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UK Government agrees damages for failure to grant marketing authorisation

Brian Cordery (Bristows) · Wednesday, October 20th, 2010

It is trite that in most jurisdictions, the grant of a patent is only a negative right, in that it does not give the patentee the right to work the invention, merely to prevent others from doing so. For example, the invention claimed may fall within the scope of a prior 'master' patent, of which the patentee will need to take a licence. Further, the patentee may need to satisfy regulatory requirements before selling a product falling within the claims of its patent. The life sciences sector represents the most extreme illustration of this principle, so much so that many jurisdictions have introduced patent term extensions, such as supplementary protection certificates, to compensate parties for the lost period of exclusivity before marketing authorisation can be obtained from the relevant regulatory authority. Although not strictly a patent case, a recent announcement from the UK Government illustrates the potential state liability that arises from the misapplication of EU law in this sector.

The case arises from Synthon's development of a generic version of paroxetine, a medicinal product for the treatment of depression that was originally developed by SmithKline Beecham ("SKB"). SKB had been granted a marketing authorisation to sell paroxetine in the UK and elsewhere, in the form of the hydrochloride hemihydrate salt. In reliance on Article 10(1) of Directive 2001/83 on the Community Code Relating to Medicinal Products for Human Use, Synthon applied in Denmark for a marketing authorisation for paroxetine mesylate under the abridged procedure, with SKB's paroxetine **hydrochloride hemihydrate** as the reference product. The application was made to the Danish Medicines Agency, which granted the marketing authorisation on the basis that Synthon's product had the same active moiety in paroxetine and therefore there was essential similarity between the two products.

Synthon then applied to the UK regulatory authority, the Licensing Authority (now the Medicines and Healthcare Products Regulatory Agency), for mutual recognition of its Danish marketing authorisation. This was refused by the Licensing Authority on the basis that medicinal products containing different salts of the same moiety could not be considered to be essentially similar. Synthon brought an administrative law challenge to the decision, on the basis that the UK regulatory authority had acted unlawfully in refusing the grant of a UK marketing authorisation under the EU mutual recognition procedure.

(As an aside, at around the same time Synthon had also brought a patent revocation action against SKB, seeking to revoke a patent for paroxetine methanesulfonate, a case which led to the House of Lords' judgment in Synthon v SmithKline Beecham , which remains the leading UK judgment on

patent novelty.)

In the meantime, the grant of the Danish marketing authorisation was challenged by SKB in the Danish courts, which resulted in a reference to the European Court of Justice for a preliminary ruling. In that case, the ECJ held that an application for a marketing authorisation under the EU abridged procedure was not prevented where the medicinal product contains the same therapeutic moiety as the reference product but combined with another salt (Case C-74/03).

Synthon therefore resubmitted its application to the UK Licensing Authority, which (following the ECJ decision) this time granted Synthon a marketing authorisation for paroxetine mesylate. Despite this, Synthon continued with its judicial review challenge, seeking declaratory relief and damages pursuant to the principles laid down by the ECJ in Francovich (Joined cases C-6/90 and C-9/90) and Brasserie du Pêcheur / Factortame (Joined Cases C-46/93 and C-48/93). A reference for a preliminary ruling to the ECJ was made by the English Court on the question of damages.

In C-452/06 , the ECJ held that under the mutual recognition procedure a Member State cannot call into question another Member State's assessments for evaluating a medicinal product, except on the grounds of risk to public health under Article 29 of the Community Code. The UK Licensing Authority had not refused to grant a UK marketing authorisation on this basis, but instead on the basis that it always refused to grant a marketing authorisation under the abridged procedure where the medicinal product was in a different salt form than the reference product. Although the question of whether different salt forms of a medicinal product could be considered to be essentially similar was complex and had only recently been clarified by the ECJ in the C-74/03 case, what was clear was that this was not a ground for refusing to recognise a marketing authorisation granted by a different Member State under the mutual recognition procedure, which was limited to that expressed in Article 29. In other words, whilst it might have been understandable (although wrong) for the first Member State, in this case Denmark, to refuse a marketing authorisation under the abridged procedure on this basis, the mutual recognition procedure imposed clear and precise obligations on the second Member State, in this case the UK, which could not rely on that uncertainty.

The ECJ went on to consider whether the breach of EU law by the UK Licensing Authority was sufficiently serious for the UK to incur liability for damage suffered by Synthon. Although the Court noted that in principle it was for the national courts to determine whether the conditions for state liability identified by the ECJ in previous cases had been established, it went on to conclude that the failure of a Member State to recognise the grant of a marketing authorisation by another Member State under the mutual recognition procedure on the grounds advanced by the UK was a sufficiently serious breach of Community law that it was capable of rendering the first Member State liable in damages.

What appears to be the final chapter in the story is the announcement of the UK Government, made on 13 October 2010, that the UK Department of Health has now agreed to pay Synthon €33.25 million in full and final settlement of Synthon's claim for damages (including legal costs).

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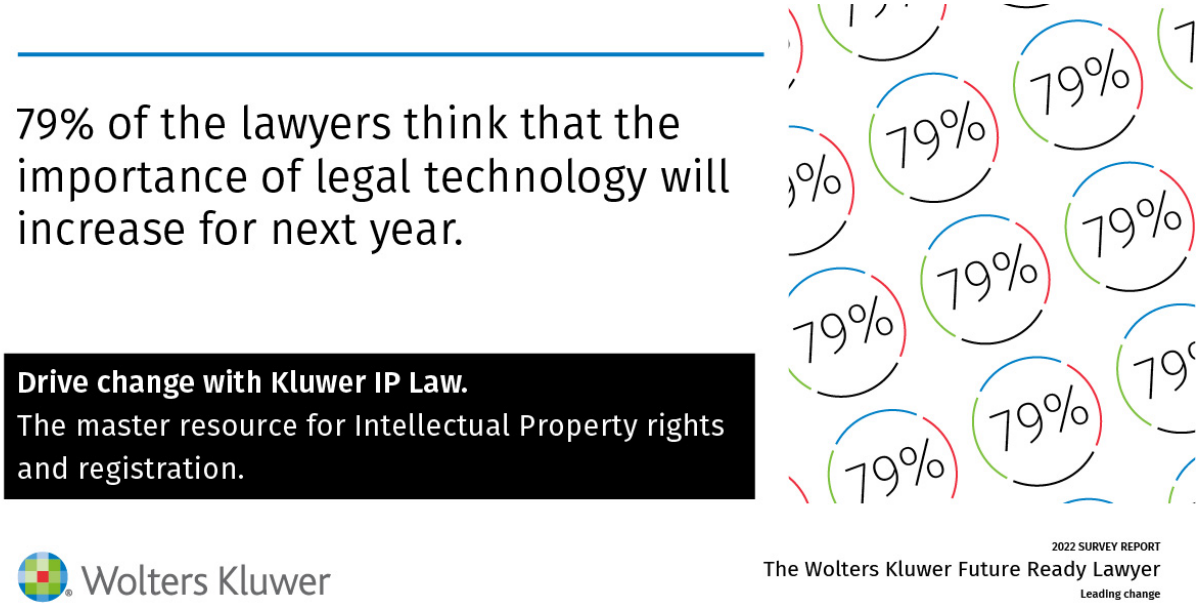

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