



BL O/277/05

20 October 2005

## PATENTS ACT 1977

BETWEEN

Yeda Research and Development Co. Ltd.

Claimant

and

Rhone-Poulenc Rorer International (Holdings)  
Inc. and ImClone Systems Inc.

Defendants

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PROCEEDINGS

Reference under section 37 of the Patents Act 1977 in  
respect of patent number EP(UK) 0667165 B1

HEARING OFFICER

R C Kennell

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## SECOND PRELIMINARY DECISION

### Introduction

- 1 The grant of the patent in suit was mentioned in the European Patent Bulletin on 27 March 2002. It relates to therapeutic compositions containing certain monoclonal antibodies in combination with anti-neoplastic drugs; the antibodies are specific to a human receptor for epidermal growth factor (EGF) and can inhibit the growth of human tumour cells that express human EGF receptors by binding to the extra-cellular domain of the receptors to form an antigen-antibody complex. The invention rests on a discovery that the combined treatment is more efficient than the use of either agent by itself because it kills the cancer cells (a cytotoxic effect) rather than merely prevents them from replicating (a cytostatic effect, as would be the case with the monoclonal antibody alone) and because it allows the use of lower amounts of toxic or subtoxic anti-neoplastic drugs such as doxorubicin or cisplatin.
- 2 The claimant launched these proceedings on 26 March 2004, one day before the expiry of the two-year period specified in section 37(5) of the Act, which states:

*“On any such reference no order shall be made under this section transferring the patent to which the reference relates on the ground that the patent was granted to*

*a person not so entitled, and no order shall be made under subsection (4) above on that ground, if the reference was made after the end of the period of two years beginning with the date of the grant, unless it is shown that any person registered as a proprietor of the patent knew at the time of the grant or, as the case may be, of the transfer of the patent to him that he was not entitled to the patent.”;*

this was followed by a lengthy exchange of correspondence between the parties and the Office on whether the proceedings should be stayed to await the outcome of various parallel proceedings in other jurisdictions. However, in my decision BL O/163/05 of 17 June 2005 following a preliminary hearing on 4 March 2005, I declined the defendants’ request to stay the proceedings to await the outcome of proceedings in the US, and gave them a period of 28 days to file their counter-statement.

3 At the hearing the claimant’s representative said the claimant had proposed an amendment to the US proceedings to allege sole, rather than joint, ownership, although no concluded view had at that point been taken whether to amend their statement for the UK proceedings. However, on 29 June 2005, shortly after I gave my decision, the claimant did indeed file an amended statement in which sole ownership was advanced as an alternative to joint ownership and material was added in support of this allegation.

4 The defendants took objection to this, and wanted the allowability of the amendment to be decided before they filed a counterstatement. This prompted another substantial exchange of correspondence about the future course of the proceedings, which I do not need to go into in detail. The outcome was that the Office issued a letter on 5 August 2005 requiring the defendants to file a counterstatement by 19 August 2005, without prejudice to amendment at a later stage should the amendments to the claimant’s statement be found unacceptable. The defendants duly filed a counter-statement addressing both the original statement and the amendments thereto, and the matters of the allowability of those amendments and the future course of the proceedings came before me at a second preliminary hearing on 16 September 2005. As before, Mr Tim Powell of Bristows appeared for the claimant Yeda, Mr Andrew Lykiardopoulos, instructed by Bird & Bird, appeared as counsel for Rorer, and Mr Daniel Alexander QC, instructed by Millbank Tweed Hadley & McCloy, appeared as counsel for ImClone (the exclusive licensee of Rorer) and made a joint submission on the part of both defendants.

5 I should add that Rorer is still the registered proprietor of the patent although an application has been made to change the name to Aventis Holdings Inc. following corporate restructuring.

### **The amendments to the statement**

6 In its original statement of case, the claimant Yeda alleged that it was entitled to be a joint proprietor with Rorer and that Professor Michael Sela, Dr Esther Pirak and Dr Esther Hurwitz (the “Weizmann inventors”), who were employed by the Weizmann Institute of Science (“Weizmann”) in Israel at the relevant time, were entitled to be mentioned as co-inventors. This was on the grounds that the Weizmann inventors had unexpectedly discovered the synergistic effect of the combination of the monoclonal antibodies and anti-neoplastic drugs, and that they

and Weizmann had in August 2002 assigned their rights to Yeda (who marketed and commercialised developments arising from Weizmann's work). The claimant further alleged that, when the work which the Weizmann inventors were carrying out on the use of EGF as a potential carrier for anti-neoplastic agents had turned in October 1986 to the use of antibodies to the EGF receptors rather than EGF itself, one of the named inventors, Dr Joseph Schlessinger, had provided two specific antibodies, identified in the patent as "108" and "96". He was for this reason named as a co-author in a paper published in December 1988 on which the first US priority application (filed on 15 September 1988) supporting the patent was based. It was alleged that Dr Schlessinger had been shown a draft of this paper earlier in 1988.

