupuytren's disease, i.e. an original second medical use claim. Referring to its earlier judgment of 2005, *Arzneimittelgebrauchsmuster* (Case X ZB 7/03, GRUR 2006, 135), the BGH ruled that (1) the subject-matter of such claims lies in the suitability of a substance – which may be a known substance – for a specified medical indication so that such suitability is an inherent characteristic of the substance, (2) such claims correspond to purpose-limited product claims and (3) that these two principles apply whether the claim is an original

second medical use claim or, as would apply in the future, an EPC 2000 claim (translation take from IIC 2015, 470):

> "[17] The subject of such a claim is the suitability of a known substance for a specific medical application and thus ultimately an inherent characteristic of the substance (BGH, order of 5 October 2005 - X ZB 7/03, BGHZ 164, 220, 222 = GRUR 2006, 135 marginal 11 - *Utility model for medicinal products*). This corresponds in fact to a purpose-related protection of substances, as § 3 (4) Patent Act and Art. 54 (5) EPC now expressly provide for further indications. This applies irrespective of whether the patent claim is, according to its wording, expressly directed to the use of the medicament, to its preparation for a specific purpose or – which might be most expedient in the future in view of the new legal regulation – to purpose-related substance protection."

160. The two principles were repeated by the BGH in *Pemetrexed* (Case X ZR 29/15, GRUR 2016, 92) and the court added expressly (as was implied in *Kollagenase I*) that they applied likewise to Swiss-form claims (translation taken from IIC 2017, 208):

> "[83] According to the case law of this Court, the subject-matter of a patent claim directed to the use of a substance to treat a disease is the suitability of the substance for a certain medical use, and thus ultimately a property inherent in the substance. This corresponds substantively to a purpose-limited product protection, as expressly provided for in Sec. 3(4) Patent Act and Art. 54(5) EPC in the version in effect since 13 December 2007. This is the case regardless of whether the wording of a patent claim is directed to purpose-limited product protection, to the use of the medicament or to its manufacture for a certain use.
>
> [84] The same is true for claims that are directed to the use of a substance to manufacture a medicament, as is consistent with the earlier legal practice of the European Patent Office. This special kind of claim wording known as the 'Swiss-type claim' made allowance for the fact that the use of a substance to treat a disease was in the view of the European Patent Office not susceptible to patenting. The solution chosen instead, of directing the protection to use to produce a medicament, does not change the fact that substantively a special property of the substance is protected that is likewise inherent to the product medicament."

Sinnfällige Herrichtung

161. A persistent problem for courts in relation to all three types of claim has been the resolution of a means to determine whether an alleged infringer's product is "for", or is "for use in", the treatment of the indication specified in the claim of the patent in suit. The German courts have developed the doctrine of *sinnfällige Herrichtung* to deal with this. Professor Haedicke said that the term has been translated into English variously as "manifest arrangement", "obvious arrangement", "manifest making up" or "manifest preparation", although it is not an exhaustive list. As will be seen, instead of the noun the German courts sometimes use the verb – *sinnfälliges herrichten* – or the past participle – *sinnfällig hergerichtet* – to convey the same meaning.

162. The general idea (I do not aim for precision here) is that where the accused product has been manifestly arranged in a manner for use according to the purpose identified in the

claim, it will satisfy the purpose limitation of the claim. In an EPC 2000 claim – "Compound X for use in the treatment of indication Y" – if the *sinnfällige Herrichtung* of the accused compound is clearly in accordance with treatment of indication Y, then in law the compound is for use in the treatment of indication Y.

163. I mentioned earlier that a term used by the experts during the trial when explaining the application of *sinnfällige Herrichtung* was "earmarked". It has also been used by German courts at least on one occasion – in German *zweckgebunden*. I find this to be a convenient means of expression. My references to the "earmarking" of a product for use in the treatment of the specified indication should be taken to mean that the *sinnfällige Herrichtung* of the product is for use in the treatment of that indication.

164. Chronologically the first and now a well-established way of earmarking a pharmaceutical product in German law was to formulate the product appropriately for treatment of the relevant indication, with labelling and/or an instruction leaflet informing the user that the product is for that indication. However, *sinnfällige Herrichtung* has also been used in relation to non-pharmaceutical products and formulation is not applicable to most of those. The courts in Germany have considered whether there are alternative means to satisfy the requirement.

165. The requirement was a development of the earlier test of *augenfällige Ausrichtung* (see above) and was possibly first used by the BGH in the *Antivirusmittel* judgment in 1987 (Case X ZR 51/86, GRUR 1987, 794):

> "Since the patent in suit derives the patentability of the teaching protected by it solely from the fact that 1-aminoadamantane and/or its hydrochloride are particularly effective in treating viral infections and similar diseases, and the general reference in the patent specification to the extraordinary effectiveness of said compounds as pharmaceutical agents does not disclose any specific possibility to use them for other diseases, the protection conferred by the patent in suit, if considered as a use patent, is limited to the obvious preparation [*sinnfällige Herrichtung*] of the active agents 1-aminoadamantane or 1-aminoadamantane hydrochloride as a medicament for use in the prevention or treatment of viral infections and similar diseases."

166. Further understanding of the term can be found in more recent judgments. In *Verwendungspatent* (Case 6 U 50/12, GRUR 2014, 764), the *Oberlandesgericht* ("OLG") Karlsruhe considered an allegation of infringement of a patent claiming the use of glass fibres of a specified composition for purposes where the risk of cancer was excluded with reasonable certainty. The claims were treated as purpose-limited product claims:

> "(2) As stated above, claim 1 comprises the meaningful preparation [*sinnfällige Herrichtung*] of objects containing the said fibres for all purposes where the risk of cancer is to be excluded with reasonable certainty. The meaningful preparation can be achieved not only by a special design of the object, but also by instructions for use in the form of an instruction leaflet or in any other way enclosed with the object when it is sold (BGH, GRUR 1990, 505, 506 et seq.) It is therefore necessary that the described object is visibly oriented to the intended use so that it is obvious to the purchaser that the object is to be used in the manner specified in the patent.

> In this case, the meaningful preparation is that the attacked products, which contain glass fibres with demanding geometrical and chemical properties, are designed and marketed as insulating boards and thus as building materials for building construction. Because in the case of building materials for structural engineering, the risk of cancer must be excluded with sufficient certainty."

167. It was enough to establish infringement that the defendant's insulation boards contained glass fibres of the composition specified in the claims and were sold as building materials, since their marketing for that purpose implied that they satisfied the purpose limitation of the claims: cancer-free application. It was not necessary that the boards were sold with instructions or product information stating that they could be installed without a risk of causing cancer.

168. The decision and reasoning of the OLG Karlsruhe was approved on appeal by the BGH in *Glasfasern II* (Case X ZR 30/14, GRUR 2016, 257). The BGH said:

> "[58] In the case in dispute, according to the determinations by the Appellate Court that are not contested, Defendants sold the contested products for construction purposes. Thus, with regard to the cited rules of the Chemicals Prohibition Ordinance they obviously arranged the products [they were *sinnfällig hergerichtet*] for lawful use as non-carcinogenic glass fibres. No special circumstances from which any other assessment might result were stated, nor were any asserted by the appeal on a point of law."

169. The *Östrogenblocker* judgment (Case I-2 W 6/17) of the OLG Düsseldorf concerned an appeal from the refusal of the *Landgericht* to grant an interim injunction. The appeal was dismissed on the ground that the applicant had delayed excessively in launching its proceedings for patent infringement. The applicant appears to have argued that it was not in a position to start its action sooner because of the uncertain state of the law. The OLG was unimpressed by the argument, approving a summary of the law which had appeared in the patent infringement handbook:

> "[36] Since the 'Pemetrexed' decision, it had to be clear to any knowledgeable person that Swiss-type claims worded as use-for-manufacture claims have to be treated like purpose-related substance claims (substance X for the treatment of disease Y) (drafted after the EPC 2000) in infringement proceedings. It is true that in its previous rulings, the *Federal Supreme Court* did not make any explicit comments on which specific liability requirements and legal consequences are associated with such 'purpose-related substance' protection. Furthermore, it may also be true that this was not further addressed in literature and case law of the lower instance courts, and that the relevance of purpose-related substance protection for liability and its legal consequences were written down for the first time in the 9th edition of the 'Handbuch der Patentverletzung' [Patent infringement handbook]. Yet the insights contained in it are by no means as groundbreaking and surprising as the applicant tries to suggest. Instead, it would also have been easy for the applicant and its counsel to gather that purpose-related substance protection is an option whenever the use of the protected object according to the patent is factually ensured, regardless of whether the party who offers and sells the object is responsible for it (by an obvious preparation [*sinnfällige Herrichtung*])."

170. Thus, the OLG Düsseldorf endorsed the suggestion that in the context of an alleged infringement of an EPC 2000 claim, provided the defendant's product was earmarked, infringement could be established even if the defendant had done nothing to the product to achieve the earmarking.

171. The court continued:

> "[38] The considerations the applicant had to make in the present case were extremely straightforward, because the *Federal Supreme Court* case law discussed above already mapped out the way medical use patents have to be handled in the case of infringement, so that only very few logical conclusions were necessary in order to recognise the liability criteria relevant for purpose-related substance patents: A first important insight already follows from the *Federal Supreme Court*'s qualification of medical use and use-for-manufacture patents as 'patents conferring purpose-related substance protection'. This insight is that such patents – like any other product patent – are governed by the provision in Sec. 9 No. 1 PatG, according to which, if the subject matter of the patent is a product, any third party is prohibited from manufacturing, offering, placing into circulation, or using or importing or possessing this product for the above purposes. In contrast to regular substance patents which confer absolute protection to their proprietor and therefore apply independently of the specific purpose for which the patent-protected object is offered or sold, it is a special feature of purpose-related substance patents that – as an inevitable consequence of the fact that the substance protection is tied to a purpose – the acts listed in Sec. 9 no. 1 PatG need to be performed to achieve a very specific therapeutic purpose. Purpose-related substance patents (also in the form of use-for-manufacture patents) therefore prohibit any third party from offering and/or selling the protected substance for the purpose protected by the patent (sic: the patented medical indication). Under this classification, the actual act of use no longer takes place when the object is used in therapy in the end (as an act similar to a process), but when it transitions into commerce through an offering and sale; offering and sale is then not prohibited per se, but – in a limited fashion – only if it is performed for the specific, patent-protected therapeutic purpose. Since substance protection is limited by being tied to a purpose, a direct use of the usepatent/purpose-related substance patent is therefore only present, if the required achievement of a therapeutic purpose to which patent protection is limited, is inherent in the object offered or sold."

