Case No: A3/2012/1456

Neutral Citation Number: [2012] EWCA Civ 1638

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE
CHANCERY DIVISION (PATENTS COURT)
His Honour Judge Birss QC
[2012] EWHC 1602 (Pat)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 14/12/2012

Before:

LADY JUSTICE ARDEN
LORD JUSTICE JACKSON
and
LORD JUSTICE KITCHIN

- -

Between:

Smith & Nephew plc	**Claimant/ Appellant**
- and -	
Convatec Technologies Inc (a company incorporated under the laws of the State of Nevada, USA)	**Defendant/ Respondent**

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- -

James Mellor QC and Miss Charlotte May (instructed by Bristows)
for the Appellant
Piers Acland QC (instructed by Bird & Bird LLP)
for the Respondent

Hearing date: 30 October 2012

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Judgment

Lord Justice Kitchin:

Introduction

1. This appeal concerns moist wound dressings which contain gel-forming polymers and ionic silver as an antimicrobial agent. The antimicrobial properties of ionic silver have been known for very many years but it suffers from the drawback that it is not stable in the presence of light. The respondent (Convatec) is the proprietor of European Patent (UK) No 1,343,510 ("the patent") which has a priority date of 29 November 2001 and, in its amended form, describes and claims of ways of making moist wound dressings containing ionic silver in a light stable form. The patent is of great commercial importance to Convatec because it protects a number of silverised wound dressing products with sales in the UK of about £14.7m each year.

2. In these proceedings the appellant (Smith & Nephew) applied to revoke the patent on the basis that it was obvious in the light of two earlier publications referred to as Kreidl and Gibbins, and that it did not describe the invention sufficiently and clearly enough for it to be performed by a person skilled in the art. Convatec conceded that the patent was invalid in the form in which it was granted but applied to amend it. Smith & Nephew resisted the application to amend the patent both on the basis that the amendment would result in the specification disclosing additional matter and on the basis that the patent as proposed to be amended would still be invalid for obviousness and insufficiency.

3. The action came on for trial before HHJ Birss QC in March 2012. In his judgment of 13 June 2012, the judge held that the amendment was allowable and rejected all the attacks upon the patent in its amended form. Upon this appeal, Smith & Nephew contends that the judge fell into error in failing to find the patent obvious in the light of Kreidl. It does not seek to challenge any of the judge's other findings.

The skilled team and the expert evidence

4. The patent is addressed to a notional skilled but unimaginative team likely to have a practical interest in its teaching. In this case there was no dispute as to the composition of that team. It would include a biomedical engineer, a chemist and a materials scientist. The biomedical engineer would have practical experience of wound dressing development; the chemist would have an understanding of silver chemistry; and the materials scientist would have practical experience of dressing structures and components.

5. The judge heard evidence from two witnesses, Professor Burrell for Smith & Nephew and Professor Kennedy for Convatec. Professor Burrell is Professor of Chemicals and Materials Engineering at the University of Alberta in Canada, has worked in the field of wound dressing since 1991 and has a particular interest in the use of silver in wound management.

6. Professor Kennedy spent his academic life up to the priority date at Birmingham University, gaining his first degree in Chemistry, then a PhD and, in due course, becoming a lecturer and then a senior lecturer. He has always had a particular interest in monomolecular and macromolecular carbohydrates. As the judge explained, Professor Kennedy was faced with a difficulty in this case in that he was instructed

only shortly before the trial when Convatec's expert up to that point, Professor Qin, fell seriously ill. As a result, Professor Kennedy's evidence consisted of annotated versions of the reports Professor Qin had already prepared.

7. Each side attacked the other's expert but the judge found neither attack well founded. He formed the view that both experts gave their evidence fairly. He also recognised that Professor Burrell had much more experience of the use of silver in wound dressings than Professor Kennedy. Nevertheless, he found that in general he preferred the evidence of Professor Kennedy as to the thinking of the skilled team because Professor Burrell was a man of exceptional innovative talent and a problem solver who would persist in pursuing a hypothesis even in the face of negative experimental results. The judge considered Professor Burrell's evidence attributed too much of that persistence to the skilled team. Professor Kennedy's evidence, on the other hand, was generally straightforward and plausible.

Technical background and the common general knowledge

8. The judge set out the technical background and identified the common general knowledge of the skilled team at [6]-[8] and [31]-[38]. This has not been challenged by Smith & Nephew but I would mention the following matters which are of particular relevance to the issues arising on this appeal.

9. Traditional wound dressings were designed to absorb all exudates and so keep the wound dry. They were commonly made of cotton, a soft, naturally occurring cellulose based material which comprises many different fibres, each of which consists of a long tubular cell. The cell wall is rather thin and surrounds a lumen which occupies two thirds of the breadth of the fibre. Cotton absorbs water by drawing it into the lumen of each of its fibres by capillary action.

10. In the 1960s it was found that wounds heal more quickly if they are kept moist. In the 1980s and 1990s this knowledge led manufacturers to develop new gel-forming wound dressings based upon materials such as hydrogels and alginates which have the ability both to absorb wound exudates and maintain a moist wound surface. One well known dressing comprising a gel-forming material was made by Convatec and called Aquacel. It contains sodium carboxymethyl cellulose or simply NaCMC.

11. Moist wound dressings do, however, suffer from the drawback that they encourage infection. Hence there was a need to provide moist wound dressings with some kind of antimicrobial activity.

12. That brings me to the common general knowledge concerning silver chemistry. As I have said, ionic silver (normally in the form of Ag^+ ions) was known to have antimicrobial properties and indeed there were commercial products on the market which used ionic silver as an antimicrobial agent. A further advantage of ionic silver is that it has a low toxicity. However, it is highly light sensitive, that is to say that in the presence of light or other radiant energy it is reduced to silver metal which causes the loss of its antimicrobial activity and a significant discolouration of the material or solution in which it is contained.

