Neutral Citation Number: [2011] EWHC 907 (Pat)

Case No: HC10C0883

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 14/04/2011

Before :

THE HON MR JUSTICE FLOYD

- -

Between :

H. LUNDBECK A/S	**Claimant/Part 20 Defendant**
- and -	
(1) NORPHARMA SpA	**Defendants/Part 20**
(2) INFOSINT S/A	**Claimants**
- and -	
(3) LUNDBECK LIMITED	**Third, Fourth and Fifth**
(4) LUNDBECK PHARMACEUTICALS LIMITED	**Parties/ Part 20 Defendants**
(5) LUNDBECK GROUP LIMITED	

- -
- -

Justin Turner QC and **Dominic Hughes** (instructed by **Wragge & Co LLP**) for the **Claimant and Part 20 Defendants**
Andrew Lykiardopoulos (instructed by **Cumberland Ellis**) for the **Second Defendant**

Hearing dates: 16th-18th; 21st and 23rd-24th March 2011

- -

Judgment

Mr Justice Floyd:

Introduction

1. The claimant H. Lundbeck A/S ("Lundbeck") brings this action to revoke European Patent (UK) 1 118 614 ("the 614 patent"). The 614 patent now belongs to Infosint A/S, the second defendant, ("Infosint"), as a result of an assignment in 2002 from Norpharma SpA, the first defendant ("Norpharma"). By counterclaim, Infosint alleges infringement of the 614 patent by Lundbeck and the third, fourth and fifth parties, all wholly owned subsidiaries of Lundbeck. No arguments were advanced which made it necessary for me to distinguish between the various Lundbeck companies, so I will refer to them collectively and individually as "Lundbeck".

2. The 614 patent relates to a method of making 5-carboxyphthalide (5-cbx). 5-cbx is an intermediate compound used in the manufacture of Lundbeck's anti-depressant drug citalopram.

Issues

3. Lundbeck assert that the 614 patent is invalid for lack of novelty over two papers by a Mobil scientist called Forney and a Danish patent application. However, by the end of the trial, the lack of novelty objection was limited to the Danish application. Lundbeck also contend that the 614 patent is invalid for obviousness over the Forney papers, and that claim 22 is invalid for insufficiency.

4. There are further issues relating to infringement by current and past processes operated by Lundbeck. Lundbeck also contend that they have a defence under section 64 of the Patents Act 1977 ("the Act") arising out of acts performed before the priority date which they maintain give them a right to continue to do acts which would otherwise infringe.

5. Next there is an issue about the consequences, having regard to section 68 of the Act, of the delayed registration of the assignment from Norpharma to Infosint at the UKIPO.

6. It was agreed that a further group of issues concerning a limitation defence can be dealt with on the hearing of the enquiry as to damages or account of profits, should they arise.

7. As, by the time of the counterclaim, the issues were those of a conventional infringement action, Infosint opened the case and called its evidence first. Mr Andrew Lykiardopoulos appeared for Infosint; Mr Justin Turner QC and Mr Dominic Hughes appeared for Lundbeck.

Expert witnesses

8. Infosint called Dr John Scott and Dr John Moses. Dr Scott is a process chemist. He was the Vice President of Research and Development at Hoffmann La-Roche from 1990-1997 and was then Executive Director of Process Research & Development at Bristol Myers-Squibb from 1998-2003. Since 2003 he has acted as a consultant. He is a highly experienced industrial process chemist, and gave his evidence fairly and impressively. He was called primarily to deal with issues of infringement, but his expertise was such that he could have given all the expert evidence which it was necessary for Infosint to call in this case. He was a little hesitant about areas of the case from which he had been insulated: but when he was unsure he made this plain to the court.

9. Dr Moses is an Associate Professor in Organic Chemistry at the University of Nottingham. Prior to this he was at the School of Pharmacy in London. He has been a member of the Royal Society of Chemistry since 2005. Although he has also worked as an industry consultant, his industrial experience was far less than that of Dr Scott and Mr Ward. I found his approach to the issues a little adversarial, appearing at some points in his evidence to be arguing a legal case on behalf of Infosint, rather than giving technical reasons to support a point of view. It was, in any event, not clear to me why Infosint needed to call two experts in a case involving process chemistry which was entirely within the expertise of Dr Scott. In the end, Lundbeck chose to put nearly all aspects of their validity case to Dr Scott, as they were fully entitled to do. Nevertheless, I have taken account of Dr Moses' points when reaching my conclusions.

10. Lundbeck called Mr Neal Ward and Professor Stephen Davies. Mr Ward is an industrial chemist, currently an independent consultant. Prior to April 2002 he was employed by GlaxoSmithKline as a project manager in Chemical Development, both developing new molecules and improving production processes. Infosint criticised his evidence as "didactic and without compromise" and submitted that he had difficulty seeing things in any way other than his own. I do not think this is fair. He did express confident views. However, he was equally capable of seeing a fair point made against him and agreeing with it. I found his evidence overall to be balanced.

11. Professor Davies is the Waynflete Professor of Chemistry at the University of Oxford and Chairman of the Department of Chemistry. He also founded Oxford Assymetry Company which specialised in preparing compounds with high stereochemical purity. He is an acknowledged expert on stereochemistry. His evidence was originally directed to a narrow point about the technical background to the construction of claim 22. On the pretext that one of Professor Davies' papers had been mentioned by Dr Moses, Lundbeck also asked him to give some evidence in relation to Forney. No criticism was made of Professor Davies as a witness.

Fact Witnesses

12. Infosint called Mr Luigi Zanetti, a former director of Norpharma and Infosint and now a consultant to Infosint. He gave evidence directed to the issue of registration of the assignment of the 614 patent. Mr Zanetti found the process of giving evidence through an interpreter very difficult. It is not possible to say how much this was his fault and how much was the fault of the interpreter, who was provided by Infosint – I

suspect it was a little of each. Despite this I was able to understand the gist of his evidence. His credibility was attacked to a degree by Lundbeck, but I make no criticism of him, given the difficulties he was labouring under. The facts on this part of the case were not really in dispute.

13. Lundbeck called Mr Poul Nielsen and Mr Peter Trickett. Mr Nielsen gave evidence of the processes used by Lundbeck, including those adopted before the priority date. His cross-examination had to be interrupted because it transpired that Lundbeck had given inadequate disclosure of documents relating to the work he carried out before the priority date. The work Mr Nielsen had described turned out not to be the first work he had performed on the relevant reaction. Moreover he had not himself been back to his original notebooks. Given that the work was carried out more than 30 years ago, and he had little actual recollection of the details of the work, this was not an adequate way of ensuring that the court was put in possession of an accurate history.

14. Infosint did not go as far as to suggest that Mr Nielsen was setting out to mislead the court, and I do not think he was. However, the manner which he and Lundbeck set about putting this evidence before the court was, in my judgment, wholly unacceptable. If parties decide to rely on secondary evidence of this kind, they must make sure that the evidence is fairly and accurately put before the court. As a result of these failures by Lundbeck, I am left with no confidence in this Lundbeck story at all.

15. Mr Trickett gave evidence of the history of citalopram production in the UK both before and after the priority date. He was an entirely fair witness.

The skilled addressee or team

16. The patents are addressed to an industrial process chemist. Such a person will have a degree in chemistry or chemical engineering and some years of practical experience.

17. There was some debate about whether the skilled person was someone having an interest in citalopram, which is discussed in the introduction of the patent and claimed as an end product in claim 22. The argument was that, as the patent mentions the use of 5-cbx as an intermediate for making, amongst other things, citalopram, it follows that the skilled person was to be deemed to be interested in making citalopram.

18. In *Schlumberger Holdings Limited v Electromagnetic Geoservices AS* [2010] EWCA Civ 819; [2010] RPC 33 at [30] to [70] the Court of Appeal explained that the skilled team required to implement the patent and to understand its teaching was not necessarily the same as the team used to interpret the prior art and as the touchstone for the question of inventive step. This might be so in cases where the invention changed the art or married two unrelated arts together.

19. A similar but not identical point arises in the present case because claim 22 claims the use of 5-cbx made by the claim 1 process in the manufacture of citalopram. I will need to call upon the hypothetical skilled person both to understand the scope of claim 22 and to determine whether the invention of claim 22 is obvious over the Forney papers. For the former purpose the skilled person is plainly aware of and interested in citalopram. But for the purpose of determining whether claim 22 is obvious it seems

to me that it would be quite wrong to assume from the beginning that the skilled person was aware of citalopram, far less that he was interested in it, given that the main prior art references are not in the pharmaceutical field at all. It is quite possible that it would never have occurred to the skilled person to think of citalopram in the context of any given item of prior art. The skilled person's knowledge of or interest in citalopram will depend on the contents of the prior art, where it would lead him and what was part of his common general knowledge.

The common general knowledge

20. The law about the distinction between matter which is part of the common general knowledge, and matter which is merely known or even widely known is stated in *Beloit v Valmet* [1997] RPC 489 at 494-495, relying on the well known judgment of the Court of Appeal in *General Tire v Firestone* [1972]RPC 4. The matter must be "generally accepted as a good basis for further action" amongst those skilled in the art. The distinction is important in the law of obviousness because, although it is in general permissible to combine the contents of an individual published citation with matter which is part of the common general knowledge, it is impermissible to make so-called mosaics of individual citations (unless it would be obvious to do so).

21. Matter which the skilled person would uncover as a matter of routine in the course of work based on a particular disclosure does not form part of the common general knowledge. In *Generics (UK) v Daiichi Pharmaceutical* [2008] EWHC 2413 (Pat); [2009] RPC 4 at [40] Kitchin J said:

> "I can readily accept that, faced with a disclosure which forms part of the state of the art, it may be obvious for the skilled person to seek to acquire further information before he embarks on the problem to which the patent provides a solution. But that does not make all such information part of the common general knowledge. The distinction is a fine one but it may be important. If information is part of the common general knowledge then it forms part of the stock of knowledge which will inform and guide the skilled person's approach to the problem from the outset. It may, for example, affect the steps it will be obvious for him to take, including the nature and extent of any literature search."

22. Kitchin J's judgment was approved by the Court of Appeal: [2009] EWCA Civ 646 at [26] to [28]. Jacob LJ said:

> "It would be wholly subversive of patents and quite unfair to inventors if one could simply say "piece of information A is in the standard literature, so is B (albeit in a different place or context), so an invention consisting of putting A and B together cannot be inventive." The skilled man reads each specific piece of prior art with his common general knowledge. If that makes the invention obvious, then it does. But he does not read a specific citation with another specific citation in mind, unless the first causes him to do so or both are part of the matter taken to be in his head.

> So, for example, if a particular device depends upon expansion of a metal, say brass, and clearly the coefficient of expansion matters to its operation, one can legitimately say that the skilled person knows there are tables of coefficients of expansion and would go to them to see what other metals or alloys had similar coefficients and would therefore probably work. But not so if it was far from evident that the coefficient of expansion mattered."

