Neutral Citation Number: [2014] EWHC 1511 (Pat)

Case Nos: HC12E02962, HP13A01487, HP13B04212, HP13E04604, HP13B05505, HP14D00753, HP14A01611, HP14F01792

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Rolls Building
Fetter Lane, London, EC4A 1NL

Date: 15 May 2014

Before :

THE HON MR JUSTICE ARNOLD

- -

Between :

(1) ACTAVIS UK LIMITED	**Claimants**
(2) ACTAVIS GROUP EHF (FORMERLY ACTAVIS GROUP HF)	
(3) ACTAVIS GROUP PTC EHF	
(4) MEDIS EHF	
(5) ACTAVIS DEUTSCHLAND GMBH & CO. KG	
(6) MEDIS PHARMA GMBH	
(7) MEDIS PHARMA FRANCE SAS	
(8) ACTAVIS FRANCE SAS	
(9) ACTAVIS SPAIN S.A.	
(10) ACTAVIS ITALY SPA A SOCIO UNICO	
- and -	
ELI LILLY & COMPANY	**Defendant**

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Richard Meade QC, **Thomas Raphael** and **Isabel Jamal** (instructed by **Bird & Bird LLP**) for the **Claimants**
Simon Thorley QC, **Thomas Mitcheson QC** and **Stuart Baran** (instructed by **Hogan Lovells International LLP**) for the **Defendant**

Hearing dates: 9-10, 15-16 April 2014

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Approved Redacted 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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THE HON MR JUSTICE ARNOLD

MR JUSTICE ARNOLD :

Contents

Introduction

1. Pemetrexed disodium is a cancer treatment which has been marketed by the Defendant ("Lilly") or its subsidiaries under the brand name Alimta since 2004. Pemetrexed and its pharmaceutically acceptable salts were protected by European Patent No. 0 432 677 ("677"), which expired on 10 December 2010. The protection conferred by that patent has been extended by Supplementary Protection Certificates ("the SPCs") which will expire on 10 December 2015. Lilly also owns European Patent No. 1 313 508 ("the Patent"), which will not expire until June 2021, for the use of pemetrexed disodium in combination with vitamin B12 or a pharmaceutical derivative thereof and optionally a folic protein binding agent. The Claimants (whom I will refer to as "Actavis" save when it is necessary to distinguish between them) intend to launch a generic pemetrexed product the active ingredient in which will be either pemetrexed diacid, pemetrexed dipotassium or pemetrexed ditromethamine. Actavis intend to obtain regulatory approval for their product by reference to Alimta. Actavis contend that dealings in their product will not infringe the Patent. Lilly disputes this. Actavis would like a resolution of this issue in good time for them to enter the market on expiry of the SPCs. Furthermore, Actavis wanted the issue to be determined with respect to the French, German, Italian, Spanish and United Kingdom designations of the Patent, which cover the major pharmaceutical markets in Europe, in a single trial. Accordingly, Actavis commenced these proceedings seeking declarations of non-infringement ("DNIs") in respect of each of those designations of the Patent. Lilly has counterclaimed for threatened infringement only of the UK designation.

2. At an early stage of these proceedings, I heard a jurisdictional challenge by Lilly in relation to the French, German, Italian and Spanish designations which I rejected for the reasons given in my judgment dated 27 November 2012, [2012] EWHC 3316 (Pat) (affirmed [2013] EWCA Civ 517, [2013] RPC 37). Since then, there have been a number of developments, of which the following are the most significant for present purposes. A detailed procedural timetable is set out in paragraphs 237-292 below.

3. First, as indicated in paragraph 1 above, Actavis now seek DNIs in relation to pemetrexed diacid and ditromethamine as well as dipotassium. Indeed, the diacid is currently Actavis' lead candidate.

4. Secondly, a number of additional Actavis subsidiaries have been joined as claimants. Recently, however, Actavis Deutschland GmbH & Co KG, Actavis France SAS and Actavis Spain SA have ceased to be claimants consequential upon the sale of those companies to the Aurobindo Group.

5. Thirdly, as explained in more detail below, Lilly brought proceedings against Actavis for threatened infringement of the German designation of the Patent before the Düsseldorf Landgericht (Regional Court). Despite the fact that this court was first seized, Actavis' jurisdictional challenge was rejected and on 3 April 2014 the Düsseldorf Regional Court gave judgment on the merits of Lilly's claim. In those circumstances, Actavis decided to discontinue the present proceedings so far as they relate to the German designation.

6. Fourthly, whereas it was common ground at the time of the hearing before me in November 2012, as I recorded in my judgment at [30], that the law applicable to the

question of whether this Court has power to grant DNIs with regard to the non-UK designations of the Patent was English law as the *lex fori*, since this was a question of procedure or remedy, Lilly subsequently changed its position and now contends that the applicable law is the law of the country in question. Furthermore, Lilly contends that Actavis have not satisfied certain requirements, which Lilly characterises as requirements of *locus standi* and Actavis characterise as procedural requirements, under French, Italian and Spanish law.

7. Fifthly, in an attempt to circumvent Lilly's objections under the foreign laws, Actavis have brought a series of further claims. In essence, Actavis say that, even if Lilly's procedural objections were well founded as at the date of the first and second actions, the relevant procedural requirements had been satisfied by the date of one or more of the later actions. Lilly contend that the bringing of the later actions amounts to an abuse of the process of the court. In a judgment given on 27 November 2013 ([2013] EWHC 3749 (Pat)) I dismissed an application by Lilly to strike out the fourth and fifth actions as an abuse of process, primarily on the ground that, for the reasons given in that judgment, the application was premature.

8. Sixthly, at a pre-trial review on 20 March 2014, I ruled, for the reasons given in my first judgment of that date ([2014] EWHC 838 (Pat)), that there should be no cross-examination of the foreign law experts upon their reports. I also ruled, for the reasons given in my second judgment of that date ([2014] EWHC 839 (Pat)), that there should no cross-examination of Dr Maria Rotaru of Sindan Pharma SRL ("Sindan"), who had verified a Product and Process Description ("PPD") served by Actavis in lieu of giving disclosure with regard to relevant properties of pemetrexed diacid, dipotassium and ditromethamine. As a result, and thanks to the industry and efficiency of counsel on both sides, the hearing was completed in less than four days. Indeed, the cross-examination of all five witnesses was completed in only just over one court day.

9. I make no apologies for the length of this judgment. There are many significant issues between the parties, I must consider and apply the laws of four different countries and a great deal of money is at stake. I was provided by the parties with 546 pages of written submissions and 41 files of evidence and other materials, which I have done my best to assimilate. Nevertheless, I shall endeavour to express my findings and reasoning as succinctly as I can.

The witnesses

Fact witness

10. The only factual witness who gave evidence was Dr Stefán Stefánsson, Director of IP for the Actavis Group, who gave evidence about Actavis' preparations to launch a generic pemetrexed product. He was a straightforward witness.

Technical experts

11. *Actavis' experts*. Professor Michael Seckl is currently Professor of Molecular Oncology at Imperial College London, where he is head of the Lung Cancer Research Group and of the Experimental Cancer Medicine Research Centre, and an honorary Consultant Medical Oncologist at Imperial College NHS Healthcare Trust. In

addition, he is director of the Charing Cross Gestational Trophoblastic Disease ("GTD") Centre. He obtained a BSc in Immunology from University College London in 1983, an MBBS in 1986 and a PhD on the development of novel therapies for small cell lung cancer in 1995. He was appointed as a Senior Lecturer and honorary Consultant by Imperial in 1995, Reader in 2000 and Professor in 2002. His principal research interests are in the fields of small cell lung cancer and GTD. He has used pemetrexed since 2007.

12. Dr Peter Spargo is currently an independent consultant whose areas of expertise are in Chemistry, Manufacturing and Controls ("CMC") associated with research and development in the pharmaceutical industry. He obtained a BA in Natural Sciences (Chemistry) from Cambridge University in 1983 and a PhD in Synthetic Organic Chemistry from Cambridge in 1986. From 1986 to 1988 he was a Post-Doctoral Research Fellow at Columbia University. From 1988 to 2003 he was employed by Pfizer successively as Medicinal Chemistry Team Leader, Process Chemistry Team Leader, then Section Head, Manager and Director of Process Research and Development and finally Head of Chemical R & D. In these capacities he was involved in numerous drug discovery and development projects. From 2003 to 2006 he was employed by Scientific Update LLP, becoming its Managing Director towards the end of that period. From 2007 to 2008 he was Vice President and then Senior Vice President of Novexel SA and from 2011 to 2013 he was Senior Vice President of Creabilis.

13. *Lilly's experts*. Until very recently, Professor David Ferry was Professor of Medical Oncology at Wolverhampton University and a Consultant Medical Oncologist at New Cross Hospital, Wolverhampton and Clinical Director of the Greater Midlands Cancer Research Network. He obtained a BSc in Molecular Pharmacology from the University of Leicester in 1984, a PhD in Molecular Pharmacology from the University of Geissen in 1984 and an MBBS from Leicester in 1987. From 1990 to 1995 he was a Pulmonary Oncology Research Registrar at the Cancer Research Campaign. He was appointed as Senior Lecturer in Medical Oncology at the University of Birmingham and Heartlands NHS Trust in 1995. He was appointed as Consultant Medical Oncologist at the Royal Wolverhampton Hospitals NHS Trust in 2001 and was appointed as Professor in 2003. Coincidentally, he was recently recruited by Lilly to be Senior Director, Strategy and Clinical Development for GI tumours. I am satisfied that this did not influence his evidence before me in any way.

14. Professor David Thurston is currently Professor of Drug Discovery in the Department of Pharmacy and the Institute of Pharmaceutical Sciences at King's College London. He obtained a BSc in Pharmacy from University of Portsmouth in 1976, qualified as a pharmacist in 1977 and obtained an MSc in Community Pharmacy Practice in 2010. He obtained a PhD from Portsmouth in 1980. From 1980 to 1983 he was a Post-Doctoral Fellow at the Universities of Kentucky and Texas at Austin. From 1983 to 1986 he was a junior faculty member at Texas. From 1987 to 1999 he was at Portsmouth, from 1999 to 2001 at Nottingham University and from 2001 to 2011 at University College London. He is the author of a standard work of reference *Chemistry and Pharmacology of Anticancer Drugs* (CRC Press, 2006), a second edition of which is in preparation.

15. *Assessment*. All of the technical experts were good witnesses who did their best to assist the court. The only points about their evidence that merit comment are as

follows. First, Prof Ferry struggled to put himself in the position of the skilled team. Secondly, and more importantly, there was some divergence between what Prof Ferry said in his oral evidence and what he had stated in his written reports both for these proceedings and for the German proceedings. In the end, there was little disagreement between him and Prof Seckl. Thirdly, Prof Thurston's area of expertise was of much less relevance to this case than that of Dr Spargo. Indeed, Prof Thurston had not come across either Berge or Stahl & Wermuth (as to which, see below) before. When it came to questions about salt formation and selection, in general Prof Thurston agreed with Dr Spargo's evidence or deferred to Dr Spargo's experience. To the extent that he differed, I prefer Dr Spargo's evidence.

French law experts

16. Actavis' expert on French law is Professor Jean-Christophe Galloux. Since 2000 he has been Professor of Private Law at the University of Panthéon-Assas (Paris II), where he has directed the Masters program in Industrial Property Law since 2008. He is also a professor at the International Center for Industrial Property Studies (CEIPI) in Strasbourg and a visiting professor at several universities, including Montreal, Budapest, Munich, Columbia, Tokyo, Moscow and Saint Petersburg. Since 2010 he has been the President of the Research Institute in Intellectual Property of Paris. Since 2013 he has been a member of the French National Pharmaceutical Academy. He is also a member of the Scientific Advisory Board at the Munich Intellectual Property Law Centre. He is the author of several books, including *Droit de la Propriété Industrielle* (*Industrial Property Law*) (Précis Dalloz, 7th edition, 2012) with Prof Azema. In addition to his academic work, Prof Galloux has been a member of the Paris Bar since 1984 and is an arbitrator and mediator.

17. Lilly's expert on French law is Professor Jacques Azéma. He is currently Professor Emeritus at Jean Moulin University (Lyon III), Honorary Director of the Paul Roubier Centre, an intellectual property training institute set up jointly by the Law Faculty of Lyon III and the Lyon Chamber of Commerce, and Honorary Chairman of the French Group of the International Association for the Protection of Intellectual Property (AIPPI). He is the author of several books, including the book he has co-authored with Prof Galloux. From 1990 to 2006 he was a member of the Paris Bar.

Italian law experts

18. Actavis' expert on Italian law is Professor Mario Franzosi. From 1963 to 1994 he was Professor of Intellectual Property Law and then of Business Law at the University of Parma. He is currently a visiting Professor of European Patent Law at the University of Washington. He has been a member of the Italian Bar since 1959 and a member of the Supreme Court Bar since 1974. In 1963 he founded the law firm which is now Avvocati Franzosi Dal Negro Setti. He is the author of, or a contributor to, a number of books on intellectual property law.

19. Lilly's expert on Italian law is Professor Giovanni Guglielmetti. He has been Professor of Intellectual Property Law at the University of Milano-Bicocca since 2008, having previously been an associate professor and adjunct professor at the same institution since 1998. He has been a member of the Italian Bar since 1990. Since 2006 he has been head of the intellectual property department in the law firm Bonelli

Erede Pappalardo. He is the author of a book on patents and copyrights in computer software.

Spanish law experts

20. Actavis' expert on Spanish law is Professor Manuel Desantes Real. He has been Head of the Department of Philosophy of Law and Private International Law at the University of Alicante since 2011. From 1985 to 1998 he was employed by the Spanish Ministry of Justice to negotiate the Brussels and Lugano Conventions. From 1993 to 1998 he was Professor of Private International Law at the University of Alicante, where he was director of the Masters in Intellectual Property from 1994 to 1998. From 1998 to 2001 he was a national expert in the Legal Service of the European Commission. From 2001 to 2008 he was Vice-President (Directorate General 5 – Legal and International Affairs) of the European Patent Office. He returned to the University of Alicante in 2008. Since 2010 he has also worked for the law firm Elzaburu. He is the author of five books.

21. Lilly adduced evidence from two experts on Spanish law, Professor Rafael Arenas Garcia and Professor Alberto Bercovitz. Since 2005 Prof Arenas has been Professor of Private International Law at the Autonomous University of Barcelona, where he had been a lecturer since 1996. He was a member of the Catalan Codification Commission between 2007 and 2010. He is co-author of a book on international business law. Prof Bercovitz is currently Emeritus Professor of Commercial Law at the Spanish National Distance Education University, where he has been a professor since 1978. Since 1970 he has been a member of, and since 2006 he has been President of the Commercial Law Section of, the Spanish Codification Commission. From 2004 to 2011 he was a member of the Scientific Advisory Board at the Munich Intellectual Property Law Centre. He is the author of several books, including three monographs on aspects of patent law.

22. By an order dated 17 October 2013, I gave each party permission to adduce reports from one expert witness on each of (i) the patent laws of France, Germany, Italy and Spain and (ii) the conditions for DNIs and the burden of proof under the laws of those countries. Save in the case of Lilly and Spain, both parties managed to find a single expert from each country to deal with both topics. While Lilly cannot be criticised for adducing evidence from two experts, it is regrettable that there was a substantial degree of overlap, and hence duplication, between the reports of Prof Arenas and Prof Bercovitz with regard to topic (ii). I have not accorded Lilly's evidence any greater weight because some of the points made were supported by two experts rather than one.

General comments on the evidence of foreign law

23. All of the foreign law experts are distinguished experts in their fields who appear to have discharged their responsibilities as expert witnesses in an exemplary manner. Their reports are generally clear and comprehensive. As directed by the order dated 17 October 2013, they prepared memoranda setting out points of agreement and disagreement. Points that are agreed I shall recite without further comment. Where the experts have disagreed, it is generally because the law in their respective countries is not settled. The experts have supported their opinions by extensive reference to legislation, case law and commentaries. It would considerably lengthen what is

already a lengthy judgment, and further delay its delivery, if I were to set out in detail the experts' views, all the supporting materials they rely upon and my analysis of those views and materials on every issue. I shall therefore concentrate on setting out my conclusions as to the foreign law and identifying the principal materials those conclusions are based on, with only brief explanations of why I have preferred one expert's view to another's. Furthermore, I shall concentrate on the main points which are necessary for my decision, ignoring points which are not necessary for my decision or are peripheral. I shall quote the foreign law sources only in English translation. Where there is an agreed translation, I shall quote that. Where there are rival translations, I shall quote the one which appears to me to be most accurate.

Burden of proof

24. I do not understand there to be any real dispute between the parties as to the incidence of the burden of proof. So far as the UK designation of the Patent is concerned, as noted above, Lilly has counterclaimed for threatened infringement by Actavis, and thus the burden of proving infringement lies on Lilly. Actavis admit that they intend, if it is lawful to do so, to market a generic pemetrexed product which will be pemetrexed diacid, dipotassium or ditromethamine. Furthermore, Actavis admit that the product is to be administered in combination with vitamin B12 and folic acid. Accordingly Lilly only needs to show either that the proposed products fall within the scope of the claims of the Patent or that the supply of the proposed products would amount to indirect infringement of the Patent. If Lilly fails to establish infringement, the burden of proving it is appropriate to make a DNI lies on Actavis. So far as the French, Italian and Spanish designations are concerned, the burden lies on Actavis to establish that the proposed products do not fall within the scope of the claims of the Patent, that the supply of the proposed products would not amount to indirect infringement and that the applicable criteria for making DNIs are satisfied, although the burden lies on Lilly to prove any positive allegations it makes. As will appear, however, I have not found it necessary to resort to the burden of proof in order to resolve any of the issues between the parties.

The Patent

25. The Patent has an earliest claimed priority date of 30 June 2000, was applied for on 15 June 2001, and was granted on 18 April 2007. As explained in my first judgment, there is no challenge to the validity of the Patent in these proceedings. The Patent was opposed before the European Patent Office by Teva Pharmaceutical Industries Ltd ("Teva"). The Opposition Division rejected the opposition in a decision dated 27 December 2010, but Teva has appealed to the Technical Board of Appeal. At the time of the hearing before me, no date had been set for the hearing before the Board of Appeal.

26. The title of the Patent is "Combination containing an antifolate and methylmalonic acid lowering agent". The specification begins at [0001] by stating that "Potentially, life-threatening toxicity remains a major limitation to the optimal administration of antifolates".

27. The specification goes on at [0002] to say that "Antifolates represent one of the most thoroughly studied classes of antineoplastic agents, with aminopterin initially demonstrating clinical activity approximately 50 years ago". Having explained that

"Antifolates inhibit one or several key folate-requiring enzymes of the thymidine and purine biosynthetic pathways, in particular, thymidylate synthase (TS), dihydrofolate reductase (DHFR), and glycinamide ribonucleotide formyltransferase (GARFT), by competing with reduced folates for binding sites of these enzymes", it identifies several antifolate drugs as being in development. In this context, it states:

> "… pemetrexed disodium (Alimta®, Eli Lilly and Company, Indianapolis, IN) has demonstrated thymidylate synthase, dihydrofolate reductase, and glycinamide ribonucleotide formyltransferase inhibition."

28. The specification then explains at [0003] that a limitation to the development of these drugs is that the cytotoxic activity and subsequent effectiveness of antifolates may be associated with substantial toxicity for some patients.

29. In [0004] the specification discusses previous work on the use of folic acid as a treatment for toxicities associated with GARFT and on vitamin B12 as a predictor of cytotoxic events related to the use of GARFT inhibitors. In this context, it states:

> "The role of folic acid in modulating the toxicity and efficacy of the multitargeted antifolate LY 231514 (pemetrexed) was discussed in Worzalla *et al.* (Anticancer Research 18: 3235-3240 (1998) Worzalla JF, Chuan S and Schultz RM)."

30. The specification then explains the broad idea underlying the invention in the following terms:

> "[0005] Surprisingly and unexpectedly, we have now discovered that certain toxic effects such as mortality and nonhematologic events, such as skin rashes and fatigue, caused by antifolates, as a class, can be significantly reduced by the presence of a methylmalonic acid lowering agent as vitamin B12, without adverse adversely affecting therapeutic efficacy. The present invention thus generally relates to a use in the manufacture of a medicament for improving the therapeutic utility of antifolate drugs by administering to the host undergoing treatment with a methylmalonic acid lowering agent as vitamin B12. We have discovered that increased levels of methylmalonic acid is a predictor of toxic events in patients that receive an antifolate drug and that treatment for the increased methylmalonic acid, such as treatment with vitamin B12, reduces mortality and nonhematologic events, such as skin rashes and fatigue events previously associated with the antifolate drugs. Thus, the present invention generally relates to a use in the manufacture of a medicament for reducing the toxicity associated with the administration of an antifolate to a mammal by administering to said mammal an effective amount of said antifolate in combination with a methylmalonic acid lowering agent as vitamin B12.

> [0006] Additionally, we have discovered that the combination of a methylmalonic acid lowering agent as vitamin B12 and folic acid synergistically reduces the toxic events associated with the administration of antifolate drugs. Although, the treatment and prevention of cardiovascular disease with folic acid in combination with vitamin B12 is known, the use of the combination for the treatment of toxicity associated with the administration of antifolate drugs was unknown heretofore."

31. Paragraphs [0007]-[0009] are consistory clauses expressed in terms of "an antifolate". Paragraphs [0010]-[0015] are consistory clauses expressed in terms of "the antifolate pemetrexed disodium".

32. At [0016] the specification states:

> "The current invention concerns the discovery that administration of a methylmalonic acid lowering agent such as vitamin B12 or a pharmaceutical derivative thereof, in combination with an antifolate drug such as pemetrexed disodium reduces the toxicity of the said antifolate drug."

33. Paragraphs [0017]-[0022] and [0028]-[0029] contain a number of definitions, including the following:

> "[0021] As used herein, the term 'in combination with' refers to the administration of the vitamin B12 or pharmaceutical derivative, pemetrexed disodium, and optionally the folic acid; in any order such that sufficient levels of methylmalonic acid lowering agent and optionally folic acid are present to reduce the toxicity of an antifolate in a mammal. The administration of the compounds maybe simultaneous as a single composition or as two separate compositions or can be administered sequentially as separate compositions such that an effective amount of the agent first administered is in the patient's body when the second and/or third agent is administered. …
>
> [0022] The terms 'antifolate' and 'antifolate drug' generally refer to a chemical compound which inhibits at least one key folate-requiring enzyme of the thymidine or purine biosynthetic pathways, preferably thymidylate synthase ('TS'), dihydrofolate reductase ('DHFR'), or glycinamide ribonucleotide formyltransferase ('GARFT'), by competing with reduced folates for binding sites of these enzymes. The 'antifolate' or 'antifolate drug' for use in this invention is Pemetrexed Disodium (ALIMTA®), as manufactured by Eli Lilly & Co.
>
> [0028] The term 'FBP binding agent' as used herein refers to a folic binding protein binding agent which includes folic acid, (6R)-5-methyl-5,6,7,8-tetrahydrofolic acid, and (6R)-5-formyl-

> 5,6,7,8-tetrahydrofolic acid, or a physiologically-available salt or ester thereof. …
>
> [0029] 'Physiologically-available salt' refers to potassium, sodium, lithium, magnesium, or preferably a calcium salt of the FBP binding agent. 'Physiologically-available...ester' refers to esters which are easily hydrolyzed upon administration to a mammal to provide the corresponding FBP binding agent free acid, such as for example C1-C4 alkyl esters, and mixed anhydrides."

34. Methods of administration are described in [0026]. Dosages are discussed in [0027]. From [0034] to [0056] the specification describes a number of examples, which relate to animal and human tests. The details of these do not matter, but two points should be noted. First, the only antifolate used is pemetrexed disodium, which is consistently referred to in this part of the specification (24 times) as "pemetrexed disodium (ALIMTA®)". Secondly, the specification indicates at [0044] that, in a typical cancer evaluation, the antifolate is to be administered in four doses over a two week period by rapid intravenous injection followed by two weeks of non-therapy.

The claims

35. Claims 1-11 of the Patent are Swiss form claims and claims 12-14 are product claims. It is only necessary to refer to claims 1, 2 and 12, which are as follows:

> "1. Use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumor growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof, said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin or cobalamin.
>
> 2. Use according to claim 1 wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof, said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin or cobalamin, and a folic binding protein binding agent selected from folic acid, (6R)-5-methyl-5,6,7,8-tetrahydrofolic acid and (6R)-5-forinyl-5,6,7,8-tetrahydrofolic acid or a physiologically available salt or ester thereof.
>
> 12. A product containing pemetrexed disodium, vitamin B 12 or a pharmaceutical derivative thereof said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo10-chlorocobalamin perchlorate, azidocobalamin,

> chlorocobalamin or cobalamin, and, optionally, a folic binding protein binding agent selected from the group consisting of folic acid, (6R)-5-methyl-5,6,7,8-tetrahydrofolic acid and (6R)-5-formyl-5,6,7,8-tetrahydrofolic acid, or a physiologically available salt or ester thereof, as a combined preparation for the simultaneous, separate or sequential use in inhibiting tumor growth."

The prosecution history of the Patent

36. The Patent was applied for by an International Application under the Patent Co-operation Treaty filed on 15 June 2001 and published on 10 January 2002 under number WO 02/02093 ("the PCT"). The PCT included 28 claims: claims 1-10 were directed to a method of treatment, claims 11-24 were Swiss form claims and claims 25-28 were purpose-bound product claims.

37. When the PCT entered the European regional phase, Dr Ivan Burnside, Lilly's in-house European Patent Attorney, filed a revised set of claims which omitted the method of treatment claims under cover of a letter dated 8 January 2003. Claims 1 and 2 were as follows:

> "1. Use of a methylmalonic acid lowering agent in the preparation of a medicament useful in lowering the mammalian toxicity associated with an antifolate, and the medicament is administered in combination with an antifolate.
>
> 2. Use of a methylmalonic acid lowering agent in the preparation of a medicament useful in lowering the mammalian toxicity associated with an antifolate, and the medicament is administered in combination with an antifolate and a FBP binding agent."

Claim 10 was a dependent claim "wherein the antifolate is ALIMTA". Claims 13-17 were purpose-bound product claims, with claim 15 being a dependent claim "wherein the antifolate is ALIMTA". None of the claims was directed to a use or product wherein the antifolate was pemetrexed.

38. On 9 March 2004 the EPO examiner issued an official communication which raised objections under Article 52(4) of the European Patent Convention (patentability), Article 54 EPC (novelty), Article 56 EPC (inventive step), Article 83 EPC (disclosure) and Article 84 EPC (clarity). The clarity and lack of disclosure objections were expressed as follows:

> "Present claims 1-11, 13-16 relate to an extremely large number of possible combinations of compounds defined as 'antifolate', 'methylmalonic acid lowering agent', 'FBP binding agent'.
>
> In fact, the claims contain so many options and variables that a lack of clarity (and conciseness) within the meaning of Article 84 EPC arises.

