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The CMA *Remicade* decision: discount schemes and abuse of dominance – effects matter!

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Authors: James Killick, Assimakis Komninos, Strati Sakellariou-Witt, Axel Schulz

Summary

On 14 March 2019, the UK Competition and Markets Authority (CMA) decided to close its investigation into a discount scheme by Merck Sharp & Dohme Limited (MSD).[1] The CMA concluded that there were no grounds for it to take action, since MSD's discount strategy was not likely to limit competition in anticipation of the market entry of competitive products. In other words, when analysing a discount, the CMA looked at the likelihood of it having exclusionary effects. Since it found no such likelihood, the investigation was closed.

Background

In December 2015, the CMA opened a formal investigation, alleging that MSD had abused its dominant position by offering a discount scheme for the sale of Remicade in the UK, contrary to section 18 of the Competition Act 1998 and Article 102 of the Treaty on the Functioning of the European Union (TFEU).

MSD's Remicade (molecule: infliximab) was the only product used in the UK to treat autoimmune inflammatory disorders before March 2015. After its patent expired on 24 February 2015, a number of biosimilar infliximab products entered the UK market (and specifically Inflectra by Hospira, Resmina by Napp, and Flixabi by Samsung Biopis). Infliximab is a prescription-only medicine purchased by the National Health Service (NHS) Trusts in the UK through tenders. In principle, the NHS's purchasing decisions are based on cost-effective principles assessing the pharmaceutical companies' pricing and tender offers against the market dynamics.

The under review rebate scheme for the sale of Remicade designed by MSD was based on (i) a matrix that set out a series of bands, with each band being associated to a specific price and a specific purchase volume of Remicade; and (ii) a quarterly review mechanism where purchases of Remicade would be reviewed against the volume specified in the matrix mentioned above. In the investigation at issue, the CMA examined whether MSD's discount scheme was likely to lead to market foreclosing effects for the period from 1 April 2015 to 31 December 2015.

The CMA Decision

Market definition and dominant position

Although a final position on the definition of the relevant market and on MSD's alleged dominance was not necessary given the absence of grounds for action, the CMA worked on the assumption that the relevant market was the supply of infliximab products in England, and that MSD held a dominant position therein.

[1] See the CMA's statement at: https://www.gov.uk/government/news/cma-warns-businesses-after-ending-remicade-investigation

The relevant product market was defined as Remicade and infliximab biosimilars. The CMA considered defining it more widely based on the products' therapeutic substitutability. This criterion would have led to a wider product market, encompassing other biological medicines and TNF alpha inhibitors. However, the CMA chose a narrower market, notably because of the way the products were administered. Remicade was (at that time) administered in a hospital by intravenous injection. Other TNF alpha inhibitors were administered in the home by subcutaneous injection (a pen) by the patient himself. The CMA considered this an important difference. The relevant geographic market was limited to England because of the different tendering procedures through which infliximab was marketed in different parts of the UK.

As regards MSD's alleged dominant position, the CMA took into account the following elements: (i) the biosimilars' barriers to enter the market and grow due to the NHS's clinical caution, (ii) the evolution of MSD's market shares by volume and value, and (iii) the absence of constraints on MSD's conduct through countervailing buyer power.

Discount schemes by dominant undertakings are not *per se* abusive

In terms of abuse, and in line with the ECJ case law in *Intel*, [2] the CMA's starting point was that "*not all discounts granted by undertakings in a dominant position are*" abusive. [3] Rather, a variety of factors need to be assessed in order to determine the existence of an abuse. These factors include the rules applicable on the grant of the discount as well as the discount's tendency to bar competitors from accessing the market, to strengthen the dominant position of the undertaking concerned and to influence purchasing behaviour.

On that basis, the analysis of the CMA focused on the likelihood of MSD's discount scheme to produce exclusionary effects. Thus, the CMA, in line with *Intel*, highlighted the importance of the effects-based approach for the assessment of the abusive nature of the applicable discounts.

The likelihood of exclusionary effects matters

The CMA examined the rules applicable to the discount scheme and considered that it was designed with the alleged intention of disincentivising the NHS to switch to biosimilar products. The idea was that biosimilar suppliers would have to charge low prices in order to compete with MSD, essentially for contestable new patients. The CMA also considered that, at the time of the introduction of the rebate scheme, the NHS believed that the scheme could lead to exclusionary effects.

Nonetheless, the turning point for the CMA's reasoning was the objective assessment of the circumstances of the market when the discount scheme was introduced in March and April 2015. The CMA clarified that "*the likely effect of a dominant undertaking's conduct should be assessed by reference to the point at which the allegedly abusive conduct was implemented rather than at some point after the allegedly abusive conduct had been in place*". [4] After carrying out detailed research which included surveying NHS staff, the CMA concluded that the market reality at that time prevented the scheme from developing any likelihood of exclusionary effects, since it proved that MSD's assumptions as to the NHS's potential reaction were incorrect. In effect, the NHS showed less clinical caution and a much greater willingness to use infliximab biosimilars. This meant that the pricing scheme did not have the alleged anticipated effect, as the contestable part of the market was much greater.

Thus, the CMA concluded that even if the discount scheme may have allegedly intended to exclude biosimilars from the market, there was no abuse of any dominant position since it could not practically lead to such anticompetitive effects.

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2 In *Intel*, the Court of Justice broke with its more formalistic previous case law on rebates and stipulated that: "*the case law must be further clarified where the undertaking concerned submits, during the administrative procedure, on the basis of supporting evidence, that its conduct was not capable of restricting competition and, in particular, of producing the alleged foreclosure effects*." (par. 138) In essence, the EU court underscores that, if evidence is adduced that rebates are not capable of foreclosing access to the market at issue, then dominant undertakings cannot be accused of any antitrust infringement irrespective of the discount system's design.

3 See page 42 of the CMA's Remicade Decision at: https://assets.publishing.service.gov.uk/media/5c8a353bed915d5c071e1588/Remicade_No_Grounds_For_Action_decision_PDF_A.pdf

4 *Ibid*, page 63.

The role of the as-efficient competitor test

In reply to MSD's arguments, the CMA justified the choice not to apply the as-efficient competitor test (AEC price/cost test) in the Statement of Objections, by stressing that – despite being informative and useful – it was not required here. (While this may not entirely reflect the framework of analysis set out in the CJEU's judgment in the *Intel* case, the CMA cannot be criticised for not applying the AEC price/cost test in a case where it closed the investigation based on no effects.) In any event, the CMA focused on the importance of assessing all the relevant circumstances of each case as stipulated in *Intel*.

Conclusions

The CMA's decision that there were no grounds for action in respect of Remicade is a development that endorses the effects-based approach in unilateral conduct cases. The CJEU spelled out that the European Commission should carry out an economic analysis of the effects of discount schemes in cases of dominant undertakings. That is exactly what the CMA has done in the *Remicade* case. Without over-relying on the alleged intention of the dominant undertaking in question, it conducted its own economic analysis and concluded that MSD's discount scheme could not have produced any anticompetitive effects. In short, the CMA confirmed that effects matter.

White & Case LLP
Wetstraat 62 rue de la Loi
1040 Brussels
Belgium

T +32 2 239 26 20