13. It was also generally known that silver ions (Ag^+) react strongly with chloride ions (Cl^-) to form silver chloride (AgCl). Silver chloride has a low solubility and will

precipitate out of solution, though due to the dynamic equilibrium between the ionic species and the salt, there will always be a small proportion of silver ions in solution. It was also known that in the presence of a large excess of chloride ions, coordination complexes can be formed, these being species in which the silver ion is bound to more than one chloride ion. So, for example, silver chloride with two chloride ions will have the formula $AgCl_2^-$. Silver chloride complexes were known to be more soluble than silver chloride and the greater the excess of halogen, the more soluble they tend to be.

14. As for light stability, silver chloride was known to be unstable when exposed to light. Silver chloride coordination complexes are light stable or, at any rate, more light stable than silver chloride itself, but this was not generally known.

15. The judge also recorded (at [38]) that it was common ground that AgCMC was known to be unstable when exposed to light, although it was more light stable than AgCl. The judge had his doubts as to whether this was truly common general knowledge but since it was common ground, he accepted it.

16. The final aspect of the common general knowledge which I must mention concerns the difference between absorption and adsorption. As the judge explained, absorption involves the uptake of a substance into a material. Adsorption, on the other hand, is a gathering of a substance on the surface of a material where it may be held by electrostatic binding caused by the interaction of oppositely charged dipoles on molecules – so called Van der Waals forces.

The patent

17. The specification begins with the field of the invention and a statement that the invention relates to light stabilised antimicrobial materials and ways of preparing them.

18. There follows a description of the background of the invention and, at paragraph [0003], an acknowledgement that it was known to include silver as an antimicrobial agent in salt form in wound dressings but that such silver-containing materials are sensitive to light which causes uncontrolled discolouration. The specification explains there was therefore a need for hydrophilic polymeric materials containing silver in a light stable form.

19. Against this background the specification explains that the invention is directed to a way of preparing light stable materials comprising gel-forming polymeric fibres treated with silver which provide effective and non-toxic antimicrobial activity upon hydration.

20. In the first step a source of silver, for example silver nitrate ($AgNO_3$), is mixed with an organic solvent. The organic solvent may include an element of water provided it does not swell or hydrate the polymeric material to be treated. The concentration of silver should be sufficient to provide the desired concentration of silver in the final material.

21. In the second step a material containing gel-forming fibres containing one or more hydrophilic, amphoteric or anionic polymers is subjected to the silver and organic

solvent solution prepared in the first step. This is done for a period of time sufficient to incorporate the desired silver concentration into the polymer.

22. In the third step, which may take place during or after the second step, the polymer is subjected to one or more agents which facilitate the binding of the silver and the polymer together. A number of suitable facilitating agents are identified in the specification, including chlorides, for example sodium chloride.

23. There is only one claim in issue, namely claim 1 which defines the method I have summarised in the following terms:

> "A method of preparing a light stabilized antimicrobial material, **characterised in that** the method comprises the steps of:
>
> a) preparing a solution comprising an organic solvent and a source of silver in a quantity sufficient to provide a desired silver concentration in said material;
>
> b) subjecting a material which includes gel-forming fibres containing one or more hydrophilic, amphoteric or anionic polymers to said solution for a time sufficient to incorporate said desired silver concentration into said polymer, wherein said polymer comprises a polysaccharide or modified polysaccharide, a polyvinylpyrrolidone, a polyvinyl alcohol, a polyvinyl ether, a polyurethane, a polyacrylate, a polyacrylamide, collagen, or gelatin or mixtures thereof; and
>
> c) subjecting said polymer, during or after step (b) to one or more agents selected from the group consisting of ammonium salts, thiosulphates, chlorides and peroxides which facilitate the binding of said silver on said polymer, the agent being present in a concentration between 1% and 25% of the total volume of treatment, which material is substantially photostable upon drying, but which will dissociate to release said silver upon rehydration of said material."

The prior art – Kreidl

24. That brings me to the disclosure in Kreidl, a US patent published in 1946. I must deal with this in some detail because, as I elaborate later in this judgment, Smith & Nephew contends that the judge fell into error in failing to have proper regard to its clear teaching.

25. Kreidl relates to disinfectant products and to methods of making them; and it particularly relates to disinfectant products containing silver in combination with halogen.

26. Kreidl begins by explaining that the disinfectant action of silver is well known but that silver preparations are difficult to prepare, have an undesirable dark colour and are not stable upon exposure to light. An object of the invention is therefore the provision of a disinfectant product having silver halide in a stabilised form as the effective agent. It then says (at page 1, column 1, lines 39 – 44):

> "This invention is based on the discovery that disinfectant silver halide preparations of an increased stability, more particularly with respect towards the action of light, may be obtained by having the silver halide protected by an excess of halide."

27. The specification continues that the theory of the action of the excess halide is not well understood (at page 1, column 2, lines 10-25):

> "Although the theory of the action of the excess halide is not quite understood, and the actual molecular structure of such combination products do not form part of this invention, it may be assumed that the silver halide products, according to this invention owe their increased stability to a complex formation of the simple silver halide (AgC1, AgBr, AgI) with other halides. It appears that in this protected state, the silver is more tightly bound to the halogen and thus not readily reduced by the solarizing influence of light. Regardless of any possible theory, our invention may be more clearly defined by the actual methods of carrying it out and by the description of the products resulting therefrom."

28. The specification gives a further exposition of the nature of the complexes that may be formed and then (at page 2, column 1, lines 3-37) explains the implementation of the invention in the form of stable solutions:

> "According to one modification of our invention, stable solutions of the silver halides of chlorine, bromine and iodine which are highly suitable for disinfectant and the like purposes, but which are also of advantage for the preparation of solid silver halide preparations of limited solubility, as will be discussed more in detail in later parts of this specification, may be obtained by having the silver halides in solution in the presence of an excess of halide in the form of soluble halides of the halogen acids of chlorine, bromine and iodine, or in the form of the halide acids themselves. Without restricting this invention to any theory it may be assumed that the stability of such solutions may be due to the formation of complex silver halide compounds as described above. It need not be mentioned that not all of the excess halide will or need participate in the said complex formation, but, as appears to be witnessed by the increased solubility of the silver halides in more concentrated halide solutions, the formation of complex-like silver halides seems to be favored by increasing concentration of the halide type compounds. It was found, and this forms an important part of our invention, that such stable soluble silver halide compounds will not coagulate proteins and thus will not have any of the undesirable properties of the hitherto known silver disinfectants or other protein coagulating antiseptics. This property of the silver halide solutions according to this invention renders them particularly useful

where they are to be used for bacteriostatic action in the treatment of the human body."