> Moreover claims 1-11, 13-16 relate to a compounds defined by reference to desirable characteristics or properties, namely 'antifolate', 'methylmalonic acid lowering agent', 'FBP binding agent'.
>
> The claims cover all compounds having these characteristics or properties, whereas the application provides support within the meaning of Article 84 EPC and disclosure within the meaning of Article 83 EPC for only a very limited number of such compounds. In the present case, the claims so lack support, and the application so lacks disclosure. Support is only to be found in the present application for those parts relating to the compounds/compositions prepared in the examples and those specifically defined by chemical name in claims 8-10, 12, 14-17.
>
> Independent of the above reasoning, claims 1-3, 6-12 also lack clarity (Article 84 EPC):
>
> A therapeutic application is defined in terms of a result to be achieved: 'reducing toxicity' (claims 1-3). No therapeutically defined use or disease is clearly encompassed under such wording.
>
> Again, this lack of clarity in the present case does not comply with Art 84 EPC. (See also Decision of the Board of Appeal T1048/98).
>
> Furthermore the abbreviations 'FBP' expressed on claims 2, 6, 7, 9, 13, 16 and 'ALIMTA' expressed on claims 10, 12, 15, 17 are unclear (Art 84 EPC). They should be replaced by the appropriate wording.
>
> …."

39. Dr Burnside replied to the official communication in a letter dated 23 December 2004, under cover of which he filed new claims 1-16 to replace claims 1-17 previously on file. New claims 1 and 2 were as follows:

> "1. Use of pemetrexed in the manufacture of a medicament for use in combination therapy for inhibiting tumor growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof.
>
> 2. Use according to claim 1 wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof and a folic binding protein binding agent selected from folic acid, (6R)-5-methyl-5,6,7,8-tetrahydrofolic acid and (6R)-5-formyl-5,6,7,8-tetrahydrofolic acid or a physiologically available salt or ester thereof."

Claims 13-16 were purpose-bound product claims with claim 13 similarly limited to pemetrexed.

40. In support of the new claims, Dr Burnside argued *inter alia* as follows:

> "The Applicant, having reviewed the scope of the application and in order to expedite the application proceeding to grant, has elected to amend the claims so as to more closely reflect the specific examples provided. The present amendments are made without prejudice to the Applicant's right to obtain protection for other patentable subject matter in one or more divisional applications.
>
> Claims 1-12 have been refocused on the use of the antifolate compound pemetrexed. Basis can be found at page 2 line 6-7 and page 6 line 16 of the application as filed. The term 'methylmalonic acid lowering agent' has been replaced by 'vitamin B12 or a pharmaceutical derivative thereof'. Basis for this can be found page 6 lines 19-21 and page 7 line 5 of the application as filed.
>
> …
>
> In claim 2 the term 'FBP binding agent' has been expounded in full following page 8 lines 6-7. Additionally, this term has been further refined according to page 8 lines 7-9 of the application as filed.
>
> …"

41. On 17 May 2005 the EPO examiner issued a further official communication objecting to the admissibility of the new claims on the following grounds:

> "**Amendments (Art. 123 (2) EPC)**
>
> The amendments filed with letter 23.12.2004 do not comply with the requirements of Art. 123(2) EPC in so far as they introduce subject matter beyond the content of the originally filed documents.
>
> The amendments concerned are the following:
>
> The subject matter of claims 1-16 and description pages 4, line 18- page 4a.
>
> The subject matter of present claims 1 reading 'use of pemetrexed... ' and claim 13 "a product containing pemetrexed... ' do not find base in the application documents as filed. The term 'pemetrexed' in the wording of these claims and the corresponding passages on amended description is certainly a distinct compound (CAS Registry number 137281-23-3) of the 'pemetrexed disodium' (CAS Registry number 150399-23-

> 8) expressed on original document description page 2, line 6 and page 6, line 16. Said amendment beyond the content of the original document is therefore not allowable (Art. 123 (2) EPC).
>
> Dependent claims 2-12, 14-16 in so far as related to 'pemetrexed' are consequently not allowable according to Art. 123(2) EPC. "

42. The examiner also raised a number of other objections to the new claims, including an objection under Article 56 EPC premised on the ground that "the problem underlying the present invention is to reduce the toxic events associated with the administration of the antifolate drug pemetrexed disodium (namely ALIMTA, LY 231514 or MTA)."

43. Dr Burnside replied to the official communication in a letter dated 8 March 2006, under cover of which he filed new claims 1-14 to replace claims 1-16 previously on file. The new claims were limited to pemetrexed disodium.

44. In support of the new claims, Dr Burnside argued *inter alia* as follows:

> "The Claims have been amended to refer to the preferred embodiment, the use of pemetrexed disodium (ALIMTA®) as manufactured by Eli Lilly and Company, as the antifolate drug. The Claims have also been amended to incorporate the list of vitamin B12 derivatives set out on page 7 lines 6-7 of the application as filed."

45. The examiner accepted the new claims, and the application proceeded to grant. Three additional points should be noted. First, Lilly did not challenge the examiner's objections, still less appeal against them. Secondly, Lilly has admitted that making the amendments was "a deliberate and conscious act on the part of Lilly". Thirdly, although Lilly reserved the right to file divisional applications, no divisional application has been published or granted.

The skilled person or team

46. There is a significant dispute between the parties as to the correct identification of the person or team skilled in the art to whom the Patent is addressed. Both parties addressed me by reference to UK law on this subject, which is intended to be consistent with the jurisprudence of the EPO Boards of Appeal. Neither party relied on any evidence as to what the foreign laws have to say on this topic, if anything.

UK law: general

47. A patent specification is addressed to those likely to have a practical interest in the subject matter of the invention, and such persons are those with practical knowledge and experience of the kind of work in which the invention is intended to be used. The addressee comes to a reading of the specification with the common general knowledge of persons skilled in the relevant art, and he (or she) reads it knowing that its purpose is to describe and demarcate an invention. He is unimaginative and has no

inventive capacity. In some cases the patent may be addressed to a team of persons having different skills.

48. Jacob LJ, with whom Waller and Sullivan LJJ agreed, reviewed the law with regard to the correct identification of the skilled person or team in *Schlumberger Holdings Ltd v Electromagnetic Geoservices AS* [2010] EWCA Civ 819, [2010] RPC 33 at [30]-[65]. He held that the person skilled in the art was not necessarily the same when considering pre-grant issues such as obviousness (inventive step) as when considering post-grant issues such as sufficiency and infringement. In essence, this was for two reasons. First, because in the post-grant scenario the skilled person was deemed to have read the patent whereas in the pre-grant scenario he was not. Secondly, because the making of the invention could in itself change the art. Furthermore, he held at [42] that, at least when considering obviousness, the court should have regard to "the combined skills (and mind-sets) of real research teams in the art".

49. In the situation where the specification is clearly aimed at a set of skills that would be possessed by a team of people as opposed to a single individual, in general the team has no boss and each member of the team is assumed to play his/her own part: see *Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2006] EWCA Civ 1715 at [14] (Jacob LJ delivering the judgment of the Court of Appeal). There may, however be cases where the skilled team is led by a particular member, who would take advice from other members of the team: see e.g. *KCI Licensing Inc v Smith & Nephew plc* [2010] EWHC 1487 (Pat), [2010] FSR 31 at [103]. In the latter situation, however, one cannot ignore the supporting team members when considering the relevant common general knowledge.

UK law: Swiss form claims

50. A significant aspect of the dispute which emerged in the course of counsel's submissions concerns the proper identification of the addressee of Swiss form claims i.e. claims in the form "use of substance X in the manufacture of a medicament for therapeutic use Y". The history of, and rationale for, granting patents with claims in this form was considered in detail by Jacob LJ giving the judgment of the Court of Appeal in *Actavis UK Ltd v Merck & Co Inc* [2008] EWCA Civ 444, [2009] 1 WLR 1186 at [7]-[49] and by Kitchin J (as he then was) in *Ranbaxy (UK) Ltd v AstraZeneca AB* [2011] EWHC 1831 (Pat), [2011] FSR 45 at [42]-[56].

51. As those judgments explain, the purpose for which Swiss form claims were devised was in order to provide protection for second medical uses of known substances while avoiding the problems of (i) lack of novelty and (ii) the prohibition on patenting methods of treatment which was formerly contained in Article 52(4) EPC 1973: see G 05/83 *Eisai/Second medical indication* [1985] OJ EPO 64.

52. For present purposes, the following points may be noted. First, in the course of analysing G 05/83, Jacob LJ commented at [21]:

> ".. The board is clearly saying that this form of claim does *not* fall foul of article 52(4). Making up the substance for administration is not in itself administration—is not treatment. That would seem to be the case whether the substance is made up in a factory … or in a pharmacy (where it may even be

> patient-specific). We emphasise this because sometimes in the discussion there is a tendency to conflate the novelty and therapeutic treatment objections, as though one followed from the other. What worried the board was only novelty."

53. Jacob LJ went on at [75] to hold that the claim under consideration in that case was not a claim to a method of treatment for reasons he encapsulated as follows:

> "… There is nowhere near the degree of involvement of medical personnel which turned the case in the *Bristol-Myers Squibb* case. In its essence the claim here is to the use of finasteride for the preparation of a medicament of the specified dosages. It is not aimed at and does not touch the doctor—it is directed at the manufacturer. …"

54. Secondly, again in the course of analysing G 05/83, Kitchin J commented:

> "54. It is, I think, inherent in all this reasoning that the skilled person would generally understand a Swiss form claim to mean that the medicament must contain the active ingredient for which the new and inventive use has been found. But for the exclusion contained in art.52(4) EPC 1973, the claim would have been directed to the new and non obvious use of that ingredient.
>
> 55. I do not go so far as to suggest that a claim cast in Swiss form must always be construed as being directed to the use of an active ingredient for the manufacture of a medicament which contains that ingredient. The proper meaning of the claim must be determined having regard to the words of the claim when construed purposively in the light of the specification and the common general knowledge, as the Court of Appeal emphasised in *Monsanto & Co v Merck & Co Inc (No.1)* [2000] R.P.C. 77. However, it seems to me that is how it would normally be understood. Moreover, the skilled person would appreciate that to construe it otherwise would render the claim vulnerable to an attack of insufficiency."

55. As Kitchin J explained at [57]-[61], the coming into force of EPC 2000 amended the relevant provisions so that what was Article 52(4) EPC 1973 is now Article 53(c) EPC 2000 and Article 54(5) now permits the granting of patents for known substances for use in a method referred to in Article 53(c) provided that it is novel. It follows that the legal fiction involved in Swiss form claims is no longer required, and instead it is possible for the patentee to obtain a claim to "Substance X for use in method of treatment Y". Accordingly, the Enlarged Board of Appeal has held that it is no longer appropriate to grant claims in the Swiss form: see G 02/08 *Abbott Respiratory/Dosage regime* [2010] EPOR 26.

Assessment

56. Actavis contend that, at least for the purpose of post-grant issues such as infringement, the Patent is addressed to a team consisting of a number of persons with a range of skills, but in particular (i) a medical oncologist and (ii) someone with experience in pre-formulation work, who could be a process chemist or a formulation scientist (and who I will refer to for brevity as a chemist), supported by an analytical chemist. Lilly's original position, as pleaded in its Statement of Case on Common General Knowledge and stated in its opening skeleton argument at trial, was that the Patent was directed solely, or at least primarily, to a medical oncologist. In closing submissions, however, Lilly modified its position to some extent, as described below.

57. In assessing the rival contentions, it is convenient to begin with the fact that claim 1 of the Patent is in Swiss form, whereas claim 12 is a purpose-bound product claim. Apart from that slight difference, the scope of claim 12 is the same as that of claim 1. Counsel for Lilly suggested that there was a difference in scope. If I understood him correctly, this was for one of two reasons. The first was that claim 12 corresponded to claim 2. This overlooks the fact that in claim 12 the folic protein binding agent is optional, however. The second is that claim 12 was limited to a single combined preparation of the two or three ingredients. This overlooks the definition in [0021] and the fact that claim 12 expressly refers to "simultaneous, separate or sequential use", however.

58. Despite this, counsel for Lilly submitted in his closing submissions that claim 1 was directed to a medical oncologist, whereas he accepted that claim 12 was directed to a team consisting of a medical oncologist and a chemist. I do not accept that claim 1 and claim 12 are directed to different addressees. Counsel for Lilly cited no authority in support of the proposition that different claims of the same scope in the same patent may be addressed to different skilled persons even for the purposes of the same issue. I am aware of no such authority and in my judgment such an approach would be contrary to principle.

59. Counsel for Lilly sought to support his submission by arguing that what mattered was claim 1, since Lilly could apply to delete claim 12 and did not assert claim 12 for the purposes of its counterclaim for threatened infringement of the UK designation. Lilly has not applied to delete claim 12, however, and Actavis seek a declaration of non-infringement in respect of all claims of the Patent. (I would add that, as counsel for Lilly accepted, it is clear that Actavis' proposed product will infringe claim 2, as well as claim 1, if those claims extend to pemetrexed diacid, dipotassium and ditromethamine, since Actavis intend to seek regulatory approval by reference to Lilly's product which is administered together with both vitamin B12 and folic acid.)

60. Counsel for Lilly also suggested that the addressee of the Patent could be different for the purposes of considering the scope of the claim (and hence infringement) and for the purpose of considering sufficiency. In the alternative, he suggested that the addressee could be different for the purposes of considering *Improver* question 1 on the one hand and *Improver* questions 2 and 3 on the other hand. Again, he cited no authority for these propositions and in my judgment they are contrary to principle.

61. In my view counsel for Lilly was correct to accept that claim 12 is addressed to a team comprising a medical oncologist and a chemist. It is clear from the evidence of

both Prof Ferry and Prof Seckl that a medical oncologist would be unable to make a single combined preparation for simultaneous use falling within claim 12, whether the combination consisted just of pemetrexed disodium and vitamin B12 (or derivative) or all three components, and would require the assistance of a chemist for this purpose. In my judgment it follows that claim 1 is also addressed to the same team.

62. I would reach the same conclusion if claim 1 stood on its own. I do not accept the argument advanced by counsel for Lilly that, because claim 1 is a Swiss form claim which was a legal fiction designed to circumvent Article 52(4) EPC 1973, therefore it should be interpreted as if it were a claim to a method of treatment. I accept that, as indicated by *Virgin v Premium*, the skilled person interpreting the claim is deemed to have some understanding of relevant drafting conventions, but that does not warrant interpreting claim 1 as if it was to a method of treatment. Even under the EPC 2000, the method of treatment would not be patentable. Claim 1 is directed at the manufacturer of the pemetrexed disodium medicament, and it embraces a single combined preparation for simultaneous use. Furthermore, it is clear from the evidence of Dr Spargo that in the real world the teams who deal with developing and making medicaments for use in treatment comprise a range of disciplines, and in this context would comprise both a medical oncologist and a chemist.

63. I would add that, if Lilly is correct that, in addition to pemetrexed disodium, other forms of pemetrexed may fall within the scope of the claims, then it necessarily follows that the skilled team must include a chemist. As Prof Ferry accepted, the choice of an appropriate alternative salt would not be something that the medical oncologist could assist with. To put it another way, if the skilled team did not include a chemist and the claim extended to alternative salts, the claim would be insufficient for that reason alone.

64. Finally, counsel for Lilly relied on the decision of the Opposition Division, in which the Opposition Division considered inventive step from the perspective of a medical oncologist, as supporting Lilly's case as to the addressee. Even assuming that that assessment is correct, however, for the reasons given in *Schlumberger*, it does not follow that the skilled team is the same for the purposes of sufficiency and infringement.

Common general knowledge

65. Again, both parties addressed me by reference to UK law on this subject, which is intended to be consistent with the jurisprudence of the EPO Boards of Appeal. Neither party relied on any evidence as to what the foreign laws have to say on this topic, if anything.

UK law

66. I reviewed the law as to common general knowledge in *KCI Licensing Inc v Smith & Nephew Ltd* [2010] EWHC 1487 (Pat) at [105]-[115]. That statement of the law was approved by the Court of Appeal [2010] EWCA Civ 1260, [2011] FSR 8 at [6]. Counsel for Lilly relied on what I said at [112]:

> "… even if information is neither disclosed by a specific item of prior art nor common general knowledge, it may

> nevertheless be taken into account as part of a case of obviousness if it is proved that the skilled person faced with the problem to which the patent is addressed would acquire that information as a matter of routine. For example, if the problem is how to formulate a particular pharmaceutical substance for administration to patients, then it may be shown that the skilled formulator would as a matter of routine start by ascertaining certain physical and chemical properties of that substance (e.g. its aqueous solubility) from the literature or by routine testing. If so, it is legitimate to take that information into account when assessing the obviousness of a particular formulation. But that is because it is obvious for the skilled person to obtain the information, not because it is common general knowledge."

67. A point which I did not address in KCI was the relevant date at which to assess the common general knowledge. It is settled that, when considering validity, the relevant date is the filing date or the priority date if there is a valid claim to an earlier priority date. Although the matter is not settled, the weight of authority supports assessment as at the publication date for the purposes of infringement: see *Terrell on the Law of Patents* (17th ed) at §§9-10 to 9-11. In practice, however, English courts tend to assess the common general knowledge as at the filing or priority date for this purpose as well.

Assessment: common general knowledge of the oncologist in 2000/2001

68. There is little dispute as to the relevant common general knowledge of the oncologist in 2000/2001. It may be summarised as follows.

69. *Antifolates.* It was well known that antifolates were a class of drugs which were used in cancer chemotherapy. Some drugs in this class, such as methotrexate, had been used for a considerable period of time, but others were under development. There was some understanding of the mechanism of action of antifolates. It was well known that the use of antifolates in chemotherapy caused toxic side effects which it would be desirable to avoid or reduce if possible.

70. *Pemetrexed*. It was known that an antifolate called pemetrexed was the subject of clinical trials for use in chemotherapy, that it targeted multiple enzymes and that it was administered intravenously, but that it had not yet received regulatory approval. The only form of pemetrexed which had been shown to be effective and safe, to the extent that this had been shown, was pemetrexed disodium, which was manufactured by Lilly under the trade mark Alimta.

71. Prof Seckl's view was that in 2000/2001 an oncologist who had not been personally involved in the Alimta clinical trials would only have had a limited knowledge of pemetrexed, whereas Prof Ferry thought that the oncologist would have had a greater degree of knowledge about pemetrexed. This difference of opinion is immaterial, because it is common ground that, before embarking on any research involving pemetrexed, an oncologist who did not know much about it would carry out a literature search and find out what was known about it.

72. *Vitamin B12 and folic acid.* Both vitamin B12 and folic acid had been well known for a considerable period of time, and their characteristics, structure and functions were well understood. In particular, it was known that vitamin B12 and folic acid were both involved in DNA synthesis repair. It was well known that there were a number of different safe and effective forms of both vitamin B12 and folic acid available.

73. *Salt forms and counter-ions*. It is clear from the evidence of both Prof Seckl and Prof Ferry that skilled oncologists (even research clinicians) do not think about drugs like pemetrexed in their ionic form, nor do they consider issues regarding the choice of counter-ion or the effect, if any, of counter-ions on the efficacy, safety or other properties of the drug. Importantly, Prof Ferry agreed with Prof Seckl that the choice of salt form was really the province of the chemist and that the oncologist would not be involved in this. He also agreed that the properties of salt forms and free acids were difficult to predict and that the chemist would need to address this problem by conducting experiments.

Common general knowledge of the oncologist in 2007

74. It is common ground that, by 2007, the oncologist would have been far more familiar with pemetrexed than in 2000/2001. Neither side suggested that this made any real difference to the issues in the case, however.

Common general knowledge of the chemist in 2000/2001 and in 2007

75. Again, there is little dispute as to the common general knowledge of the chemist. Furthermore, it is common ground that there was no material difference between 2000/2001 and 2007. It may be summarised as follows.

76. *Salts and counter-ions*. Drugs frequently contain one or more acidic or basic groups. Where this is the case, it is generally possible to form different salts of the parent molecule by reacting it with a complementary base or acid. The salt will typically have different properties from the parent molecule. For example, a salt may be a solid at room temperature, whereas the parent molecule is a liquid; a salt may be soluble in water, whereas the parent molecule is not; and so on. Furthermore, different salts will typically have different properties from each other. For these reasons, salt screening is a routine, but important, part of the process of determining the most suitable form of a drug for formulation.

77. Formation of a salt involves the transfer of one or more protons (hydrogen ions) from the acid to the base, resulting in a negatively charged species (an anion) and a positively charged species (a cation). The ion which is not derived from the parent molecule is generally referred to as the "counter-ion". Where the parent molecule is an acid, it will form an anion when reacted with a base. The base will provide the counter-ion. Thus pemetrexed diacid reacts with sodium hydroxide to form pemetrexed disodium salt. In this case the counter-ion is sodium, which is a cation.

78. Solid salts consist of the anions and cations regularly arranged in a fixed lattice structure. In sodium chloride, for example, each ion is surrounded by six ions of the opposite charge in a structure known as a face-centered cubic lattice. It is possible to draw a cube containing a number of ions which is a repeating element in an infinite array. In a salt consisting of a single cation and a single anion, there are equal

numbers of alternating cations and anions in the lattice. Where there are different ratios of cations and anions, this gives rise to different lattice structures. The different lattice structures in turn give rise to different crystal structures. Although lattices contain infinite numbers of cations and anions, the fact that the cations and anions are present not only in fixed proportions, but also fixed relative positions, means that it is possible to speak meaningfully of the salt as being present in solid form.

79. It is important to appreciate that, when a salt like pemetrexed disodium is dissolved in a solvent like water, the ions dissociate from each other and become surrounded by solvent molecules. The result is free cations and anions in solution. It follows that the salt does not exist as such in the solution, but rather there is a solution containing the separate constituent cations and anions. Thus a solution of sodium chloride does not contain sodium chloride, it contains sodium cations and chloride anions. It is commonplace to refer to "a salt solution" or "a salt in solution", but this is a convenient shorthand which is not technically entirely accurate.

80. *The impact of the salt form on a drug and the difficulties in making salts*. The evidence of Dr Spargo and Prof Thurston on these topics can be summarised as follows:

i) the salt form can have a significant impact on the effectiveness of a drug;

ii) salt forms can modify the solubility, therapeutic use, pharmaceutical dosage forms, pharmacokinetic properties (e.g. absorption, distribution, metabolism and excretion of the parent molecule in the body) and the chemical and physical stability of the drug, and its suitability for industrial processing;

iii) in particular, in relation to solubility, if a salt form has poor solubility and dissolution, this can result in poor bioavailability, as good solubility and/or dissolution are indicators of how likely it is that the drug will be absorbed in the gut. When considering a drug for intravenous chemotherapy, the solubility of the salt form is crucial;

iv) by contrast, if a salt is too soluble, then it may not result in direct crystallization or precipitation of the desired salt, and therefore the salt cannot be made in solid form in the first place;

v) there can be other problems trying to make salts before one can consider testing them further, including solvents or other impurities being trapped in the lattice. In such cases, although a salt has been made, the solid form would rarely be robust or commercialisable;

vi) in general, there can be many dead-ends and false leads when attempting to prepare salts of a parent molecule for the first time.

81. *Salt screening*. When deciding which counter-ions to test in a salt screening process, the chemist would routinely refer to the lists of commonly used counter-ions which had been identified in standard texts. The two most common standard texts were Berge, Bighly and Monkhouse, "Pharmaceutical Salts", *J. Pharm. Sci.*, 66, 1-19 (1977) ("Berge") and Stahl and Wermuth (eds), *Handbook of Pharmaceutical Salts: Properties, Selection and Use* (Wiley-VCH, 2002) ("Stahl & Wermuth"). Both of

these texts contain tables showing the most common counter-ions found in approved pharmaceuticals. At the time of Berge, the most common counter-ion for acidic parent molecules was sodium, followed by potassium, calcium, zinc, lithium, magnesium and aluminium. By the time of Stahl & Wermuth, sodium was still the most common, now followed by calcium, potassium, magnesium, meglumine, lysine and a variety of others.

82. *Predictability of the viability of salts*. It was common ground between the experts that one could not predict in advance (a) whether one could make a particular salt form of a parent molecule, (b) what its properties would be once the salt form was made or (c) whether it would affect the efficacy of the drug. As Dr Spargo explained in his reports, the screening and selection process for salt forms is an empirical one involving trial and error. As Prof Thurston agreed, this remains the case even if one has already identified a suitable salt (such as the sodium salt) and is looking for an alternative. In particular, one cannot predict the solubility of any particular salt form in advance of making and testing it. A typical approach would be to screen a handful of potential candidates. Once these had been made (assuming this could be achieved), they would be tested for solubility, stability and so forth. Thus, while the chemist tasked with finding an alternative salt to pemetrexed disodium would have a reasonable expectation of being able to find a suitable alternative, he would not be confident that any particular salt would be suitable before making and testing it. I would add that Dr Stefánsson's evidence is entirely consistent with this.

83. *Sodium salts*. It was well known that sodium was the most preferred counter-ion. Thus sodium would be the chemist's first choice. It was known that sodium salts were generally not toxic. Sodium salts would generally be expected to be reasonably soluble, but they were not always easy to make.

84. *Potassium salts*. Potassium was known to be used in pharmaceutical compositions. Although it had a general tendency to be in the "more soluble" class of salt with sodium, there were exceptions to this tendency. It was known that there were some concerns about the potential toxicity of potassium salts in terms of cardiac side effects. This is something which would require particular consideration if large quantities of the drug (such as gram quantities) were to be administered.

85. *Tromethamine salts*. Tromethamine salts were very much in the minority in 2000/2001 and there were only a small handful of examples of its use. It is still not particularly high on the list to be used as a counter-ion even now. It was known that tromethamine salts might well be too soluble, such that one would not be able to make and harvest the solid form.

86. *Free acids*. In principle, an acidic parent molecule could be administered in the form of the free acid, and this is something that the chemist would consider. It was often the case, however, that there was a need or desire to change from the free acid to a salt form in order to improve kinetics, absorption or physicochemical properties. In particular, the free acid might not be adequately soluble, and a common way to try to address that was through salt formation.

Article 69 and the Protocol

87. France, Germany, Italy, Spain and the UK are all parties to the European Patent Convention 2000. Article 69(1) EPC provides:

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

88. The Protocol on the Interpretation of Article 69 of the Convention provides:

> "**Article 1**
>
> *General principles*
>
> Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.
>
> **Article 2**
>
> *Equivalents*
>
> For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims."

