

THE HIGH COURT

COMMERCIAL

2010 7635 P

BETWEEN

**ASTRAZENECA AB AND
ASTRAZENECA UK LIMITED (AZ UK)**

PLAINTIFFS

AND

**PINEWOOD LABORATORIES LIMITED AND
KRKA, TOVARNA ZDRAVIL, D.D., NOVO MESTO**

DEFENDANTS

JUDGMENT of Mr. Justice Kelly delivered on the 5th day of May, 2011

Introduction

This is my decision on an application by the first defendant (Pinewood) for discovery of five species of documents against the plaintiffs (Astra) in this patent infringement suit. The judgment deals, *inter alia*, with the question of the discoverability of material concerning a parent patent when its divisional patent is in suit. That issue has not arisen in this jurisdiction before, as far as I am aware.

This Action

The two plaintiffs are bodies corporate which have their registered offices in Sweden and the United Kingdom respectively.

Pinewood is an Irish company with its registered office in Co. Tipperary.

The second defendant (Krka) is registered in Slovenia.

The first plaintiff is the proprietor of Irish Patent No. 1020461 (the patent) which is derived from European Patent No. EP1020461 (the 461 patent).

The second plaintiff is authorised to sell and supply the subject of the patent in this State.

The subject of the patent is a medicament for the inhibition of gastric acid secretion which is manufactured through use of a magnesium salt with certain chemical characteristics as claimed in claim 1 of the patent. This is marketed by Astra in this State using the name 'Nexium'.

It is alleged that the defendants are infringing the patent by, *inter alia*, putting on the market in the State products which inhibit gastric acid secretion using the mark 'Nexazole' and 'Esomeprazole Krka'. These products are sold in 20mg and 40mg gastro-resistant tablets.

On this application, I am concerned only with Pinewood. It does not manufacture the products but accepts that it sells the product 'Nexazole' in the State. It denies that it sells the product 'Esomeprazole Krka'. It denies that 'Nexazole' infringes the patent and it counterclaims that the patent ought to be revoked on the grounds of want of novelty and inventive step, insufficiency and added matter.

It is to be noted that there are revocation proceedings in respect of the 461 patent which are taking place in at least four other EU Member States. There are also infringement proceedings taking place elsewhere in respect of the 461 patent.

Legal Principles

Before considering each of the discovery requests it is desirable that I should shortly state the principles which are applicable to the determination of disputes on discovery.

Under O. 31, r. 12 of the Rules of the Superior Courts, an applicant for discovery has to demonstrate that the documents sought are both relevant and necessary for the fair disposal of the case or to save costs.

The onus of establishing relevance and necessity is on the moving party.

The court, in considering an application for discovery, must also bear in mind the concept of proportionality. That involves a consideration of the extent or volume of the documents to be discovered and the degree to which the documents are likely to advance the case of an applicant or damage the case of his opponent. The public interest in the proper administration of justice is not confined to the relentless search for perfect truth. (See the observations of Fennelly J. in *Ryanair Plc v. Aer Rianta Cpt* [2003] 4 I.R. 264 and those of Murray J. in *Framus v. CRH Plc* [2004] 2 I.R. 20.)

One further matter to be considered is the capability of obtaining the desired information in a less costly and less time consuming manner by the use of interrogatories or notices to admit facts (see my judgment in *Anglo Irish Bank v. Browne* [2011] IEHC 140).

The general principles which I have just mentioned are as applicable to discovery in patent actions as in any other actions. In this regard see the decisions of Finlay Geoghegan J. in *Schneider (Europe) GmbH v. Conor Medsystems Ireland Limited* (2nd February, 2007) and in *Medinol Limited v. Abbott (Ireland)* [2010] IEHC 6 and my own decision in *Medtronic, Inc v. Guidant Corporation* [2007] IEHC 37.

Two particular citations from those decisions have a relevance to the instant application.

In *Medtronic*, I pointed out that the observations of Brett L.J. in the *Peruvian Guano Case* [1882] 11 Q.B.D. 55 remain the guiding norm. He said that the following are relevant:-

"Every document relating to the matters in question in the action, which not only would be evidence upon any issue, but also which, it is reasonable to suppose contains information which may – not which must – either directly or indirectly, enable the party requiring the affidavit either to advance his own case or to damage the case of his adversary."