23. Relevant aspects of the common general knowledge in this case are the following:

    i) Oleum is the common name for a mixture of sulphur trioxide (SO_3) and sulphuric acid (H_2SO_4). It can exist with any amount of SO_3, although pure SO_3 would not be called oleum.

    ii) Oleum was commercially available in various SO_3 concentrations ranging from 15 to 80% SO_3. Those that the process chemist would have on the laboratory shelf might be in the range 20-30%.

    iii) Pure SO_3 and oleum are both hazardous chemicals. Both are used very widely in the production of detergents, plastics and dyes. Both chemicals must be treated with care because they produce a corrosive mist containing droplets of H_2SO_4. Overall, as Dr Scott said, oleum would be regarded as a less hazardous reagent than SO_3, but this is a matter of degree.

    iv) SO_3 is a powerful dehydrating agent. When it reacts with water it forms sulphuric acid so that water is mopped up from the reaction. So pure SO_3 will become oleum if reacted with less than one mole equivalent of water.

    v) Formaldehyde (CH_2O) is an extremely well known chemical reagent. It can conveniently be produced in reactions from paraformaldehyde and trioxane which are solids.

    vi) Terephthalic acid is the common name for benzene 1,4 dicarboxylic acid. It, too, is an extremely well known chemical reagent used on a large scale in the manufacture of plastics. PTFE (Teflon) is a polymer made from terephthalic acid.

    vii) Chemical reactions are sensitive to conditions of temperature and pressure, which can affect both the rate of reaction and the degree of conversion.

24. Lundbeck do not assert that either of the cited Forney papers were part of the common general knowledge. They were right not to do so.

The 614 patent

25. The 614 patent is entitled "Process for the preparation of 5-carboxyphthalide" i.e 5-cbx. It has a priority date of 18 January 2000.

26. At [0002] the specification points out that 5-cbx is:

> "a useful intermediate in the preparation of several chemical compounds, particularly dyes, resins and drugs. In particular, [5-cbx] is an intermediate useful in the synthesis of citalopram, a well known anti-depressant drug, whose preparation is described in International Patent Application WO 00023431 and the corresponding Italian Patent Application IT1999 MI 0001724, whose contents must be considered as integral part of the present description."

27. From [0003] to [0008] reference is made to prior art methods of making 5-cbx, including Forney 2. At [0008] the specification says:

> "Reaction conditions like these, however, are not suitable for the industrial scale because pressure reactors and strong acidity conditions are required."

28. At [0009] it is stated that:

> "It has now surprisingly been found that by addition of terephthalic acid to fuming sulphuric acid (oleum) containing between 20-33% by weight, of SO_3, by subsequent addition of formaldehyde to the mixture and by heating, 5-carboxyphthalide is obtained in good yields and in a high degree of purity under easily controllable conditions, in open and however not pressurized reactors, and without any risk in handling the reaction mixtures."

29. At [0010] the specification states that the invention provides a method in which terephthalic acid is added to fuming sulphuric acid containing 20-33% by weight of SO_3, subsequently adding formaldehyde thereto, heating the mixture to 120-160^{o}C and isolating the obtained 5-cbx. The range of 120-160^{o}C is not replicated in the claims.

30. At [0011] it is explained that, in a preferred embodiment, solid "forms of" formaldehyde may be used, for example 1,3,5 trioxane. What is meant here is that trioxane is a precursor which produces formaldehyde in the reaction pot. Paraformaldehyde would be another alternative to this.

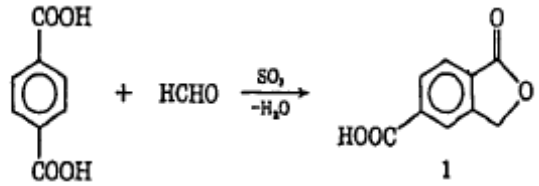
31. At [0013] the specification gives the following information about temperature and the exothermic (heat generating) nature of the reaction:

> "….the mixture thus obtained is treated with 1,3,5-trioxane at a temperature of 30-35^{o}C and subsequently heated at a temperature of 120-145^{o}C, preferably at 130-135^{o}C. Generally, it is sufficient to heat to 120^{o}C so that the temperature of the reaction mixture increases by spontaneous exothermia up to 130-135^{o}C. Preferably, having reached 120^{o}C, it is suitable to wait about 15 minutes in order to verify whether such exothermia has occurred. In the negative, the temperature is brought up to 130-145^{o}C and, after a 2-5 hour heating at this

> temperature, there is formed compound III which concurrently dehydrates to give 5-carboxyphthalide."

32. There are six examples. In each of the examples terephthalic acid is added to oleum followed by 1,3,5 trioxane, as the source of formaldehyde. All the examples use oleum containing between 25 and 27% SO_3. The temperature ranges of the main heating stage are 135-140; 130-135; 135-145; 130-133; 135-140; 130-133^oC.

33. In summary, the skilled person would understand that the chemical reaction being described in the patent was between terephthalic acid and formaldehyde. It involves the elimination of a molecule of water in a medium containing SO_3, and so can be conventionally depicted thus:



34. The figure above comes, for convenience, from one of the Forney papers. But it is common ground that this is the chemistry which the 614 patent is describing.

The claims in issue

35. Infosint relies on claim 1 of the 614 patent. It also relies on claim 22 as being independently valid. Claim 1 is to:

> "A process for the preparation of [5-cbx] … in an open and however not pressurised reactor which comprises adding formaldehyde and terephthalic acid … to fuming sulfuric acid containing 20-33% by weight of SO_3, heating the mixture at 120-145^oC and isolating the [5-cbx] thus obtained."

36. Claim 22 is to:

> "A process for the synthesis of citalopram, in which a process for the synthesis of [5-cbx] according to claim 1 is contained."

Construction

37. The approach to construction is not in dispute. It is as stated by Lord Hoffman in *Kirin Amgen v TKT* [2005] RPC 9. The task for the court is to determine what a person skilled in the art would have understood the patentee to have used the language of the claim to mean.

38. In *Virgin v Premium Aircraft* [2009] EWCA Civ 1062, [2010] RPC 8 at [5], Jacob LJ said this, approving a summary by Lewison J of the applicable principles:

> "5. One might have thought there was nothing more to say on this topic after *Kirin-Amgen v Hoechst Marion Roussel* [2005] RPC 9. The judge accurately set out the position, save

that he used the old language of Art 69 EPC rather than that of the EPC 2000, a Convention now in force. The new language omits *the terms of* from Art. 69. No one suggested the amendment changes the meaning. We set out what the judge said, but using the language of the EPC 2000:

[182] The task for the court is to determine what the person skilled in the art would have understood the patentee to have been using the language of the claim to mean. The principles were summarised by Jacob LJ in *Mayne Pharma v Pharmacia Italia* [2005] EWCA Civ 137 and refined by Pumfrey J in *Halliburton v Smith International* [2005] EWHC 1623 (Pat) following their general approval by the House of Lords in *Kirin-Amgen v Hoechst Marion Roussel* [2005] RPC 9. An abbreviated version of them is as follows:

(i) The first overarching principle is that contained in Article 69 of the European Patent Convention;

(ii) Article 69 says that the extent of protection is determined by the claims. It goes on to say that the description and drawings shall be used to interpret the claims. In short the claims are to be construed in context.

(iii) It follows that the claims are to be construed purposively—the inventor's purpose being ascertained from the description and drawings.

(iv) It further follows that the claims must not be construed as if they stood alone—the drawings and description only being used to resolve any ambiguity. Purpose is vital to the construction of claims.

(v) When ascertaining the inventor's purpose, it must be remembered that he may have several purposes depending on the level of generality of his invention. Typically, for instance, an inventor may have one, generally more than one, specific embodiment as well as a generalised concept. But there is no presumption that the patentee necessarily intended the widest possible meaning consistent with his purpose be given to the words that he used: purpose and meaning are different.

(vi) Thus purpose is not the be-all and end-all. One is still at the end of the day concerned with the meaning of the language used. Hence the other extreme of the Protocol—a mere guideline—is also ruled out by Article 69 itself. It is the terms of the claims which delineate the patentee's territory.

(vii) It follows that if the patentee has included what is obviously a deliberate limitation in his claims, it must have a meaning. One cannot disregard obviously intentional elements.

> (vii) It also follows that where a patentee has used a word or phrase which, acontextually, might have a particular meaning (narrow or wide) it does not necessarily have that meaning in context.
>
> (vii) It further follows that there is no general "doctrine of equivalents."
>
> (viii) On the other hand purposive construction can lead to the conclusion that a technically trivial or minor difference between an element of a claim and the corresponding element of the alleged infringement nonetheless falls within the meaning of the element when read purposively. This is not because there is a doctrine of equivalents: it is because that is the fair way to read the claim in context.
>
> (ix) Finally purposive construction leads one to eschew the kind of meticulous verbal analysis which lawyers are too often tempted by their training to indulge.

39. The Protocol on the Interpretation of Article 69 of the EPC 2000 now requires, as a result of an amendment introduced in EPC 2000, that due account be taken of "any element which is equivalent to an element specified in the claim". The approach approved by Jacob LJ in *Virgin* takes due account of equivalents in sub-paragraph (viii). The provision was certainly in Lord Hoffmann's mind when he gave the leading speech in *Kirin Amgen*: see paragraph [49].

"open and however not pressurised reactor"

40. There are two parts to this oddly expressed limitation. An "open" reactor would not, in 2000, connote one which is open to the atmosphere. An open reactor is one vented to atmosphere by a suitable scrubber system (a pollution control device). The term "not pressurised" means that the reactor is at or close to atmospheric pressure. A conventional scrubber system may lead to a slight increase over atmospheric pressure. The experts indicate that this might be about 50 millibars in the reactor. Beyond this, I do not think that "not pressurised" leaves much room for argument. There is no attempt to claim a range of pressures, as in the case of temperatures. Mr Lykiardopoulos said that the contrast was with the sealed glass tubes of Forney 2, given the reference to Forney 2 at [0007] of the specification. That may be so, but it does not justify allowing Infosint to cover, by a process of construction, the whole, or indeed part of the range between atmospheric and whatever pressure would be generated in a sealed glass tube. Neither side ventured any suggestion as to what the skilled person would imagine were the pressures in the sealed glass tubes of Forney 2 in any event. The truth is that the claim requires not only an unsealed reactor: it requires an unsealed and unpressurised one. Accordingly, with the minor exception of the sort of pressures which would be generated by the presence of a scrubber system and similar devices in an open reactor, the claim requires the reactor to be unpressurised.

"heating the mixture at 120-145^{o}C"

41. Lundbeck submit that the temperature range means what it says: if the mixture is heated outside this range then there is no infringement. The range was freely chosen by the patentee, and he cannot have meant to cover temperatures outside the range. The reference to a range of 120-160°C at [0010] shows that the patentee knew what he was doing.

42. Infosint submits that the range would not be understood by the skilled reader to be exact and covers temperatures "a few degrees higher than 145°C." Infosint submits that even a well run process aiming to hit a steady 145°C would be likely to fluctuate a few degrees over. It submits that the skilled person would know (also relying on the reference to the reaction running at 160° at [0010]) that a few degrees would not have a material effect on the way the invention works.

