Kluwer Patent Blog

Wyeth taken by Carr to winning position in vaccine battle

Brian Cordery (Bristows) · Friday, May 20th, 2016

by Rachel Mumby

Bexsero, the Meningitis B vaccine marketed by GSK, has been the subject of many newspaper headlines in the UK over the last year, with parents seeking to persuade the UK Government to offer the vaccine to all children under the age of 11 as a matter of routine. Few will have been aware that Bexsero was also the subject of patent litigation in the UK, with GSK seeking the revocation of a patent owned by Wyeth (a subsidiary of Pfizer) and a declaration of non-infringement. Wyeth counterclaimed for infringement, but for public health reasons did not seek injunctive relief. Wyeth has developed its own Meningitish B vaccine, Trumenba, but this has not yet received approval in Europe.

In a lengthy judgment from Carr J, which provides helpful summaries of the law on the skilled addressee, common general knowledge, claim construction, plausibility, added matter, priority, novelty and inventive step (the application of each of which were hotly contested), the patent was found to be valid and infringed.

In order that the reader isn't left wishing they'd just read the judgment themselves, the note below picks out some of the bigger points.

Common General Knowledge

Carr J applied the legal principles set out by Arnold J, and later approved by the Court of Appeal, in **KCI Licensing v Smith & Nephew [2010]**, but also agreed with Sales J's statements in **Teva v AstraZeneca [2014]** that the concept of common general knowledge needs to be kept up-to-date in the age of the internet and digital databases of journal articles. Carr J held that material which the skilled addressee knows to be available on-line and which is generally accepted as a good basis for further action (such as material which might be found off-line in a textbook or key journal article) may constitute common general knowledge. In doing so, Carr J poured cold water on any broader interpretation of Sales J's statements, whilst acknowledging that the law has to keep up with the changing research practices of today's scientists and engineers.

Plausibility – AgrEvo obviousness/insufficiency

There was no dispute over the principles to apply in relation to plausibility and **AgrEvo** obviousness/insufficiency, and once issues of construction had been dealt with, the **AgrEvo** obviousness allegation fell away. Carr J then considered that both experts more or less agreed that

the disclosure of the patent was plausible. Indeed, both experts recognised that the disclosure of the Patent was very significant – even GSK's expert acknowledged that the patent disclosed a vaccine candidate with promise, and of considerable interest (not therefore an arbitrary, implausible selection).

Carr J also rejected further plausibility arguments, for example that the skilled addressee would be concerned by the fact that data in the patent do not support the killing of some strains of meningococci by all compositions comprising a relevant protein with 100% homology with the equivalent protein of the tested bacterial strain. He held that the skilled person would not be surprised by exceptions to the general trend (especially considering the experiments had been carried out on complex biological systems) and would still consider the claims to the credible. In addition, whilst Carr J accepted that on the basis of the data in the patent, it would be preferable to select a lipidated rather than a non-lipidated protein, that did not make it implausible that a non-lipidated protein would give a bactericidal effect.

Added Matter

The main attack from GSK was that Wyeth had made a series of arbitrary selections from lists. GSK relied on EPO case law such as T 667/08 and T 12/08, together with the EPO Guidelines for Examination, and argued that since a selection from two lists can be novel for the purposes of patentability, then it will also constitute added matter if the selection was not to be found in the application as filed. In a paragraph which will be music to the ears of many patentees who feel scorned by recent harsh decisions on added matter, Carr J held as follows:

"*In my judgment, selections from two or more lists may well amount to impermissible added matter, but this is not a rigid rule. In order to see whether there is a new combination of independent features from two or more lists, the whole contents of the application as filed must be considered, including its general disclosure. It is necessary to avoid a mechanistic approach, and to compare the disclosures of the application as filed and the patent, through the eyes of the skilled person, in order to answer the overall question of whether the skilled person would learn new technical subject matter which was not disclosed in the application*"

