Neutral Citation Number: [2010] IEHC 6

THE HIGH COURT

COMMERCIAL

2008 10436 P

BETWEEN

MEDINOL LIMITED

PLAINTIFF

AND

ABBOTT IRELAND AND

ABBOTT VASCULAR INTERNATIONAL B.V.B.A.

AND BY ORDER 6TH JULY 2009,

ABBOTT CARDIOVASCULAR SYSTEMS INCORPORATED,

ABBOTT VASCULAR DEVICES HOLLAND B.V.

AND ABBOTT LABORATORIES INCORPORATED

DEFENDANTS

JUDGMENT of Ms. Justice Finlay Geoghegan delivered on the 19th day of January, 2010

1. This judgment is given on the disputed portions of motions by the plaintiff seeking discovery from the defendants and by the defendants seeking discovery from the plaintiff. Those applications have to be considered in the context of the claim and counterclaim in the proceedings.

2. The plaintiff is the proprietor of a European patent EP1 181 902 ("the Patent") for a flexible expandable stent . In these proceedings, the plaintiff alleges that the defendants (or the companies in the former Guidant Group in respect of which they have assumed liability) have infringed the Patent. It is alleged that the defendants have done so by making a range of medical stents referred to in the proceedings as the Vision, Mini-Vision, Xience, Mini-Xience, Promus, Multi-Link 8 and Xience Prime products at the defendants' premises in Clonmel, and by offering putting on the market and using the said products which are alleged to infringe certain claims of the Patent.

3. The defendants, in their defence, accept that the first named defendant makes the products in question and counterclaims that the Patent is invalid as set forth in the Particulars of Objection on the grounds of lack of novelty, lack of inventive step, insufficiency and added matter. The defendants also deny that the products infringe the Patent, if valid.

4. The plaintiff, in the Particulars of Infringement, alleges that the defendants' products infringe, *inter alia*, Claim 1 of the Patent which is in the following terms (as amended in accordance with the First Auxiliary request - amended language underlined):

> "1. A flexible, expandable stent formed of an elongated cylindrical unitary tube (30) having in a non-expanded form and in its expanded form a patterned shape, the patterned shape comprising first meander patterns (11) extending in a first direction and second meander patterns (12) extending in a second direction, different from the first direction, wherein the first and second meander patterns comprise loops and are intertwined such that loops (14, 16) of each of the first meander patterns (1) are disposed between each of the neighbouring second meander patterns (12) and that <u>one single loop</u> (18, 20) of each of the second meander patterns (12) is disposed between each of the neighbouring first meander patterns (11), and wherein the first and second meander patterns (11, 12) define a plurality of enclosed spaces (42a, 42b, 44a, 44b)."

Legal principles

5. The parties are in agreement that the legal principles applicable to the determination of the disputes between them on the two discovery motions herein are those set out in two judgments of the High Court of February 2007: *Schneider (Europe GmbH) v. Conor Medsystems Ireland Limited* [2007] IEHC 63, and *Medtronic Inc. and Others v. Guidant Corporation and Others* [2007] IEHC 37. The relevant principles and authorities are fully set out by Kelly J. and me in the above judgments, and I think it suffice to say that under O. 31, r. 12 of the Rules of the Superior Courts, each of the applicants for discovery has to demonstrate that the documents sought are both relevant and necessary for the fair disposal of the case or to save costs. Further, that the onus of establishing relevance and necessity for the purposes mentioned in the rule is on the moving party. Finally, the general principles are applicable to discovery in patent actions as in any other action. The dispute between the parties is as to the proper application of the principles to the present proceedings and the documents sought.

Plaintiff's application for discovery
6. At the time of the hearing, a dispute persisted in relation to the plaintiff's request for documents in Categories 1(a), 1(d), 1(e) and 4. I propose considering these sequentially.