172. Thus, there can be direct infringement of a pharmaceutical use claim if the defendant carries out any act specified in s.9(1), including manufacturing the relevant product. There was infringement on the facts in issue only if the infringing act – here an offer for sale or sale of the product – was tied to the purpose specified in the claim, i.e. manifested in the *sinnfällige Herrichtung*. Such a tie could be inherent in the product. The OLG then explained further:

> "[39] This can be actively accomplished, by the pharmaceutical composition specifically being obviously prepared [*sinnfällig hergerichtet*] for the purpose of the patent prior to its sale, i.e. prepared in such a manner that the protected therapeutic use will foreseeably take place. A formulation, packaging, dosage, external packaging, or instructions for use enclosed with the object, directed at the specific purpose, can serve to achieve this. Since, in the opinion of the

> Federal Supreme Court, the objective suitability of the respective drug for being used in accordance with the patent is at the centre of the protection conferred by a use-for-manufacture patent, liability of the distributor of the preparation is also conceivable without him performing any measures of obvious preparation. Taking into account the not comprehensive, but limited, i.e. purpose-related substance protection, only two conditions need to be met, which ensure by other means that the protected substance is tied to a specific purpose: Firstly, the product must be suitable for the purpose in accordance with the patent, and secondly, the distributor needs to take advantage of circumstances which – in a similar way to an active obvious preparation – ensure that the purpose-related therapeutic use of the preparation offered or sold actually takes place. The latter requires a sufficient and not just occasional use according to the patent in suit, as well as the supplier's respective knowledge, or at least its bad faith ignorance thereof. When the underlying external conditions for the offering and sale of a product already imply its patent-protected therapeutic use, a separatepreparation by the supplier becomes unnecessary, which is why it cannot be considered as the decisive criterion for liability. There is indeed no reason for requiring this, in view of the fact that according to the case law of the Federal Supreme Court, the protection conferred by the patent – regardless of the concrete wording of the claim – relates to the suitability of the known substance for the specific medical purpose and thus, in the end, a property inherent in the substance. In view of patent protection understood in this manner, it is downright off the mark to limit the requirements for liability in the case of claims based on a use-for-manufacture patent to situations in which the therapeutic use in question automatically occurs due to an active act of preparation by the distributor, yet to deny patent protection if, given the same suitability of the object, said patent-protected therapeutic use occurs due to othercircumstances (such as a common cross-label use)."

173. I draw two points from this paragraph. First, the OLG repeated that a product may satisfy the requirement of *sinnfällige Herrichtung* even if nothing is done to the product; the product may inherently fulfil the requirement. Secondly, only two conditions need to be met for there to be the necessary *sinnfällige Herrichtung*: (1) the product must be suitable for the purpose specified in the patent and (2a) the alleged infringer must take advantage of circumstances which ensure that use of the product for that purpose actually takes place, which (2b) requires sufficient and not just occasional use of the product for that purpose and (2c) requires knowledge on the part of the alleged infringer that the relevant circumstances are in place, or alternatively if the alleged infringer has no such knowledge, that his ignorance is a consequence of bad faith.

174. *Östrogenblocker* was followed about 10 months later by another judgment of the OLG Düsseldorf dealing with an appeal from a refusal to grant an interim injunction: *Dexmedetomidin* (Case I-2 U 30/17, GRUR-RS 2018, 2410). The Swiss-form claim was for the use of the pharmaceutical dexmedetomidine for the manufacture of a medicament for the sedation of a patient in administrative care, wherein administration is by a charging and then a maintenance dose so that a specified plasma concentration is achieved. The OLG repeated its two criteria for assessing whether there was *sinnfällig Herrichtung* and its ruling that an alleged infringer may be liable even if it has not itself undertaken any *sinnfällig Herrichtung*, adding that this would be in exceptional cases.

175. In both *Östrogenblocker* and *Dexmedetomidin* the active substance was old, so there was no question of infringement solely by the manufacture of that substance. Both were "skinny label" cases, i.e. the labelling of the product was not specific as to its use. The OLG was concerned to ensure that where the medicament was apparently marketed for a non-protected use but was in fact used for the purpose specified in the claims of the patent in suit, usually because of physician's prescription, the supplier should be made liable where there is knowledge of the actual use or there is bad faith.

176. The judgment of the OLG Düsseldorf in *Fulvestrant* (Case 2 U 27/18, GRUR 2019, 279) concerned the substantive infringement action following the application for interim relief in *Östrogenblocker*. The Court endorsed its earlier rulings of law.

177. The judgment of the *Landgericht* ("LG") Mannheim dated 8 October 2019 (Case 2 O 35/16, BeckRS 2019, 27104) was concerned with an allegation of infringement of a patent which claimed the use of an "endless" elastic industrial belt for transporting vessels in a vessel inspection machine. The court found that the patent had been infringed and among other things considered whether, as part of the relief granted, the defendant was obliged to recall infringing products:

> "[55] … the literature (Kühnen, *Handbuch der Patentverletzung*, 11th ed., Chapter A, marginal 367) is of the opinion that in the case of infringement of a patent for use there is only a claim to recall, whereas a claim to destruction is excluded. The Board does not fully follow this view. The literature based on the wording of the law is not convincing in its differentiation, because both paragraphs of Sec. 140a Patent Law refer to 'products which are the subject-matter of the patent'. In the opinion of the Board, this includes products which have been sensibly prepared [the *sinnfällige Herrichtung* of which is] for a patented use, at least if the latter – as in the case in dispute – is already apparent from their technical design, i.e. if the sensibly prepared design is inherent in the product. This is supported by the protection under Sec. 9 PatG, which is earlier than that of a process patent, in the case of a patent for use. Admittedly, there is no claim to destruction in case of a contributory patent infringement with regard to the means within the meaning of Sec. 10 (1) Patent Law. However, this is due to the fact that the offence of contributory patent infringement prohibits the indirect user of the patent from offering and supplying contributory patent-infringing items within the scope of application of the Patent Act if these are objectively suitable and intended for the use of the invention, but not the possession, offering and supplying of contributory patent-infringing items in areas outside the scope of application of the Patent Act and for purposes other than the use of the invention (BGH, GRUR 2006, 570 marginal no. 32 - *Extracoronal attachment*; see on the right of recall according to OLG Düsseldorf judgement of 5 July 2018 - I-2 U 41/17, juris marg. nr. 211 mwN). In the case of a patent for use, however, unlike under Sec. 10 Patent Law, export (BGHZ 88, 209, 217 - *Hydropyridin*) and possession (Benkard/Scharen, PatG, 11th ed. § 9 marginal 50) are also subject to the Patent holder reserved. If the obvious preparation in Germany already marks the beginning of use in the sense of the prior protection of a patent

> for use (see BGH, GRUR 2016, 257 marginal 46, 55 - *Glass fibres II*), destruction claims also exist with regard to the product which is the subject matter of the patent due to this commenced use, at least if the obvious preparation is embodied in the product itself."

178. Thus, the LG drew a clear distinction between direct infringement under s.9(1) PatG and contributory infringement under s.10. In the case of infringement of an EPC 2000 claim by the defendant's supply of an earmarked product, including where the earmarking is apparent from the technical design of the product so that its *sinnfällige Herrichtung* is inherent in the product, the patentee is entitled to the relief prescribed by the PatG where there has been direct infringement of a patent claim under s.9(1), including destruction.

The Handbook of Patent Infringement

179. Professor McGuire referred to a recent commentary by Dr Thomas Kühnen in *Handbuch der Patentverletzung* (Handbook of Patent Infringement), 12th ed. 2020. Dr Kühnen is the Presiding Judge at the Düsseldorf OLG. Having explained the extent of protection afforded by a use claim (at margin nos. 442-445), Dr Kühnen sets out what is not protected at 446-8, including this:

> "446 By contrast, the protected use does not cover
>
> "447 – the mere manufacture of the object without its obvious preparation for the use"

180. The point made there by Dr Kühnen is on its face uncontroversial. But he explains his reasoning in a footnote:

> "Basically, regardless of the BGH case law (BGHZ 88, 209, 217 – *Hydropyridin*) it is doubtful if upstream protection should already be recognised for the obvious preparation [*sinnfälliges Herrichten*]. Since the offering/placing on the market of products prepared to be used according to the patent precedes the actual use, which alone is protected by the patent, strictly speaking, there is actually no good reason to extend patent protection even further to the level of manufacture."

181. I understand Dr Kühnen to be saying that notwithstanding the BGH's ruling in *Hydropyridin*, he doubts that the owner of a use patent should be able to prevent acts done before the use of the earmarked product. It is the use which is protected by the patent and so there should be no protection for upstream acts, particularly extended to the act of manufacture. I find this surprising because for the reasons discussed above, the act of infringement is bound to be upstream of the use.

182. However, at margin no. 450 Dr Kühnen seems to move on from his misgivings and to accept that any act covered by s.9(1) Pat G is a potential act of infringement, including the manufacture of an API, provided that the criterion of *sinnfällige Herrichtung* is satisfied and subject to territorial considerations. I will return to the whole of his commentary at 449 and 450 below in the context of whether an EPC 2000 claim can cover the manufacture of a product for export from Germany.

The claim category of an EPC 2000 claim

183. As mentioned above, a potentially important proposition advanced by Professor McGuire was that EPC 2000 claims are regarded by German courts as process claims. Professor Haedicke's evidence was that they are characterised as purpose-limited product claims and was not challenged.

184. Professor McGuire was cross-examined on this question by reference to the judgments of the BGH in *Kollagenase I* and *Pemetrexed* and what had been said by the OLG Düsseldorf. She laid emphasis on the BGH's use of word "corresponds". For instance, in *Pemetrexed* the BGH said that the subject-matter of pharmaceutical use claims, as explained by the Court

> "corresponds substantively to a purpose-limited product protection, as expressly provided for in Sec. 3(4) Patent Act and Art. 54(5) EPC."

