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THE HIGH COURT

[2006 No. 363 SP]

IN THE MATTER OF AN APPEAL AGAINST A DECISION OF THE CONTROLLER OF PATENTS, DESIGNS AND TRADE MARKS UNDER COUNCIL REGULATION (EEC) 1768/92 AND THE PATENTS ACT 1992

BETWEEN

NOVARTIS AG

PLAINTIFF

AND

THE CONTROLLER OF PATENTS, DESIGNS AND TRADEMARKS

DEFENDANT

Judgment of Mr. Justice McGovern delivered on the 20th day of December, 2007

1. This is an appeal from a decision of the defendant *("the Controller")* made on the 10th March 2005, rejecting the plaintiff's application for a grant of a Supplementary Protection Certificate *("SPC")* pursuant to Council Regulation (EEC) 1768/92, for the pharmaceutical product "*Valsartan or a pharmaceutically acceptable salt or ester thereof in combination with hydrochlorothiazide*" which is branded under the trade mark *Co-Diovan*". (In the course of this judgment hydrochlorothiazide may be referred to from time to time as "HCTZ"). The appeal is brought to the Court pursuant to section 96 of the Patents Act 1992.

Background

2. Regulation 1768/92/EEC ("*the Regulation*") created Supplementary Protection Certificates which applied to medicinal products for human or animal use. The Regulation was brought into force to address a problem which is expressed as follows in the Preamble to the Regulation:-

> "The period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research."

3. The duration of patent protection in Ireland is 20 years and this accords with the position in most European countries. The patent shall take effect from the date on which notice of its grant is published in the Patents Office Journal. (Section 36 Patents Act 1992). The purpose of the Regulation was to encourage research by compensating the holders of a patent for the period of patent protection eroded as a result of the time taken to get authorisation to market a medicinal product. An SPC compensates patentees for the period during which they were unable to exploit a patented invention due to the need to obtain regulatory approval. If an SPC is granted it extends the patent term in respect of the product. One of the recitals to the Regulation states:-

> "Whereas the duration of the protection granted by the certificate should be such as to provide adequate effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusively (stet) from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community; (It appears that the word "exclusively" should be exclusivity since the French text of the Regulation uses the words "...doit pouvoir bénéficier au total de quinze années d'exclusivité au maximum à partir de la première autorisation de mise sur le marché, dans la Communauté, du médicament en question;")

4. The application for a certificate shall be lodged within six months of the date on which the marketing authorisation in the relevant State was granted. Where the authorisation is granted before the basic patent, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

5. An SPC takes effect when the patent expires and has a term equal to the period which elapsed between the date on which the application for the patent was lodged and the date of the first authorisation to place the product on the market in the community, reduced by five years. The maximum duration of an SPC is five years.

6. In the course of these proceedings a motion was brought by the plaintiff to extend the time for bringing the appeal against the Controller's decision of 10th March 2005 and by order made on the 12th day of March 2007 the time for appeal was extended up to and including the 4th day of August 2006.

The facts

7. On the 26th February 1999 the applicant filed a request for the grant of an SPC for

> "Valsartan or a pharmaceutically acceptable salt or ester thereof in combination with hydrochlorothiazide" and with the name "*Co-Diovan*".

8. On the request form the applicant gave Irish patent 71155 with the title "*Acyl Compounds*" as the basic patent in force as required under article 3(a) of the Council Regulation (EEC) No. 1768/92. In order to satisfy the Controller that the product was protected by this patent, the applicant/plaintiff stated in particular "*Valsartan is disclosed in Example 16 and is specifically claimed in claim 26 of patent 71155*". The applicant/plaintiff provided the required information relating to the first authorisation to place Co-Diovan on the market in Ireland, namely product authorisation number 13/91/1 issued by the Irish Medicine's Board on the 10th December 1998. The applicant/plaintiff also provided on the filing date, information regarding the identity of the products authorised and a copy of the notice detailing the publication of the authorisation from the Official French Journal.