7 In the amended statement, the claimant now believes that the facts support an alternative case for sole proprietorship on the part of Yeda, and for the Weizmann inventors alone to be named as co-inventors rather than the presently named inventors Joseph Schlessinger, David Givol, Françoise Bellot and Richard M Kris (the "Rorer inventors"). The claimants accordingly seek to make a number of amendments of substance to the statement, which I can summarise as follows:

- The contribution of the Rorer inventors was not sufficient to found a claim to ownership because they did not in any way contribute to the actual conception of the invention but merely provided an antibody which the Weizmann inventors unexpectedly found to be capable of inhibiting the growth of tumour cells;
- Throughout the relevant period Dr Schlessinger and Dr Givol were employees of Weizmann so that even if they had made an invention any rights they had in it would have vested in Weizmann and would now vest in Yeda by virtue of an agreement dated 21 October 2004 between Weizmann and Yeda. This amendment rests on an allegation that Dr Schlessinger and Dr Givol were either on sabbatical or on leave from Weizmann at all material times, and so remained employees of Weizmann by virtue of Israeli law and of Weizmann's rules concerning sabbaticals;
- The 108 and 96 antibodies were produced by immunising mice with CH 71 cells or CH 71 cell membrane preparation as described in the patent, but CH 71 cells were the property of Weizmann and they were used by Rorer and the Rorer inventors without the knowledge or consent of either Weizmann or Yeda; and
- The draft 1988 article had been shown to Dr Schlessinger in circumstances importing an obligation of confidence and the application for the patent had been filed in breach of that obligation, and also in breach of obligations to Weizmann under Israeli law by virtue of their employment.

8 The claimant says that events in the parallel proceedings in Germany and the US had given rise to an appreciation that the underlying facts supported a claim to sole proprietorship. Thus in Germany the defendants were making out a positive case that Dr Schlessinger had conceived the idea underlying the invention as early as late 1985 or the beginning of 1986 whilst employed full time at Weizmann, which had focussed the claimant's mind on his employment status. Further, as a result of the US depositions and disclosure documents it appeared that none of the

Rorer inventors except Dr Schlessinger were contending that they played a part in the conception of the invention, and that Rorer had no conception of the invention until informed of the results by Weizmann.

### **Arguments and conclusions**

- 9 For the defendants, Mr Alexander argued on the basis of the Civil Procedure Rules (“CPR”) that I should not accept these amendments. He said that I was being asked to accept an amendment to a statement after the two-year limitation period imposed by section 37(5) of the Act for bringing the reference had expired, and that I was therefore obliged to have recourse to r.17.4 CPR, the relevant parts of which state:

*“Amendments to statements of case after the end of a relevant limitation period*

*(1) This rule applies where -*

*(a) a party applies to amend his statement of case in one of the ways mentioned in this rule; and*

*(b) a period of limitation has expired under -*

*.....*

*(iii) any other enactment which allows such an amendment or under which such an amendment is allowed.*

*(2) The court may allow an amendment whose effect will be to add or substitute a new claim, but only if the new claim arises out of the same facts or substantially the same facts as a claim in respect of which the party applying for permission has already claimed a remedy in the proceedings. ....”.*

In his view the Patents Act 1977 was an enactment “under which such an amendment is allowed” for the purposes of r.17.4(1)(iii) because amendment was not expressly prohibited, this following from the reasoning in *Parsons v George* [2004] EWCA Civ 912, [2004] 1 WLR 3264 on corresponding wording in r.19.5 CPR concerning change of parties after the end of a limitation period.

- 10 It was common ground that if r.17.4 applied to the Patents Act 1977 - which the claimant did not necessarily accept - it would be by virtue of r.17.4(1)(iii). However, Mr Powell argued that this was not primarily a matter of jurisdiction under r.17.4. Rather it was a question of whether I should exercise discretion on the basis stated by Peter Gibson LJ in an unreported Court of Appeal case of 9 August 1999, *Cobbold v London Borough of Greenwich* (mentioned in the Office’s “Patent Hearings Manual”, March 2005 edition, at paragraph 2.41):

*“The overriding objective is that the court should deal with cases justly. That includes, so far as practicable, ensuring that each case is dealt with not only expeditiously but also fairly. Amendments ought in general to be allowed so that the real dispute between the parties can be adjudicated upon provided that any prejudice to the other party or parties caused by the amendment can be*