43. I do not think that there is any difficulty about what the numerical upper limit of the claim actually means: it means 145°C. As it is expressed as a whole number, it probably covers 145.4°C as well. Apart from that, I cannot see any basis on which it can sensibly be argued that 145°C means some higher temperature. On that basis a reaction which is conducted at 145.5°C or above does not infringe.

44. There is however a further and related point about whether "heating at" the specified temperature range means that the temperature has to be maintained within the prescribed range for the whole or substantially the whole of the reaction period and if not, for how much of it. The parties were divided on this point as well. Infosint submitted that if any 5-cbx is made by heating for any period (apart from the initial heating up period) at a temperature within the temperature range, then there would be infringement, even if for some of the time the temperature was outside the range. Lundbeck submitted that the temperature must be maintained within the range for the whole period of the reaction.

45. I do not think that Lundbeck's position represents the meaning that the skilled person would extract from this feature of the claim. Lundbeck's position allows a party to escape infringement if there is a short temperature spike within a process operated substantially within the range. I did at one point think that Lundbeck's position could be supported by the closing words of the claim which require the 5-cbx "thus obtained" to be isolated. "Thus obtained" means by heating at 120-145°C. If the 5-cbx at the end of the reaction had been made at temperatures both within and outside the range, it would not be possible to separate out the 5-cbx which had been "thus obtained" because there is no difference between 5-cbx made at one temperature from that made at another. So all the heating must be within the range. In the end I was persuaded by Mr Lykiardopoulos that this is probably too lawyerly a point: a classic case of the "meticulous" approach outlawed by sub-paragraph (ix) of the summary approved by Jacob LJ in *Virgin.* And it was not advanced with any enthusiasm by Mr Turner.

46. I think therefore that one must start by noting that the claim does not specify any period of time for which the reaction must be run at the specified temperature, or indeed any degree of completion of the reaction. There is no reason why a reaction run for ten minutes at the specified temperature *and then stopped* should not be said to be using the patented process, provided that some 5-cbx is made and could be isolated. If such a process is "heating the mixture at 120-145°C", then there is no

reason why a process in which the reaction mixture is heated outside the range, after a ten minute period within the range, should not infringe as well.

47. I therefore accept Infosint's submission on this question. The skilled person would understand that, provided that he made some 5-cbx within the specified temperature range (ignoring the warming up period) then he will infringe, even if the rest of the 5-cbx is made at a temperature outside the claimed range.

48. Accordingly, if the temperature of the process is set to 145^{o}C, then the process will be likely to infringe, notwithstanding the fact that the temperature went into and out of the range. As Mr Lykiardopoulos submitted, that is in accord with what one would expect.

49. It is arguable that there may come a point where the amount of time that the process is within the range is so small that it can be ignored. Obviously if the time is so short that no 5-cbx is made during that time, then this does not infringe. I did not hear argument on whether there should be a "de minimis" limit and, if so, what it might be. The point is not free of authority: see the observations of Pumfrey J in *Monsanto v Cargill* [2007] EWHC 2257 (Pat) in connection with a product claim. As I do not think that infringement by any of the processes with which I am concerned really turn on this point, I say no more about it here.

50. A further point about whether "heating the mixture" excludes a two-pot process in which a mixture of paraformaldehyde in oleum is added to a preheated mixture of terephthalic acid in oleum was abandoned by the end of the trial. I think that Lundbeck were right to do so. The fact that some of the heating is done before the claimed reaction commences does not mean that the reaction mixture is not heated.

"citalopram"

51. The skilled person reading the patent would know that citalopram was a chiral molecule, that is to say a molecule which can exist in two enantiomeric forms: a left-handed and a right-handed form. Normally citalopram will exist in the form of a racemic mixture, i.e. a 50/50 mixture of the two enantiomers. There is often a marked difference in pharmacological activity between enantiomers due to the highly specific interaction which occurs between the drug molecule and the receptor at the site of action. One enantiomer may produce the desired effect, but the other enantiomer, because of the different arrangement of the atoms, does not interact with the receptor either at all or to the same extent.

52. Infosint submit that the skilled reader of the specification would understand claim 22 as extending to citalopram when in the form of either of its isomers.

53. Mr Lykiardopoulos expands on this by referring to the documents cross-referred to in the patent at [0002] and which are to be taken as an "integral part of the present description". The purpose of the incorporation of these documents by reference is to show the preparation of citalopram from 5-cbx. The Italian patent application shows at page 11 that the process there disclosed, which includes 5-cbx as an intermediate, can be used to prepare the two enantiomers of citalopram. The International Patent Application contains a similar passage at page 10 lines 14-18.

54. Mr Lykiardopoulos submits that the patentee is saying "here is a novel process to make 5-cbx which can be used to make citalopram as discussed in these other applications". Those applications discuss using 5-cbx to make both the racemate and the enantiomers. There is no logical reason why the patentee would be understood to cover one and not the other.

55. Professor Davies expressed the contrary view, making the point that citalopram and the two separated enantiomers are different compounds. That is correct. Nevertheless, words derive their meaning from context. For the purpose of the invention described in the 614 patent, and in that context, the stereochemical form of the citalopram produced is completely irrelevant. In other contexts, it may be incorrect to use the term citalopram to describe anything other than the racemic mixture. In the context of the 614 patent the skilled person would understand it to extend to the enantiomeric forms as well.

The prior art

Forney 1

56. Forney was a scientist working in the Research and Development Laboratories of Mobil Chemical Company in Edison, New Jersey. Forney 1 is a short "Note" appearing in the Journal of Organic Chemistry, a highly respected and peer-reviewed journal. "Notes" are intended for disclosing the important information about a piece of research. A Note will often be followed up by a more detailed paper, in that journal or elsewhere.

57. Forney 1 is entitled "*Reaction of Terephthalic Acid with Formaldehyde in Sulfur Trioxide Media*". The author explains that terephthalic acid is an aromatic molecule which is strongly resistant to electrophilic substitution – a particular mechanism of chemical reaction. The burden of the disclosure is contained in the third paragraph:

> "We wish to report the condensation of terephthalic acid with formaldehyde in sulfur trioxide media, a process which produces [5-cbx] cleanly and in excellent yield. The reaction is generally free of by-product formation over a fairly wide range of reaction conditions, although terephthaloyloxyacetic acid (2) has been identified (as its dimethyl ester) from reaction in the presence of excess formaldehyde and from reaction media containing <20% SO_3."

58. This passage therefore indicates that a range of reaction conditions have been tried and found successful. "Reaction conditions" normally include such matters as temperature and pressure, but include other matters such as relative amounts of reactants and the nature of the solvent. Those two matters are called out for specific mention here. Whilst excellent yields have been obtained, the by-product terephthaloyloxyacetic acid dimethyl ester ("the by-product") has been observed if the SO_3 concentration in the reaction media falls below 20%. There is a dispute about whether the skilled person would understand the "reaction media" as the whole contents of the reactor or merely the solvent for the reaction. I think it is clear that it means the solvent. Indeed that is what Dr Moses, Infosint's expert, said in paragraph 10 of his second report (although he later seemed to suggest in cross examination that

this was wrong). Moreover he had no real answer to a point made by Professor Davies that if Forney had meant the percentage of the contents of the reaction vessel, there would be insufficient liquid in the reaction mixture in the main experiment described to form the described slurry.

59. This passage therefore contains a clear implication that the reaction has been tried at SO_3 concentrations in a solvent of 20% or above. Furthermore, it conveys the information that the reaction is generally free of by-product formation unless and until one lowers the SO_3 concentration in the solvent to below 20%.

60. Forney 1 points out that prior routes involved several-step processes or provided a mixture which was difficult to separate. He says that his synthesis is believed to represent the first reported substitution of terephthalic acid with an electron-deficient carbon species.

61. In the "Experimental section" Forney 1 discloses two experiments. The first reaction is on a reasonably large scale – much bigger than one could perform in a glass tube. It would be understood as intended to demonstrate that the reaction works at a preparative scale. It is noted that SO_3 is used in the form of Sulfan B. The skilled person would be able to discover that Sulfan B is 100% SO_3, in a stabilised form. It is pointed out that the reaction is exothermic. The resultant slurry was heated at 120-130^oC and the excess SO_3 distilled off. Forney gives no express indication in this experiment as to the nature of the reaction vessel. The write up is also silent as to pressure. The effect of the evidence was, however, that in the absence of any indication of the use of pressure, the skilled person would assume that the reaction was carried out in what would be regarded as an open, unpressurised reactor. If the reaction being reported was indeed carried out under pressure, then the writer would have been guilty of a serious omission, as such a detail is as important to the reader as the temperature. Furthermore, it is clear that when Forney did use sealed vessels, he said so.

62. A second experiment is directed towards making the by-product. This experiment was conducted in a sealed glass tube. Terephthalic acid, formaldehyde (in a large excess) and sulphuric acid (98%) are reacted together at 150^oC. The reaction products were analysed by gas chromatography. They included 83.2% of dimethyl terephthalate, 1.1% of 5-cbx and 15.7% of the by-product.

63. This second experiment therefore discloses that, in the absence of significant amounts of SO_3 and in the presence of a large excess of formaldehyde, the yield of 5-cbx is very low, even in a sealed tube which would raise pressure. 5-cbx is, nevertheless, formed. The second experiment also shows that concentrated sulphuric acid (probably with no significant amount of SO_3) can be used as the solvent.

64. There was some evidence of the significance of the fact that the by-product reaction was conducted in sealed glass tubes. Mr Ward's explanation (with which Dr Scott agreed) was that reactions are often conducted in sealed glass tubes when an analysis is being performed, to ensure that no product escapes and to allow accurate analysis of the reaction products. Dr Moses was cross-examined on this, but I was not clear that he disagreed with Dr Scott and Mr Ward. He accepted that this could be one reason for doing the experiment in a sealed tube, but equally it could be because one wanted to pressurise the reaction.

65. I think that the skilled person would infer from the fact that Forney does not at any stage discuss the need for pressure, and his reference to the fairly wide range of reaction conditions where by-product formation does not occur, that pressure is not required for the preparative reactions which Forney describes in the third paragraph of the paper.

66. I would add that the skilled person would understand that the reaction described for making the by-product was entirely consistent with the third paragraph of the paper. Having observed by-product formation when there is excess formaldehyde and where solvents with low SO_3 concentrations are used, Forney does an experiment with concentrated sulphuric acid and a large excess of formaldehyde. These reaction conditions are designed to maximise the production of the by-product which can be then be isolated and analysed. There is a very clear hint here that the reaction media with 20% SO_3 would be based on sulphuric acid: i.e. oleum. Lundbeck now accept however that this is not a clear disclosure of oleum for the purposes of a novelty attack.

Forney 2

67. Forney 2 is a much longer contribution than Forney 1. It too is concerned with the reaction of formaldehyde and terephthalic acid. Much of it is concerned with questions of the precise chemical mechanism of the reaction which is not relevant to the issues I have to decide. It cross refers more than once to the work reported in Forney 1.

