EXHIBIT 12

IN THE COURT OF APPEAL

ON APPEAL FROM THE HIGH COURT OF JUSTICE — CH 1992 K No 8550

CHANCERY DIVISION — CH 1993 K No 937

PATENTS COURT — CH 1993 B No 4552

CH 1993 C No 6076

IN THE MATTER OF EUROPEAN PATENTS (UK) Nos. 148,605; 205,564; 209,539; 411,678

AND IN THE MATTER OF PETITIONS FOR REVOCATION THEREOF BY BOEHRINGER MANNHEIM GmbH and CILAG LIMITED

AND IN THE MATTER OF ACTIONS FOR INFRINGEMENT THEREOF BY, INTER ALIA, KIRIN-AMGEN INCORPORATED AND BOEHRINGER MANNHEIM GmbH

AND RESPONDENTS'

APPELLANTS' SKELETON ARGUMENT

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SUMMARY

(i) This appeal happens to arise in a piece of major patent litigation but it is not primarily involved with issues relating to patents. It concerns a point of general application namely the degree to which litigants can, when the stakes are high enough, turn international litigation into a war of attrition by relitigating previously decided issues of fact irrespective of the waste of resources (in this case legal fees, executive and witness time as well as scarce judicial resources) thereby engendered.

(ii) The litigation presently before this Court is but one battle in a much wider conflict between two sets of litigants in numerous jurisdictions throughout the world. The significant aspect for the purposes of this appeal is that a large number of the factual issues involved in that conflict have already been fought over extensively in previous litigation in the United States of America. That litigation was fought hard by both sets of litigants and involved pleadings, extensive discovery, depositions, expert testimony, cross examination, 30 days' of witness evidence and extensive written and oral argument. The issue was the right to monopolise the United States' market in respect of recombinant erythropoietin ("rEPO"), a novel, valuable, genetically engineered product of immense benefit to the patient population. The value of the United States' market being fought over was considerable; it is currently worth in excess of US$1 billion in sales. Every aspect of the history and background was examined in the minutest detail; there is no evidence or suggestion by the Respondents that any significant point was overlooked or not appreciated as being significant by either side. The United States District Court, the Court of First Instance[1], and the Court of Appeals for the Federal Circuit ("CAFC") gave reasoned decisions in the course of which they made certain factual findings which underlay their legal conclusions.

(iii) Litigation is now pending in several European jurisdictions including the United Kingdom. Given that patents are national and create national rights, there will be numerous, essentially domestic questions to be considered and argued about. The trial

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[1] The trial at first instance was a "bench trial" that is to say it was not a jury trial.

(currently set for April 1997) will be substantial and is set for 5 to 6 weeks. However, the Respondents go further than seeking to deal with those issues peculiar to the United Kingdom. They are seeking to re-run history and re-litigate the factual matters which were determined in the earlier United States litigation. The Appellants say that that should not be permitted and seek to invoke the doctrine of issue estoppel to prevent factual issues having to be argued all over again. The issue on this application and appeal is whether in all the circumstances of the litigation that power ought to be exercised. The Appellants' submission is that in all fairness, having regard to all the circumstances, the doctrine of issue estoppel can and ought to be applied to the findings of fact in the present case.

(iv) The Respondents dispute that issue estoppel can be applied in the present instance. They do so by submitting that the Courts have established a strict, narrow test as to the circumstances in which issue estoppel may apply and argue that the present case does not meet that test. They do this in two ways; first they argue that each finding of the United States Courts cannot be said individually to be so essential to the earlier decisions that those decisions "cannot stand" without those findings. Secondly, they argue that the two main parties in the United Kingdom litigation, namely the Boehringer Mannheim companies, ought not to be bound by those earlier findings because they were not parties to the previous United States litigation. This is despite the fact that Boehringer Mannheim GmbH's ("BMG") right to sue in the half of these proceedings in which the Respondents are Plaintiffs (action CH 1993 B No.4552) is entirely derived from its Co-Plaintiff, GI, which was the corresponding litigant in the US proceedings; and despite the fact BMG was intimately involved with the acts of GI in the United States and paid a significant part of the damages which GI had to pay in the US litigation.

(v) What is particularly striking about the Respondents' resistance to the application is that despite the voluminous affidavit evidence and argument (both written and oral) which has been adduced so far the Respondents have failed to identify, save in one very minor respect, any aspect of the various factual issues which they contend might be decided differently if they are allowed to re-litigate them in the UK. Simply put, the

facts do not change. The Respondents have not given any rationale for not adopting the United States facts here except for a dissatisfaction with history. Furthermore, the Respondents have not disputed the fact that if estoppel effect is given to the various issues in question then substantial time and costs at trial will be saved. Instead, the Respondents simply seem to submit that they should be allowed "to have their day in court" and re-litigate these issues, notwithstanding the vast amount of judicial resource and cost which will be squandered and the inconvenience to the personnel (both legal and lay) involved in the litigation.

(vi) The Appellants submit that the arguments put forward by the Respondents are narrow and technical and do not relate to the way in which issue estoppel has developed. Moreover, they bear no relationship to the modern world of commerce and the modern approach to litigation. This is especially so in the context of international patent disputes in which parallel rights exist concurrently in a multitude of jurisdictions. To adopt the Respondents' position is to condemn patentees and their opponents to many years of expensive litigation in a multitude of jurisdictions, with the same factual issues being fought out over and over again. It is also to condemn National Courts to hearing the same points being disputed over and over again simply to satisfy the hopes of one of the litigants that "something will turn up". In this respect the Appellants respectfully adopt the statement of Judge Easterbrook, a Judge of the United States District Court in the case of ***Vas Cath v Muharkar*** [745 F. Supp 533 (MDI11 1990)]. In this case the US Court applied issue estoppel to prevent one party to a patent action relitigating factual matters which had been decided in parallel Canadian proceedings.

> *"Patent litigation is costly, and the Canadian case was hard fought. Why begin from scratch? Conservation of resources is the principal objective of the law of preclusion [issue estoppel], and that is a vital objective when costs are high, the more so when similar patents have been secured in many of the industrial countries. Patent litigation should not be allowed to become a war of attrition, in which after the conclusion of one battle parties move on to another and duplicate the engagement. If litigation squanders the returns to*

invention we will have less innovation - a depressing thought given the importance of invention to economic growth. Whenever there is a choice, a court ought to opt for cost-saving and decision-expediting devices ... ."[2]

(vii) The Appellants suggest that the Court should adopt this approach and, if necessary, extend the existing doctrine of issue estoppel as a matter of Judicial policy. The Appellants' primary submission, however, is that the English authorities support their case and the Respondents' narrow, restrictive approach does not stand up to analysis. This will be explained in greater detail in the body of the skeleton argument. The Appellants contend that the proper approach can be summed up by the question "Is it fair in all the circumstances that the other party should be bound by the prior findings?". In answering this question the Court needs to be satisfied essentially as to three matters: first, that the procedure of the foreign Court has provided a proper hearing, second, that the decision is clear as to the factual matters in issue and third, that at the previous trial the points in issue were argued fully because they were seen to be important. If these conditions are met there is no reason not to apply issue estoppel and it is submitted that to do so complies with the current public policy to limit the costs and complexities of civil litigation. There is a particular need for such measures in the case of patent litigation which is notorious for its expense and complexity.

(viii) In any event the Appellants contend that a proper analysis of the factual issues in question shows that they meet even the narrow, restrictive test put forward by the Respondents.

(ix) If the court allows this appeal, some witnesses will not need to be called at trial at all and the evidence of many others will be very much confined. By way of example, the inventor of the Appellants' patent, Dr Lin gave 4 days of oral testimony at the US trial preceded by 7 days of depositions. If this application is successful Dr Lin will

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[2] Per "Easterbrook J, United States District Court; Vas Cath v Mubarkar; 745 F.Supp.533 (ND I11 1990) at 525

not be required as a witness before the English Court. If the application is refused (on appeal) Dr Lin will inevitably be called as a witness to go over the very same ground he has already testified fully about. Similarly, two of the Respondents' inventors. Edward Fritsch and Rodney Hewick, will not be required to give evidence if this application is successful. If it is refused, however, the Appellants will have no alternative other than to take those individuals through all aspects of their work in order to re-establish the findings of the United States Courts. The same can be said for independent witnesses as well. The amount of resources and Court time involved in that process will be considerable. The Respondents will still be entitled to raise whatever legal arguments are available to them under English law, but they should not be entitled to have a go at rewriting history with the hope that something different will turn up.

A. INTRODUCTION

1. This skeleton argument is structured as follows:

Section B: The history of the litigation and the relevant technology is explained briefly. This is necessary background material in order to understand what the case is about and the relevance of the findings of the US Court.

Section C: The basis of this application and the findings the subject of it are explained.

Sections D-F: The Appellants' submissions as to the applicable law are developed. The legal issues concern "the correct test for issue estoppel", "privity of title" and "privity of interest".

Sections G&H: The appropriate legal principles are applied to the facts, first in relation to the '539 patent and then the '605 patent.

Section I: The issue of privity of interest between the Amgen Litigants is dealt with.

2. This skeleton argument has three appendices:

Appendix 1 contains a list of abbreviations;

Appendix 2 summarises the various parties and proceedings; and

Appendix 3 sets out the detailed submissions relating to the question of privity of interest between the BMG Litigants.

3. In order to minimise the amount of documentation before the Court of Appeal, the parties have agreed Core Bundles containing the most relevant documents which were before the Court at first instance. These Core Bundles are arranged as follows:

Bundle Number	Contents
1	Notice of Appeal, Respondents' Notice, First Instance Judgment and Pleadings
2	Affidavits
3 & 4	Exhibits
5	Appellants' Additional Evidence

All bundle references in this Skeleton are to the Core Bundles.

4. The parties have also exchanged lists of authorities and composite sets of the authorities being relied upon both parties are being lodged with the skeletons.

B. HISTORY OF THE LITIGATION RELATING TO ERYTHROPOIETIN AND ITS MANUFACTURE BY RECOMBINANT DNA TECHNOLOGY

(i) Subject-Matter

5. This litigation concerns the patent rights relating to a recombinant version of the hormone erythropoietin ("EPO") and the manufacture thereof by recombinant DNA technology. In the body natural EPO is manufactured in the kidneys of healthy mammals, including humans. Its primary function is to cause bone marrow to produce red blood cells. Natural EPO has never been isolated because it is present in only minuscule quantities in the blood. Prior to the invention of recombinant EPO ("rEPO") the only form of EPO that had been isolated was a form purified from the urine of patients suffering from a certain anaemic condition. This "uEPO" was

purified in 1976 but only a few milligrams were obtained starting from thousands of litres of urine. uEPO has not been shown to be useful as a therapeutic product.

