What a Chemist Needs to Know…
… about Patents

Prepared for
SCI

April 2014

Litigation Case Studies of Patent Validity

Outline of presentation - The attacks to be addressed

- Lacks Novelty
- Obvious
- Insufficient (Specification does not enable the skilled person to put the invention into practice)

Lack of Novelty/Anticipation - a Reminder

Section 2 Patents Act 1977

- *(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.*

Lack of Novelty/Anticipation a Reminder

- Why should someone be entitled to a monopoly if the world already knows how to perform the invention?
- Why should someone who was already performing the invention be prevented from doing so by virtue of a patent?

Self Anticipation

What did you do that will come back to bite you?

Did you enable the Public to make or obtain the invention before the priority date?

What to watch out for...

Self Anticipation 1

Lux Traffic Controls Ltd v Pike Signals Ltd [1999] RPC 107

Self Anticipation 1

Lux Traffic Controls Ltd v Pike Signals Ltd [1999] RPC 107

- *Patent for a traffic control system*
- *Claim 1:*

  A traffic light control system comprising a moving vehicle detector for each unit of a set of lights and a common controller responsive to the detection of a moving vehicle to turn the lights of the unit associated with the detection vehicle green after ensuring that the lights of the other units are compatible, wherein a minimum green period is initiated by a first detection, and wherein a second detection, within that period, is used to check consequential traffic flow and if it does not materialise to extend that period.

Self Anticipation 1

Lux Traffic Controls Ltd v Pike Signals Ltd [1999] RPC 107

The defendant alleged that claim 1 was anticipated by:

1. oral disclosure by Mr. Lux (of the Patentee) at a meeting of the Association of Road Traffic Sign Makers held on 28 September 1982;
2. disclosure by the Patentee to the Department of Transport in a letter dated 22 June 15 1982; and/or,
3. the use by the Patentee of a prototype traffic controller in Somerset between 20 September 1982 and February 1983.

Self Anticipation 1

Lux Traffic Controls Ltd v Pike Signals Ltd [1999] RPC 107

Point 1 (oral disclosure)

- At the time when Lux had developed a prototype controller which included the features of the invention, and before filing the patent application, Mr Lux (of the patentee) provided certain information to a meeting of the Assocaition of Road Traffic Sign Makers
- Minutes of that meeting provided a summary of Mr Lux's report, but were not conclusive as to what was said.
- There was no specific evidence of what was said, and if Mr Lux had provided an anticipating disclosure, it would have conflicted with the minutes.
- The judge found that it was likely that the minutes were correct. No anticipation.

Self Anticipation 1

Lux Traffic Controls Ltd v Pike Signals Ltd [1999] RPC 107

Point 2 (Letter to the Department of Transport)

- Lux had sent a confidential letter to the DoT outlining the details of the invention.
- The Defendant's argued that by the time of the priority date the DoT would not have considered itself bound to keep the information confidential.
- Evidence from the DoT refuted this argument.
- No Anticipation.

Self Anticipation 1

Lux Traffic Controls Ltd v Pike Signals Ltd [1999] RPC 107

Point 3 (Testing in Somerset)

- Lux trialled prototype controllers in Somerset before the priority date.
- Those performing the trial were told about the importance of keeping information secret.
- BUT:
  - The controller had been used in public.
  - If the skilled person had taken the time to test the way traffic lights worked using the controller the skilled person would have worked out the basis of the invention.
  - It was not necessary for a skilled person to have actually witnessed the trial, or indeed come to such conclusions. The possibility of making or obtaining the invention was enough.

Self Anticipation 2

Folding Attic Stairs Ltd v The Loft Stair Company Ltd & anr. [2009] EWHC 1221

Self Anticipation 2

Folding Attic Stairs Ltd v The Loft Stair Company Ltd & anr. [2009] EWHC 1221

- Patent for folding attic stairs - applied for on 5 November 1996
- Around 18 January 1996 a photographer from the Irish Times and the Irish Minister for Trade attended the patentee's factory.
- A prototype of the relevant attic stairs was being tested in the factory and the Minister was photographed in front of the prototype.