68. Experiments reported in the paper (see Table II) include a run using oleum with a 30% SO_3 concentration as solvent. Forney 2 reports that the conversion is quite sensitive to the nature of the solvent used for the reaction, but that conversion in 30% oleum and one other solvent were much greater than those using other media. "Relatively high conversions were observed in solvents characterised by their free SO_3 content" with the exception of methanesulfonic acid. In a strictly non-comparable run with 100% SO_3 an excellent conversion (recorded as 94%) was achieved.

69. Figure 1 in Forney 2 is a graph of conversion against "mole % SO_3" in sulphuric acid and one other solvent. I reproduce it here:

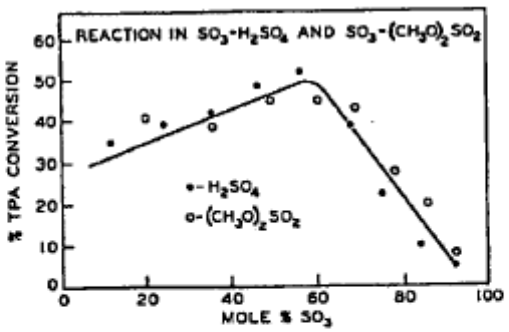


Figure 1.—Yield of 5-carboxyphthalide in sulfuric acid (black dots) and methyl sulfate (open circles) solutions containing varying amounts of SO_3. Conditions were: 1 *M* terephthalic acid and 1 *M* formaldehyde, reacted in sealed glass tubes for 1 hr at 150 ± 0.2°.

70. Later the author says: "The conversion in both solvents reaches a maximum at 60 mol % SO_3 content". The skilled person would understand that, as these reactions were stopped after one hour, the comparison in Figure 1 is simply an indication of rate of reaction in that first hour – a point made elsewhere in the paper (page 691, left hand column). The reactions reported in the Table II runs were conducted for two hours and show near complete conversion at 30% SO_3, whereas Figure 1 shows less than 50% conversion for this concentration after one hour.

71. There is again a dispute about whether the "mole %" recorded on the x-axis of Figure 1 means mole % in the solvent or mole % in the reaction pot. I prefer the evidence of Mr Ward that what is being shown in Figure 1 is the percentage of SO_3 in the solvent, not the percentage of all the ingredients in the pot. The use of mole % rather than weight % is explained by the fact that there are two solvents being shown on a comparable basis in the Figure. To use weight % would give a misleading comparison.

72. Forney 2's reactions are all conducted in sealed glass tubes. At page 693 he says this:

> "When the [5-cbx] synthesis is run with a large excess of formaldehyde, or in dilute oleum mixtures, terephthaloyloxyacetic acid appears as a product of the reaction."

73. This passage echoes the corresponding passage in Forney 1, although it is now expressly made clear that the "reaction media" included oleum. There is a dispute about whether "dilute oleum mixtures" would be understood differently from "<20%" in Forney 1, to which I will return.

74. Finally, other experiments in Forney 2 concerned with added salts all use 30% oleum.

The Forney Patent

75. Forney applied for (in 1969) and was granted (in 1971) US patent No 3607884. This is not cited as prior art, but for reasons which appear below is relied on by Infosint as part of their response to the obviousness attack as they say it would be found on an obvious search conducted by the reader of Forney 1 or 2. It is therefore convenient to describe its disclosure here as well.

76. The essential disclosure of the Forney patent is that terephthalic acid and formaldehyde dissolved in liquid SO_3 react at atmospheric pressure to produce 5-cbx. Example 1 is effectively the main preparative example which was subsequently published in Forney 1. The patent includes a reference to some prior art (three US patents and an article by Le Blanc *et al*) in which a phthalic acid (not terephthalic) is reacted with formaldehyde in 10-65% oleum. It is said that these references also mention the use of liquid SO_3 but that it is necessary to use pressure equipment. It is against this background that performing the reaction with terephthalic acid and liquid SO_3 at atmospheric pressure is presented as inventive.

The Danish application

77. The Danish application with which I am concerned is the priority document of Lundbeck's Patent Application PCT/DK00/0585. The Danish Application discloses a method for making 5-cbx. It is available for an attack on novelty only under section 2(3) of the Act. The significance of that fact is that it is therefore not available for obviousness.

78. The Danish Application refers to Forney 1 in the following terms:

> "According to [Forney 1] [5-cbx] is the synthesised by reaction of terephthalic acid with trioxane in oleum. During this process, trioxane sublimates and precipitates thereby obstructing the equipment."

79. This is reading more into Forney 1 than was actually expressly disclosed. Read strictly, Forney 1 disclosed "reaction media" containing <20% SO_3 and pure SO_3. But the disclosure in the Danish application is nevertheless a disclosure of oleum.

80. The Danish application continues by describing its invention as providing a process for the manufacture of [5-cbx] comprising the reaction of terephthalic acid and paraformaldehyde in oleum. It is explained that:

> "… as compared with the prior art process [Forney 1], the process of the invention takes place without precipitation of sublimated trioxane which obstructs the equipment e.g. by precipitating in condensers."

81. The reaction is said to be most preferably carried out at about 120° C. There is no indication of the concentration of SO_3 in the oleum used. The description is silent about pressure.

The 513 application

82. 513 is a Lundbeck international patent application published in May 1998. It discloses a method of making citalopram from 5-cbx. Its relevance is that Lundbeck seek to combine its disclosure with Forney 1 in an obviousness attack.

Lack of novelty

Law

83. Section 2 of the Act which gives effect to Article 54 of the European Patent Convention ("EPC") provides:

> "2.-(1) An invention shall be taken to be new if it does not form part of the state of the art.
>
> (2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or

> elsewhere) by written or oral description, by use or in any other way.
>
> (3) The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied, that is to say-
>
> (a) that matter was contained in the application for that other patent both as filed and as published; and
>
> (b) the priority date of that matter is earlier than that of the invention."

84. This part of the law of patents was reviewed by the House of Lords in *Synthon's Patent* [2006] RPC 10. There are two requirements for a claim to be anticipated by a prior document: disclosure and enablement. As to disclosure, Lord Hoffman, who gave the leading judgment, began by citing passages from what he described as two judgments of "unquestionable authority": the speech of Lord Westbury LC in *Hills v Evans* (1862) 31 LJ Ch (NS) 457 at 463 and the judgment of the Court of Appeal in *General Tire and Rubber Co v FirestoneTyre and Rubber Co Ltd* [1972] RPC 457 at 485-486. In the latter case the Court of Appeal said:

> "If the prior inventor's publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent, the patentee's claim will be shown to lack the necessary novelty".

85. At paragraph 22 Lord Hoffmann says this:

> "If I may summarise the effect of these two well-known statements, the matter relied upon as prior art must disclose subject-matter which, if performed, would necessarily result in an infringement of the patent. That may be because the prior art discloses the same invention. In that case there will be no question that performance of the earlier invention would infringe and usually it will be apparent to someone who is aware of both the prior art and the patent that it will do so. But patent infringement does not require that one should be aware that one is infringing: "whether or not a person is working [an] ... invention is an objective fact independent of what he knows or thinks about what he is doing": *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] R.P.C. 76, 90. It follows that, whether or not it would be apparent to anyone at the time, whenever subject-matter described in the prior disclosure is capable of being performed and is such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied. The flag has been planted,

> even though the author or maker of the prior art was not aware that he was doing so."

86. It follows from the above that a generic disclosure will not normally take away the novelty of a subsequent claim to a member of the class. For example disclosure of "fixing means" is not a disclosure of a nail.

87. Mr Turner submits that different considerations apply when one comes to a disclosure of a broad range in a prior art document and an overlapping range in the patent claim. He relies on the decision of the EPO in *Unilever* Case T 666/89. In that case the patent required 8-25% anionic sufactant with 0.001-0.1% cationic polymer. The prior art disclosed 5-25% anionic surfactant (a larger numerical range) and 0.1-5.0% cationic polymer, a small overlap. The Board held the patent nevertheless lacked novelty, despite the fact that a combination of percentages falling within the claim was nowhere specifically taught in the prior art:

> "The Respondent also submitted in the course of oral proceedings that, as a matter of law, it was not permissible to cross the legal borderline between novelty, in the strict sense of a clear and specific disclosure in a prior document of the particular narrow combination of claimed ranges in question on the one hand, and the obviousness of choosing such a combination of ranges from that prior art document containing a disclosure of the broader range, on the other hand. In this connection the Board wishes to set out the general legal principles that apply to so-called "selection" patents. The most important one is that under the EPC patents are not granted for inventions for the sole reason that they are "selections", but only for new and inventive subject–matter of certain defined kinds (Articles 52 to 57 EPC). Selection is in fact only a conceptual tool, used principally in the field of chemical inventions, for deciding novelty in certain situations, which novelty can, however, only be decided under the express provisions of Article 54, and in particular Articles 54(2) and (3) EPC. Article 54 (2) EPC defines the state of the art as comprising "everything made available to the public by means of written or oral description, by use or in any other way". The term "available" clearly goes beyond literal or diagrammatical description, and implies the communication, express or implicit, of technical information by other means as well. Now it is of course true that in the case of documents the natural mode of communicating information is by written or diagrammatical description. However, this is not the end of the matter in deciding what information content has been made available: cf. G 02/88, OJ EPO 1990, 003, para. 10 of the reasons. One example of the available information content of a document extending beyond this literal descriptive or diagrammatical content is the case where the carrying out of a process, specifically or literally described in a prior art document, inevitably results in a product not so described. In

such a case, the prior art document will destroy the novelty of a claim covering a product; cf. T 12/81, "Diastereomers", OJ EPO 1982, 296. It is thus content, express and implied, rather than mere form, that is decisive of the issue of novelty in general, and "selection" novelty in particular (cf. T 198/84, 'Thiochloroformates", OJ EPO 1985, 209, para, 4 of the reasons, English version corrected in T 124/87, "Copolymers", OJ EPO 1989, 491, para 3.2 of the reasons; T 26/85, "Thickness of magnetic layers", OJ EPO 1990, 22, para. 8 of the reasons).

Clearly, the decision on this issue will depend on the facts of each case. Nevertheless, the Boards' jurisprudence has generated certain general principles and broadly applicable concepts, sometimes (erroneously) referred to as "tests". Thus it is clear, (cf. G 02/88 cited above), that matter that is hidden, not in the sense of being deliberately concealed but rather in the sense of being reconditely submerged in a document, will not have been "made available" in the above sense. In the case of overlapping ranges of physical parameters between a claim and a prior art disclosure, what will often help to determine what is "hidden" as opposed to what has been made available, is whether or not a skilled person would find it difficult to carry out the prior art teaching in the range of overlap (T 124/87, OJ EPO 1989, 495, para. 3.4). A similar approach adopted by a Board of Appeal (cf. T 26/85 OJ EPO 1990, 22) for assessing the novelty of a claim in a case where overlapping numerical ranges of certain parameters exist between a claim and a prior art document, is to consider whether a person skilled in the art would, in the light of all the technical facts at his disposal, seriously contemplate applying the technical teaching of the prior art document in the range of overlap. Provided the information in the prior art document, in combination with the skilled person's common general knowledge, is sufficient to enable him to practise the technical teaching, and if it can reasonably be assumed that he would do so, then the claim in question will lack novelty.