185. Professor McGuire said that although the BGH had said EPC 2000 claims correspond to purpose-limited product claims, the Court had never said that they were such claims.

186. I find Professor McGuire's position on this surprising and untenable. I can see no reason why the BGH should have said, three times, that they correspond to purpose- limited product claims unless the BGH meant that they had the same effect in law as purpose-limited product claims.

187. Moreover, that is clearly how the OLG Düsseldorf interpreted the BGH's judgments. I repeat part of the decision in *Östrogenblocker* quoted above:

> "[36] Since the 'Pemetrexed' decision, it had to be clear to any knowledgeable person that Swiss-type claims worded as use-for-manufacture claims have to be treated like purpose-related substance claims (substance X for the treatment of disease Y) (drafted after the EPC 2000) in infringement proceedings."

188. Dr Kühnen, whose views Professor McGuire pressed upon this court in another context, unsurprisingly agrees with the OLG Düsseldorf. It seems to me that Dr Kühnen was entirely accurate in saying at the start of his commentary at margin no. 450 in *Handbuch der Patentverletzung*:

> "… use claims in the field of pharmaceutical substances, which, according to BGH case law, are uniformly understood as substance claims tied to a specific purpose"

189. Professor McGuire's interpretation of *Kollagenase I* and *Permetrexed* on this issue and her position that the OLG Düsseldorf has misunderstood BGH judgments had the merit of remaining consistent but were not shown to be supported anywhere. I reject Professor McGuire's evidence on this point.

Boehringer's arguments

190. Boehringer's case on the effect of EPC 2000 claims and more specifically EP 705 under German law was supported by nine arguments.

191. The first was based on three uncontroversial assertions: (a) German courts would not construe EPC 2000 claims to cover that which is old; (b) the usual circumstances which in the past have given rise to the three types of pharmaceutical use claims have been the discovery of a new purpose B for a known drug with known purpose A (or a new purpose C, over known purposes A and B, and so on); (c) the effect of EPC 2000 claims must be the same in all cases.

192. Boehringer argued that if the effect of EPC 2000 claims were to make the manufacture of the product an act of infringement, the effect in the usual run of cases would be that the claims cover an old product. Therefore EPC 2000 claims cannot have that effect. In cross-examination, Boehringer continued, Professor Haedicke had no coherent answer to the point put to him that if his view of the effect of such claims were correct, they could cover something old.

193. Secondly, DP-IV inhibitors other than linagliptin were known at the priority date. Royalty Pharma's view of the effect of EP 705 would mean that it would cover the manufacture of old DP-IV inhibitors. This too was conceded by Professor Haedicke.

194. Thirdly, if Royalty Pharma were correct then in almost every case the manufacture of an API would infringe an EPC 2000 claim.

195. Fourthly, the claims of EP 705 are *use* claims. Linagliptin, the API, cannot be used to treat patients, only the formulated Linagliptin Products may be used. Therefore the claims protect the Linagliptin Products, not the API.

196. Fifthly, in *Sitosterylglykoside* the BGH said that the scope of pharmaceutical use claims covers "the evident orientation of the active substance for use in the therapeutic treatment of said diseases". This means that *sinnfällige Herrichtung* denotes that something has been prepared. It is the act of preparation which is the act of infringement, serving as a proxy for the subsequent use of the formulation prepared. This is supported by the BGH's judgment in *Hydropyridin*.

197. Sixthly, there has never been a case in which any German court has come close to saying that the manufacture of an API can infringe a pharmaceutical use claim. Boehringer pointed to judgments in which the BGH has said the opposite: *Benzolsulfonylharnstoff*, *Sitosterylglykoside* and *Trigonellin*. The BGH has also said that this does not depend on the form of the pharmaceutical use claim; it applies with equal force to EPC 2000 claims.

198. Seventhly, Boehringer's approach to the scope of pharmaceutical use claims is consistent with the decision of the Enlarged Board of Appeal ("the EBA") of the European Patent Office ("EPO") in G5/83 *Eisai*. The approach set out in G5/83 *Eisai* is reflected in the judgment of the BGH in *Antivirusmittel*.

199. Eighthly, s.10 PatG, which provides for indirect infringement of a patent, would become completely obsolete if Royalty Pharma's and Professor Haedicke's stated view of direct infringement of EPC 2000 claims were correct. This was confirmed by Professor Haedicke in cross-examination.

200. Ninthly, the view expressed by Professor Haedicke in cross-examination was inconsistent with what he says in his forthcoming book.

Discussion

201. Boehringer was correct to say in its first argument that the effect of EPC 2000 claims must be such that it works in law for all such claims, not just the claims in suit in this case. In particular, they must work in relation to the usual run of pharmaceutical use cases in which the product is old and only the use is new. However, Boehringer elided that uncontroversial assertion into an argument that the effect of EPC 2000 claims must be assessed as if all disputes over such claims, without exception, concern an old product and a new use. The present case shows that this is false.

202. Linagliptin was unknown at the priority date of EP 705. If it is correct to say that the manufacture of linagliptin infringes EP 705, this would not create a liability in respect of any act which could have been done before the priority date. Certainly, in the usual run of cases, making the manufacture of an API an act of infringement would mean that the patent covers that which is old, because the API was old at the relevant priority date. But on the present facts it does not. I reject Boehringer's first argument.

203. I also do not agree with the suggestion that Professor Haedicke conceded in cross-examination that his and Royalty Pharma's view would result in EPC 2000 claims covering that which is old. I here reproduce a passage of cross-examination set out in Boehringer's closing submissions said to support Professor Haedicke's concession:

> A. … The basic reasoning is that the interest of the patent-holder who makes and develops a new use should be protected against acts which are clearly earmarked towards his patented use. It does not really matter, it is secondary, of secondary importance whether this earmarking takes place by means of formulation, by means of putting a customer leaflet inside, by dosage or even by manufacture, as long as the earmarking accords with the patent is actually at issue.
>
> Q. Even if that means the claim covers something which is old?
>
> A. The claim does not cover anything which is old.
>
> Q. The compound may be old.
>
> A. The use of the patent protects the use of the compound according to thenew use. We have clear case law on that, that this innate property of the [product] is what is the essence of the purpose-limited product claims. So, you do not have a patent on an old product, but the purpose-limited use of the product, the product being manufactured, being formulated, being somehow manifestly arranged for the patent, the purpose is what is protected under the patent."
>
> (Day 2, 157-158. The word "product" is in square brackets is my substitution. It is rendered "patent" in the transcript, which is probably incorrect.)

204. As I understand Professor Haedicke, he was making the simple point that on the facts of this case there can be no objection to EP 705 covering the manufacture of linagliptin because linagliptin was not old at the priority date of EP 705. He makes the further point that the case law does not specify how earmarking is to be done – depending on

the facts it may be done by formulation or a customer leaflet, or earmarking may be achieved by the innate property of the product itself.

205. Boehringer's second argument was that on Royalty Pharma's view, EP 705 would restrain the manufacture of old DP-IV inhibitors, i.e. those other than linagliptin. Again, Professor Haedicke was said to have conceded the point:

> "MR. SPECK: Professor, you are muddling up two different things. The number of uses for an individual compound, linagliptin, or any of the other DP-IV inhibitors, and how many DP-IV inhibitors are within the claim. I want to ask you about the latter. The point I am making to you is this claim covers, and therefore its construction must work in a principled way, over old DP-IV inhibitors, i.e. those known at the date of the patent. That is right, is it not?
>
> A. In so far, that is correct.
>
> Q. Why would you not be concerned about that when trying to work out what the proper scope of the claim is?
>
> A. Because as I said before, there is just one authorised use of the substancewhich falls under the patent and which actually can be made use of and which is an SmPC which is authorised.
>
> Q. You are giving me the same irrelevant answer again. I am asking you notabout how many uses there are, but how many different compounds are covered. Your case, your argument is that making an old compound, a different DPP-IV inhibitor which is old, just making the raw compound, infringes this patent claim, is it not?
>
> A. Can you repeat the question?
>
> Q. Your argument is that making API, which must apply to any API, must apply to old DP-IV inhibitors, infringes this patent, even though you are makingan old compound on that premise?
>
> A. If it is used according to the patent, that is correct." (Day
>
> 2, 118-119)

206. I understand Professor Haedicke's answer to have been that if an old DP-IV inhibitor is earmarked for the new use specified in EP 705, manufacture of such an inhibitor would infringe the patent. The manufacturer of the old DP-IV would be exploiting the use protected by the patent. I think this rested on two related assumptions, both part of Professor Haedicke's view of the law. The first was that the manufacture of the product specified in an EPC 2000 claim can on certain facts be an act of infringement.Secondly, that it is possible for an API, i.e. an unformulated and unlabelled product, to be earmarked solely by reason of its inherent characteristics. I will return to both.

207. However, on those assumptions it is unlikely that an old DP-IV inhibitor would ever infringe. Unlike linagliptin, old DP-IV inhibitors will almost certainly have been authorised for some other purpose. Therefore it would not be possible to say that in its unformulated and unlabelled state any of them is in law earmarked for the purpose of

EP 705. One can postulate unlikely facts – a change in the regulatory regime so that an old DP-IV inhibitor can only be used to treat type 2 diabetes – in which case the manufacture of the product *would* be earmarked for the use protected by EP 705 and the manufacturer would infringe. But this is so improbable that I think it is safe to say that EP 705 will in practice almost certainly never cover the manufacture of an old DP-IV inhibitor. Even if it did, that would be because the infringer is exploiting the inventive concept of EP 705, namely the use of a DP-IV inhibitor for treating type 2 diabetes.

208. Turning to Boehringer's third argument, the manufacture of an API will infringe only if on the facts the API is earmarked for the relevant purpose in its unformulated and unlabelled state. That would require facts similar to those in the present case, which are exceptional.

209. As to the fourth argument, there is a danger in attaching too much importance to the title "use claim". It is just a label. The case law of the BGH indicates that the act of infringement of a pharmaceutical use claim is not the use itself, i.e. the use of the pharmaceutical in the course of treatment. It cannot be because of art. 53(c) EPC and s.2a(1).2 PatG. Swiss-form claims – the use of X for the manufacture of a medicament for use in the treatment of indication Y – seemingly sought to overcome this particular anomaly by making it apparent that the act of using the product for the manufacture of the medicament was the act of infringement. The formulation of EPC 2000 claims retains the anomaly.