*compensated for in costs, and the public interest in the administration of justice is not significantly harmed. I cannot agree with the judge when he said that there would be no prejudice to Greenwich in not being allowed to make the amendments which they are seeking. There is always prejudice when a party is not allowed to put forward his real case, provided that it is properly arguable.”*

- 11 Mr Powell also took me to other parts of the Patent Hearings Manual (“PHM”), including paragraphs 1.74 - 1.76 on the relevance of the CPR, to suggest that I ought not to be overly influenced by court rules governing fine legal points on pleadings and that I should adopt a pragmatic approach to the question of whether the amendments should be allowed. He reminded me of the overriding objective, just as applicable to proceedings before the comptroller as before the courts (1.75 PHM), to deal with cases justly.
- 12 As the PHM explains at paragraph 1.74, although the comptroller is not bound by the CPR and their associated Practice Directions, they have a significant influence on proceedings before him. The paragraph gives a number of examples based on the identical powers of the comptroller and the High Court as regards the giving of evidence and related matters. Paragraph 1.76 however makes the point that the comptroller is expected to be a cheaper forum than the High Court and this should be borne in mind when deciding how far to follow court procedures.
- 13 This I think argues for a substantial measure of caution in deciding whether to adopt the provisions of the CPR in any particular case before the comptroller. I certainly do not think that I am bound to apply the CPR in all cases where there might be a lacuna in the procedures prescribed by the Patents Acts and Rules, still less that I should regard the CPR as some sort of “gloss” which automatically applies as a further layer of rules governing these procedures. In my view the most that can be said is that the CPR will be indicative in some cases, but by no means all, of the approach to be adopted by the comptroller. With that in mind I will deal with the arguments advanced by Mr Powell and Mr Alexander on the relevance of the CPR and cases decided thereunder, Mr Powell arguing on the basis that even if r.17.4 applied the claimant satisfied the tests that it laid down.

### ***The position under the Civil Procedure Rules***

#### **1. Does the time limit prescribed by section 37(5) of the Patents Act 1977 import a period of limitation for the purposes of r.17.4 CPR?**

- 14 Mr Powell disputed the suggestion made by Mr Alexander, on the basis of statements made in correspondence, that the parties were in agreement that section 37(5) established a limitation period. In his view section 37(5) merely provided a time limit which could be extended if the person bringing the reference alleged bad faith (which was not in issue here). The claimant had made the reference within the time limit, and so long as that condition was satisfied the allowability of the amendments was purely a matter of discretion and no separate limitation point arose. Indeed I observed that the language of section 37(5) (“No order shall be made ... if the reference was made after the end of the period ....”) might arguably not be understood as a limitation period.

15 Mr Alexander thought that as a practical matter it made no sense to allow allegations to be made after the two-year time limit if it was not possible to obtain the desired remedy. Further, he noted that paragraph 37.12 of the “CIPA Guide to the Patents Act” (Sweet & Maxwell, 5<sup>th</sup> edition) referred to the provision of section 37(5) as a “time bar” which could be lifted if bad faith could be shown, and that section 37 was one of those sections which was required by section 130(7) of the Act to be interpreted in the same manner as the corresponding provisions of the European Patent Convention and the Community Patent Convention. Thus as explained in the CIPA Guide at pages 714 and 1075 the corresponding provision is Art 23 of the CPC as amended in 1989 which reads:

*“1. If a Community patent has been granted to a person who is not entitled to it under Article 60(1) of the European Patent Convention, the person entitled to it under that provision may, without prejudice to any other remedy which may be open to him, claim to have the patent transferred to him.*

*2. Where a person is entitled to only part of the Community patent, that person, may in accordance with paragraph 1, claim to be a joint proprietor.*

*3. Legal proceedings in respect of the rights specified in paragraphs 1 and 2 may be instituted only within a period of not more than two years after the date on which the European Patent Bulletin mentions the grant of the European patent. This provision shall not apply if the proprietor of the patent knew, at the time the patent was granted or transferred to him, that he was not entitled to the patent.” ;*

and this clearly imported a limitation period.

16 In the light of the analogy with Art 23 CPC, I will proceed for the moment on the basis that the two-year period in section 37(5) can constitute a limitation period for the purposes of r.17.4.

2. Do the amendments satisfy the tests of r.17.4(2) CPR?

17 It was not I think disputed that the judgment of Park J in *Hoechst UK Ltd v Inland Revenue* [2003] EWHC 1002 (Ch) at paragraphs 22 - 23 provides a convenient starting point for the analysis of amendments proposed outside a limitation period. As Park J explained, there is no discretion to allow such an amendment if it involves the addition of a new cause of action and if the new cause of action did not arise out of the same facts or substantially the same facts as already pleaded. Nor was it disputed that, as stated by Diplock LJ in *Letang v Cooper* [1965] 1 QB 232 at pages 242 - 243:

*“A cause of action is simply a factual situation, the existence of which entitles one person to obtain from the court a remedy against another person.”*

(so that in this case there were not two causes of action when the same factual situation gave rise to claims for both negligence and trespass to the person).