In *Schneider*, Finlay Geoghegan J. noted the observations of Whitford J. in *Vickers PLC v. Horsell Graphic Industries Limited* [1988] R.P.C. 421 when considering the relevance of documents on the US application file to English patent proceedings where he said:-

"My opinion as regards documents is this. I go no further than saying that quite plainly vast numbers of documents are filed in connection with foreign applications, and mostly they are going to be irrelevant. I entirely accept that opinions which may have been expressed or experiments which may have been conducted in connection with foreign applications are at the end of the day not necessarily likely to be conclusive and may indeed prove to be of only limited importance, but they do assist a defendant. They disclose the line which may be taken in connection with the defence to the attack upon the validity which is going to be put forward. They disclose the approach to the issue of infringement."

Finally, it is important not to confuse discoverability with admissibility. In *Schneider*, Finlay Geoghegan J. drew attention to the *obiter dicta* of Aronovitch P. in *Eli Lilly & Company v. Apotex Inc.* [2006] 4 FCR 104 where he said:-

"Discovery is not to be confused with admissibility. The fact that the test for the determination of a ground of invalidity is objective, and that the knowledge or opinion of the inventor may not be relevant in the sense that it cannot be relied upon to construe the patent, does not imply that the facts of the process of invention cannot be collaterally relevant to the issues or that they will not be considered by the Court, whatever their ultimate probative value. Moreover, documents, relating to the inventive process may be discoverable on the basis that they can contain relevant facts or ones leading to a line of inquiry that will be helpful to advance the case of one of the parties to the suit – for example, prior art references that may not be known to the party pleading invalidity."

I now turn to a consideration of each of the categories in dispute.

Category 2

Pinewood seeks discovery of:-

"The prosecution files and all documents (including without limitation any and all correspondence, notes, advice letters and memoranda) in respect of and relating to:-

- (i) the application for the parent patent EP 0652872 (the parent patent) for the European Patent Office;*
- (ii) the opposition proceedings before the European Patent Office; and*
- (iii) the appeal proceedings before the boards of appeal of the European Patent Office."*

Pinewood has offered not to pursue this request if discovery of category No. 6 is ordered. Even though I will be granting discovery of category 6, I propose dealing with the issue of principle raised.

Astra have agreed to make discovery of like, non-public, documentation in respect of the application for the 461 patent. The issue which is raised here is that of relevance of the documentation sought.

The parent patent was revoked on grounds of lack of inventive step. Whilst that patent is not in issue in these proceedings, it is accepted that the 461 patent is a divisional patent of the parent patent. The difference is the addition of the technical characteristic of optical purity in the 461 patent.

It is not disputed that some of the same prior art that is being employed in these proceedings was used to challenge the validity of the parent patent.

Astra contend that the claims in the parent and divisional patents are not the same and consequently different considerations apply as regards issues of validity. Therefore the material sought is not relevant, it is said.

This calls for a consideration of the relationship between a divisional patent and a parent patent.

Divisional Patents

The topic of divisional patents was considered by the Court of Appeal in *Napp Pharmaceutical Holdings Limited v. Ratiopharm GmbH* [2009] EWCA Civ. 252. In delivering the judgment of the court in that case, Jacob L.J. said this:-

"Divisional Patents

7. The two patents have, for practical purposes, the same text because they are 'divisionals'. The differences lie in their respective claims, and in variations of the text consequential upon the dividing out process. For present purposes it is common ground, as it was below, that we can work mainly from the text of 730.

8. We should say a word about 'divisionals'. The basic procedure for applying for a patent is laid down in Art. 75 of the EPC. This allows an inventor to apply for a patent by filing his/her application at the EPO (or a national office of an EPC member if the law of that state allows it). The relevant date for the purposes of judging patentability (the 'priority date') will be the date of that application, though an earlier priority date may be claimed if the patentee has made an earlier

(but within one year) application in a Paris Convention country. The application can be made to the EPO via the machinery of the Patent Co-Operation Treaty (PCT). That was used to make the application leading to the patents in suit in this case.

9. However Art 76 of the EPC allows for an elaboration of the basic procedure. It goes by the jargon 'divisional'. Art 76 says:-

76(1) A European divisional application must be filed directly with the European Patent Office at Munich or its branch at The Hague. It may be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed; in so far as this provision is complied with, the divisional application shall be deemed to have been filed on the date of filing of the earlier application and shall have the benefit of any right to priority.

10. So what a patentee can do, having made an initial application, is to apply for a divisional patent. Provided the subject-matter of this does not extend beyond the content of the earlier application, he can get a free-standing patent for the divisional application. Because the date of filing is deemed to be that of the 'parent' as the jargon goes, a patentee cannot extend the period of protection by applying for a divisional.