210. The BGH has shown that in respect of EPC 2000 claims the act of infringement must be upstream of the specified use. Therefore, when assessing infringement, focussing only on the product used in the relevant therapeutic treatment is beside the point. The question is whether any act upstream of that use qualifies in law as an act of infringement of the claim.

211. Boehringer's fifth argument was that *sinnfällige Herrichtung* requires something to be done, i.e. the preparation of the product in some sufficient way. It is this act of preparation which is the act of infringement.

212. This is the passage in *Sitosterylglykoside* on which Boehringer relied:

> "13 d) Based on the present application, the applicant claims a pharmaceutical product consisting of β-sitosterol glycosides for treating benign prostate hypertrophy and rheumatoid diseases. The applicant derives patentability of the subject matter of this application exclusively from the surprising effectiveness of this active substance in treating the specified illnesses. According to this reasoning, the patentability of the subject matter of this application essentially depends on the novelty, the progress and the inventive step involved in using the specified compounds for treating these illnesses. The protection of its patent claim, too, does not differ, at least not in material respects, from the protection of a correspondingly formulated use claim which does not directly cover the manufacture and distribution (offering for sale and marketing) of the said compounds, but rather the evident orientation of the active substance for use in the therapeutic treatment of said diseases (BGHZ 68, 156, 181 – *Benzolsulfonylharnstoff* (benzene sulfonyl urea))."

213. In this passage, the BGH was considering the claims of the patent in suit, not pharmaceutical use claims generally. The product of the claims, β-sitosterol glycosides, were known – see paragraph 1 of the judgment. Unsurprisingly, the BGH said that the claims did not directly cover the manufacture of those compounds, only the *augenfällige Ausrichtung* of the active substance for the relevant use.

214. In cross-examination Professor McGuire drew from this a general proposition that pharmaceutical use claims, including EPC 2000 claims, cover the *sinnfällige Herrichtung*. In closing, Boehringer took this a step further, arguing that the *sinnfällige Herrichtung* serves as a proxy for the act of using and is thus the act of infringement.

215. I cannot agree with this proposition. *Sitosterylglykoside* was an early case (1982) in which the BGH felt it necessary to emphasise that the patent could only protect the product insofar as it was evidently oriented for the relevant use. On the facts of the case – and it is those facts being discussed in the passage relied on, the BGH was not making a general proposition of law – the patent could not cover the manufacture of the product because the product was old (see paragraph 1). In my view no general proposition of law can be derived from this passage.

216. Moreover, the *sinnfällige Herrichtung* of itself cannot necessarily be the act of infringement of a pharmaceutical use claim because it may not require any act to be done, see the judgment of the BGH in *Glasfasern II*, the judgments of the OLG Düsseldorf and Karlsruhe and that of the LG Mannheim discussed above.

217. The sixth argument, that no German court has said that the manufacture of an API can infringe a pharmaceutical use claim, is correct. But in all other cases to which I have been referred the API was known at the priority date. The point could not arise.

218. In its seventh argument Boehringer relied on EBA decision G5/83 *Eisai*. I take the view that this decision is of little relevance. In its decision the EBA expressly distanceditself from the judgments of the BGH in *Benzolsulfonylharnstoff*, *Sitosterylglykoside* and *Hydropyridin.* After the EBA's decision was given, the BGH acknowledged it and accepted Swiss-form claims in *Pemetrexed*. But by then they had been overtaken by art.54(5) EPC, s.3(4) PatG and thereby the introduction of EPC 2000 claims. The BGH said that all three types of pharmaceutical use claims were to be treated as being of the same effect. It seems to me to be irrelevant whether or not the German courts have subsequently followed *Eisai* and/or other decisions of the EPO. Whether or not they have, German law is what the German courts have stated it to be.

219. Boehringer submitted that the principles set out in *Eisai* are reflected in the following part of the BGH's *Antivirusmittel* judgment:

> "In its *Benzolsulfonylharnstoff* decision (BGHZ 68, 156 (161) = NJW 1977, 1104 = LM § 1 PatG No. 45), the Court applied to, turning away from the comment contained in the *Schädlingsbekämpfungsmittel* judgment, ruled that protection of a claim directed at the use of a certain active agent for fighting a certain disease does not only begin with the prescription by the doctor and application of the medicament, but with the [upstream] commercial use in the manufacture of the medicament, i.e. the formulation and preparation of the medicament, its dosage and packaging in ready-to-use form. Accordingly, all

> commercial acts that precede this medical application are covered by such a use claim."

220. This does no more than summarise the BGH's earlier judgment in *Benzolsulfonylharnstoff*. As in that earlier case, in *Antivirusmittel* the product specified in the use claim was known. The first new product in the chain of events beginning with the manufacture of the old product would be the product as formulated for use (in the prevention or treatment of viral infections and similar diseases). The act of infringement upstream of the use specified in the claim was therefore the act of formulating the product.

221. Boehringer submitted that Professor Haedicke once more made a concession: in *Antivirusmittel* the BGH ruled that only acts carried out with respect to a formulated medicament can infringe an EPC 2000 claim. I do not understand that to have been his evidence (Day 2, 169-170) although I accept that it was what Professor McGuire said in her cross-examination. But this does not seem to me to be a point requiring expert evidence. I have read the translation of *Antivirusmittel* and the cross-examination of neither expert turned on a point of inaccurate translation from German or the appreciation of any technical content of the judgment. On my reading of *Antivirusmittel* I disagree with Professor McGuire.

222. The eighth argument depended on what yet again was said to have been an important concession by Professor Haedicke: that s.10 PatG and indirect infringement would become completely obsolete on his views of direct infringement of EPC 2000 claims. That is not what he said:

> "Q. … as I understand your evidence, Section 10 is just completely superfluous in these cases.
>
> A. There may be cases in which Section 10 may apply if there is no earmarking whatsoever in the substance being used, so if it is not clear that the purpose will be fulfilled, then under very, very rare circumstances you may come into Section 10, but in general, you are correct in the proposition that section under German law, due to the fact that sinnfällige Herrichtung is very far in the forefield, you generally do not come to Section 10 of the Patents Act.
>
> Q. For instance, Section 10 only applies when you actually know that it is intended that that is what they are going to do. I think what you are saying is that you are always going to be in Section 9 anyway?
>
> A. You will most likely be in Section 9 in nearly all the cases. There may be some cases which are far away, combination therapy is something where youmay possibly be in Section 10, but generally the concept of sinnfällige Herrichtung, manifest arrangement, is that as soon as a product is earmarked and it is clear that the product is used according to the patented purpose, you arein Section 9, you have a direct infringement of a product patent, purpose-limited product patent."
>
> (Day 2, 131-2)

> "A. … Once [the API] is prepared and earmarked for the patent of use and then alternative users, I think we are in section 9 and we have a direct patent infringement, yes.
>
> Q. Yes. Indirect infringement would become completely obsolete?
>
> A. That is correct. The effect of the large applicability of section 9 and the *sinnfällige Herrichtung* or in the other cases, decided by the Düsseldorf courts, leads to a limitation of the scope of application of section 10, that is correct. But, as I said before, it is necessary to look at the direct infringement before youlook at indirect infringement.
>
> (Day 2, 197-8)

223. Professor Haedicke was here discussing the application of s.9(1) to pharmaceutical use claims generally, not just in relation to whether the manufacture of an API could be an act of infringement. I find his evidence unsurprising. The BGH has ruled that s.9(1) applies to the infringement of such claims, subject to the doctrine of *sinnfällige Herrichtung*. To the extent that this will lead to a broad application of s.9(1), s.10 will be of correspondingly narrow application.

224. I turn finally to Boehringer's ninth argument: that Professor Haedicke's forthcoming book support's Boehringer's case. The book is entitled in translation "Direct and indirect infringement of claims for the use of non-significant objects outside the second medical indication". The passage relied on is in a section headed "Contributory patent infringement and second medical indication". It begins:

> "The question arises as to what scope of application remains for the contributory patent infringement outside the second medical indication in view of the broad definition of the facts of direct patent infringement described above."

225. In re-examination Professor Haedicke was asked whether this opening of the section meant that the section was about something other than medical use. He said that was correct. The question was leading and I give no weight to the answer. Also, given the heading and content of the section, I doubt that his answer was accurate. Professor Haedicke may or may not have understood what he was being encouraged to say.

226. This is the passage in that section of the book on which Boehringer relied:

> "Starting point for the understanding of the scope of application of contributory patent infringement was - at least so far - the realization that the obvious preparation [*sinnfällige Herrichtung*] represents the limit of the scope of application of direct patent infringement. Thus, for example, there was no direct patent infringement if an active ingredient was supplied but the patent-related purpose - namely the use for the patent-protected therapy - was not aimed at or achieved according to plan. In such a case there was a lack of targeted action. Against this background, a right of use could always be infringed, but also only indirectly, if the means offered or supplied is suitable and intended to be used for the 'sensible preparation' [*sinnfällige Herrichten*] of a product. In contrast, the non-prepared [*nicht hergerichtete*] substance must remain completely outside the protective effects of the earmarked substance claim."

227. The translation seems imperfect. But as I read it, in the first sentence Professor Haedicke says that in order to understand contributory infringement of a pharmaceuticaluse claim, it must be realised that direct infringement is limited by the doctrine of *sinnfällige Herrichtung*. He continues: the supply of an API will not directly infringe if the purpose specified in the claim is neither targeted nor achieved (i.e. there is consequently no *sinnfällige Herrichtung*). Against this background – which I take to mean: if the specified purpose of the product is neither targeted nor achieved – a pharmaceutical use claim can still be infringed indirectly if the means (relating to an essential element of the invention) offered or supplied is suitable for, and is intended to be used for, the *sinnfällige Herrichtung* of a product. In contrast – i.e. where the means is not suitable for or intended to be so used – there is no direct or indirect infringement and so the product remains outside the protection of the claim.

