

# REGULATORY RISK UPDATE

Pharmaceutical sector — clarification on approach to market definition for prescription medicines

## SUMMARY

A decision handed down by the UK Court of Appeal earlier this month provides useful guidance on the correct approach to defining the market in relation to pharmaceutical products<sup>1</sup>. The Court of Appeal held that a patented pharmaceutical product should not be regarded as a distinct market. In its judgment, the Court of Appeal dismissed Chemistree's appeal, affirming the High Court's refusal to grant an interim injunction against the supplying pharmaceutical company for an alleged abuse of dominance<sup>2</sup>. The Court of Appeal ruled only on the dominance aspect of the case and concluded that it was, therefore, not necessary to address the allegations of abuse.

## BACKGROUND

AbbVie is a pharmaceutical research and development company which manufactures the patented product Kaletra, a medicine used in HIV treatment. Chemistree is a prescription home delivery and medicine administration service. In 2005, Chemistree entered into a supply agreement with AbbVie for the supply of Kaletra for home delivery in London. Specifically, the contract was entered into in order for Chemistree to fulfil its contractual obligations with NHS Trusts to deliver HIV medicine to patient homes across the city of London.

Over a period of time, Chemistree's demand for Kaletra rose, spiking at the end of 2012 to over three times the volume it required at the start of that year. As a result, AbbVie found it had a shortage of supply for the UK market. It requested a breakdown from Chemistree as to its requirements, in order to verify stock supplies to meet UK patient needs and not to meet wholesale purchases. It transpired that Chemistree had also been including in its orders for Kaletra additional quantities of the medicine for prescriptions outside of the UK (to Lithuania) and also for wholesale activities. Just 15% of the total volume of product ordered at the end of 2012 related to the homecare supply contract.

Chemistree had not notified AbbVie of its wholesaling activities and was not authorised to wholesale by AbbVie. In fact, AbbVie's policy was not to supply any wholesalers with Kaletra in mainland UK (having a separate supply chain for that part of the business). AbbVie subsequently reduced the amount of Kaletra it supplied to Chemistree in order that Chemistree could fulfil its London contracts for homecare supply, but AbbVie declined to supply Kaletra in relation to the other orders (ie the remaining 85%).

<sup>1</sup> *Chemistree Homecare Ltd v AbbVie Ltd Court of Appeal (Civil Division) [2013] EWHC Civ 1338*, judgment of 7 November 2013  
<sup>2</sup> *Chemistree Homecare Ltd v AbbVie Ltd [2013] EWHC 264 (Ch)*, judgment of 11 February 2013

## APPLICATION FOR INTERIM RELIEF

In January 2013 Chemistree issued a claim against AbbVie, claiming that AbbVie's refusal to supply Chemistree with ordered quantities of Kaletra was an abuse of AbbVie's alleged dominant position in the relevant market and seeking an injunction forcing supply.

Chemistree's application for an interim injunction was unsuccessful before Roth J, a judge with the competition law expertise in the Chancery Division necessary to hear this case. The High Court found that Chemistree had not fulfilled the test to establish its application for an injunction, namely it had not established any real prospect of success of showing at trial that AbbVie held a dominant position in the relevant market or that, if AbbVie did hold a dominant position, that it had abused that position by refusing to supply Chemistree the full order of Kaletra. The High Court also found that Chemistree had failed to show that damages in lieu of an interim injunction would be an adequate remedy and that on the balance of convenience it should not be granted an injunction.

It is worth noting that in September 2008, in a case with similar facts, the ECJ decided that it was not an abuse of a dominant position for a supplier to refuse to fulfil orders that were "out of the ordinary"<sup>3</sup>. In that case, GSK reduced the supply of medicines to Greek wholesalers who supplied Greek hospitals and pharmacies but also exported the medicines. GSK then supplied the medicines directly to the Greek hospitals and pharmacies. Later, GSK resumed limited supplies to the wholesalers and this limited supply was challenged. The ECJ held that although GSK was in a dominant position, it was not an abuse of dominance to refuse to fulfil orders that were "out of the ordinary".

The High Court in the present case considered that Chemistree's reselling of products in the wholesale market without the knowledge of AbbVie could not be regarded as "regular commercial practice", and accepted that Chemistree's conduct was "disingenuous".

Roth J concluded that there was no serious question to be tried on the issue of AbbVie's dominance in the relevant market, as there could well be alternative treatments to Kaletra which are substitutable. In any case, the High Court found that AbbVie had not abused the alleged dominant position as there was no outright refusal to supply; AbbVie had, in accordance with its policy, merely reduced the supply to meet the needs of Chemistree's London homecare contracts (Chemistree's "ordinary" orders). Accordingly, the High Court found that the test for an abuse set out in GSK/Greece had not been met. As a result, Chemistree had failed to establish any reasonable prospect of successfully putting its case at trial.

## APPEAL OF THE REFUSAL TO GRANT RELIEF

Chemistree appealed the refusal to grant an interim injunction, leave to appeal being granted by Lord Justice Lewison and the appeal was heard on 8-9 October 2013 before Rimer, Lewison and Treacy LLJ. The decision was handed down just short of a month after the hearing.

Chemistree sought to challenge the definition of the relevant market for prescription medicines. In support of its arguments, it noted that in the UK it is a criminal offence for a pharmacy to supply a patient with a drug different to that printed on the prescription. Chemistree sought to argue that pharmacies, as customers of the pharmaceutical companies, do not have a choice in the product they purchase to supply to the patient, and have no control over a doctor's prescribing authority. As a result, the prescribed drug alone represents the relevant market, and it was wrong of the High Court to consider the substitutability of other drugs when defining the relevant market in this case.

This argument was rejected by the Court of Appeal. It held that a pharmacy is "a middle man buying exclusively to serve the needs of the end consumer, the patient".<sup>4</sup> The Court of Appeal took the view that the prescribing doctor, either alone or in consultation with the patient, will decide which medicine to prescribe, and that this is the relevant part of the buying chain for the purpose of identifying the relevant product market.<sup>5</sup>

<sup>3</sup> *Lelos and Others v GSK AEVE*, Judgment of the Court (Grand Chamber) of 16 September 2008 (Joined Cases C-468/06—C-478/06)

<sup>4</sup> Court of Appeal judgment at paragraph 46

<sup>5</sup> *Ibid* at paragraph 46

The Court of Appeal agreed with the High Court that for some patients (patients who had previously been prescribed Kaletra, or those for which Kaletra was deemed to be the most suitable medicine) Kaletra is a must-have medicine. However, this did not narrow the relevant product market. New patients, ie those patients recently diagnosed and awaiting their first prescription have access to the whole range of substitutes. The Court of Appeal concluded that without any evidence identifying Kaletra's market share (which Chemistree failed to provide), there was no reason to narrow the definition of the relevant product market to Kaletra alone. Chemistree had therefore failed to show that there was a serious issue to be tried that AbbVie was dominant in the relevant product market. The Court of Appeal therefore held no injunction could be granted.

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