18 In his skeleton argument, Mr Powell considered that the claims for sole proprietorship and consequential matters were not the addition of new causes of action, but merely claims for new or additional remedies arising out of the facts in dispute. He drew my attention to *Lloyds Bank*

*plc v Rogers* [1999] 3 EGLR 83 to illustrate the difference between introducing a new cause of action and claiming a new or different relief when the cause of action remained the same. In this case the bank was allowed to amend a claim for a money judgment so as to add a claim for possession of property in a situation where the original particulars would have justified such a claim (although I note that Auld and Evans LJ differed as to whether there was in fact a new cause of action). Mr Powell accepted that in the present case the amendments introduced further particulars of the factual background to the dispute, but thought that even if there was an additional cause of action, it arose out of substantially the same facts. As he put it in his skeleton argument, the basic factual situation, pleaded in the original statement and remaining unchanged, was that Yeda was entitled to relief because Rorer had through the actions of Dr Schlessinger appropriated the experimental work devised and carried out, and the invention made by the Weizmann inventors, at the Weizmann Institute.

- 19 Mr Alexander did not see it this way. In his view the amended statement had added a claim of sole entitlement, claims to new relief, a claim to rights granted under any supplementary protection certificate, and allegations of breach of confidence and of Israeli law. He did not think that these could be said to arise out of the same or substantially facts as originally pleaded. I have summarised above the extra material that has been introduced; Mr Alexander pointed out that all of this was going to involve matters which would not have needed to be considered under the reference as originally pleaded. This would require different and more extensive evidence to be furnished, including evidence of Israeli and US employment and patent law and evidence of breach of confidence to support the allegation now made that any inventive contribution made by Professor Schlessinger or Dr Givol vested in Weizmann. Mr Alexander stressed that a different claim to entitlement was now being made: not “I contributed to the invention and should have a share in it” but “Even if it was completely invented by you, it belongs to me anyway”.
- 20 Mr Alexander took me to a number of authorities to illustrate that the courts took a narrow view of whether there was a new claim or cause of action and whether it arose out of the same or substantially the same facts. He particularly drew my attention to *P & O Nedlloyd BV v Arab Metals Co* [2005] EWHC 1276 (Comm) to show that the test as to whether facts were substantially the same was not simply whether the background was the same. In *Nedlloyd*, Colman J held (paragraph 42) that to be allowable the amendment must “involve something going no further than minor differences likely to be the subject of enquiry but not involving any major investigation and/or differences merely collateral to the main substance of the new claim, proof of which would not necessarily be essential to its success”. This test was not satisfied where the claimants on the original claim needed only to rely on the contents of a fax, but would need to rely on evidence about it to make good the new claim.
- 21 Mr Alexander sought to distinguish another recent judgment, *The Convergence Group plc v Chantrey Vellacott* [2005] EWCA Civ 290 in which allegations of negligence were made against a firm of accountants and the amendments (which were allowed) had the effect of adding a further year to the period over which negligence was alleged. The Court of Appeal held that although there was a new claim, it arose out of substantially the same facts as already pleaded. It observed (paragraph 105) that in a case of such factual complexity it was almost inevitable that new allegations of fact were made. However (paragraphs 107 - 108), the new allegations

arose from the same retainer, related to the same matter (the proposed restructuring of the Group), relied on the same duties owed by the accountants and introduced no new allegations of loss. Further (paragraphs 109 -112), with or without the amendments it was inevitable that evidence of the advice given in the first year was going to be put before the court and the nature of that advice was going to be under scrutiny. I think this quite simply summarised in paragraph 106 where the Court of Appeal saw on the pleadings a continuous course of conduct over a period and cumulative delay causing losses at the end of that period.