Construction of the UK Patent

UK law: general

89. Although UK law as to the construction of patent claims is fairly well settled, it is appropriate to set out a much fuller exposition than I normally would. This is both because of the nature of the issue in the present case, and to facilitate comparison with the foreign laws and with the judgment of the Düsseldorf Regional Court.

90. The modern UK law of patent claim construction begins with the famous passage in the speech of Lord Diplock, with whom the other members of the House of Lords agreed, in *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183 at 242-243:

> "My Lords, a patent specification is a unilateral statement by the patentee, in words of his own choosing, addressed to those likely to have a practical interest in the subject matter of his invention (i.e. 'skilled in the art'), by which he informs them what he claims to be the essential features of the new product or process for which the letters patent grant him a monopoly. It is those novel features only that he claims to be essential that constitute the so-called 'pith and marrow' of the claim. A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge. The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that *any* variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.
>
> The question, of course, does not arise where the variant would in fact have a material effect upon the way the invention worked. Nor does it arise unless at the date of publication of the specification it would be obvious to the informed reader that this was so. Where it is not obvious, in the light of then-existing knowledge, the reader is entitled to assume that the patentee thought at the time of the specification that he had good reason for limiting his monopoly so strictly and had intended to do so, even though subsequent work by him or others in the field of the invention might show the limitation to have been unnecessary. It is to be answered in the negative only when it would be apparent to any reader skilled in the art that a particular descriptive word or phrase used in a claim cannot have been intended by a patentee, who was also skilled in the art, to exclude minor variants which, to the knowledge of both him and the readers to whom the patent was addressed, could have no material effect upon the way in which the invention worked."

91. *Catnic* was a decision on a patent granted under the Patents Act 1949, but it was subsequently taken by the English courts to represent the correct approach to patents granted under the Patents Act 1977, and hence to comply with Article 69 EPC 1973 and the Protocol.

92. In *Improver Corp v Remington Consumer Products Ltd* [1990] FSR 181 at 289 the then Hoffmann J analysed the guidance given by Lord Diplock in *Catnic* with regard to equivalents as follows:

> "If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or

> acontextual meaning of a descriptive word or phrase in the claim ('a variant') was nevertheless within its language as properly interpreted, the court should ask itself the following three questions:
>
> (1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no?
>
> (2) Would this (ie that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes?
>
> (3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.
>
> On the other hand, a negative answer to the last question would lead to the conclusion that the patentee was intending the word or phrase to have not a literal but a figurative meaning (the figure being a form of synecdoche or metonymy) denoting a class of things which include the variant and the literal meaning, the latter being perhaps the most perfect, best-known or striking example of the class."

93. These questions, referred to initially as "the *Improver* questions" and latterly as "the Protocol questions", were routinely used by first instance judges and the Court of Appeal for some 15 years. One of the important cases decided by the Court of Appeal during this period was *American Home Products Corp v Novartis Pharmaceuticals UK Ltd* [2001] RPC 8. In that case the patentee argued that the word "rapamycin" in the claim meant "rapamycin itself and derivatives thereof which exhibit the same type of inhibition to organ rejection as rapamycin". The Court of Appeal rejected that construction, and in doing so considered it relevant that the specification gave no indication that any derivatives of rapamycin would in fact work (see [20]). The Court also held that the patentee could not adopt a construction which included "all variants that did not materially affect the invention" and therefore effectively by-pass *Improver* questions 1 and 2 (see [23]-[24]). In relation to *Improver* question 3 the Court considered it important that, if the words of the claims were not complied with strictly and instead covered derivatives of rapamycin that worked, then such a claim would not have been allowed by the European Patent Office as it would have lacked support and would have been speculative (see [31]).

94. The UK approach to patent claim construction was reviewed nearly 10 years ago by the House of Lords in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46, [2005] RPC 9. In a magisterial speech which continues to repay close study, the then Lord Hoffmann, with whom the other members of the House agreed, considered almost every facet of the question. For present purposes, five aspects of Lord Hoffmann's analysis merit emphasis.

95. First, Lord Hoffman made some general observations about construction:

> "32. …. Construction is objective in the sense that it is concerned with what a reasonable person to whom the utterance was addressed would have understood the author to be using the words to mean. Notice, however, that it is not, as is sometimes said, 'the meaning of the words the author used', but rather what the notional addressee would have understood the author to mean by using those words. The meaning of words is a matter of convention, governed by rules, which can be found in dictionaries and grammars. What the author would have been understood to mean by using those words is not simply a matter of rules. It is highly sensitive to the context of, and background to, the particular utterance. It depends not only upon the words the author has chosen but also upon the identity of the audience he is taken to have been addressing and the knowledge and assumptions which one attributes to that audience. ...
>
> 33. In the case of a patent specification, the notional addressee is the person skilled in the art. He (or, I say once and for all, she) comes to a reading of the specification with common general knowledge of the art. And he reads the specification on the assumption that its purpose is to both to describe and to demarcate an invention—a practical idea which the patentee has had for a new product or process—and not to be a textbook in mathematics or chemistry or a shopping list of chemicals or hardware. It is this insight which lies at the heart of 'purposive construction'. … The purpose of a patent specification, as I have said, is no more nor less than to communicate the idea of an invention. An appreciation of that purpose is part of the material which one uses to ascertain the meaning. But purpose and meaning are different. … There is no presumption about the width of the claims. A patent may, for one reason or another, claim less than it teaches or enables.
>
> 34. 'Purposive construction' does not mean that one is extending or going beyond the definition of the technical matter for which the patentee seeks protection in the claims. The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance. The conventions of word meaning and syntax enable us to express our meanings with great accuracy and subtlety and the skilled man will ordinarily assume that the patentee has chosen his language accordingly. As a number of judges have pointed out, the specification is a unilateral document in words of the patentee's own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document *inter rusticos* for which broad allowances must be made. On the other hand, it must be recognised that the patentee is trying to

> describe something which, at any rate in his opinion, is new; which has not existed before and of which there may be no generally accepted definition. There will be occasions upon which it will be obvious to the skilled man that the patentee must in some respect have departed from conventional use of language or included in his description of the invention some element which he did not mean to be essential. But one would not expect that to happen very often.
>
> 35. One of the reasons why it will be unusual for the notional skilled man to conclude, after construing the claim purposively in the context of the specification and drawings, that the patentee must nevertheless have meant something different from what he appears to have meant, is that there are necessarily gaps in our knowledge of the background which led him to express himself in that particular way. The courts of the United Kingdom, the Netherlands and Germany certainly discourage, if they do not actually prohibit, use of the patent office file in aid of construction. There are good reasons: the meaning of the patent should not change according to whether or not the person skilled in the art has access to the file and in any case life is too short for the limited assistance which it can provide. It is however frequently impossible to know without access, not merely to the file but to the private thoughts of the patentee and his advisors as well, what the reason was for some apparently inexplicable limitation in the extent of the monopoly claimed. One possible explanation is that it does not represent what the patentee really meant to say. But another is that he did mean it, for reasons of his own; such as wanting to avoid arguments with the examiners over enablement or prior art and have his patent granted as soon as possible. This feature of the practical life of a patent agent reduces the scope for a conclusion that the patentee could not have meant what the words appear to be saying. It has been suggested that in the absence of any explanation for a restriction in the extent of protection claimed, it should be presumed that there was some good reason between the patentee and the patent office. I do not think that it is sensible to have presumptions about what people must be taken to have meant, but a conclusion that they have departed from conventional usage obviously needs some rational basis."

96. Secondly, Lord Hoffman concluded that the *Catnic* principle of purposive construction was precisely in accordance with the Protocol for reasons he encapsulated at [47] as follows:

> "The Protocol, as I have said, is a Protocol for the construction of art.69 and does not expressly lay down any principle for the construction of claims. It does say what principle should not be followed, namely the old English literalism, but otherwise it

> says only that one should not go outside the claims. It does however say that the object is to combine a fair protection for the patentee with a reasonable degree of certainty for third parties. How is this to be achieved? The claims must be construed in a way which attempts, so far as is possible in an imperfect world, not to disappoint the reasonable expectations of either side. What principle of interpretation would give fair protection to the patentee? Surely, a principle which would give him the full extent of the monopoly which the person skilled in the art would think he was intending to claim. And what principle would provide a reasonable degree of protection for third parties? Surely again, a principle which would not give the patentee more than the full extent of the monopoly which the person skilled in the art would think that he was intending to claim. Indeed, any other principle would also be unfair to the patentee, because it would unreasonably expose the patent to claims of invalidity on grounds of anticipation or insufficiency."

97. Thirdly, Lord Hoffmann gave careful consideration to the question of equivalents:

> "41. There is often discussion about whether we have a European doctrine of equivalents and, if not, whether we should. It seems to me that both the doctrine of equivalents in the United States and the pith and marrow doctrine in the United Kingdom were born of despair. The courts felt unable to escape from interpretations which 'unsparing logic' appeared to require and which prevented them from according the patentee the full extent of the monopoly which the person skilled in the art would reasonably have thought he was claiming. The background was the tendency to literalism which then characterised the approach of the courts to the interpretation of documents generally and the fact that patents are likely to attract the skills of lawyers seeking to exploit literalism to find loopholes in the monopoly they create. (Similar skills are devoted to revenue statutes.)
>
> 42. If literalism stands in the way of construing patent claims so as to give fair protection to the patentee, there are two things that you can do. One is to adhere to literalism in construing the claims and evolve a doctrine which supplements the claims by extending protection to equivalents. That is what the Americans have done. The other is to abandon literalism. That is what the House of Lords did in the *Catnic* case …
>
> 44. Since the *Catnic* case we have art.69 which, as it seems to me, firmly shuts the door on any doctrine which extends protection outside the claims. …
>
> 49. Although art.69 prevents equivalence from extending protection outside the claims, there is no reason why it cannot

> be an important part of the background of facts known to the skilled man which would affect what he understood the claims to mean. That is no more than common sense. It is also expressly provided by the new art.2 added to the Protocol by the Munich Act revising the EPC, dated November 29, 2000 …
>
> 52. … When speaking of the '*Catnic* principle' it is important to distinguish between, on the one hand, the principle of purposive construction which I have said gives effect to the requirements of the Protocol, and on the other hand, the guidelines for applying that principle to equivalents, which are encapsulated in the Protocol questions. The former is the bedrock of patent construction, universally applicable. The latter are only guidelines, more useful in some cases than in others. …. "

98. Fourthly, Lord Hoffman discussed the approaches of the Dutch and German courts to Article 69 and the Protocol. In this context he observed at [75]:

> "The German courts have their own guidelines for dealing with equivalents, which have some resemblance to the Protocol questions. In the 'quintet' of cases before the Bundesgerichtshof (see, for example, *Kunstoffrohrteil* [2002] G.R.U.R. 511 and *Schneidemesser 1* [2003] E.N.P.R. 12 309) which concerned questions of whether figures or measurements in a claim allow some degree of approximation (and, if so, what degree), the court expressly said that its approach was similar to that adopted in *Catnic*. But there are differences from the Protocol questions which are lucidly explained by Dr Peter Meier-Beck (currently a judge of the 10th Senate) in a paper to be published in the International Review of Intellectual Property and Competition Law (IIC). For example, German judges do not ask whether a variant 'works in the same way' but whether it solves the problem underlying the invention by means which have the same technical effect. That may be a better way of putting the question because it avoids the ambiguity illustrated by *American Home Products Corp v Novartis Pharmaceuticals UK Ltd* [2001] R.P.C. 8 over whether 'works in the same way' involves an assumption that it works at all. On the other hand, as is illustrated by the present case, everything will depend upon what you regard as 'the problem underlying the invention.' It seems to me, however, that the German courts are also approaching the question of equivalents with a view to answering the same ultimate question as that which I have suggested is raised by Art.69, namely what a person skilled in the art would have thought the patentee was using the language of the claim to mean."

99. Fifthly, Lord Hoffmann discussed the impact of new technology, and the problems that this gave rise to in answering the second *Improver* question. In this context he observed at [80]:

> "I do not dispute that a claim may, upon its proper construction, cover products or processes which involve the use of technology unknown at the time the claim was drafted. The question is whether the person skilled in the art would understand the description in a way which was sufficiently general to include the new technology. There is no difficulty in principle about construing general terms to include embodiments which were unknown at the time the document was written. One frequently does that in construing legislation, for example, by construing 'carriage' in a 19th century statute to include a motor car. In such cases it is particularly important not to be too literal. It may be clear from the language, context and background that the patentee intended to refer in general terms to, for example, every way of achieving a certain result, even though he has used language which is in some respects inappropriate in relation to a new way of achieving that result. …."

He went on to refer again to *AHP v Novartis* at [82] as an example of the difficulty of applying the second *Improver* question to new technology.

100. Since *Kirin-Amgen*, the *Improver* questions have fallen out of fashion and have rarely been referred to in judgments of the English courts in the last 10 years. This may be regarded as unfortunate given that, although the *Improver* questions have their limitations for the reasons given by Lord Hoffmann, they do provide a structured approach to the question of equivalents and they have been influential across Europe.

101. The principles established by *Kirin-Amgen* were summarised by Jacob LJ giving the judgment of the Court of Appeal in *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors UK Ltd* [2009] EWCA Civ 1062, [2010] RPC 8 at [5] as follows.

> "(i) The first overarching principle is that contained in Article 69 of the European Patent Convention.
>
> (ii) Article 69 says that the extent of protection is determined by the claims. It goes on to say that the description and drawings shall be used to interpret the claims. In short the claims are to be construed in context.
>
> (iii) It follows that the claims are to be construed purposively - the inventor's purpose being ascertained from the description and drawings.
>
> (iv) It further follows that the claims must not be construed as if they stood alone - the drawings and description only being used to resolve any ambiguity. Purpose is vital to the construction of claims.
>
> (v) When ascertaining the inventor's purpose, it must be remembered that he may have several purposes depending on the level of generality of his invention. Typically, for instance,

> an inventor may have one, generally more than one, specific embodiment as well as a generalised concept. But there is no presumption that the patentee necessarily intended the widest possible meaning consistent with his purpose be given to the words that he used: purpose and meaning are different.
>
> (vi) Thus purpose is not the be-all and end-all. One is still at the end of the day concerned with the meaning of the language used. Hence the other extreme of the Protocol - a mere guideline - is also ruled out by Article 69 itself. It is the terms of the claims which delineate the patentee's territory.
>
> (vii) It follows that if the patentee has included what is obviously a deliberate limitation in his claims, it must have a meaning. One cannot disregard obviously intentional elements.
>
> (viii) It also follows that where a patentee has used a word or phrase which, acontextually, might have a particular meaning (narrow or wide) it does not necessarily have that meaning in context.
>
> (ix) It further follows that there is no general 'doctrine of equivalents.'
>
> (x) On the other hand purposive construction can lead to the conclusion that a technically trivial or minor difference between an element of a claim and the corresponding element of the alleged infringement nonetheless falls within the meaning of the element when read purposively. This is not because there is a doctrine of equivalents: it is because that is the fair way to read the claim in context.
>
> (xi) Finally purposive construction leads one to eschew the kind of meticulous verbal analysis which lawyers are too often tempted by their training to indulge."

102. Jacob LJ went on at [6]-[22] to hold that the skilled reader is to be taken to know (i) the purpose of including reference numerals in patent claims, (ii) the purpose of dividing claims into pre-characterising and characterising portions and (iii) the practice of filing divisional applications, and to bring that knowledge to bear when he considers the scope of the claim. In this context, Jacob LJ said at [15]:

> "We think it would unrealistic – indeed perverse – for the law to say that the notional skilled reader, probably with the benefit of skilled advice, would not know and take into account the explicit drafting conventions by which the patent and its claims were framed. Likewise when there is a reference to the patent being a divisional application, it would be perverse to work on the basis that the skilled man would not know what that means. A real skilled man reading a patent which, as in the case of the Patent, refers to 'the parent application' would surely say

> 'what's a parent application?' – and he would go on to ask a man who knows, probably a patent agent."

103. I would add the following observations on two aspects of the question of equivalents. The first point is that it is vital not to lose sight of the fact that the claim must be construed in the same manner for the purpose of considering both infringement and validity. Article 69 and the Protocol govern the interpretation of the claim for both purposes. It follows that, once due account has been taken of equivalents in determining the scope of the claim in accordance with Article 2 of the Protocol, that claim scope is determinative of questions of both of infringement and validity. To put it bluntly, one cannot use equivalents to extend the scope of the claim just for infringement and not for validity. Still less can one use equivalents to extend protection outside the claims for the purposes of infringement, but confine attention to the claims when considering validity.

104. The second point is that experience shows that patentees resort to arguments about equivalents in three main classes of case. The first is where, with the benefit of hindsight, it can be seen that the patent was unfortunately drafted, whether because of poor instructions from the inventor or poor drafting by his patent attorney or a combination of these things. *Improver* might perhaps be regarded as an example of this. The second class is where technology has moved on since the priority or filing date of the patent. *Kirin-Amgen* might perhaps be regarded as an example of this. The third class is where the patentee now regrets a decision taken during the course of prosecution of the patent application, whether by himself or by the examiner, and is trying to avoid the consequences of that decision. As will appear, in my view the present case is a clear example of this.

105. In the first class of case, the law recognises that drafting patent claims is a difficult and imprecise art and that third parties should not be allowed to exploit infelicities of drafting where it is reasonably clear that those infelicities should not affect the scope of the claim. This is in order to provide "fair protection for the patent proprietor". The law also recognises, however, the countervailing consideration that third parties are entitled to rely on the drafting of the claim when deciding on a commercial course of action. There is no tort of avoiding a patent claim. Thus it is also necessary to provide "a reasonable degree of legal certainty for third parties". The problem, of course, is that what is fair protection to one person is legal uncertainty to another. Conversely, what is reasonable legal certainty to the second person is a denial of protection to the first. The courts have to strike a balance. In striking that balance, it is important to bear in mind that, as Lord Hoffman and Jacob LJ have pointed out, both the patentee and the third party will generally rely on skilled professional advice (and may have a remedy if the advice is incompetent).

106. In the second class of case, the problem is more acute. It is difficult for an applicant for a patent to anticipate how technology may evolve during the 20 year life of the patent. The law is sympathetic to the proposition that third parties should not be able to avoid infringement merely by employing new technical means to implement the invention. But on the other hand, a claim may be drafted in a manner which is inescapably tied to the old technology. There is no easy answer to this conundrum. It is not necessary to explore this question any further for the purposes of the present case, however.

107. In the third class of case, there is no reason why the law should be sympathetic to the patentee. Not only do applicants generally rely on skilled professional advice, but also they can appeal against adverse decisions of examiners during the course of prosecution if they consider that those decisions are wrong. If the courts allow decisions as to claim scope made by the examiner during the course of prosecution which have not been successfully appealed effectively to be overturned by decisions on claim construction, the courts undermine the important role of the examiner. This is still more so if the courts allow decisions as to claim scope made by the applicant during the course of prosecution effectively to be reversed by decisions on claim construction.

UK law: prosecution history as an aid to construction

108. As is well known, US patent law has a doctrine of equivalents and, to counterbalance it, a doctrine of "file wrapper estoppel". It is common ground that the UK has no doctrine of prosecution history estoppel. It is also common ground, however, that the prosecution history is admissible as an aid to construction. Actavis contend that in an appropriate case, of which this is an example, the prosecution history can be illuminating as to the correct construction of the claim, in particular because it may shed light on the answer to *Improver* question 3. Lilly contend that, as a general rule, the prosecution history is rarely useful as an aid to construction and that the present case is no exception to that general rule.

109. Most of the relevant case law is helpfully summarised in *Terrell* at §§9-100 to 9-103. The main cases where consideration has been given to the issue are *Bristol Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [1999] RPC 253, *Rohm & Haas Co v Collag Ltd* [2002] FSR 28 and *Kirin-Amgen* (see the passage at [35] quoted above). Strictly speaking, the statements about prosecution history in those and the other cases cited in *Terrell* are *obiter* because either the issue did not arise and was merely commented upon in passing (*Bristol Myers*, *Kirin-Amgen*) or because the decision was reached on other grounds (*Rohm & Haas*). Furthermore, the decision in *Rohm & Haas* pre-dated *Kirin-Amgen*.

110. Counsel for Actavis nevertheless submitted that the relevant passage in the judgment of Robert Walker LJ in *Rohm & Haas* was persuasive:

> "40. There seens to be no clear English authority on the point, even at first instance. In *Bristol-Myers Squibb Co. v. Baker Norton Inc.* [1999] R.P.C. 253 at pp. 274–275 Jacob J. has given a useful summary of the problems associated with taking account of what he called prosecution history—that is, the vicissitudes of an application file's progress through the official system—as an aid to construction of the final specification. But Jacob J. said that he did not have to decide anything about the point.
>
> 41. This court was shown a decision of the Supreme Court of the Netherlands, *Ciba-Geigy v. Oté Optics* (January 13, 1995) which contains a helpful statement of principle. In explaining that the Court of Appeal had gone too far in excluding all reference to the file, the Supreme Court said:

> 'Article 69, paragraph 1 of the EPC as interpreted in accordance with the Protocol relating thereto does indeed purport (among other things) to ensure reasonable certainty for third parties, but it does not follow that the information from the granting file that is available to third parties may never be used in support of the interpretation given by the patentee to his patent. The requirement of reasonable certainty for third parties does, however, call for restraint in using arguments derived from the granting file in favour of the patentee. Consequently, a court will only be justified in using clarifying information from the public part of the granting file, when it holds that even after the average person skilled in the art has considered the description and the drawings, it is still open to question how the contents of the claims must be interpreted. In this connection must also take into consideration that the risk of any ambiguities due to careless wording of the patent specification must in principle lie with the patentee.'

42. Apart from the last sentence (which raises a different point, and on which Mr Floyd did not rely) I would treat this as persuasive guidance. The letter to the European Patent office did not have the same status as published prior art identified in a specification, which is readily admissible. But it did contain objective information about and commentary on experiments which were conducted in response to official observations, and it could be of assistance in resolving some puzzling features of the specification. Although the prosecution process may sometimes superficially resemble a process of negotiation between the applicant and its advisers and the officials who scrutinise the file, it is not the sort of commercial negotiation which is still rigidly excluded in the construction of a written contract (see *Investors Compensation Scheme v. West Bromwich Building Society* [1998] 1 W.L.R. 896 at 913). Had it been necessary for the judge to take account of the letter in order to resolve the issue of construction, I consider that he would have been entitled to do so."

111. In my judgment this reasoning is persuasive, and it is supported by the subsequent judgment of the Court of Appeal in *Virgin v Premium*. I accept that, for the reasons explained by Jacob J in *Bristol-Myers Squibb* and Lord Hoffmann in *Kirin-Amgen*, courts should be cautious before relying upon prosecution history as an aid to construction. In the real world, however, anyone who is interested in ascertaining the scope of a patent and who is professionally advised will obtain a copy of the prosecution file (most, if not all, of which is generally open to public inspection) and will consider it to see if it sheds light on the matter. In some cases, perhaps not very many, the prosecution history is short, simple and shows clearly why the claims are expressed in the manner in which they are to be found in the granted patent and not in

some broader manner. In such a situation, there is no good reason why the court should shut its eyes to the story told by the prosecution file. On the contrary, consideration of the prosecution file may assist in ensuring that patentees do not abuse the system by accepting narrow claims during prosecution and then arguing for a broad construction of those claims for the purpose of infringement. For the reasons discussed below, I consider that the present case provides a good illustration of this.

112. Counsel for Lilly submitted that, if the prosecution history was useful as an aid to construction at all, this was only if the claims had been limited during prosecution to avoid objections of novelty or obviousness over prior art, and not where the claims had been limited to avoid objections of lack of support/added matter or clarity. I do not accept this. As a matter of principle, I can see no good reason why the prosecution history should only be useful as an aid to construction in the former type of case and not in the latter. Counsel for Lilly argued that an amendment made in order to address an objection of lack of support/added matter could not shed any light on the meaning which the applicant (subsequently the patentee) intended, because there was a distinction between the disclosure of a specification and the scope of a claim. I entirely accept that there is such a distinction. I also accept that it follows that, in some cases, a claim can be broadened during prosecution without adding subject matter. I do not accept that it follows that a limitation made to a claim during prosecution in order to avoid an objection of lack of support for a broader claim cannot shed light on the patentee's purpose in framing the claim in the manner that he did and hence upon the meaning that the skilled person would have understood the patentee to have been intending to convey by that choice of language.

Assessment

113. The key issue in this case is as to the scope of claims 1 and 12, and in particular as to the meaning of the expression "pemetrexed disodium" in those claims when interpreted in the context of the specification and taking into account the common general knowledge of the skilled team to whom the Patent is addressed.

114. Actavis' construction is that the skilled team would understand the expression "pemetrexed disodium" to mean pemetrexed disodium and nothing else. In brief summary, Actavis contend that this is a precise chemical expression with a clear meaning, that the skilled team would understand that the inventor's purpose in choosing this expression was to identify a specific chemical for use in the invention, that this understanding would be confirmed by the contrast between the reference to pemetrexed disodium on the one hand and the references to vitamin B12 (or a pharmaceutical derivative thereof) and a selected folic protein binding agent on the other, that consideration of the prosecution history confirms that the limitation to pemetrexed disodium was both intentional and made for good reason and that the claims would be invalid if construed more broadly.

115. Lilly's construction is that the skilled team would understand the expression "pemetrexed disodium" to mean (at least) pemetrexed diacid and any salt of pemetrexed which is pharmaceutically acceptable (i.e. is able to be made, is safe, sufficiently stable and does not affect the efficacy of the drug) and sufficiently soluble. As counsel for Lilly made clear, Lilly reserves the right to contend that the meaning of the expression is broader still, and embraces e.g. analogues of pemetrexed; but it is not necessary for Lilly to go that far for the purposes of the

present case. In brief summary, Lilly contends that it would be obvious to the skilled team that substitution of the free acid or a different salt would have no material effect on the way in which the invention works, in particular because (a) the invention is about reducing the toxicity, while maintaining the efficacy, of pemetrexed and (b) the active chemotherapeutic principle is the pemetrexed anion, and the skilled team would therefore conclude that "pemetrexed disodium" was being used in a figurative sense which was exemplary of the means of obtaining the benefits of the invention.

116. I shall concentrate on the question whether the scope of the claim extends to pemetrexed diacid, both because that is Actavis' lead candidate and because, if it does, then it must also embrace the dipotassium and ditromethamine salts, whereas the converse does not necessarily follow.

117. There can be no dispute that pemetrexed diacid is not pemetrexed disodium according to its "primary, literal or acontextual meaning". To use the terminology of *Improver*, it is a variant. Partly for this reason and partly for consistency with their arguments in respect of the French, Spanish and Italian designations, both parties argued their positions at least partly by reference to the *Improver* questions. I agree that these provide a helpful framework for consideration of the issue.