29. These solutions are said (at page 2, column 2, lines 43-60) to have not only a relatively high silver concentration and be stable to light but also to have the benefit that they do not readily react with organic material so they may be used to disinfect a great variety of objects such as surgical instruments and containers for pharmaceuticals and foodstuffs.

30. The specification then turns to another embodiment of great importance to this appeal, namely solid disinfectant silver halide preparations. These are said to be only slightly soluble but nevertheless release a small but effective amount of active silver. In an important passage (at page 3, column 1, lines 24-61), the specification says:

> "According to another modification of our invention solid disinfectant halide preparations may be prepared which are only slightly soluble and, accordingly, at any given time will give off only small, though effective, amounts of the active silver and, accordingly will have a more or less permanent disinfecting property. Such solid products, according to our invention, will be characterized by the fact that they contain more halogen than corresponds to the stoichiometric composition of the simple silver halide (AgC1, AgBr, AgI) the excess halogen being present in the form of a halide type compound of chlorine, bromine, and iodine, the excess halogen, however, being not great enough as to increase the solubility of the formed stabilized compound substantially over that of the simple silver halide or that of the theoretical halogen compounds. The stability of such solid slightly soluble silver halide preparations according to this invention will be greatly increased by having them truly adsorbed on carrier such as on natural vegetable fibres, such as cotton fibres, or on adsorbent minerals, such as clays, and other adsorbent silicates and aluminium compounds. It is believed, although the invention is not limited by the theory, that the adsorption forces have a similar favorable effect on the stability of the solid, slightly soluble silver preparations, according to our invention, as the much greater excess of halides in the case of our liquid preparations. The increased stability of such adsorbed silver halide products is evidenced by the fact that only such adsorbed silver halide products of a slightly soluble character are not split by water but will give off gradually small amounts of the silver halide compound to a solvent without being affected by their light stability."

31. I would draw attention to the following aspects of this teaching upon which Smith & Nephew placed particular reliance. First, an excess of halide is still required, though not so much as to increase the solubility of the preparations substantially over that of the simple silver halides. Second, the stability of the silver halide preparations is increased by having them adsorbed on carrier fibres, such as cotton, or on adsorbent materials such as clays, silicates and aluminium compounds. The teaching of Kreidl

is therefore not solely about cotton. This aspect of the teaching is reinforced by a further passage later in the specification at page 5, lines 8-25, which says that the nature of the adsorbent material will be of importance. So, for example, the presence of natural vegetable fats on sized or raw fibres may influence the adsorption process. Further, materials which by their nature are non-adsorbent may be treated so that they become adsorbent.

32. Returning to page 3 of the specification, it continues (at page 3, column 1, lines 62-74) that the solid disinfectant silver halide adsorption products of the invention may be prepared in many different ways but care has to be taken to remove any non-adsorbed silver halide which may not be stable to light.

33. Kreidl teaches two ways of impregnating the carrier materials it has described. I need only refer to the first, a two-stage process in which the carrier is impregnated initially with a silver salt and then with a halide compound. This is exemplified (at page 3, column 2, lines 37-67) by the impregnation of a gauze which is soaked in silver nitrate solution, dried and then dipped into a suitable halide solution, such as sodium chloride. After completion of the reaction, the gauze is washed to remove any non-adsorbed salts.

34. Kreidl illustrates the invention with thirteen examples (page 5, column 2, line 50 – page 6, column 2, line 8). They involve the impregnation of a variety of materials, such as gauze, aluminium hydroxide, clay, glass powder, cotton duck and burlap. But the only examples which specifically describe the effect of exposure to light are examples 5 and 6 which involve the impregnation of a bandage gauze.

Obviousness – general principles

35. We were referred by both parties to the recent decision of this court in *MedImmune Ltd v Novartis Pharmaceuticals UK Ltd* [2012] EWCA Civ 1234 at [84] - [95] and [177] - [186]. I would emphasise the following points which have a bearing on this appeal. First, any analysis of obviousness must be founded upon the statutory tests set out in ss.1(1) and 3 of the Patents Act 1977 (corresponding to Articles 52(1) and 56 EPC): an invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art having regard to any matter which forms part of the state of the art at the priority date.

36. Second, it is often convenient, but by no means essential, to consider an allegation of obviousness using the structured approach explained by this court in *Pozzoli v BDMO SA* [2007] EWCA Civ 588, [2007] FSR 37 at [23]:

> "(1) (a) Identify the notional 'person skilled in the art';
>
> (b) Identify the relevant common general knowledge of that person;
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> (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?"

37. Third, the skilled person is equipped with the common general knowledge and is deemed to have read any piece of prior art properly and in that sense with interest.

38. Fourth, it may be appropriate to take into account whether or not it was obvious to try a particular route to an improved product or process. In this regard Smith & Nephew focused particularly on [90] – [93] of my judgment in *MedImmune*:

> "90. One of the matters which it may be appropriate to take into account is whether it was obvious to try a particular route to an improved product or process. There may be no certainty of success but the skilled person might nevertheless assess the prospects of success as being sufficient to warrant a trial. In some circumstances this may be sufficient to render an invention obvious. On the other hand, there are areas of technology such as pharmaceuticals and biotechnology which are heavily dependent on research, and where workers are faced with many possible avenues to explore but have little idea if any one of them will prove fruitful. Nevertheless they do pursue them in the hope that they will find new and useful products. They plainly would not carry out this work if the prospects of success were so low as not to make them worthwhile. But denial of patent protection in all such cases would act as a significant deterrent to research.
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> 91. For these reasons, the judgments of the courts in England and Wales and of the Boards of Appeal of the EPO often reveal an enquiry by the tribunal into whether it was obvious to pursue a particular approach with a reasonable or fair expectation of success as opposed to a hope to succeed. Whether a route has a reasonable or fair prospect of success will depend upon all the circumstances including an ability rationally to predict a successful outcome, how long the project may take, the extent to which the field is unexplored, the complexity or otherwise of any necessary experiments, whether such experiments can be performed by routine means and whether the skilled person will have to make a series of correct decisions

along the way. Lord Hoffmann summarised the position in this way in *Conor* at [42]:

> "In the Court of Appeal, Jacob LJ dealt comprehensively with the question of when an invention could be considered obvious on the ground that it was obvious to try. He correctly summarised the authorities, starting with the judgment of Diplock LJ in *Johns-Manville Corporation's Patent* [1967] RPC 479, by saying that the notion of something being obvious to try was useful only in a case where there was a fair expectation of success. How much of an expectation would be needed depended on the particular facts of the case."