Self Anticipation 2

Folding Attic Stairs Ltd v The Loft Stair Company Ltd & anr. [2009] EWHC 1221

Defendants argued:

1. The published photograph disclosed the invention; and
2. The invention had been disclosed to the minister and the photographer during the tour of the factory.

Self Anticipation 2

Folding Attic Stairs Ltd v The Loft Stair Company Ltd & anr. [2009] EWHC 1221

- The photograph did not anticipate the invention not all of the relevant information was revealed to the skilled person.
- Not all of the key parts of the ladder could be seen!

Self Anticipation 2

Folding Attic Stairs Ltd v The Loft Stair Company Ltd & anr. [2009] EWHC 1221

- The Minister and the Photographer could however see all aspects of the invention and they were not subject to any terms of confidentiality.
- But – (distinguishing from *Lux*)
  - as the viewing was on private property (so not open to the skilled person theoretically dropping by); and,
  - as the Minister and photographer were not themselves persons skilled in the art;

  the judge considered that the Minister and photographer would not have been able to describe the key features of the invention.

Self Anticipation 2

Folding Attic Stairs Ltd v The Loft Stair Company Ltd & anr. [2009] EWHC 1221

- "Would an abstruse chemical formula displayed on private premises be 'made available to the public' if none were present except a child who could not understand it;..."
- "In sum I would hold that there is no irrebuttable presumption of law that information that is capable of being perceived by persons who are on private premises is in fact perceived by them, if the circumstances are such as to make it unlikely that those persons were interested in the subject matter"

Self Anticipation 3

Qual-chem Ltd v Corus UK Ltd [2008]
EWPCC (1)

Self Anticipation 3

Qual-chem Ltd v Corus UK Ltd [2008] EWPCC (1)

- Qual-chem had a patent for “a method of introducing additives in steel making”
- Qual-chem had however trialled the process at Corus’ works from 8 August 1999 to 6 September 1999.
- 10 Days later Qual-chem filed the patent.
- Later Qual-chem accused Corus of infringement for using the patented method.

Self Anticipation 3

Qual-chem Ltd v Corus UK Ltd

- The trials were an enabling disclosure to a Mr Govan of Corus.
- However:
  - Whilst employees of Corus such as Mr Govan were present during the trial and participated in the Corus trial, they were not 'free in equity and law' whatever use they wished of any information gleaned from any of the Qual-chem experimental trials.
  - Evidence showed that the trials had not used all of the patented method, in particular they did not use 'integer E'.
- The patent was valid (and later found to be infringed)

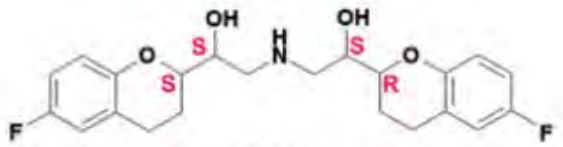
Self Anticipation 4

Actavis UK Ltd. v Janssen Pharmaceutica N.V. [2008] EWHC 1422 (Pat)

Self Anticipation – Finally Some Chemistry!

Actavis UK Ltd. v Janssen Pharmaceutica N.V. [2008] EWHC 1422 (Pat)

- Janssen held a patent which covered the stereochemical blood pressure drug nebivolol.
- Actavis sought to revoke the patent, which grounds included self anticipation.
- Actavis claimed that the structure and stereochemistry were disclosed by an employee of Janssen.



l-Nebivolol

Self Anticipation – Finally Some Chemistry!

Actavis UK Ltd. v Janssen Pharmaceutica N.V.

- The Starting Point – EPO Board of Appeals in T 0296/87 Hoechst (Enantiomers).
- Enantiomers are not disclosed by the racemate!

Self Anticipation – Finally Some Chemistry!