9. On the 31st July 2003 the Controller notified the applicant/plaintiff of an outstanding requirement relating to the request for the SPC. In particular the Controller notified the applicant/plaintiff of the following matters:-

> "(i) The medicinal product for which an SPC was sought, i.e. "Valsartan or a pharmaceutically acceptable salt or ester thereof in combination with hydrochlorothiazide" did not appear to be protected by the basic patent 71155 in force.
>
> (ii) The Irish marketing authorisation had been granted for a medicinal product, Co-Diovan, containing a combination of two active ingredients, namely, Valsartan and Hydrochlorothiazide however the basic patent did not appear to protect this combination.
>
> (iii) An SPC (SPC1997/012) had already been granted for the medicinal product Diovan containing the active ingredient Valsartan."

10. On the 28th November 2003 the applicant/plaintiff responded with the following arguments:-

> (i) Any combination of a compound of Formula I with any active ingredient was covered by claims 35 and 36 of the basic patent 71155.
>
> (ii) A medicinal product at issue, Co-Diovan, a combination of Valsartan and Hydrochlorothiazide, fell within the scope of composition claimed 35 and 36.
>
> (iii) The limitation of the protection of the certificate to the medicinal product as authorised should not be confused with the meaning of the term "*product*" as "*protected by the basic patent*".

11. On the 22nd June 2005 the defendant wrote to the plaintiff and restated his opinion that the request for the grant of an SPC did not comply with the requirement of article 3(a) of Regulation 1768/92. The defendant further notified the plaintiff that in the absence of a reply indicating that the plaintiff would comply with the requirements of the defendant as stated, that he would reject the application subject to the applicant's right to apply for a hearing under section 90 of the Patents Act 1992.

12. On the 30th June 2005 the plaintiff formally requested a hearing on the matter pursuant to rule 68(1) of the Patent Rules and a hearing was conducted on the 26th October 2005 before the defendant's hearing officer, Dr. Michael Leydon, in the presence of two examiners. Dr. Leydon is "*a person skilled in the art*", as that expression is understood in patent law.

13. At the hearing the plaintiff was represented by Ms. Assumpta Duffy of F.R. Kelly & Co. who are the Irish patent agents of the plaintiff. Ms. Duffy can be regarded as a person "*skilled in the art*". At the hearing before Dr. Leydon it was agreed that the fundamental issue in question was whether or not the product, i.e., the combination of the active ingredients, Valsartan and HCTZ, was protected by the basic patent 71155 as required by article 3(8) of Regulation 1768/92. Ms. Duffy argued that the combination was protected by the basic patent by virtue of independent claim 35 and its dependant claim 36 and in particular she argued that the term "*comprising*" in claim 35 had a well-established meaning in patent law to the effect of "*including the following elements but not excluding others*". In the application for the patent and the claims made in respect of the product, claims 35 and 36 are as follows:-

> "35. A pharmaceutical preparation comprising as active ingredient a compound according to any one of claims 1 to 34, in free form or in the form of a pharmaceutically utilizable salt, if appropriate in addition to customary pharmaceutical excipients.
>
> 36. An antihypertensive pharmaceutical preparation according to claim 35, wherein an antihypertensive active ingredient is selected."

14. Ms. Duffy asserts while the combination of Valsartan and HCTZ was not specifically disclosed in the basic patent, it was not excluded from the scope of the claims in view of the presence of the term "*comprising*" in claim 35. She argued that the expression "*as active compound*" in claim 35 was not restricted to a sole active compound and that the term "*comprising*" in the claim did not exclude the possibility that one or more additional active compounds may be present in the composition.

Having heard the arguments made by Ms. Duffy and the examples and case law furnished by her to illustrate her arguments, the hearing officer rejected the application for an SPC

> "...on the grounds that the product, namely the combination of Valsartan and HCTZ is not protected by a basic patent in force as required by article 3(a) of the same Regulation". (The Regulation referred to was Regulation 1768/92).

