Intellectual Property Office

BL O/144/15

02 April 2015

PATENTS ACT 1977

BETWEEN

TEVA PHARMA B.V. — Claimant

and

AMGEN Inc
AMGEN MANUFACTURING Ltd — Defendants

PROCEEDINGS

Application under section 13 and reference under section 37 in respect of EP(UK) 1482046 B1 and EP(UK) 2345724 B1

HEARING OFFICER A C Howard

Miss Charlotte May QC (instructed by Carpmaels & Ransford LLP) appeared on behalf of the claimant

Mr Tom Hinchliffe (instructed by Messrs J A Kemp) appeared on behalf of the claimant

Hearing date: 15 September 2014

DECISION

I. Introduction

1 The claimant ("Teva") launched these proceedings on 11 December 2013. They concern a reference under section 37 of the Patents Act 1977 ("hereafter the Act") in relation to entitlement, and a related application under section 13 of the Act regarding inventorship.

2 Teva also seek a decision from the comptroller declining to deal with the section 37 reference – thus allowing the entitlement proceedings to move to the Patents Court. The defendants (collectively "Amgen") oppose this course of action. In addition, the defendants seek summary judgment in their favour, or striking out of the claimant's statement of case.

3 In the course of the proceedings, EP2345724 ("the 724 patent") was revoked both in the UK and centrally before the EPO, with the agreement of both parties (more of this below). The central revocation was confirmed after the hearing took place, and I

am grateful to both parties for making written submissions on the effects of this development. I have taken these submissions into account in my decision.

II. The patents in suit, and related products

4 EP(UK) 1482046 ("the 046 patent") is entitled "*G-CSF analog compositions and methods*" and was granted on 11 April 2012 to Amgen Inc. It is a divisional application originating from EP0612846. The inventor is named as Dr Timothy Osslund.

5 The invention relates to a modified Granulocyte colony stimulating factor ("G-CSF") polypeptide which comprises a specific amino acid sequence and a chemical moiety derived from polyethylene glycol attached via a second chemical moiety to one of two possible external loops, the AB loop or the CD loop, formed by the amino acid sequence.

6 The 724 patent is also entitled "*G-CSF analog compositions and methods*" and was granted on 3 July 2013 to Amgen Inc. It is also a divisional application arising from EP0612846. Again, Dr Osslund is the named inventor.

7 The invention relates to a modified Granulocyte colony stimulating factor ("G-CSF") polypeptide for use in the treatment of neutropenia. The polypeptide comprises a specific amino acid sequence and a chemical moiety derived from polyethylene glycol attached via a second chemical moiety to the CD loop formed by the amino acid sequence.

8 The 046 patent entered into force in the UK but was allowed to lapse for non payment of renewal fees on 27 January 2013. The 724 patent was assigned to Amgen Manufacturing Limited on 13 August 2013. It expired on 27 January 2014.

9 The 046 and 724 patents each concern a G-CSF polypeptide which has been chemically modified with polyethylene glycol. This process is usually referred to as PEGylation. Both parties to these proceedings have PEGylated G-CSF products. Teva's product is called *Lonquex* (RTM) and was launched in the UK on 25th February 2014. Amgen has its own PEGylated G-CSF product called *Neulasta* (RTM) but it is PEGylated on the N-terminus of the protein and, as such, it does not fall within the claims of either of the patents at issue in these proceedings.

III. The wider context of this dispute

10 These proceedings are part of a series of disputes between the claimant and defendant taking place in a number of European jurisdictions.

11 Amgen Inc initiated proceedings in Germany on 14 August 2014 in relation to alleged infringement of the 046 patent by Teva's product *Lonquex* (RTM).

12 As well as the current proceedings, Teva initiated entitlement proceedings in Germany concerning the 046 patent on 13 November 2013. Teva also launched corresponding proceedings on the 046 patent in five further jurisdictions in Europe (France, Italy, The Netherlands, Ireland and Norway). The 724 patent is also involved in all of these proceedings except the proceedings in Germany. At the

hearing Teva indicated that the various proceedings are at early stages and no decision has been reached in any of the jurisdictions.

13 Teva also launched opposition proceedings against the 724 patent at the EPO on 11 October 2013. Amgen indicated in their agent's letter to the EPO, dated 5 September 2014, that they that no longer approved of the text of the 724 patent, that they will not be submitting any amendments and, as a consequence, they are requesting revocation of this patent. Teva initially opposed this request under Rule 78 of the implementing rules to the European Patent Convention (EPC), and asked that the opposition proceedings be stayed because entitlement proceedings were in progress in a number of national jurisdictions, including Germany, in relation to the 724 patent. Rule 78 EPC requires that a third party is involved in the entitlement proceedings and Teva pointed out that in Ireland, for example Norton (Waterford) Ltd (trading as Teva Pharmaceuticals Ireland) were involved in these proceedings and that the request for suspension of opposition proceedings was being made on their behalf also.