Category 1(a)
7. During the hearing, counsel for the plaintiff indicated that the plaintiff was willing to limit the documents sought within this category. The defendants had contended that the categories of documents sought were too wide and should be limited to the design and not include research and development. The amended Category 1(a) now reads:

> "1(a) Any document detailing the design of each size of the "Vision", "Mini-Vision", "Xience", "Mini-Xience", Promus", "Multi-Link 8" and "Xience Prime" stents (as referred to in the pleadings), in either expanded or unexpanded form, these documents are to include documents detailing the progression of the design of these stents in respect of the replacement of straight connectors with curved connectors in so far as they show these changes or touch upon the effect of such changes. These documents are to include (for the avoidance of any doubt):-
>
> (i) design drawings and specifications so detailing;
>
> (ii) engineering files so detailing;
>
> (iii) CAD files so detailing; and
>
> (iv) Schematic diagrams so detailing."

8. The defendants did not make any substantive objection to this reduced category. I am satisfied that as the defendants deny that the products infringe the Patent, if valid, that such documents are relevant and necessary and should be discovered.

Category 1(d)
9. 1(d) "All documents disclosing or evidencing any evaluation of whether the features, configuration or design of the said products were the subject of patent protection."

10. I have concluded that this category should be discovered. The documents appear relevant to the issue of infringement within the classic statement of the judgment of Brett L.J. in the *Peruvian Guano* case [1882] 11 Q.B.D. 55, where he stated:

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

11. As the defendants deny infringement of the Patent, any such documents come within the above rubric. They may contain information which would enable the plaintiff advance its claim of infringement or damage the defence denying same. The fact that some such documents may be privileged does not now prevent them being the subject of an order for discovery. Accordingly, there will be an order for discovery of this category.

Category 1(e)
12. Counsel for the plaintiff indicated that if an order was made for Category 1(a) as amended, that he was not pursuing the request for this category. Accordingly, there will be no order in respect of this category.

Category 4
13. "4. All documents constituting, or relating to, communications between any of the defendants or their agents, on the one hand, and Boston Scientific or any other entity engaged in the distribution of the said stents, on the other hand, concerning possible infringement by the said stents of the defendants of the plaintiff's patent and/or the validity of the patent."

14. The plaintiff, in support of its application for this category, asserts that Boston Scientific acts as a distributor of the defendants' "Promus" stents in issue in the proceedings. This is not denied. Further, the plaintiff contends that communications passing between the defendants and their distributor, Boston Scientific, may well involve the raising by the latter of the issue of patent infringement and responses from the defendant concerning the question of infringement and of the validity of the Patent. The defendants submit that the category of documentation is not relevant and constitutes a fishing expedition. They draw attention to the fact that the averments supporting the application for this category are made only by the solicitor for the plaintiff and not by an officer of the company.

15. As it is not in dispute that Boston Scientific is a distributor, it does not appear to me that this application is simply a fishing expedition. If there were no communications between the defendants and Boston Scientific in relation to possible infringement, then the category will be easily discovered. If such correspondence does exist, then, depending on its content, it may well fall within the *Peruvian Guano* principles which may damage the defendants' denial that the accused products do not infringe the Patent. Accordingly, I would allow this category.

Defendants' application for discovery
16. The categories of documents sought by the defendants may be considered in groups.

Categories 2.3 and 2.4
17. In the course of the hearing, the defendants, through counsel, proposed a revised Category 2.3 and indicated that if such documents were ordered they were not pursuing an application in relation to Category 2.4 as originally drafted. The revised Category 2.3 is:

> "Documents created within the period 1 July 1992 to 30 July 1997 that have at any time been considered or evaluated by or on behalf of the Plaintiff as to its potential effect upon the patentability of any claim of the Patent."

18. The defendants submit that this category of documents is a relevant to the counterclaim for invalidity and is similar to categories allowed by Kelly J. in *Medtronic Inc*. In *Schneider*, I allowed an analogous category, though in some respects, more limited as it referred only to consideration of the prior art referred to or related to that listed in the Particulars of Objections.

