

Best Method Challenge Continues to Offer “a Material Advantage” – Zoetis Services LLC v Boehringer Ingelheim Animal Health USA Inc [2024] FCAFC 145

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Finding against Zoetis, the Full Federal Court held that Zoetis’ three patent applications relating to pig vaccines were invalid due to the failure to disclose the best method.

The Court’s analysis focused on one of Zoetis’ patent applications (the 535 Application), as the parties agreed that the finding would apply to the other patent applications. The key issue was whether Zoetis’ disclosure of a range of varying antigen concentrations for its investigational vaccine products (IVPs) satisfied the best method requirement. Notably, the antigen concentration disclosed in the specification was provided relative to a reference vaccine, the concentration of which was not disclosed.

The best method arguments centered around the observations in *Apotex v Servier* that the patentee “has an obligation to include aspects of the method of manufacture that are material to the advantages it is claimed the invention brings”. In addressing this question, the Full Court concluded:

- The specific (absolute) antigen concentration was material to the alleged advantages of the claimed invention and therefore had to be disclosed;
- Zoetis knew the specific (absolute) antigen concentration that conferred the advantages as it had produced IVPs and conducted trials;
- Within the antigen ranges claimed by Zoetis, different experimental compositions demonstrated different levels of efficacy; and
- The disclosure of a possible range of concentration of antigens failed the best method requirement as it was not a ‘fair disclosure’ of the best method.

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