

Court of Appeal affirms approach to plausibility

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by Steven Willis

Yesterday, the Court of Appeal handed down its decision in **Idenix v Gilead** [2016] EWCA Civ 1089, a dispute involving SOVALDI® (sofosbuvir), which is sold by Gilead as a treatment for chronic hepatitis C infection in adults. At first instance, Arnold J held (in an epic 621 paragraph judgment) that Idenix's Patent claiming a family of nucleoside analogues for treating HCV and other *Flaviviridae* infections ("the Patent") would have been infringed by the making and selling of SOVALDI but that the Patent was invalid for lack of novelty, lack of inventive step, insufficiency and added matter. The Court of Appeal has upheld Arnold J in all material respects.

Inventive Step

Perhaps the most interesting element of the judgment concerns inventive step. Gilead contended that the Patent failed to render it plausible that substantially all of the compounds encompassed by the claims (some 50 billion) would be effective against *Flaviviridae*. To support its position, Idenix asserted that more information formed part of the CGK than Gilead, a position which Arnold J had reflected on as being unusual and potentially indicative of an attempt to remedy deficiencies in the Patent.

A key finding which was subject to appeal was whether it was CGK that the patented family of nucleoside analogues had the potential to be efficacious in treating HCV. Idenix argued that Arnold J had set the bar too high and asked himself whether or not the compounds were in fact active and whether this was known to all persons interested in the field rather than whether the compounds were generally regarded as a good basis for further action by the bulk of those engaged in the field. The Court reiterated *inter alia* Laddie J's guidance in **Raychem Corporation's Patents** [1998] to the effect that CGK is not limited to knowledge that is in the mind of the skilled person but includes material that he/she "knows exists and which they would refer to as a matter of course if they cannot remember it and which they understand is generally regarded as sufficiently reliable to use as a foundation for further work." Despite acknowledging the relatively broad scope of CGK, the Court of Appeal nevertheless held that Arnold J had correctly applied the authorities and that his finding that it was not CGK that the compounds were potentially efficacious was "unassailable".

Having upheld Arnold J on CGK, the Court turned its attention to the thorny issue of plausibility. The Court reminded itself of the Supreme Court's treatment of the concept within the context of industrial applicability in **HGS v Eli Lilly** [2012] where it was held that "even an educated guess" as to the practical application for a claimed product can be sufficient to overcome the plausibility hurdle. Similarly, in **Warner-Lambert v Actavis** [2016], the Court of Appeal recently stated, within the context of an allegation of insufficiency of a Swiss form second medical use claim, that plausibility is a "low threshold test" which "is not designed to prohibit patents for good faith predictions which have some, albeit manifestly incomplete basis". The Court of Appeal has confirmed that the same approach should be adopted when assessing plausibility within the context of obviousness. However, despite endorsing the status of plausibility as a low, threshold test, in light of *inter alia*: (i) the lack of relevant experimental data in the Patent; (ii) the lack of "a theory or rationale" as to why the claimed compounds may be effective; and (iii) the Court's finding in relation to the CGK, Arnold J's finding that there was no plausible disclosure of efficacy was upheld.

Insufficiency

There are elements of the Court's approach to insufficiency which are also worthy of note. Firstly, it is often stated that the Appellate Courts in England and Wales are reluctant to interfere with first instance findings of obviousness, which are considered a kind of jury question (see e.g. **Biogen v Medeva** [1996]). The Court of Appeal, citing *inter alia* the House of Lords in **Smith Kline Beecham** [2006] stated that a similarly cautious approach should be adopted when considering an appeal of a finding of insufficiency.

Perhaps the Court had this in mind when considering the question of whether Arnold J had erred in finding that the Patent did not allow the skilled person to make the claimed compounds without undue burden. Idenix contended that Arnold J had erred by considering enablement by reference to whether the compounds could have been made using "a routine method" rather than whether or not making them required "undue effort". This alleged error in approach, Idenix argued, led to "a refusal to allow the skilled person to read the relevant literature" in order to assist him in making the compounds. However, Kitchin LJ endorsed Arnold J's approach as "entirely appropriate"; the patentee need not describe "routine" or "ordinary" steps which the skilled person must take in order to implement the invention. Furthermore, while in some circumstances the skilled person may reasonably be expected to carry out a literature search in order to implement aspects of the teaching, whether or not the necessity of such a search renders the patent insufficient will depend on all the circumstances "including the nature and purpose of the search that is required".

Novelty/Priority

The final point of interest arose within the context of Gilead's contention that the Patent was anticipated by one of Gilead's own patent applications. This allegation required Gilead to demonstrate that it was entitled to claim priority from an earlier filed US application. The Court of Appeal did not consider that it needed to decide these issues in light of its findings in relation to the other grounds of invalidity. However, it did make an interesting obiter statement concerning the question of whether the transfer of equitable title to an invention is sufficient to render the transferee a "successor in title" for the purposes of Article 4A of the Paris Convention, i.e. for the purpose of claiming priority.

At first instance, Arnold J followed two first instance English Court decisions which suggest that the transfer of equitable title is sufficient (**KCI v Smith & Nephew** [2010] and **HTC v Gemalto** [2013]). Kitchin LJ provisionally agreed with these authorities and opined that "*the Paris Convention does not purport to identify the requirements for the effective transfer of title to an invention and ... these matters are left to the relevant national law.*" However, Kitchin LJ noted that it had emerged during argument that there may be other materials and decisions that could challenge this orthodoxy. It appears therefore that there may be some scope to challenge a patentee's right to claim priority in circumstances where the patentee is unable to show that legal title has been transferred from the priority applicant to the patentee during the priority year and seeks to rely on the transfer of equitable title. However, in light of Kitchin LJ's provisional stance, such a challenge will surely be an uphill battle.