"...the substances in question can indeed occur in many conceivable configurations (D- and L-enantiomers); that alone does not mean, however, that these configurations are disclosed in individualised form. The novelty of the D- and L-enantiomers is therefore not destroyed by the description of the racemates."

Self Anticipation – Finally Some Chemistry!

“The situation is different if the state of the art includes enantiomers - howsoever designated (D, d, L, l or + or -) - which are specifically named and can be produced. The Board's present view accords with its established case law on the novelty of chemical substances whereby the only technical teachings prejudicial to novelty are those which disclose a substance as the inevitable result of a prescribed method or in specific, i.e. individualised, form (cf. T 12/81, "Diastereomers", OJ EPO 1982, 296; T 181/82, "Spiro compounds", loc. cit.; T 7/86, "Xanthines", OJ EPO 1988, 381).”

Self Anticipation – Finally Some Chemistry!

Actavis UK Ltd. v Janssen Pharmaceutica N.V.

- Actavis argued that the employee showed a slide with the patented structure and stereochemistry.
- The abstracts of the Guildford meeting were published 6 months after the priority date and showed the structure and stereochemistry.
- Janssen's witness was found to have no independent recollection of the presentation.
- One slide was missing from the disclosure.
- Judge found that the employee did show such a slide, despite no actual evidence of this.

Self Anticipation – To think about...

- *Confidentiality*
- *Access to your research*
- *Publication v.s. patent*
- *Who you show to your lab*
- *What you say outside of confidence*
- *What you put in presentations and posters*
- *What you put in publications*

Third Party Anticipation

The uncontrollable quantity

If you have a valuable patent, your competitors will leave no stone unturned in trying to find a way to stop your monopoly and will spend far more time and money than on the prior art search undertaken when the patent was examined.

Third Party Anticipation

Windsurfing International v Tabur Marine [1985] RPC 59

- Claimant held a patent for a “wind propelled vehicle”.
- Priority date of 27 March 1968.
- Unfortunately for the Claimant, a boy of 12 created a Windsurfer on Hayling Island for use on summer weekends around 10 years before the priority date.
- The use of the board was in public – inlets off the coast of Hayling Island.

Third Party Anticipation

Windsurfing International v Tabur Marine [1985] RPC 59

- The Claimants argued that it was:

  "...contrary to common sense that a patent which has resulted in a considerable commercial success over the past ten years should be invalidated as a result of the use, years ago and on a comparatively obscure holiday beech, of a primitive play thing put together by an adventurous youth."

- The Court of Appeal did not find it contrary to common sense at all:

  "...it would be wrong to prevent a man from doing what he has lawfully done before the patent was granted."

No Inventive Step - Obvious

What would the skilled person do based upon the prior art?

Can’t predict at grant - hard to determine without the art and a court expert

Inventive Step - a Reminder

Section 3 Patents Act 1977

- An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art,....
- Who is the person skilled in the art?

The Skilled Person

- There are often disputes about the attributes of the skilled person (or skilled team).
- What is obvious to one group of professionals in one technical field, may not be obvious to others in an unrelated field.
- The skilled person (or team) is identified by considering the art in which the problem that the invention solves lay.
- It is the notional person (or team) in that art that is relevant.

Attributes of The Skilled Person

- "It is settled that this man, if real, would be very boring – a nerd."
- "...the hypothetical addressee is a skilled technician who is well acquainted with workshop technique and who has carefully read the relevant literature."
- "He is supposed to have an unlimited capacity to assimilate the contents of, it may be, scores of specifications but to be incapable of scintilla of invention."
- "When dealing with obviousness, unlike novelty, it is permissible to make a "mosaic" out of the relevant documents, but it must be a mosaic which can be put together by an unimaginative man with no inventive capacity."

Attributes of The Skilled Person

- "The no-mosaic rule makes him also very forgetful. He reads all the prior art, but unless it forms part of his background technical knowledge, having read (or learnt about) one piece of prior art, he forgets it before reading the next unless it can form an uninventive mosaic or there is a sufficient cross reference that it is justified to read the documents as one."
- The level of skill of the skilled person will depend upon the subject matter of the patent and the prior art.
- Often the level of skill walks a fine line between obviousness and insufficiency.