14 After the hearing took place, Teva withdrew its request for suspension of the opposition proceedings and the 724 patent was subsequently revoked (Consent Order agreed between parties, dated 20 October 2014).

15 No opposition proceedings were launched at the EPO in relation to the 426 patent, by the defendant or any other party, within the necessary time period.

16 In the UK, there have been three sets of proceedings in the Patents Court between the claimant and the defendant concerning the 724 patent only, namely:

a. A revocation action (HP13B04226) launched on 19 September 2013;
b. An action for declaration of invalidity of a prospective Supplementary Protection Certificate (HP13F04399) based on the marketing authorisation obtained by Teva (EU/1/13/856 for *Lonquex (RTM) / lipegfilgrastim* launched on 7 October 2013; and
c. An action for declaration of non-infringement (HP13F04807) in relation to the making of Lonquex available in the UK, launched on 6 November 2013.

These proceedings have subsequently been terminated with Amgen agreeing to the revocation of the 724 patent.

IV. The claims and remedies sought

17 Teva claim that they are entitled to the patents by virtue of rights derived from Dr Christopher Hill (a post-doctoral researcher at the University of California), who they say should be named as sole inventor in respect of both patents, or, in the alternative, that he should be named as a co-inventor with Dr Osslund.

18 However, Teva also requests under section 37(8) of the Act that the comptroller exercise his discretion to decline to deal with the matter because it would more properly be dealt with by the court. They further request that their application under section 13 of the Act is stayed pending resolution of the entitlement reference by the court (since there is no provision for the comptroller to transfer section 13 proceedings to the court).

19 In Teva's submissions following the revocation of the 724 patent, Teva maintains its entitlement request in relation to the 046 patent. Although these submissions may be read as indicating that Teva is no longer interested in pursuing its claims in relation to the 724 patent, this is not made explicit and I shall therefore consider all the elements of their case.

20 Amgen reject the claim that Dr Hill should be named as an inventor or co-inventor for either patent. They consider that there is no basis for the entitlement dispute in relation to either of these patents, or following revocation, to the 046 patent alone. They ask that the Hearing Officer strike out the claim or give summary judgment in their favour.

21 Both sides are seeking their costs.

V. Amgen's Application for Summary Judgement or Strike Out

V.1 The Law

22 The rules governing proceedings before the comptroller are set out in Part 7 of the Patents Rules 2007 (as amended) ("the Rules") (see particularly rules 73-88) which provides a general procedural code for the conduct of proceedings heard before the comptroller. Rule 83 of the Rules refers to strike out and summary judgement in relation to such proceedings before the comptroller. Rule 74, entitled "Overriding objective", indicates that the objective of the procedural code set out in this part of the Rules is to enable the comptroller to deal with cases justly.

23 Rule 83 provides that:

> *(1) A party may apply to the comptroller for him to strike out a statement of case or to give summary judgment.*
>
> *(2) If it appears to the comptroller that—*
>
> > *(a) the statement of case discloses no reasonable grounds for bringing or defending the claim;*
> >
> > *(b) the statement of case is an abuse of process or is otherwise likely to obstruct the just disposal of the proceedings; or*
> >
> > *(c) there has been a failure to comply with a section, a rule or a previous direction given by the comptroller,*
>
> *he may strike out the statement of case.*
>
> *(3) The comptroller may give summary judgment against a claimant or defendant on the whole of a case or on a particular issue if—*
>
> > *(a) he considers that—*
> > > *(i) that claimant has no real prospect of succeeding on the case or issue, or*
> > > *(ii) that defendant has no real prospect of successfully defending the case or issue; and*
> >
> > *(b) there is no other compelling reason why the case or issue should be disposed of at a hearing.*

24 Rule 74 states:

> *(1) The rules in this Part set out a procedural code with the overriding objective of enabling the comptroller to deal with cases justly.*
>
> *(2) Dealing with a case justly includes, so far as is practicable—*
>
> *(a) ensuring that the parties are on an equal footing;*
>
> *(b) saving expense;*
>
> *(c) dealing with the case in ways which are proportionate—*
>
> *(i) to the amount of money involved,*
>
> *(ii) to the importance of the case,*
>
> *(iii) to the complexity of the issues, and*
>
> *(iv) to the financial position of each party;*
>
> *(d) ensuring that it is dealt with expeditiously and fairly; and*
>
> *(e) allotting to it an appropriate share of the resources available to the comptroller, while taking into account the need to allot resources to other cases.*
>
> *(3) The comptroller shall seek to give effect to the overriding objective when he—*
>
> *(a) exercises any power given to him by this Part; or*
>
> *(b) interprets any rule in this Part.*
>
> *(4) The parties are required to help the comptroller to further the overriding objective*.