19. I note that in *Medtronic*, Kelly J., whilst allowing a broader category to that now sought in the revised form of 2.3, did so with some reservations. Nevertheless, I have concluded that such documents are relevant to the counterclaim for invalidity and in particular, to the grounds of lack of novelty and lack of inventive steps/obviousness referred to in the Particulars of Objections insofar as they may disclose a line of enquiry which the defendants may wish to pursue with their expert witnesses and which may advance its counterclaim or damage the plaintiff's defence to the counterclaim. I have concluded, therefore, that those documents are necessary for the fair disposal of the issues on the pleadings and will allow this category.

Categories 2.6 to 2.11
20. These Categories are:

> "2.6 All Documents concerning the advertising and/or marketing of the Plaintiff Covered Products including but not limited to press releases, product literature and catalogues, brochures, meeting agendas, meeting minutes, training materials, training plans, promotional tips or guidelines, CD-ROMs, competitive targeting or analyses, on-line advertising, marketing materials, promotional materials, presentations materials, technical literature, FDA-approved Instructions for USE (IFU), launch plans, transcripts, recordings (visual or audio), DVD, and videotapes or any speeches, presentations, or promotional talks concerning any Plaintiff Covered Products.
>
> 2.7 All Documents concerning any efforts to obtain CE Approval and/or FDA approval of a Plaintiff Covered Product including, without limitation, the design history file for each Plaintiff Covered Product, all submissions and any related correspondence or other communications concerning the CE Approval and/or with the FDA.
>
> 2.8 All Documents concerning the research, development, design, construction, manufacture, structure, function, description, production and operation of each Plaintiff Covered Product including, but not limited to, product specifications and drawings (*e.g.* engineering drawings), protocol and manuals.
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> 2.9 All images (and for the avoidance of doubt the Defendants do not require any duplicate images) of any Plaintiff Covered Product and related Documents including but not limited to formal and informal drawings and diagrams; photographs; lightmicrographs or images; electron micrographs or images; X-Ray and CT scans or images; sonically derived images; magnetically derived images, including MRI images or moving pictures, holograms; and two (2) physical samples (in the unopened packaging in which they are commercially sold) of each of the Plaintiffs' Covered Products.
>
> 2.10 All Documents concerning any Finite Element Analysis ("FEA") of a Plaintiff Covered Product including but not limited to all computer models, all data used to model the Plaintiff Covered Product, all computer files used during or generated by the FEA, all results of the FEA, all communications with any other persons who performed the FEA of any Plaintiff Covered Product.
>
> 2.11 All Documents and things constituting, referring or relating to any packaging, labelling, advertisements, literature, manuals and/or instructions for use relating to the Plaintiff Covered Products."

21. The defendants submit that the above categories of documents are relevant on two bases. Firstly, they submit that it is relevant to compare the defendants' accused products with the plaintiff's covered product as an embodiment of the claims in the Patent. The plaintiff disputes this and submits that for the purposes of infringement, what is relevant is only to compare the defendants' accused products with the claims in the Patent. The plaintiff submits that its covered product is only one embodiment of the claims in the Patent.

22. The second basis upon which the defendants seek some or all of the above categories is that as those documents describe the plaintiff's covered product which is an embodiment of the claim, it will assist them in understanding the claims in the Patent.

23. It is not in dispute that for the purposes of determining infringement, the comparison must be made between the defendants' accused products and the claims in the Patent. I am not required at this stage to decide upon the admissibility of evidence relating to the plaintiff's covered product as an embodiment of the claim, and any potential comparisons between the defendants' accused products and the plaintiff's covered product. The categories of documents sought are very broad. I am not satisfied that the defendants have established that all those categories are relevant or

necessary for the fair disposal of the issues in these proceedings. Even if evidence of comparison between the defendants' accused products and the plaintiff's covered product is permissible, a limited category of documents would be sufficient to permit the defendants to fully understand or examine the plaintiff's covered product and compare it with the accused products.

