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Armchair patent fails to get off the ground

Brian Cordery (Bristows) · Tuesday, March 13th, 2012

The English High Court has upheld the decision of the UK Intellectual Property Office to refuse the grant of a patent for the treatment of inflammatory bowel disease (IBD) with zinc (El-Tawil v The Comptroller General of Patents [2012] EWHC 185 (Ch)). Although the case does not break new ground, it provides a useful review of the approach of the English courts to some patentability questions (and a critique of the difficulties that patent applicants litigating in person may create for themselves).

Claim 1 of the patent application in suit described a mechanism of action by which addition of zinc to a treatment regimen might treat IBD (the use of zinc for treating IBD having previously been described). The judge, Mann J, held that the application was to a second medical use, and following existing case law (Bristol-Myers Squibb v Baker Norton [2001] RPC 1) ruled that a different mechanism of action should be rejected as lacking novelty, as the mechanism of action is irrelevant to the question of patentability. The applicant also argued that, even on this analysis, the prior art did not anticipate as it related to a form of a clinical trial (i.e. it did not describe an accepted treatment regimen) and he criticised some of the science set out in the prior art article. However, the Court held that the source of a prior art disclosure and its scientific rigour was not relevant, but rather the disclosure itself. Furthermore, such a claim (defined by the newly-identified mechanism of action) would define a discovery, which was not patentable under section 1(2)(a) of the Patents Act 1977 (“the Act”).

Claims 2 and 3 related to particular dosage ranges of zinc sulphate administered as an enema or infusion respectively for the treatment of specific IBDs. The prior art described other routes of administration. The Court agreed with the decision of the Intellectual Property Office that the alternative routes of administration were obvious. Furthermore, the Court considered the established law on dosage regimes (Actavis v Merck [2008] EWCA Civ 444), holding that novel dosage regimes were inventive only in unusual circumstances as it is standard practice to investigate appropriate dosage regimes. This was not such a case.

The Judge also considered whether the claims lacked support, contrary to section 14(5) of the Act. The Court held that the application contained no support that the use of zinc would operate through the mechanisms of action claimed. Case law from both the English Court and the Technical Boards of Appeal of the EPO recognises that tests relied on in a patent application do not need to be full, rigorous, detailed and conclusive and that in some cases they can be very rudimentary. However, in this case, the Court held that the claimed inventive steps were mere assertions and that the applicant had not even satisfied this relatively low hurdle. The applicant had sought to rely on one

prior art publication as providing support for much of the description. The Court held that this paper was not capable of providing the support that was missing from the description. The document did not provide anything in the nature of evidence of tests which supported the claimed invention (i.e. the claimed mechanisms of action). Instead it provided some support for the prior art from which the invention was said to flow. As such, it could not provide material support for the invention. Furthermore, had it provided the required support, as it was published before the application was made it would have anticipated the patent application.

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