Attributes of The Skilled Person

- The court is assisted however assisted in understanding the skilled man by experts who are more often than not far far far more skilled and inventive than the nominal skilled person would be.

Common General Knowledge

- Identifying what was common general knowledge is important as this feeds into the understanding of the skilled person.
- In invalidity actions, the claimant will often rely upon obviousness over GCK in addition to particular pieces of ‘prior art’.

Common General Knowledge

- Per Laddie J in *Raychem Corp's Patents*
- *"The common general knowledge is the technical background of the notional man in the art against which the prior art must be considered.*
- *This is not limited to material he has memorised and has at the front of his mind. It includes all material in the field he is working in which he knows exists, which he would refer to as a matter of course if he cannot remember it and which he understands is generally regarded as sufficiently reliable to use as a foundation for further work or to help to understand the pleaded prior art.*
- *This does not mean that everything on the shelf which is capable of being referred to without difficulty is common general knowledge."*

Common General Knowledge

- Per Jacob LJ in *Generics v Daiichi* (regarding the above quotation)
- *“Of course material readily and widely to hand can be and may be part of the common general knowledge of the skilled person – stuff he is taken to know in his head and which he will bring to bear on reading or learning of a particular piece of prior art.*
- *But there will be other material readily to hand which he will not carry in his head but which he will know he can find if he needs to do so (my emphasis). The whole passage is about material which the skilled man would refer to "as a matter of course." It by no means follows that the material should be taken to be known to the skilled man if he has no particular reason for referring to it..”*

Obvious?

Case Study - Generics (UK) Ltd and others v H Lundbeck A.S.

- The dispute concerned Lundbeck's patent for the anti-depressant escitalopram.
- Escitalopram is the (+) enantiomer of citalopram.
- Citalopram was first synthisized by Lundbeck in 1972 and launched as an anti-depressant in Denmark in 1989.

Obvious?

Case Study - Generics (UK) Ltd and others v H Lundbeck A.S.

The approach a court takes in assessing obviousness is set out in earlier case law (*Windsurfing International Inc. v Tabur Marine* :

- Identify the inventive concept of the claim.
- Assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and impute to him what was, at that date, common general knowledge in the art in question.
- Identify the difference(s) between the prior art under consideration and that in the inventive concept of the claim.
- Ask whether the difference(s) would have been obvious or required invention.

Obvious?

Case Study - Generics (UK) Ltd and others v H Lundbeck A.S.

- The inventive concept was (generally speaking) the new anti-depressant compound, (+) citalopram.
- But was that inventive, particularly given that the court found there to be a motive to resolve chiral compounds!

Obvious?

Case Study - Generics (UK) Ltd and others v H Lundbeck A.S.

"102. ...by 1988 it was well understood by medicinal chemists that:

- the activity of the individual enantiomers of a racemate might well be different;
- an inactive enantiomer might properly be considered an impurity;
- an inactive enantiomer might nevertheless have pharmacological or toxicological effects;
- in the course of drug development, a manufacturer should therefore consider both enantiomers, as well as the racemate, to be potential drugs;
- when filing an IND application with the FDA the applicant should ideally have either separated the various enantiomers or synthesised them separately and provided data in relation to each of them."

Obvious?

Case Study - Generics (UK) Ltd and others v H Lundbeck A.S.

- The court was required to assess the various different methods that the skilled person could have used (or tried) to resolve the racemate.
- The Claimants (revocation action) argued that the skilled man would have tried and would have succeeded in usingL
  - chiral HPLC techniques (using Chiracel OD); and/or,
  - a chiral intermediate.
- Naturally these were techniques which (with hindsight) did result in success.
- Would the skilled person have gone down these roads?

Obvious?

Case Study - Generics (UK) Ltd and others v H Lundbeck A.S.