In the Board's view, there is no fundamental difference between examining novelty in situations of so-called "overlap" or "selection", and in doing so in other situations, although it may be helpful, in order to verify a preliminary conclusion of a novelty examination in cases of overlap, to investigate whether or not a particular technical effect is associated with the narrow range in question. It needs to be stressed, however that such a particular effect is neither a prerequisite for novelty nor can it as such confer novelty: its existence can merely serve to confirm a finding of novelty already achieved (following T 198/84, OJ EPO 1985, 209, para 7).

> The above concept of "seriously contemplating" moving from a broad to a narrow (overlapping) range, while seemingly akin to one of the concepts used by the Boards for assessing inventive step, namely, whether the notional addressee "would have tried, with reasonable expectation of success" to bridge the technical gap between a particular piece of prior art and a claim whose inventiveness is in question, is fundamentally different from this "inventive-step concept" because in order to establish anticipation, there cannot be a gap of the above kind.
>
> In summary, and in dealing with the Respondent's submission outlined previously, under the EPC novelty must be decided by reference to the total information content of a cited prior document, and in assessing the content for the purpose of deciding whether or not a claim is novel, the Board may employ legal concepts that are similar to those used by them in deciding issues of obviousness, without, however, thereby confusing or blurring the distinction between these two separate statutory grounds of objection."

88. I derive the following guidance from this passage of relevance to this case:

    a) The term "available" goes beyond the strict literal meaning and includes what is implicit as well;

    b) On the other hand, matter may be contained in a document but so submerged in it as not to be available (compare *Dr Reddy's Laboratories v Eli Lilly and Company* [2009] EWCA Civ 1362);

    c) Novelty in the case of overlapping ranges is no different from novelty in other circumstances.

89. What I find, with great respect, more difficult to follow is the notion that it may be legitimate to find lack of novelty because the skilled person would "seriously contemplate" moving from a broad range to a narrow range. Merely by stating the proposition in that way one can see that it is inconsistent with the approach approved by the House of Lords in *Synthon*. There is no disclosure of the narrower range. Moreover, assuming no specific individual value is disclosed, there are no clear directions to use a value within the narrower range. A person carrying out the disclosure of the prior range will not inevitably fall within the claim of the later patent. If the "serious contemplation" approach is indeed the correct approach in the case of overlapping ranges, then overlapping ranges are a special case in the law of novelty, a proposition which is inconsistent with the third proposition derived from T 666/89 itself.

90. As will appear, however, I have not found it necessary to reach a concluded view on whether the cited EPO decision is correct.

Lack of novelty over the Danish Application

91. Lundbeck asserts that the 614 patent is invalid for lack of novelty over the Danish Application. The Danish application does not disclose any specific percentage of SO_3 in sulphuric acid. It just talks about oleum.

92. Mr Turner submitted, firstly, that the Danish application nevertheless disclosed by implication a range of SO_3 concentrations from 1 to 99%. He then submitted, founding himself on the EPO case law which I have referred to above, that the broad range deprived claim 1 of 614 of novelty because the skilled person would seriously contemplate working within the 20-33% range claimed.

93. I think this argument fails at the first hurdle. On no view does the Danish application disclose a range of SO_3 concentrations. It is simply silent on the concentration of SO_3 used. One simply cannot convert an absence of disclosure into the disclosure of a range of concentrations. It is not implicit that the Danish application is referring to a range from 1 to 99% either.

94. It is therefore not necessary for me to decide whether to follow the EPO case law on which Mr Turner relies, particularly as the point does not arise directly. Decisions of an expert tribunal such as the Technical Board of Appeal of the EPO are entitled to respect. On the other hand the court is not bound to follow such a decision. In *Actavis v Merck* [2008] EWCA Civ 444 Jacob LJ likened the EPO to a commodore leading a fleet of ships in a convoy. But he said:

> "In the unlikely event that we are convinced that the commodore is steering the convoy towards the rocks we can steer our ship away."

Obviousness

Law

95. A patent will be invalid on the ground called "obviousness" if the invention is obvious to a person skilled in the art having regard to any matter which formed part of the state of the art: Sections 72(1)(a), 1(1)(b) and 3 of the Act, which enact Article 56 of the EPC.

96. The structured analysis adopted in *Pozzoli v BDMO* [2007] FSR 37, is a helpful guide to the fact finding tribunal, but is not to be regarded as a substitute for the statutory test. The structured approach is as follows:

> "(1) (a) Identify the notional "person skilled in the art";
>
> (b) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;

> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?"

97. Kitchin J concisely summarised the law in *Generics v Lundbeck* [2007] RPC 32 at [72] subsequently approved by the Court of Appeal in that case and the House of Lords in *Conor v Angiotech* [2008] R.P.C. 28 at [42]:

> "The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success."

Over the Forney papers

98. I have identified the person skilled in the art and the common general knowledge above. The inventive concept of claim 1 is the process for making 5-cbx identified in that claim, as I have construed it. I consider this claim first of all. The differences between the Forney papers and claim 1 are (a) to the extent that it is not made absolutely explicit, the use of an unpressurised open reactor; (b) the use of such a reactor in combination with the 20-33% oleum solvent described in Forney 2.

99. Because lack of novelty was thought still to be in issue, much of the cross examination was conducted on the basis of the individual papers. By the end of the trial it was clear that whether the skilled person started from Forney 1 or from Forney 2, he or she would end up with both papers. That is because anyone sufficiently interested in the Note in Forney 1 would chase up the fuller paper, and anyone interested in Forney 2 would note and follow up the cross-reference to Forney 1. Mr Lykiardopoulos submitted that the evidence also established that the skilled person would at least do a patent name search with the name Forney, and would come across the Forney patent. I think that conclusion is justified as well.

100. The overall picture presented by the Forney work is that the chemical reaction of terephthalic acid with formaldehyde in an SO_3-containing medium is a robust reaction over a wide range of reaction conditions. Forney demonstrates a preference for 100% SO_3, but makes it clear that the reaction will give comparably good results with 30% oleum and 30% SO_3 in dimethylsulphate.

101. The evidence established that the skilled person would start by repeating Forney 1's preparative example. This would involve using Sulfan B, i.e. stabilised 100% SO_3 at atmospheric pressure. There is no suggestion that the skilled person would fail to achieve Forney's results.

102. The skilled person would naturally turn to think about whether the reagents described by Forney were the best for his purposes. Dr Scott agreed with Mr Ward that it would be natural to consider alternatives which were less hazardous than 100% SO_3.

103. Once the skilled person considers the use of an alternative reagent the evidence establishes to my satisfaction that oleum is a natural choice. Firstly, it is, to a degree, less hazardous than 100% SO_3. Secondly, it did not seem to me from the evidence that there was much of a choice of "SO_3-containing media" that would occur to the skilled person as being suitable. Oleum is certainly the one that would first come to mind. Thirdly, there is a broad hint in Forney 1 that Forney himself had done experiments in oleum: contrast the third paragraph with the by-product experiment. Fourthly, the skilled person would know that the reaction in 100% SO_3 will produce sulphuric acid: each molecule of water eliminated in the reaction will react with a molecule of SO_3 to form sulphuric acid. The medium is therefore SO_3 in sulphuric acid in any event. Finally Forney 2 makes it clear that the reaction has been tried in 30% oleum and achieved a similar conversion to that achieved with 100% SO_3, albeit both in sealed tubes.

104. It seems to me, therefore, that the skilled person would have every incentive to try oleum in the place of liquid SO_3. The real questions are what sort of oleum (i.e. what SO_3 content) would the skilled person use and whether he would use an open and unpressurised reactor.

What type of oleum?

105. Mr Lykiardopoulos submitted that the skilled person would not naturally choose an SO_3 concentration in the patented range, for a number of reasons. Firstly, he submitted that Forney warns against "dilute oleum" which the skilled person would understand as encompassing 20-33% oleum. He relied on some answers given by Dr Scott and Mr Ward about the ranges of oleum that they would have on their shelf. So Mr Ward said that 20-30% was the "lower range" as indeed it was. Dr Scott's answer was that the lowest available form was about 20%. Secondly, Mr Lykiardopoulos submitted that the Figure 1 graph in Forney 2, coupled with the statement about maximum conversion at 60 mol% would point the skilled person towards higher concentrations of SO_3. Thirdly he points to the fact that SO_3 is said to be "critical to the reaction."

106. I do not accept these submissions. In the context, which includes Forney 1, the skilled person would understand the reference to dilute oleum as being to oleum containing less than 20% SO_3. Above this level the product is produced in excellent yield, a conclusion confirmed by the 30% oleum results in Forney 2. The answers relied upon from Mr Ward and Dr Scott were the only ones they could have given, but were divorced from the context of the Forney papers. There is no indication in the Forney papers that by-product formation is a problem at 30% concentration, which is used extensively in Forney 2. There is no "warning" against 30% SO_3.

107. The reference to the conversion reaching a maximum at 60% also needs to be read in context. Firstly - a fairly minor point - the mol% translates to 55% by weight in the case of oleum. Secondly it must be remembered, as Mr Ward points out, that the comment is made in relation to Figure 1, which only records conversion after one hour. Table II shows that 95% conversion can be achieved in 30% oleum after two hours, which is similar to the results for 100% SO_3 both with and without pressure.

108. Finally the statement that SO_3 is "critical to the reaction" would not be understood as telling the skilled reader that he should adopt a high concentration of SO_3. The

skilled person would understand that the presence of SO_3 was essential, but that conversion did not depend on concentration. So much would be clear from the fact of 95% conversion at only 30% SO_3.

109. Armed with a proper understanding of the papers the skilled person would naturally reach for the sort of oleum he is likely to have at his disposal, which is likely to be in the 20-30% range. Although he might try to obtain a more concentrated oleum, that would not detract from the fact that a 30% oleum was a natural choice.

What type of reactor?

110. There remains the question as to whether the skilled person would try 30% oleum in an open and unpressurised reactor. There is no specific experimental write-up of such a reaction in any of the Forney documents. Lundbeck's case was that it was obvious to use unpressurised reactions if one could, and the statement about the wide range of conditions for the reaction in the third paragraph of Forney 1 would encourage one to believe that one could.

111. Dr Moses's main answer to this was that, although the skilled person might wish to try to do the reaction with oleum in an open and unpressurised reactor, he would not be confident about the results. His view was that there would be doubt about whether the SO_3 would boil away. If enough of it boiled away the SO_3 concentration might fall below 20% and lead to by-product formation.

112. There is, however, no substance in the concern about the SO_3 concentration falling below 20%. Mr Ward explained that there was no reason why the skilled person would not do the preparative reaction in a round bottomed flask using a reflux condenser. In cross examination Dr Moses said this:

> "If I was heating a reaction and trying to keep the reagent concentration above 20%, whatever 20% refers to, I would consider doing it in a sealed vessel. I may consider doing it in an open vessel if I put a condenser on it. I would not know the outcome. I would not be able to reasonably predict whether the SO_3 concentration would drop below 20%. I cannot say that claim 1 is therefore obvious."