92. Moreover, whether a route is obvious to try is only one of many considerations which it may be appropriate for the court to take into account. In *Generics (UK) Ltd v H Lundbeck*, [2008] EWCA Civ 311, [2008] RPC 19, at [24] and in *Conor* [2008] UKHL 49, [2008] RPC 28 at [42], Lord Hoffmann approved this statement of principle which I made at first instance in *Lundbeck*:

> "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."

93. Ultimately the court has to evaluate all the relevant circumstances in order to answer a single and relatively simple question of fact: was it obvious to the skilled but unimaginative addressee to make a product or carry out a process falling within the claim. As Aldous LJ said in *Norton Healthcare v Beecham Group Plc* (unreported, 19 June 1997):

> "Each case depends upon the invention and the surrounding facts. No formula can be substituted for the words of the statute. In every case the Court has to weigh up the evidence and decide whether the invention was obvious. This is the statutory task.""

39. Lewison LJ put it this way at [178] – [182]:

"178. These articles [Arts. 52 and 56 EPC] find their domestic equivalent in sections 1 and 3 of the Patents Act 1977. As Jacob LJ pointed out in *Actavis UK Ltd v Novartis AG* [2010] EWCA Civ 82 [2010] FSR 18 (§ 17):

> "So at bottom the question is simply whether the invention is obvious. Any paraphrase or other test is only an aid to answering the statutory question."

179. The same point is made in *Johns-Manville Corporation's Patent* [1967] RPC 479, which is the starting point in domestic law of the idea of "obvious to try". In that case Diplock LJ said:

> "I have endeavoured to refrain from coining a definition of "obviousness" which counsel may be tempted to cite in subsequent cases relating to different types of claims. Patent law can too easily be bedevilled by linguistics and the citation of a plethora of cases about other inventions of different kinds. The correctness of a decision upon an issue of obviousness does not depend upon whether or not the decider has paraphrased the words of the Act in some particular verbal formula. I doubt whether there is any verbal formula which is appropriate to all classes of claims."

180. In the same case Willmer LJ said:

> "I would, however, desire to associate myself particularly with what Diplock, LJ said as to the undesirability of coining phrases for the purpose of paraphrasing the words of the Act."

181. These sentiments seem to have been largely ignored by the profession. It cannot be said too often that the statutory question is: was *the invention* obvious at the priority date? It is not: was it obvious to try? In my judgment too much elaboration of the statutory question has been attached to it. The questions of the degree of expectation of success and the length of time thought to be needed to undertake a trial have taken on lives of their own. I think that this happened in our case. Insistence on the statutory question is not a novel thought. It is also an obvious one: see *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2007] EWCA Civ 5 [2007] RPC 20 (§§ 44, 45 per Jacob LJ, approved on appeal: [2008] UKHL 49

> [2008] RPC 28 § 42 per Lord Hoffmann; § 49 per Lord Walker; § 55 per Lord Neuberger). In *Generics (UK) Ltd v H Lundbeck A/S* [2007] EWHC 1040 (Pat) [2007] RPC 32 (§72) Kitchin LJ (as he then wasn't) said:
>
> > "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."
>
> 182. This statement of principle was also approved by the House of Lords in *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc*. One of the important points, to my mind, is that all these considerations interact with each other. In short, it all depends. MedImmune's argument proceeded on the basis that Novartis needed to establish (a) a fair prospect of success (b) within a reasonable time, as if these were two independent conditions that had to be satisfied. They are not successive hurdles to be jumped; they are no more than aspects of the statutory question: was the invention obvious? We should stick to the statutory question, which has to be applied in all sorts of circumstances and in all sorts of different fields of endeavour."

40. The question whether it was obvious to try a particular route with reasonable or fair expectation of success may therefore be a relevant consideration. All must depend upon the circumstances of the case. Importantly, there is, at the end of the day, only one question, namely whether it was obvious to make a product or carry out a process falling within the claim.

Obviousness - the issue

41. In this case there was no dispute about the identity or attributes of the skilled person, here a team. I have also addressed the common general knowledge of that team, the inventive concept of the patent and the disclosure of Kreidl. As the judge explained at [169], Kreidl contains a clear teaching of a method of preparing a light stabilised antimicrobial material for use in wound dressings with the same basic steps as the patent and the result is a light stable product. The difference between the inventive concept of the patent and the disclosure of Kreidl is that Kreidl does not describe the use of the invention in relation to gel forming fibres such as Aquacel. The critical question was whether this difference constituted an obvious step to take at the priority date.

The judgment

42. The judge began by considering the evidence given by the experts, Professor Burrell and Professor Kennedy. As will be seen, they adopted very different positions.

43. Professor Burrell said in his written evidence that it was obvious to apply the teaching of Kreidl to the new material Aquacel which was, by 2001, part of the common general knowledge. His reasons were summarised by the judge as being that (i) Kreidl's method expressly applies to a range of materials and there is no suggestion it cannot be used with others; (ii) it can be applied to water soluble or water swellable materials using organic solvents that will avoid premature swelling; (iii) the skilled person would appreciate that the chemistry of the method could be applied equally to more modern materials; and (iv) there was a general motivation to use modern materials because they were readily available and had their own advantages, including keeping the wound moist.

44. As the judge recognised at [173], on the face of it, these were all good reasons why it was obvious to apply Kreidl's teaching to Aquacel and so take the step to the invention.