- For the Chiral HPLC case, the Claimants set out a number of steps that were said to be obvious for the skilled team to take, and which would lead to separation:
  - It would occur to any skilled team who had not been able to or who had difficulty in obtaining enantiomers of citalopram by classical methods to look to chiral HPLC as a method of obtaining them.
  - The skilled team would recognise that citalopram was a reasonably promising candidate for resolution; although it would not be known in advance that it would be successful.
  - The team would not be deterred from trying by general considerations of “unpredictability” in this as in any other field of chemistry.
  - The obvious approach would be to do a literature search and see what guidance was available and what columns were available, and to obtain the manufacturers’ literature on suitable column types; they would prefer columns and media where preparative work was described as possible and where preparative columns were commercially available.

Obvious?

Case Study - Generics (UK) Ltd and others v H Lundbeck A.S.

- They would exclude columns which would plainly not work such as the Pirkle and ligand exchange columns.
- They would rapidly see there was a limited shortlist of columns from three classes, namely: Beta-cyclodextrins, Daicel polysaccharide and protein based columns.
- Protein columns would be disfavoured because of their poor potential for preparative work.
- Other columns such as microcrystalline cellulose triacetate would have also have been worth trying; perhaps also polymethyl methacrylates.
- The upshot would have been a list of columns essentially including the polysaccharide, inclusion complex and protein based CSPs.

Obvious?

Case Study - Generics (UK) Ltd and others v H Lundbeck A.S.

- There were very few manufacturers, the principal ones being Daicel, Machery-Nagel and Astec.
- The skilled person would then prioritise the testing of the various possible columns and would be likely to choose beta-cyclodextrin and Chiralcel OD.
- The skilled person would try and get separation on an analytical size column and then scale up.

Obvious?

Case Study - Generics (UK) Ltd and others v H Lundbeck A.S.

- The judge did not agree:

  "I believe that this is one of those cases where each step seems very simple and logical with the benefit of hindsight. This, it must be remembered, was a fast moving field and by the mid 1990s many techniques were routine which were still very much at an experimental stage in 1988."

- A similarly detailed analysis of the proposed intermediary route was undertaken by the judge.

- At each step the judge sought to determine what additional options the skilled team had, and what expectation of success they thought the relevant step might have.

Obvious?

Case Study - Generics (UK) Ltd and others v H Lundbeck A.S.

- The two routes were not obvious.

  "For all these reasons I have reached the conclusion that the reaction schemes described in the Patent would not have been obvious to the skilled person in 1988. Professor Davies thought it is only with hindsight that it is possible to explain the outcome of a reaction which would otherwise have been unexpected. I agree with that opinion. As I shall explain, this conclusion is supported by the work carried out at Lundbeck."

  ...

  "In conclusion, I do not believe it was obvious to resolve citalopram on a preparative scale using chiral HPLC in 1988. It was a rapidly evolving field. The ordinary skilled analytical chemist would have had no practical experience of preparative chiral HPLC and the ordinary skilled medicinal chemist would probably not have heard of it. ***The team would have been faced with a research programme with an uncertain outcome****." (emphasis added)*

Obvious?

Case Study - Generics (UK) Ltd and others v H Lundbeck A.S.

- The obvious nature of the chiral intermediary was a point taken on appeal. The decision was upheld.

> *"[the judge] took into account, first, that there were "a number of avenues of research" open to the skilled man seeking a solution to the problem and that therefore he would not have taken the diol route unless satisfied there was a "real prospect" that the necessary reaction would work. The claimants' case that the diol route was obvious to try was based upon Dr Newton's opinion that there was a "high expectation that the experiment would be a very facile ring closure and that it would work." But the judge rejected this assessment. Once he had done so, his conclusion that the diol route was not obvious seems to me unassailable."*

Obvious?

Obvious to try.

- One question that pops up in chemical cases (and selection cases) is whether the successful route (or a sucesful selection) was obvious to try.
- The UK Courts do not like this particular phrase and prefer to stick to the language of the statute.
- However, in practice, one does have to ask the question.