- 22 Other cases relied on by Mr Alexander were *Hoechst v Inland Revenue* mentioned above and *Paragon Finance plc v D B Thakerah & Co* [1999] 1 All ER 400. In *Hoechst*, which can I think be contrasted with *Convergence*, a claim to overpayment of 1995 advance corporation tax (ACT) was not allowed to be added even though the original claim was a generic one relating to ACT paid since 1989. Although the background to the new cause of action was the same, it did not arise out of substantially the same facts because the central fact giving rise to a cause of action was the payment of a specific dividend and the consequential payment of ACT calculated by reference to the dividend. However, the original claim, although generic, had not been quantified by reference to the 1995 dividend.
- 23 In *Paragon Finance*, the claimant sought to add an allegation of fraud to allegations of breach of contract, breach of fiduciary duty and breach of duty of care in respect of advice given in respect of mortgage loans. In the Court of Appeal Millett LJ thought it “incontrovertible” that an allegation of intentional wrongdoing involved a different cause of action since it had not previously been alleged that there was any intentional wrongdoing. He also considered it “contrary to common sense” that a claim based on allegations of negligence and incompetence on the part of a solicitor could involve substantially the same facts as an allegation based on fraud and dishonesty, and there could be “no sharper line” than that separating such cases.
- 24 At the hearing Mr Powell was prepared to accept that the addition of an allegation that entitlement vested initially in Weizmann by virtue of the work done by Dr Schlessinger and/or Dr Givol whilst employed by Weizmann was a new claim, in that it was a new basis on which the claimant might be able to claim ownership. However, he maintained that all this was all part of the same story and would largely have come out during the evidence stages and in cross-examination, except perhaps for the points on employment law. He did not think that there was anything very much in the allegation of breach of confidence, since this would have been something that Dr Schlessinger would naturally have understood.
- 25 Mr Powell also took me to case law to support his arguments. In addition to *Lloyds Bank plc v Rogers* [1999] 38 EG 187 discussed above, he relied on paragraphs 105-106 of the *Convergence* case to show that the courts in fact took a broad view of the matter, and that it was almost inevitable that further factual matter would come to light. In a similar vein he mentioned the case of *Circle Thirty-Three Trust Ltd v Fairview Estates (Housing) Ltd* [1984] 1 Const LJ 282 where it was sought to supplement a claim, that a building development was not properly carried out because the *houses* were defective, by adding an allegation that the specification and drawings, and hence the *design*, were defective. Everleigh LJ thought that whilst in theory there might be two separate causes of action, the amendment could be allowed because the substance of the claimants’ case was that they had not been given the buildings they



contracted for. As I read it, the judge was aiming to prevent the defendants getting off on a technicality by arguing that the original claim failed because the work carried out was beyond reproach and the fault lay in the design.

- 26 In analysing all the above case law to decide whether there is a new cause of action and, if there is, whether it relies on the same or substantially the same facts as originally pleaded, I accept that the judgment is essentially a qualitative one (see paragraph 104 of the *Convergence* case) or a “matter of impression” as indicated by Millett LJ in *Welsh Development Agency v Redpath Dorman Long* [1994] 1 WLR 1409.
- 27 If - and I repeat if - I am constrained by r.17.4 CPR, then on balance I would find Mr Alexander’s argument the more persuasive. Thus, *prima facie* by analogy with *Paragon Finance* a claim to sole ownership would seem to be something quite different from a claim to joint ownership. Further, the amendments do not rest on an essentially unchanged set of facts as in *Lloyds Bank*. Although Mr Powell argued that there was a continuing research programme which would be under investigation, I think that the amendments fall a little way short of being part of a course of conduct which would inevitably be under investigation, as in *Convergence*, or of being desirable for reasons analogous to *Circle Thirty-Three*. The situation seems to me to have more in common with *Hoechst* and especially *P & O Nedlloyd* since it would be difficult to regard the amendments as minor matters not requiring major new investigation - even if most of them might have “come out in the wash” in the course of the proceedings.

3. Is a reference under section 37 sufficiently analogous to a claim or cause of action before the court?

- 28 However, I think all this misses an important point. Under section 37 the claimant makes a reference to the comptroller to settle a question of who should be the true proprietor of the patent. In determining that question the comptroller can make such order as he thinks fit, and is not constrained by the particular form of order which the claimant seeks. Even if the reference alleges joint ownership and seeks that as a remedy, the comptroller is perfectly entitled to give a different remedy and to make an order for sole ownership without requiring amendment of the pleadings if he considers that appropriate in the light of the evidence before him including the results of cross-examination.
- 29 Therefore in my view, and irrespective of any analogy with Art 23 CPC, amending a reference to the comptroller under section 37 is not on all fours with adding a new claim or cause of action to an action before the court. That being the case, I do not consider myself bound to follow the procedures of r.17.4 CPR or the authorities cited under it, which I think lead me down a blind alley. I agree with Mr Powell that no limitation point arises, and that I do have discretion to accept the amendments. The lateness or otherwise in seeking the amendments, including the fact that they were sought outside the section 37(5) period, is simply one factor to be considered in deciding whether to exercise discretion.