6. Since at least the 1960s those working in the field identified the need for a product having the biological properties of EPO as a treatment for anaemia but this need could not be met. At the priority date of the patents in suit several groups had tried to clone the gene for human EPO hoping that that would enable the production of an EPO product by recombinant DNA technology but none had been successful. The search for a product having the biological activity of human EPO had been likened to looking for a needle in a haystack. If anything, that was an understatement.

7. The person who achieved the cloning of the EPO gene and the production of rEPO was Dr Fu-Kuen Lin of Amgen who isolated the gene encoding for human EPO in October 1983. This success was the result of a herculean effort; Dr Lin worked up to sixteen hours a day, six and seven days a week for over two years. Dr Lin tried unsuccessfully various techniques before achieving success by adopting a cloning approach which had never been successfully employed previously. The Appellants' patent in suit ("the '605 patent"[3]) results from the work of Dr Lin. The factual detail of this work is set out in the judgment of the Massachusetts District Court[4]. This rEPO resulting from the disclosure of the '605 patent provided for the first time the availability of a therapeutically useful form of EPO.

(ii) The Success of rEPO

8. One of the main applications of rEPO is in the treatment of anaemia, especially chronic anaemia associated with renal failure. Patients who lose their kidney function also lose the ability to produce natural EPO. rEPO has proven to be extremely useful as a replacement for the natural protein and rEPO therapy virtually eliminates the anaemia and the pre-existing need for blood transfusions in these patients. rEPO is

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3 Exhibit "SMO 1" [Bundle 3, Tab 1, p1]

4 [Bundle 1, Tab 21, p 164]

also approved for treatment of other conditions including for the treatment of cancer patients undergoing extensive chemotherapy.

9. The effect of rEPO on the health and quality of life of patients, especially kidney dialysis patients, is truly remarkable. Patients involved in the initial human clinical trials described rEPO as a "wonder" drug in that it "brought them back from the dead" and "gave them back their life". Consequently rEPO is the most successful product of the biotechnology industry. World-wide sales of rEPO exceed $2 billion. The European market for rEPO has annual sales in excess of $300 Million. Hundreds of thousands of patients are treated with rEPO worldwide.

(iii) Other Major Biotechnology Laboratories Failed to Clone the EPO Gene

10. Prior to Dr Lin's success many of the most highly skilled groups of workers in the field of recombinant DNA technology had been trying to clone the EPO gene. As described in the decision of the Massachusetts District Court, Biogen Inc ran an unsuccessful project to clone the EPO gene from the end of 1981 until March 1985 at a cost of $4 to $6 Million. Biogen utilised the extensive resources of three different laboratories including that of Professor Walter Gilbert, a Nobel Laureate at Harvard University. A team at Genentech Inc led by the renowned gene cloning expert, Dr Axel Ullrich, also began a project in 1981 to clone the EPO gene which extended from 1 to 1½ years and ended in failure. Genetics Institute Inc. ("GI") began an EPO cloning project in 1982 and were unsuccessful for about 2 years. After the success of Dr Lin was announced GI changed their strategy and duplicated Dr Lin's work as a result. Dr Sylvia Lee-Huang of New York University believed she had cloned the EPO gene in 1984 and published her results in the Proceedings of the National Academy of Science but on analysis her efforts were found not to have succeeded. Between 1980 and 1983 Dr Sytkowski and Dr Orkin at the Children's Hospital Massachusetts also tried, without success, to clone the EPO gene.

11. Evidence of some of these failures was adduced at the US trial and the detailed facts set out in the Massachusetts judgment. These facts together with the factual findings

on Dr Lin's work form part of the collection of facts on which estoppel is sought on this motion.

(iv) Genetics Institute

12. At GI, Dr Edward Fristch cloned the EPO gene after he learned of Dr Lin's success. Two of the patents in suit - EP411 678 and EP205 564 - relate to that work. The third GI patent EP209,539 ("the '539 patent"[5]) relates to the alleged further purification of uEPO by Dr Rodney Hewick. In the US the corresponding Hewick patent ("the '195 patent") was held invalid by the CAFC for failing to disclose how to obtain the claimed "homogeneous EPO"[6]. The facts relied upon by the CAFC in so holding form the other part of the facts in respect of which estoppel is sought.

13. The parties to this action are aligned as they were in the US Litigation. On the Amgen side stands Amgen Inc., Kirin Brewery of Japan, Kirin-Amgen Inc. (the patent proprietor of the '605 patent and a joint venture company owned by Amgen & Kirin) and Johnson & Johnson (in the form of Ortho Pharmaceutical Corporation ("Ortho"), the exclusive licensee under the patent and Janssen-Cilag Limited, its UK trading operation). In the UK litigation, these companies are referred to collectively as "the Amgen Litigants". On the other side stands Genetics Institute Inc ("GI") and Boehringer Mannheim (in the form of Boehringer Mannheim GmbH ("BMG"), the exclusive licensee under the GI patents and Boehringer Mannheim (UK) Pharmaceuticals Ltd ("BMUK"), its UK trading operation). In the UK litigation, these companies are referred to collectively as "the BMG Litigants". In the USA, the Japanese company Chugai Pharmaceuticals Inc. is also a member of the GI "camp" because it was the US licensee under GI's equivalent US patent rights.

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5 Exhibit "SMO 2" [Bundle 3, Tab 2, p 61]

6 See Judgment of CAFC [Bundle 1, Tab 22, p 225]

(v) United States Litigation

14. In the United States, patent infringement proceedings began in 1987 with both Amgen Inc. and GI suing each other and their respective US licensees under their respective patents. Amgen Inc. initially brought suit on their US patent corresponding to the European '605 patent (the '008 patent) and GI subsequently sued on their US patent corresponding to the European '539 patent (the '195 patent). The main action was fought in the US Federal Court, in particular the District Court for the District of Massachusetts ("the Massachusetts District Court") at a trial which took place in the autumn of 1989 ("the first Massachusetts action"). The Massachusetts District Court gave judgment on 11 December 1989. The outcome of this action was that both Amgen's '008 patent and GI's '195 patent were found to be valid and infringed. On appeal, the CAFC upheld the judgment below in relation to Amgen's '008 patent but reversed the finding of validity in relation to the relevant claims of GI's '195 patent, holding that GI had never successfully used the purification methods disclosed in the '195 patent and that the '195 patent did not enable[7], that is to say teach members of the public how to produce the EPO claimed, namely EPO having a specific activity of "at least" 160,000 IU/AU[8]. Copies of the judgments of the Massachusetts District Court and the CAFC are contained in Bundle 1 at Tabs 21 and 22.

(vi) Europe

15. The European Patent Office granted the '605 patent on 25 July 1990 and the '539 patent on 20 May 1992. Opposition proceedings were begun before the Office (each side, amongst others, opposing the other's patents). The opposition to the '605 patent was rejected at first instance. On appeal the Technical Board of Appeal upheld the grant of the '605 based on slightly amended claims.

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7 The US concept of "enablement" is closely equivalent to the UK law of sufficiency (see Section 72(1)(c) of the 1977 Patents Act)

8 Specific activity expressed as IU/AU is a measure of the units of biological activity of EPO per absorbance units at 280nms which is one way to quantify the amount of protein present in a sample.

16. As regards the '539 patent two of its three claims were revoked in the opposition at first instance. An appeal remains pending in relation to the '539 patent but only in relation to the remaining third claim. GI has not sought to re-instate the two claims revoked by the Opposition Division.

17. This appeal is not directly concerned with matters relating to the other two GI patents in suit (Nos 411,678 and 205,564) but in the context of the complexity and expense of this litigation it is to be noted that both these patents have been held invalid and revoked by the Opposition Division of the European Patent Office. The order for the revocation of the '678 patent has been stayed pending appeal to the Appeal Board of the EPO. The opposition hearing relating to the '564 patent took place on 12 and 13 June 1996 at the end of which the Opposition Division gave an oral decision that the patent is invalid. The formal written reasons are awaited. Despite the status of the two patents, the Respondents are insisting on litigating them at the trial due next year - if the appeals in the European Patent Office fail the costs of these actions will be completely wasted whatever the outcome of the English action.

18. Proceedings in the UK began with a petition for revocation of the '605 patent filed on behalf of BMG in October 1992. A writ for infringement of the '605 patent was issued in February 1993. A writ for infringement of the '539 and the '678 patents was issued by BMG, as GI's exclusive licensee, in July 1993 against Cilag UK Limited, the predecessor to Janssen Cilag. A petition for revocation of the '539 and '678 patents was presented by Cilag and served on GI in September 1993. Subsequently GI has joined in the infringement proceedings as a Plaintiff alongside BMG. The proceedings as a whole - along with claims for infringement and revocation of the other GI patent (Patent No EP205,564) - are due to come to a composite trial in April 1997 before Mr David Young QC sitting as a Deputy Judge of the Patents Court. A summary of the various parties and proceedings in the US and UK is provided in Appendix 2.

19. Copies of the '605, '008, '539 and '195 patents comprise exhibits "SMO 1", "SMO 2", "SMO 5" and "SMO 6" [Bundle 3].

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C. THIS APPLICATION AND APPEAL AND THE MATTERS IN ISSUE

(i) Purpose of this Application

20. The purpose of this application is to prevent re-litigation of various basic findings of fact made by the two US Courts referred to above. The relevant facts are set out in full in two annexes to the judgment of Deputy Judge David Young QC[9]. The facts fall into two groups:

(i) in relation to the '539 patent the facts sought to be made the subject of estoppel are (1) the fact that GI never successfully used the methods disclosed in the '195/'539 patent to purify any form of EPO and (2) the fact that GI failed to prove that by following the specification of the '195 patent anyone was able to manufacture "homogenous EPO" (recombinant or urinary) having a specific activity of "at least" 160,000 IU/AU in vivo.

(ii) in relation to the '605 patent the facts sought to be made the subject of estoppel are broadly[10], (1) the work of Dr Lin in cloning the EPO gene for the first time, (2) the failure by GI to clone the EPO gene themselves and (3) the failures of other well established biotechnology companies to clone the EPO gene[11]. These are the basic matters of the history of the development of rEPO, summarised above in this skeleton argument.