As noted in part (3) of this rule, the comptroller is required, when exercising any power or interpreting any rule in Part 7, to give effect to the overriding objective, and the parties to such proceedings are required to help the comptroller to further the overriding objective.

25 As mentioned in Part 1 of Schedule 3 to the Rules, this general procedural code applies to applications made under section 13(3) and section 37(1) of the Act[1,2].

V.2 DIscussion

26 Mr Hinchliffe argued that, in light of the facts that relate to the expiry of the patents, there is no real prospect that the comptroller will exercise his discretion in order to grant entitlement to Teva. He also commented in relation to this application and the one to strike out the proceedings that, "*it is the same argument and whether it is in the summary judgment box or abuse of process box, in our submission does not*

[1] Application under section 13(3) of the Act to the comptroller to remove person mentioned as an inventor)
[2] Application under section 37(1) of the Act for determination of right to patent after grant

really matter". According to Mr Hinchliffe, the following uncontested facts are relevant;

(i) the 046 patent has lapsed and expired;
(ii) the 724 patent has expired and will either be revoked by the EPO or by the High Court – it has now been revoked by the EPO (see above);
(iii) no SPC has been filed based on either patent;
(iv) there were no accrued rights of action under either patent;
(v) Teva did not launch their product until after expiry of both patents;
(vi) Amgen's product does not fall within Teva's product; and
(vii) there is no evidence of any third party doing anything at all.

27 Mr Hinchliffe explained that the ground for Amgen's strike out application was abuse of process based on these facts, the consequence of which, in Mr Hinchcliffe's view, are that the entitlement proceedings are completely pointless, in that the outcome will affect nobody in the UK. In his words "*There is no point about arguing over entitlement when there are no rights going forward and no accrued rights from the past*". Mr Hinchliffe characterised this as an example of proceedings where there was nothing of value to fight over. He referred to the decision in *Markem v Zipher*[3]*,* where the court, at paragraph 88, indicated that *"Only when there is self-evidently no bone should the dogs be prevented from fighting over it*" and indicated that this was such a situation where there was no "bone" and, accordingly, the parties should be stopped from fighting. Mr Hinchliffe focussed his arguments particularly on the fact that there is no value in the UK in pursuing the litigation over the title to the two patents because these rights have lapsed or expired and no rights have accrued. As such, it would be an abuse of process to allow these entitlement proceedings to proceed before the IPO, never mind the UK courts.

28 Miss May disagreed with this view. She submitted to me that the parties are entitled to have issues of entitlement resolved even after a patent has expired. There is no time limit on this question under the Act or Rules. Although the relief available to the comptroller may be time limited – for example, as set down in sections 37(5) and 37(9) of the Act and he has some discretion in what kind of order he can make once the matter is decided, the matter of entitlement still has to be decided first. The consequence of this is that it ensures that a patent proprietor cannot avoid entitlement proceedings by allowing the patent to lapse or expire in the period following grant.

29 While Miss May acknowledged at the hearing that there are no known accrued rights, she pointed out that there is still the potential for such rights to emerge. If the comptroller were to strike out the entitlement proceedings, before expiry of the six year limitation period, this would prevent Teva from being able to exploit any opportunity that would arise if a third party was found to be exploiting the rights covered by these patents. Although the 724 patent has been revoked with the agreement of both parties and the proceedings in the High Court have as a consequence fallen away, this does not change the fact that the 046 patent is still the subject of entitlement proceedings. Teva are maintaining their entitlement request in relation to the 046 patent and thus one still needs to take account of the potential for accrued rights in this patent.