118. *Improver question 1*. Actavis accept that *Improver* question 1 should be answered yes with regard to each of pemetrexed diacid, dipotassium and ditromethamine. It is important to be clear, however, as to why Actavis accept this. It is for a combination of two reasons. First, looking at the invention from the oncologist's perspective, the active anti-cancer principle in an aqueous solution of pemetrexed disodium for intravenous administration is the pemetrexed anion. From the oncologist's perspective, the source of the pemetrexed anion is immaterial, since it will not affect the efficacy or safety of pemetrexed as a treatment for cancer. Nor will it affect the efficacy of co-administration of vitamin B12 (or a derivative) and a folic protein binding agent as a means of the reducing toxic side effects of pemetrexed.

119. Secondly, looking at the invention from the chemist's perspective, it must be assumed for this purpose that pemetrexed diacid, dipotassium and ditromethamine are in fact all pharmaceutically acceptable and sufficiently soluble. This is because Actavis will not obtain regulatory approval to market products containing these active ingredients if that is not the case. In order to obtain regulatory approval, Actavis will need to establish that its product is bioequivalent to Alimta. Furthermore, as described below, Actavis has done some work on establishing the pharmaceutical acceptability and solubility of each form, and so far has not encountered any fundamental obstacles.

120. *Improver question 2*. Actavis contend that *Improver* question 2 should be answered no, whereas Lilly contends that it should be answered yes. As is so often the case, resolving this question depends crucially on what one means by "the way in which the invention works", and in particular the level of generality at which that is assessed. The problem is much the same if one asks whether the variant solves the problem underlying the invention by means which have the same technical effect.

121. As I see it, Actavis do not seriously dispute that, considering the matter from the oncologist's perspective, it would be obvious that, *provided the diacid yielded a sufficient concentration of pemetrexed anions in solution and did not introduce side effects which were not obtained with the disodium salt or other complications*, then

using the diacid would have no material effect on the invention. This is because, as explained above, it would not affect the efficacy or safety of pemetrexed as an anti-cancer agent, nor would it affect the benefit to be obtained by co-administration of vitamin B12 (or a derivative) and a folic protein binding agent.

122. Actavis say that this is not the end of the matter, however, because, as is clear from the evidence of Prof Seckl and Prof Ferry, the oncologist would have no idea what the effect of substituting the diacid for the disodium salt would be on the solubility or pharmaceutical acceptability of the source of pemetrexed anions. Accordingly, the oncologist would ask the chemist. It is clear from the evidence of Dr Spargo and Prof Thurston that the chemist's answer would be, in short, "I do not know until I have tested it". It appears that the chemist's uncertainty would be greatest in relation to the diacid, less in relation to the ditromethamine salt and lowest in relation to the dipotassium salt; but even in relation to the dipotassium salt the chemist would not be confident of success before testing it (in particular because of the potential toxicity of potassium given the quantities of pemetrexed required). This is far from the level of confidence required for an affirmative answer to *Improver* question 2: see *Merck & Co Inc v Generics (UK) Ltd* [2003] 2842 (Pat), [2004] RPC 31 at [78] (Laddie J).

123. As counsel for Actavis pointed out, the uncertainty is illustrated by the position concerning pemetrexed calcium. Based on the tables in Berge and in Stahl & Wermuth, calcium would be high on the list of potential alternative counter-ions. It turns out, however, that pemetrexed calcium is not sufficiently soluble. As described below, it is for this very reason that Actavis have not pursued pemetrexed calcium although it was one of their original candidates.

124. As counsel for Actavis also submitted, it is irrelevant that, as is clear from the evidence of Dr Spargo and Prof Thurston, the chemist would be reasonably confident that he could come up with an alternative counter-ion to sodium. That is not the question.

125. Lilly has three different answers to this argument. The first I have already considered and rejected, namely that the Patent is solely addressed to the medical oncologist.

126. Lilly's second answer is that the question should be approached on the basis the skilled team knows that the variant has received regulatory approval, and hence that they know it is pharmaceutically acceptable and sufficiently soluble. I do not accept that this is the correct way in which to approach *Improver* question 2. The correct approach is to ask whether it is obvious from the skilled team's common general knowledge. As counsel for Actavis submitted, assuming that the skilled team knows that the variant has received regulatory approval is really an attempt to short circuit the analysis by providing the skilled team with the answer to the question in advance. The skilled team must be able to ask and answer question 2 before investing what may be four years' effort and considerable expense to obtain regulatory approval even on the basis of bioequivalence.

127. Lilly's third and most important answer is that Actavis' argument involves mischaracterising the invention. The invention, Lilly argues, is all about reducing the toxic side effects of pemetrexed by co-administration of vitamin B12 (or a derivative) and a folic protein binding agent. It is not about providing a convenient and safe source of pemetrexed anions in solution. The source of the pemetrexed anions makes

no difference at all to the reduction in toxic side effects achieved by such co-administration. The problem is solved by means which have precisely the same technical effect as pemetrexed disodium.

128. This is a powerful argument. In the end, however, and not without considerable hesitation, I do not feel able to accept it. My reasons are similar to those I have given in relation to the question of the identity of the addressee. Although it is true to say that the underlying invention is an improved method of treatment, that invention was not and is not patentable as such. The only patentable invention is the use of the drug for the manufacture of a medicament for use in the combination therapy (claim 1) or a product containing the drug in combination with the other ingredient(s) for use in therapy (claim 12), depending on whether one is looking at it from the perspective of EPC 1973 or EPC 2000. Either way, the patentable invention involves the making of the medicament or the product. If the proposed source of pemetrexed anions is not sufficiently soluble or is not pharmaceutically acceptable for some other reason, then as a practical matter the skilled team cannot make that medicament or product and therefore cannot obtain the benefit of the patented invention. To that extent, therefore, it would not be obvious to the skilled team that pemetrexed diacid would have no material effect on the way the invention works. The same goes for pemetrexed dipotassium and ditromethamine.

129. *Improver question 3*. Even if question 2 is answered yes, Actavis contend that *Improver* question 3 should be answered yes, whereas Lilly contends that it should be answered no. In considering this question I shall assume that, contrary to the conclusion I have just reached, question 2 is to be answered yes.

130. Actavis rely on a number of considerations as showing that the skilled team would nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the "primary, literal or acontextual meaning" of pemetrexed disodium was an essential requirement of the invention.

131. First, Actavis rely on the nature of the expression in issue. Pemetrexed disodium is the name of a specific, known chemical compound with a specific atomic formula and molecular structure. There is no sense in which it can be regarded as a figurative expression. It is not as if the expression used was "pemetrexed", which might well cover any suitable form of pemetrexed. Pemetrexed diacid, dipotassium and ditromethamine are all different chemical compounds with different atomic formulae and molecular structures. As a matter of language, therefore, this integer of the claims means only one thing and does not mean other, different things.

132. Secondly, Actavis contend that the specification is supportive of this reading. As Actavis point out, the specification begins with very broad general statements of the inventive concept expressed in terms of "an antifolate", but thereafter it concentrates specifically on pemetrexed disodium. Further, the only data contained in the specification relate to pemetrexed disodium.

133. Thirdly, Actavis rely on the fact that the claims are explicit that the pemetrexed disodium may be combined with a selected pharmaceutical derivative of vitamin B12 or a selected folic protein binding agent. Furthermore, in the latter case the claims explicitly contemplate the use of "a physiological salt or ester thereof". Actavis contend that the skilled team would not only notice this difference in language, but

also would regard it as explicable by reference to the fact that no other form of pemetrexed was known to be efficacious and safe whereas other forms of vitamin B12 and folic acid were known.

134. Fourthly, Actavis contend that this reading is supported by the expert evidence. Prof Seckl's unchallenged evidence was that the oncologist member of the skilled team, when faced with the Patent, would have assumed that the chemist involved had specifically chosen pemetrexed disodium for a reason, would not have made any assumptions one way or another regarding the adequacy of any other salt form of pemetrexed, and would have deferred to a chemist with expertise in such matters. Importantly, Prof Ferry entirely agreed with this in cross-examination. It is clear from the evidence of Dr Spargo and Prof Thurston that the chemist member of the team would not assume that any other form of pemetrexed was equivalent to pemetrexed disodium, but would appreciate that any alternative form would have to be tested for solubility and pharmaceutical acceptability. Accordingly, as Prof Thurston agreed, it would be reasonable for the chemist to assume that the patentee meant specifically that chemical form because it was the only form which had been made and tested.

135. Fifthly, Actavis contend that the skilled team would appreciate that there were a number of other reasons why the patentee might have wished to limit the claims to pemetrexed disodium even if the use of other forms of pemetrexed had no material effect on the way in which the invention worked. These include the following: so as precisely to cover the commercial embodiment, Alimta; because broader claims would lack support or be unclear; because the patentee opted for narrow claims in order to get the Patent granted rapidly; or for some other reason known only to the patentee.

136. Sixthly, Actavis ask rhetorically: if the claims are not limited to pemetrexed disodium, what are the boundaries of the claims? In essence, Lilly's construction amounts to "anything that works". As noted above, Lilly reserves the right to argue that the claims embrace pemetrexed analogues. But why stop there? If "pemetrexed disodium" is being used figuratively, why does the claim not extend to any antifolate whose toxicity is reduced by co-administration with vitamin B12 and folic acid?

137. Seventhly, Actavis rely on the prosecution history which I have set out in paragraphs 36-45 above. It is very clear from this why the claims are limited to pemetrexed disodium. In short, Lilly attempted to obtain broader claims, first to an antifolate and secondly to pemetrexed, but the examiner objected to those claims. In particular, the examiner objected that the amendment to introduce claims to pemetrexed lacked support in the description and therefore constituted added matter. The description contained textual support (but not supporting data) for broad claims to an antifolate, but it did not even contain textual support for claims to pemetrexed. Rather than argue the point, Lilly opted for narrow claims to pemetrexed disodium in order to obtain rapid grant of a patent. It also reserved the right to file a divisional application, but apparently did not do so.

138. Eighthly, Actavis contend that, if claims 1 and 12 are construed as Lilly contend, then it follows that they are invalid for added matter and/or for insufficiency for the reasons given by the examiner.

139. Lilly's answer to Actavis' first three points is that these all involve the sins of literalism and meticulous verbal analysis. The correct approach, Lilly says, is to ask what technical purpose the skilled team would think there was for specifying pemetrexed disodium in the claims and whether the skilled team would think that pemetrexed disodium was being specified in contradistinction to other suitable forms of pemetrexed.

140. Lilly's answer to Actavis' fourth point is to rely upon the fact (which must be assumed to be the case for this purpose) that it would be obvious to the skilled team that the use of a different suitable form of pemetrexed made no difference to the way in which the invention worked.

141. With respect to Actavis' fifth point, Lilly argues that none of the suggested considerations provides a cogent reason for giving a negative answer to Lord Diplock's nutshell question, which in the circumstances of the present case may be expressed as follows:

> "Does the specification make it obvious to the skilled addressee that the reference to pemetrexed disodium as being the source of pemetrexed in an intravenous solution could not have been intended to exclude some other source of pemetrexed which made no material difference to the way pemetrexed worked when administered in conjunction with vitamin B12?"

142. As for Actavis' sixth point, Lilly says that it does not matter where the boundary of the claims might or might not be. All that has to be decided is whether the scope of the claims is sufficiently broad to encompass pemetrexed diacid, dipotassium and ditromethamine.

143. With regard to the prosecution history, Lilly contends that this does not assist Actavis because the application always included claims in which the antifolate was pemetrexed disodium (or Alimta, which amounts to the same thing). Counsel for Lilly argued that the fact that broader claims were abandoned during prosecution sheds no light on the meaning of "pemetrexed disodium", particularly given that the reason for the amendments was to avoid objections of lack of support/added matter.

144. As to Actavis' eighth point, Lilly points out that the validity of the Patent is not in issue in these proceedings.

145. In my judgment Actavis' arguments are more persuasive than those of Lilly. I consider that all of Actavis' points have force, but I would add the following comments with respect to points six, seven and eight.

146. So far as the sixth point is concerned, while Lilly is correct that it is only necessary to decide whether the claim extends to pemetrexed diacid, dipotassium and ditromethamine, it is relevant to consider where the logic of Lilly's argument leads.

147. With regard to the prosecution history, I consider that this supplies a clear answer to the question why the claims are limited to pemetrexed disodium and that this does shed light on the correct interpretation of the claims. I disagree with Lilly's argument for the reasons I have already given.

148. Lilly is correct that validity is not in issue in these proceedings, but it does not follow that the court cannot consider what the consequences of Lilly's construction would be for the validity of the Patent: see e.g. *AHP v Novartis*. Furthermore, counsel for Lilly expressly accepted that (i) there was no basis in the application as filed for a claim to pemetrexed or any pharmaceutically acceptable (and sufficiently soluble) salt thereof and (ii) Lilly would have been unlikely to have succeeded in obtaining a claim framed in that manner, because it would have been rejected by the EPO on the grounds of added matter. If Lilly could not have obtained claims which explicitly referred to pemetrexed or any pharmaceutically acceptable and sufficiently soluble salt thereof because such claims would have been invalid, I cannot see how it can be right to construe "pemetrexed disodium" in claims 1 and 12 as granted as having that meaning for the purposes of infringement.

149. Having considered all of the points individually, it remains necessary to stand back and to consider overall which construction of the expression "pemetrexed disodium" accords with the Protocol and combines fair protection for the patentee and reasonable certainty for third parties. In my judgment this is Actavis' construction. Lilly deliberately limited the claims of the Patent to pemetrexed disodium. There was nothing to prevent Lilly seeking broader claims if it thought it was entitled to them. There is nothing in the specification or the common general knowledge of the skilled team to suggest to the skilled team that Lilly intended to use the expression "pemetrexed disodium" in anything other than its conventional sense or that it made some mistake in using that expression, and the prosecution history shows that the opposite is the case. Confining Lilly to the scope of claim that it chose with the benefit of skilled professional advice provides Lilly with fair protection, and does not expose Lilly to the risk of the Patent being invalid on the grounds of added matter and/or insufficiency. Construing the claim as extending to (at least) any form of pemetrexed which is pharmaceutically acceptable and sufficiently soluble would not provide a reasonable degree of certainty for third parties. Any other conclusion would fail to give effect to the Protocol and would be tantamount to treating the claims as a mere guideline.

The judgment of the Düsseldorf Regional Court

150. Lilly issued proceedings against Actavis Group PTC ehf (the Third Claimant in these proceedings) and Actavis Deutschland GmbH & Co KG (the Fifth Claimant until recently) before the Düsseldorf Regional Court on 20 July 2012. These proceedings were served on Actavis on 9 August 2013. At that time, Lilly's only claim was in respect of pemetrexed dipotassium, since that was the only salt which had been mentioned in Bird & Bird's letter dated 12 July 2012. Actavis challenged the jurisdiction of the German court on the ground that the English court was first seized of the dispute, but that challenge was rejected both by the Düsseldorf Regional Court and by the Düsseldorf Oberlandesgericht (Court of Appeal). On 14 June 2013 Lilly joined Kálmán Petró, the managing director of Actavis Management GmbH (the parent company of Actavis Deutschland GmbH & Co KG and not a claimant in these proceedings) as a defendant to the German proceedings and added claims in respect of pemetrexed diacid and ditromethamine.

151. In its judgment dated 3 April 2014 the Düsseldorf Regional Court (Judges Dr Voss, Dr Reimnitz and Dr Thom) held that the use of pemetrexed dispotassium would infringe claim 1 of the German designation of the Patent. In essence, it held that there

was no literal infringement, but that there was infringement on the basis of the doctrine of equivalents. It went on to hold that there was a threat by Actavis Group PTC ehf to infringe the Patent by dealings in pemetrexed dispotassium, but not by Actavis Deutschland GmbH & Co KG or Mr Petró. By contrast, it held that there was no threat by the defendants in relation to pemetrexed diacid or ditromethamine. Accordingly, it did not consider whether the diacid or ditromethamine fell within claim 1.

152. The Düsseldorf Regional Court is an experienced patent court, and its judgments are entitled to considerable respect. Furthermore, its judgment is detailed, careful and clearly reasoned. Nevertheless, I am unable to agree with its conclusion with regard to pemetrexed dipotassium. I will not lengthen this judgment still further by giving an exhaustive explanation of my reasons for this disagreement. Most of them will be apparent from a comparison of my reasoning with that of the Düsseldorf Regional Court. I would, however, draw attention to the following points.

153. First, the evidence before me was different to the evidence before the Düsseldorf Regional Court. In particular, although the Düsseldorf Regional Court had written evidence from Prof Ferry before it, it did not have the advantage which I had of hearing Prof Ferry being cross-examined on his written evidence. As I have observed above, there was some divergence between Prof Ferry's oral evidence and his written evidence. Likewise, the Düsseldorf Regional Court did not have the benefit of the hearing the chemists cross-examined on their reports.

154. Secondly, it appears that the arguments on both sides differed in some respects from those before me. In particular, Lilly relied on the fact that 677 disclosed that pemetrexed could be used in the form of a pharmaceutically acceptable salt, including specifically potassium, as supporting its case. Furthermore, the Düsseldorf Regional Court accepted this argument (see page 42 of the translation). By contrast, Lilly placed no reliance upon 677 before me, no doubt anticipating the riposte that the skilled team would notice the contrast between 677 and the Patent and draw the conclusion that limitation of the latter to pemetrexed disodium was intentional.

155. Thirdly, the Düsseldorf Regional Court considered the matter solely from the perspective of the oncologist. I have explained above why I do not agree with this.

156. Fourthly, in finding infringement by reason of equivalence alone, I respectfully consider that the Düsseldorf Regional Court has not given proper effect to the Protocol, but rather has treated the claims as a mere guideline. As the evidence of the German law experts (Uwe Scharen, a former judge of the Düsseldorf Regional Court, Court of Appeal and Bundesgerichsthof (Federal Supreme Court) and Professor Dr Klaus Melullis of Karlruhe Institute of Techology) filed by the parties before me confirms, German law addresses the question of equivalence by asking the three questions identified in the quintet of cases decided by the Federal Supreme Court on 14 March 2002 to which Lord Hoffmann referred in *Kirin-Amgen* at [75]. These questions are similar to the *Improver* questions, although, as Lord Hoffmann noted, there is a difference in the way in which the German courts formulate the second question. In particular, as the Federal Supreme Court (Judges Prof Dr Meier-Beck, Keukenschrijver, Mühlens, Dr Grabinski and Schuster) recently confirmed in its judgment dated 10 May 2011 in Case X ZR 16/09 *Occlusion Device* at [36], German law does have the equivalent of *Improver* question 3 (as the late Laddie J had

concluded in *Celltech R & S Ltd v MedImmune Inc* [2004] EWHC 1124 (Pat) at [59]-[63]). In the present case, it seems to me that the Düsseldorf Regional Court's answer to question 3 simply reiterates its reasoning in answering question 2.

157. Fifthly, the Düsseldorf Regional Court did not have regard to the prosecution history (see page 52 of the translation). As I understand it, the position in German law with regard to use of the prosecution history is similar to that in UK law: the prosecution history is admissible as an aid to construction, but reference to it is generally discouraged. For the reasons I have explained, I consider that in the present case the prosecution history is directly relevant to, and helpful in determining, the issue of interpretation.

158. Finally, the Düsseldorf Regional Court did not consider the consequences of its construction for the validity of the Patent.

Construction of the French designation of the Patent

French law

159. There is little dispute as to the applicable principles of French law. It is convenient to quote from the joint memorandum prepared by Prof Galloux and Prof Azéma:

> "**General comments on the French legal system**
>
> After discussion, neither of the two experts noted any disagreement on this section.
>
> They also agreed, in particular, on the following conclusions:
>
> - They reiterate that case-law does not constitute a real source of law: Only legislation (whether or not codified, and administrative texts such as decrees) is applied by the Courts which never refer to previous case rulings.
>
> - The '*cours*' and '*tribunaux*' (Courts) are indeed prohibited from handing down '*arrest de règlement*', i.e. from giving a general and impersonal solution in the particular case on which they are ruling.
>
> - It is nonetheless true that homogeneous sets of case-law, referred to as '*jurisprudence constante*' may have an influence on the way the Courts rule, as do the rulings of the Supreme Court (*Cour de cassation*), since the role of said Court is, precisely, to harmonise the case-law of the lower Courts.
>
> **Doctrine of equivalents**
>
> After discussion, neither of the two experts noted disagreement on this section either.
>
> They comment in particular:

- France is bound by Article 69 of the European Patent Convention (EPC) and by its Protocol on Interpretation, amended on revision of the EPC in 2000. Article L.613-2 of the Intellectual Property Code (IPC) introduced Article 69 of the EPC into French law.

Regarding European patents designating France, said provisions are directly applied by the Courts.

- However, the doctrine of equivalents is not, as such, enshrined in French law. It is the subject of a doctrinal definition which has been widely adopted by the Courts, in particular the Supreme Court, according to which means which are different in form but perform the same function to achieve a similar result, are equivalent. Thus equivalence is characterised by identical function.

- For this doctrine to apply, there is no need for the claim to be unclear or for it to be widely worded (thus referring to 'general means')

- On the other hand, where the claim is narrowly worded, the doctrine of equivalents only applies on condition that the function is a new one. Should the function of the means be known, the scope of the claim shall be limited to the claimed structure. Should the function be new, any means which perform the same function with a view to the same result shall be considered to be equivalent to the claimed means, even if the latter is precisely claimed.

- Equivalents are distinguished from simple embodiment variations ('*variants d'exécution*') which are insignificant changes affecting non-essential means of the invention, i.e. which do not produce or do not contribute to producing a technical effect.

Use of the prosecution history before the EPO

After discussion, neither of the two experts noted any disagreement on this section. In particular, they agree:

- That the French Courts quite often refer to the prosecution history file where interpretation of the claims is concerned, and to assess the scope of protection granted. The Supreme Court accepts such a consideration so long as the claims remain the source of interpretation.

- Said documents are considered as being factual data amongst all such data subject to the Court's assessment. From this point of view, the French Courts do not distinguish between the different types of document arising from the prosecution file

> (letters from the examiner, statements by the patentee or by third parties etc.): all these documents have the same probative value.
>
> - Reference to said file is not restricted to cases where infringement by equivalence is alleged."

160. It is worth elaborating on two points. The first is the penultimate point made by the experts under the heading "Doctrine of equivalents". Where the claim is narrowly worded to cover specific means ("*moyens particuliers*") rather than general means ("*moyens généreaux*"), then the court must consider the function of that means and consider whether it is a novel function. If the function of the means is not novel then the claim monopoly is limited to the particular claimed structure. An example of this principle being applied is in the judgment of the Cour de Cassation (Supreme Court) in Appeal S 09-15668 *Institut Pasteur v Chiron Healthcare* of 23 November 2010. In that case the means in question was a specific means of DNA/RNA hybridization to detect HIV with a probe composed of a particular DNA fragment. The function of the specific means was known at the priority date and so the claim integer could not be extended to cover any other method of hybridization that achieved the same function. Another example of this principle being applied is in the judgment of the Tribunal de Grande Instance (High Court) of Paris in Case 09/01863 *Mundipharma Laboratories GmbH v Sandoz SAS* of 2 July 2010. In that case the integer that was said to be infringed by equivalence was the use of cellulose ether (the alleged equivalent being xanthan gum). The function of the cellulose ether was not novel at the priority date and as such the scope of the claim could not be extended to cover any means which achieved that function.

161. Conversely, if the function of the particular claimed means is novel, then even though the claim is explicitly drafted in a narrow sense, the claim will be treated as covering a means which performs the same function and which achieves a similar result. Thus in the judgment of the Supreme Court in Appeal No. 06-17915 *B2M Industries v Acome* of 20 November 2007 the function of the particular integer that was said to be infringed pursuant to an equivalent was held to be novel, and therefore because the means that was said to be equivalent to that integer performed the same function and produced the result sought by the invention the means was equivalent to that integer.

162. Secondly, the prosecution history is of particular relevance when the scope of the claims have been narrowed during the prosecution process, in particular where that narrowing was necessary to obtain the grant of the patent at issue. Both experts cited the judgment of the Cour d'Appel (Court of Appeal) of Paris in Case No. 08/00882 *Hewlett Packard GmbH v Agilent Technologies Deutschland GmbH* of 27 January 2010 as illustrating this principle. In that case the patentee argued that its claim to a pumping apparatus covered all devices whose volume per stroke of the pistons was controlled in response to the desired flow, because the patent was the first to teach such a device. The Court of Appeal rejected this argument, and held as follows:

> "But whereas if it is accepted, in the presence of a groundbreaking invention, that the patent can describe a way of carrying out the invention and claim any other possible way of carrying it out, it cannot be given a general scope, even if it is groundbreaking, if its claims are drafted in restrictive terms;

> Whereas more specifically, a non-ambiguous claim with narrow scope cannot through interpretation be given a general scope, in particular when the patentee has been forced, in order to distinguish the invention from the prior art, to limit the scope of the claim in the context of the granting process;
>
> …
>
> Yet whereas the patentee who amended its clauses to give them a limited scope may not, without putting the safety of third parties at risk, claim that the amendments were not necessary, nor that the limited claims have the same scope as the broader claims;
>
> …"

Assessment

163. As I understand it, it is common ground that none of pemetrexed diacid, dipotassium and ditromethamine are within the scope of the claims of the Patent on a literal interpretation. The issue is whether they are within the scope of the claims of the Patent applying the doctrine of equivalents.

164. In my judgment they are not within the scope of the claims for two main reasons. First, the doctrine of equivalents does not apply in the circumstances of the present case. The means in issue is "pemetrexed disodium", which is a specific means (*moyen particulier*). The function of that means was not novel: its function was its efficacy in inhibiting tumour growth, and that was known at the date of the Patent. It follows that the expression "pemetrexed disodium" must be interpreted as being limited to the particular compound specified by that expression.

165. Secondly, the prosecution history shows that the claims were limited to pemetrexed disodium in order to obtain the grant of the Patent. In those circumstances it would not be appropriate to interpret the claims as having a broader scope.

Construction of the Italian designation of the Patent

Italian law

166. There is some common ground between the experts as to Italian law, but also some disagreement. As in France, the law is contained in the relevant statutory provisions. Case law illustrates how the courts apply those provisions, but even decisions of the Corte Suprema di Cassazione (Supreme Court) are not binding, although they are normally followed. The following matters were agreed by the experts in their joint memorandum:

> "Articles 69 EPC and Protocol are directly applicable in Italy.
>
> There is in Italy a doctrine of equivalence which applies when not all the claimed features are reproduced literally by the accused product or process.