21. On 26 July 1995, the Deputy Judge gave directions for the hearing of the Amgen Litigants' application for the matter of the estoppel to be heard as a preliminary

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9 [Bundle 1, Tab 4, pp 42-55]

10 The term "broadly" is used because, in detail, what the Appellants seek to be made the subject of issue estoppel consists of a mass of factual material making up a section of the judgment of Magistrate Saris (section VI a to d - CLONING AND EXPRESSION OF EPO) [Bundle 1, Tab 21, pp 172 - 180]

11 See Judgment of David Young QC - page 5 [Bundle 1, Tab 4, p 21]

issue[12]. The matter came before the Learned Judge on 28 and 29 February and 1 March 1996. In a reserved judgment[13] the Judge refused to accede to the application, finding that "the Amgen Litigants have failed to establish that BMG and BM (UK) should be estopped from contesting any of the findings of Magistrate Saris or those of the CAFC"[14]

22. The basic requirements of issue estoppel are common ground[15] between the parties but there is substantial disagreement as to what the requirements mean and how they are to be applied. The basic requirements for issue estoppel are that:

(1) the same question must be decided in both proceedings;

(2) the judicial decision said to create the estoppel must be final;

(3) the parties to the judicial decision or their privies were the same persons as the parties to the proceedings in which the estoppel is raised or their privies[16]

23. The decision in ***Carl-Zeiss Stiftung v Rayner Keeler (No.2)*** [1967] AC 853 established definitively that issue estoppel can arise from judgments of foreign Courts. The opinions show that caution is necessary where the procedures of the overseas Court are unfamiliar particularly where it is not easy to determine what exactly was decided. However, this problem does not arise in the present case where the legal system is based on the common law and fully reasoned decisions have been given. There is no reason to give decisions of the Courts of the United States (or other common law jurisdictions) less weight in establishing estoppels than domestic decisions. Certainly in this case no reason has been given for treating the decisions in question differently from decisions of other UK Courts.

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12 See Amended Notice of Motion, [Bundle 1, Tab 5, p56]

13 [Bundle 1, Tab 4, p17]

14 Judgment page 25, 2nd last paragraph [Bundle 1, Tab 4, p 41]

15 As recorded by the Learned Judge at the bottom of page 6. [Bundle 1, Tab 4, p 22]

16 Per Halsbury's Laws Vol 16 Estoppel - paragraph 977

24. The major disputes between the parties fall into two groups:

(a) Whether the findings of fact relied upon by the Appellants can form the basis of issue estoppel in the first place. The Appellants contend that, under the doctrine, the court has the power to order that the Respondents be bound by the findings of fact concerned and that the court ought to exercise that power to do so in the present case. The Respondents' main contentions are that the relevant facts either are not "issues" for the purpose of issue estoppel or that they are actually mixed questions of fact and law.

(b) The other major area of dispute is the status of the Respondents, BMG and BM(UK), in relation to the third Respondent, GI. The question is whether BMG and BM(UK) are privies with GI for present purposes. The Appellants submit that BMG has privity of title with GI in relation to the '539/'195 patents and also that both BMG and BM(UK) have privity of interest with GI in relation to both the '539/'195 patents and the '605/'008 patents.

25. The area of dispute identified in para 24(a) above raises the first question in this appeal namely:

(1) What kind of findings of a former tribunal can or should be made the subject of issue estoppel?

The Appellants submit the answer to this question is findings which were "directly (not collaterally or incidentally) in issue"[16]. The Respondents contend for a narrower, stricter test which presumably they argue applies whether the earlier decision is of a United Kingdom Court or of a foreign Court.

26. The area of dispute identified in para 24(b) above raises two further questions, namely:

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16 Per Halsbury's Laws Vol 16 Estoppel para 977

(2) Can a licensee whose locus standi to sue derives wholly from its licensor be free to re-litigate findings which are binding on that licensor?

(3) What is the test for privity of interest?

27. A further question on this appeal concerns the Amgen Litigants and whether there is a sufficient degree of identification between them so as to make them privies, whether by way of title and/or interest. That issue is dealt with in Section I.

D. THE FIRST QUESTION - WHAT KIND OF FINDINGS OF A FORMER TRIBUNAL CAN OR SHOULD BE MADE THE SUBJECT OF ISSUE ESTOPPEL?

28. As stated above, there is a fundamental difference between the parties as to how to apply the basic requirements for issue estoppel. Before the Court below, the Appellants submitted that to constitute an issue estoppel the former findings relied upon must have been truly in issue in the former proceedings that is to say they must have been matters "*directly (not collaterally or incidentally) in issue*" (Halsbury Vol 16 para 977 and also ***Carl-Zeiss Stiftung v Rayner Keeler (No. 2)*** [1967] AC 853 at 933-935). The Appellants contend that this is intended to exclude a situation in which the point at issue in the first decision was of only minor importance and it was therefore not dealt with thoroughly but *became* of major importance in the later case. In other words, this is a practical test which would stop parties re-litigating issues which have been thoroughly dealt with but does not seek to work an injustice where matters have not been adequately considered. The latter exclusion must be right; it would obviously be wrong if a party found itself bound on a point which was of only minor importance in previous litigation, and which it did not think it worthwhile disputing, when that same point assumes much greater importance in the subsequent litigation.

29. However, the Respondents submitted that for matters to be the subject of issue estoppel they have to pass a much stricter test. For this purpose they have to be

issues "*necessary or fundamental to the earlier decision in the sense that such decision could not stand without such findings*" (Spencer Bower & Turner, Res Judicata, 2nd Ed, paras 210 and 211).

30. The submission of the Respondents relies particularly on para 211 of Spencer Bower & Turner which states:

> "In order to make this essential distinction [between the fundamental and the collateral] one has always to inquire with unrelenting severity - is the determination upon which it is sought to found an estoppel so fundamental to the substantive decision that the latter *cannot stand* without the former? Nothing less will do." [emphasis in the original].

31. The Learned Judge adopted the test put forward by Spencer Bower in this regard[17] but in doing so he relied on no authority save for the paragraphs themselves on the basis that he thought those passages had been "*recently endorsed by the Court of Appeal*"[18] in ***Re: The State of Norway's Application*** [1990] 1 AC 723. Accordingly the Learned Judge did not consider in detail the cases which had been cited by the Respondents in support of the proposition and strict test espoused by Spencer Bower and Turner. The comment in para 211 of Spencer Bower seems to be essentially based on the Australian decision of ***Blair v Curran*** [1939], 62 CLR 464 a decision which has apparently never been cited by a United Kingdom Court. However, even this case does not contain the words "unrelenting severity".

32. In coming to this conclusion the Learned Judge made four significant errors:

(a) the Learned Judge took no account of the fact that the United Kingdom cases cited by the Respondents and relied upon as supporting the narrowness of the Spencer Bower test do not in fact provide any such support;

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17 Last 2 lines of page 10 of Judgment. [Bundle 1, Tab 4, p.26]

18 Penultimate paragraph of page 10 of Judgment. [Bundle 1, Tab 4, p26]

(b) the Learned Judge drew the wrong conclusion from the decision in ***Re: The State of Norway's Application*** *supra* which is at best neutral on the question of which test to apply;

(c) the Learned Judge failed to take into account of the line of authority stretching from ***Henderson v Henderson*** [1843] 3 Hare 100 to the decision of the House of Lords in ***Arnold v National Westminster Bank*** [1991] AC 93.

(d) the Learned Judge introduced an even narrower test not supported by any authority at all.

(i) Cases cited do not support the narrowness of the Spencer Bower test

33. The Learned Judge recorded a list of cases which the Respondents contended supported the formulation proposed by Spencer Bower but none of those cases were actually addressing the difference between the tests proposed by the Respondents and Appellants in the present case. In fact these cases can all be read as supporting either proposition and each case clearly turned on its own particular facts. The cases were ***The Duchess of Kingston's*** case (1776) 20 St Tr. 355. ***R v Inhabitants of Township of Hartington Middle Quarter*** (1855) 4 E& B 780; ***Hoystead v Comm.r.s for Taxation*** (1926) AC 155; ***Penn-Texas Corp. v Murat Anstalt*** (No. 2) 1964) 2 QB 647 and ***Mills v Cooper*** [1967] 2 QB 459.

(ii) Re: The State of Norway's Application *supra*

34. In this case only Balcombe LJ actually expressed any approval of the material passage of Spencer Bower & Turner i.e. para 211[19]. May LJ did not refer to Spencer Bower & Turner para 211 at all[20]. Indeed having referred to the immediately preceding paragraph, 210, May LJ stated that he was not expressing a concluded view on the

[19] at page 751-G to 752-F

[20] at page 743-F to H

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issue[21]. Woolf LJ, to whom the Learned Deputy Judge did not refer, did not cite Spencer Bower & Turner at all. In fact he formulated a test which is entirely in line with the submission of the Appellants in the present case, namely to apply estoppel unless there is a risk of injustice. Furthermore, Woolf LJ cited (at 772-B to G) a passage from the speech of Lord Upjohn in ***Carl-Zeiss*** which itself referred to the speech of Lord Reid in the same case. The proposition contended for by the Appellants is based on the same parts of Lord Reid's speech as were referred to by Lord Upjohn and thus Woolf LJ. Thus, ***The State of Norway's Application*** can be relied on as support for both the rival propositions put forward by the Appellants and the Respondents and is not in itself conclusive either way.

(iii) Henderson v Henderson and Arnold v National Westminster Bank

35. The ***Arnold v National Westminster Bank*** decision is the clearest recent authority for the proposition that issue estoppel applies not only to cases in which an issue has actually been decided but also cases where in subsequent proceedings it is sought to raise a point which might have been raised in the earlier proceedings but which a party failed to raise[22] ("Non issue estoppel"). In arriving at that conclusion the House of Lords applied the classical statement of the rule by Wigram VC in ***Henderson v Henderson***. The statement of Wigram VC has been applied in many cases subsequently, see for example ***Hoystead v Commissioners for Income Tax***[23], ***Yat Tung v Dao Heng***[24] and ***Talbot v Berkshire County Council***[25]. The ***Arnold Case*** and the line of cases upon which it relies was applied by Mr Justice Aldous (as he then was) in relation to patents in the High Court decision in ***Chiron v Organon***

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21 at page 744-A

22 Per Lord Keith at page 106-B

23 1926 AC 155

24 1975 AC 581

25 1994 QB 291

Teknika (No.6)[26]. The proposition approved of in ***Arnold*** cannot be reconciled with the Learned Deputy Judge's conclusion that for issue estoppel, the issue in question must be one so fundamental to an earlier decision that without it the decision cannot stand. If an issue was not raised at all it cannot possibly be one without which the earlier decision cannot stand. Yet such an issue can form the basis of an estoppel.

(iv) The New Test

36. When applying the law in relation to the findings concerning the '008/'605 patent the Learned Judge sought to investigate whether the facts found by the US courts were essential to the same issue in the USA as are before the English court (i.e. obviousness in both cases). There is, however, no such requirement in law.