[3] Markem Corporation & Anor v Zipher Ltd [2005] EWCA Civ 267 (22 March 2005), [2005] RPC 31;

30 A further argument advanced by Mr Hinchliffe was that these proceedings, even if considered to be well constituted, should be struck out as an abuse of process because they are disproportionate to the cost and the use of court time. Referring to the summary of the relevant case law provided by Judge Hacon in the decision of the Intellectual Property Enterprise Court in *Lilley v DMG*[4], he argued that abuse of process is not just a concern of the parties; it is also a concern of the court which has to consider the allocation of its resources to ensure that they are attributed in a proportionate manner. If the potential benefit from the action is so small that it can be considered to be disproportionate to the cost of having such proceedings, then the court can and, indeed, should strike out the proceedings as an abuse of process (even though the proceedings are properly constituted). On this basis he argues that deciding the issue of entitlement to both patents in this country would "serve no practical benefit."

31 According to Miss May, there is value in the entitlement proceedings being decided in the UK because of the value of a judgement from the courts here to help with such entitlement disputes in other jurisdictions. For example, a decision from the UK courts on some of the points of fact that arise in the entitlement proceedings in relation to 046 patent are likely to be very helpful and persuasive because such issues of fact will be the same in each jurisdiction. The claimant is being sued for infringement by the defendant in Germany and a defence to this action is one based on entitlement, thus the claimant will potentially have a significant benefit to gain from the outcome of the entitlement proceedings in the UK. Miss May put it to me that resolution of an entitlement dispute in one jurisdiction can be very helpful in getting the parties to settle the dispute in other jurisdictions and made reference to the *TNS*[5] and *IPCom*[6] decisions in support of this point.

32 Mr Hinchliffe argued that the claimants have failed to provide any evidence that the foreign proceedings would benefit from a decision from the UK courts or tribunal, for example, something to show that the issues are the same or that another jurisdiction would consider a UK decision to be of help. Also, given that the infringement proceedings are in Germany and entitlement proceedings have been launched in a number of national jurisdictions in Europe in addition to UK, it was not clear why a decision from the UK jurisdiction would be of value over a decision , from the courts in Netherlands, France, Germany, Norway, Ireland or Italy. At best, Mr Hinchliffe suggested that this was speculation and it would be an abuse of process to try a case in the UK solely for the reason that it will assist foreign courts. I have some sympathy with the Defendant on this point. I do not think that pursuing proceedings in the UK solely for its value in helping with disputes in others jurisdictions is a particularly strong reason on its own to continue with such proceedings. However, if there is a valid question to ask and it is appropriate for it to be dealt with in UK proceedings the fact that it may also be helpful in other jurisdictions is an additional consideration that can be taken into account.

33 I consider that if I am to strike out the claimant's case as an abuse of process I have to be satisfied that there is no value in pursuing these proceedings. I am unable to come to this conclusion based on the material that has been put before me, at least

[4] Victor George Lilley v DMG Events, [2014] EWHC 610 (IPEC)
[5] TNS Group Holdings Ltd v Nielson Media Research, [2009] EWHC 1160 (Pat)
[6] IPCom GmbH & Co Kg v HTC Europe Co Ltd, [2013] EWCA Civ 1496

in respect of the 046 patent. Although this patent has lapsed it may still give rise to valuable rights. Moreover it is part of a complex web of litigation across several countries, and while I am not in a position to come to a definitive view on the underlying motivations of the parties in pursuing and defending this particular action, it is difficult to escape from the conclusion that it is of importance to both sides and the outcome will be of material interest.

34 Thus I can find no grounds to strike out the claimant's statement of case in relation to the 046 patent as an abuse of process.

35 Neither side made very much at the hearing of Amgen's request for summary judgment. However for the avoidance of doubt, I confirm that in my view there are substantive questions which would need to be resolved through the consideration of evidence before a decision can be reached on the matter of entitlement, not least in relation to Dr Hill's relationship with the University at the time the invention was alleged to have been made. In these circumstances, summary judgment would not be appropriate.

Impact of revocation of the 724 patent

36 As the 724 patent has been revoked, I need to consider what impact this has on the application under section 13 as well as the application under section 37. In their written submissions following the hearing on the effect of the revocation, Teva referred to the effect of Article 68 of the European Patent Convention (EPC), entitled "*Effect of revocation or limitation of the European Patent*", which states:

> *"The European patent application and the resulting European patent shall be deemed not to have had, from the outset, the effects specified in Articles 64 and 67, to the extent that the patent has been revoked or limited in opposition, limitation or revocation proceedings*."