45. Professor Kennedy expressed a very different opinion. He did not think the skilled person would have paid much attention to Kreidl at all. As he said in his first composite report at [138] :

> "… turning now to the value of [Kreidl] to me in 2000. If I had the objective of making a high tech moist wound dressing, and was given [Kreidl], I would not have read it in its entirety but would have put the document on one side as low interest and low priority given: i) its age; ii) its lack of understanding of anything in terms of high tech dressings; iii) applying only to a cotton gauze; and iv) my view that it is only a possibility that the silver might have an association with the cotton gauze, which is by no means definitely the case. [Kreidl] largely teaches sterilising solutions. It also teaches the use of those solutions to impregnate a material, which itself then becomes a sterilising material. Notice that it is to sterilise and not to prevent microbial attack or to deal with an existing microbial infection on or in a human. The emphasis is on sterilising. I do not think that someone skilled in the art in 2000 and with the already stated quest of developing high-tech wound dressings would have paid a lot of attention to [Kreidl] for these reasons."

46. A little later, at [174] of his report, Professor Kennedy addressed Kreidl's teaching about adsorption forces providing a stabilising effect and expressed the view that the skilled person would conclude that if there was any stabilisation it was probably being achieved by physical shielding of the silver chloride by the walls of the cotton fibres:

> "[Kreidl] theorises that the "adsorption forces" of the carrier which have a similar effect on stability as the excess halide in the liquid preparations (page 3, left hand side lines 48-54). Perhaps the authors of [Kreidl] envisaged that some kind of

> non-specific interaction between the cellulose hydroxyl groups and the silver halide was at work. However in the absence of a clear explanation of the underlying mechanism, I believe that the skilled person would conclude that if there was any stabilization, it was most likely being achieved by physical shielding of the silver halide from the light. As I explained above, cotton fibres have an internal capillary running through the fibre. During the process, it is highly likely that a significant amount of the silver chloride that is formed (or the solid silver complexes) will be retained within these capillaries. If this is the case then they will be physically well shielded from light by the rest of the cotton fibre. This may well have a significant effect on the ability of the silver to discolour the surrounding organic material. Also, if there were to be a reaction between the silver and the internal surfaces of the capillary, the resulting discolouration may not be evident."

47. Then, at [194] of his report, Professor Kennedy explained that the skilled person would have thought that any such shielding (including of silver halide complexes) would not have been likely to happen with gel forming fibres as they do not contain the same physical structure as cotton.

48. The judge again recognised (at [176]) these were, on the face of it, good reasons why it would not be obvious to apply Kreidl's teaching to a gel forming fibre such as Aquacel.

49. The judge then summarised the effect of the cross examination. As for Professor Burrell, the judge summarised his evidence in this way at [178]:

> "i) He accepted that shielding would occur to the skilled person as possible in Kreidl but did not accept that shielding was the only rational explanation.
>
> ii) Although the skilled person would understand that Kreidl will be producing silver complexes, it was not common general knowledge that complexes were light-stable. Prof Burrell's view was that the reader may believe that it is the adsorbed form of complex which gives stability. This probably involved Van der Waals forces acting on complexes but the effect of this was not known to the skilled person."

50. So Professor Burrell accepted there were two possible mechanisms, surface adsorption and shielding. The judge considered the "upshot" of Professor Burrells' cross examination was that he accepted it would not be obvious to try Kreidl's method on Aquacel if that method worked by physical shielding. But that was not a premise Professor Burrell was prepared to accept and he maintained that Aquacel was an obvious material to try if the skilled person accepted Kreidl's teaching that adsorption provided stability.

51. Turning to Professor Kennedy, the judge summarised the key matters arising from his cross examination in these terms at [181]:

> "i) He maintained his view that he would have put Kreidl aside.
>
> ii) He accepted that the key teaching of Kreidl was to create silver halide preparations with an excess of halide to bring about light stability and that the stability of such halides could be further increased by having them truly adsorbed on the material.
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> iii) He accepted that the teaching of Kreidl was not limited to cotton. Clays are offered as alternatives.
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> iv) He accepted that Kreidl forms silver chloride complexes and they will be adsorbed onto cotton by Van der Waals forces.
>
> v) He did not accept that the term "adsorption" used in Kreidl would be understood by a skilled person in 2001 in its normal technical meaning."

52. The judge thought the "upshot" of Professor Kennedy's evidence was that shielding from light explained the light stability of the cotton product in Kreidl but there was no possibility of shielding occurring with clay, and this was also described in Kreidl.

53. The judge then began his analysis and made the following findings, rejecting many of the points made by Professor Kennedy:

    i) The skilled person would not simply put Kreidl aside (at [184]).

    ii) This was not a case in which the age of Kreidl in and of itself gave rise to an inference of non-obviousness; it was only with the more recent increase in antibiotic resistance that interest in silver had returned (at [185]). Nevertheless, a skilled person reading Kreidl in 2001 would notice that it dated from 1946 and would take that into account (at [186]).

    iii) The skilled person reading Kreidl in 2001 would not think that adsorption was being used other than in its usual sense (at [187]).

54. The judge made an important finding that this was not an art where the skilled person would carry out an experiment without having a rationale for doing so. He put it this way at [190]:

> "… in my judgment this is not a case in which the skilled person would simply try it and see. In some factual situations it might be obvious to a skilled person to have a go with an experiment even though they have no opinion about whether it will actually work. It may be obvious to test 10 different reagents in parallel with a reasonable expectation that one is likely [to] work albeit the skilled person does not know which one. That is not this case. Having heard both Professors, it seems to me that in this art the skilled person will not perform a test without thinking about the rationale for what they are

> doing. The skilled person in this field will consider how and why the test they are considering may or may not work before they carry it out. ”

55. It followed, as the judge held at [192], the skilled person would consider the rationale for Kreidl’s results and would think about the implications of this rationale for a putative test on Aquacel.

