



## HIGH COURT OF AUSTRALIA

11 December 2024

COMMONWEALTH OF AUSTRALIA v SANOFI (FORMERLY SANOFI-AVENTIS) & ORS  
[2024] HCA 47

Today, a majority of the High Court dismissed an appeal from a decision of the Full Court of the Federal Court of Australia. The Full Court had dismissed an appeal by the Commonwealth of Australia ("the Commonwealth") from a decision of the Federal Court, which held that the Commonwealth was not entitled to compensation pursuant to an undertaking as to damages given by Sanofi when obtaining an interlocutory injunction.

Sanofi held a patent in Australia in respect of the drug clopidogrel. On 25 September 2007, Sanofi obtained an interlocutory injunction which prevented Apotex Pty Ltd ("Apotex") from competing with Sanofi by manufacture and sale of generic clopidogrel products which it had developed. Sanofi gave the usual undertaking as to damages in terms that it would "submit to such order ... as the Court may consider to be just for the payment of compensation ... to any person ... adversely affected by the operation of" the interlocutory injunction.

On 11 April 2013, the Commonwealth sought compensation from Sanofi on the undertaking as to damages for loss it said it suffered as a result of Apotex being prevented from supplying its generic clopidogrel products and obtaining listing on the Pharmaceutical Benefits Scheme ("PBS") for those products. The Commonwealth claimed that but for the interlocutory injunction, Apotex would have obtained listing of its clopidogrel products on the PBS on 1 April 2008, and accordingly, that Sanofi's conduct in obtaining the injunction prevented reduction in the prices for clopidogrel products. The Commonwealth contended that this required it to pay higher subsidies and claimed compensation of approximately \$325 million.

The Federal Court concluded that the Commonwealth had not discharged its onus of proof because the Court was not persuaded that Apotex would have sought and obtained a PBS listing of its clopidogrel products from 1 April 2008 if the interlocutory injunction had not been granted. That conclusion was unanimously affirmed by the Full Court. In the High Court, the principal issue concerned whether the Full Court erred in affirming that conclusion of the primary judge.

On the principal issue, the High Court held that absent circumstances such as plain injustice or clear error, the High Court will not engage in a detailed review of concurrent factual findings of lower courts. The majority held that this appeal does not concern any individual rights, nor expose any plain injustice or clear error, and that the concurrent findings of fact of the primary judge and the Full Court were not clearly wrong – they were open and compelling. Based on the undisturbed findings of the primary judge, only \$11 million of the alleged losses was within the scope of the undertaking as to damages.

The High Court also affirmed that no rigid legal rule may be applied to constrain how the evidential onus – in the sense of the burden of adducing evidence – may shift in a proceeding assessing compensation on an undertaking as to damages.

*This statement is not intended to be a substitute for the reasons of the High Court or to be used in any later consideration of the Court's reasons.*