37 In their submission, there is an important distinction between deeming a revoked patent never to have existed, and deeming that it has not, from the outset, had any legal effect. They referred to a recent judgement[7] in the on-going litigation between *Smith & Nephew* and *Convatec* where Birss J referred to the possible significance of this difference. In relation to the current case, Teva said that the existence of the 724 Patent led them to bring the claim for entitlement to the 724 Patent, and its continued existence up until the time that Amgen agreed to the revocation of this patent led Teva to maintain their claim for entitlement. However, as Amgen pointed out in their written submissions on the impact of the revocation, the authority referred to is an interim judgement and it has been left to the main hearing to determine, if necessary, the ramifications of this difference. Thus, in Amgen's view, this point is not one that is settled under English law. However, in order to avoid "further expense", they indicated in their submission that they were content for me to issue my decision on the basis that the 724 patent had been deemed never to have any legal effect, as suggested by Teva.

38 On this basis, I consider that the outcome of at least that part of the claim which falls under section 37 of the Act can have no practical significance, as Articles 64 and 67

[7] *Smith & Nephew Healthcare Limited & others v Convatec Limited & others*, [2014] EWHC 3162 (Pat)

of the EPC relate to the rights conferred by a European patent which give a patent its value. However the right to be mentioned as an inventor is different. This is not one of the rights covered by Articles 64 and 67, and the fact that the patent is revoked does not alter the fact that an application existed and was granted; moreover revocation has no bearing on the value of any remedy the comptroller could award under section 13.

39 I therefore consider that it is appropriate for me to strike out only that part of Teva's statement which relates to the claim under section 37 in relation to the 724 patent.

VI Teva's request for the comptroller to decline to deal under section 37(8)

VI.1 The Law

40 Where the comptroller has jurisdiction to hear an issue under the Act, in some instances he has the power to decline to deal with the matter and pass the jurisdiction to the court. This power is available in patent proceedings under sections 8, 12 and 37 of the Act. Section 37 deals with determination of the right to a patent after it has been granted. While section 37(1) sets out how a person having an interest in the granted patent can raise this with the IPO, section 37(8) also indicates that the comptroller can decline to deal with the matter if appropriate. These sections read:

> *(1) After a patent has been granted for an invention any person having or claiming a proprietary interest in or under the patent may refer to the comptroller the question -*
>
> > *(a) who is or are the true proprietor or proprietors of the patent,*
> > *(b) whether the patent should have been granted to the person or persons to whom it was granted, or*
> > *(c) whether any right in or under the patent should be transferred or granted to any other person or persons;*
>
> *and the comptroller shall determine the question and make such order as he thinks fit to give effect to the determination.*
>
> *.....*
>
> *"(8) If it appears to the comptroller on a reference under this section that the question referred to him would more properly be determined by the court, he may decline to deal with it and... the court shall have jurisdiction to do so."*

41 Guidance on how the comptroller should consider the question of whether to decline to deal with a case was given by Warren J in *Luxim*[8]. In each case, the test laid down in the Act is whether it appears to the comptroller that the issue involves matters which would "*more properly be determined by the court*"

42 Under sections 8, 12 and 37 of the Act, questions are in the first instance referred to the comptroller. He is then the arbiter about which forum is the more appropriate. The default being that that the case remains with the comptroller unless it appears to

[8] *Luxim Corporation v Ceravision Limited [2007] EWHC 1624 (Ch), [2007] RPC 33*

him that the question (or the matter involved) is more proper to be determined by the court.

43 The comptroller had hitherto declined to deal only where the issues were so difficult and complex that the hearing officer felt he could not address them effectively. The *Luxim* judgment found that this was the wrong approach, and that the question to be considered by the comptroller was whether the court could "more properly" determine the issue. The comptroller should consider exercising discretion to decline to deal whenever a case was complex and should not do so "sparingly" or "with caution". In making the determination, it was necessary to consider the technical, factual and legal aspects of the case and judge these against the expertise and experience of a hearing officer as compared with that of a judge. Technical matters, expert witness evidence, English or foreign patent law would not indicate transfer to the court. Fraud, breach of fiduciary duty, and legal issues falling outside patent law, for example, might do so.