> No specific rules are set forth by Italian law on the relevance of the file history to the purpose of claim construction.
>
> No decisions of the Supreme Court have been delivered acknowledging the relevance of the file history.
>
> …
>
> The Supreme Court starting from the *Barilla*'s case has broadened the scope of the doctrine of equivalence also to solutions which are inventive, even though Prof. Franzosi believes that the issue is not the inventive step of the infringing solution but the relation of the accused infringement and the claims.
>
> On the equivalence, Prof. Franzosi agrees with the summary of the principles of the case law of the Supreme Court in paragraph 70 of Prof. Guglielmetti's report, even though Prof. Franzosi believes that such case law does not properly reflect the present law.
>
> …
>
> As to the date to be considered for determining the common general knowledge available to the skilled person in order to assess the infringement, Prof. Franzosi and Guglielmetti agree that the date to be considered is that on which the infringement is to be assessed, although Prof. Franzosi thinks that the case law is not entirely clear."

167. The statutory provision currently in force in Italy regarding the scope of protection of patent claims is Article 52 of the Code of Industrial Property ("CIP"), which states as follows:

> "1. Claims indicate, specifically, what is intended to form the object of the patent.
>
> 2. The limits of protection are determined by the claims; however description and drawings serve to interpret (have the function of interpretation) the claims.
>
> 3. The rule of sect. 2, above, has to be understood so as to guarantee at the same time a fair (equitable) protection to the owner and a reasonable legal security for third parties.
>
> 3*bis*. For determining the scope of protection conferred by a patent, due consideration is given to every element equivalent to an element indicated in the claims."

168. With the exception of section 3*bis*, this provision came into force on 19 March 2005. Section 3*bis* was added by Legislative Decree No. 131/2010 with effect from 13 August 2010 to give effect to the revised Protocol to Article 69 in EPC 2000. It is

common ground that there have been no Supreme Court decisions addressing issues of infringement by equivalence since Article 52 CIP came into force. Although there have been Supreme Court judgments addressing equivalence since 2010, these are all cases that were applying the law in force before the CIP, namely Royal Decree No. 1127 dated 29 June 1939 (the "LI"), and its implementing regulation Royal Decree No. 244 of 5 February 1940 ("the RI"), as amended by the Decree of the President of the Republic No. 338 dated 22 June 1979 ("the DPR"). Article 5 of the RI stated that:

> "The description, including the indications laid down by Art.28 of [the LI] must begin with a summary that is for technical information purposes only, and must end with one or more claims in which it must be specifically indicated what is intended to form the subject matter of the patent."

169. There is a debate between the experts as to whether or not the enactment of Article 52 CIP changed the previous law. Prof Franzosi considers that it did, whereas Prof Guglielmetti considers that it did not. Both experts refer to the fact that the DPR was drafted by a commission chaired by Professor Giorgio Floridia following the ratification of the EPC 1973 by Italy in order to adapt Italian law to the Convention. The Floridia Commission considered that it was not necessary to amend the final part of the original wording of Article 5 of the RI in order to make it consistent with Article 69 EPC. On the other hand, Prof Franzosi states that Article 52 CIP was inserted as a result of his personal insistence with the commission which drafted the CIP because of the reluctance of Italian legal culture to accept the controlling role of the claims.

170. In my judgment it cannot be assumed that the enactment by the Italian legislature of a new statutory provision which more clearly reflects Article 69 and the Protocol than the old provision will have no effect on the law. On the contrary, it seems to me to be calculated to require Italian courts to focus more closely on what is required by Article 69 and the Protocol. This is particularly true with the recent addition of section 3*bis* to Article 52 CIP. As Prof Franzosi points out, this requires the court to consider equivalence on an element by element basis, dividing the claim into integers and considering whether or not each integer is present either literally or by equivalence. As is stated in an article commenting on the 2010 reform cited by Prof Guglielmetti in paragraph 38 of his first report, "The centrality of the claims is confirmed by these regulations".

171. With regard to the question of equivalents, as can be seen from the joint memorandum, Prof Franzosi accepts that Prof Guglielmetti has accurately summarised the existing jurisprudence of the Supreme Court in cases such as Case No. 257 *Forel SpA v Lisac* (13 January 2004), Case No. 30234 *Barilla GER Fratelli SpA v Pastifico Fazion SpA* (30 December 2012) and Case No. 622 *Entsorga Italia Srl v Ecodeco Srl* (11 January 2013) in paragraph 70 of his first report:

> "(i) the '*inventive core*' of the patent must first be identified;
>
> (ii) the contested device infringes the patent if it reproduces the '*inventive core*' of the patent, unless it is non-obvious in respect of the '*inventive core*';

(iii) when some elements of the infringing device include non-obvious modifications, it does not automatically exclude infringement by equivalence if the modifications do not exclude the use, even in part, of the patent; and

(iv) the mere lack of some elements of the patented device in the contested device does not automatically exclude infringement if the '*inventive core*' of the idea protected by the patent is reproduced in the contested device, and if the removal of those elements in the contested device is not inventive."

172. It is also common ground between the experts that, in addition or in the alternative to the "obviousness" test outlined above, Italian courts frequently apply a "triple identity" test: does the variant (i) perform substantially the same function (ii) in substantially the same way (iii) to achieve substantially the same result?

173. Nevertheless, Prof Franzosi expresses the opinion that this jurisprudence does not correctly reflect the current statutory provisions because it pays insufficient regard to the role of the claims. In particular, it is his view that, if it is evident that there has been a conscious limitation to the claim, then the doctrine of equivalence is excluded. For the reasons given above, I consider that in future the Italian courts will be bound by Article 52 CIP to pay closer attention to the wording of the claims. Furthermore, Prof Franzosi was able to point to some recent lower court decisions which support this point of view. An example is Case 4114/2011 *EG SpA v AstraZeneca AB* (Ordinary Court of Turin, 1 April 2011), where the court held that EG's product did not infringe a claim requiring a minimum of 99.8% enantiomeric excess of magnesium esomeprazole because this was clear limitation in the claim and the accused product did not have the required purity level (consistently with the decision of Kitchin J in *Ranbaxy v AstraZeneca*). Accordingly, I accept Prof Franzosi's opinion on this point.

174. So far as the prosecution history is concerned, it is common ground between the experts that (i) there is no doctrine of prosecution history estoppel and (ii) there is no clear rule as to the relevance, if any, of the prosecution history as an aid to interpretation of the claims. The Supreme Court has not opined on the latter point, and decisions of lower courts can be found going both ways. Prof Guglielmetti considers that the weight of authority points away from reliance on the prosecution history, whereas Prof Franzosi considers that there is a recent trend towards reliance upon it. Again, *EG v AstraZeneca* is an example of this.

175. In my judgment the Supreme Court can be expected, when called upon to consider this question, to adopt a similar position to that adopted by other European appellate courts on this issue. In short, I consider that the Supreme Court will not encourage reference to the prosecution history, but nevertheless will hold that, in an appropriate case, the prosecution history can be relied upon as an aid to construction of the claims, particularly where it is clear the applicant has intentionally limited the scope of the claims during the course of prosecution. This would accord with the argument advanced by Prof Guglielmetti in an article which he acknowledges in paragraph 29 of his first report.

Assessment

176. As I understand it, it is again common ground that none of pemetrexed diacid, dipotassium and ditromethamine are within the scope of the claims of the Patent on a literal interpretation. The issue is whether they are within the scope of the claims of the Patent applying the doctrine of equivalents.

177. Lilly contends that it is clear that pemetrexed diacid, dipotassium and ditromethamine are equivalent to pemetrexed disodium whether one applies the "obviousness" or "triple identity" tests, and accordingly they fall within the scope of the claim.

178. Counsel for Actavis did not argue that pemetrexed diacid, dipotassium and ditromethamine were not equivalent to pemetrexed disodium under Italian law. Rather he argued that the correct interpretation of the claims was that such equivalents were nevertheless excluded from the scope of protection. This was for two reasons. First, because on its face the Patent clearly demonstrated a conscious intention of the patentee to limit the claims to pemetrexed disodium. Secondly, because if there was any doubt about that, it was amply confirmed by the prosecution history.

179. With some hesitation in respect of the first of these points, but rather less in respect of the second, I accept both these points. Accordingly, I conclude that pemetrexed diacid, dipotassium and ditromethamine are not within the scope of the claims.

Construction of the Spanish designation of the Patent

Spanish law

180. Again, there is some common ground between the experts as to Spanish law, but also some disagreement. So far as precedent is concerned, the experts are agreed that only reiterated decisions of the Tribunal Supremo (Supreme Court) are binding on the lower courts. In the lower courts, the majority of patent cases are heard by the courts of Madrid and Barcelona, with the latter tending to handle the pharmaceutical cases. Accordingly the judgments of those courts are particularly persuasive.

181. With regard to substantive law, the following matters were agreed by the experts in their joint memorandum:

> "**a. General issues on Spanish Law (questions addressed in the reports issued by Prof. Bercovitz and Desantes)**
>
> 1. The sources of Spanish Law.
>
> 2. The scope of binding effect of Spanish jurisprudence.
>
> 3. The direct effect and direct applicability in Spain of International Treaties, including the European Patent Convention (EPC).
>
> 4. The primacy of the EPC over national Law in Spain.
>
> 5. The EPC should be the basis for the interpretation of the corresponding Spanish patent Law.

6. The direct effect, direct applicability and primacy in Spain of Article 69 EPC and the Protocol on its Interpretation.

7. Art. 1 of the Protocol of Interpretation constitutes a compromise between the extremes of strictly literal claim construction and the relegation of the claims to the status of guidelines.

8. Art. 69 EPC and its Protocol of Interpretation have played an important role in Spain for extending the protection of the patent to infringement by equivalence cases.

b. Direct patent infringement. Equivalents (questions addressed in the reports issued by Prof. Bercovitz and Desantes)

1. The notion of equivalence.

2. The Spanish Courts understand that the scope of the patent should be objectively based on claim content regardless of the subjective intention of the patentee.

3. The scope of protection of the patent extends to equivalents.

4. In Spain, the doctrine of equivalents is not applied to the invention as a whole but to each of the elements described in the claims - element by element analysis.

5. In Spain, the scope of protection of the claims must in all cases be construed in the light of the description and the drawings.

6. The EPC does not impose on national courts any specific and closed definition of equivalents.

c. Application of the doctrine of equivalents by Spanish Courts (question addressed in the reports issued by Prof. Bercovitz and Desantes)

1. The doctrine of equivalents cannot be used to extend the scope of the patent beyond what the applicant has protected nor should equivalence be used to allow the patentee to portray a claimed feature as ‘irrelevant’ or to compensate for mistakes.

2. Spanish Courts have been alternating various types of tests, as shown by the Supreme Court judgment dated 10 May 2011 (Olanzapine case).

3. The relevance of the test of obviousness, amongst others, in pharmaceutical cases (Olanzapine case)

4. Spanish Courts in fact apply the doctrine of one's own acts (*doctrina de los actos propios*) while sometimes they refer

erroneously to the 'prosecution history estoppel' doctrine, which is not applied as such.

5. The doctrine of one's own acts is a general civil law doctrine which applies not only to patent claim construction but also to any other civil law issue.

6. An own act can be something different than a change of a claim.

7. The requirements for the application of the doctrine of one's own acts.

8. None of the judgments quoted in paragraph 60 of the Expert Report by Prof. Bercovitz refer to patents but to general civil law cases and there are cases where the doctrine has been applied to patents.

9. Limitations are also possible in other areas further than prior art.

10. The Spanish Courts have never considered whether the relevant date is the priority date or the publication date in a case on which this issue was relevant for the outcome of the case."

182. As appears from this, the leading case on equivalents is the Supreme Court's decision in Judgment No. 309/2011 *Laboratorios Cinfa SA v Eli Lilly & Co Ltd* ("Olanzapine") of 10 May 2011. In that case the Supreme Court considered a number of tests that had previously been applied, but did not settle on a definitive test. The experts are agreed that in a pharmaceutical case a test that is particularly likely to be applied is an adapted *Improver* test which is sometimes referred to as the "obviousness" test. This involves asking the following questions:

"1. Does the variant alter the functioning of the invention? If the answer is yes, equivalence does not exist. If the answer is no, i.e. the functioning of the invention is not altered, it is necessary to ask the next question.

2. Would the variant have been obvious to a skilled person who read the patent on the date when it was published? If the variant was not obvious i.e. it is inventive, there is no equivalence. If the answer is yes, it is still necessary to ask the third question.

3. Would the person skilled in the art who read the patent have understood, given the terms used in the claim, that the patent holder intended that strict compliance with the literal wording was an essential requirement of the invention? If the answer is yes then there can be no equivalence. But if strict compliance is not essential then the variant may be equivalent."

183. Despite the phraseology of the second question, the experts agree that this does not involve the same test as the step of inventive step for validity purposes. Rather the question is whether it is obvious to the skilled person or team that the variant is equivalent to the claimed integer. It is only obvious if this would be predictable: see the decision of Audiencia Provincial (Court of Appeal) of Barcelona in Judgment No. 434/2012 *H. Lundbeck A/S v Laboratorios Cinfa SA* of 19 December 2012.

184. As indicated in the joint memorandum, the experts agree that the "doctrine of one's own acts" should be applied if there is relevant material in the prosecution history. An "own act" can include an amendment to a claim, but it is not limited to amendments. It is agreed that this doctrine is applied restrictively, but there is a slight disagreement as to how restrictively. I shall adopt the summary given by the Spanish national group in its response to AIPPI Question 229 regarding the use of prosecution history in post-grant patent proceedings which is quoted by Prof Bercovitz in paragraph 72 of his second report:

> "The '*actos proprios*' doctrine, as established in Spanish case law, is very clear on the requirement whereby the 'statements' must be unequivocal, clear, precise, conclusive, undoubted and must not reflect any kind of ambiguity. From that perspective, only explicit statements would have to be considered."

185. More importantly, the experts do not agree as to whether or not the doctrine is only applicable where the patentee has expressly limited the claim to overcome a prior art objection. In my judgment the evidence shows that the doctrine is most likely to be applied in such a situation, but does not establish that it is limited to that situation. Thus the Spanish national group's response to AIPPI Question 229 was that it did not matter why the amendments or arguments were made. Counsel for Lilly relied in particular on a passage from the decision of the Court of Appeal of Madrid in Judgment No. 292/2008 *Ros Roca Group SL v Sistemas y Vehícuols de Alta Technología SA* of 1 December 2009, where reference was made to amendments to overcome prior art objections, as in the case under consideration. The Court went on, however, to state the applicable principle in the following way:

> "The Chamber deems it a contradiction with his own acts for the patent's applicant to have renounced a broader scope of protection during the patent's application proceedings, by introducing technical features which reduce the scope protected by its claims, and, subsequently, after the registration, to have attempted to broaden the scope of protection to include in its features that had been excluded from it by virtue of restrictions added by the applicant himself."

Assessment

186. As I understand it, it is again common ground that none of pemetrexed diacid, dipotassium and ditromethamine are within the scope of the claims of the Patent on a literal interpretation. The issue is whether they are within the scope of the claims of the Patent applying the doctrine of equivalents.

187. Applying the adapted *Improver* questions, Actavis do not dispute that the answer to question 1 is yes. In my judgment the answer to question 2 is no for the reasons I have given when answering the equivalent question under UK law. Even if the answer to question 2 is yes, I consider that the answer to question 3 is yes for the reasons I have given when answering the equivalent question under UK law. In so far as those reasons involve considering the prosecution history, I consider that the requirements for application of the "own acts" doctrine are met. The amendments to the claims made by Lilly, and the reasons for making those amendments, are explicit, unequivocal, clear, precise, conclusive, undoubted and do not reflect any kind of ambiguity. The principle stated by the Madrid Court of Appeal in the *Ros Roca* case applies here. Accordingly, I conclude that pemetrexed diacid, dipotassium and ditromethamine are not within the scope of the claims.

Actavis' proposed products

188. In a confidential letter dated 10 December 2013 Actavis set out details of the formulations of their proposed products on which Actavis were focussing. The precise details of these proposed formulations are confidential and are not important. In summary, the proposed products are as follows:

    i) pemetrexed diacid supplied as a concentrated aqueous solution for dilution [REDACTED];

    ii) pemetrexed dipotassium as a lyophilised (i.e. freeze-dried) powder;

    iii) pemetrexed ditromethamine as a lyophilised powder [REDACTED].

Direct infringement

189. For the reasons given above, I have concluded that neither pemetrexed diacid, nor pemetrexed dipotassium nor pemetrexed ditromethamine falls within the scope of the claims 1 or 12 of the UK, French, Italian or Spanish designations of the Patent. It is common ground that it follows that dealings in pemetrexed diacid, dipotassium and ditromethamine by Actavis will not constitute direct infringement of the UK, French, Italian or Spanish designations of the Patent. Accordingly, it is not necessary for me to set out the details of the relevant French, Italian or Spanish law.

Indirect infringement

Infringement of the UK designation

190. *The law*. Section 60 of the Patents Act 1977 provides, so far as is relevant, as follows:

> "(2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable

> for putting, and are intended to put, the invention into effect in the United Kingdom.
>
> (3) Subsection (2) above shall not apply to the supply or offer of a staple commercial product unless the supply or the offer is made for the purpose of inducing the person supplied or, as the case may be, the person to whom the offer is made to do an act which constitutes an infringement of the patent by virtue of subsection (1) above."

191. Section 130(7) declares that a number of sections in the 1977 Act, including section 60, "are so framed as to have, as nearly as practicable, the same effect in the United Kingdom as the corresponding provisions of the European Patent Convention, the Community Patent Convention and the Patent Co-operation Treaty have in the territories to which those Conventions apply." Section 130(6) provides that references to the CPC are to "that convention as amended or supplemented".

192. Article 26 of the CPC, as revised in 1989, provides as follows:

> "*Prohibition of indirect use of the invention*
>
> 1. A Community patent shall also confer on its proprietor the right to prevent all third parties not having his consent from supplying or offering to supply within the territories of the Contracting States a person, other than a party entitled to exploit the patented invention, with means relating to an essential element of that invention, for putting it into effect therein, when the third party knows, or it is obvious in the circumstances, that these means are suitable and intended for putting that invention into effect.
>
> 2. Paragraph 1 shall not apply when the means are staple commercial products, except when the third party induces the person supplied to commit acts prohibited by Article 25.
>
> 3. Persons performing the acts referred to in Article 27(a) to (c) shall not be considered to be parties entitled to exploit the invention within the meaning of paragraph 1."

193. The background to Article 26 CPC, and hence section 60(2) of the 1977 Act, was explained by Jacob LJ in *Grimme Landmaschinefabrik GmbH v Scott* [2010] EWCA Civ 1110, [2011] FSR 7 at [82]-[98].

194. *The facts*. These are not in dispute. Section 6.6 of the Summary of Product Characteristics for Alimta states as follows:

> "3. Reconstitute 500mg vials with 20 ml of sodium chloride 9 mg/ml (0.9%) solution for injection, without preservative, resulting in a solution containing 25 mg/ml pemetrexed. Gently swirl each vial until the powder is completely dissolved. The resulting solution is clear and ranges in colour from colourless to yellow or green-yellow without adversely

> affecting product quality. The pH of the reconstituted solution is between 6.6 and 7.8. **Further dilution is required**.
>
> 4. The appropriate volume of reconstituted pemetrexed solution must be further diluted to 100 ml with sodium chloride 9 mg/ml (0.9%) solution for injection, without preservative, and administered as an intravenous infusion over 10 minutes."

195. The effect of this reconstitution and dilution is that there will be present in a solution of Alimta used for the infusion both pemetrexed ions and sodium ions which emanate both from the pemetrexed disodium and from the saline solution. Thus there will be an excess of sodium ions. The solution will also contain chloride ions from the saline.

196. Actavis admit that their product will be reconstituted and diluted in the same way, save that in the case of the diacid it will simply be diluted. The result will be a solution containing pemetrexed ions, sodium ions and chloride ions. Again, there will be an excess of sodium ions present, albeit that they are all derived from the saline. If the product is pemetrexed dipotassium, there will also be potassium ions present. If it is pemetrexed ditromethamine, ditromethamine ions will be present.

197. Actavis also admit that it would be obvious to the skilled team that this will occur.

198. Finally, Actavis also admit that the product will be administered in combination with vitamin B12 and folic acid, and that they know this.

199. *Assessment*. Lilly contends that, even if pemetrexed diacid, dipotassium and ditromethamine do not fall within claim 1 of the Patent and therefore dealings in those products by Actavis will not constitute direct infringement, such dealings will amount to indirect infringement under section 60(2). (As noted above, Lilly does not rely on claim 12. In any event, Lilly cannot be in a better position with regard to claim 12.) In summary, Lilly's argument runs as follows:

    i) Pemetrexed diacid, dipotassium and ditromethamine are means relating to an essential element of the invention since they provide a source of pemetrexed ions.

    ii) The means is for putting the invention into effect. The reconstituted and diluted solution of Actavis' product (or the diluted solution in the case of the diacid) will put the invention into effect in precisely the same manner as a reconstituted and diluted solution of Alimta, since both will contain pemetrexed ions (and sodium ions for that matter).

    iii) Actavis have the requisite knowledge.

    iv) The persons to whom Actavis' product will be supplied are not entitled to work the invention.

200. Actavis deny indirect infringement. Actavis point out that the issue only arises if the expression "pemetrexed disodium" in claim 1 of the Patent means pemetrexed disodium and not any form of pemetrexed that is pharmaceutically acceptable and sufficiently soluble. Accordingly, Actavis contend that they cannot be liable for

indirect infringement because at no point is pemetrexed disodium used in the manufacture of a medicament by anyone. The fact that, when Actavis supply their product to third parties who reconstitute (or in the case of diacid, dilute) the Products with saline, there will be sodium ions and pemetrexed ions floating around, does not mean that those third parties are implementing the invention; they have not used pemetrexed disodium in the manufacture of a medicament as required under claim 1. It is no answer to this to say that pemetrexed ions on their own constitute an essential element of the invention, as this is just another way of saying that the claim does not require pemetrexed disodium, but merely requires any form of pemetrexed which makes pemetrexed ions available.

201. I agree with Actavis' analysis. Accordingly, I conclude that there will be no indirect infringement by Actavis of the UK designation of the Patent.

Infringement of the French, Italian and Spanish designations

202. The experts considered the French, Italian and Spanish laws in their respective reports. There was a substantial measure of agreement in each case. In very brief summary:

i) In France, Article L 613-4 of the Intellectual Property Code ("IPC") is very similar to section 60(2). As I understand it, it is also intended to implement Article 26 CPC.

ii) In Italy, it does not appear that there is any specific statutory provision for indirect infringement derived from Article 26 CPC. Rather, Italian law provides for contributory infringement applying the general rules on tortuous liability. The effect of the case law is broadly similar to the law in the other countries.

iii) In Spain, Article 51 of the Spanish Patents Act ("SPA") is very similar to section 60(2). As I understand it, it is also intended to implement Article 26 CPC.

203. I do not consider it necessary to go into further detail, because I did not understand counsel for Lilly to contend that, if Lilly failed to establish indirect infringement applying UK law, Lilly could nevertheless succeed applying any of the foreign laws. I therefore conclude that Actavis will not infringe the French, Italian or Spanish designations either.

Law applicable to the DNI claims

204. As I stated in my judgment of 27 November 2012 at [31], it is common ground that, by virtue of Article 8(1) of European Parliament and Council Regulation 864/2007/EC of 31 July 2007 on the law applicable to non-contractual regulations ("the Rome II Regulation"), the law applicable to the question of whether Actavis' proposed acts would infringe each non-UK designation of the Patent is the *lex loci protectionis*, that is, the substantive patent law of the relevant country. As indicated above, however, an important dispute has arisen between the parties to the law which is applicable to the other conditions which must be satisfied by Actavis in order to obtain DNIs: is this the *lex fori* (as Actavis contend) or is it the *lex loci protectionis*

(as Lilly contends)? It is common ground that this issue depends on the proper interpretation of the Rome II Regulation.

205. Before I proceed further, I should explain for the benefit of foreign readers that the *lex loci protectionis* with regard to the UK designation of the Patent is UK law, since it is governed by the UK Patents Act 1977, and there is no difference between the law of England and Wales and the laws of Scotland and Northern Ireland in this respect. The *lex fori*, however, is the law of England and Wales (or English law for short) since this Court is a court of England and Wales. There are differences between the rules of evidence and procedure of England and Wales, Scotland and Northern Ireland respectively.

The relevant provisions of the Rome II Regulation

206. Recital (6) states:

> "The proper functioning of the internal market creates a need, in order to improve the predictability of the outcome of litigation, certainty as to the law applicable and the free movement of judgments, for the conflict-of-law rules in the Member States to designate the same national law irrespective of the country of the court in which an action is brought."

207. Article 1 provides:

> "**Scope**
>
> 1. This Regulation shall apply, in situations involving a conflict of laws, to non-contractual obligations in civil and commercial matters. …
>
> 3. This Regulation shall not apply to evidence and procedure, without prejudice to Articles 21 and 22."

208. Article 15 provides:

> "**Scope of the law applicable**
>
> The Law applicable to non-contractual obligations under this Regulation shall govern in particular:
>
> (a) the basis and extent of liability, including the determination of persons who may be held liable for acts performed by them;
>
> (b) the grounds for exemption from liability, any limitation of liability and any division of liability;
>
> (c) the existence, the nature and the assessment of damage or the remedy claimed;

> (d) within the limits of powers conferred on the court by its procedural law, the measures which a court may take to prevent or terminate injury or damage or to ensure the provision of compensation;
>
> (e) the question whether a right to claim damages or a remedy may be transferred, including by inheritance;
>
> (f) persons entitled to compensation for damage sustained personally;
>
> (g) liability for the acts of another person;
>
> (h) the manner in which an obligation may be extinguished and rules of prescription and limitation, including rules relating to the commencement, interruption and suspension of a period of prescription or limitation."

209. Article 22 provides:

> "**Burden of Proof**
>
> 1. The law governing a non-contractual obligation under this Regulation shall apply to the extent that, in matters of non-contractual obligations, it contains rules which raise presumptions of law or determine the burden of proof.
>
> 2. Acts intended to"

Brief summary of the rival contentions

210. Actavis contend that the rules for obtaining negative declaratory relief are matters of procedure within Article 1(3) and hence fall outside the scope of the Regulation. Lilly contends that the rules for obtaining negative declaratory relief are not questions of procedure, but fall within the scope of the *lex causae* as determined by Article 15. Lilly particularly relies upon Article 15(c), but it also relies on Article 15(h) and Article 22 by way of analogy. It is common ground that, if Actavis are right that the matter falls outside the scope of the Regulation, the question of the applicable law is to be determined by English private international law and that, under English private international law, the applicable law is the *lex fori*, because English law regards the rules for obtaining negative declaratory relief as being procedural: see *Plastus Kreativ AB v Minnesota Mining and Manufacturing Co* [1995] RPC 438 and *Messier-Dowty Ltd v Sabena SA* [2000] 1 WLR 2040 at [8], [27], [33], [34], [42], [43], [46] (Lord Woolf MR).