15. In the course of his decision the hearing officer said that in his view it was appropriate to consider the relevant sections of the Act. He said that section 20 provides that:-

> "The claim or claims shall define the matter for which protection is sought, be clear and concise and be supported by the description".

16. Furthermore section 45(1) of the act provides the statutory basis for determining the extent of protection and says

> "The extent of the protection conferred by a patent or a patent application shall be determined by the terms of the claims; nevertheless the description and drawings shall be used to interpret the claims."

He quoted from the second schedule to the act which states

> "Section 45 should not be interpreted in the sense that the extent of the protection conferred by a patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawing being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties."

17. It is clear that an important part of the decision of the hearing officer is based on his view that the interests of third parties such as producers of generic drugs have to be considered in the context of SPC applications.

Regulation

18. On the 18th June 1992 Council Regulation 1768/92/EEC was adopted for the purpose of creating a Supplementary Protection Certificate ("*SPC*") for medicinal products for human or animal use. The Regulation was given effect on the 5th May 1993 by the European Communities (Supplementary Protection Certificate) Regulations 1993 and deemed to have come into operation on the 2nd January 1993. Under the Regulations an SPC can only be granted for a medicinal product for human or animal use. "*Product*" means the active ingredient or combination of active ingredients in a medicinal product. Article 2 provides that

> "Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Council Directive 65/65/EEC4 or

Directive 81/851/EEC5 may, under the terms and conditions provided for in this Regulation, be the subject of a certificate."

19. Article 3 of the Regulation is important and sets out the conditions for obtaining a certificate. It states

> "A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
>
> (a) the product is protected by a basic patent in force;
>
> (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC ...;
>
> (c) the product has not already been the subject of a certificate;
>
> (d) the authorisation referred to in (b) is the first authorisation to place the product on the market as a medicinal product."

20. Article 4 provides that within the limits of the protection conferred by the basic patent, the protection conferred by an SPC shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

21. The certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations - article 5. The application for a certificate must be lodged within six months of the date on which the authorisation to place the product on the market as a medicinal product was granted or within six months of the date of grant of the patent, whichever is the later - article 7.

22. It seems to me that the regulations set out above and at the beginning of this judgment are the relevant regulations for the purposes of the matters in issue before the Court and set out the relevant requirements to be complied with before an SPC can be granted.

The law

23. In *Ranbaxy Laboratories Limited v. Warner Lambert Co*. [2006] 1 I.R. 193 the Supreme Court held that the interpretation of a patent was a question of law. The Court said that the statutory interpretation as expressed in section 45 of the act and the second schedule thereof confirmed the approach taken by Diplock LJ in *Catnic Components Ltd. v. Hill & Smith Ltd*. [1982] R.P.C. 183 where he stated at p. 243:-

> "A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge. The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked". In the *Ranbaxy* case, McCracken J., in referring to the above passage, said at page 197 "The relevance of this passage to the present case is the emphasis on the understanding of persons with practical knowledge and experience rather than being on the actual intention of the patentee. Frequently, as in the present case, claims in a patent are of a very technical nature and the nuances of such claims would not be understood by the ordinary man in the street. The test therefore is not what the claim would mean to the man in the street but rather what it would mean to an expert in the field to which it relates, or what has been expressed in a number of cases as a person skilled in the art. A patent is addressed to and intended to be read and understood by such persons. It may well be that the understanding of such persons may not be a meaning which was actually intended by the patentee or the inventor, but as the purpose of a claim in a patent is to provide certainty as to the extent of the monopoly granted, the relevant test is the understanding of the persons to whom it was addressed rather than the understanding of the patentee or inventor."

24. The construction is objective in the sense that it is concerned with what it would mean to a "*person skilled in the art*". It depends not only upon the words chosen by the patentee in setting out his claims for the product but also upon the identity of the audience to whom it is addressed namely persons "*skilled in the art*" and the knowledge and assumptions which one attributes to that audience. See *Kirin-Amgen Inc & Ors v. Hoechst Marion Roussel Ltd & Ors* [2005] 1 All E.R. 667 at p.680.