***Whether discretion should be exercised to allow the amendments***

- 30 In deciding this I come back to the overriding objective to deal with cases justly, and I think that Peter Gibson LJ's comment in *Cobbold v London Borough of Greenwich* which I have quoted above is very much to the point. On the basis of that case, Mr Powell argued that I should allow the amendments unless to do so would cause irremediable harm to the other party, which was not the case here. He thought that there was no prejudice to the defendants, who had not demonstrated any intention to plead to the original statement, and that it would be a draconian measure to refuse the amendments and so prevent the claimant from putting its full case.
- 31 I find this argument attractive, not least because it hardly seems sensible to go ahead with what will clearly be a substantial hearing before the comptroller if the full case is not in issue. Nevertheless, as explained at paragraph 2.43 PHM, I do need to consider this in the light of the objections raised by the defendants, the diligence of the claimant in putting forward the amendments, and whether any delay in so doing is unjust to the defendants or against the public interest.
- 32 Mr Alexander suggested a number of reasons why the amendments should not be accepted. He said that there was still no proper explanation as to why the amended statement had not been pleaded much earlier, and suggested that the matters relied on had been within the claimant's knowledge for many years - for instance, the terms under which Dr Schlessinger and Dr Givol were employed by Weizmann were at all times known to the referrer.
- 33 Mr Alexander drew my attention to *Nedlloyd* (discussed above), where Colman J said that, even if he was wrong on the r.17.4 point, he would still have refused to exercise discretion in the applicant's favour because the new claims could have been pleaded at any time during the limitation period, and no explanation had been given for the failure to do so. Thus in the present case, the reference having been made at the last possible moment before the expiry of the section 37(5) period, it was incumbent on the claimant to bring forward its entire case at that time. As he did at the earlier preliminary hearing, Mr Alexander emphasised what he saw as a lack of diligence on the part of the claimant in bringing the relevant matters to light, bearing in mind that the patent resulted from a divisional application published in 1995 and that the parent application had been published in 1990.
- 34 Mr Powell emphasised that the facts supporting the amendments had come to light during the period of *de facto* suspension of the UK proceedings while the defendants' application for a stay was under consideration. The claimant had not thought it sensible to proceed with an amended statement until it was known whether the proceedings would continue, bearing in mind that the defendants had not indicated any intention to plead to the original statement.
- 35 Indeed Mr Powell suggested that there was an air of unreality to the defendants' continuing objection to the statement now that the pleadings had been exchanged on the basis of the amended statement. I asked Mr Alexander at the hearing what was the real prejudice to the defendants - and I put to him a possible argument that in effect everything had been on ice whilst the question of whether to stay the proceedings was under consideration, but, after a delay which prejudiced the claimant if anyone, the proceedings were now under way on the basis of the amended statement and the defendants' counter-statement.

- 36 In addition to the points he had made about the need for further investigation as a result of the amendments, Mr Alexander thought it quite reasonable to suppose that there was going to be commercial prejudice in such a delay in getting the real case under way. In his view the two-year period of section 37(5) was there to ensure that those who had patents could be secure in their rights after a given period. Also in this case third parties were entitled to assume that after the expiry of that period the case would proceed as a claim for joint, not sole, ownership, and arrange their affairs accordingly. Mr Powell suggested that this was purely hypothetical, given that proceedings alleging sole entitlement were already under way on corresponding patents in France, Austria and the US.
- 37 Having carefully considered all these points, it is my view that all the amendments to the statement should be accepted. In the light of Peter Gibson LJ's judgment in *Cobbold*, I think the public interest in the administration of justice makes it desirable for the full case to be pleaded, and that if there is prejudice to the defendants it should be reflected in costs (which I deal with below). Even if the facts pleaded in the amendments are not part of a continuous course of conduct which was already in issue in the sense explained in *Convergence*, I think there is nevertheless an underlying overall research programme which the comptroller needs to consider in order to decide who is entitled to the patent including whether it should be solely or jointly owned.
- 38 I accept that it was sensible for the claimant to defer formally amending the statement until it was known whether the UK proceedings were going to continue. As regards the length of time which it has taken these matters to come to light since the publication of the divisional application, this was dealt with in my earlier decision O/163/05 at paragraphs 59 -62 where I did not accept Mr Alexander's argument. I see no reason to revisit this point.
- 39 I do not think that the concerns put forward by Mr Alexander really hold water. Conceivably there could be situations where an amendment to a statement after the expiry of the section 37(5) time limit might so change the nature of the case that to allow the amendment would be unjust. However, bearing in mind that I do not consider myself bound by the authorities cited under r.17.4 CPR, I do not think that is the situation here. As to possible commercial prejudice and prejudice to third parties, I cannot seriously conceive that once the question of the claimant's rights of ownership had been referred to the comptroller, anyone would have ordered their affairs on the basis suggested by Mr Alexander.
- 40 More important, I do not think the defendants are significantly disadvantaged by going ahead on the basis of the amended statement. I do not think that they can in any way said to be surprised by an allegation of sole ownership, since it is not disputed that this has been in issue in parallel foreign proceedings before the amendment was formally made to the UK proceedings more than three months ago. Whilst I accept that the new allegations may require investigation, the evidence rounds are not yet under way and I do not think that the defendants now start from a worse position than any other defendant as regards the time now needed for preparation and filing of their evidence. If difficulties do arise on that score, they can be dealt with in the course of the evidence rounds, which I consider below.