24. The interpretation of the claims in the Patent in accordance with established case law, including *Ranbaxy Laboratories and Others v. Warner Lambert Company* [2006] 1 I.R. 193, is the matter for objective construction by the Court with the assistance of the evidence of persons skilled in the field. I am prepared to accept, for the purposes of this application, that it could be of assistance to the defendants' case to have a full understanding of the plaintiff's covered product for the purpose of, *inter alia*, instructing their experts. However, a more limited category of documents than those sought in paras. 2.6 to 2.11 inclusive appears sufficient. I have concluded that not all of the categories sought at paras. 2.6 to 2.11 are necessary for the fair disposal of the issues in the proceedings.

25. I have decided that I should allow certain of the documents sought in Category 2.8 which will disclose the full nature of the plaintiff's covered product. Documents relating to research, development, construction, manufacture or production of the plaintiff's covered product do not appear relevant. I propose allowing only Category 2.8 amended to read:

> "All documents which show the design, structure, function, description and operation of each plaintiff covered product, including, but not limited to, product specifications and drawings (*e.g.* engineering drawings), protocol and manuals."

26. I have concluded that the remaining categories are too broad and of marginal relevance to make them necessary. Insofar as the defendants seek, in Category 2.9, two physical samples in the unopened packaging in which they are commercially sold, these are products which the defendants can, presumably, purchase, and an order for discovery is unnecessary in respect thereof.

Category 2.12
27. The defendants, in the course of the hearing, amended this to read:

> "All Documents and things that constitute, refer or relate to communications by the Plaintiff or any of its officers, directors, employees, agents or attorneys regarding any Accused Product in this litigation concerning possible infringement of the Plaintiff's Patent by the Defendants."

28. The defendants are entitled to discovery of this category for reasons similar to those for which I have permitted discovery of Category 1(d) sought by the plaintiff. They may advance the defendants' defence or damage the plaintiff's claim. Certain of the documents may be privileged but can be made the subject of a claim for privilege in the affidavit of discovery in the normal way.

Category 4.2
29. The defendants, at the hearing, sought an amended Category 4.2 in the following terms:

> "(i) Documents considering or analysing the benefits over and above the state of the art, of the claims of the Patent; and
>
> (ii) Documents relating to any of the Plaintiff's contentions regarding third party infringement of the Patent."

30. The defendants rely upon the decision of Kelly J. in *Medtronic,* in which a category of documents similar to Category 4.2 as originally drafted was ordered. I have concluded that Category 4.2, as redrafted, should be permitted. Category 4.2(1) appears relevant for the reasons given by me above in relation to Category 2.3. Category 4.2(ii) is the converse of the documents sought by the plaintiff and which I allowed as Category 1(d). They are relevant and necessary for similar reasons.

Category 4.3
31. "All documents concerning any experimental use of any alleged invention claimed in the patent and any related patent or related patent application."

32. The defendants again rely upon the decision in *Medtronic* to order a similar category of documents. They submit that such documents may assist in their analysis of the Patent and the analysis of a person skilled in the art of the patent and any related patents. They also seek the documents on the basis that they may assist in demonstrating the comparison between the plaintiff's products that allegedly work the invention and the accused products. I am in agreement with the view expressed by Kelly J. in *Medtronic* that this category is relevant and necessary, having regard to the test of relevance in *Peruvian Guano*. I will allow this category.

Relief
33. On the plaintiff's application, there will be orders for discovery of the documents in Categories 1(a), 1(d) and 4 in the amended or revised terms each are set out in this judgment.

34. On the defendants' application, there will be orders for discovery of the documents in Categories 2.3, 2.8, 2.12, 4.2 and 4.3 in the amended or revised terms each are set out in this judgment.

35. I will hear Counsel as to the timing and identity of deponents of the affidavits of discovery.