VI.2 Discussion

44 Miss May summarised the test elucidated by Warren J in *Luxim* in the following terms: there are two parts to the statutory test: firstly to assess whether or not the question of entitlement is more properly to be determined by the court; and secondly, if so, whether or not the comptroller should exercise his discretion thereby and decline to deal with the questions. However, Miss May also indicated that, as the Court also pointed out, answering these two questions separately may prove to be very difficult and that in practice they will often roll into one question. Often it is the very same reason that the comptroller will identify as being the reason why the court is better placed to determine the issue and why, at the same time, he should exercise his discretion thereby in declining to deal with it. Miss May considers that this question should not be seen as requiring an absolute answer in the sense that there needs to be evidence beyond reasonable doubt that the transfer should take place. It is only necessary that the comptroller satisfy himself that the “it appears that the questions would be more properly determined by the court.” It is not necessary according to Miss May that the comptroller has to satisfy himself that that the questions would be more properly determined by the court. In her words at the hearing: “*He does not have to decide that it will definitely be more properly determined by the court or, indeed, that the question is one which the comptroller himself could not answer*.” Thus, she considers that it is perfectly proper for the comptroller in the exercise of his discretion to decline to deal with a case which is one that he could handle himself but, nevertheless, is still better placed to be considered and dealt with by the court.

45 In making the assessment of whether or not to deal with a case, it is not simply a question of considering the extent to which the case is technically complicated. There is a lot more to the assessment than that and, in her view, the comptroller must not restrict the way in which he exercises his discretion. In particular, he is not required to exercise the discretion sparingly or with great caution. She considers that the comptroller should not be influenced, in any way, by the fact that the primary jurisdiction is granted to the comptroller under section 37. This is not a test whereby the case must stay with the controller absent special circumstances. Instead, what the comptroller is being asked to do is to balance all of the competing factors in assessing which jurisdiction is the better place for the questions to be determined.

46 Nothing that Mr Hinchliffe said at the hearing or in his skeleton argument indicated that he disagreed with Miss May's analysis.

47 I agree that the decision that the comptroller is being asked to make is not one where, absent special circumstances, it must stay in his jurisdiction but rather it involves a balancing all of the competing factors in order to determine which jurisdiction is better placed to deal with the questions that arise in each case.

48 Miss May then went on to outline the first of the factors that she considered relevant to the determination that the court is the better place to resolve the questions of entitlement in this case. She referred to the overlapping issues between the entitlement proceedings before the comptroller and the proceedings started in the High Court. She acknowledged that this factor only applied in the UK in relation to one of the two patents, the 724 patent, and not to the 046 patent. At the hearing Mr Hinchliffe made a number of points as to why the ongoing proceedings before the High Court were not relevant. However, as referred to above, the High Court proceedings are no longer in train because the 724 patent has been revoked centrally at the EPO. There is no longer any overlap of issues between proceedings before the court and those before the comptroller. Thus, a good argument in favour of the case being transferred to the court, i.e., consolidation of all the issues so that they can be dealt with in one go by the court, falls away. However there are a number of other factors to be taken into consideration which I shall now consider.

49 The first relates to the complex issues of fact to be resolved. These will involve a detailed analysis to try and identify what contributions the individuals involved – Hill and Osslund - made to the inventive concept and in so doing to identify who is the inventor for the purposes of the Act. While acknowledging that this was the type of inquiry which the comptroller undertakes regularly in the context of an entitlement dispute, Miss May considered that the difference in this case which points to the court as a better jurisdiction in which to resolve these issues of fact, is the lapse of time between when the invention was devised and now. This case concerns events which took place some 12 to 15 years ago and, as a result, there will inevitably be some difficulty with recollection as to exactly what happened, when and by whom. In order to resolve such questions of fact, the tribunal or the court will only be able to do so by reference to a combination of written witness statements, oral cross-examination and analysis of contemporaneous disclosure. In Miss May's submission, this is a difficult exercise to undertake involving the evaluation of oral evidence by reference to the disclosure and establishing a view about the credibility of the witnesses and as such is better undertaken by a judge who has much more significant experience in undertaking such an evaluation. It is the province of the judge to assess the credibility of witnesses in the witness-box; it is the kind of thing they do every day involving a balancing between what witnesses have said and the way in which they have said it with the information gleaned from the contemporaneous documentation.

50 Miss May thus considered that as a result of the investigation needed to establish the facts in this case and who did what and when and its relevance to the inventive concept, this means that the proceedings will require in her words "*comprehensive disclosure from both sides*". This is likely to involve a significant volume of material – lab notebooks etc – given the lapse of time and the need for contemporaneous documentation. Miss May also pointed out that the court is better placed to handle

disclosure because, for example, it has automatic rules for disclosure for two years either side of the disclosure window.

51 Mr Hinchliffe disagreed with Miss May that the need for disclosure was as relevant to her request to decline to deal as she proposed. Every entitlement case before the comptroller requires an analysis of issues of fact in order to determine who came up with the inventive concept and working out who did what, who did what and when they did it is part and parcel of every such inquiry. While acknowledging that 12-15 years ago is "a while ago", it is not that uncommon for entitlement proceedings to arise some period of time apart from the events that they relate to. Proceedings before the IPO can and do involve cross examination and in this situation the hearing officer does carry out an assessment of the evidence and of the credibility of the witnesses.