Obvious?

Obvious to try.

- *Medimmune v Novartis* [2012] EWCA Civ 1234
  - Whether a particular approach was “obvious to pursure” with a “reasonable or fair expectation of success as opposed to a hope to succeed” can be an appropriate manner of assessing the statutory question
- Novartis v Generics (UK) [2012] EWCA Civ 1623
  - Where the skilled person has multiple pathways to take from the prior art, one of which leads to the claimed invention, the court will ask whether that particular step was obvious to take (try/attempt/pursue).

Insufficient

The Price of the Monopoly

The patentee holds back to hinder competitors after the monopoly is over.

The Skilled Person cannot determine how to work the Invention

Insufficiency - a Reminder

Section 72 Patents Act 1977

Power to revoke patents on application..

(1) Subject to the following provisions of this Act, the court or the comptroller may on the application of any person by order revoke a patent for an invention on (but only on) any of the following grounds, that is to say—

...

(c)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;

Insufficient

Insufficiency

- Classic Insufficiency
- Directions in the patent are inadequate
- *American Home Products Corporation v Novartis Pharmaceuticals UK Ltd* [2001] RPC 8

"There is a difference between on the one hand a specification which requires the skilled person to use his skill and application to perform the invention and, on the other, a specification which requires the skilled person to go to the expense and labour of trying to ascertain whether some product has the required properties. When carrying out the former the skilled person is trying to perform the invention, whereas the latter requires him to go further and to carry out research to ascertain how the invention is to be performed. If the latter is required the specification would appear to be insufficient."

Insufficiency

So-called ‘Biogen’ insufficiency

- The claims encompass products and processes which owe nothing to the teaching of the patent.
- The key to determining Biogen Insufficiency is identifying the true inventive step in the patent.

  Case Example: *Generics (UK) Ltd and others v H Lundbeck A.S.*

Insufficiency

- *Generics (UK) Ltd and others v H Lundbeck A.S.*
  - The Claimants argued, supposedly in line with the decision of the House of Lords in *Biogen*, that the patent claimed the enantiomer citalopram however obtained, but that the specification did not enable all ways to obtain citalopram and thus the patent was insufficient.
  - At first instance the judge agreed, finding that the invention did not lie in the product *per se*, because that was an obvious destination, but instead in finding a particular way to separate the racemate.
  - The monopoly would therefore be disproportionate to the technical contribution of the patent if the Patent were to cover all ways of making the enantiomer.

Insufficiency

- *Generics (UK) Ltd and others v H Lundbeck A.S.*
  - The question on insufficiency went all the way to the House of Lords.
  - The key issue was what was the technical contribution of the patent? The answer would determine whether the contribution was enabled or not.
  - The House of Lords found that the technical contribution of a simple product claim was the product itself.
  - The patent was therefore sufficient as the specification enabled the product to be made.

Insufficiency

Principles of general application

- *Regeneron Pharmaceuticals Inc v Bayer Pharma AG* [2013] EWCA Civ 93

Insufficiency

Principles of general application

- *Regeneron Pharmaceuticals Inc v Bayer Pharma AG* [2013] EWCA Civ 93
  - Claim 1

"Use of a hVEGF antagonist in the preparation of a medicament for the treatment of a non-neoplastic disease or disorder characterised by undesirable excessive neovascularisation, wherein the hVEGF antagonist is:

(a) an anti-VEGF antibody or antibody fragment;

(b) an anti-VEGF receptor antibody or antibody fragment; or

(c) an isolated hVEGF receptor."

Insufficiency

Principles of general application

- *Regeneron Pharmaceuticals Inc v Bayer Pharma AG* [2013] EWCA Civ 93
- Key arguments:
  - *"The claimants say that it was not possible to make a reasonable prediction from the data in the patent that anti-VEGF therapy would be effective in the whole range of diseases claimed. Accordingly they say that the patent is insufficient for undue breadth of claim.*
  - *Genentech say that the patent discloses a principle of general application as regards the relevant claim integer, and accordingly justifies a claim of this breadth."*
- How to spot the difference?