37. The core of the Learned Deputy Judge's reasoning on this point seems to have been that because the facts *might* have been central to legal issues which have no place in UK patent law (e.g. best mode, first to conceive, reduction to practice, etc.)[27] then there was no identity of subject matter because the facts were not shown to his satisfaction to be fundamental to the US issues of obviousness and enablement (the issue to which these findings are relevant in the UK litigation). However, there is no basis for such a requirement in the case law and it is submitted that the suggestion that there is such a requirement is fundamentally wrong not least because it would limit significantly the application of issue estoppel. The development of the doctrine of issue estoppel (which relates to findings independent of the conclusion of the judgments in which they are found) as a separate doctrine from *res judicata* (in which the findings of fact and their consequences are binding) specifically allows for facts found in one context and in relation to one legal issue to be conclusive of the same factual issue in a different context or in relation to a different legal issue. For example, there is no reason why a finding that two parties were validly married in a paternity suit in one jurisdiction should not form the basis of an issue estoppel in an

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26 1994 FSR 448

27 See Judgment page 4 [Bundle 1, Tab 4, p 20]

application by the wife for maintenance in subsequent proceedings in another jurisdiction. Moreover, the Learned Deputy Judge failed to appreciate that a good portion of the findings were essential to the identical issues in the United States as in the United Kingdom, e.g., obviousness and sufficiency.

(v) **What kind of findings should be binding? - Conclusion**

38. Issue estoppel is related to the concept of abuse of process (see e.g. ***House of Spring Gardens v Waite*** [1991] 1 QB 241, and the decision of this Court in ***Chiron v Organon Technika (No.6)*** on the appeal from the decision of Mr Justice Aldous referred to above [unreported]). It is submitted that the underlying principle is one of fairness and justice. The question must be: were the facts found important enough in the previous litigation that they were fully argued? If that be established then it would be an abuse of process for one party to be allowed to argue them all over again. Public policy militates against a narrow approach which would drastically restrict the application of the estoppel doctrine.

E. THE SECOND QUESTION - CAN A LICENSEE WHOSE LOCUS STANDI TO SUE DERIVES WHOLLY FROM ITS LICENSOR BE FREE TO RE-LITIGATE FINDINGS WHICH ARE BINDING ON THAT LICENSOR?

39. This question arises in relation to the Respondent GI's '539 patent. The '539 patent is the European equivalent of the '195 patent revoked in the US proceedings.

40. GI now seeks to assert the '539 patent against the Amgen Litigants. It is submitted that, on the assumption that the findings of fact in the US Action meet the tests discussed in the previous section, it is manifest that GI must be bound by those earlier findings in the United States.

41. BMG also sue in these proceedings under the '539 patent. They claim as the exclusive licensees of the proprietor, GI. As such the Patents Act 1977[28] gives them "the same right as the proprietor" to bring proceedings under the patent. BMG can only have a claim as a result of the grant of a right (the Licence) from GI and it is submitted BMG's necessarily derivative title to sue cannot be free of any fetters on the underlying property in respect of which the Licence is granted.

42. If that is not correct then it leads to the following absurdities. It would mean that a licensee could avoid an estoppel giving rise to a finding of invalidity which would have arisen against the patentee. The result would be that the licensee was able to maintain in force a patent which the actual owner could not.

43. Secondly, if the view is taken that estoppel cannot apply in this case because BMG has its own independent right to contest these issues, what would be the position if Amgen were to issue a separate petition against GI seeking revocation of the '539 patent? In that instance both named parties would be identical to those which took part in the US litigation. Would that mean that issue estoppel would apply to that action and not to this?

44. Thirdly, a finding that BMG can have a better right to contest these issues than GI would lead to the position that any patent holder which thought that it might be subject to issue estoppel in a subsequent suit could simply avoid those adverse consequences by granting a licence to an "independent" third party and then claiming that there was no estoppel because that party had its own right to contest the matters in issue.

45. It is submitted that the answer to the second question is plainly No. If a party's claim comes from the property of another how could that party not be in "privity of title" with that other?

[28] Section 67(1)

F. THE THIRD QUESTION: WHAT IS THE TEST FOR PRIVITY OF INTEREST?

46. The question of privity of interest arises in various areas of this dispute but is most acute on the question of whether BMG have privity of interest with GI in relation to the '008/'605 case. The point is also relevant for the '195/'539 case but there BMG also have privity of title; if the Appellants are correct in their submissions on that issue, then the question of interest in relation to that case takes on less significance.

47. As has been stated in a number of authorities, including ***Carl-Zeiss***, it remains unclear what amounts to necessary privity. Accordingly the dispute here is as to the application of the general legal principles to the particular facts of this case.

48. No precise legal test has been formulated for what constitutes "privity of interest" - nor is the search for a definitive test likely to prove fruitful. For example Halsbury's Laws Volume 16 at para 990, p 874 states: "*It is not easy to detect from the authorities what amounts to a sufficient interest. The question seems to be determined by an examination of the factual identity of interests of the parties and the fairness of binding them by a decision in which they were not represented.*"

49. The context of the speeches in ***Carl-Zeiss*** needs to be borne in mind given the nature of the summons which was before the House (see p. 860 at A-C). The finding that the solicitors were not privy to the West German litigation was understandable - see Lord Reid at 911C-E. Lord Hodgson at 928G-929B, Lord Guest at 936B-C and Lord Upjohn at 945. It should be noted that Lord Reid approved the American Restatement at 912F-G. It is also to be noted that Lord Upjohn stated at p.947 D-E:

> "*All estoppels are not odious but must be applied so as to work justice and not injustice and I think the principle of issue estoppel must be applied to the circumstances of the subsequent case with this overriding consideration in mind.*"

On the issue of privity of parties Lord Wilberforce, in a dissenting speech at 968B - 969E, stated that one must look to see who is really behind the action and who are the effective parties.

50. Because of the complicating feature of the status of the solicitors and the claim made against them, the House of Lords did not give consideration in ***Carl-Zeiss*** to the extent of privity within the doctrine of issue estoppel. However, that fell to be considered in ***Gleeson v J. Wippell & Co. Ltd.*** (1977) 1 WLR 510. There Sir Robert Megarry VC considered the issue of privity discussed in ***Carl-Zeiss***. His judgment on this issue is to be found at pp 515-516. At p 515-G he stated that

> *"there must be a sufficient degree of identification between the two to make it just to hold that the decision to which one was party should be binding in proceedings to which the other is party".*

51. The statement of Sir Robert Megarry VC quoted above is the closest the courts have come to formulating a test for privity of interest. Given the many and varied ways in which parties might have concurrent interests, it is submitted the principle (whether it is strictly a "test" or not) is a sound one.

52. The Learned Deputy Judge set a three fold test for the question of whether two parties had sufficient privity of interest in order to be bound by issue estoppel[29]. To Megarry VC's general principle (a sufficient identification so as to be just to bind the party) he added requirements:

(1) that at the time of the earlier proceedings the later party had some real interest, even if not identity of interest, in the actual subject matter of the foreign proceedings and not merely an interest in the outcome;

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[29] Judgment page 13 [Bundle 1, Tab 5, p 29]

(2) that the later party's interests can be sufficiently identified with the former party's interests with regard to such earlier proceedings

53. With respect to the Learned Judge it is not entirely clear what distinctions these limbs are trying to draw. Plainly the party described as the "later party" must have a real interest in the subject matter of the proceedings. Equally plainly the interests of each party must be sufficiently identified with the other. However, that does not take the matter any further. In the end the question will be a matter of judgment - were the interests of the one in the first action sufficient so as to make it just to bind that one in the second action? That is Megarry VC's principle.

G. APPLICATION OF LAW TO FACTS - '539 PATENT

(a) *Identity of subject matter generally (applicable to both '539 and '605)*

54. Before considering the '539 patent specifically it is useful to look at the matter generally. The first point to note is that there is identity of subject matter between the earlier proceedings in the United States and the proceedings currently pending before the English Courts. The rEPO product RECORMON which is sold by BMG and BMUK and alleged in Action 1993 K No. 937 to infringe the '605 Patent, is expressed by exactly the same DNA which was in issue in the US proceedings. The DNA is expressed in host cells descended from the GI host cells which were in issue in the United States proceedings and found therein to infringe Amgen's '008 patents. Furthermore, the fear of the prospective suit and a potential injunction in the United States proceedings led to BMG and GI arranging to have the infringing host cells being shipped to Germany - see Eisen 2 para 4[30]. Those host cells are the direct antecedents of the host cells which BMG currently use to make their RECORMON product.

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[30] [Bundle 2, Tab 16, p 158]

55. Similarly, the rEPO product EPREX sold by Janssen-Cilag Limited and alleged in Action 1993-B-No. 4552 to infringe, inter alia, the '539 patent is manufactured by Ortho under licence from Kirin Amgen. In all material respects it is identical to the product which was alleged to infringe the '195 patent in the first Massachusetts Action. It is identical to the product which was alleged to infringe the '195 patent in the Californian Action and which was also the subject of the Delaware Action and the second Massachusetts Action[31].

56. The disclosures of the '008 and the '605 patents are the same as are the disclosures of the '195 patent and the '539 patent;[32] the only material respect in which the '195 and '539 patents differ is the deletion from the '539 patent of Example 2 which was admitted by GI to be a failed attempt to purify rEPO by the methods disclosed in the patent.

57. Kirin-Amgen's '605 patent claims priority from the same application which gave rise to the '008 patent in the USA and GI's '539 patent derives from the same application which gave rise to its '195 patent in the USA.[33]

58. There are no material differences in the corresponding claims of the '605 and '008 patents and the '539 and '195 patents[34]. Amendments arising from oppositions at the European Patent Office do not alter or affect the issues that are sought to be relied upon in this hearing.

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31 The various United States actions are set out in Section B of Appendix 2. The significance of the Delaware Action and the second Massachusetts Action in relation to the issue of privity between Amgen and Ortho is explained in paras 80 and 81 below.

32 Moss 7, paras 7 and 14 [Bundle 2, Tab 9, p 85]

33 Odre 1, para 11 [Bundle 2, Tab 1, p 6]

34 Moss 7, paras 7, 8 & 16 [Bundle 2, Tab 9, pp 85-86 and 89]

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(b) ***Findings of fact in relation to the '195/'539 Patent***

59. The Learned Judge did not expressly consider the importance of the findings of fact in relation to the '195/'539 patent. It is submitted this was for the simple reason that those findings were obviously crucial to the case relating to that patent and the Judgments plainly could not stand without them. Thus they pass even the narrow, strict test proposed by the Respondents.