52 I am not persuaded that the fact that events of concern took place some 12 to 15 years ago is significant in determining who is best placed to hear the action. A patent has a 20 year life and the comptroller is experienced in dealing with questions relating to inventorship arising from events occurring in this time period. The possible need for disclosure is not determinative, as the comptroller has the same powers of a High Court judge to order disclosure, although the likely extent of disclosure is a factor to be weighed, as disclosure in proceedings before the comptroller is normally of limited scope.

53 Miss May suggested to me that the factor which tips the balance in favour of the court over the comptroller were the issues of non-patent law that needed to be dealt with. She summarised these as being a mixed question of fact and law: (i) what contractual terms of employment applied to Dr Hill while working at the university in America where the results described in the patents were obtained; and (ii) what was the impact of the terms of employment that he was subject to at that university, especially in relation to the ability to assign rights to his employer and/or to a third party. In order to understand what legal provisions applied to Dr Hill at the time that the work was carried out, it will be necessary to have evidence from suitable expert witnesses. If both sides were to use such experts, a judge would be better placed than the comptroller to resolve competing views from such experts. Miss May considered that dealing with such non-patent law issues, in the words of Warren J in *Luxim* is "*ordinarily regarded as the province of the judge*".

54 Mr Hinchliffe acknowledged that the need for experts on foreign law was possible but did not consider that how they would be dealt with in the court and before the comptroller would be so different as to tip the balance in the manner Miss May suggests. He pointed out that it was usual practice in the High Court that when taking evidence from experts on foreign law that it does not allow for cross examination of these experts. The judge makes an assessment based on the written statements from the experts. The hearing officer before the comptroller is also capable of making an assessment from such written statements.

55 It was clear that both parties had very different views on the degree to which this factor would have to be investigated. However, both accepted that it would be necessary to examine the employment arrangements for Hill and Osslund at the US university where the work described in the two patents was carried out. This examination would involve an assessment of foreign non-patent law issues

concerning US employment law and, in so far as it related to employment, US contract law, in order to work out if Hill was entitled to be named as the sole inventor or as a co-inventor of the 046 patent.

56 In my view, the mere fact that an issue of non-patent law is raised does not necessarily mean that the comptroller cannot deal with it. The comptroller deals with issues of employment law and how to assess the contribution of an employee to an invention under sections 39-43 of the Act and also does consider and evaluate expert evidence as part of its inter-partes proceedings.

57 However in this case, the foreign non-patent law issues as outlined above are in my view likely to be complex and do point to the court being the appropriate forum.

58 There was a significant divergence of views between the parties on the likely duration of the proceedings. Consistent with what she said in relation to the need to deal with oral evidence, cross examination and the material from the disclosure as well as the need for expert evidence on the non-patent law issues, Miss May estimated that any proceedings would likely take 7 days but could be up to 10 days.

59 Mr Hinchliffe countered that Miss May's estimate was overgenerous. In his view, she had only really identified the need for two witnesses i.e. Hill and Osslund and raised the possibility that one other (Professor Eisenberg, who was working at the lab at the same time) might also be involved. While he accepted that experts in foreign law would be involved, Mr Hinchliffe pointed out that as it was usual practice in the High Court when taking evidence from experts on foreign law not to allow cross examination of these experts, this would also not take as much time as Miss May suggested. Thus he considered that 5 days would be more than enough. Miss May responded to say that she did not accept Mr Hinchliffe's submission that it is not usual to cross-examine legal experts in a High Court. Such cross-examination does occur and it is a matter for the discretion of the judge in the exercise of his case management role.

60 Although it was not discussed in detail, I do not think that there would need to be a lot of time devoted to the technical issues in relation to the PEGylated G-CSF product and it characterisation and properties, i.e. the technical content of the 046 patent, or to identifying the contribution made by Hill and Osslund in this regard. Such matters I think are likely to be dealt with quite quickly and in a straightforward manner. The main focus of the hearing would be to investigate the foreign non-patent law issues (discussed above) in order to decide what rights Hill and Osslund had to be named as inventors or co-inventors and/or to assign any rights. On this basis I think an estimate in the vicinity of 5 days for the duration is about right. Although Mr Hinchliffe suggested to me that this would be "*nothing out of the ordinary*" and could be dealt with by the comptroller, I disagree: while not unheard of, 5 days is extremely long for a hearing before the comptroller.