Characterisation of the rules

211. Before considering the proper interpretation of the Rome II Regulation, it is necessary to characterise the relevant rules.

212. Each of the national legal systems in issue in this case has its own rules which specify the conditions which must be satisfied by a claimant in order to obtain a DNI in

addition to establishing that the product or process in question does not infringe the patent in question.

213. Counsel for Actavis submitted, and I agree, that, while these rules all have their own specific modes of operation, broadly speaking two different kinds of mode of operation can be identified:

i) First, there are rules based on a fact-sensitive concept of interest or purpose. The notion of "real commercial interest" or "useful purpose" under the English inherent jurisdiction is an instance of this. So too are the rules in Article L 615-9 IPC under French law, Article 100 CCP under Italian law and Article 127.1 SPA under Spanish law considered below. The relevant interest or purpose required differs from legal system to legal system, but the nature of the issue is essentially the same.

ii) Secondly, there are rules based on pre-action notification requirements. Section 71 of the Patents Act 1977 is an example of this. So too is Article L615-9 IPC under French law and Article 127.2 SPA under Spanish law.

214. Counsel for Actavis submitted, and I agree, that, despite the differences in mode of operation, all of these rules are dealing with the same kind of issue. Accordingly, they must be characterised in the same way. As I understand it, it is common ground that they must be given an autonomous characterisation for the purpose of the Rome II Regulation. How they are characterised under the various national laws is not determinative.

215. Lilly describes these rules as rules of "title to sue" or "*locus standi*", while Actavis describe them as "procedural rules", but both of these descriptions tend to pre-empt the question to be decided.

216. In seeking to characterise these rules, it seems to me that it is useful to start by considering the purpose of a claim for a DNI. Normally, courts determine claims by claimants seeking to establish that defendants are liable and that a particular remedy should be granted. A claim for a DNI is an unusual kind of proceeding, because the claimant seeks a declaration by the court that there is no liability. Other than that declaration, the claimant seeks no relief. Why should the claimant want to obtain a DNI? Leaving aside considerations of forum shopping, the usual reason why the claimant wants a DNI is to provide legal certainty. In particular, he wants to know whether it is safe to commercialise a particular product or process before he exposes himself to the possibility of a claim for infringement, and hence the possibility of being subject to an injunction and/or of paying substantial damages (or accounting for his profits). If the patentee were to acknowledge that his product or process did not infringe, the claimant would not need to bring a claim for a DNI, because the acknowledgement would provide him with sufficient legal certainty. If the patentee were to sue him and do so quickly, the claimant would not need to bring a claim for a DNI either, because he could obtain legal certainty by defeating the patentee's claim. The claimant only needs to seek a DNI where the patentee declines either to give him an acknowledgement of non-infringement or to sue for infringement within a commercially acceptable time frame. This is particularly important where the patentee has a weak case and would prefer to rely on the uncertainty created by the absence of a decision than to obtain a determination by the court.

217. Against this background, it can be seen the rules identified in paragraph 213 above serve two main purposes. The first kind of rule serves to ensure that the claimant for a DNI has a sufficient justification for seeking an adjudication by the court. Justification, that is, not in terms of the substantive merits of his case, but in terms of needing the court to make a declaration rather than requiring the claimant to wait until the patentee decides whether or not to sue. Suppose, for example, that the claimant has devised a clearly non-infringing product, but has no intention to commercialise that product. In those circumstances, he has no need of the court's assistance despite having an unanswerable case on the merits. The question whether he would infringe the patent is an academic question.

218. The second kind of rule serves two objectives. First, it aims to avoid unnecessary litigation. If the patentee will give an acknowledgement of non-infringement, the prospective claimant for a DNI need not bring his claim. Counsel for Lilly submitted that the objective went further, and included giving the patentee the opportunity to bring a claim. Whatever may have been the thinking of the national legislatures in question, I do not consider that this is the true rationale. A patentee who wishes to sue will do so. He does not require a *locus poenitentiae* for that purpose. Again, therefore, the second kind of rule serves to ensure that the claimant for a DNI has a sufficient justification for seeking an adjudication by the court.

219. Secondly, the second kind of rule seeks to ensure that the dispute is sufficiently well defined for the court to adjudicate upon it. In the normal infringement scenario, one can determine the issue of infringement by reference to an actual product or process. By contrast, the claimant for a DNI frequently wants to obtain a DNI before he has a commercial product or process ready, because he wants to know whether it is safe to make the necessary investment. It follows that it may well be necessary to determine the issue of infringement by reference to what the claimant is proposing to do. For this purpose, it is necessary for the claimant to particularise what he is going to do.

220. Thus I would characterise the relevant rules in the following manner. They are rules which are designed to ensure that the machinery of the court is only invoked to determine disputes which genuinely require adjudication by the court and to ensure that the dispute is sufficiently well defined for the court to adjudicate upon it. They are not rules concerned with the substantive rights and obligations of the parties with regard to infringement of the patent in suit. In particular, the rules are not rules about who has title to sue in the sense of having a substantive right to bring a claim (as for example, is the requirement under English law that the claimant in a patent infringement claim be either the proprietor of, or an exclusive licensee under, the patent). Thus the evidence shows that decisions made under these rules that claims for DNIs are inadmissible do not give rise to any *res judicata* with regard to the substantive rights and obligations of the parties. Furthermore, the court can adjudicate upon the substantive rights and obligations of the parties with regard to the infringement of the patent in suit without these rules being engaged at all, namely if the patentee brings a claim for infringement.

Interpretation of the Regulation

221. Both sides relied upon the recent decision of the Court of Appeal in *Wall v Mutuelle de Poitiers Assurances* [2014] EWCA Civ 138, [2014] CP Rep 23. In that case Mr Wall was severely injured while riding a motorcycle in France as a result of a

collision with a motor car driven by a driver insured by MPA. MPA admitted that the driver was negligent, that it was liable and that Mr Wall could bring proceedings against it in England. The only remaining issue was as to quantum. Mr Wall wanted to adduce evidence from a number of independent experts in different disciplines in the usual English way. MPA contended that expert evidence should be placed before the court in the same manner in which it would be in France, namely by a single agreed or court-appointed expert or pair of experts. The trial of a preliminary issue was ordered as to whether the issue of what expert evidence the court should order fell to be determined by English law or French law. Tugendhat J held that it was English law by virtue of Article 1(3) of the Rome II Regulation. The Court of Appeal dismissed MPA's appeal. On the appeal, however, a further issue emerged, which was whether the applicable law under Article 15 included guidelines for the assessment of damages. The Court of Appeal held that it did.

222. On the first point, the Court of Appeal held that the expression "procedure and evidence" was to be given its normal meaning and rejected MPA's submission that it should be narrowly construed: see Longmore LJ at [11]-[12], Jackson LJ at [40]-[41] and Christopher Clarke LJ at [47]. In this context, Longmore LJ specifically rejected MPA's argument that "the aim of Rome II was to promote certainty and uniformity and discourage forum-shopping and that it therefore followed that an English court applying foreign law should ensure (or at any rate do its best to ensure) uniformity of outcome, irrespective of which country tries the … claim". He went on to conclude that, given the exclusion of "evidence and procedure", it was inevitable that trial of the same dispute in different countries might result in different outcomes (see [15]).

223. So far as the second point was concerned, it was common ground that, pursuant to Article 15(c), the quantum of damages was to be governed by French law. There was a debate, however, as to whether the French law on the quantum of damages included judicial guidelines as to the assessment of damages, which a French court would take account of, but which were "soft law" rather than "hard law". The Court of Appeal concluded that such guidelines were law, and so fell within the scope of the law applicable to non-contractual obligations.

224. I accept the submission made by counsel for Actavis that, in so far as Lilly's argument relies upon the propositions that Article 1(3) should be narrowly construed and/or that the objective of the Regulation is to ensure uniformity of outcomes, then *Wall* is authority to the contrary. Apart from that, however, the decision sheds relatively little light on what kinds of rule fall within the scope of "procedure".

225. As is common ground, the purpose of Article 15 of the Regulation is to determine the scope of the law applicable to the non-contractual obligation and thus to harmonise the differing national approaches to that question. It can be seen that some of the matters specified in the various paragraphs are matters that some national laws (such as English law) would have regarded as subject to the *lex fori*. As noted above, Lilly relies in particular on Article 15(c), and in particular the reference to "the remedy claimed". This prompted Actavis to rely upon the other language versions of Article 15(c). I was provided in Annex H to Actavis' Closing Submissions with a comparison table of the other language versions and literal English translations of the other language versions obtained by the parties. Many of the English translations are agreed, while a number are not. The disagreements do not affect the broad picture, however. The majority of the other language versions do not use a term equivalent to

"remedy". Instead, they use a term equivalent to "compensation", "indemnity" or "reparation". By way of example, I would instance the French "*la réparation demandée*" and the Italian "*l'indennizzo chiesto*". Actavis contend that this shows that Article 15(c) is concerned with damage and compensation for damage.

226. In response to this, Lilly sought to rely upon some materials indicating that the revision to the English wording was suggested by the United Kingdom as a consequence of the decision of the Court of Appeal in *Harding v Wealands* [2004] EWCA Civ 1725, [2005] 1 WLR 1539 (subsequently reversed by the House of Lords [2006] UKHL 32, [2007] 2 AC 1). As counsel for Actavis submitted, however, these materials are neither an admissible aid to construction of the Regulation nor very illuminating.

227. Nevertheless, it seems to me that Actavis' approach to Article 15(c) is unduly narrow. It must be interpreted in a manner which gives effect to the objectives of the Regulation. While the Regulation does not aim for uniformity of outcomes, it does aim to ensure a consistent application of the law applicable to the non-contractual obligation. I consider that it is well arguable that, as suggested by a minority of language versions, Article 15(c) extends beyond the assessment of damages and embraces the financial remedy claimed. On this basis, it would extend to the question of whether a proprietary remedy, such as tracing, is available. Coming closer to the present context, this interpretation of Article 15(c) would mean that the question of whether a successful patentee in an infringement claim can elect between an award of damages and an account of profits is governed by the *lex causae* rather than the *lex fori* (subject to the impact of Article 13 of the European Parliament and Council Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights).

228. On the other hand, it also seems to me that Lilly's approach to Article 15(c) is too broad. "Remedy" in Article 15(c) cannot extend to any remedy. The question whether an injunction may be granted to restrain future infringement is clearly governed by the *lex causae*, as Sir Andrew Morritt C held in *OJSC TNK-BP v Lazurenko* [2012] EWHC 2781 (Ch) at [20], but that is because this is provided for by Article 15(d). In that regard, I consider that it is telling that Article 15(d) contains the qualification "within the limits of powers conferred on the court by its procedural law". In my judgment this makes it clear that there is a distinction between the question of principle as to whether an injunction should be granted, which will be a matter for the *lex causae*, and the procedural conditions which must be observed, which will be a matter for the *lex fori*. Thus the rule under English law that three clear days' notice must be given of an application for an interim injunction, save where circumstances of urgency justify giving less notice or where it is justified to take the defendant by surprise by giving no notice at all, is a procedural condition which is a matter for the *lex fori*.

229. I have considerable doubts as to whether a DNI is a remedy in this sense at all. Under English law, it is little more than a formal record of the court's decision on the substantive issue. I can conceive that, under some systems of law, one would not need or obtain even that much, but merely a judgment of the court. Even if a DNI is a remedy, and even if it is a remedy within Article 15(c), it seems to me that Article 15(c) should be interpreted as only having the effect that the question of principle as to whether a DNI is available at all is a matter for the law applicable to the non-

contractual obligation. It does not follow that rules of the kind presently under consideration, which are essentially concerned with whether it is necessary or possible for the court to consider the substantive issue at all, fall within Article 15(c).

230. In this regard, it is worth emphasising that I have already decided that dealings by Actavis in their proposed products will not infringe the French, Italian and Spanish designations of the Patent. Thus I have already decided the substantive issue between the parties on the merits. Even on that basis, if a DNI was simply not available at all under, say, Spanish law, then there would be some logic in this Court declining to make a declaration that no Spanish court could make. It does not follow that it makes sense for this Court to try to apply the rules which a Spanish court would apply in order to decide whether it was necessary and possible to adjudicate upon the dispute *before* it made a determination on the merits.

231. In my view Lilly's reliance upon Article 15(h) is misplaced. There is obviously room for a divergence of view as to whether rules as to limitation and prescription are substantive or procedural (as used to be the case under English law before the Foreign Limitation Periods Act 1984). Article 15(h) makes it clear that they are to be governed by the *lex causae*. I see no analogy between a rule of limitation or prescription and the rules presently under consideration, however. The same goes for Article 22, and the burden of proof.

232. Both sides relied upon the *travaux préparatoires* for the Regulation. These show that what became Article 1(3) was introduced by the European Parliament. As the Juri Committee explained:

> "This amendment takes account of the universal principle of *lex fori* within private international law that the law applicable to procedural questions, including questions of evidence, is not the law governing the substantive legal relationship (*lex causae*), but, rather, the law of the forum."

It does not seem to me, however, that the *travaux* shed much light on the correct answer to the present question.

233. I was also referred to a number of academic articles. Interesting as these are, I have not found many of them particularly helpful so far as the present issue is concerned. A number of commentators have suggested that "evidence and procedure" should be narrowly construed, but this is inconsistent with the decision of the Court of Appeal in *Wall*. In any event, it is not clear that they were addressing their minds to the kind of rules in issue here. The commentary I have found most helpful, perhaps only because it fits most closely with my own thinking, is that of Professor Maria Pertegas on the draft Regulation in "Intellectual Property and Choice of Law Rules" in Alberto Malatesta (ed), *The Unification of Choice of Law Rules on Torts and other Non-Contractual Obligations in Europe: the "Rome II" Proposal* (CEDAM, 2006) at 221-248, in particular the following passage at 240-241:

> "A distinction should be made between the availability of a given remedy – generally, injunctive relief and/or damages – and the procedure(s) available to the plaintiff to request those remedies. It is submitted that only the latter is governed by the law of the forum.

> If this distinction is applied to the thorny question of the applicable law to an action for interim injunctive relief, a distinction must be made between two legal issues. First, the court must investigate whether the claimed remedy is available under the *lex loci protectionis*. Provided this is so, it is up to the national procedural rules to determine whether shortened and/or accelerated proceedings are available to the plaintiff."

234. Counsel for Actavis pointed out that Article 1(3) of European Parliament and Council Regulation 593/2008/EC of 17 June 2008 on the law applicable to contractual obligations ("the Rome I Regulation"), and the Rome Convention before that, contain a parallel exclusion for "evidence and procedure". There have been many claims for negative declarations in relation to contractual liability under the Rome Convention and the Rome I Regulation. Counsel for Actavis asserted that such claims have always proceeded on the basis that the conditions for obtaining a negative declaration were matters for the *lex fori* rather than the law governing the contract. On the other hand, it does not appear from anything I have been shown that the question has ever been argued.

235. Finally, counsel for Actavis relied upon the consequences of deciding that the rules in question were governed by the *lex causae*, as shown by the issues and evidence in the present case. As he submitted, these demonstrate that one ineluctably gets drawn deep into the procedures of the foreign legal system. This is particularly graphically illustrated by the debates with regard to the requirements under French and Spanish law. By way of example only, I would instance the issues as to whether it is possible to rely upon letters requesting the patentee to take a position sent during the pendency of the proceedings. One also gets entangled in questions of what evidence would be acceptable to the foreign court. By way of example, I would instance the issue under Spanish law with regard to the requirement for the taking position letter to be sent "through notarial channels".

236. Having taken all of these matters into account, I conclude that the rules presently in issue are matters of procedure within Article 1(3) and are not governed by the law applicable to the non-contractual obligation in accordance with Article 15. It follows that they are governed by English law.

Procedural timetable

237. Due to the objections raised by Lilly to Actavis' claims for DNIs in respect of the French, Italian and Spanish designations of the Patent, it is necessary for me to set out a detailed procedural timetable.

238. On 12 July 2012 Actavis' solicitors, Bird & Bird wrote to Lilly "C/O Ivan J. Burnside, Lilly Research Centre, Erl Wood Manor, Windlesham, Surrey GU20 6PH". This letter is quoted in my judgment dated 27 November 2012 at [7]. This letter sought a written acknowledgement from Lilly that Actavis' importation, keeping, offering to dispose of and disposing in the UK and in Spain, France, Italy and Germany of a medicament containing pemetrexed dipotassium for use in combination therapy for inhibiting tumour growth in mammals would not infringe the UK and the foreign designations of the Patent in the respective countries.

239. On 26 July 2012 Lilly's solicitors, Hogan Lovells, wrote to Bird & Bird, not giving the acknowledgment sought, but instead seeking further information about the proposed acts, in particular asking about the details of the pharmaceutical form, including qualitative and quantitative composition and a list of excipients (see [PP/3]).

240. On 26 July 2012 Bird & Bird replied saying that the claims of the Patent do not claim particular forms, posology or excipients.

241. On 27 July 2012 Actavis Group ehf (the Second Claimant) issued the Claim Form in action HC12E02962 ("the First Action"), seeking (1) a declaration pursuant to section 71 of the Patents Act 1977 that dealings in pemetrexed dipotassium in the UK as proposed in Bird & Bird's letter dated 12 July 2012 would not infringe any claim of the UK designation of the Patent and (2) a declaration pursuant to the Court's inherent jurisdiction that dealings in pemetrexed dipotassium in France, Germany, Italy and Spain as proposed in Bird & Bird's letter dated 12 July 2012 would not infringe the relevant designations of the Patent.

242. On 31 July 2012 Hogan Lovells replied to Bird & Bird confirming that they were instructed to accept service on behalf of Lilly.

243. On 1 August 2012 Bird & Bird wrote to Hogan Lovells enclosing by way of service the Claim Form, Particulars of Claim and Response Pack in the First Action.

244. On 15 August 2012 Hogan Lovells filed an acknowledgement of service on behalf of Lilly contesting jurisdiction.

245. On 23 August 2012 Hogan Lovells wrote to Bird & Bird disputing that Bird & Bird's letter of 1 August 2012 constituted valid service of the Claim Form in the First Action.

246. On 29 August 2012 Lilly filed an application contesting the Court's jurisdiction to hear the First Action in respect of the non-UK designations.

247. Also on 29 August 2012 Medis ehf (the Fourth Claimant) issued the Claim Form in action HC12 A03340 ("the Second Action"), seeking the same relief as that sought in the First Action. On the same day Bird & Bird wrote to both Hogan Lovells and Dr Burnside enclosing the Claim Form, Particulars of Claim and the Response Pack in the Second Action by way of service.

248. On 4 September 2012 Hogan Lovells wrote to Bird & Bird disputing service of the Claim Form in the Second Action insofar as it related to the non-UK designations of the Patent.

249. On 26 September 2012 Lilly filed an application contesting the Court's jurisdiction to hear the Second Action in respect of the non-UK designations.

250. On 11 October 2012 Bird & Bird wrote to Lilly at the Windlesham address enclosing the Claim Form, Particulars of Claim etc. in the First Claim without prejudice to the contention that these documents had already been served.

251. On 27 November 2012 I handed down my judgment dismissing Lilly's applications contesting jurisdiction. Lilly appealed against this decision.

252. On 17 April 2013 Actavis (i.e. all of the Claimants) issued and served the Claim Form in the action HC13 A01487 ("the Third Action") seeking DNIs in relation to the use of pemetrexed ditromethamine and pemetrexed diacid, as well as in relation to pemetrexed dipotassium.

253. On 1 May 2013 Lily filed an acknowledgement of service in respect of the Third Action contesting jurisdiction.

254. On 15 May 2013 Lilly filed an application contesting the Court's jurisdiction to hear the Third Action in respect of the non-UK designations.

255. On 21 May 2013 the Court of Appeal dismissed Lilly's appeal contesting jurisdiction. In its judgment the Court of Appeal concluded that the Second Action was unnecessary, and for that reason only dismissed it.

256. On 26 June 2013 Lilly filed an acknowledgement of service in the First and Third Actions defending the claim.

257. By a consent order dated 27 June 2013 the parties agreed that Lilly's application challenging jurisdiction of the non-UK designations in the Third Action be dismissed and that the First and Third Actions be case managed together, with Actavis serving a combined Particulars of Claim.

258. On 3 July 2013 Actavis served their Combined Particulars of Claim.

259. On 18 July 2013 Lilly served its Combined Defence in the First and Third Actions. Lilly contended in its Defence, contrary to its previous position, that the applicable law for determining the conditions of negative declaratory relief was that of the *lex loci protectionis*, and claimed that Actavis had not complied with various requirements for obtaining DNIs under the relevant laws of France, Italy, Germany and Spain. The Defence also stated that Actavis was required to prove that the use of sodium hydroxide as an excipient did not result in literal infringement. Lilly also brought a counterclaim for infringement of the UK designation of the Patent.

260. On 16 September 2013, as a response to Lilly's claim in the Defence that Actavis had not complied with certain requirements under French and Spanish law, Actavis sent a further taking position letter to Lilly. This letter was sent through an English notary.

261. On 18 September 2013 Actavis issued and served the Claim Form in action HP13 E04212 ("the Fourth Action"). The Fourth Action included for the first time claims in relation to pemetrexed dipotassium by Claimants other than Actavis Group ehf. Actavis also applied to amend its Claim Form in the First and Third Actions to add the other Actavis companies as Claimants and to include the other products as well as the dipotassium product.

262. On 30 September 2013 Actavis served its Combined Reply in the First and Third Actions, which explained Actavis' position that the applicable law relating to the conditions for seeking negative declaratory relief was the *lex fori*, but that in any event Actavis had complied with the relevant requirements under foreign law.

263. On 7 October 2013 Lilly filed an acknowledgement of service in the Fourth Action, defending the claim.

264. On 17 October 2013 I gave directions for the trial of the First and Third Actions at a case management conference. Among other things I granted Actavis permission to amend the Claim Forms in the First and Third Actions. The effect of those amendments was to introduce claims by all the Claimants in respect of pemetrexed diacid and ditromethamine in the First Action and by all the Claimants in respect of pemetrexed dipotassium in the Third Action. The amended Claim Forms were issued and served on 22 October 2013.

265. Also on 17 October 2013 Actavis issued and served the Claim Form in action HP13 E4604 ("the Fifth Action"), which was brought by Actavis to overcome Lilly's reliance on an alleged one month's notice requirement under Spanish law (as the claim was started one month after the 16 September 2013 letter), but without prejudice to Actavis' primary case that it did not need to send the 16 September 2013 letter.

266. On 1 November 2013 Lilly acknowledged service of the Fifth Action, defending the claim.

267. On 11 November 2013 Lilly applied to stay the Fourth and Fifth Actions until 28 days after judgment on the First and Third Actions on the ground that the Fourth and Fifth Actions were an abuse of process.

268. On 12 November 2013 Actavis issued an application for the Fourth and Fifth Actions to be heard together with the First and Third Actions.

269. On 27 November 2013 I dismissed Lilly's application to stay the Fourth and Fifth Actions and gave directions for the trial of the Fourth and Fifth Actions with the First and Third Actions.

270. On 3 December 2013 Actavis served their amended Combined Particulars of Claim in the First, Third, Fourth and Fifth Actions.

271. On 10 December 2013 Bird & Bird wrote to Hogan Lovells providing some confidential information about the formulations of the products which Actavis had been working on and explaining that Actavis had no intention to use sodium hydroxide or any other sodium salt as an excipient.

272. On 11 December 2013: Lilly served its amended Combined Defence and Counterclaim in the First, Third, Fourth and Fifth Actions. The amended Combined Defence alleged that the Fourth and Fifth Actions were an abuse of process.

273. On 20 December 2013 Actavis served on Lilly a draft re-amended Combined Reply, which referred to and relied upon the information set out in Actavis' letter of 10 December 2013.

274. Also on 20 December 2013 Actavis issued and served the Claim Form in action HP13 B05505 ("the Sixth Action") and served Further Particulars in the First, Third, Fourth and Fifth Actions re-iterating Actavis' claims, both of which were intended to

overcome Lilly's reliance on an alleged three months' notice requirement under French law (as the claim was started three months after the 16 September 2013 letter).

275. Lilly did not file an acknowledgement of service in respect of the Sixth Action, and thus did not dispute jurisdiction in respect of it.

276. On 7 January 2014 it was ordered by consent that the Sixth Action should be tried with the First, Third, Fourth and Fifth Actions.

277. On 13 January 2014 Actavis sent Lilly a further "taking position" letter referring to, relying on and enclosing copies of the letters dated 16 September 2013 and 10 December 2013, although again without prejudice to their primary case that they did not need to send this further taking position letter. This letter was again sent through an English notary. On the same date Actavis served Dr Stefánsson's first witness statement explaining Actavis' preparations for launch of the pemetrexed diacid, dipotassium and ditromethamine products.

278. On 7 February 2014 there was a case management conference at which Lilly objected to Actavis' amendments to the Reply relating to and relying upon the 10 December 2013 letter. Actavis were given permission to make some of the amendments to the Reply on condition that they amended the prayer for relief in the Combined Particulars of Claim to clarify that they were not seeking a declaration in relation to the use of the products with sodium hydroxide or any other sodium salt as an excipient.

279. On 14 February 2014 Actavis served a re-amended Combined Particulars of Claim with the clarification regarding the scope of the declaration pursuant to the order of 7 February 2014 and an amended Combined Reply.

280. On 18 February 2014 Actavis issued and served the Claim Form in action HP14 D00753 ("the Seventh Action"). This action was issued in order to overcome Lilly's reliance on the alleged one month's notice requirement under Spanish law (as the claim was started one month after Actavis' 13 January 2014 taking position letter).

281. On 26 February 2014 Lilly served a re-amended Combined Defence, which alleged that the Sixth Action was also an abuse of process.

282. Lilly did not file an acknowledgement of service in respect of the Seventh Action, and thus did not dispute jurisdiction in respect of it.

283. On 17 March 2014 it was ordered by consent that the Seventh Action be tried with the First, Third, Fourth, Fifth and Sixth Actions.

284. Also on 17 March 2014 Actavis served a re-re-amended Combined Particulars of Claim which incorporated the Seventh Action.