56. Standing back, the judge thought that three matters stood out which he explained in these terms at [193]:

> “Looking at the matter overall, it seems to me that three things will stand out to a skilled person reading Kreidl in 2001. First, the strong positive aspect is that here is a simple teaching which reports clear, successful results producing a light-stable silver impregnated wound dressing made of cotton gauze. Second however, I think the skilled person would be faced with a puzzle. He or she will certainly consider what is going on in Kreidl and see its teaching about complexes. There is nothing in his or her common general knowledge which supports Kreidl’s idea that surface adsorption of complexes is the key to it. I find that the skilled person would also consider that shielding may well be the much simpler explanation. The fact that Kreidl teaches that clay can be used is clear support for the surface adsorption theory but in the end the skilled person is not interested in stabilising silver on clay, he or she is interested in stabilising silver in wound dressings. Third, the date of the document will stand out to a reader in 2001. Gel forming dressings such as Aquacel were a relatively recent invention in 2001 and did not exist in 1946. The skilled person would be aware of that. In terms of dressing materials, Kreidl focuses on cotton gauze and does not purport to refer to the modern gel forming dressing materials. The explanation why they are not referred to is obvious enough (they did not exist) but the fact remains that this is a document from the 1940s which is not concerned with modern materials. ”

57. All of these matters are important but to my mind it is particularly significant that the judge thought the skilled person would be faced with a puzzle; he would consider Kreidl’s teaching about the surface adsorption of complexes; but he would also consider that shielding might well be the much simpler explanation.

58. The judge returned to the consequences of these rival theories at [195]-[196]:

> “195. I have no doubt that the skilled person would consider whether to test Aquacel in Kreidl’s conditions (using an organic solvent) but the problem is the existence of alternative explanations for Kreidl’s results. If surface adsorption of complexes is the explanation, the test on Aquacel has a prospect of achieving success. It might work. Nevertheless Aquacel is different from cotton gauze. It is one of the modern

> gel forming dressing materials and is not referred to in Kreidl. The skilled person would have no certainty that the test would work. It might or might not.
>
> 196. However if shielding is the explanation for Kreidl's cotton results then the method has no prospect of working with Aquacel at all. There are no places for the silver to be shielded in Aquacel. It may also be that both mechanisms are relevant in which case the skilled person will know that shielding will not provide any help with Aquacel."

59. The judge then reached his conclusion at [197], finding, in substance, that it would not be obvious to the skilled person which theory was right; nor would it be obvious to press on and simply try Kreidl's method on Aquacel:

> "I think the key to the problem is that it would not be obvious to the skilled person which theory was right. Plainly the test could be done very simply but that is not enough. To run the test and see if the Kreidl conditions work for Aquacel, when the skilled person knows that the simpler explanation for Kreidl's results is one which will lead to certain failure and the other explanation by no means guarantees success, is not the act of an unimaginative person. I think it is the act of an inventive person. The obviousness case over Kreidl is a powerful and simple one but I am not persuaded that Convatec's claim lacks an inventive step. I find that the claim is valid over Kreidl."

The appeal

60. On this appeal, the parties were represented as they were before the judge; Mr James Mellor QC and Ms Charlotte May appeared for Smith & Nephew and Mr Piers Acland QC and Mr Geoffrey Pritchard appeared for Convatec.

61. Mr Mellor recognised that this court should be very cautious about interfering with a finding on the issue of obviousness for the reasons explained by Lord Hoffmann in *Biogen v Medeva* [1997] RPC 1 at 45. However, he contended that in this case the judge made a series of significant errors of principle which require this court to set aside his overall finding and reconsider the issue.

62. I shall address these alleged errors of principle in turn. But first I must say a little more about Kreidl's teaching and Professor Kennedy's theory of physical shielding. I begin with Kreidl which, it will be recalled, describes stable solutions of silver halides and their use for disinfectants and the like, but also solid silver halide preparations. As for the former, the passages on pages 1 and 2 of Kreidl, set out at [27] and [28] above, suggest the greater stability of the silver halide solutions may be attributable to the formation of complexes which protect the silver ions against the effects of light. As Professor Burrell accepted in cross examination on day 2, pages 215-218, this would be a matter the skilled team would wish to investigate, there being nothing in their common general knowledge which would give them any confidence the theory is correct.

63. Turning to Kreidl's solid preparations, these again contain more halogen but, unlike Kreidl's solutions of silver halide complexes, not so much as to render them significantly more soluble than the simple silver halides. These, Kreidl postulates, on page 3 in the passage cited at [30] above, acquire increased stability by being adsorbed onto the surface of a carrier. This further theory was also put to Professor Burrell in cross examination. He did not accept that the skilled team would reject it as being totally far-fetched but said once again that it was something they would want to prove, as emerges clearly from this passage of his cross examination on day 2 at 220-221:

> "Q. There is nothing in the skilled person's common general knowledge that would allow him to give that theory any particular credence, is there – the idea of adsorption conferring stability?
>
> A. I would have to think of examples of that because we are here specifically talking about conferring photostability.
>
> Q. Correct.
>
> A. Correct. There are clearly examples where you can, through adsorption, effect other forms of stability.
>
> Q. Indeed.
>
> A. Again, it is not totally far-fetched, but it is something you would want to prove.
>
> Q. Indeed. It is more than just wanting to prove, is it not, because the common general knowledge does not provide him with any support for the proposition that adsorption can confer photostability?
>
> A. Yes. The common general knowledge would not, no.
>
> Q. Indeed, one might say the skilled person would say, "That really cannot be right, reading this in 2001, because 50 years on after the publication of this document, or thereabouts, photoreduction of silver is a known problem with wound care products."
>
> A. I would agree; it still is."

64. That brings me to Professor Kennedy and what Mr Mellor termed "the Kennedy theory" but I prefer to call physical shielding. This was explained by Professor Kennedy at [174] of his composite report cited at [46] above. Importantly, Professor Kennedy thought that the skilled team would conclude that if there was any stabilisation of silver halide or silver halide complexes, it was most likely being achieved by physical shielding by the walls of the cotton fibres. Further, and contrary to a submission advanced by Mr Mellor, I understand Professor Kennedy's theory to include the physical shielding of both simple silver halides and silver halide complexes. Such is clear from [174] of his report.

65. There is, of course, a further possibility, namely the skilled team would consider that Kreidl's successful results in relation to cotton were achieved by a combination of physical shielding and adsorption. Indeed Professor Burrell accepted this possibility in his second report at [46]:

> "In the case of cotton, physical shielding might well occur to some degree, however stabilised silver chloride would also be physisorbed to the cotton as described above."