61 Miss May referred to the fact that the comptroller is also invited to take into account such factors as costs. Both parties to these proceedings can afford the litigation and there is no need to take account of ability of either party to pay or the impact of an adverse decision on the losing party as a reason against a transfer to the court. In her view, given the resources that both partes have already committed to the case in terms of patent agents, counsel and solicitors, it is in both parties interests to be able

to get the benefit of the High Court costs regime because, rather than the scale of costs available to the comptroller, the winning party in the High Court is entitled to recover all reasonable costs that they have incurred in relation to the proceedings. Miss May also suggested, that if the costs of the proceedings are of concern to Amgen, and this appears to be a concern they raised in their application to strike out these proceedings, then the cost regime in the High Court would offer a greater flexibility for Amgen to recover some, if not all, of their costs than would be possible before the comptroller.

62 Mr Hinchliffe said that his client did not think that this case merited consideration by the patents court with all the associated costs and commitment of resources and that it could be properly dealt with by the comptroller. His client should not be put to the expense of dealing with this case before the court when, as they have argued in relation to the strike out, there is in effect nothing of value to fight over. If the comptroller is not minded to accept their application for strike out or summary judgement, then this case should be dealt with before the comptroller because it is a much more proportionate use of tribunal resources in relation to the value of the dispute.

63 The effort and resources that have been expended on both sides in this dispute so far does lead me to conclude that the outcome does have significance for both parties and that costs are not a major factor in their considerations. According to Miss May, the market for the defendants' *Neulasta* product was worth approximately €100 million annually in Germany, and so the value of the product in the wider European market was even greater. While I accept, as pointed out by Mr Hinchliffe, that I am concerned with the value of the proceedings in the UK and that this would only be a part of the overall value, it would still be significant. In these circumstances, it does seem likely that the party that was unsuccessful in these proceedings would give serious consideration to an appeal, and, indeed, Miss May made this point in her submissions. By declining to deal with this matter, the comptroller could well reduce one tier of costs. I do not think that I can avoid taking account of this and the fact that this dispute is one of a range of such disputes in Europe that affect the 046 patent. A judgment at the level of the English High Court would clearly carry more weight in this wider context than a decision of the comptroller.

64 Taking into account all the above considerations, it is my view that this is a question that would more properly be determined by the court.

65 The claims under section 13 for both patents may continue before the comptroller, but as regards to the facts to be considered and issues to be determined, there will considerable overlap with the action under section 37 in relation to the 046 patent. It will therefore be appropriate to stay the section 13 actions pending the outcome of any respective proceedings before the court or, if no such proceedings are launched, until the deadline for doing so has passed.

VII. Conclusions and order

66 I have found no grounds to issue summary judgement or to strike out the claimant's statement of case in the entitlement proceedings in relation to EP(UK) 1482046 B1.

67 It appears to me that the question of whether or not Teva are entitled to EP(UK) 1482046 B1 is one that would more properly be determined by the court. I therefore exercise discretion under section 37(8) to decline to deal with this part of the reference.

68 Having so decided under section 37(8), I stay the related application under section 13 pending resolution of this matter in the courts.

69 Following revocation of EP(UK) 2345724 B1, this patent is deemed not to have had legal effect. I accordingly order that the part of the statement relating to the claim under section 37 in relation to this patent be struck out.

70 The claim under section 13 of the Act in relation to EP(UK) 2345724 B1 is stayed pending the outcome of any proceedings in relation to EP(UK) 1482046 B1 in the court.

VIII. Costs

71 Both sides are seeking their costs. I received no representation from either party that I should consider an award of costs off-scale and I do not consider that there is any reason for such an award.

72 Given my conclusion above in relation to Teva's request to decline to deal and Amgen's applications for strike out or summary judgement, I consider that Teva are entitled to costs of £1200 based on the published sale of costs. This takes account of dealing with their own and Amgen's statements, the small amount of other material filed and preparation and attendance at a half day hearing. I have reduced slightly the amount to take account of the fact that revocation of the 724 patent has resulted in the strike out of the section 37 application in relation to this patent, and that, had Teva not taken action to delay the proceedings before the EPO, it would have simplified to a limited degree the arguments that had to be considered.

73 I accordingly order that the defendant Amgen pay the claimant Teva the sum of £1200, the deadline for payment being seven days after the expiry of the period for appeal.

IX. Appeal

74 Any appeal must be lodged within 28 days

A C Howard
Divisional Director acting on behalf of the Comptroller