41 I should add that reference was made at the hearing to the way these matters had been dealt with in the parallel proceedings in Germany, but I do not think that is relevant to my decision.

42 Mr Alexander also noted that the claim for sole ownership appeared to be at variance with suggestions made by Professor Sela during the US depositions regarding Dr Schlessinger's role. However, I agree with Mr Powell that this is a matter which can be tested in cross-examination and is not a reason for refusing the amendments.

### **The future conduct of the proceedings**

43 Having decided that the amendments may be allowed, it remains for me to settle a number of differences between the parties as to how the proceedings should be continued.

#### Service of a reply

44 Mr Alexander sought an opportunity to file a reply before the evidence rounds began. He said that although this was not usual in proceedings before the comptroller, it was standard before the court and made sense where it would assist to have the case set out clearly. However, to my mind it is the purpose of the pleadings to define the respective cases which the parties wish to make with sufficient clarity. If there is any lack of clarity the answer lies in amending the statements, not in building a further stage into the proceedings which is not contemplated by the Patents Rules. Like Mr Powell I would see this as merely introducing unnecessary delay.

45 In any case no substantial reason was given by Mr Alexander as to why a reply should be needed at this stage, beyond a suggestion that the pleadings were not especially particularised and this was likely to be a case of substantial length. I cannot see that any of this holds water: the defendants have formulated a counter-statement which on the face of it addresses in some detail the alternatives of both joint and sole ownership. I therefore see no reason why the case should not now proceed to the evidence rounds.

#### Evidence rounds

46 Mr Powell had initially contended that the standard six-week periods for each of the evidence rounds should apply from the date of the hearing, which would enable the matter to be brought to a substantive hearing in Spring 2006. However at the hearing he accepted that it would be appropriate for the timetable to run from the date of this decision. Mr Alexander argued that it would make sense for there to be a little more leeway than usual, and that the six-week periods provided by the Patents Rules were merely a default position which I was free to depart from: working back from May 2006 he thought that it would be sensible to set eight-week periods. Mr Powell accepted that this would probably not make a great deal of difference, but thought that it was preferable to deal with extensions to the prescribed periods as the need arose.

47 I believe that Mr Powell is right. As explained at paragraph 2.55 PHM the six-week periods are expected to be sufficient in most cases and there is therefore a general presumption against extending them. They therefore represent a norm rather than a default position. If genuine

difficulties do arise in complying with these periods they can be extended at the comptroller's discretion but there must be material upon which the exercise of discretion can be based. So that there should be no doubt, I emphasise that if any extension is sought I will require a clear indication of what the particular difficulty is and why that makes it impossible to meet the time limit - not a mere generalised reference to the difficulties of finding suitable witnesses and of collecting evidence in foreign jurisdictions. Both sides have been aware for some time now of the matters on which evidence might be needed, and should have been able at least have made some preliminary enquiries.

- 48 I am therefore going to set the usual six-week periods prescribed by rule 54 of the Patents Rules 1995, starting the timetable from the date of this decision. That should still enable a hearing to take place around May 2006 if there are no further delays. I note that no date yet appears to have been fixed for the US proceedings which were the subject of the previous unsuccessful request to stay these proceedings.

#### Disclosure

- 49 The claimant is resisting the defendants' request for mutual disclosure on the grounds that this is not normal in proceedings before the comptroller, and the defendants are asking me to order that such disclosure take place. Mr Powell suggested that by virtue of the disclosure in the US proceedings, the parties were well aware of the documents likely to be needed, and they were available for use in the UK proceedings by virtue of a protective order. Mr Alexander on the other hand thought it unreasonable for disclosure to be treated as already given. Economical case management required the parties to identify and list the documents from the massive disclosure exercise in the US (possibly some 30,000 pages) which they regarded as relevant, and this should not be an undue burden. This was standard procedure in the High Court and it would be proportional to adopt a similar procedure for a case of this magnitude.
- 50 What the defendants are seeking does not accord with the normal procedures before the comptroller and I do not propose to make any such order. Those procedures are explained in the PHM at paragraphs 3.40 - 3.57, and, again so that there should be no doubt, I will emphasise the salient points.
- 51 Disclosure is not common in proceedings before the comptroller, because the time and effort involved in identifying what may be a very large number of documents can all too easily negate the advantage of the comptroller as a relatively inexpensive jurisdiction in comparison to the High Court. It is therefore manifestly unlikely that the comptroller would ever order "standard" disclosure of relevant documents in accordance with r.31.6 CPR - which seems to be what the defendants are asking for. Orders for disclosure in proceedings before the comptroller are usually orders for specific documents or classes of documents in accordance with r.31.12 CPR, and the tests to be applied are still those stated by Aldous J in *Merrell Dow Pharmaceuticals Inc's (Terfenadine) Patent* [1991] RPC 221, namely whether the documents concerned relate to matters in question in the proceedings, and whether their disclosure is necessary to dispose fairly of the proceedings or to reduce costs.
- 52 Before approaching the comptroller for a disclosure order, the party requesting it should