60. The question of whether or not one could use the procedures of the '195 patent to achieve the claimed invention was clearly a matter in issue in the US Litigation - indeed, with respect to the '195 patent it was the main issue. Irrespective of whether one is considering enablement under US law or sufficiency under European or UK law, the best evidence is whether the patentee or anyone else had actually used the methods disclosed to make the products claimed. This was an issue which "went to the root of the matter" (see Lord Shaw of Dunfermeline in ***Hoystead v Commissioner of Taxation*** [1926 AC @171]) and was "clearly part of the subject matter of the litigation" (Sommervell LJ in ***Greenhalg v Mullard*** [1947] 2 All E R 255 @ 257). As the CAFC made clear all of the evidence pointed against GI's allegations. The onus was clearly on GI to bring forward the evidence in support of their case. They failed to do so and cannot now be heard to state that they wish to have "a second bite at the cherry".

61. The only conclusion the Learned Judge at first instance came to on the question of identity of subject matter regarding the ('195/'539 Patent) was that the US court's findings in general were "predominantly conclusions of law or conclusions of mixed fact and law"[35]. It is submitted that this conclusion is simply wrong.

62. The CAFC is an appeal Court. Inevitably, therefore, in its review of the decision of the lower Court it does not rehearse all the evidence which was placed before the lower Court. Rather it cites to the evidence upon which it relies to support its

[35] Judgment para 23

decision. Thus, the relevant part of its Judgment is considerably shorter than the extract of the judgment of the District Court relied upon in relation to the '605 Patent.

63. Nevertheless, there are clear findings of fact. To test the matter, consider, for example, the third sentence of the passage in the judgment of the CAFC relied on. It reads:

> "The district court found that GI reported to the FDA that the specific activity of uEPO, based on *in vivo* bioassays, was only 109,000 IU/AU"

This is a plain fact. The significance of the fact is that the '539 patent purports to disclose how to make "homogenous" EPO of a specific activity of 160,000 IU/AU (just as the US '195 patent did). Accordingly, for that and other reasons, the US court decided that GI never successfully used the methods disclosed in the patent to purify any form of EPO to the claimed levels. That finding was manifestly fundamental to the decision that the specification of the '195 patent did not enable the preparation of EPO having those characteristics. These are the findings sought to be made the subject of issue estoppel and plainly the judgment of the CAFC could not stand without them.

64. Given the importance of this and the other findings to the United States Litigation it is inconceivable that GI did not bring forward their best case on the matter. After they did so competent courts decided the matter and no good reason has been proposed by anybody to suggest why it makes sense to re-litigate those matters. If they failed to put forward their best case (which has not so far been suggested) the principles of "non-issue" estoppel should apply.

(c) ***Privity - the '539 patent***

65. The facts on privity of title are set out in paras 39-45 above.

66. The Appellants also contended that BMG has privity of interest; that aspect is considered in detail in the next main section in relation to '605.

H. APPLICATION OF LAW TO FACTS - '605 PATENT

(a) *Facts in relation to the '008/'605 Patent*

(i) Identity of the subject matter

See paras 54 - 58 above.

(ii) Can the findings of fact be the subject of issue estoppel?

67. As stated in section D above para 28, the Appellants contend that the correct test is whether the facts were "*directly (not collaterally or incidentally) in issue*". Mr Tootal, the Respondents' own solicitor, characterised these facts as "*central to the issues in the UK*"[36] and was plainly correct in that assertion. The evidence establishes that all the matters in the schedule to the judgment were directly (not collaterally or incidentally) in issue before the US courts (see First Affidavit of Dennis Allegretti) and are plainly directly in issue in these proceedings. In respect of the findings relating to the '008/'605 patent - the history of the search for the EPO gene, Dr Lin's successful cloning of the gene, the development of rEPO and failures of others - all directly relate to the issue of obviousness, see para 2 of the Re-Amended Reply and Defence and Counterclaim in the '605 infringement Action CH 1993 K No. 937 [Bundle 1, Tab 11, pp 83-86].

68. It should be noted that, in relation to the Massachusetts District Court's findings relating to the '008 patent, what the Appellants are seeking is that estoppel effect be given to the whole matrix of factual findings. The Appellants submit that this is preferable to citing isolated portions of the findings and rely upon the whole matrix

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36 2nd Affidavit paragraph 3(G) [Bundle 2, Tab 4, p 34]

of background facts to avoid being accused of only selecting the favourable findings. The Respondents' response to that is to adopt a forensic approach by taking each individual finding and asking rhetorically whether that particular finding was essential to the decision. This was categorised in the Court below as the "salami slicing approach". It is submitted that it is a fundamentally flawed approach. The background matrix formed part of the overall decision. It is clear from the issues which the Massachusetts Court had to consider that the background facts were central to a decision on those issues. Whilst it might not be possible to say that each and every individual finding of itself formed a crucial element in that decision, taken as a whole the background facts clearly did so. They were matters which came directly in issue in the proceedings; they were not collateral or incidental.

69. It is true in relation to the issue of obviousness in the United Kingdom, not all of the individual background facts are of equal significance. Some of the facts, e.g., Lin's failure, Fritsch's failures, the failures of Biogen and Genentech, and how Lin ultimately succeeded, have more direct bearing on showing the invention to be non-obvious. However, the Appellants have not tried to draw a distinction between more important and less important findings, because the Respondents would simply point to individual findings and say "why this one and not that one". Thus the Appellants submit that it is proper to give estoppel effect to the whole of the background matrix which forms the matters which were directly in issue. Further, the "salami slicing approach" would lead to the result that complex findings of background fact could always be re-litigated.

70. It is to be noted that the Respondents have not pointed to any facts within the matrix which they say fell within the "trivial" category in so far as the United States litigation was concerned but which now come within the "crucial" category for the purposes of the United Kingdom Litigation. It is not difficult to see why given the identity of subject matter and issues before the two sets of Courts.

(iii) **Application of the Spencer Bower's narrow test - could the US judgments stand without the findings of fact?**

71. It is submitted that in any event the findings of fact in relation to the '008/'605 patent set out in the schedule to the Judgment below and which the Appellants seek to make the subject of estoppel were sufficiently fundamental so that the US judgments could not stand without them. Accordingly those facts or "issues" are such that they pass the narrow test put forward by the Respondents and accepted by the Learned Deputy Judge at first instance. The Learned Deputy Judge held to the contrary but it is submitted that in reaching this conclusion he did not consider what the impact on the US judgments and in particular the question of obviousness considered there would have been had the facts in question been found to be different.

72. It is submitted that the importance of the findings in relation to the US judgments can be gauged by imagining a judgment in which those facts had been found to be different. For example if there were no failures of other well established groups to achieve the same results as Dr Lin and all those who tried to clone the EPO gene, including Dr Lin achieved success immediately using means available in the art, that would surely have had a fundamental impact on the judgment. Why, one might ask, did the parties before the US court spend so long on litigating these issues[37] if they were not fundamental to the matters in issue.

(b) ***Privity of Interest - (Both Patents)***

73. The Learned Deputy Judge correctly characterised the relationship between BMG and GI, against the submissions of BMG Litigants, as one which it "*would be fair to call a joint venture*"[38]. However he still thought that BMG did not have a have privity of interest with GI. It is submitted that the Learned Deputy Judge drew the wrong

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37 e.g. Dr Lin was deposed for 7 days and gave oral testimony at trial for 4 days

38 Judgment page 18 bottom of the page [Bundle 1, Tab 4, p 34]

conclusion from the mass of evidence pointing to the very close relationship between these companies with respect to rEPO and the US litigation (See Appendix 3).

74. Appendix 3 to this skeleton sets out in detail the Appellants' case as to why BMG have had at all material times privity of interest with GI in relation to this dispute. In summary the main matters the Learned Deputy Judge failed to give any or any sufficient weight to were the following:

(a) BMG's own commercial interest was deployed before the US court as a reason not to grant an injunction.

(b) BMG were joint tortfeasors in the United States with GI;

(c) the claim to common interest privilege in communications passing between BMG and GI;

(d) BMG paid a large portion of GI's damages in the US proceedings;

(e) BMG had to approve the US settlement with Amgen;

(f) BMG could have applied to intervene in and thus participate in the US proceedings.

75. The overwhelming evidence (not really challenged by the Respondents), was that BMG could have intervened in and thus participated in the US proceedings had they wished to do so. This is a very important consideration when deciding whether a party should be bound by the outcome of litigation to which it is not actually a party, for obvious reasons. The Learned Deputy Judge said he "[did] not see why BMG should have intervened [in the US proceedings]"[39]. That is not a sufficient answer to the matter. The evidence is that BMG had a very real interest in the subject matter

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[39] Judgment page 20, para 3 [Bundle 1, Tab 4, p 36]

of the US action and their commercial interests would be significantly affected by the outcome. The evidence established that, such was BMG's involvement with GI's acts of infringement, they could have been joined to the US proceedings as an additional defendant along with GI[40]. If BMG had thought the litigation was not being conducted by GI in a way which suited their own interests it is highly unlikely that they would simply have stood by and allowed it to continue. In fact when BMG's interests were going to be directly harmed by an interlocutory injunction, GI deployed affidavits from BMG to successfully discharge the injunction.

76. In deciding that there was no privity of interest the Learned Deputy Judge relied on two authorities on privity, namely ***Gleeson v Wippell supra*** and ***Mercantile Investment v River Plate (1894)*** 1 Ch 578. In the ***Gleeson*** case a purchaser was found not to have privity of interest with a vendor and in the ***Mercantile*** case an indemnor was found to have no privity with the person indemnified. However the point in the present case is that BMG was, amongst many other things, both a purchaser from GI and indemnor of GI. The fact that in and of itself being a purchaser (***Gleeson***) or indemnor (***Mercantile***) is insufficient for privity does not mean that BMG, being both and much more besides, was not privy.

I. THE FOURTH QUESTION - PRIVITY BETWEEN THE AMGEN LITIGANTS

77. In the light of his judgment the Learned Deputy Judge did not find it necessary to decide whether Kirin-Amgen Inc. had privity of interest with Amgen Inc. He ought to have concluded that they did have sufficient interest for the purposes of issue estoppel.

78. The Learned Deputy Judge also thought that he did not have sufficient evidence about the relationship between Kirin-Amgen and Ortho on the one hand and Amgen Inc. on

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40 Day, para 34(c) [Bundle 2, Tab 7, p 74]

the other to satisfy him about privity of interest had he wished to decide the point. If and insofar as the evidence was insufficient in this respect the Appellants will seek leave to adduce the Ninth Affidavit of Gary Moss[41] as to those matters because it only became apparent that the Boehringer litigants intended to take a point of this nature, on exchange of skeletons and at a very late stage in the preparation of this preliminary issue. The point was not properly foreshadowed by the Boehringer litigants' either in their affidavits or in any other way. Indeed, the Boehringer Litigants' Solicitor, Mr Tootal, listed the grounds they were relying on in his Second Affidavit (para 3)[42] and made no mention of a challenge to privity between the Amgen Litigants.