25. Section 96 of the Act states that an appeal to the Court shall lie from any decision or order of the Controller other than the decision under *section 22 (2) or section 28 (5).* "*The Court"* in this context means the High Court. The case of *Carrickdale Hotel Ltd. v. Controller of Patent* [2004] 3 I.R. 410 suggests that in a matter of this kind the test to be applied in determining whether the decision of the Controller should be confirmed, annulled or varied is whether the plaintiff has established as a matter of probability that, taking the adjudicative process as a whole, the decision reached was vitiated by a serious and significant error or a series of such errors. In applying the test regard must be had to the degree of expertise and specialist knowledge which the adjudicator has. See remarks of Laffoy J. at p. 423. In the *Carrickdale Hotel Ltd* case Laffoy J reviewed a substantial number of decisions dealing with the Court's role in hearing appeals from decisions of expert tribunals. In considering recent authorities on the subject, she said at p. 417: "*I take as the starting point the decision of the Supreme Court in Henry Denny and Sons (Ireland) Limited –v. The Minister for Social Welfare [1998] 1 I.R. 34*. In that case, Hamilton C.J. made what was subsequently described as "a very strong statement in favour of deference" (per Barron J. in *Orange Ltd. v. Director of Telecoms (No. 2)* [2000] I.R. 159). In the following passage at pp. 37 to 38 he said:-

> "I believe it would be desirable to take this opportunity of expressing the view that the Courts should be slow to interfere with the decisions of expert administrative tribunals. Where conclusions are based upon an identifiable error of law or an unsustainable finding of fact by a tribunal such conclusions must be corrected. Otherwise it should be recognised that tribunals which have been given statutory tasks to perform and exercise their functions, as is now usually the case, with a high degree of expertise and provide coherent and balance judgments on the evidence and argument heard by them it should not be necessary for the Courts to review their decisions by way of appeal or judicial review."

26. It seems to me that that it is not sufficient for the plaintiff to establish that this court would, on the facts, have decided the matter differently. The Court must look at the matter in the context of a person "*skilled in the art*" and must be satisfied this the

Controller's decision lacks a reasonable basis or that the decision was, in the words of Laffoy J., "...*vitiated by a serious and significant error or a series of such errors*," at all times having regard to the degree of expertise and specialist knowledge which the Controller had in making his decision.

27. The plaintiff points to the fact that in a significant number of other European jurisdictions it has been granted an SPC in respect of the product Co-Diovan. It submits that insofar as the Controller sought to support his decision on the judgment of Jacob J in *Takeda Chemical Industries v. Comptroller General of the Patent Office* [2003] EWHC 649 (Pat). He was in error. In that case the unsuccessful applicant for an SPC failed to either disclose or suggest in the basic patent that Lamsoprazole, the active ingredient protected by that patent, could be combined with any other active ingredient, and in particular, specific antibiotics.

28. The respondent contends that his decision was in line with the judgment of Jacob J. in the Takeda case and also with a decision of the Supreme Administrative Court in Stockholm in AB Hassle (case No. 3 428-1996). In that case the application for an SPC related to a combination of two active compounds namely Felodipin and Metroprolol. The basic patent in that case protected only one of the mentioned active compounds name Felodipin. At no point in the patent claim or in the general part of the description was it mentioned or suggested that any additional active compound would be contained in the pharmaceutical preparation. The Swedish court therefore held that the requirements of article 1(c) and article 3(8) of Regulation 1768/92 were not complied with and an SPC should not be granted.

29. Counsel for the defendant says that the decision of the Controller was consistent with earlier decisions made by his office with regard to the grant of SPC numbers 9/93 and 10/93 where the second active ingredient, HCTZ, had been expressly disclosed in the basic patent. The decision to refuse an SPC in respect of Co-Diovan was consistent with these decisions insofar as the failure of the plaintiff to disclose HCTZ in the context of the basic patent for Valsartan effectively precluded the grant of an SPC in respect of Co-Diovan to the plaintiff. It appears that the plaintiff has not yet made an application for an SPC in the United Kingdom, France, Germany or Sweden. Counsel for the defendant invites the Court to take this in to account.