Novelty

In relation to the first citation, patent application "WO885", Carr J applied **Dr Reddy's v Eli Lilly [2010]** and considered whether the prior art provided a sufficiently individualised disclosure. He acknowledged that this is a matter of degree. Carr J held that the prior art was in "books in the Bodelian" or "leaves in Sherwood Forest" territory, rather than being sufficiently individualised. WO885 included a list of potential antigens by reference to a series of other documents, including patent application "WO280", and then later in WO885 there was a list of the antigens from WO280. He noted that the relevant sequence is not one that the skilled person is directed to by WO885 (or WO280). In order to pick the right antigen, the skilled addressee would be required to "pluck out" the relevant protein from a list of 1510 proteins from WO280, the references to WO280 in WO885 being no more than a reference to the document as a whole and with no technical information.

The second novelty citation was to the prior use of a Cuban Vaccine. However, Carr J found that on the balance of probabilities, this vaccine did not contain the relevant protein pre-priority. Even if he was wrong on that, after carefully considering the House of Lords case of **Merrell Dow v**

Norton [1996] (which he noted to be consistent with the EBA in G1/92), Carr J found that there would have been no enabling disclosure. Carr J held that if the Cuban Vaccine could not be analysed to identify the presence of the relevant protein, then the supply of that vaccine and its administration to patients conveyed no information which would have enabled anyone to work the invention. For the Cuban Vaccine to anticipate, it must have been possible for the skilled person to identify the presence of the relevant protein in the vaccine and to reproduce it without undue burden – Carr J found that GSK had not proved that it would have been possible to identify the relevant protein either at all or without undue burden. In addition, the relevant protein was in such low abundance in the Cuban Vaccine that it would have made no material contribution to the immune reaction (thus not anticipating claims 18-20 mentioned above).

Inventive Step

Carr J once again set out the relevant legal principles and, following the trend in recent cases, criticised GSK's expert for hindsight. GSK's expert had come to the cited prior art with knowledge of the protein of significance to the case. He had obtained this from reading 885 (and 280), the patent application cited for novelty in this case – yet again showing the importance of giving the expert the documents in the right order.

Conclusion

This will be a comforting decision for patentees facing attacks on all possible grounds, and wondering whether it will be possible to fight all of them off without being squeezed on multiple fronts into any traps. Carr's non-mechanistic approach will also be welcomed by the patentee community. However, with quite so many points in issue, and GSK only needing to win one of them to get a different outcome, we expect to see an appeal.

A link to the decision can be found here

To make sure you do not miss out on regular updates from the Kluwer Patent Blog, please subscribe here.

Kluwer IP Law

The **2022 Future Ready Lawyer survey** showed that 79% of lawyers think that the importance of legal technology will increase for next year. With Kluwer IP Law you can navigate the increasingly global practice of IP law with specialized, local and cross-border information and tools from every preferred location. Are you, as an IP professional, ready for the future?

Learn how **Kluwer IP Law** can support you.

79% of the lawyers think that the importance of legal technology will increase for next year.

Drive change with Kluwer IP Law.
The master resource for Intellectual Property rights and registration.

Wolters Kluwer

2022 SURVEY REPORT
The Wolters Kluwer Future Ready Lawyer
Leading change

This entry was posted on Friday, May 20th, 2016 at 5:58 pm and is filed under Art. 123(2) of the European Patent Convention (EPC), a European patent (application) may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. Adding subject-matter which is not disclosed would give an applicant an unwarranted advantage and could be damaging to the legal security of third parties. (G 1/93, OJ 1994, 541) *The 'gold standard'* of the European Patent Office's Board of Appeal is that "*any amendment can only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the documents as filed" (G 3/89, OJ 1993,117; G 11/91, OJ 1993, 125).*">Added matter, Inventive step, Novelty, Pharma, Priority right, Public prior use, Revocation, Sufficiency of disclosure, United Kingdom, Validity

You can follow any responses to this entry through the Comments (RSS) feed. Both comments and pings are currently closed.