66. So the skilled team would understand there to be three possible mechanisms of action: surface adsorption of silver halide complexes; physical shielding; and a combination of surface adsorption and physical shielding. The judge plainly had all of them in mind in expressing his conclusions at [195]-[196].

67. Mr Mellor submitted the physical shielding theory contradicts Kreidl because it does not proceed on the basis of complexes. But I see no such contradiction. As I have explained, Kreidl does no more than advance a theory as to how stability is achieved. More importantly, the physical shielding theory advanced by Professor Kennedy applies to both simple silver halides and silver halide complexes. Both can be shielded by the walls of the cotton fibres.

68. Mr Mellor also submitted that the third possibility, that both mechanisms are involved, suffers from the same flaw as the second; and that it is not possible to combine Kreidl's teaching with Professor Kennedy's theory of physical shielding because one contradicts the other. But, as I have said, I see no such contradiction and nor, it seems to me, did Professor Burrell.

69. I come then to the alleged errors of principle and Mr Mellor's first submission that when the judge came to the final question: would the skilled team carry out a simple and straightforward test to see if the clear teaching of Kreidl would work on Aquacel, using materials readily to hand, the judge fell into error because, as is clear from [195] and [197] of his judgment, he was looking for a guarantee or certainty of success or, at the very least, too high an expectation of success.

70. Mr Mellor continued that, in effect, the judge was saying that it would have to be obvious whether Kreidl's theory or Professor Kennedy's theory was right before the skilled team would try out the method described in Kreidl in relation to Aquacel. He submitted that this reasoning turned the world on its head because there was a very simple way for the skilled team to find out which theory was right: by carrying out the Kreidl method with the materials they had to hand. To require it to be obvious which theory was right before embarking on this simple trial was, in effect, to require a guarantee of success.

71. In my judgment this is not a fair characterisation of the approach the judge has adopted. The judge found (at [190]) that in this art the skilled team would not carry out a test without thinking about its rationale. There was no challenge to that finding, nor, realistically, could there have been. It was no doubt with this in mind that the judge found (at [192]) the skilled team would consider how the results in Kreidl came about or, put another way, the technical basis for them in considering any test in relation to Aquacel. But at this point, as the judge continued at [193], the skilled team would be faced with a puzzle in that they would read the discussion and teaching in

Kreidl about complexes, appreciate that there was nothing in the common general knowledge which supported this theory and would consider that physical shielding might well be the simpler explanation.

72. It is against this background that the process of reasoning upon which the judge embarked at [195]-[197] must be considered. The judge concluded it would not be apparent to the skilled person which theory was right. If Kreidl's theory was right, then the method it disclosed might or might not work on Aquacel, a new material. If, on the other hand, Professor Kennedy's theory of physical shielding was right then the method would fail. If it was a combination of the two, then it would all depend, as Professor Burrell accepted on day 2 at 245:

> "Q. … Let us think about what your expectation would be in relation to such a product. If you know or you assume that Kreidl's photostability is delivered by a combination of, let us call it, physical shielding, and physisorption on the surface of the fi[b]ers –
>
> A. Yes.
>
> Q. – given that Aquacel does not have a lumen, then your assumption must be, "I can use it in relation to Aquacel but it is not going to be particularly effective."
>
> A. And that is the point I was trying to get to. Were both required or not? That is what I was saying. If the physisorption is an important part of it, then you might try it. But recognising that Aquacel did not have a lumen, if you believed the lumen was a significant part of it, you would be in the same position if you believed that the lumen was the only way. You probably would not do it. The only way you would do it is if you thought that physisorption was an important part of it."

73. In circumstances such as these, where the skilled team does not carry out a test without thinking about its basis, the judge concluded it would not have been obvious to them what to do.

74. In reasoning as he did, I think it clear the judge did not misdirect himself as to the statutory test. Further, I reject Mr Mellor's contention that the judge asked himself the question: would it have been obvious to the skilled person which theory was right? To the contrary, he asked himself the question: was it obvious to carry out Kreidl's method on Aquacel? I believe this was the right question and he decided it was not obvious. His reasoning reveals no error of law. I would therefore reject Mr Mellor's first submission.

75. Mr Mellor then turned to Professor Kennedy's theory and submitted the judge fell into error in treating this as having equal or possibly greater force than the clear teaching in Kreidl. Mr Mellor used the expression "greater force" because the judge described it as "the much simpler explanation". Mr Mellor continued that this error was itself based upon no fewer than seven different errors of principle.

76. First, Mr Mellor contended that Professor's Kennedy theory is inconsistent with and contradicts the teaching in Kreidl. I agree that the Professor Kennedy's physical shielding theory is very different from Kreidl's theory of protection by adsorption. But this is a matter which the judge had well in mind and was considered by the experts in their reports and explored with them in cross examination. In the end, the judge formed the view, having regard to that evidence and the teaching of Kreidl, including, no doubt, the fact that the only worked example of Kreidl involved a cotton product, that the skilled person would consider the physical shielding theory might well be the much simpler explanation. I believe this was a view he was entitled to form on the evidence before him.

77. Second, Mr Mellor argued that for the skilled team to reject the clear teaching in Kreidl and think up their own theory required greater imagination than the final decision whether to perform the simple test of applying the method of Kreidl to Aquacel.

78. Mr Acland responded, and I agree, that this is no more than a submission and does not constitute an error of principle. In any event I do not accept that Kreidl provides a clear teaching that its method works by adsorption. Rather, it advances this as a theory and it is one which, as Professor Burrell accepted, had no foundation in the common general knowledge at the priority date, some 50 years after Kreidl's publication.

79. Third, Mr Mellor submitted that Professor Kennedy's physical shielding theory was just one of a number of points made by him as to why he would not find Kreidl of any use. All of the other points were rightly rejected by the judge and many arose because Professor Kennedy did not read Kreidl properly. Having rejected those other points the judge failed to consider the impact of them on the status of Professor Kennedy's own theory.