79. In addition to the foregoing evidence, before the learned Deputy Judge the Appellants relied on two further factors as indicating that there was privity of interest between Amgen and Ortho in relation to the first Massachussetts action. The first was that GI had sued Ortho under the '195 patent in California. The background to that litigation is set out in paras 9-15 of the first affidavit of Steven Odre[43]. Basically, it was an attempt by GI to be cast as the Plaintiff in the litigation. The fact that GI chose to sue Ortho along with Amgen and Kirin-Amgen indicates that at that stage GI considered that all those parties were "in the same camp". The learned Judge dismissed the significance of the California action by saying that those proceedings were stayed[44]. With respect that misses the point. As the Amgen deponents made clear, that litigation was stayed pending the outcome of the Massachussetts action and the Appeal to the CAFC. Once the '195 patent was declared invalid, that California Action had no further purpose. However, the fact that it was stayed does not detract from its significance vis à vis the perceived relationship between Amgen and Ortho.

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41 [Bundle 5, Tab 1, p 1]

42 [Bundle 2, Tab 2]

43 [Bundle 2, Tab 1, p 7]

44 See Judgment, page 24. [Bundle 1, Tab 4, p 40]

80. The second factor upon which the Appellants relied was the decision of Judge Young in the Second Massachussetts action[45]. The learned Deputy Judge dismissed this factor firstly by saying that the question of the privity of Ortho as a licensee was never argued or decided in that case and secondly, that even if it had been held that Ortho was a privy of Amgen for the purposes of the second Massachussetts action it would not follow that they were privies of Amgen with regard to the first Action[46].

81. With respect to the Learned Judge the first point is plainly wrong. The only parties to the Second Massachussetts action, apart from GI, were Amgen and Ortho (and Ortho's related companies). It was Ortho, and not Amgen, which had been sued in Delaware. Judge Young's decision in Massachussetts was that GI could not assert the '837 patent against Amgen and its privies. The reference to privies can only refer to Ortho and its related companies. (See also the sections of the Judgment quoted in para 8 of Mr Odre's second affidavit [Bundle 2, Tab 5, pp 46 & 47].) That is confirmed by the fact that the second Massachusetts action was dismissed as to all parties and that, following that decision, the action in Delaware has ceased. With regard to the second point, it is difficult to see on what basis Ortho could be a privy for the purposes of the second action but not the first. There had been no material change in the relationship between Amgen and Ortho between the two actions and no significant alteration in circumstances. Ortho was still operating under the same licence agreements and manufacturing the same product. On both occasions Ortho had been sued in other States under the '195 patent, on the first occasion in California and on the second occasion in Delaware. Its interest in the outcome of the Second Massachussetts action was no greater or less than had been its interest in the outcome of the first Massachussetts action.

82. It is submitted the correct position is:

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45 Exhibit SMO 13 [Bundle 4, Tab 10, p 131]. For an explanation of the background to the Delaware Action and the Second Massachussetts action leading up to this judgment see the second affidavit of Steven Odre [Bundle 2, Tab 5, p 46 & 48]

46 See Judgment, page 25. [Bundle 1, Tab 4, p41]

(a) Kirin-Amgen has privity of title with Amgen in relation to the '605 patent.

(b) Ortho have privity of title with Kirin-Amgen (and thus Amgen) in relation to the '605 patent.

(c) Ortho, Kirin-Amgen and Amgen have privity of interest with each other in relation to both patents.

(d) Cilag and Janssen-Cilag are privies with Ortho (and thus Kirin-Amgen and Amgen).

J. DISCRETION GENERALLY

83. Having taken a view of the case which was too narrow and technical, the Learned Judge then failed to consider the matter of issue estoppel generally bearing in mind that it is an exercise of the court's discretion. He failed to take into account either properly or at all the following significant matters which all bear on the exercise of the court's discretion and point in favour of finding a binding issue estoppel:

(a) a finding of issue estoppel would result in a very substantial saving of costs and court time;

(b) no substantial explanation was ever provided by the BMG Litigants as to why they wish to re-litigate the various matters, thereby incurring substantial costs and time;

(c) there was no evidence the English court was likely to find any of the various facts to be different from those found by the US courts;

(d) it was never suggested in their voluminous evidence or arguments that any substantial prejudice to the BMG Litigants would take place if they were bound

by the findings; in particular there was no evidence that any point was not fought because it was thought unimportant in the US;

(e) there was no challenge to the competence or procedure of the two US Courts.

84. The Appellants return to what was said by Judge Easterbrook in the ***Vas Cath*** decision. The Respondents were afforded ample opportunity to contest these various issues before Courts whose concepts and procedures are very similar to our own. Having heard all that both parties had to say on these issues, those Courts made certain factual findings. The Respondents should not be permitted to "have another go" and waste considerable amounts of legal fees and Court time purely in the hope that something will turn up. Facts are facts; they do not change by reason of being litigated over time and time again. The Appellants submit that it is clearly just and equitable to all concerned that the background findings previously made by the US Courts should be adopted by the UK Court, leaving the parties to concentrate on the further issues and matters relevant to the UK litigation.

85. If, contrary to the Appellants' submissions the law of issue estoppel has hitherto been subject to a number of rigid and narrow rules, it is respectfully submitted that such restrictions, whatever their historical origin, should be swept away and a practical test of fairness on the lines referred to above substituted. There is precedent for this in the decision of this Court in ***Habib Bank v Habib Bank A.G. Zurich*** [1982] R.P.C. 1 with regard to another branch of estoppel[47].

Antony Watson QC
Colin Birss

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47 See in particular the leading judgment of Oliver LJ at p 36

APPENDIX 1

Abbreviations

"Amgen"	Amgen Inc
"Kirin-Amgen"	Kirin-Amgen Inc
"Ortho"	Ortho Pharmaceutical Corporation
"Cilag"	Cilag Limited
"Janssen-Cilag"	Janssen-Cilag Limited
"BMG"	Boehringer Mannheim GmbH
"BMUK"	Boehringer Mannheim UK Pharmaceuticals Limited
"GI"	Genetics Institute Inc
"The '605 Patent"	*European Patent (UK) 148,605*
"The Epo Patent"	ditto
"The '539 Patent"	European Patent (UK) 209,539
"The Purification Patent"	ditto
"The '564 Patent"	European Patent (UK) 205,564
"The '678 Patent"	European Patent (UK) 411,678
"The Amgen Litigants"	Collectively - Amgen, Kirin-Amgen, Ortho, Cilag and Janssen-Cilag
"The BMG Litigants"	Collectively - BMG, BMUK and GI

APPENDIX 2

Summary of Identity of Various Parties and Proceedings

A. **THE PARTIES**

(a) **The Amgen Litigants**

(i) **Kirin-Amgen Inc**

Kirin-Amgen is proprietor of the '605 patent, First Plaintiff in UK Action CH 1993 K No 937, Respondent to the Counterclaim in Action CH 1993 K No 937 and Respondent to Petition 1993 K No 8550. It was also a co-Defendant in the California Action (Odre 1, para 6a)).

(ii) **Ortho Pharmaceutical Corp.**

Ortho is exclusive licensee under the '605 patent, a licensee under the '008 patent, Second Plaintiff in UK Action CH 1993 K No and co-Defendant in the California Action. It was also a Defendant in the Delaware Action and Intervening Plaintiff in the Second Massachusetts Action.

(iii) **Amgen Inc**

Amgen is proprietor of the US '008 patent, Plaintiff in the First and Second Massachusetts Actions and co-Defendant in the California Action.

(iv) **Cilag Limited and Janssen-Cilag Limited**

Cilag (now in liquidation) is the Petitioner in proceedings CH 1993 C No. 6076. Cilag was the Defendant in Action No. CH 1993 B No 4552 and was replaced by Janssen-Cilag in November 1995. Cilag and then Janssen-Cilag have sold EPREX in the United Kingdom.

(b) **The BMG Litigants**

(i) **Genetics Institute**

GI is the proprietor of the '539, '678 and '564 patents. It is the Second Plaintiff in Action CH 1993 B No 4552 alleging infringement of the same and the Respondent to the Counterclaim in that Action. It is also Respondents to Petition CH 1993 C No. 6076. GI was a co-Defendant in the First Massachusetts Action, a co-Plaintiff in the California Action, Plaintiff in the Delaware Action and a Defendant in the Second Massachusetts Action.

(ii) **Boehringer Mannheim GmbH**

BMG claims to be the exclusive licensee under the '539, '678 and '564 patents, co-Defendant in Action CH 1993 K No 937, co-Plaintiff in Action CH 1993 B No 4552 and Petitioner in Petition CH 1993 K No 8550.

(iii) **Boehringer Mannheim (UK) Pharmaceuticals Limited**

BMUK is co-Defendant in Action CH 1993 K No 937. It sells RECORMON in the United Kingdom.

(iv) **Chugai Inc.**

Chugai was an exclusive licensee under the '195 patent, co-Defendant in the First Massachusetts Action and co-Plaintiff in the California Action.

B. **THE PROCEEDINGS**

The following list summarises the various parties to the various claims, counterclaims and petitions in the US and the UK:

1. **United States Litigation**

(a) **District Court of Massachusetts**

(i) ***Amgen v GI & Chugai***

Action under '008 (EPO)

Revocation of '195 (Purification)

(ii) ***GI & Chugai v Amgen***

Revocation of '008 (EPO)

Action under '195 (Purification)

(b) **District Court of California**

(i) ***GI v Amgen, Kirin-Amgen & Ortho***

Action under '195 (Purification)

(ii) ***Amgen, Kirin-Amgen & Ortho v GI & Chugai***

Revocation of '195 (Purification)

Action under '008 (EPO)

(iii) ***GI & Chugai v Amgen, Kirin-Amgen & Ortho***

Revocation of '008 (EPO)

(c) **District Court of Delaware**

GI & Chugai v. Ortho

Claim under '837 (derived from '195) purification

(d) **District Court of Massachusetts [No 2]**

Amgen & Ortho v. GI

Action to prevent litigation of '837 patent in light of First Massachusetts litigation.

2. United Kingdom Litigation

(a) Petition No CH 1992 K No 8550

BMG v Kirin-Amgen

Revocation of '605 (EPO)

(b) Action No 1993 K No 937

(i) **Kirin-Amgen & Ortho v BMG & BM (UK)**

Action under '605 (EPO)

(ii) **BMG & BM (UK) v Kirin-Amgen & Ortho**

Revocation of '605 (EPO)

(c) Action No CH 1993 B No 4552

(i) **BMG & GI v Cilag/Janssen-Cilag**

Action under '539 (Purification)

Action under '678 (o-glycosylation)

Action under '564 (sequence)

(ii) **Cilag/Janssen-Cilag v. BMG & GI**

Revocation of '539 (Purification)

Revocation '678 (o-glycosylation)

Revocation of '564 (sequence)

(d) Petition No CH 1993 C No 6076

Cilag/Janssen-Cilag v GI

Revocation of '539 (Purification)

Revocation of '678 (o-glycosylation)

Revocation of '564 (sequence)

APPENDIX 3

Privity of Interest between BM and GI in detail

Set out below are the relevant facts relating to the relationship between BMG and GI. It is submitted that, taken as a whole, these facts are more than sufficient to make it just that BMG (and BM(UK)) be bound by the findings of fact made in the previous US proceedings.