228. If I have understood this passage in Professor Haedicke's book correctly, it is consistent with his evidence at the trial. This is what he said when the passage was put to him in cross-examination, specifically the last two sentences:

> "Q. Professor, where you are talking about the indirect infringement, whereyou say that the active ingredient to be supplied has to be both suitable and intended to be used to make up the preparation, that is a case where we would know that the API was inevitably destined for formulation into a medicament that was authorised and labelled for the patented indication. That is right, is it not?
>
> A. Yes.
>
> Q. You are saying very clearly this is not direct infringement, you are saying it is indirect infringement. The non-prepared substance must remain completely outside the protective effects of the claim.
>
> A. Again, I just do not talk about situations in which we have a prepared situation and if there is a preparation, in the largest sense, then we are in the field of direct patent infringement. By the way, that is not the law, that is how I understood the law at that time, and, well, I think the courts are rather clear what the reason of manifest preparation is, and if we are in the field of manifest preparation, there is no space for contributory, for indirect patent infringement."
>
> (Day 2, 208-9)

229. Although I do not find the last answer clear, I think Professor Haedicke was saying that he has come to realise since writing his book that where there is *sinnfällige Herrichtung*, there is a likelihood of direct infringement. So the need to rely on indirect infringement is more limited than he suggests in the book. I do not understand him to have conceded that his book is otherwise inconsistent with his evidence given at the trial.

Concluding discussion

230. An EPC 2000 claim will be directly infringed if the alleged infringer carries out a s.9(1) act in Germany in relation to the product of the claim, where the product is sufficiently tied to the use specified in the claim such that the requirement of *sinnfällige Herrichtung* is satisfied.

231. The first question is whether the manufacture of a product can, in principle, constitute an act of infringement. None of the cases to which I have been referred expressly say so and in the early cases the BGH emphasised that manufacture of the product was not an act of infringement. But in each instance the BGH had in mind relevant circumstances which always included the fact that the product in question was old.

232. It seems to be clear that an act of infringement of an EPC 2000 claim will be an act conducted upstream of the use specified in the claim. Professor McGuire said that in the context of the present facts this could only be the act of formulating the API into the medicament to be administered to the patient. Professor Haedicke said that in principle the manufacture of an API could be an act of infringement.

233. Since the act of infringement is upstream of the use, I see no reason in principle why only some s.9(1) acts should qualify. The BGH has repeatedly ruled that a pharmaceutical use claim has the same effect as a purpose-limited product claim and is thereby governed by s.9(1). The BGH has not qualified this by adding that the effect of s.9(1) is limited in some special way in respect of pharmaceutical use claims.

234. The OLG in *Östrogenblocker*, *Dexmedetomidin* and *Fulvestrant* implied that the act of infringement of an EPC 2000 claim could be any s.9(1) Pat G act, including the manufacture of a product as opposed to its formulation into a medicament, although the point did not arise on the facts. Dr Kühnen expressly discussed the possibility in his Handbook. He may have had misgivings, but he appears to accept that in law the act of manufacture of a product could in appropriate circumstances be an act of infringement, including the manufacture of an API. I conclude that this is the law.

235. The next question is whether an API can in principle satisfy the requirement of *sinnfällige Herrichtung* in its unaltered state, i.e. without having been formulated into a medicament or labelled. The experts differed.

236. It is clear from *Verwendungspatent* and *Glasfasern II* that formulation and labelling is not the only means of achieving *sinnfällige Herrichtung*. Also, although that term and its variants probably carry to a German speaker's ear a notion of something having been done – as does "earmarking" in English – that is not a requirement in law; *sinnfällige Herrichtung* may be inherent in a product, see *Glasfasern II*, *Östrogenblocker*, *Dexmedetomidin*, *Fulvestrant* and the Endless Belt judgment of the LG Mannheim. These judgments cumulatively suggest that an API could in principle satisfy the requirement of *sinnfällige Herrichtung* by reason of its inherent properties alone.

237. I have the impression that in the early years of the doctrine German courts tended to think of pharmaceutical use claims only in terms of a new use for an old product. They spoke of *sinnfällige Herrichtung* as a criterion by reference to which the court could assess whether the old product made and sold by the alleged infringer was sufficiently tied to the new use. On the facts of those early cases, this required the formulation of the product for the new use and/or labelling. More recently the courts have indicated that what matters is the tie, not how it is achieved. None of the judgments have ever stated how close the tie must be. I doubt that it is necessary for the *sinnfällige Herrichtung* to make it inevitable that the product will be used for the purpose specified in the claim. Alternative purposes can always be posited which, though farfetched and even absurd, are nonetheless theoretically possible. I interpret the word "ensure" in the second condition for *sinnfällige Herrichtung* in *Östrogenblocker* accordingly.

238. I therefore take the view that in German law as it has been explained by the courts it is possible for the requirement of *sinnfällige Herrichtung* to be satisfied in respect of an API either specified in an EPC 2000 claim or falling within a class of products specified in the claim and also possible that it is satisfied at the time of the manufacture of the API. Adopting by analogy the ruling of the OLG in *Östrogenblocker* and subsequent cases, this will be the case if (1) the API is suitable for use for the purpose specified in the claim, (2a) the manufacturer of the API has taken advantage of circumstances which ensure that use of the API for that purpose will actually take place, (2b) such prospective use being sufficient and not just occasional use and (2c) the manufacturer knows that the relevant circumstances are in place, or alternatively if he does not, his ignorance is a consequence of bad faith.

239. I have adapted condition (2b) to be a prospective use. Since manufacture is in principle an act of the infringement, at the time of manufacture the use of the product must be prospective and the manufacturer's knowledge must relate to the nature of the prospective use.

240. I would assume that the OLG also intended other relevant circumstances to be taken into account and that where the only authorised use of the API in question was for the purpose specified in the claim, that will count as a powerful factor in favour of a finding that the circumstances are in place to ensure that the API will be used for that purpose to the knowledge of the manufacturer.

241. If according to those principles there is a *sinnfällige Herrichtung* of the API for use for the relevant purpose at the time of its manufacture, the act of manufacture directly infringes the claim.

242. I turn to the facts of the present case. I have discussed Boehringer's admissions above and I have found that the linagliptin API manufactured in the relevant period was suitable for use for the purpose specified in claim 1 of EP 705. The only authorised use of linagliptin was for that purpose, as part of a Product along with excipients, and therefore the circumstances were in place to ensure that the linagliptin would be used for that purpose. Boehringer knew that it would be used exclusively, not occasionally, for that purpose, as it subsequently was.

243. It follows, in my judgment, that at the time Boehringer manufactured the linagliptin, in German law the requirement of *sinnfällige Herrichtung* was satisfied in relation to the purpose specified in claim 1 of EP 705. Subject to the export point discussed below, the manufacture of the linagliptin was an act of infringement of EP 705.

EXPORT AND EPC 2000 CLAIMS

244. Boehringer submitted that an EPC 2000 claim can only be infringed by an act of manufacture if the product manufactured is used in Germany. In other words, there can never be infringement by the manufacture of products for export.

245. Boehringer accepted that this is contrary to what the BGH said in *Hydropyridin*. This is the relevant part of that judgment:

> 246. "… this Court has regarded inventions providing chemical substances formulated for treatment of the human body by therapy and the application of

> such substances for use on the human organism in order to maintain or restore its health as being susceptible of industrial exploitation, which amounts to being susceptible of industrial exploitation. In so doing, this Court has made possible appropriate protection for inventions of this type. It has regarded the displayed formulation [*augenfällige Herrichtung*] of a chemical substance for use in treatment by therapy as being covered by the subject-matter of the use claim, thus ensuring that this 'industrial' part of the claimed use is also covered directly by the exclusive right of the patent proprietor (Section 6 of the Patent Law). The patent proprietor thus enjoys effective protection against a third party in Germany industrially preparing the therapeutic substance for therapeutic use, offering it for sale or bringing it onto the market, or in Germany offering for sale or bringing onto the market a substance formulated abroad for such use. He can also take effective action against export of the substance; this would be Impossible if his sole recourse were against an indirect infringement of his patent."

247. Boehringer made two points. First, the BGH's observation regarding export was obiter. Secondly, Professor McGuire said that at the time of the *Hydropyridin* judgment an earlier version of the PatG was in force and that under the old Act there was no self-standing provision for indirect infringement. A claim for indirect infringement was possible, but only by reliance on the German Civil Code.

248. It is not clear to me how the revision of the Act could have made a difference. In *Hydropyridin* the BGH said that effective action against an exporter was made possible by the Court's recognition of the possibility of direct infringement. Indirect infringement did not afford such protection. In that sense nothing at all changed with the introduction of the new law. To establish a relevant difference Professor McGuire would have had to show that the wording of the current s.9(1) PatG and/or its interpretation by the German courts has narrowed the protection afforded to a patentee against direct infringement when compared with the relevant section of the old Act. Professor McGuire pointed to no relevant change in statutory wording or to any case law in this context.

249. Boehringer relied on Dr Kühnen's discussion of the question of export in his Handbook of Patent Infringement at margin numbers 446 and 448-450:

> "446 By contrast, the protected use does not cover
>
> …
>
> 448 – the obvious preparation for a use which, according to the overall objective circumstances, has been planned to take place abroad.
>
> 449 This is clear if there is no protection by a use patent abroad, but it also applies if a parallel patent exists. Based on the following consideration, the obvious preparation [*sinnfällige Herrichtung*] in Germany for a subsequent patent-protected use abroad is not a domestic property right infringement. The case law regarding the obvious preparation for a specific use affords protection at an early stage which is deemed appropriate for two reasons. Firstly, because the use often merely takes place in the private sphere and therefore entirely outside the patent law;

> and secondly, because even where there is commercial activity, the patent proprietor cannot react but very late – i.e. it can only react to the ultimate use. In order to improve the position of the patent proprietor, the patent proprietor is to be enabled to exercise its monopoly rights even before the patented use occurs, namely against acts which, although they precede the use, are of such a nature that they 'pave the way' for patent-protected use and 'initiate' it, by preparing the object to be used for precisely the patent-protected use in an obvious manner. Taking into account the inherent connection between the preparation on the one hand and the use on the other, the obvious preparation of an object can only be relevant to a property right if a property right-infringing act actually follows, or at least if a property right-infringing act may follow according to the ordinary course of events. Due to the territoriality of property rights, it is not permitted to argue across property rights and accept that the obvious preparation ultimately leads to a use protected by a patent anyway, even if this is a use of a different, i.e. corresponding foreign property right.
>
> 450. This also applies to use claims in the field of pharmaceutical substances, which, according to BGH case law, are uniformly understood as substance claims tied to a specific purpose, independently of their claim wording. While, due to their characterisation mentioned above, they are basically covered by Sec. 9 no. 1 PatG, which also includes a prohibition of manufacture, and while individual types of use have to be considered legally independently, and also independently of one another, the earmarking for a specific purpose according to the patent must also be fulfilled for the act of manufacture, because otherwise, the substance protection which has only been conferred for a specific purpose, would be treated like absolute product protection, which is not what it is. This earmarking for a purpose clearly has a geographic component as well, which consists in the therapeutic use of the active substance in Germany as the territory in which the purpose-related patent enjoys protection. Where no such use is present, there can be no protection for the manufacture, because the fact that the active substance or pharmaceutical preparation is manufactured in Germany may fulfil the element of manufacture, but not the required earmarking for a specific purpose which must accompany the act of manufacture."