80. I accept that the judge rejected many of the points advanced by Professor Kennedy. I have set out the most important of them at [53] above. But it does not follow that the judge ought to have rejected Professor Kennedy's other evidence and the opinions he expressed. The judge carefully evaluated all of the evidence given by Professor Burrell and Professor Kennedy and, as I have said at [7] above, preferred the evidence of Professor Kennedy as being straightforward and plausible. He obviously found this evidence helpful in assessing the reaction of the notional skilled but unimaginative team upon reading Kreidl. The judge had the advantage of seeing and hearing the expert witnesses give their evidence and I see no reason to interfere with the view to which he came.

81. Fourth, Mr Mellor submitted that Professor Kennedy came up with his theory because he did not read Kreidl properly or approached it in a disinterested frame of mind. The skilled team, by contrast, is deemed to have read Kreidl with interest and would have been bound to conclude that Professor Kennedy's theory could not explain Kreidl's teaching that its method applied to other adsorbent materials such as clays, silicates and aluminium compounds.

82. In my judgment this criticism of Professor Kennedy is not justified. It seems to me from his reports and his cross examination that he considered the disclosure of Kreidl with great care. His difficulty was that he could not understand how adsorption forces might be achieving the increased stability which Kreidl describes. Nor was there any

basis for Kreidl's theory in the common general knowledge. So he thought that any stabilisation was probably the result of physical shielding. That was a view to which he adhered in his cross examination and the judge found his evidence persuasive, as he was plainly entitled to do.

83. Fifth, Mr Mellor argued that for the judge to dismiss the teaching of Kreidl on the basis that the skilled person was not interested in stabilising silver on clay was a plain error of principle. He submitted this teaching provides clear and important support for the surface adsorption theory.

84. The judge dealt with clays at [193] of his judgment which I have set out at [57] above. He recognised that the fact that Kreidl teaches that clay can be used provides support for the adsorption theory but took the view that the skilled person was not interested in clay and so would pay little attention to it. In assessing this reasoning I think it important to have the following points in mind.

85. First of all, there is no example in Kreidl which demonstrates that the use of the method in relation to clay will produce a light stable product. The judge was therefore entitled to form the view that the generalised teaching which Kreidl contains about clay and other materials would be unlikely to affect the view of the skilled team at the priority date that physical shielding may well be the much simpler explanation for the stability seen with cotton. Indeed, Professor Burrell did not suggest that clay formed an important part of Kreidl's disclosure. Moreover, as we have seen, Professor Burrell accepted that both physical shielding and surface adsorption may be occurring when Kreidl's method is applied to cotton. But, as he also explained in the passage of his evidence set out at [72] above, once the method is applied to a material without a lumen, the position becomes even more uncertain. As for Professor Kennedy, he said that clays are different from cotton in that they do not have a lumen, but he also thought that clays and other mineral materials are so different from organic materials in structure and nature that any process of adsorption would be very different in relation to each of them.

86. For all these reasons I think the judge was entitled to conclude that the limited teaching in Kreidl about the use of the method in relation to clays would not be of interest to the skilled team thinking of silverising Aquacel.

87. Sixth, Mr Mellor submitted that the theory propounded by Professor Kennedy can have no application to any material which does not have a lumen or any other ability to act as a shield. In my view this alleged error of principle adds nothing to those with which I have already dealt and I need say no more about it.

88. Seventh, Mr Mellor argued that Professor Kennedy's theory has no explanation for the requirement in Kreidl for an excess of halide, which Kreidl teaches is the key to obtaining light stable silver.

89. There are two answers to this point. The first is that Professor Burrell accepted that the notion that halide complexes provide stability to the silver ions is something the skilled team would wish to investigate. The second is that the aspect of Kreidl's teaching of particular relevance to Aquacel is the preparation of solid preparations. As I have explained, these contain more halide than necessary to form simple silver halide but not so much as substantially to increase their solubility. It is in this context

that adsorption is said to be important for stability, a theory which Professor Burrell said the skilled team would wish to investigate and Professor Kennedy doubted.

90. Mr Mellor then turned his attention to [193] of the judgement and submitted that the judge was wrong to find that the teaching in Kreidl required support from the common general knowledge before it could be accepted or used as a basis for further action.

91. In my judgment this submission is misconceived. The judge did not find any such thing. He simply took into account that the skilled team reading Kreidl would appreciate that it was a relatively old publication and that the theories it propounded had gained no foothold in the common general knowledge over the intervening years. In particular, nothing was known about the nature and extent of the forces said to be holding the complexes to the surface of the substrate.

92. Finally, Mr Mellor advanced the overarching point that the judge was wrong to allow the inadequate and incomplete theory advanced by Professor Kennedy to displace Kreidl's clear teaching. Professor Kennedy's reasons as to why the skilled team would put Kreidl aside were, he submitted, shot through with resistance and an unwillingness to accept any of its teaching. The Kennedy theory was the result of Professor Kennedy's own personal approach to Kreidl and the judge never considered whether it was tainted as a result. Mr Mellor submitted it plainly was.

93. There is nothing in this ground of appeal. As I have said, the judge had the benefit of seeing and hearing the witnesses and he formed the view that Professor Kennedy's evidence was straightforward and plausible. Mr Mellor has failed to persuade me that there is any reason for this court to interfere with the judge's assessment.

Conclusion

94. The judge recognised that this was a difficult case. Kreidl taught a method which, if applied to Aquacel, would have worked and would have been a method in the claim. Further, it would have been easy to perform, requiring no great time or effort. But it is all too easy to find an invention obvious with the benefit of hindsight. The issue of obviousness must be considered without any knowledge of the invention. The judge found this was a field in which the skilled team would not embark upon an experiment without thinking about its rationale. They would have read Kreidl with interest and not simply put it on one side; but it would have presented them with a puzzle. They would have considered the surface adsorption of complexes theory, and also the physical shielding theory. In the result the judge found it was not obvious to apply the teaching of Kreidl to modern wound dressing materials such as Aquacel. That, it seems to me, was a conclusion he was entitled to reach on the evidence before him.

95. I would therefore dismiss the appeal.

Lord Justice Jackson:

96. I agree.

Lady Justice Arden:

97. I also agree.