113. I think that, in this passage and elsewhere, Dr Moses was saying that he would not be sure about the precise result. His statement about the final question of obviousness must be read in that light. He did not really have any quarrel with the suggestion that an open reactor was a sensible way to proceed.

114. I think all that would be involved would be the sort of routine process investigation that a skilled industrial process chemist would be obliged to perform as part of his job. The skilled person is not going to use a pressurised reactor if the reaction proceeds satisfactorily under atmospheric pressure. It is true, as Dr Moses emphasised regularly, that one would not be certain, or sure, of what the results would be. As he said, if that were the case, one would not have to run the test. But I gained the impression that the uncertainty with which he was concerned was about how good the conversion would be. He did not advance any coherent reason why the reaction

would not proceed, or why, given the strong statement made in Forney 1, one would not be confident that it would do so.

115. I should add that Mr Lykiardopoulos sought to characterise the necessary testing as a research project. He reminded me of what I said in *Teva v Merck* [2010] FSR 17 at [88]-[98] namely that the court should proceed "with caution" when faced with an obviousness attack based on the suggestion that the skilled person would embark on a research program in the course of which he would discover that a product was effective.

116. I do not think that this is that type of obviousness case at all. Mr Ward explained that in the following exchange:

> "Q. He cannot predict the outcome, but he is doing this in order to cover all bases, basically. He picks the papers up and he does a full range of experiments.
>
> A. I would not quite agree that you cannot predict the outcome because I think Forney gives him a very powerful pointer, saying that he can do this over a wide range of conditions. He starts these things with the expectation that he is going to get a lot of positive results rather than a whole host of negative ones."

117. Mr Lykiardoupoulos also pointed to the fact that the patent teaches at [0007] that the invention "allows" the synthesis of 5-cbx with "high yield and purity and easily controllable in the industrial scale". He submits that it would not be obvious that a process which used 20-33% oleum in an open, unpressurised reactor would achieve these good results.

118. I think this submission seeks an answer to the wrong question, because it incorrectly characterises the inventive concept of the claim. Firstly, to bring the good results into the claim, it is necessary for the results to be obtainable across the breadth of the claim: *Brugger v Medic-Aid* [1996] RPC 635 at 656-657. There is, however, no limitation in the claim about either yield or purity. On the construction of the claim which I have adopted, the claim is infringed whenever the prescribed conditions are used to make 5-cbx, even if the process is not taken to completion, or low purity product is obtained. It follows that it is not legitimate to use the results which the invention "allows" to formulate the question for the purposes of determining inventive step.

119. Secondly, the relative terms "high yield and purity and easily controllable conditions" are nowhere defined. The evidence does not enable me to conclude that these parameters for the claimed process are any better or worse than those obtained using 100% SO_3. In the opposition proceedings in the European Patent Office, Infosint relied on some experiments which purported to show improvements, but they elected not to rely on such material here.

120. The result is that one cannot approach obviousness on the basis that the claimed process is better, or even as good as Forney's preferred SO_3 process. It is simply another set of process conditions for performing the same reaction.

121. I have come to the conclusion, therefore, that the skilled industrial process chemist, starting from the Forney work, would arrive at the use of 20-30% oleum in an open and unpressurised reactor without invention. Claim 1 is therefore invalid for obviousness. I would have reached the same conclusion were Forney 1 the only citation to be considered.

122. I have been able to reach this conclusion without relying on the work at Lundbeck before the priority date. In view of the unsatisfactory way in which that material was put before the court, I do not think it would be safe to place reliance on it in the way that Lundbeck would wish. Mr Turner suggested that I could, nevertheless, place reliance on some answers given by Dr Scott, commenting on the work by Lundbeck. He said that I could do so notwithstanding the inaccuracy of the account which was put to him. I think it would be wrong to do so. The material was put to Dr Scott on the footing that this was what Lundbeck had done, and it was reasonable for them to have proceeded in that way. It was hard for Dr Scott to answer that it was not reasonable. He was not given the opportunity of answering the question in the light of a proper explanation of what had happened. Moreover, part of what drove Lundbeck forward was Mr Nielsen's mistaken belief that the preparative example in Forney 1 was oleum, when it was not. It is difficult to place much weight on the work once that mistake had been made. Finally, if the newly disclosed material is indeed the whole of the work which Mr Nielsen did, it seems to have started with a dehydrating agent which is neither oleum nor SO_3. This is not consistent with the way in which the experts were agreed the skilled person would proceed, namely by trying what is disclosed first. I do not think there is anything on which either party can rely in the history. I have disregarded it.

Claim 22

123. The inventive concept of claim 22 is the use of the claim 1 process in a process of making citalopram. Lundbeck advance two cases of obviousness of claim 22. The first is that the skilled person seeking to make use of the process of making citalopram disclosed in 513 would need a method for making the disclosed intermediate, 5-cbx. He would be led to perform a search for methods of making 5-cbx, which would uncover the Forney work, with the obvious consequence that he would use the claimed process to make the intermediate, and the rest of 513 to make citalopram. I call this "the searching argument".

124. Lundbeck's alternative case is that claim 22 is a mere aggregation of features. Forney renders obvious the process of claim 1 for making 5-cbx; 513 discloses a process of converting 5-cbx into citalopram. To take these two process steps and perform them in sequence is not an invention: it is a mere aggregation of process steps. I call this "the aggregation argument".

The searching argument

125. It is common ground that all 513 discloses about the way to make 5-cbx is that it:

> "is commercially available and may be prepared by well known procedures (Tirouflet, J.; Bull. Soc. Sci. Bretagne 26, 1959, 35)."

126. So far as the evidence goes, 5-cbx was not commercially available, and the reference, Tirouflet, does not disclose a method of making 5-cbx. It follows that the skilled person who wishes to put 513 into effect must find a way of making 5-cbx.

127. The Beilstein Handbook of Organic Chemistry is the standard reference for the preparation of organic compounds. It was first published in 1881, set up by a German chemist of that name. It is a practical reference source in the sense that it records what chemists have actually made. As Mr Ward put it, "*you can be sure that entries in Beilstein are useful*". It is now available on-line, but in 2000 the bound volumes would also have been readily available. A search against the formal chemical name for 5-cbx would have uncovered Forney 1 with the indication "(*Prep*)" which means that the paper gives a preparative method.

128. The Dictionary of Organic Compounds is also a standard reference work which the skilled person would be likely to consult. It was first published in 1934. An entry for "Phthalide-5-carboxylic acid" (5-cbx) in the 1996 edition identifies Forney 1 and gives an indication that it provides a synthesis.

129. For completeness, Mr Ward did a search through Chemical Abstracts. This is a much larger database which catalogues almost every publication in the area of chemistry. In my judgment, the skilled person would be more likely to consult Beilstein and/or the Dictionary of Organic Compounds before resorting to Chemical Abstracts.

130. On the basis of these materials, Lundbeck submit that the skilled person would obviously and inevitably find and read Forney 1. I think that is correct.

131. Infosint answers this case in the following way. The evidence showed that, in addition to Forney, the Beilstein search, whether done manually or on-line, would have turned up a number of other papers. These were not placed before the court, and, for all one knows, might have led the skilled person in other directions.

132. Attractively though this argument was presented by Mr Lykiardopoulos, I am not persuaded by it. Firstly, if there were any material in these other documents which would have rendered Forney's synthesis less attractive, then I would have expected this material to be put to Lundbeck's expert. After all, Mr Ward had made clear that he would find Forney 1 and what he would do on finding it. Secondly, it is difficult to see what these other publications could say which would detract from Forney's plain instruction that he has a robust process for making 5-cbx. The fact that there might be other suggestions would not be sufficient to prevent Forney from being at least one obvious process to use.

133. Accordingly, in my judgment, the skilled person starting from 513 would be led to the other Forney materials and to a process within claim 1 for making 5-cbx. Claim 22 is therefore obvious over 513 and Forney.

The aggregation argument

134. It is not therefore necessary for me to deal with the aggregation argument. Mr Turner recognised that it was a more difficult argument both in law and on the facts. It can sometimes be the case that connecting two known processes together in series can be obvious: see the sausage machine case *Williams v Nye* (1890) 7 RPC 602. The EPO

Guidelines for Examination has a similar principle which it expresses in the following way:

> "Obvious and consequently **non-inventive combination** of features:
>
> The invention consists merely in the **juxtaposition** or association of known devices or processes functioning in their normal way and not producing any non-obvious working inter-relationship.
>
> Example: Machine producing sausages consists of known mincing machine and that known filling machine disposed side-by-side." (original emphasis)

135. Equally one can have a claim which identifies two separate and distinct solutions to two separate and distinct problems as in *Sabaf SPA v MFI Furniture Centres Limited* [2004] UKHL 45; [2005] RPC 10. There is no need in those circumstances to show that there was some obvious motive to combine the solutions, if no special advantage flows from the combination. But it is not necessary on the facts of this case to explore these considerations further. For the reasons I have identified in dealing with the searching argument, there was no invention in the present case in combining the teaching of 513 with that of Forney, and it was obvious to do so.

Insufficiency

136. A patent will be invalid for insufficiency (section 72(1)(c) of the Act; Article 123(2) of the EPC) if:

> "the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art."

137. A number of cases have addressed the problem of whether it is enough, where a claim covers a class of products or processes, for the specification of the patent to teach only one, or some but not all, of those products and processes. In *Lundbeck v Generics* [2009] UKHL 12; [2009] RPC 13, the House of Lords held that, in the case of a claim to a single chemical compound (in that case escitalopram), it was necessary only to disclose one way of making it. Lord Neuberger emphasised that statements of general principle in relation to inventions with many embodiments, in which class he included the judgment of the House of Lords in the earlier case of *Biogen Inc v Medeva* [1997] RPC 1, might be irrelevant to a case which consists of a single chemical compound.

138. In *Biogen* Lord Hoffmann explained the principle in the following terms, at 48 line 42:

> "… the specification must enable the invention to be performed to the full extent of the monopoly claimed. If the invention discloses a principle capable of general application, the claims may be in correspondingly general terms. The patentee need not show that he has proved his application in every individual

> instance. On the other hand, if the claims include a number of discrete methods or products, the patentee must enable the invention to be performed in respect of each of them."

139. In the later case of *Kirin-Amgen v Hoechst Marion Roussel Ltd* [2004] UKHL 46; [2005] RPC 9, Lord Hoffmann explained what was meant by a principle of general application in this context:

> "In my opinion there is nothing difficult or mysterious about it. It simply means an element of the claim which is stated in general terms. Such a claim is sufficiently enabled if one can reasonably expect the invention to work with anything which falls within the general term."

The insufficiency alleged here

140. Lundbeck attack claim 22 of the 614 patent on the basis of insufficiency only if claim 22 is not invalid for obviousness. The points on insufficiency do not therefore arise. I will deal with them shortly, in case it turns out that my decision on obviousness of claim 22 is wrong.