250. There is a footnote to Dr Kühnen's commentary at margin no. 448 suggesting that his view there stated is not universally held:

> "Different opinion: Benkard, Sec. 9 Rn50; Busse, Sec. 9 no 140."

251. The footnote refers to two other commentaries: Benkard, *Patentgesetz*, 11th ed. 2015, s.9 and Busse/Keukenschriver, *Patentgesetz* 2016, s.9. Both are clearly seen to provide highly authoritative summaries of the law since they were repeatedly cited by Professors McGuire and Haedicke in their respective reports. Benkard states at margin no. 50:

> "In the case of a patent for application or use (*Anwendungs- bzw. Verwendungspatent*), which is characterised by the application or use of a

> product for a particular purpose, past court rulings have concluded that a direct act of utilisation (*Benutzungshandlung*), which is exclusive to the patent holder and forbidden for third parties, is not only deemed to have been committed if direct application has occurred, see also section 14 margin nos. 49f. In the case of a patent for application/use, utilisation is deemed to occur directly when the thing to be used is made available for a particular purpose, and thus third parties are already forbidden from committing such acts whereby the product is aligned to, i.e. evidently (or rather: obviously) prepared [*sinnfällig hergerichtet*] for the protected application or use in objective terms, [references follow, including *Benzolsulfonylharnstoff*, *Hydropyridin*, and *Trigonellin*].
>
> …
>
> The patent holder is thus afforded effective protection against third parties offering the substance/thing being used, bringing it into circulation, utilising it or introducing or possessing it for the specified purposes in Germany, irrespective of where the obvious preparation took place, BGHZ 88, 209, 217 – *Hydropyridin*. They can, ultimately, also effectively contest the export of such prepared things to third countries;"

252. Busse's commentary at margin no. 141 seems more relevant than that at margin no. 140, which is about process claims. Dr Kühnen may have meant 141:

> "4. In the case of a use patent, purposeful preparation in Germany for exportfalls within the scope, as does the offering or the placing on the German market of a product that has been purposefully prepared abroad [footnote cites *Hydropyridin*]. In the absence of purposeful preparation, there is no patent infringement."

253. Both Benkard and Busse thus take the view that the BGH's statement in *Hydropyridin* represents the current law. In cross-examination Dr McGuire said that the commentaries have been updated since their publication in 2015 and 2016 respectively and may now refer to the more recent judgments given by the OLG in Düsseldorf. If they do, I doubt that there will have been any relevant change to the commentaries. Neither party provided copies of the new editions and I assume that if either of them expressed a significantly different opinion about export I would have been told about it.

254. Leaving aside the reference to private acts done outside patent law, Dr Kühnen's analysis at 449 includes the proposition that the *sinnfällige Herrichtung* can only be relevant to a use claim if it is followed or may be followed in the ordinary course of events, by an infringing act.

255. I have some difficulty with this, although I am very conscious that the difficulty may be caused by an imperfect translation or my lack of understanding, not by what Dr Kühnen meant. According to this analysis the infringing act is apparently the act of use. I find that hard to reconcile with the judgments of the BGH. If the use were the act of infringement or part of it then (a) in the case of pharmaceutical use patents this would be in breach of art. 53(c) EPC and s.2a(1).2 PatG and (b) there would have beenno need for the doctrine of *sinnfällige Herrichtung* – there would be a guaranteed tie between the upstream act and the use because there could be no infringement unless

and until the use specified in the claim has occurred. As I understand the line of cases, the idea of *sinnfällige Herrichtung* was developed by the BGH precisely because the act of infringement is upstream of the use and so there must be a means to ensure that it is sufficiently tied to the use.

256. I also have difficulty with the analysis at margin note 450, with the same qualifications regarding translation and my possible lack of understanding. It says that the use must take place in the territory protected by the patent – here Germany. That would make sense if the use were the act of infringement, but as I have said, I do not understand the case law in that way. I agree that a use claim is territorial just as much as a product or process claim. But I would be surprised if the territorial rule under German law in relation to both the latter types of claim is different to that which applies in English law, namely that the act of infringement must take place in the territory of the patent. It seems to me that if the act of infringement of a use claim is, for instance, making the product, it is that act of making which must take place in Germany. If it does, the rule on territoriality is satisfied.

257. Dr Kühnen may have had a different point in mind: as a matter of law *sinnfällige Herrichtung* requires there to be a sufficient tie between the upstream act of infringement and use *in Germany* of the type specified in the claim. But although both experts referred to this passage in Dr Kühnen's Handbook, which they will have read in its original and their native German, neither said that this is what Dr Kühnen meant. Nor did either of them advance this as a correct characterisation of *sinnfällige Herrichtung*. I would respectfully add that if this is what Dr Kühnen meant, it is an assertion without any stated support independent of his view that the infringing act is the use and so the use must take place in Germany. It would also imply that *sinnfällige Herrichtung* as contemplated by the BGH in *Hydropyridin* was significantly different from the concept in later judgments of the BGH, yet there is no hint in those later judgments of such a major shift.

258. Turning back to the cases, there is support for the *Hydropyridin* approach in *Antivirusmittel* (cited above). The Patent Office had granted the patent in suit in the form of a product claim at the request of the patentee. This was before the change in the law beginning with the BGH's *Benzolsulfonylharnstoff* judgment. In the *Antivirusmittel* judgment the BGH records the Patent Office as having been of the view at that time that product claims were preferred because use claims prevented the Office from

> "… granting the inventors reasonable protection, namely also for the import and export of such substances."

259. An inference can be drawn that the BGH believed that since *Benzolsulfonylharnstoff* and subsequent judgments a use claim could afford the patentee the same reasonable protection, including for export.

260. The LG Mannheim endorsed the *Hydropyridin* approach in its recent Endless Belt decision (cited above) where direct infringement under s.9 PatG was being discussed (at [55]):

> "In the case of a patent for use, however, unlike Sec. 10 Patent Law, export (BGHZ 88, 209, 217 – *hydropyridin*) and possession (Benkard/Scharen, Pat G, 11th ed. § 9 marginal 50) are also subject to the Patent holder reserved."

261. Boehringer also relied on *Verwendungspatent* but I do not see that the judgment of the OLG Karlsruhe is on point in this regard.

262. Professor Haedicke remained consistent in his view that there need not be use in Germany for infringement of an EPC 2000 claim. Professor McGuire took the opposite view, relying on the observations of Dr Kühnen in his Handbook, although she said in cross-examination that the Handbook does not hang together well as written.

263. In the end I must be guided by the case law as it is. I appreciate that the BGH could, for policy reasons of which I am not aware and which were not explored before me, decide that an EPC 2000 claim is infringed only if the prospective use for the relevant purpose will take place in Germany. But it has not done so. In *Hydropyridin* the BGH ruled, albeit obiter, that this is not necessary. The ruling was endorsed by the BGH in *Antivirusmittel* and more recently by the LG Mannheim. I must follow that line of cases. I find that an EPC 2000 claim may be infringed where there is a s.9(1) infringingact in Germany, such as the manufacture of a product, including where the product is destined for export.

264. It follows that Boehringer's manufacture of linagliptin in the period relevant to the present case would have infringed EP 705 but for the licence granted by the Amended Agreement. The acts of manufacture generated royalties under the Amended Agreement to be paid by reference to sales of Product containing the linagliptin irrespective of where the sales took place.

INTEREST

265. The disputes on interest turned on whether English or German law governs the rate of pre-judgment interest on Royalty Pharma's claim for a contractual debt and, separately, on Boehringer's counterclaim for overpayment.

Royalty Pharma's claim

266. Rule 20 in Dicey (15th ed., 2012) reads (footnotes omitted):

> "RULE 20 – (1) The liability to pay contractual interest and the rate of such interest payable in respect of a debt, e.g. in respect of a loan, are, in general, determined by the law applicable to the contract under which the debt is incurred, e.g. by the law applicable to the contract under which the loan is made.
>
> (2) The liability to pay interest as damages for non-payment of a debt is determined by the law applicable to the contract or non-contractual obligation under which the debt is incurred. *Semble*, the rate of such interest is, in general, determined by English law; but (*semble*) the rate of such interest is determined by the law applicable to the non-contractual obligation where the Rome II Regulation (Regulation (EC) 864/2007) applies.
>
> (3) The rate of interest awarded by virtue of clause (2) of the Rule is a matter for the discretion of the court pursuant to s.35A of the Senior Courts Act 1981,

> and in the exercise of that discretion the court will, prima facie, award the rate applicable to the currency in which the debt is expressed."

267. The comment in Dicey in relation to Rule 20 begins by underlining the distinction between the circumstances of Rule 20(1) on the one hand and Rule 20(2) and (3) on the other (footnotes omitted):

> "Interest may be payable either by virtue of an express or implied term of a contract or by way of damages. Clause (1) of the Rule is concerned with the former situation, clauses (2) and (3) with the latter."

268. Rule 20(2) indicates that it is not clear which law governs the rate of interest but there is a probable distinction: generally English law governs, subject to the possible exception that where Regulation (EC) 864/2007 on the law applicable to non-contractual obligations ("Rome II") applies, the *lex causae* governs.

269. Royalty Pharma's claim arises out of a contract, so the starting point is Regulation (EC) No. 593/2008 on the law applicable to contractual obligations ("Rome I"). Art.66 of the Agreement on the Withdrawal of the UK from the European Union provides that both Rome I and Rome II continue to apply in respect of contracts or non-contractual obligations concluded before the end of the Brexit transition period.