285. On 19 March 2014 Lilly served a re-re-amended Combined Defence which alleged that the Seventh Action is an abuse of process. Lilly also alleged for the first time that the letters of 16 September 2013 and 13 January 2014 were not sent through proper notarial channels, although it did not explain why.

286. On 20 March 2014 Actavis re-sent the letter of 13 January 2014 through a Spanish notary (without prejudice to its case that this is not necessary). Lilly has acknowledged that it received this at its premises in Indianapolis, Indiana, USA on 31 March 2014. The Spanish notary has produced a certificate of transmission and by the date this judgment is handed down will have produced a certificate of receipt.

287. On 21 March 2014 Lilly served a response to a Request for Further Information alleging that the letter of 13 January 2014 had not been properly notarised as it did not comply with certain features of Spanish notarial practice which it alleged was required.

288. On 24 March 2014 Actavis served a re-amended Combined Reply which incorporated the Seventh Action.

289. On 26 March 2014 Actavis served Mr Stefánsson's second witness statement, updating Actavis' preparations for launch.

290. On 4 April 2014 Actavis sent a new taking position letter with regard to the French and Spanish designations of the Patent, referring to, relying on and enclosing copies of the letters dated 16 September 2013, 10 December 2013 and 13 January 2014 and Dr Stefánsson's second statement. Again, this letter was sent without prejudice to Actavis' case that it is not necessary, and as a precaution. This was notarised by a Spanish notary and hand delivered by a US notary to Lilly at its premises in Indianapolis on 4 April 2014.

291. On 14 April 2014 Actavis issued and served the Claim Form in action HP14 A01611 ("the Eighth Action"), and I made an order that it be tried with the earlier actions.

292. On 6 May 2014 Actavis issued and served the Claim Form in action HP14 F01792 ("the Ninth Action").

Actavis' preparations for launch of a pemetrexed product

293. Again due to Lilly's objections under French, Italian and Spanish law, I must describe Actavis' preparations for launch of a pemetrexed product and how they have developed over time. Since Actavis regards the details of its preparations as confidential, I shall be circumspect in what I say.

294. It was Dr Stefánsson's idea to develop an alternative salt to pemetrexed disodium in order to avoid infringing the Patent. This was discussed internally at Actavis at a meeting in [REDACTED]. Dr Stefánsson suggested three alternatives and another person suggested a fourth. [REDACTED].

295. On [REDACTED] a business case was finalised and expenditure on the project was approved by Actavis' Pipeline Committee. In [REDACTED], solubility tests were carried out on the calcium salt which showed that it was insufficiently soluble. The results of those tests are in evidence. [REDACTED] As a result, Actavis' Research & Development department came up with some alternative suggestions, which led to the selection of pemetrexed diacid and ditromethamine as additional candidates some time before 17 April 2013.

296. [REDACTED] Actavis' manufacturing site in Nerviano, Italy is owned and operated by Actavis Italy SPA a Socio Unico ("Actavis Italy"), the Tenth Claimant. Actavis Italy has been chosen to perform the industrial scaling up necessary for the commercial manufacture of whichever of the pemetrexed formulations gets legal clearance and goes through the regulatory process. In due course, the manufacture of commercial batches of Actavis' pemetrexed product will also be done at Nerviano.

297. Actavis' Confidential PPD dated 28 November 2013 sets out test data obtained by Actavis by that date in respect of the (a) solubility, (b) stability, (c) shelf-life and (d) toxicity of pemetrexed disodium, dipotassium, diacid and ditromethamine. [REDACTED]

298. Exhibit SES3 to Dr Stefánsson's first witness statement shows the status of the project as at 17 December 2013. [REDACTED]

299. Exhibit SES6 to Dr Stefánsson's second witness statement shows the status of the project as at 19 March 2014. [REDACTED]

300. Actavis' Confidential Supplementary PPD dated 21 March 2014 sets out additional test data obtained by Actavis since the date of the original PPD. [REDACTED]

301. In addition to the test data which they have generated themselves, it appears that Actavis have obtained some data from the manufacturer of the API, although the evidence does not establish precisely what data they have obtained from this source.

302. As stated above, Actavis' preferred candidate at present is pemetrexed diacid. [REDACTED]

303. Dr Stefánsson explains in his witness statements that the launch companies in each country are planned to be chosen from among the remaining Claimants in these actions near to the launch date. If necessary, Actavis will launch through Actavis Italy in France, Germany and Spain as well as in Italy.

DNI in respect of the UK designation applying English law

304. Under its inherent jurisdiction, this Court has a broad discretionary power to grant a negative declaration if it is in the interests of justice to do so: see *Messier-Dowty* at [41]-[42] (Lord Woolf MR). The old restrictive approach under which a negative declaration would not be granted unless there was a claim of right (*Re Clay* [1919] 1 Ch 66) has been abandoned. The modern law is that a negative declaration will be granted if it is right in all the circumstances to do so, and in particular if it will serve a "useful purpose": *Messier-Dowty* at [41]-[42]. It will do so if the claimant has a "real commercial interest" in the negative declaratory relief sought or a "real commercial reason" for it to be granted: *Nokia Corp v InterDigital Technology Corp* [2006] EWCA Civ 1618, [2007] FSR 23 at [19]-[20] (Jacob LJ).

305. Lilly does not seriously dispute that, if Actavis establish that dealings in their products would not amount to an infringement of the UK designation of the Patent, then Actavis should be granted a DNI in respect of that designation pursuant to the inherent jurisdiction of the Court. It follows that it is unnecessary for me to consider whether Actavis have satisfied the requirements of section 71 of the Patents Act 1977.

306. I would emphasise that, although I have found it convenient in writing this judgment to address this issue after determining the substantive issue between the parties on the merits, which is the same order adopted by the parties in their submissions, it would make no difference if I had considered the issues the other way round. I would add that Lilly did not seek the trial of this issue as a preliminary issue, as it could have done if there had been any real doubt about Actavis' entitlement to a DNI even if Actavis were right on the substantive issue.

DNI in respect of the French, Italian and Spanish designations applying English law

307. If, as I have concluded, the law applicable to the question of whether Actavis are entitled to a DNI in respect of the French, Italian and Spanish designations of the Patent is English law, then I consider that Actavis should be granted DNIs in respect of those designations pursuant to the inherent jurisdiction of the Court because Actavis have clearly demonstrated that they have a real commercial interest in obtaining such declarations and such declarations would serve a useful purpose. Nevertheless, in case I am wrong about the applicable law, in the remainder of this judgment, I shall consider the position on the assumption that the relevant law is the law applicable to the non-contractual obligation.

DNI in respect of the French designation applying French law

French law

308. Article L 615-9 IPC provides as follows:

> "Any person who proves exploiting industrially on the territory of a Member State of the European Economic Community, or serious and effective preparations to that effect, may invite the owner of a patent to take position on the opposability of his title against such industrial exploitation, the description of which shall be communicated to him.
>
> If such person disputes the reply that is given to him or if the owner of the patent has not taken a position within a period of three months, he may bring the owner of the patent before the Court for a decision on whether the patent constitutes an obstacle to the industrial exploitation in question, without prejudice to any proceedings for the nullity of the patent or subsequent infringement proceedings if the working is not carried out in accordance with the conditions specified in the description referred to in the above paragraph"

309. Article 31 of the Civil Procedure Code ("FCPC") provides as follows:

> "The right of action is available to all those who have a legitimate interest in the success or dismissal of a claim, without prejudice to those cases where the law confers the right of action solely upon persons who it authorises to raise or oppose a claim, or to defence a particular interest."

310. There are a number of issues between the parties concerning these provisions. The first concerns the relationship between Article L 615-9 IPC and Article 31 FCPC. Prof Azéma considers that Art L 615-9 IPC is a special derogation from Article 31 FCPC and that this provision was necessary because a DNI was not previously allowed under Art 31 FCPC. Prof Galloux considers that Article L 615-9 IPC is not a derogation from Art 31 FCPC and that a DNI can be obtained under Article 31 FCPC even if the conditions laid down by Article L 615-9 are not satisfied.

311. On this question I prefer the opinion of Prof Azéma, which is supported by three main points:

    i) Before Article L 615-9 IPC was introduced in 1984, no action for a DNI was in fact admitted by a French court.

    ii) The weight of scholarly comment on Article L 615-9 IPC accords with Prof Azéma's view.

    iii) The maxim *specialia generalibus derogant* (the specific overrides the general) applies. This is supported by the decision of the President of the First Instance Court of Lyon in *Eurodif v Gravisse* dated 17 January 1995.

312. The second issue is whether it is always necessary for the party seeking a DNI pursuant to Article L 615-9 IPC to show that it has invited the patent owner to take a position three months before bringing the action. Lilly admits in paragraph 25 of its Combined Defence that it is possible for the party seeking the declaration to avoid this procedure "if the patentee has expressed his position irrevocably and unambiguously in a patent infringement action brought against the party seeking the declaration". The existence of this qualification is supported by the decisions of the Court of First Instance of Paris in *Yamanouchi Pharmaceutical Co Ltd v Biogen NV* of 16 March 1999 and *Alcon v Corneal* of 16 November 2007 cited by Prof Galloux.

313. Prof Galloux considers, however, that it is not necessary for the patentee to have expressed its position irrevocably or in a patent infringement action provided that the patentee has unambiguously expressed its position on the opposability of its French patent to the other party's product. In support of his opinion Prof Galloux cited the decision of the Court of Appeal of Bordeaux in *Hembert v Composites Aquitaine SA* of 9 April 2002, in which a claim by Composites Aquitaine under Article L 615-9 IPC was held admissible where the patentee had sent letters alleging infringement to another defendant, to the Ministry of Industry and to the Maritime Prefect of Toulon, and the allegation of infringement had been widely disseminated amongst potential customers. (Prof Galloux also cited the decision of Court of First Instance of Paris in *SEB SA v Euromenage SARL* of 22 April 2003, but in that case Compania Menaje Domestico SL ("CMD") had sent a request for an acknowledgement of non-infringement in respect of a modified product a few days after Euromenage had applied to join CMD as a third party to infringement proceedings brought by SEB against Euromenage in respect of a product supplied by CMD, and SEB subsequently alleged that the modified product also infringed.)

314. I accept Prof Galloux's opinion on this point. Although Prof Azéma states in paragraph 13 of his second report that the "amicable phase" set out in the first paragraph of Article L 615-9 IPC is a pre-requisite to obtaining a DNI, he does not

explicitly contradict what Prof Galloux says in his first report on this issue, nor does he comment on the case law cited by Prof Galloux.

315. The third issue is whether it is also possible for the party seeking a DNI to avoid the requirement to show that it has made serious and effective preparations for industrial exploitation if the patentee has unambiguously expressed its position on the opposability of its French patent to the other party's product. Prof Galloux considers that this is possible, but as I understand it, on the basis that a DNI could still be obtained under Article 31 FCPC. I have already concluded that it is not possible to obtain a declaration under Article 31 FCPC if it is not available under Article L 615-9. Furthermore, I note that in the *Hembert* case the Court of Appeal went on to consider whether Composites Aquitaine had made serious and effective preparations, holding that the Court of First Instance had been entitled to conclude that it had. One can understand why the Court of Appeal was willing to dispense with strict compliance with the requirement for a "taking position" letter to be sent when the patentee had unambiguously alleged infringement in letters to other parties, but nevertheless required Composites Aquitaine to show that it had a sufficient interest in obtaining a DNI.

316. The fourth issue is whether it is possible for the party seeking a DNI to rely upon a taking position letter, and the failure of the patentee to give an acknowledgement of non-infringement within the following three months, sent during the pendency of the proceedings. Prof Galloux considers that this is possible in accordance with Articles 122 and 126 FCPC, and his opinion is supported by the decisions of the Court of First Instance of Paris in *Biberian v Commissariat a l'Energie Atomique* of 22 November 1996 and *Justamente v Hopital Broussais* of 28 June 2000 he cited. It appears to me that it is also supported by the judgment in the *SEB* case. Prof Azéma considers that this is not possible, and that it is necessary for the claimant to start a new action, but he does not address Articles 122 and 126 FCPC or the case law cited by Prof Galloux. I therefore prefer Prof Galloux's opinion.

317. The fifth issue is what is meant by "industrial exploitation". Prof Azéma considers that this means manufacture, whereas Prof Galloux considers that it includes marketing the product. Prof Azéma's opinion is supported by three first instance decisions: *Boston Scientific SA v Palmaz* (28 October 1998), *Boston Scientific SA v Cordis Corp* (23 June 1999) and *Abbott Ireland v Evysio Medical Devices ULC* (14 January 2009). Prof Galloux's opinion receives some support from the *Yamanouchi* judgment. In my judgment the superior French courts will conclude that marketing the product is enough for this purpose. Marketing an infringing product is a form of industrial exploitation and it is an act of direct infringement. Furthermore, there is no rational reason for restricting the availability of DNIs to manufacturers.

318. The sixth issue is what is meant by "serious and effective preparations". The experts agreed that this "supposes that investments have already been launched, or at least, means have been put in place to enable an exploitation to be implemented". Lilly contends that the seriousness and effectiveness of the preparations must be assessed at the date the action is commenced, whereas Actavis contend that it is possible to rely upon further preparations during the pendency of the proceedings. Prof Galloux's evidence supports Actavis' position, as do the decisions in *SEB*, *Dijkstra* and *Yamanouchi* cited by him. Prof Azéma does not contradict Prof Galloux, and so I accept Prof Galloux's opinion.

Assessment

319. Actavis rely upon no less than six alternative "routes to admissibility" of their claim for a DNI in respect of the French designation. Lilly contends that all six routes fail for one or more of four reasons: (i) Article L 615-9 IPC must always be complied with; (ii) Actavis have not given Lilly three months' notice; (iii) Actavis have not carried out the necessary serious and effective preparations; and (iv) it is not possible for Actavis to cure defects within an existing action, but only by starting again and commencing a new action. For reasons that will appear, I consider that it is sufficient for me to deal with Actavis' first three routes.

320. *Route 1*. Actavis contend that, by the date of the Sixth Action (20 December 2013), Lilly had unambiguously taken a position on the opposability of the French designation of the Patent to each of pemetrexed diacid, dipotassium and ditromethamine. In support of this contention, Actavis rely in particular on (i) Lilly's counsel's confirmation at the case management conference on 17 October 2013, which was formally recited in the order made on that date, that "it is Lilly's positive case in these proceedings that Actavis' proposed products fall within the scope of the claims of the foreign designations of [the Patent], whether literally or by equivalence", (ii) Lilly's pleading with regard to the scope of the claims of the French designation of the Patent in its Statement of Case served pursuant to that order on 8 November 2013 and (iii) Lilly's statement in a letter from Hogan Lovells to Bird & Bird dated 10 December 2013 that "It necessarily follows [from Lilly's positive case on the construction of the claims] that Lilly considers that the products do fall within the scope of those claims …". Lilly relies on the facts that (i) counsel for Lilly also made it clear that, as the recital to the order continued, "Lilly raises no positive case of infringement in respect of the foreign designations" and (ii) no allegation of infringement was made in the Statement of Case or in the letter dated 10 December 2013.

321. In my judgment Lilly did unambiguously take a position on the opposability of the French designation of the Patent to each of Actavis' proposed products at the case management conference on 17 October 2013 and in its Statement of Case. It is immaterial that Lilly did not positively allege infringement (or threatened infringement) by Actavis. Furthermore, the reality of Lilly's position was perfectly clear by that date from the fact that Lilly had (i) brought a counterclaim for threatened infringement of the UK designation and (ii) brought proceedings in Düsseldorf for threatened infringement of the German designation. The only reason why Lilly had not positively alleged infringement of the French designation was that it wanted, so far as possible, to preserve its position that Actavis should have brought the claim in France in accordance with French procedure rather than in England in accordance with English procedure, and thereby make it more difficult for Actavis to obtain a DNI even if they were right on the merits.

322. Accordingly, I agree with Actavis that it does not matter whether they had properly complied with the requirement to send a taking position letter three months before the Sixth Action. I do not agree that this relieves Actavis from the obligation to demonstrate that they have made serious and effective preparations, however.

323. In my judgment the evidence demonstrates that Actavis had made serious and effective preparations to manufacture and market each of the products, and

particularly the diacid, by 20 December 2013 and certainly by the time of the trial. By 20 December 2013 Actavis had concrete and well-developed plans to manufacture and market each of the products, had taken a number of steps towards implementing those plans and had invested a certain amount of time, effort and money in doing so. By the trial Actavis had taken further steps and invested a lot more money. By 20 December 2013, and still more so by the trial, Actavis had a developed formulation of each product which they could be reasonably confident would receive regulatory approval and which they could manufacture on an industrial scale, although further work remained to be done. This was particularly true of the diacid. Accordingly, I conclude that Actavis are entitled to a DNI pursuant to Article L 615-9 IPC. Even if only the intended manufacturer can obtain a DNI, Actavis Italy is the intended manufacturer and will, if necessary, import the product into France.

324. *Route 2*. For the purpose of considering route 2, I shall assume that Lilly is correct that Actavis cannot circumvent the requirement of Article L 615-9 IPC for a taking position letter by relying upon Lilly's statements in these proceedings because Lilly has not positively asserted infringement by Actavis. Actavis contend that, by the date of the Sixth Action, more than three months had elapsed since Actavis' taking position letter dated 16 September 2013, and accordingly Actavis had fully complied with the requirements of Article L 615-9.

325. Lilly does not concede that the letter dated 16 September 2013 satisfied the requirements of Article L 615-9 IPC, but in my judgment it did. In closing submissions counsel for Lilly raised a new argument that Actavis could not rely upon this letter since it was sent during the currency of earlier actions, in particular the First and Third Actions, but this point is unpleaded and unsupported by the expert evidence. More than three months elapsed between the date of the letter and the date the Sixth Action was commenced. I have already held that Actavis had made serious and effective preparations to manufacture and market each of the products, and particularly the diacid, by 20 December 2013, and certainly by the date of the trial. Accordingly, I conclude that Actavis are also entitled to a DNI pursuant to Article L 615-9 IPC on this basis.

326. *Route 3*. Although my conclusion in relation to routes 1 and 2 makes it strictly unnecessary to consider route 3, I shall do so because it is relied upon by Actavis as one of their answers to Lilly's abuse of process argument (as to which, see below). Route 3 is essentially the same as route 2, except it relies upon the First and Third Actions and the contention that Actavis can rely upon a taking position letter sent during the pendency of those proceedings. I have concluded that Actavis are right about that. I have already held that Actavis had made serious and effective preparations to manufacture and market each of the products, and particularly the diacid, by 20 December 2013, and certainly by the date of the trial. Accordingly, I conclude that Actavis are also entitled to a DNI pursuant to Article L 615-9 IPC on this basis.

DNI in respect of the Italian designation applying Italian law

Italian law

327. Article 100 of the Code of Civil Procedure ("CCP") provides:

> "In order to state a claim or to oppose the same, the claimant and the opponent must have a legitimate interest."

328. It is common ground that this applies to claims for DNIs. It is also common ground that the test for a legitimate interest in relation to a claim for a DNI is that there is an objective uncertainty giving rise to a present, concrete prejudice to the claimant which the judgment of the court is capable of curing. It is also common ground that there is no need for a cease-and-desist letter to have been sent.

329. Prof Gugliemetti considers that there must be some form of actual, articulated objection ("*contestazione*") from the patentee in order for the required uncertainty to exist. Prof Franzosi does not agree with this, although he does agree that the uncertainty must not be academic or hypothetical. Both experts have referred to a number of cases as supporting their respective positions.

330. Prof Franzosi's position is supported by some decisions of the Supreme Court in non-patent cases, and in particular Case 17026 *VS v TA* of 26 July 2006, in which the Court stated:

> "The most recent case law of the Supreme Court has in fact broadened the scope of enforceability of declaratory actions or of actions of mere declaratory assessment, observing that the interest in bringing forth a lawsuit for a mere declaratory judgment does not necessarily imply the actual occurrence of an infringement on a right or a dispute (*contestazione*) as a state of objective uncertainty is sufficient with regards to the exact scope of rights and mutual obligations arising from any legal transaction as in the present case."

331. Prof Franzosi's position is also supported by some recent decisions of the lower courts in patent cases, in particular three decisions of the Ordinary Court of Milan (Case 77566/2011 *Medexpo International Srl v Medel Group SpA* (1 February 2012), Case 89281/2012 *Ranbaxy UK Ltd v AstraZeneca AB* (12 February 2013) and Case 11770/2011 *Mylan SpA v AstraZeneca* AB (2 April 2013)) and one of the Court of Appeal of Milan (Case 4074/2009 *M.E.P. Maccine Elettroniche Piegatrici SpA v Titanfer Srl* (19 May 2011)). Of these cases, I find the analysis in *Ranbaxy v AstraZeneca* the most comprehensive, helpful and persuasive. In this judgment the Court is explicit that it is not necessary for an objection already to have been made. Thus Italian law on this question appears to be evolving in the same direction as English law has evolved. Accordingly, I accept Prof Franzosi's opinion on this issue.

332. It does not appear to be disputed that, as stated by Prof Franzosi, legitimate interest is to be assessed at the date of the court's decision and therefore events after the issue of the claim can be taken into account. Prof Gugliemetti does say that a subordinate counterclaim under Italian procedure cannot give rise to a legitimate interest. Prof Franzosi disagrees with this, but in my view it does not matter who is right, because these proceedings have not been conducted in accordance with Italian procedure and Lilly has not made a subordinate counterclaim.

Assessment

333. Actavis contend that they have a legitimate interest in obtaining a DNI in respect of the Italian designation of the Patent because there is an objective uncertainty giving rise to a present, concrete prejudice to Actavis which the declaration of the court is capable of curing. I agree with this. Actavis are well advanced with plans to manufacture and market a generic pemetrexed product. They contend that none of pemetrexed diacid, dipotassium or ditromethamine fall within the scope of the claims of the Italian designation of the Patent. Lilly disputes this. This means that, objectively viewed, there is uncertainty. That gives rise to present, concrete prejudice to Actavis, because they need a determination of the issue in order to know whether they will be safe to launch their product. In short, the uncertainty affects their business. A declaration of the court will cure this uncertainty.

334. If, contrary to the conclusion I have reached above, an objection from Lilly is required, I consider that there has been an objection by Lilly for this purpose. Lilly has expressly alleged that pemetrexed diacid, dipotassium or ditromethamine fall within the scope of the claims of the Italian designation of the Patent and has adduced evidence and arguments in support of that allegation. Indeed, paragraph 88 of Lilly's Combined Defence alleges in relation to the Italian designation of the Patent that "There is infringement by equivalence ….". It is immaterial that Lilly has not expressly alleged that Actavis have committed or threaten to commit any infringing acts. Again, it is clear that the only reason why Lilly has not done so is because it would prefer Actavis to have to bring their claim in the Italian courts.

<u>DNI in respect of the Spanish designation applying Spanish law</u>

Spanish law

335. Article 127 of the Spanish Patents Act 1986 ("SPA") provides as follows:

> "1. Any interested person may file an action against the owner of the patent so that the competent judge may declare that a particular act does not constitute infringement of the patent.
>
> 2. Before filing the action, the interested person shall, through notarial channels, demand that the patent owner make known his position on the opposability of the patent to the industrial exploitation carried out in Spain by the claimant or serious and effective preparations being made for that purpose. The person making the demand may file the action provided for in the preceding paragraph if the patent owner has not replied within one month of the date of the demand, or if he does not agree with the reply.
>
> 3. The action specified in paragraph 1 above may not be filed by any person against whom a claim for infringement of the said patent has been brought.

> 4. Where the claimant proves that the act referred to in the claim does not constitute infringement of the patent, the judge shall grant the declaration that was demanded.
>
> 5. The claim shall be notified to all persons owning rights in the patent who are duly entered in the Register, so that they may appear and take part in the proceedings. Nevertheless, holders of contractual licenses may not appear in the proceedings where their license contracts so specify.
>
> 6. The action referred to in the present Article may be brought jointly with an action to declare the invalidity of the patent."

336. There are a considerable number of issues between the parties with regard to this provision, and there is a great deal of expert evidence on those issues (and not merely because of Lilly's use of two experts to address some of them). I shall confine my attention to the issues which matter and deal with them as concisely as I can. In particular, I do not propose to enter into the debate between the experts as to whether Article 127 is procedural or substantive as a matter of Spanish law. Nor, to the extent that it is a separate question, do I propose to enter into the question of whether Article 127 is a provision as to standing as a matter of Spanish law. Nor, to the extent that it is a separate question, do I propose to enter into the debate as to the relationship between Article 127.1 and Article 127.2. In so far as these matters relate to the issue over the interpretation of Rome II, as I have already said, they are not determinative. While it is fair to say that the debates over these issues are linked with debates over the issues considered below, it does not appear to me that it is essential to resolve them in order to resolve the issues considered below.

337. The first issue is whether it is necessary for the claimant to comply with the requirement of Article 127.2 for a demand through notarial channels one month before filing the action if the patentee has already clearly taken a position on the opposability of its patent to the product. Prof Desantes considers that it is not, relying in particular on the decision of the Court of First Instance of Bilbao in Judgment 156/02 *Teodosio v Metro Bilbao SA* of 24 June 2012 concerning a dispute as to whether the domain name metrobilboa.com registered and used by the claimant infringed the defendant's trade mark METRO BILBAO. In that case the Court rejected the defendant's argument that the claimant had not complied with Article 127.2 (which the Spanish trade mark law applies to trade marks) because the purpose of the notarised request was to allow the trade mark owner to take a position with regard to the activity in question, but there was no need for this in the instant case because the trade mark owner had already filed a complaint against the claimant with the World Intellectual Property Organisation's Arbitration and Mediation Centre.

338. Prof Bercovitz accepts in paragraph 143 of his first report that this decision showed that "under exceptional circumstances, where the purpose of such requisites had been deemed to have been fulfilled", it was not necessary to send a notarial request and wait for a month as required by Article 127.2. In paragraph 118 of his second report he states that Article 127.2 has not been dispensed with in any other case and the decision "cannot be extrapolated to any *de facto* circumstance imaginable in which there has been no notarial request". In paragraph 30 of his third report, he points out that there was no appeal, and so one does not know what the position of the higher

courts would have been. He does not go so far as to say that the decision is wrong, however. Similarly, Prof Arenas states in paragraph 57 of his second report that in that case "the purpose sought by the notarial request had been achieved by an equivalent channel: (i) the trademark holder was aware of the claimant's activity; (ii) the trademark holder had 'sufficient time' to assess the infringement …; (iii) the trademark holder had an opportunity to file an infringement complaint".