therefore have attempted to reach voluntary agreement with the other party as to what documents should be disclosed. A party applying for specific disclosure should explain its reasons in full and should identify the documents or classes of documents that it seeks as clearly as possible.

- 53 Although I accept that this is a complex case in which disclosure may be appropriate, no reason has been shown why I should depart from the above principles, and I would in any case do so only for the most compelling of reasons. If the parties cannot reach agreement on disclosure, I will consider on its merits any subsequent request for an order for *specific* disclosure, and I will deal with it in accordance with the principles that I have explained above.

#### Timetable for expert evidence

- 54 Mr Alexander also suggested that a timetable for expert evidence might be desirable insofar as it was sensible for the experts to comment on the factual evidence. It may well be sensible for experts to offer such comment, but I do not think I should start building any such timetable into the proceedings. If it is a factor which causes difficulty in meeting a time limit for the filing of evidence, it can be dealt with on its merits at the appropriate time.

#### General considerations

- 55 I have to say that I am far from happy at the way the case has progressed to date. So far, two substantial hearings have been necessary to deal with preliminary issues, and 18 months after the launch of proceedings the evidence rounds have yet to begin. Whilst I accept that there were points of some legal complexity which the defendants were fully entitled to raise and to argue, the substantial and incessant exchange of correspondence between the parties, all copied to the Patent Office, has at times made it difficult for the Office to progress the case in an orderly manner and has had the effect of dragging out the proceedings (as was made clear in the Office's letter of 5 August 2005 to the parties). It is only fair to say that Mr Alexander at the hearing regretted any inconvenience which might have been caused, and explained that, it having been mooted at one time that a decision might be made on the papers, ImClone had felt it desirable to make full submissions and copy all correspondence between the parties to the Office.
- 56 In the hope that difficulties of this sort can be avoided in future, I will emphasise one or two points that arise from the defendants' submissions on the future course of the proceedings. Although accepting that it was not necessary to slavishly follow court procedures, Mr Alexander nevertheless urged on me the need to adopt procedures commensurate with a case of this complexity and importance. As explained above, the case has involved a massive disclosure exercise in the US, and Mr Alexander stressed that substantial case management is going to be necessary as it may involve evidence from most, if not all, of the seven named or alleged inventors and expert evidence on foreign law.
- 57 I fully accept that this a case of some complexity and that a considerable amount of money is at stake. Nevertheless I see no reason why, in order to meet the overriding objective of dealing with this case justly, I need to depart to any substantial degree from the procedures prescribed

by the Patents Act and Rules and elaborated in the “Patent Hearings Manual”. Questions in respect of the entitlement to a granted patent are required by section 37 to be referred to the comptroller, except where he declines under section 37(8) to deal with the matter. I think this involves a presumption that such references should be accommodated within the comptroller’s normal procedures (which include the power to call case management conferences and pre-hearing reviews if necessary) and I see no insuperable difficulty in doing so in the present case. The likely duration of the substantive hearing and the complexity of the case are not to my mind sufficient reasons on their own for adding extra stages to the usual procedures in the ways suggested by the defendants.

#### The next steps

- 58 I accept the claimant’s amended statement and the defendant’s counterstatement into the proceedings. The claimant now has a period of six weeks from the date of this decision (which period will be suspended in the event of an appeal) to file evidence in support of its case, and should send a copy of that evidence to the defendants. Thereafter the evidence rounds will continue in accordance with rules 54(5) - (7) of the Patents Rules 1995.

#### **Costs**

- 59 At the hearing the parties expressed a preference to make submissions on costs after receiving my decision. I will therefore give the parties a period of 28 days from the date of this decision to make any submissions, in addition to those that they have already made, on whether I should make a further award of costs at this stage in the proceedings and whether I should depart from the comptroller’s standard scale.

#### **Appeal**

- 60 Under the Practice Direction to Part 52 of the Civil Procedure Rules, any appeal against this decision must be lodged within 28 days.

**R C KENNELL**

Deputy Director acting for the Comptroller