270. Art.1(3) of Rome I states that the Regulation does not apply to matters of procedure:

> "*3. This Regulation shall not apply to evidence and procedure, without prejudice to Article 18.*"

271. Art.18 is concerned with the burden of proof and raises no issue here.

272. Art.12(1)(c) of Rome I provides:

> "*1. The law applicable to a contract by virtue of this Regulation shall govern in particular:*
>
> *…*
>
> *(c) within the limits of the powers conferred on the court by its procedural law, the consequences of a total or partial breach of obligations, including the assessment of damages in so far as it is governed by rules of law;*"

273. The comment in Dicey on Rule 20(2) includes this at 7-098 and 7-103 (footnotes omitted):

> "**Clause (2) of the Rule.** Clause (2) of the Rule requires that a distinction be drawn between the question of the law governing the right to interest payable by way of damages, and the law which governs the rate at which any interest so payable is to be paid. It is submitted that the existence of a right to claim interest is properly classified as a substantive matter and thus should be referred to the *lex causae* of the relevant claim. This accords with modern developments in which the courts have considered the right to damages as an issue of substance to be determined by the *lex causae* and with the approach in the Rome I and II

> Regulations. By contrast, it is also tentatively submitted that English law as the *lex fori* determines the rate at which interest is payable since this has been regarded as a procedural matter at common law and after the entry into force of the Rome Convention; although the issue is beset by uncertainty under the Rome I Regulation and, as will be seen below, the better view is that rates of interest are to be classified as substantive under the Rome II Regulation.
>
> …
>
> After the entry into force of the Rome Convention, it was held in the Court of Appeal and at first instance that the *lex fori* determines the rate of interest claimed as damages for breach of contract. This is despite Art.10(1)(c) of the [Rome] Convention stipulating that the law governing the contract shall apply 'within the limits of the powers conferred on the court by its procedural law [to] … the assessment of damages in so far as it is governed by rules of law'. In principle, therefore, the same approach should apply under the Rome I Regulation, which contains a similar provision on the scope of the law governing the contract in Art.12(1)(c). The matter cannot be free from doubt, however, the essential question being how widely the exclusion of matters of evidence and procedure in the Rome I Regulation should be construed. It is suggested below that the *lex causae* should determine the rate of interest under the Rome II Regulation, even though this creates an unfortunate dichotomy between the Rome I and II Regulation. The European Court may yet rule that the issue of rates of interest falls within the scope of the Rome I Regulation and is subject to the applicable law of the contract. But on the state of the English authorities at present, it would appear that rates of interest were a procedural matter under the Rome Convention; and there would appear to be insufficient justification to classify them any differently under the Rome I Regulation."

274. The judgments of the Court of Appeal and at first instance referred to at the start of the second passage of Dicey just quoted are *Lesotho Highlands Development Authority v Impregilo SpA* [2003] EWCA Civ 1159 and *Rogers v Markel Corporation* [2004] EWHC 1375 (QB).

275. *Lesotho Highlands* was an appeal against, among other things, an order for interest made in an arbitration under the Arbitration Act 1996. Brooke LJ (with whom Latham and Holman LJJ agreed) noted (at [45]) that under art.10(1)(c) of the Rome Convention entitlement to interest falls to be determined by the applicable law of the contract. Art.10(1)(c) is the predecessor to, and in material respect is in the same terms as, art.12(1)(c) of Rome I. Brooke LJ went on to say:

> "[50] So far as the rate of interest is concerned, in the absence of express agreement this is a matter for the arbitrators to decide as a matter of the *lex fori* (see Dicey & Morris (13th ed.) par. 33-387) …"

276. In the passage of the 13th edition of Dicey referred to, the authors discussed a judgment of Bristow J, who concluded that the rate of interest is a procedural matter governed by the *lex fori* and another judgment, by Kerr J, who reached the conclusion that it was governed by the applicable law of the contract. The authors noted that the Law Commission had examined the question and had preferred the view of Bristow J.

277. In *Rogers*, Treacy J likewise discussed the judgments of Kerr J and Bristow J:

> "[80] This latter decision [of Bristow J] has been preferred to the views expressed by Kerr J by the Editors of recent editions of *Dicey & Morris on the Conflict of Laws*, by the Law Commission (Law Com. No. 124, Foreign Money Liabilities (1983)), and by the Court of Appeal in*Lesotho Highlands Development Authority v Impreglio Spa and Others* [2003] EWCA Civ 1159. The essential reasoning behind these views and the Court of Appeal's decision is that rate of interest is a procedural matter and thus to be governed by the *lex fori*.
>
> [81] It seems to me that the weight of authoritative learning and judicial decision supports the decision of Bristow J rather than the obiter views of Kerr J. I therefore follow their views both on the basis of the weight of authority and on the ground that rate of interest (as opposed to right to interest) is a matter of procedure and thus appropriate to be dealt withunder the *lex fori*."

278. *Lesotho Highlands*, *Rogers* and Dicey all point towards English law, the *lex fori*, as the law governing the rate of interest once the right to interest has been established under the law of the contract.

279. Royalty Pharma submitted that this is not an absolute rule, rather one which will depend on the facts. I agree. It implicit in what Brooke LJ said in *Lesotho Highlands*, see paragraph 50 quoted above. If, for example, there is a term in the contract stating that in certain circumstances a party shall be entitled to interest and if so, it will be awarded at the rate prevailing under the law of the contract, it would seem that the rate to be applied would be a substantive right under the contract, not a procedural matter, and would not be excluded from the application of Rome I by art.1(3).

280. Royalty Pharma argued that the exception to the general rule is broader than that example. The argument progressed by reference to s. 288(1) and (2) BGB. They provide:

> "*Section 288*
>
> *(1) Any money debt must bear interest during the time of default. The default rate of interest per year is five percentage points above the basic rate of interest.*
>
> *(2) In the case of legal transactions to which a consumer is not a party the rate of interest for claims for payment is nine percentage points above the basic rate of interest*."

281. Royalty Pharma submitted that the right conferred by s.288(1) and (2) was substantive, not procedural. It was part of Royalty Pharma's cause of action, was pleaded as such, and was therefore governed by the *lex causae*, German law. In fact, the submission continued, the claim to damages fell neither under Rule 20(1) in *Dicey*, because it was not a contractual claim to interest, nor under Rule 20(2), because it was not a claim to damages for non-payment of a debt. It was a claim apparently outside the contemplation of Dicey.

282. In support of this argument Royalty Pharma relied by analogy on a judgment concerning Rome II: *Troke v Amgen Seguros Generales Compania de Seguros y Reaseguros SAU* [2020] EWHC 2976 (QB). It was too recent to have been the subject of comment in *Dicey*, including the most recent supplement (1 July 2018)). *Troke* was an appeal from a recorder at first instance who had held that the rate of interest on a claim in tort against the defendant insurer was governed by English law. The recorder found that the question was a procedural matter excluded from Rome II by art.1(3) of that Regulation (which, materially, is in identical terms to art.1(3) of Rome I). Therefore the *lex fori*, English law, applied.

283. Royalty Pharma drew attention to paragraph 44 of the judgment of Griffiths J as support for the strength of the analogy between cases decided under Rome I and Rome II, particularly where they turned on those Regulations' art.1(3):

> "[44] Rome I and Rome II form part of a policy scheme for the harmonisation of private international law across the member states, which should be expected to be broadly consistent in its interpretation and application across the two Regulations. The fact that article 1(3) of Rome II is identical to article 1(3) of Rome I, coupled with the observation of Flaux LJ in *Actavis UK Ltd* [[2015] EWCA Civ555] at para 133 that 'Whether a rule is to be classified as one of substance or one of procedure or evidence under Rome II is a matter of EU law', strongly suggests that the interpretation of article 1(3) in Rome I and Rome II respectively should be the same."

284. The next paragraph underlines the importance of the distinction between a procedural right and a substantive right in the context of art.1(3):

> "[45] Whether the award of interest is to be characterised as a procedural rather than a substantive right may depend on the basis upon which interest is claimed. If there is a contractual right to interest, as there sometimes is, that would be governed by Rome I and not Rome II, and it would be a claim of substantive right (under the contract) and would not, therefore, be excluded by article 1(3) of Rome I."

285. In response Boehringer submitted that the distinction drawn in *Troke* between a procedural right and a substantive right was solely in the context of the right to be awarded interest at all. It had nothing to do with the law which governs the rate of interest.

286. I am not sure that is right. As I read the judgment, the recorder had found at first instance that interest was available under Spanish law, the *lex causae*. Independently of that he had elected to award interest under English law as the *lex fori*. He followed the judgment of the Court of Appeal in *Maher v Groupama Grand Est* [2009] EWCA Civ 1191 and took the view that he was entitled to award interest under English law whether or not the foreign *lex causae* provided for a substantive right to interest. This independent application of English law was a matter of procedure and was permitted because it was not governed by Rome II pursuant to that Regulation's art.1(3).

287. On appeal in *Troke* the judge found that the recorder had been entitled to apply English law in that way and had therefore been entitled as a matter of discretion to apply the

rate of interest prevailing in England. By way of an aside, Griffiths J said the recorder might equally have exercised his discretion to apply Spanish rates, not under the *lex causae* but pursuant to his discretion under the *lex fori*, save that he had not been asked to do so (see [52]-[58]).

288. However, this finding appears to have been subject to a further argument which Griffiths J went on to consider. It is this part of the judgment which has most bearing on the submission advanced by Royalty Pharma in the present case. The further argument was that the recorder had not correctly characterised the Spanish law on rates of interest, that properly understood this Spanish law gave rise to a substantive right as part of the remedy claimed because of the tort, that it was therefore not excluded from the governance of Rome II by art.1(3) of that Regulation and that in consequence its application as part of the *lex causae* was obligatory pursuant to art.15(c) of Rome II. Art.15(c) of Rome II provides:

> "*The law applicable to non-contractual obligations under this Regulation shall govern in particular:*
>
> *…*
>
> *(c) the existence, the nature and the assessment of damage or the remedy claimed.*"

289. By inference, the claimant's argument in *Troke* was that the obligatory assessment of interest according to Spanish law either precluded the exercise of the court's discretion to award and assess interest under English law or, more likely and consistently with *Maher*, it made the exercise of that discretion redundant.