141. Lundbeck's pleaded case is:

> "(a) the Patent discloses a process for producing [5-cbx] and not a process extending to the production of citalopram
>
> (b) in the alternative, insofar as the Patent discloses how to make citalopram from 5-cbx, it does so only by reference to a method described in International Patent Application WO 000243431 and in Italian Patent Application IT1999MI0001724 and not by any other methods. For this reason claim 22 is objectionable insofar as it extends to other ways of making citalopram from 5-cbx."

142. Lundbeck elaborated the first point in the following way. Claim 22 is what Lundbeck call a "reach-through" claim. This is intended to convey the notion that the inventive concept of the claim lies in how to make 5-cbx, not in how to make citalopram from 5-cbx. Lundbeck point out that although the addition of the step of making citalopram narrows the claim in some respects, it enables Infosint to complain of the importation of citalopram made from 5-cbx abroad, when this would not have been possible if the patent only had claims to a process for making 5-cbx. Lundbeck submits that the monopoly in these circumstances extends beyond the contribution to the art.

143. I cannot accept this submission. The technical contribution of claim 22 is making citalopram via 5-cbx made by the process of claim 1. So a monopoly which prevents dealings in citalopram made in that way does not extend beyond the contribution. Points made about the consequent scope of protection have nothing to do with insufficiency.

144. The objection pleaded in sub-paragraph (b) relies on passages in the judgment Lord Hoffmann in *Biogen* as subsequently explained by the House of Lords in *Lundbeck v Generics.* Lundbeck rely on the fact that a process claim needs to be sufficient across its entire breadth. The 614 patent discloses only some ways of making citalopram from 5-cbx, not all the ways.

145. Claim 22 is a claim to the general principle of using 5-cbx made by the claim 1 process to make citalopram. Insofar as it relates to making citalopram from 5-cbx it is claimed in entirely general terms. One could reasonably expect the invention to work with any process which produced citalopram from 5-cbx. As such it would have been enabled provided it taught one method by which to make citalopram from 5-cbx. There is no suggestion that the skilled person would have encountered any difficulty in doing so.

Infringement

146. From a date before the priority date both LUPUK and LUMSAS (Lundbeck's facilities in the UK and Denmark respectively) were operating a process for making 5-cbx. Thereafter other companies, identified below in the way they were referred to at trial, became involved in making 5-cbx for Lundbeck. All of the 5-cbx is now made in India. I deal with each process below.

LUMSAS low temperature process

147. This was operated in Denmark from 1986 to April 2003, i.e. both before and after the priority date. The reaction mixture is supposed to be heated to 115-145^{o}C for 17-21 hours. This is a one-pot process: all the reactants are heated up in the same open and unpressurised reactor. Whilst there was some debate in the evidence about individual batches, Infosint accepts that Lundbeck have a defence under section 64 (see below) in relation to the operation of this process up to July 2003. It is therefore not necessary to discuss it further.

LUPUK low temperature process

148. This process was operated in the UK from 1995 to July 2003, again both before and after the priority date. As with the LUMSAS low temperature process, it is accepted that section 64 applies.

LUMSAS and LUPUK high temperature processes

149. This was a two-pot process, introduced in an attempt to avoid the 614 patent. The oleum and terephthalic acid were first heated to 150°C before paraformaldehyde was slowly added, keeping the temperature at about 150°C and maintaining the temperature at about 150°C thereafter.

150. The difference between a one-pot and a two-pot process is no longer relied on as avoiding infringement. Infosint now accepts, however, that Lundbeck have a defence in relation to these processes on the ground that the temperature exceeds 150^{o}C. There is therefore no infringement here either.

Siegfried

151. The temperature here was within the claimed range but the pressure was 1.4 to 1.7 bar above atmospheric. These are undoubtedly pressurised conditions. On the view which I have taken of construction there is no infringement.

CF Pharma

152. This was a multi-pot process. A mixture of terephthalic acid in oleum is first heated up to the reaction temperature before a mixture of paraformaldehyde in oleum is slowly added. Additional SO_3 is then distilled over into the mixture from a third vessel. Lundbeck accept for the purposes of these proceedings that at least one batch falls within the claims. There is therefore infringement. There is an issue about whether section 64 applies to this process.

LUPI

153. These processes were operated at Lundbeck's plant in Italy. The reactor was operated at 0.2 to 0.4 bar above atmospheric.

154. As originally implemented in 2001, the process used 66% oleum. It is common ground that this high oleum process did not infringe.

155. Later, LUPI used an oleum concentration within the claimed range. Dr Scott accepted that the reaction was being run under pressure, but maintained that the reaction was technically equivalent because the extra pressure had no effect on the reaction. He had not, however, done any analysis to determine whether the additional pressure might have a minor effect on impurities or yield. As I have construed the claim, pressurised reaction conditions are not covered. There is therefore no infringement.

SF Chem

156. This process is also run at 1.5 to 1.7 bar over atmospheric. The conclusion is the same as for Siegfried and LUPI: pressurised conditions do not infringe.

Ramdev

157. There are two Ramdev processes, one run at 140-145^{o}C (up to 26th October 2009) and the other at 147-152^{o}C (thereafter). Both are two-pot processes.

158. The first process infringes the claims, subject only to the section 64 defence.

159. The batch records for the post-26th October 2009 process reveal:

    i) Trial Bundle G1 tab 12 shows that the recorded temperatures were all above 145^{o}C.

    ii) Trial Bundle H tab 7 shows that the temperatures were all above 145^{o}C.

160. There is therefore no evidence of any infringement of the claims by these processes.

Jet

161. This is a two pot process. The batch record at Trial Bundle H tab 8 shows the process is supposed to run at 145°C but was measured once at 148.1°C, just before the reaction ended. I consider that, on the balance of probabilities, 5-cbx is being made at temperatures within the claimed range. It seems overwhelmingly likely given the intended temperature and the 148.1°C reading, that in practice the temperature would fluctuate above and below the 145°C mark. 5-cbx is accordingly likely to be made within the claimed range.

Suven

162. This is run at above 145°C and is two-pot. Trial Bundle I tab 10 reveals a process where the temperature varied with time between 146 and 147°C. The batch record at Trial Bundle H tab 9 reveals slightly higher temperatures. This one is very close to the line, but I think it is just outside the temperature range specified. It does not infringe.

Section 64

163. Section 64 of the Act provides:

> "(1) Where a patent is granted for an invention, a person who in the United Kingdom before the priority date of the invention –
>
> (a) does in good faith an act which would constitute an infringement of the patent if it were in force, or
>
> (b) makes in good faith effective and serious preparations to do such an act,
>
> has the right to continue to do the act or, as the case may be, to do the act, notwithstanding the grant of the patent; but this right does not extend to granting a licence to another person to do the act.
>
> (2) If the act was done, or the preparations were made, in the course of a business, the person entitled to the right conferred by subsection (1) may–
>
> (a) authorise the doing of that act by any partners of his for the time being in that business, and
>
> (b) assign that right, or transmit it on death (or in the case of a body corporate on its dissolution), to any person who acquires that part of the business in the course of which the act was done or the preparations were made.
>
> (3) Where a product is disposed of to another in exercise of the rights conferred by subsection (1) or (2), that other and any person claiming through him may deal with the product in the same way as if it had been disposed of by the registered proprietor of the patent."

164. In *Lubrizol Corp. v Esso Petroleum* [1997] RPC 195, Jacob J (as he then was) noted an apparent difference in judicial opinion on the scope of the defence that had arisen between the decision of Aldous J (as he then was) in *Helitune v. Stewart Hughes* [1991] FSR 171 at 205-206 and Mr Laddie QC sitting as a Deputy Judge of the Patents Court (as he then was) in *Lubrizol v. Esso (No.1)* [1992] RPC 281 at 295. Aldous J had appeared to suggest that s.64 provided a general licence under the patent. On appeal in *Lubrizol Corp. v Esso Petroleum* [1998] RPC 727 at page 770, Aldous LJ explained the approach as follows:

> "It seems that the words used by me in *Helitune* have been read in a way not intended. Clearly the right given by section 64 cannot be a right to manufacture any product nor a right to expand into other products. However I do not believe that identicality is required. I believe that the judge was right in this case when he said:
>
> > If the protected act has to be *exactly* the same (whatever that may mean) as the prior act then the protection given by the section would be illusory. The section is intended to give a practical protection to enable a man to continue doing what in substance he was doing before."

165. LUMSAS and LUPUK were operating the processes I have described as their low temperature process from dates before the priority date of the 614 patent. They continued to operate substantially the same processes thereafter until the temperature was changed to the non-infringing high temperature process. I have already recorded the fact that it is common ground that they had a section 64 defence in respect of the importation of citalopram made by those processes. There are really only two issues left on the facts. The first is whether importation of product made from 5-cbx made by the two-pot processes which would otherwise come within the scope of the claims is within the scope of the right given by section 64. The second is whether the importation of the enantiomer, escitalopram, is within that right.

The two pot process

166. The two-pot process was introduced by Lundbeck in an attempt, now acknowledged to be inadequate, to avoid the claims of the 614 patent. Mr Turner submitted, firstly, that it was not necessary to enquire into how the citalopram was made before it was imported. The act of importation of citalopram before the priority date gave the right to import citalopram after the priority date even if made by a different process. He says that this is the right approach because the act which gives the rise to the right under section 64 is the act in the United Kingdom – importation of citalopram.

167. Whilst the language of section 64 does not sit entirely happily with the case of infringing importation of the direct product of a process, I am unpersuaded by Mr Turner's submission. The prior act which section 64 refers to is an act which would infringe the patent if it were in force. It makes no sense to characterise this as "importation of citalopram". The only act which infringes is the importation of citalopram made by a claim 22 process. Section 64 therefore gives a right to continue to import citalopram made by a claim 22 process, not a right to import citalopram however made.

168. Mr Turner next submits that the two-pot process does not make any difference, because it is substantially the same commercial process as the one-pot process.

169. Mr Trickett was responsible for introducing the two-pot process at LUPUK. He did so under instructions to change the process for patent infringement reasons. He accepted in cross-examination that making the changes was like starting again. The new process (this is what Mr Trickett called it) involved extra equipment, new timings, a pre-heating step and new pipework. Dr Scott described the new process as "operationally different".

170. In my judgment Lundbeck are not entitled to a section 64 defence in relation to the importation of citalopram made by two-pot processes. Such processes are not substantially the same as what was done before. To the extent that those processes use the claimed process parameters, they infringe the claims.

Escitalopram

171. It is not suggested by Lundbeck that they imported or made serious and effective preparations to import escitalopram by the process of claim 22 before the priority date. The section 64 defence to the importation of escitalopram is based on the importation of racemic citalopram.

172. I do not think there is any difficulty here. The importation of escitalopram is not substantially the same act as the importation of citalopram. As Professor Davies' evidence makes clear, although escitalopram is contained within racemic citalopram, the two materials have different properties, and are different articles of commerce as a result.

Pause in production

173. There was a further point mooted about whether Lundbeck could resume production according to the LUMSAS or LUPUK low temperature processes, which they stopped using in 2003, and still rely on section 64. It does not seem to me that it arises directly, and I therefore do not need to deal with it.

Section 68 – Limitation of remedy

The Law

174. Lundbeck say that Section 68 of the Act provides them with a partial defence. The point does not arise because the patent is invalid, and for that reason not infringed. Nevertheless I will deal with the point in case I am wrong on validity.

