

Case Report: Sanofi-Aventis Deutschland v Lilly France, High Court of Paris, 15 December 2014 and 7 October 2014

High Court of Paris accepts Bolar exemption for biosimilars and for Marketing authorisations outside of the EU

These two decisions of the Paris High Court in Sanofi-Aventis Deutschland v Lilly France have made three interesting points with respect to the experimental use exemption for trials performed for the purpose of obtaining a Marketing Authorisation (also known as the “Bolar” exemption).

- 1) The exemption is available for Marketing Authorisations in respect of Biosimilars.
- 2) The exemption covers all acts required for obtaining an MA, including larger scale manufacturing.
- 3) The exemption covers all acts required for obtaining an MA including an MA outside of the EU.

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