A. INTRODUCTION

(i) BMG had a privity of interest with GI by reason of their direct interest and participation in the US proceedings and such interest was inextricably linked to the subject matter of those proceedings, namely DNA relating to EPO, EPO producing host cells, vectors and rEPO itself. It was the very project which BM had funded and were hoping to be beneficiaries under.

(ii) It is manifest that BMG were directly involved in the allegedly infringing acts of GI which were the subject of those proceedings. This is established by the facts and matters set out below. These facts are set out in Odre 1, paras 20-24 **[Bundle 2, Tab 1, pp 11-13]**, exhibits "SMO 10" and "SMO 11", **[Bundle 4, Tab 1, p 1; Tab 2, p 17]** and the First Affidavit of Schuster **[Bundle 2, Tab 3, p 26]**. The 1985 and 1988 Agreements referred to comprise Exhibits "GM 8" and "GM 9" **[Bundle 4, Tab 7, p 40; Tab 8, p 77]** and "HJS 5" **[Bundle 4, Tab 5, p 33]**. See also the extracts from the communications passing between GI & BMG **[Bundle 4, Tab 17, pp 205-287]**.

B. JOINT RESEARCH PROJECT BETWEEN GI AND BMG GAVE RISE TO SUBJECT MATTER OF BOTH PROCEEDINGS

(iii) The negotiations between BMG and GI giving rise to the 1985 agreement began in 1984. The initial meeting between the two firms took place in Germany but many negotiation sessions after that took place in Massachusetts.

(iv) The host cells which make RECORMON - the subject matter of the present proceedings - are identical to those host cells which were found to infringe the '008 patent in the US proceedings. These host cells and the process of using them to make recombinant EPO were created and/or developed as part of a joint research project and collaboration between BMG and GI funded in large part by BMG. The joint research project commenced in about 1985 pursuant to the 1985 Agreement. RECORMON is a "Licensed Compound" and/or "Licensed Product" pursuant to the 1985 Agreement.

(v) By way of example, in support of the allegation that the research project was a joint project and collaboration between BMG and GI, the Plaintiffs will point to the following passages from the 1985 Agreement namely:

Paragraph 2 of the Introduction

*"BM desires that GI, **on behalf of and in collaboration with BM**, undertake a research and development project utilising recombinant DNA technology for producing erythropoietin on a commercially feasible basis for use in humans. [...]"*

Paragraph 4 of the Introduction

"[...] GI and BM are willing to share the risks that the project herein undertaken may be held to infringe one or more of [third party] patent positions [...]"

"Clause 2.2 Inspection

Each party shall have the right to arrange for its employees and outside consultants involved in the Project to visit the other party at its offices and laboratories, and to discuss the Project work and its results in detail with the technical personnel and consultants of the other party [...]"

"Clause 2.5 Progress Reports

Each Party shall provide the other Party with written progress reports summarising the technological, clinical testing and marketing progress of the Project within 30 days after the end of each six months period, starting with January 1, 1986.

For a six months period in which a Benchmark is completed the report of the applicable Party will include a final report on the attainment of such Benchmark."

"Clause 2.6 Disclosure

GI shall disclose all Know-How as well as the production clone in confidence to BM 30 days following the signature of the Agreement or immediately after obtaining them to enable BM to manufacture and produce Licensed Compound as well as Licensed Products.

BM shall disclose in confidence to GI all animal studies, human studies and other tests or submissions to Government Regulatory Agencies arising from the Project, after having obtained such data, results and documents. GI may utilise such information outside the Territory only if agreed upon in writing between the Parties case by case."

Clause 2.8 "Commercialisation

Promptly and diligently after GI's supply of GMP-material in an amount of at least 400mg BM shall exert its best efforts, at its own expense, to:

undertake and complete galenical developments for the formulations to be used for clinical trials;

conduct all necessary and appropriate animal and human testing and clinical trials on the Licensed Products, and control the manner and extent of such testing;

provide for commercial scale production of the Licensed Products;

prepare, file and prosecute all governmental applications for approvals necessary to produce, manufacture, distribute and market the Licensed Products in the Territory; and

market the Licensed Products in the Territory on a diligent commercial basis after approval by the applicable Government Regulatory Agency.

BM shall provide information to GI upon its reasonable request as to the status of its commercialisation efforts under subsections a) through e) above."

"Clause 3.1 Research fee

In consideration of the research, development and related activities undertaken by GI with regards the Project, BM shall pay to GI the Research Fee [some $4 Million]"

"Clause 5.10 Potential Amgen Patent

The Parties recognise the existence of patent positions of third parties which may be of relevance to the production of Licensed Compound including but not limited to, applications filed by Amgen in the European Patent Office, PCT APL WO 85/02610.

GI shall use its best judgment to undertake discussions with AMGEN and/or its licensee in the Territory to unblock any blocking AMGEN patent claims in the

Territory. Depending on the timing of such potential arrangement with AMGEN, a bonus will be due to GI according to Schedule E"

(vi) The third party patent positions referred to in para 4 of the Introduction and clause 5.10 of the 1985 Agreement included the application filed in the European Patent office which matured into the '605 patent.

(vii) By clause 7.6, BMG were entitled to deduct from the royalties payable to GI any sums payable to third parties in order to be permitted to manufacture or sell Licensed Products (as defined). Those sums would include any royalties or damages which BMG would be required to pay to Amgen. Thus BMG clearly had an interest in GI securing a strong patent position in the US to enable BMG to use that in negotiations with Amgen in relation to the right to manufacture and sell rEPO in other countries.

C. BAILMENT OF CELLS

(viii) The Amgen '008 patent issued in late October 1987. In anticipation of this development and of a possible injunction against GI's further production of rEPO in the USA, GI and BMG shipped a quantity of EPO producing cells to BMG in Germany. By removing the cells from the USA, BMG and GI attempted to avoid the consequences of US law and ensured that they would be able to continue their collaboration in Germany notwithstanding any suit under the patent or adverse ruling by a United States Court. The expressed purpose of the shipment was to enable BMG to proceed to manufacture EPO some of which was then to be shipped back into the US for the trials which GI undertook on Jehovah's witnesses. Without the agreement to ship the EPO back to the US for trial with Jehovah's Witnesses, GI would not have been permitted under US Federal regulations to ship the cells to BMG in the first place **[Bundle 4, Tab 17, p 246]**. The cells which were shipped to BMG (or their descendants) are the cells which are currently used by BMG to produce the RECORMON which is alleged to infringe the '605 patent.

D. 130 GRAMS OF ERYTHROPOIETIN AND AN INDEMNITY

(ix) Clauses 3.1 and 3.3 of the 1988 Agreement **[Bundle 4, Tab 8, pp 82 & 82A]** provided:

> *"BM hereby places an order for 130 grams of INTERMEDIATE [ie. erythropoietin] to be manufactured at GI's Cambridge facility. GI shall supply this material to BM [...]"*
>
> *"BM agrees to indemnify GI for all damages exceeding one third of GI's manufacturing revenue which results or arises from an award or settlement in a suit charging GI with infringement of a United States patent [such as the '008 patent] arising out of GI's manufacture of the aforesaid 130 grams. [...]"*

(x) Pursuant to the 1985 and 1988 Agreements GI used infringing DNA and host cells to make recombinant EPO for BMG and supplied it to BMG.

E. ERYTHROPOIETIN FOR JEHOVAH'S WITNESSES

(xi) In 1988 BMG agreed to supply GI in Massachusetts with rEPO it had reformulated in Germany, for use in a study of Jehovah's Witnesses with end-stage renal disease. (Schuster 1, para 12 **[Bundle 2, Tab 3, pp 29-30]**.) See also **Bundle 4, Tab 17, p 246**.

F. BMG SUPPLIED WITNESSES FOR THE US PROCEEDINGS

(xii) In January 1989 Amgen obtained a temporary restraining order against GI in the First Massachusetts Action. As a result BMG proffered Professor Uwe Bicker, Executive Director of BMG's pharmaceutical products division, and Professor Karl Koch, an independent clinician engaged by BMG, to swear affidavits for use in the First Massachusetts Action in opposition to the continuation of the injunction - see Schuster 1, para 10 **[Bundle 2, Tab 3, p 29]** and his exhibits "HJS 3" and "HJS 4" **[Bundle 4, Tab 3, p 19; Tab 4, p 26]**.

(xiii) Professor Bicke in his affidavit invoked loss to BMG and the "irreparable" harm that would be done to BMG's clinical trial program as being reasons for the US Court to refuse the injunction (see paras 7 and 10)

G. BMG PAID GI'S USA DAMAGES

(xiv) On 7 February 1989 the Judge hearing the First Massachusetts Action lifted the temporary restraining order and ordered instead that all profits from GI's sale of rEPO be placed in an escrow account pending the outcome of the First Massachusetts Action. Over five million dollars was paid into that account by BMG, not by GI - see the decision of the United States District Court for the District of Massachusetts in the case of the ***Trustees of Columbia University of New York v BMG*** (Civil Action No. 93-11512-NG) **[Bundle 4, Tab 1, p 1 @ p 5]** (not contradicted by Schuster)

H. BMG CONTROLLED SETTLEMENT NEGOTIATIONS

(xv) BMG were involved in negotiations regarding the amount of damages which GI were going to pay following the final holdings in the First Massachusetts Action. During those negotiations GI stated that before any agreement could be finalised the terms of settlement had to be approved by BMG. Pursuant to the 1988 Agreement GI was obliged to obtain BMG's agreement to any settlement with Amgen - see exhibit "SMO 11" **[Bundle 4, Tab 2, p 17]** and exhibit "HJS 6" **[Bundle 4, Tab 6, p 38]**.

I. COMMUNICATIONS BETWEEN PARTIES AND COMMON INTEREST PRIVILEGE

(xvi) During the conduct of the US proceedings GI and its attorneys communicated frequently with BMG about the US proceedings (see Lee 1, para 13 **[Bundle 2, Tab 2, pp 18-19]** and Schuster 1 para 7 **[Bundle 2, Tab 3, p 28]**). Those communications, including periodic meetings and written correspondence, at least kept BMG informed of developments in and generally advised of the status of the US

proceedings. GI claimed privilege for such communications in the US proceedings - see the US privilege list at Exhibit "GM 16" to Moss 7 **[Bundle 4, Tab 9, p 98]**.

