

Omnipharm v Merial - Winner gets it spot-on

Kluwer Arbitration Blog

May 13, 2013

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Please refer to this post as: Elizabeth Guy, 'Omnipharm v Merial - Winner gets it spot-on', Kluwer Arbitration Blog, May 13 2013, <http://arbitrationblog.kluwerarbitration.com/2013/05/13/omnipharm-v-merial-winner-gets-it-spot-on/>

And Anand Varu.

In Omnipharm Limited v Merial [2013] EWCA Civ 2, the Court of Appeal of England and Wales (CA) upheld a first instance decision to revoke one of Merial's patents on grounds of insufficiency. The CA also dismissed Merial's appeal against an order to pay 40% of Omnipharm's costs and awarded costs to Merial in relation to applications made for preserving Omnipharm's security for costs.

The patents in question were EP 0,881,881 (the '881) and GB 2,317,564 (the '564), which related to "spot-on" formulations of parasiticide fipronil for protecting animals against ticks and fleas.

Background

Prior to the action Omnipharm had requested acknowledgements of non-infringement from Merial in relation to four fipronil spot-on formulations. No acknowledgements were forthcoming and Omnipharm commenced proceedings to revoke the patents on grounds of obviousness and insufficiency and to secure declarations of non-infringement.

At first instance, the '881 was upheld in an amended form, albeit that Merial had admitted in its defence that three of the four formulations did not infringe this patent.

The insufficiency attack against the '564 succeeded. The judge noted that the examples provided in the specification did not disclose any formulation details save that there should be a crystallisation inhibitor, an organic solvent and an organic co-solvent present. As there was no teaching as to how these elements are to be selected or combined, the '564 was found to lack sufficiency.

Merial was ordered to pay 40% of Omnipharm's costs.

The Appeal

On appeal, Merial argued that the judge had failed to recognise that there is no requirement for a patent to include specific examples. The CA upheld the judge's view that the absence of proper exemplification of the formulation rendered the patent's teaching inadequate to guide the skilled person to success and provided no assistance beyond the teaching of the prior art and the common general knowledge.

Merial also submitted that the judge's conclusions were inconsistent with the evidence of formulation experts, arguing that the experts considered that implementing the inventions would be routine. The CA, however, agreed with the judge's view that a relevant theory of "dermal distribution" would not form part of the common general knowledge. The CA was satisfied that the judge had a proper evidential basis upon which to find the '564 insufficient as there was disagreement between the parties' experts on key points.

On the issue of costs, Merial argued that the result failed to fairly reflect who had won and lost. On one hand, Omnipharm were successful in receiving declarations for non-infringement in respect of three formulations. On the other hand Merial maintained the '881 which covered its commercial formulations. The CA found that the judge had recognised that "giving too much weight to a decision about the overall winner might cause an unjust result" and had, therefore, appreciated the complexities involved when deciding the "overall winner". The appeal on costs was dismissed.

Comment

The CA confirmed the sufficiency of the '881 because the examples were worked through formulations, yet the '564 was held insufficient as it lacked such properly exemplified formulations. One must therefore be careful to properly exemplify any

such formulation in a patent specification and not merely provide lists and ranges without guidance on how to arrive at an end formulation. This is especially warranted where the result of such a formulation is based on unclear science.