175. Section 68 has been amended. In the section as set out below, the words in square brackets were removed and the words in bold added by the Intellectual Property (Enforcement, etc) Regulations 2006 (SI 2006/1028) coming into force on April 29 2006.

> "68. Where by virtue of a transaction, instrument or event to which section 33 above applies a person becomes the proprietor or one of the proprietors ... of a patent and the patent is subsequently infringed [, *the court ... shall not award him damages or order that he be given an account of profits in respect of such an infringement occurring*] before the transaction, instrument or event is registered, **in proceedings for such an infringement, the court ... shall not award him costs or expenses** unless –
>
> (a) the transaction, instrument or event is registered within the period of six months beginning with its date; or
>
> (b) the court ... is satisfied that it was not practicable to register the transaction, instrument or event before the end of that period and that it was registered as soon as practicable thereafter."

176. In *Siemens v Thorn* [2008] RPC 4 Mann J held that the unamended version of section 68 applies to acts of infringement committed before the section was amended. Although the Court of Appeal allowed an appeal on the non-registration point, the issue of whether or not the amendments to section 68 were retrospective was not the subject of any appeal – see the Court of Appeal's judgment at [2008] EWCA Civ 1161 at [79]. Infosint did not invite me to differ from Mann J, but reserved an argument that he was wrong for a higher court.

177. The position is therefore that, if the point is a good one, Infosint would not, if the patent had been infringed, have recovered damages or an account of profits for infringements before April 29 2006, and not recover costs thereafter.

178. Section 32(1) requires the Comptroller to maintain the register of patents. Section 32 defines "register" (as a noun) as "the register of patents" and (as a verb) as "to register particulars, or enter notice, of that thing in the register and, in relation to a person, means to enter his name in the register". Cognate expressions, in which one would include the word "registered" used in section 68, are expressly required to be construed accordingly.

179. Section 33, which is cross-referred to in section 68, is a section which sets out certain effects of registration. For present purposes it is sufficient to note that it is a section which applies by section 33(3)(a) to the assignment of a patent or application for a patent, or a right in it.

180. By Implementing Regulations pursuant to the EPC it is provided that:

> "22(1). The transfer of a European patent application shall be recorded in the European Patent Register at the request of an interested party, upon production of documents providing evidence of such transfer.
>
> 85. Rule 22 shall apply to any transfer of the European patent made during the opposition period or during opposition proceedings."

181. The provisions of the Act which govern the relationship between the European and national phases include:

> "78.-(1) Subject to the provisions of this Act, an application for a European patent (UK) having a date of filing under the European Patent Convention shall be treated for the purposes of the provisions of this Act to which this section applies as an application for a patent under this Act having that date as its date of filing and having the other incidents listed in subsection (3) below, but subject to the modifications mentioned in the following provisions of this section."

182. Section 78(2) provides that the section applies to sections 30 to 33 of the Act. Section 78(3)(f) includes as one of the incidents referred to in subsection (1):

> "(f) registration of the application in the register of European patents shall be treated as registration under this Act."

183. Accordingly, although Section 78(3)(f) is not absolutely clear on the point, it would appear that if the applicant succeeds in registering an assignment of an application for a European patent (UK) on the register kept by the European Patent Office, then that will be treated as valid registration under the Act. There is, however, no corresponding provision dealing with the assignment of the European patent. Although the EPO will, by virtue of Rule 85, register such an assignment, there is no provision deeming such registration to be registration under the Act.

184. The scope of the defence afforded by section 68(b) was explained by the Court of Appeal in *Molnlycke v Procter & Gamble* [1994] RPC 49 at 139 in the judgment of Sir Donald Nicholls VC:

> "It is relevant to consider the nature of the responsibility or obligation imposed and its meaning must depend on the conduct or actions which the person on whom the obligation is placed would ordinarily be expected to take to comply with that obligation. The purpose of the registration requirements of the

> Patents Act 1977 is to make the subject matter of the application and details of relevant transactions available to the public…
>
> In this context "practicable" means that the applicant for registration must take all the steps which the reasonable applicant acting on competent advice would take in the circumstances to secure registration."

185. In that case an application to register an assignment had been made but not acted on by the Patent Office because of a settled practice of the Office not to register assignments when there were revocation proceedings pending. There was no statutory basis for such a practice. The Court held that a competent agent could properly take the view that she had done all she reasonably could in the circumstances to obtain registration.

Facts relevant to section 68

186. The application for the 614 patent was filed by Norpharma on 18th January 2000. In February 2002 Infosint was granted an option to purchase a portfolio of patent applications and rights, including the application for the patent in suit. On 18th March 2002 Infosint stated that they intended to exercise the option and would pay the consideration to Norpharma by 25th March.

187. The patent in suit was granted on 19th June 2002. By an assignment dated 22nd July 2002 Norpharma purported to assign the application for the patent in suit to Infosint. On 11th July 2002, Italian Patent Attorneys acting for Infosint, Dragotti & Associatti ("Dragotti"), had written to the European Patent Office to notify it that the "above mentioned patent application" had been assigned from Norpharma to Infosint and asking them to record the assignment "before entering into the national phase". On 25th July the assignment was sent to the EPO by Dragotti. On 5th August the EPO sent an acknowledgment confirming that as requested "the entries pertaining to the applicant of the above-mentioned European patent application/proprietor of the above-mentioned European patent" had been amended. The registration of the change took effect on 26th July 2002.

188. On 29th July 2002 Dragotti wrote to patent attorneys in the UK. It was apparent from the letter that the patent had been granted and that it had been assigned from Norpharma to Infosint. The letter also informed the UK attorneys that the recordal of the assignment had been requested at the EPO. The purpose of the letter was to ask the UK attorneys to attend to the "formalities for recordal" of the case in the UK. On 5th August 2002 the UK attorneys wrote to the UK Patent Office giving the reference number of the granted patent and heading the letter "Infosint SA". However, the letter only expressly requested the entry of the UK attorneys as the address for service in respect of the Patent. It did not expressly request alteration of the name of the proprietor. Infosint was however recorded as the proprietor in the books and records of the UK agents.

189. On 7th August 2002, Dragotti forwarded the EPO acknowledgment concerning the registration of the assignment. This was not, so far as the correspondence shows, forwarded on to the Patent Office here.

190. A similar procedure adopted with agents in the Irish Republic resulted in the Irish register being amended to record Infosint as proprietors.

191. When the 614 patent entered the national phase in the UK it remained in the name Norpharma. Consequently, in the present proceedings Norpharma were named as defendant.

192. In consequence of the commencement of these proceedings, eight years later, on 17th May 2010, Infosint requested registration at the UKIPO of the 22nd July 2002 assignment. The assignment was registered at the UKIPO on 9th June 2010.

Discussion and conclusion

193. It is plain on these facts that the registration of the assignment at the UKIPO did not happen within six months of the date of the assignment. Infosint have two answers to this:

    i) The registration of the assignment at the EPO counts as registration for the purposes of section 68;

    ii) Alternatively, the defence under section 68(b) applies because it was not practicable to register the transaction, instrument or event before the end of that period and that it was registered as soon as practicable thereafter.

194. On the first point Mr Lykiardopoulos argues that registration of the assignment at the EPO under Rule 85 counts as registration under the Act. So the assignment was registered within 6 months of its date. I am unable to accept this argument.

195. The "transaction, instrument or event" with which this case is concerned is the assignment dated 22nd July 2002. It is true that, according to its terms, it is an assignment of the application, not the patent. But by the time it came to be executed the patent had been granted. The assignment thereby operated to convey the title to the patent on that date. It makes no sense to regard it as an assignment of the application, which had by then ceased to exist.

196. It was therefore the assignment of the patent which had to be registered, and which was registered at the EPO. There is no provision which deems such registration to be registration under the Act (unlike section 78(3)(f)). So the assignment needed to be registered here as well. That did not occur.

197. Mr Lykiardopoulos submits that this result does not give effect to the purpose of the provision, which is to put the public on notice of the assignment. He submits that this purpose is satisfied if the assignment is registered at the EPO. I do not agree. Once the patent is granted, it is a bundle of national rights, each separately assignable. It is therefore to the individual national registers that the public are required to look. The public should not be expected to check the EPO register to see whether by any chance an assignment of the patent was registered in the opposition period under rule 85 and then not registered here.

198. I turn therefore to whether section 68(b) provides an answer. The burden of Mr Zanetti's evidence was that, in the usual course, he would have expected the inventors

to have given instructions to agents to register the assignments in the individual countries to the extent it was necessary to do so, and he thought this had been done.

199. Mr Lykiardopoulos submits that Infosint have done all that was practicable by instructing its agents in this way. He focused on the words of Sir Donald Nicholls VC in *Molnlycke* and submitted that, whatever might have been done by the applicants' agents, the *applicants* had taken all the steps which the reasonable applicant acting on competent advice would take in the circumstances to secure registration.

200. I do not accept that Infosint can avail itself of section 68(b). The defence is only available if it is not practicable to register the assignment. As *Molnlycke* shows, the section requires an investigation of what was done by the applicant and his agents, not just the applicant alone. The fact that the patentee's agent has not succeeded in registering the assignment despite being instructed to do so does not mean that it was not practicable to register the assignment. It would be an odd conclusion if the effect of the section depended on whether the patentee used an employee or an agent to effect registration. Yet on Mr Lykiardopoulos' argument it would make all the difference: in the one case it would be practicable and in the other case it would not.

201. The facts demonstrate that it plainly was practicable to register the assignment, as the registration which was achieved in Ireland shows. It was practicable to register it here as well. The section 68 defence succeeds.

Conclusions

202. My conclusions are that the 614 patent is invalid. If it had been valid the patent would have been infringed by some of the processes relied on. If there had been infringement, the remedies in damages and costs would have been limited by section 68.

203. In slightly more detail:

i) Claim 1 is not invalid for lack of novelty over the Danish application.

ii) Claims 1 and 22 are invalid for obviousness over the Forney papers.

iii) Claim 22 is not invalid for insufficiency.

iv) The following processes would not fall within the scope of the claims relied upon, on oleum concentration, temperature or pressure grounds as identified in brackets:

a) The LUMSAS and LUPUK high temperature processes (temperature);

b) The Siegfried process (pressure);

c) The LUPI processes (oleum and pressure);

d) The SF Chem process (pressure);

e) The Ramdev post-26th October 2009 process (temperature);

f) The Suven process (temperature).

v) Lundbeck has a section 64 defence in relation to importation of racemic citalopram made by the LUMSAS and LUPUK low temperature processes, but not in relation to escitalopram or any two-pot process.

vi) Had the patent been valid, there would therefore have been infringement of claim 22 by importation of product made by:

a) The CF Pharma process;

b) The Ramdev pre-26th October 2009 process;

c) The Jet process.

vii) The last conclusion applies whether the product is citalopram or escitalopram, its enantiomer.

viii) If there had been infringement, the section 68 defence would have succeeded in relation to damages before 29th April 2006 and costs on and after 29th April 2006.