339. Accordingly, the experts are agreed that there can be circumstances in which it is not necessary for the party seeking a DNI to comply with the requirement in Article 127.2 for a prior demand through notarial channels. The dispute is as to what circumstances suffice for this purpose. In my judgment, the evidence demonstrates that compliance with this requirement in Article 127.2 can be dispensed with, but only if the purposes which it serves have already been achieved before commencement of the claim for DNI. This will be the case if the patentee has been made aware of the product in question, has had at least a month to consider its position and has clearly taken a position on the opposability of its patent to the product.

340. I do not consider that this conclusion is contradicted by the decision of the Court of Appeal of Navarre in Judgment 130/2011 *Laboratorios Cinfa SA v Novartis AG* of 27 May 2011 which was relied on by counsel for Lilly. In that case Cinfa had sent a letter dated 16 April 2008 to Novartis stating that it had made serious and effective preparations to market generic valsartan in Spain and asserting that its product did not infringe Novartis' patent. It does not appear that this letter identified the manufacturer of the active ingredient. Novartis replied asserting that the patent covered the marketing of such a product and formally requesting Cinfa not to market the product. On 3 June 2008 Cinfa commenced a claim under Article 127 requesting a declaration that valsartan manufactured by Química Sintética SA did not infringe the patent. Novartis objected that Cinfa had not complied with the requirements of Article 127. Prior to the trial, Cinfa sought to amend its claim to seek a declaration in respect of its own marketing of valsartan made by Química Sintética, but this application was refused and there was no appeal. The first instance court agreed with Novartis, holding that Cinfa only had *locus standi* to request a DNI in respect of its own activities and not in respect of manufacture by a different company. Cinfa's appeal was dismissed. Among Cinfa's arguments on appeal was that Novartis had given it *locus standi* by its subsequent actions and statements, namely, bringing infringement proceedings against Cinfa. The Court of Appeal rejected this argument on the ground that "The requirements for *locus standi* as claimant must exist on the date the complaint is filed, and this cannot be remedied subsequently ….". It does not follow that a prior taking of position cannot be relied upon.

341. The second issue is whether, if the patentee has stated its position clearly, this also removes the need for the claimant to show that it has made serious and effective preparations. Prof Desantes considers that this is the case, while Prof Bercovitz and Prof Arenas do not. In my judgment the logic which I have identified in the decision in *Teodosio v Metro Bilbao* for dispensing with the requirement for a notarial request one month before the claim where the purposes of that requirement have already been achieved does not justify dispensing with the requirement for serious and effective preparations. This conclusion receives some slight support from the judgment in *Cinfa v Novartis*, in which the Court of Appeal held that, if Cinfa had wanted to obtain a DNI in respect of its marketing of the product "it should have been expressly

requested in the petition section of the complaint, specifying the 'serious and effective preparations' in its complaint and accrediting the reality of the same at the evidentiary stage".

342. The third issue concerns the requirement for a demand through notarial channels ("*requerirá notarialmente*"), assuming that it is not sufficient for the patentee to have clearly stated his position on the opposability of the patent. Prof Bercovitz considers that this means that there must be a notarial summons ("*acta de requiriminto*") in accordance with Article 202 of the Notary Rules and Regulations, although he accepts that a foreign notary, rather than a Spanish notary, can be employed for this purpose where the patentee is based outside Spain. Prof Desantes disagrees, and considers that Article 127.2 merely requires a notarial notification ("*acta de notificación*"). On this point I find Prof Desantes' reasoning in paragraphs 21-24 of his fourth report convincing.

343. Even if a notarial summons is required, Prof Desantes considers that proof of transmission of the demand through notarial channels is not required where the patentee has acknowledged receipt of the demand. Prof Bercovitz and Prof Arenas disagree with this. Again, I find Prof Desantes' reasoning convincing. It seems clear that the purpose of requiring the demand to be sent through notarial channels is to ensure that the claimant can prove transmission and receipt. If the patentee has acknowledged receipt, proof by notarial means is not required. As the decision in *Teodosio v Metro Bilbao* shows, the Spanish courts will not insist upon compliance with pointless formalities.

344. The fourth issue is what constitutes "serious and effective preparations". It is not disputed that "industrial exploitation" includes marketing a product. Prof Bercovitz considers that "serious and effective preparations" requires the preparations to have reached the point that the claimant has the capacity to proceed imminently with the exploitation. In support of his opinion, Prof Bercovitz argues that "serious and effective preparations" in Article 127 should be interpreted in the same way as those words have been interpreted in the context of a prior use defence to infringement under Article 54 SPA (similar to section 64 of the UK Patents Act 1977). This argument receives some support from the decision of the Court of Appeal of Barcelona in Judgment 375/06 *Rolabo SL v Medichem SA* of 20 July 2006. That was a case concerning the interpretation of Article 54. In the course of its judgment, the court referred to a number of other provisions of the SPA, including Article 127. On the other hand, Article 127 was not itself in issue in that case. More significantly, in *Cinfa v Novartis* the Court of Appeal of Navarre adopted the judgment in *Rolabo v Medichem* to the extent it held that "experimental acts" were not sufficient to constitute "serious and effective preparations". On the other hand, that passage was what an English court would regard as *obiter*, although I appreciate that Spanish courts do not make the same distinction between *ratio* and *obiter*.

345. Against this, Prof Desantes argues that, while it is justified to interpret the words narrowly in the context of the Article 54 defence to infringement, the purpose of Article 127 is different and so it does not follow that they should be interpreted in the same way in that context. Prof Desantes points out that Article 127 is based on section 162 of the BIRPI (the predecessor to WIPO) Model Law for Developing Countries on Inventions. The commentary to section 162 states:

> "The purpose of this Section is to avoid future infringement proceedings in borderline cases. It is possible that a person's present or future activity may perhaps be an infringement, but that the person is not certain. In order to clarify the matter, he may avail himself of the procedure provided for in this Section. If the outcome is favourable to him, in other words, if the court's finding is that the performance of the act in question does not infringe the patent, the person may engage in (or continue) his activity without risk, whereas he will discontinue (or forgo) the activity if the court's finding is unfavourable to him."

Furthermore, Prof Bercovitz, who was the draftsman of the bill which introduced Article 127, himself stated in an article introducing the new law:

> "When starting or continuing a particular industrial activity it is of extreme relevance to have the assurance that no other's patents are violated. Consider, in fact, that for any productive activity it is necessary to make investments that may be lost if later that activity cannot be developed because it infringes a patent. This unfortunate situation can be avoided if in cases of doubt the action for declaration of non-infringement is filed, avoiding therefore the invidious position of a defendant accused of having infringed the rights arising from a patent."

346. Prof Desantes also points out that other commentators have interpreted "serious and effective preparations" in Article 127 more broadly. One suggests that merely experimental acts are not enough, but not a requirement of immediacy of exploitation. Another suggests that serious and effective preparations "may consist of tests following the trial period and technical and economical studies making this operation visible". Prof Desantes considers even these approaches are too restrictive, however.

347. Accordingly, Prof Desantes considers that "serious and effective preparations" is a broad concept which is for the overall factual assessment of the court, and that it could include (but would not necessarily require): (a) laboratory tests; (b) business plans to launch after a future marketing authorisation; (c) commencement of industrial scaling up; (d) preparation of a marketing authorisation dossier; or (e) starting preparations in order to be in a position to launch after expiry of SPCs.

348. In my judgment, the decision in *Cinfa v Novartis* and the weight of the commentary indicates that mere experimental acts will not suffice for "serious and effective preparations". I am not persuaded that it is necessary for the claimant to demonstrate that exploitation is imminent, which would be contrary to the purpose of Article 127 as explained by Prof Bercovitz in his article. Thus if there are concrete and well developed plans for industrial exploitation and preparations have been made to implement those plans extending beyond mere experimental acts, that will suffice.

349. The fifth issue is whether the serious and effective preparations must be in Spain. Prof Desantes considers that this is not necessary. As counsel for Actavis pointed out, Prof Bercovitz and Prof Arenas do not take issue with this, as opposed to emphasising that the serious and effective preparations must be for industrial exploitation in Spain. Prof Desantes accepts the latter point.

350. It is common ground that the question whether the claimant has made serious and effective preparations is to be assessed as at the date the claim was commenced.

351. The sixth issue is whether it is possible for the claimant in a claim under Article 127 to remedy deficiencies in his claim, such as a failure to send a demand through notarial channels one month before the claim, during the course of the proceedings. Prof Desantes considers that this is possible, relying upon various provisions of the Spanish Code of Civil Procedure. Prof Bercovitz and Prof Arenas disagree. For reasons that will appear, I do not consider it necessary to resolve this dispute.

352. The seventh issue is whether it is possible for the claimant in a claim under Article 127 to remedy deficiencies in his claim, such as a failure to send a demand through notarial channels one month before the claim, by starting a further action during the pendency of the first action. Again, Prof Desantes considers that this is possible, while Prof Bercovitz and Prof Arenas disagree. Again, I do not consider it necessary to resolve this dispute.

Assessment

353. Actavis rely upon no less than seven alternative "routes to admissibility" of their claim for a DNI in respect of the Spanish designation. Lilly again contends that all seven routes fail for one or more of four reasons: (i) Article 127.2 SPA must always be complied with; (ii) Actavis have not given Lilly one month's notice through notarial channels; (iii) Actavis had not at the relevant dates, and still have not, carried out the necessary serious and effective preparations; and (iv) it is not possible for Actavis to cure defects within an existing action, but only by starting again and commencing a new action. I shall confine my attention to routes 1, 2, 3 and 5.

354. *Route 1*. Actavis contends that, by the time the Sixth Action was commenced, Lilly had clearly taken a position as to the opposability of the Spanish designation of the Patent to the products. As with France, Actavis rely in particular on the recital to the order dated 17 October 2013, Lilly's Statement of Case and the letter dated 10 December 2003. Lilly again relies on the same points as with France. Again, I conclude that Lilly had clearly taken a position on the opposability of the Spanish designation of the Patent to the products by 20 December 2013. Again, the only reason why Lilly had not positively alleged infringement of the Spanish designation was that it wanted, so far as possible, to preserve its position that Actavis should have brought the claim in Spain in accordance with Spanish procedure rather than in England in accordance with English procedure, and thereby make it more difficult for Actavis to obtain a DNI even if they were right on the merits.

355. Accordingly, I agree with Actavis that it does not matter whether they had properly complied with the requirement to send a taking position letter through notarial channels one month before the Sixth Action. I do not agree that this relieves Actavis from the obligation to demonstrate that they had made serious and effective preparations, however.

356. In my judgment the evidence demonstrates that Actavis had made serious and effective preparations to manufacture and market each of the products, and particularly the diacid, by 20 December 2013 for similar reasons to those I have given

in relation to the French designation. Accordingly, I conclude that Actavis are entitled to a DNI pursuant to Article 127 SPA.

357. *Route 2*. For the purpose of considering route 2, I shall assume that Lilly is correct that Actavis cannot circumvent the requirement of Article 127.2 SPA for a letter to be sent through notarial channels one month prior to the action by relying upon Lilly's statements in these proceedings. Actavis contend that, by the date of the Fifth Action, more than one month had elapsed since Actavis' taking position letter dated 16 September 2013, and accordingly Actavis had fully complied with the requirements of Article 127.2. The same goes for the later actions.

358. Lilly does not concede that the content of the letter dated 16 September 2013 satisfied the requirements of Article 127.2, but in my judgment it did. Lilly contends that the letter was not sent through notarial channels as required. As is common ground, however, Lilly acknowledged receipt of the letter. Thus there is no doubt that the letter was both sent and received. I therefore conclude that the sending of the letter did comply with Article 127.2. I have already found that Actavis had made serious and effective preparations to manufacture and market each of the products, and particularly the diacid, by the date of the Sixth Action. Accordingly, I conclude that Actavis are also entitled to a DNI pursuant to Article 127 SPA on this basis.

359. *Route 3*. Route 3 again relies upon the letter dated 16 September 2013. I shall nevertheless consider it because it is relied upon by Actavis as one of their answers to Lilly's abuse of process argument. The difference from route 2 is that, instead of relying on the starting of the Fifth Action more than one month after that letter, Actavis rely upon the amendments which Actavis made to the First and Third Actions on 22 October 2013 pursuant to the order dated 17 October 2013. The effect of the amendments was to introduce claims in relation to pemetrexed diacid and ditromethamine into the First Action and pemetrexed dipotassium into the Third Action more than one month after the letter dated 16 September 2013. This raises the question of whether Actavis had made serious and effective preparations by 22 October 2013. With slightly more hesitation than in the case of 20 December 2013, I consider that they had. Lilly also advances an argument in relation to route 3 of abuse of process under English law, which I shall consider below.

360. *Route 5*. For the purpose of considering route 5, I shall assume that Actavis fail on routes 1, 2 and 3 and that Actavis must prove transmission of a taking position letter through notarial channels. In my judgment Actavis has complied with all the notarial requirements relied on by Lilly with respect to the letter dated 4 April 2014. The Ninth Action was issued more than one month after that. Furthermore, even if Actavis had not made serious and effective preparations by the dates of the Sixth Action, I consider that they had done so by the date of the Ninth Action, having continued to progress their plans. Accordingly, I conclude that Actavis are also entitled to a DNI pursuant to Article 127 SPA on this basis.

Lilly's abuse of process argument in relation to the French and Spanish designations

361. Lilly contends that, if (i) on the proper interpretation of the Rome II Regulation the law applicable to the non-contractual obligation includes the rules with regard to interest and pre-notification under French and Spanish law on which Lilly relies, (ii) the First and Third Actions were not well founded due to non-compliance by Actavis

with those rules at the dates of those actions, but (iii) the Fourth or any of the subsequent Actions was well founded because by the date of those actions Actavis had complied with the relevant rules, the Fourth and subsequent Actions should be struck out as an abuse of the process in so far as they relate to the French and Spanish designations ("the Main Abuse Argument"). Lilly also contends that, if Actavis is correct that the First and Third Actions were well founded in relation to the Spanish designation as from the date of the amendments on 22 October 2013 even if not originally, the making of those amendments was an abuse of process ("the Amendment Abuse Argument").

362. Given my earlier conclusions, I need to make clear the bases upon which I shall consider these arguments. So far as the French and Spanish designations are concerned, I have concluded that (i) Actavis will not infringe those designations applying the *lex loci protectionis*, (ii) on a proper interpretation of the Rome II Regulation the other conditions which must be satisfied for the making of a DNI are governed by the *lex fori* and (iii) applying English law Actavis are entitled to a DNI. It follows that Actavis succeed in the First and Third Actions, and the later actions were unnecessary. Even if I am wrong on point (ii), I have held that, applying French law, Actavis succeed on route 3. Again it follows that Actavis succeed in the First and Third Actions, and the later actions were unnecessary. If I am wrong about that, but right that Actavis succeed on routes 1 or 2, it follows that Actavis succeed in the Sixth Action, but not in the First and Third Actions. I shall therefore consider Lilly's contention that the Sixth Action is an abuse of process on that assumption. Applying Spanish law, I have held that (subject to the Amendment Abuse Argument) Actavis succeed on route 3. If I am wrong about that, but right that Actavis succeed on routes 1, 2 or 5, it follows that Actavis succeed in the Fifth, Sixth or Ninth Actions, but not in the First and Third Actions. I shall therefore consider Lilly's contention that the Fifth, Sixth and Ninth Actions are an abuse of process on that assumption.

363. It should be noted before proceeding further that Lilly advances these arguments in reliance upon the English law of abuse of process i.e. the *lex fori*. Lilly does not rely upon the laws of France or Spain for this purpose. It must therefore be assumed that the Fourth and subsequent Actions would not be struck out or dismissed as an abuse of process or on an equivalent ground applying French and Spanish law. As I understand it, the reason why Lilly contends that the relevant law is English law is because the court whose process Lilly claims is being abused is the English court. I am unable to understand why, if Lilly is correct that the relevant rules are substantive rules governed by the *lex loci protectionis*, the question whether it is legitimate for Actavis to try to ensure compliance with those rules by starting fresh actions during the pendency of earlier actions or by amending pending actions should be judged by reference to the *lex fori*. Be that as it may, I will consider the merits of Lilly's arguments on the assumption that it is correct as to the applicable law for this purpose.

364. It is convenient first to consider the Amendment Abuse Argument. This relates to route 3 in respect of the Spanish designation. As I have explained, route 3 relies upon the amendments to the First and Third Actions made on 22 October 2013. Counsel for Lilly submitted that route 3 failed because the amendments were an abuse of process. I do not consider that this argument is open to Lilly for the following reasons. First, the order giving Actavis permission to make those amendments provided that the amendments would be made "without prejudice to Lilly's or Actavis' ability to argue

such points as they may have as to the effect of those amendments in respect of the Fourth Action". Lilly's purpose in seeking this qualification was, as counsel for Lilly made clear at the hearing on 17 October 2013, to ensure that it was not prevented by the amendments from arguing that the Fourth (or any later) Action was an abuse of process. Lilly did not resist the amendments on the ground that they were in and of themselves an abuse of process. Secondly, Lilly has not appealed or applied to set aside that part of the order of 17 October 2013. Thirdly, Lilly has not pleaded that the amendments were an abuse of process. Even if the argument is open to Lilly, I do not accept it. As I have pointed out, Actavis were given permission to make the amendments by an order of this Court. There is no dispute that this Court had power under the Civil Procedure Rules to give Actavis permission to make the amendments. Furthermore, viewed from the perspective of English procedural law, there was nothing abusive about Actavis' application for permission to make the amendments, which is precisely why Lilly did not in the end resist it provided that permission was qualified in the way that I have described. Even if Lilly is right that no such amendment could be made under Spanish procedural law, and the claimant would have to start a new action, that is immaterial.

365. I turn to consider the Main Abuse Argument. The applicable principles can be summarised as follows. In *Hunter v Chief Constable of the West Midlands* [1982] AC 529 at 536, Lord Diplock referred to:

> "… the inherent power which any court of justice must possess to prevent misuse of its procedure in a way which, although not inconsistent with the literal application of its procedural rules, would nevertheless be manifestly unfair to a party to litigation before it, or would otherwise bring the administration of justice into disrepute among right-thinking people. The circumstances in which abuse of process can arise are very varied .... It would, in my view, be most unwise if this House were to use this occasion to say anything that might be taken as limiting to fixed categories the kinds of circumstances in which the court has a duty (I disavow the word discretion) to exercise this salutary power."

366. As Lord Bingham of Cornhill explained in *Johnson v Gore Wood & Co* [2002] 2 AC 1 at 31, this involves:

> "... a broad, merits-based judgment which takes account of the public and private interests involved and also takes account of all the facts of the case, focusing attention on the crucial question whether, in all the circumstances, a party is misusing or abusing the process of the court ..."

367. In the context of the Civil Procedure Rules, assessment of whether there is an abuse of process is inseparably bound up with the question of what the overriding objective requires. Thus, as Lord Phillips of Worth Matravers MR said in *Jameel v Dow Jones & Co Inc* [2005] EWCA Civ 75, [2005] QB 946 at [54]:

> "An abuse of process is of concern not merely to the parties but to the court. It is no longer the role of the court simply to

> provide a level playing field and to referee whatever game the parties choose to play upon it. The court is concerned to ensure that judicial and court resources are appropriately and proportionately used in accordance with the requirements of justice."

368. Furthermore, even where the claimant has been guilty of an abuse of process, it does not necessarily follow that his claim must be struck out if that would be a disproportionate sanction in the circumstances: see *Summers v Fairclough Homes Ltd* [2012] UKSC 26, [2012] 1 WLR 2004. As the decision of the Supreme Court in that case indicates, this is particularly true where there has been a fair trial of the merits of the claim and the claim has been upheld at least to some extent.

369. As was indicated in the *Hunter* case, the categories of abuse of process are not closed. There are a number of established situations in which abuse of process may be recognised. One is where the court's process is being used for an improper or collateral purpose: see in particular *Goldsmith v Sperrings Ltd* [1977] 1 WLR 478. Another is re-litigation of matters that could and should have been litigated previously: see in particular *Johnson v Gore Wood*. A third is where it is plain that the litigation is pointless and wasteful: see in particular *Jameel v Dow Jones*. A fourth is where the claimant advances a false case and/or relies upon false evidence: see in particular *Summers v Fairclough*.

370. The particular form of abuse which Lilly invokes is that which can arise where the claimant has framed its claim in such a manner as to attempt to circumvent a time restriction. Counsel for Lilly relied, in particular, upon the decision of Jackson J (as he then was) in *Carter Commercial Developments v Bedford Borough Council* [2001] EWHC 669 (Admin) applying the judgment of the Court of Appeal in *Clark v University of Lincolnshire and Humberside* [2000] 1 WLR 1988. In *Carter*, the gravamen of the complaint of abuse of process was concisely identified by the judge at [30] as follows:

> "The issues which the claimant seeks to raise are plainly public law issues and should properly be dealt with by judicial review proceedings under Part 54. The reason why the claimant has resorted to the Part 8 procedure is obvious. The claimant is seeking to circumvent the time limits contained in Part 54."

As will be clear from that quotation, the claimant was well out of time for an application for judicial review under Part 54 and was, therefore, seeking to bring private law proceedings under Part 8 instead. That was held to be an abuse of process because the claimant should have proceeded by way of judicial review. Thus the claimant was clearly using the procedures of the court in an improper way.

371. As counsel for Actavis submitted, however, it is not an abuse of process to bring a further claim on the same cause of action during the pendency of an existing claim if there is a good reason for doing so and case management tools like consolidation are used to avoid unnecessary duplication of effort and cost: see *Rozenberg v Nazarov* [2008] EWHC 812 (Ch) at [71]-[77] (Thomas Ivory QC sitting as a Deputy High Court Judge). A common example of this in the intellectual property field is where the claimant is relying upon a cause of action, such as secondary infringement of

copyright, which requires knowledge or reason for belief on the part of the defendant. Prior to the CPR, it was common for claimants, where there was doubt that the defendant had the requisite knowledge or reason for belief as at the date of the writ, but it was clear that the defendant did have it at a later date, to issue a second writ and apply to consolidate the two actions or to have them heard together. Under the CPR it is possible to take the simpler course of pleading facts arising after the date of the claim form. If there was doubt about that, however, it would not be an abuse of process for the claimant to issue a second claim form in order to ensure that it was able to rely upon the defendant's knowledge or reason for belief as at the date of the second claim form in the alternative to the date of the first claim form and then to apply for the two claims to be heard together on the same evidence.

372. In my judgment what Actavis have done in the present case is no different in principle to what I have just described. Lilly contends that it is different because the *lis pendens* effect of the First and Third Actions deprived it of the opportunity of responding to Actavis' later taking position letters by bringing infringement proceedings in France and Spain. As to that, my view remains as stated in my judgment dated 27 November 2013 at [33]:

> "… the problem which Lilly says exists is one which exists, to the extent that it does, by virtue of the First and Third Actions and the consequences of the pendency of those actions. There is, and can be, no dispute that the First and Third Actions are properly constituted actions over which it has been decided that this court has jurisdiction. Those actions have whatever consequences in terms of *lis pendens* that they have. If Lilly is correct in saying that the *lis pendens* consequences of those actions is to prevent Lilly from bringing actions in France and Spain and thus of depriving Lilly of the procedural protections to which it claims to be entitled under French and Spanish law, as to which I express no view, then that is a natural consequence of the existence of the First and Third Actions. It is not a consequence of the bringing of the Fourth and Fifth Actions. In those circumstances, I cannot see that the Fourth and Fifth Actions are an abuse. Actavis are simply taking ordinary procedural steps to overcome procedural obstacles raised by Lilly."

373. Lilly argues that this is wrong because Actavis should have discontinued the First and Third Actions before commencing the later Actions, and even before writing the letters upon which those Actions are founded. I see no reason, however, why Actavis should have been obliged to discontinue claims which were properly constituted, jurisdictionally well founded and had a perfectly good prospect of success. Even if Actavis should have discontinued the First and Third Actions because they were destined to fail, that would at best found an argument that maintaining the First and Third Actions was an abuse. It would not follow that bringing the Fourth and subsequent Actions was an abuse. So Lilly's argument has to be that, given that the First and Third Actions were maintained, it was an abuse to bring the later Actions. But that simply amounts to saying that it was an abuse for Actavis to pursue an alternative case while maintaining their primary case, which is commonplace in English litigation (and in litigation in many other legal systems).

374. I would add two points. The first is that Lilly's argument makes it clear that what Lilly is really complaining about is not the bringing of the Fourth and subsequent Actions during the pendency of the First and Third Actions, but the fact that Actavis have brought these proceedings before this Court. That complaint is not open to Lilly, however, because its jurisdictional challenge to the First and Second Actions failed and it has rightly accepted that this Court has jurisdiction over the Third and subsequent Actions. Furthermore, it is not an abuse of process for a claimant to bring a claim before a forum which he perceives to be more advantageous (e.g. because it is quicker) in order to forestall the defendant from bringing proceedings in a forum which the claimant perceives to be less advantageous (e.g. because it is slower) provided that the first forum is one which properly has jurisdiction in respect of the claim: see *Research In Motion UK Ltd v Visto Corp* [2008] EWCA Civ 153, [2008] FSR 499 at [12]-[17] (Jacob LJ) and *Pell Frischmann Consultants Ltd v Prabhu* [2013] EWHC 2203 (Ch), [2013] ICR 153.

375. The second point is that Lilly can only complain that it has been the victim of an abuse of process in this respect if it has been prevented by Actavis' conduct from bringing infringement actions against Actavis in France and Spain that it would otherwise have brought. Lilly has not adduced any evidence, nor even asserted through counsel's submissions, that it would have brought such actions but for Actavis' conduct, however. By contrast, Lilly has brought and pursued a claim in Germany even though this Court was first seized. Lilly's stance with regard to France and Spain is simply obstructive.

Summary of conclusions

376. For the reasons given above I conclude that:

i) neither pemetrexed diacid nor pemetrexed dipotassium nor pemetrexed ditromethamine falls within the scope of the claims 1 or 12 of the UK, French, Italian or Spanish designations of the Patent;

ii) accordingly dealings in pemetrexed diacid, dipotassium and ditromethamine by Actavis will not constitute direct infringement of the UK, French, Italian or Spanish designations of the Patent;

iii) nor will dealings in pemetrexed diacid, dipotassium and ditromethamine by Actavis will constitute indirect infringement of the UK, French, Italian or Spanish designations of the Patent;

iv) the law applicable to the question of whether Actavis are entitled to a DNI is English law;

v) applying English law, Actavis are entitled to a DNI in respect of the UK, French, Italian and Spanish designations of the Patent;

vi) even if French, Italian and Spanish law is the applicable law respectively, Actavis are entitled to a DNI in respect of the French, Italian and Spanish designations of the Patent; and

vii) if French and Spanish law is applicable, if the First and Third Actions are not well founded, but one or more of Actavis' later Actions are well founded, those later Actions are not an abuse of process in so far as they relate to the French and Spanish designations.