Insufficiency

Principles of general application

- *Regeneron Pharmaceuticals Inc v Bayer Pharma AG* [2013] EWCA Civ 93
  - "it is permissible to define an invention using general terms provided the patent discloses a principle of general application in the sense that it can reasonably be expected the invention will work with anything falling within the scope of these terms."

Insufficiency

Principles of general application

- *Regeneron Pharmaceuticals Inc v Bayer Pharma AG* [2013] EWCA Civ 93
  - "It must therefore be possible to make a reasonable prediction the invention will work with substantially everything falling within the scope of the claim or, put another way, the assertion that the invention will work across the scope of the claim must be plausible or credible.
  - The products and methods within the claim are then tied together by a unifying characteristic or a common principle. If it is possible to make such a prediction then it cannot be said the claim is insufficient simply because the patentee has not demonstrated the invention works in every case."

Insufficiency

Principles of general application

- *Regeneron Pharmaceuticals Inc v Bayer Pharma AG* [2013] EWCA Civ 93
  - "On the other hand, if it is not possible to make such a prediction or if it is shown the prediction is wrong and the invention does not work with substantially all the products or methods falling within the scope of the claim then the scope of the monopoly will exceed the technical contribution the patentee has made to the art and the claim will be insufficient.
  - It may also be invalid for obviousness, there being no invention in simply providing a class of products or methods which have no technically useful properties or purpose."

Insufficiency

Principles of general application

- The first instance judge found that:
  - "I consider that the patent discloses a principle of general application within the meaning of the authorities insofar as it claims anti-VEGF antagonism as a treatment for all non-neoplastic diseases.
  - The tumour data in the patent establish that VEGF blockade is likely to be a successful strategy for treatment in cancer. The skilled reader would appreciate that the reason it is likely to be successful is because blocking VEGF is a sufficient intervention to prevent angiogenesis, at least in models of cancer.
  - It is common ground that it is possible to extrapolate that reasoning to at least some non-neoplastic diseases."

Insufficiency

Principles of general application

- This decision can be contrasted with *Ciba Vision and Novartis v Johnson & Johnson*
  - *"The Patent is somewhat unusual in that it claims contact lenses partly by reference to certain desirable characteristics such as ophthalmic compatibility, corneal health and wearer comfort, and partly by reference to physical parameters such as oxygen transmissibility and ion permeability."*
- The High Court and Court of Appeal found that the claimed characteristics of this patent did not enable the skilled person to produce an extended ware contact lens.

Insufficiency

Principles of general application

(A) An ophthalmic lens having ophthalmically compatible inner and outer surfaces,

(B) wherein said ophthalmic lens is selected from the group consisting of contact lenses for vision correction, contact lenses for eye colour modification, ophthalmic drug delivery devices and ophthalmic wound healing devices,

(C) said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids,

(D) said lens comprising a polymeric material,

(E) which has high oxygen permeability and high ion permeability,

(F) said polymeric material being formed from polymerizable materials comprising:

(a) at least one oxyperm polymerizable material as defined in section I of the description, and

(b) at least one ionoperm polymerizable material, as defined in section I of the description,

(G) wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended continuous contact with ocular tissues and ocular fluids, and

(H) wherein said lens allows ion or water permeation in an amount sufficient to enable the lens to move on the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

(I) wherein said ophthalmic lens has an oxygen transmissibility as defined in section I of the description of at least about 70 barrers/mm and

(J) an ion permeability characterized either by

(1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm^2/sec, or

(2) an Ionoflux Diffusion Coefficient of greater than about 1.5×10^{-6} mm^2/min,

wherein said coefficients are measured with respect to sodium ions, and according to the measurement techniques described in sections II.F.1 and II.F.2 of the description respectively.

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