(xvii) By a letter dated 13 December 1995 the solicitors for the BMG Litigants asserted that the communications passing between GI and BMG and their respective lawyers were privileged under the doctrine of "common interest privilege" (See "GM 15" **[Bundle 4, Tab 18, p 288]**).

(xviii) Such a claim to common interest privilege can only be claimed because there is a common interest, as the Amgen Litigants contend. See in this regard the leading authority on common interest privilege ***Buttes Gas & Oil Co. v. Hammer (No.3)*** [1981] QB 223 - see at 243 A-F per Lord Denning MR, at 251G- 252A per Donaldson LJ and at 267H per Brightman LJ. It is such common interest which makes them privies.

(xix) Accordingly, such a claim amounts to an admission against interest that BMG had a sufficient common interest in relation to the US proceedings with GI such that BMG (and BMUK) ought to be bound by the findings therein.

(xx) Certain letters between the parties have been given in discovery (see bundle of GI discovery documents **[Bundle 4, Tab 17, pp 205-287]**) and give an indication of the level of involvement of BMG in assisting GI with regard to the Amgen '008. Three examples may be quoted:

> *"We refer to our telephone conversation held between you and Mr. Schuster on December 11 1989 during which we discussed the question of contingency planning on your side in the light of the decision of the Boston Court rendered by Magistrate Saris. ..... In the spirit of good cooperation we are willing to assist you in such contingency planning and therefore propose the following" (Letter from Bicker and Schuster of BMG to Eisen of GI dated 18.12.89)* **[Bundle 4, Tab 17, p 269]**.

"Reference is made to our this morning's discussions over the telephone and as indicated in the course of the conversation Boehringer Mannheim GMBH is prepared to support Genetics Institute as much as possible to overcome the major negative impacts of the recent decisions of Federal Circuit Appeal Court and any further actions which can be expected to be requested by Amgen.

Therefore it might be favourably to consider, which further possibilities of cooperation between Boehringer Mannheim GMBH and Genetics Institute would be envisaged also in the light of the fact that the decision might still allow Genetics Institute to import material into the US which is manufactured outside the US". (Letter of Abahagan of BMG to Schmergel of GI dated 11.3.91) **[Bundle 4, Tab 17, p 271]**.

"We believe that we have not only worked cooperatively together in the past few months in initiating the serum free project and in responding to the patent situation, but it is our joint responsibility to even work more closely to fight the Amgen club in every direction which seems to be reasonable and possible". (Letter from Daum and Schuster of BMG to Leicher of GI dated 02.07.91) **[Bundle 4, Tab 17, p 274]**.

Note the reference to "the Amgen Club".

I. INVOLVEMENT IN US PROCEEDINGS - INTERVENER AND JOINT TORTFEASOR

(xxi) BMG were entitled to and could have applied to intervene in and be made a party to the US proceedings and in particular the First Massachusetts Action (Odre 1, para 21 - **[Bundle 2, Tab 1, p 11]** not at any point denied by BMG).

(xxii) Further in fact (unknown to Amgen at the time) BMG were joint tortfeasors with GI in relation to the conduct of GI found to infringe the '008 patent in the USA such that

BMG could have been a co-Defendant with GI in the First Massachusetts Action - see Odre 2, para 3 **[Bundle 2, Tab 5, p 44]**; Day 1, para 34(c) **[Bundle 2, Tab 7, p 74]**.

(xxiii) It is clear that BMG induced, procured and/or otherwise collaborated in the USA with GI to produce infringing cells and vectors and to use those cells to make rEPO.

(xxiv) The Plaintiffs will refer to and rely upon the decision of the United States District Court for the District of Massachusetts in the case of ***The Trustees of Columbia University in City of New York -v- BMG*** (Civil Action No 93-11512-NG) which found that BMG induced or otherwise collaborated with GI to produce rEPO (a copy is at "SMO 10" **[Bundle 4, Tab 1, p 1]**). In the light of the matters set out above this finding was inevitable.

J. IDENTITY OF INTERESTS IN UNITED KINGDOM

(xxv) BMG, BMUK and GI have the same or substantially the same interests vis à vis this Action and the co-pending proceedings. (As regards the European proceedings see Schuster 1, para 15 **[Bundle 2, Tab 3, p 30]**).

K. PRIVITY - BOEHRINGER MANNHEIM (UK) PHARMACEUTICALS LIMITED

(xxvi) In respect of the subject matter of this Action and the co-pending proceedings no material distinction exists between the interests of BMUK and BMG. The ultimate parent company of both companies is Corange Limited, a Bermudan company owned by a private German trust. It trades on a multi-national basis and its activities are co-ordinated by Boehringer Mannheim International. Each has privity of interest with the other - see for example Moss 8, para 8 **[Bundle 2, Tab 10, p 101]** and Exhibits "GM 21" and "GM 22" **[Bundle 4, Tab 15, p 179; Tab 16, p 201]**).

(xxvii) The absence of any material distinction between BMG and BMUK is illustrated by the fact that the RECORMON product alleged to infringe the '605 patent is promoted, marketed, sold and distributed in the United Kingdom with the close and joint involvement of each of them having regard, in particular, to the facts and matters set out below:

(a) The product complained of is manufactured in Germany by BMG but is sold in the United Kingdom under invoices issued by BMUK - see Moss 8, para 5 **[Bundle 2, Tab 10, pp 2-3]** and Exhibit "GM 17" **[Bundle 4, Tab 11, p 153]**.

(b) The product complained of is sold under the trade mark "RECORMON" the proprietor of which is the BMG - Moss 8, para 5 **[Bundle 2, Tab 10, pp 2-3]** and Exhibits "GM 18", "GM 19" and "GM 20" **[Bundle 4, Tab 12, p 156; Tab 13, p 168; Tab 14, p 173]**. In the premises it is to be inferred that the said trade mark is used in the United Kingdom by BMUK with the consent of BMG.

(c) Instructions for use of the product complained of are printed in English for use in the United Kingdom but carry the name and address of BMG. A copy of the said instructions is at Exhibit "GM 18" **[Bundle 4, Tab 12, p 156]**.

(d) The said instructions and other material relating to the product, including invoices and packaging, bear the Boehringer Mannheim logo or house-mark which is used by both BMG and BMUK as an indication of their shared corporate identity - see Exhibits "GM 18", "GM 20" and "GM 21" **[Bundle 4, Tab 12, p 156; Tab 14, p 173; Tab 15, p 179]**.

(e) The application for the United Kingdom Product License for RECORMON ("the UK PLA") was taken out in the name of BMG - Moss 8, para 7(i) **[Bundle 2, Tab 10, p 100]**.

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(f) The data in support of the UK PLA was either data supplied by GI to BMG pursuant to the agreements between them or was generated by BMG itself - see Moss 8, para 7(ii) **[Bundle 2, Tab 10, p 100]** and Schuster 1, para 16 **[Bundle 2, Tab 3, p 30]**.

(g) The original UK PLA was based on manufacture of RECORMON by GI in the United States of America. A subsequent variation sought approval for manufacture at BMG's facility in Penzberg, Germany. There is no authorisation for manufacture at any facility of BMUK - see Moss 8, para 7(iii) **[Bundle 2, Tab 10, p 100]**.

(h) It is BMG which claims to be the exclusive licensee under the '539, '564 and '678 patents and which has registered its licenses at the United Kingdom Patent Office - see the Statement of Claim at Bundle A, para 1 at tab 17. However, the product RECORMON which it manufactures by way of exercise of that license is sold in the United Kingdom by BMUK.

(i) Boxes in which the product complained of has been supplied in the United Kingdom for use in clinical trials are printed in English but bear the name and address of the BMG - see Exhibit "GM 20" **[Bundle 4, Tab 14, p 173]**.

(j) The said product is supplied to the BMUK by BMG already packaged for sale and distribution in the United Kingdom - see Exhibit "GM 20" **[Bundle 4, Tab 14, p 173]**.

(k) By reason of such facts and matters BMG and BMUK have admitted joint liability in these proceedings - see the Re-Amended Defence, para 9 **[Bundle 1, Tab 9, p 69]**.

(l) It is BMG which has sought to oppose the '605 Patent at the European Patent Office and has applied to revoke the '605 Patent in the United Kingdom by

way of the Petition issued in the High Court - see the Petition heading. It does so not only for its own benefit but also for the benefit of its affiliated companies including in the United Kingdom, BMUK.

(m) BMUK is an "Affiliate" of BMG as defined in clause 1.1 of the 1985 agreement - admitted by HS in correspondence by letter dated 1st February 1996 **[Bundle 4, Tab 19, p 297]**.

(n) Note also that Schuster on the question of discovery (Schuster 2 **[Bundle D, Tab 7, p 36]**) swore the affidavit as the proper officer of both BMG and BMUK.

(xxviii) Since BMG is privy with GI with respect to the US proceedings, BMUK is privy with GI as well.

READING GUIDE

We believe that our skeleton argument deals reasonably fully with the points of fact and law arising on this appeal. References to the relevant parts of the judgment, appeal papers, pleadings, evidence and authorities are provided in the skeleton argument. However, we would suggest that the court might read, in addition to the judgment and appeal papers:

Spencer Bower, Res Judicata 2nd Edn. pp. 170-182

Carl Zeiss (No. 2) [1967] AC 853 at pp. 908E-919D; 925E-929B; 933D-938G; 942B-949E; 963A-971D.

Norway's Application [1990] 1 AC 723 at pp. 740B-744B; 751G-755C; 771D-773E, 789G-H.

Although, as we have said, references to the relevant parts of the evidence are to be found in our skeleton argument, the court may wish to read certain of the affidavits in full. We would suggest that the most important affidavits are:

Odre 1 (core bundle 2, tab 1)
Lee 1 (2/2)
Schuster 1 (2/3)
Tootal 2 (2/4)
Odre 2 (2/5)
Moss 7 (2/9)
Eisen 1 (2/12)
Lee 2 (2/13)
Eisen 2 (2/16)

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QUICK REFERENCE GUIDE TO PARTICIPANTS IN PROCEEDINGS

FIRST MASSACHUSETTS PROCEEDINGS
(Magistrate Saris & CAFC)

The '008 action	**The '195 action**
Amgen (patentee)	Amgen
v.	v.
GI & Chugai	GI (patentee) & Chugai (exclusive licensee)

UK PROCEEDINGS

The '605 action	**The '539 action**
Kirin-Amgen (patentee) & Ortho (exclusive licensee)	BMG (exclusive licensee) & GI (patentee)
v.	v.
BMG & BMUK	Janssen-Cilag (formerly Cilag)

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