11. Sometimes the EPO will say to a patentee that he has got too much in a single application (an application can only cover a single invention or group of inventive concepts, Art.82) and he must divide out or cut down. But a divisional can be sought by a patentee even if the Office does not require it. Then the patentee's purpose is to break up his/her original application into a cluster of sister patents – each having the same basic disclosure but with different claims. Much the same could be achieved by just adding these claims to the original application, but there are both real and perceived advantages in using divisionals. Firstly each patent will stand or fall on its own merits whereas otherwise there is a risk of the complications of a partially valid patent – complications with potentially different results in different Member States. Secondly a possible infringer can be sued on just the divisional(s) relevant to what he does. Thirdly if the patentee is having trouble with the examination process in respect of part of his invention, he may divide out the portion which the Office accepts is all right so that it gets early grant of that, and meanwhile he can pursue his argument with the Office in respect of the remainder.

12. It is fair to say that a clutch of divisionals is likely to make the position more difficult to assess for third parties. Here for instance there are no less than nine divisionals stemming from the original application. It is perhaps questionable as to whether the current voluntary aspect of the divisional system should continue to be permitted. That is particularly so since one of its justifications has now gone or is of less significance. A patentee need no longer fear that by having all his claimed eggs in one basket, he will lose his patent if even one egg turns out to be bad: central amendment of a granted patent is now possible pursuant to the provisions of Art.105a of the EPC (introduced by amendment pursuant to the EPC 2000).

13. One of the features of the divisional system is that each divisional must have claims which are different: the patentee cannot have the same claim in different patents. So filing a divisional involves a dividing up process: what is claimed in the divisional must be excluded from the claims of the patent from which it has been divided out. That dividing out process may, perhaps, itself add subject-matter – it is said to have done so in this case."

Astra are correct when they point out that each patent stands or falls on its own merits. Each divisional patent must have claims which are different. The patentee cannot have the same claim in different patents. But that said, it is clear that there is an extraordinarily close relationship between the parent and the divisional patents. Each have the same basic disclosure but with different claims. As was pointed out by the Court of Appeal much the same could be achieved by just adding these claims to the original application.

Given that the 416 patent is a divisional of the parent, that the parent was revoked on grounds of lack of inventive step and that some of the prior art that is being employed in these proceedings was used to challenge the validity of the parent patent it is, in my view, impossible to say that the material sought to be disclosed here is not relevant to this suit.

Whilst the claims are different they cannot be unrelated or else the 416 patent could not be a divisional of the parent patent.

The only remaining opposition is a rather lacklustre statement at para. 7 of the replying affidavit which confirms a statement contained in a letter of 8th March, 2011, to the effect that this category would result in the production of millions of documents. That assertion was made in the letter on the basis of information provided by Ms. Jenny Lidander, an official of Astra. No further information is forthcoming and no explanation is given. The letter of 8th March suggests the possibility of the information which is sought to be procured on discovery being capable of being obtained either by the service of a notice to admit facts or by interrogatories.

The utilisation of such devices is to be preferred to discovery but this topic was not debated in any detail before me. In the event, I need not concern myself with this aspect of the matter.

In principle, I have come to the conclusion that Pinewood is entitled to discovery of the documents sought in this category.

Given that I will be ordering discovery of category 6 it is not necessary to make any order in this regard because of Pinewood's offer to forego category 2 in such event.

Category 5

Pinewood seeks discovery of:-

"All documents which contain any consideration or evaluation carried out by or on behalf of the plaintiffs or by or on behalf of the named inventors as to the patentability of any claim of the patent, or the validity of any claim of the patents."

Astra has agreed to make discovery of this category of documents but only until the date of the grant of the patent. It contends that once the patent has been granted, documentation coming into existence thereafter could not be relevant.

I am unable to agree with this contention. It is clear that since the patent was granted there have been proceedings in a variety of jurisdictions concerning its validity. There must, therefore, as a matter of high probability be relevant documents in existence which postdate the grant of the patent.

In my view, Pinewood is entitled to discovery of the documents sought.

Category 6

Pinewood seeks:-

"All documents which concern or refer to the issues of the infringement and validity of the patent and the parent patent (wheresoever arising) which have been shown to, provided to, sent to or received from any expert, consultant or in house counsel and/or patent attorneys who had been retained by the first named plaintiff (the patentee) in respect of these issues."

Astra has agreed to make discovery of the documents sought under this category but only in respect of the 416 patent. They have expressly refused discovery in respect of the parent patent. In that regard, they have relied upon the same reasons as I have dealt with in respect of their refusal of category 2. As I have concluded that there is an entitlement in principle to discovery in respect of category 2, I arrive at the same decision in respect of this category for precisely the same reasons.

The fact that I am ordering discovery of this category makes category 2 unnecessary as I have already stated.

Category 9

Pinewood seeks:-

"All documents concerning any consideration or evaluation of the possible infringement of the patent by the defendants."

This is objected to on the grounds of irrelevance and lack of necessity.