290. Griffiths J reviewed the evidence (at [60]-[65]) and came to the view that the recorder had been correct on the materials before him to describe the Spanish law on rates of interest as being a procedural, as opposed to a substantive, right. This turned on whether the Spanish law on rates of interest conferred a mandatory entitlement or a discretionary one. On the evidence it was discretionary. The judge continued:

> "[71] It follows that I agree with the Judge that the award of interest in this case was a procedural matter excluded from Rome II by article 1(3); thatthere was no substantive right to interest at Spanish rates to be awardedto the Claimants under the *lex causae*; that interest could be awarded under section 69 of the County Courts Act 1984 as a procedural matter in accordance with the law of England and Wales as the *lex fori*; and thathe was entitled to award interest at English and not Spanish rates accordingly."

291. A fair inference could be drawn from Griffiths J's judgment that had the rate of interest under Spanish law been mandatory, he would have found that it was therefore part of the *lex causae* which had to be applied and that in consequence the discretionary English laws on both the availability of interest and the rate to be applied were redundant. Though not quite spelt out, I understand Royalty Pharma to have drawn an analogy between this interference in *Troke* and the present case.

292. Royalty Pharma's proposition rests on there being a secure analogy between the position under Rome I and that under Rome II in relation to the assessment of the rate of interest. Though the law remains uncertain pending a ruling from the Court of Justice of the European Union, it cannot be said that the analogy is secure.

293. *Troke* was concerned with Rome II, not Rome I. I entirely see the force of Griffiths J's observation that one would expect the division between matters of substance and matters of procedure to apply in the same way in art.1(3) of both Rome I and Rome II. Recital [7] of Rome I says that the substantive scope and the provisions of Rome I should be consistent with Rome II. However, Rule 20(2) of Dicey presents the possibility that the two arts.1(3) are not identical in their effect. The authors' explanation for their tentative view is at 7-112 and 7-113 (footnotes omitted):

> "Article 1(3) of the Rome II Regulation states that it shall not apply to evidence and procedure. Article 1(3) of the Rome I Regulation also excludes evidence and procedure. It should follow that the classification of matters as procedural should be the same in respect of both Regulations. Even so, it is notable that the wording of Art.15 of the Rome II Regulation on the scope of the *lex causae* is in somewhat broader terms than Art.12(1)(c) of the Rome I Regulation. Article 15(c) applies to 'the existence, the nature and the assessment of damage or the remedy claimed.' The intention for issues relating to the assessment of damages to be determined by the *lex causae* is clear. It might be argued that the rate of interest upon damages goes to, or is intrinsically linked with, the assessment of the overall amount which the claimant can recover in respect of a damages claim. It may be that the exclusion of evidence and procedure should be construed narrowly, at least insofar as it relates to damages.
>
> It would be unsatisfactory for the meaning and scope of the exclusions of evidence and procedure in the Rome I and II Regulations to differ. At least on the present state of the English authorities, however, rates of interest have been regarded as procedural even after the advent of the Rome Convention; and there is no compelling reason to lead to a different conclusion in respect of substantially identical wording on the scope of the governing law in the Rome I Regulation. The ambit of the exclusion of evidence and procedure in both the Rome I and Rome II Regulations may well be subject to elaboration by the European Court in due course and it is to be hoped that rates of interest will be classified in the same manner for the purposes of both Regulations. Until then, it is tentatively suggested that the rate of interest on damages in respect of tortious obligations is governed by the *lex causae*."

294. This reasoning received support in *AS Ladvijas Krajbanka v Antonov* [2016] EWHC 1679 (Comm). There had been a finding that the defendant had acted in breach of duties owed to the claimant bank under Latvian law and that the bank was entitled to damages. Leggatt J considered whether the rate of interest on damages was governed by Latvian or English law. He said:

> "[10] Article 1(3) of Rome II states that the regulation 'shall not apply to evidence and procedure.' A distinction is therefore made between matters of procedure and matters of substance. It does not follow, however, that this distinction is to be drawn in precisely the same way as it is drawn at English common law and under the 1995 Act. In particular, the authors of *Dicey &*

> *Morris,"The Conflict of Laws"* (15th Edn, 2015) at para 7-112, point out that it might be argued that the rate of interest recoverable on damages goes to, or is intrinsically linked with, the assessment of the overall amount which the claimant can recover in respect of a damages claim and thus falls within the scope of Article 15 of Rome II. It is their tentative suggestion that the rate of interest on damages is governed by the law applicable to the non-contractual obligation. I find this suggestion and the argument on which it is based persuasive. Indeed, it seems to me that the broad wording of Article 15 requires the court to exercise any power conferred by its procedural law to award interest as compensation to a claimant for being kept out of money as a result of the defendant's wrong only when and in the way that a remedy would be granted under the applicable foreign law to provide such compensation."

295. I also respectfully find the reasoning set out in Dicey persuasive. In any event, I must focus on the position under Rome I in relation to Royalty Pharma's claim. *Lesotho Highlands* and *Rogers* are clear authority for the assessment of interest on damages in a claim for breach of contract being governed by the *lex fori*, here English law. I was not directed to a contractual provision which would override that presumption.

296. By way of a fallback position, Royalty Pharma argued that if English law applies, the court should exercise its discretion to apply the rate that would be applied under German law. Royalty Pharma relied on *Maher* (cited above). *Maher* was an appeal from a judgment concerning a claim for damages by claimants who had suffered personal injuries in a road traffic collision in France against a French insurer. Moore- Bick LJ (with whom Etherton and Mummery LJJ agreed) considered the effect of s.35A of the Senior Courts Act 1981:

> "[35] It is accepted that although the court has a discretion in the matter of awarding interest, the discretion must be exercised judicially and in accordance with established principles. The ordinary rule is that a successful party is awarded interest at such rates and for such periods as the court considers will fairly compensate him for being kept out of his money. However, the discretionary nature of the power is underlined by the fact that in some circumstances the court will depart from theordinary rule. In *Jefford v Gee* [1970] 2 QB 130, 151, Lord Denning MRgave as an example the case where one party or the other has been guiltyof gross delay. Another is to be found in Part 36 of the Civil Procedure Rules. CPR r 36.14(3)(a) provides that the court may award a claimant who has obtained a judgment at least as advantageous to him as an offerhe has previously made to settle the claim interest on the whole or part of any sum of money awarded as damages at a rate not exceeding 10% above base rate. Such an award is not intended to be compensatory, but is intended to encourage defendants to accept sensible offers of settlement. These are but two examples of how the discretion may be exercised having regard to the particular circumstances of the case and the conduct of the parties to the litigation. They proceed on the footing that section 35A does not create a substantive right to interest but a remedy at the court's discretion, albeit one that must be exercisedjudicially."

297. Moore-Bick LJ went on to reach this conclusion (original italics):

> "[40] In these circumstances I agree with the judge that the existence of a right to recover interest as a head of damage is a matter of French law, being the law applicable to the tort, but whether such a substantive right exists or not, the court has available to it the remedy created by section 35A of the 1981 Act. Having said that, the factors to be taken into account in the exercise of the court's discretion may well include any relevant provisions of French law relating to the recovery of interest. To that extent I agree with the judge that both English and French law are relevant to the award of interest."

298. As indicated by Moore-Bick J, the ordinary rule is that a successful party is awarded interest at such rate as will fairly compensate him for being kept out of his money. The only reason given by Royalty Pharma for departing from the ordinary rule in the present case was that it would not be fair to award interest at different rates on cross-claims under the same agreement.

299. I do not see why it would be unfair to approach the claim and counterclaim separately. They are distinct and do not depend on one another. If different laws apply, different interest rates may apply. I will award interest at 2% over base rate in Royalty Pharma's claim. The debt on which interest is to be paid is in euros, so the base rate will be that charged by the European Central Bank (see Dicey, Rule 20(3)).

Boehringer's counterclaim

300. Boehringer's counterclaim is a non-contractual claim governed by Rome II, subject to that Regulation's art.1(3).

301. By the time of closing the sole point of difference between the parties turned on art.1(3) of Rome II. Royalty Pharma argued that if I were to find that Rome I does not govern the assessment of the rate of interest on its claim, pursuant to art.1(3) of that Regulation, it must follow that the assessment of the interest rate on Boehringer's counterclaim cannot be subject to Rome II pursuant to its art.1(3). The converse was also true. In short, either the matter was governed by the English law as the *lex fori* in both instances or it was governed by German law in both as the law applicable to the contract in the case of Royalty Pharma's claim and as the *lex causae* in the case of Boehringer's counterclaim. Royalty Pharma relied on *Troke* in support of its assertion the effect of art.1(3) in Rome I must be the same as the effect of art.1(3) in Rome II.

302. As I have discussed, despite the similarity in wording between the respective arts.1(3) of Rome I and Rome II, they must each be applied consistently with the remainder of the Regulation of which each forms part. The observation by Griffiths J in *Troke* of a strong suggestion that the interpretation of art.1(3) in Rome I and Rome II respectively should be the same formed no part of the *ratio* of his judgment. Probably the better view – and the view I will adopt – is that the rate of interest upon damages goes to, or is intrinsically linked with, the assessment of the overall amount which the claimant can recover in respect of a damages claim under art.15(c) of Rome II.

303. Therefore the *lex causae* must be applied to the rate of interest in Boehringer's counterclaim, making redundant any discretion this court may have under English law in relation to interest. The *lex causae* is German law.

304. The parties were agreed that if German law applies, pre-judgment interest on Boehringer's counterclaim is incurred from the date on which the obligee is in default. In this case it is 9 December 2015, being the date on which Boehringer gave notice to Royalty Pharma that royalties had been overpaid and were to be reimbursed to Boehringer. The rate of interest under German law during that period is 5% above the ECB base rate. Boehringer is also entitled to claim the interest that Royalty Pharma earned on overpayments in the period before 9 December 2015.

OVERALL CONCLUSION

305. Royalty Pharma's claim to unpaid royalties under the Amended Agreement succeeds, as does Boehringer's counterclaim for overpayment of royalties under the Original Agreement. Interest is due on each according to the principles I have set out above. I leave the maths to further submissions.