30. It seems to me that I should approach the matter, not on the basis of a requirement for uniformity among Member States of the European Union, but on the basis of the principles which I have set out above. The recitals to the Regulation contain the following clauses: -

> "Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market;
>
> Whereas, therefore, the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted is necessary...".

31. It is noteworthy that in the opinion of Advocate General Fennelly in the case brought by Farmitalia Carlo Erba Srl Case - 392/97 he stated the following: -

> "31. Thirdly, as stated in the seventh recital in the preamble, the SPC must be 'granted under the same conditions by each of the member states'. However the conditions for the grant of a certificate must be distinguished from those governing the protection it confers. The extent of this protection, and the rights, limitations and obligations ensuing there from, are chiefly determined by reference to the basic patent (subject, of course, to it being confined to the product which is the subject of the relevant marketing authorisation) and, thus, by national patent law. Although the Sixth recital in the preamble to the Regulation the law indicates that it was designed to provide for 'a uniform community solution' and to prevent 'the heterogenous developments of national laws leading to further disparities' which would directly affect the internal market, it is clear to me that this refers primarily to the development, before the Regulations adoption, of diverse national supplementary protection regimes. The regulation does not seek to harmonise the underlying national patent rules, upon which the supplementary protection regime is grafted. As a result, in spite of the significance of Article 69 of the European Patent Convention both for the application of that convention and in the purely national patent systems of a number of Member States, there are no grounds for concluding that the Regulation, requires a uniform approach to the question of the extent of the protection conferred by an SPC."

32. This opinion of the advocate general is one with which I would agree.

Conclusions

33. The decision of the respondent's hearing officer was given on the 16th March 2005. The decision and the grounds thereof are set out in a document which sets out in detail the consideration of the case made by the plaintiff. In particular the hearing officer considered the claim made by the patent agent on behalf of plaintiff to the effect that a skilled person would appreciate that one or more of the compounds claimed in claim 1 could be combined with a diuretic, especially HCTZ as such a combination was common in the art at the priority date of the patent. The examples offered to the hearing officer included Fosnopril and HCTZ and Captopril and HCTZ. The hearing officer reviewed the cases offered by way of example and noted that the combinations of the particular active compound with a diuretic such as HCTZ were explicitly disclosed in both the description and the claims of these patents.

The hearing officer weighed up the various arguments made on behalf of the plaintiff and considered the regulation and the legislation in addition to the basic patent 71155 and the claims made for same. He also considered the material furnished in respect of claims for an SPC in other jurisdictions.

34. He took into account that the combination of Valsartan and HCTZ was not specifically disclosed in the basic patent and this was accepted by the plaintiff's agent in making arguments before him although it was urged on him that the presence of the term "comprising" in claim 35 meant that HCTZ was not excluded from the scope of the claims. In the legal submissions made to the court counsel for the plaintiff also conceded that the combination of Valsartan and HCTZ is not specifically claimed in the basic patent but argued that it was not excluded from the scope of the claim in view of the wording of claim 35.

35. The hearing officer rejected the request for the grant of an SPC on the grounds that the product, namely the combination of Valsartan and HCTZ, is not protected by a basic patent in force as required by article 3(a) of Regulation 1768/92. It seems to me that applying the test laid down in *Carrickdale Hotel Ltd. v. Controller of Patents* that there is nothing unreasonable about the decision and I cannot find any serious or significant error in the adjudicative process. In saying this I have regard to the degree of expertise and specialist knowledge which the hearing officer had when determining the matter. The decision which he reached

appears to be one which combines a fair protection for the patentee with a reasonable degree of certainty for third parties thus satisfying the direction set out in the second schedule to the act. In interpreting section 45 of the act the court is obliged to have the regard to these directions and I do so.

36. In the circumstances I dismiss the appeal and refuse the relief sought.