Astra points out that it has agreed at category 8 to provide discovery of all documents concerning or relating to the testing of the products alleged to infringe the patent or of any substance or compound used in their manufacture, including all documents relating to the conditions of the said testing. Having regard to that, Astra contends that documents sought in category 9 will neither advance Pinewood's defence or damage Astra's claim. Astra contends that is the results of the tests referred to in category 8 which will perform such functions. Astra is, therefore, willing to make discovery of the tests of the infringing product to which reference is made and of the reports resulting therefrom.

I am of the view that this is too narrow an approach to take. It seems to me that documents demonstrating a consideration or evaluation of the possible infringement of the patent are relevant and necessary. In that regard, I note that in *Medinol*, Finlay Geoghegan J. took the view that documents sought in that case which would *"constitute, refer or relate to communications by the Plaintiff or any of its officers, directors, employees, agents or attorneys regarding any Accused Product in this litigation concerning possible infringement of the Plaintiff's Patent by the Defendants"*, was relevant because it might advance the defendant's defence or damage the plaintiff's claim. In my view, that is the position which obtains here and consequently discovery will be ordered in respect of this category.

Category 11

Pinewood seeks:-

"All documents (a) relating to any of the contentions advanced or proposed to be advanced by the first named plaintiff, as proprietor of the patent and parent patent, in any actual or threatened proceedings for infringement of the patent and parent patent by non-parties to these proceedings; and (b) concerning the contentions advanced or proposed to be advanced by any non-party to these proceedings in seeking or threatening to seek the revocation of the patent and parent patent (such documentation to include any expert evidence filed on behalf of the proprietor or the non-parties in question)."

Objection is taken to this request on the basis that the documents sought are neither relevant nor necessary since the request is directed to what is described as the collation of *"contentions"* on questions of infringement and validity which could not have any bearing on the manner in which the court adjudicates upon such matters. This objection is supported, it is said, by the decision of the Supreme Court in *Ranbaxy Laboratories Limited v. Warner Lambert Company* (2nd December, 2005) that supposedly inconsistent statements by a patentee as to what falls within the claims of a patent have no bearing on the interpretation of the claims and thus what does and does not infringe a patent.

It is important to bear in mind that the issue determined both by the High Court and the Supreme Court in *Ranbaxy* related to the admissibility of evidence of the patentee as an aid to construction of the claims in the patent. Thus, what was decided was the question of admissibility of evidence rather than the discoverability of documents.

This is a point expressly adverted to by Finlay Geoghegan J. in *Schneider*. At pp. 24 and 25 of her judgment she points out that the *Ranbaxy* decisions were given on a preliminary issue in a patent action in which the principal issue was the proper interpretation of the claims in the defendant's patent. The plaintiff brought a motion for discovery of documents which comprised correspondence between the patent agents of the defendant and the European Patent Office and the Danish Patent Office. That correspondence was alleged to express a view on the proper construction of the Irish patent. The defendant objected to discovery on the basis that the documents would not be admissible in evidence in the proceedings. A preliminary issue was then set down on the admissibility of such documents in evidence in the substantive proceedings. Finlay Geoghegan J. said:-

"It is important to note that this was the only basis upon which discovery was sought. It was not contended that the documents were relevant or necessary as leading to a 'line of inquiry' as was submitted in these proceedings. It is also important to note that the issue in the substantive proceedings in Ranbaxy Laboratories Ltd. v. Warner Lambert Company is quite different from the issues in these proceedings. It concerned only the proper interpretation of the claims in the patent. This is agreed to be a matter of law. The test is what the claim means to an expert in the field to which it relates."

On the preliminary issue the documents were determined both by the High Court and the Supreme Court to be inadmissible in evidence in the proceedings...

In these proceedings, the court may well have to interpret certain of the claims in the plaintiff's claim for infringement. However, this application for discovery in the 740 patent relates to the defendant's counterclaim for invalidity. The issues which the court will have to determine include questions of fact in relation to which the primary evidence will be the expert evidence referred to above. For the reasons already set out the documents sought by the defendant appear to me to be relevant and necessary to the determination of those issues on the counterclaim."

The documents sought under this heading are, it is said, both relevant and necessary as leading to a "*line of inquiry*". That is a perfectly legitimate basis upon which to seek discovery and in my view the case for discovery is made out.

I do not view Pinewood's application as constituting a fishing expedition. In some cases, it may be difficult to draw the line between what is a proper "*line of inquiry*" application and a fishing expedition. I have no difficulty in the present case in concluding that the request for discovery is on the correct side of that line and that consequently discovery ought to be granted.

I will hear counsel on the form of the order to be made in the light of my conclusions.