

COMPETITION LAW

CHEMISTREE v. ABBVIE LIMITED

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In February 2013, Mr Justice Roth refused an application by Chemistree Homecare Ltd (“Chemistree”) for an injunction against Abbvie Limited (“Abbvie”) in relation to the supply of Kaletra, a drug used in the treatment of HIV. In November 2013 his decision was confirmed by the Court of Appeal. This is the most recent of several claims brought by Chemistree in which it has sought to invoke Article 102 of the Treaty on the Functioning of the European Union (“TFEU”) to force suppliers to provide increasing quantities of high-value medicines for resale throughout the EU.

In his judgment, Roth J held that Chemistree had not shown an arguable case that Abbvie was dominant, nor that Abbvie’s general policy of not supplying wholesalers was abusive.

Background to the judgment

Chemistree carries on a pharmacy business and specializes in the provision of “homecare” services to NHS hospitals, including the dispensing, delivery and administration of drugs to outpatients. Abbvie (part of a larger corporate group with subsidiaries across the EU) supplies Kaletra in the UK. Given the special characteristics of HIV medicines its policy was to supply Kaletra directly to hospital pharmacies and their contracted homecare providers, not to wholesalers.

Since 2005, Abbvie supplied Chemistree with Kaletra for the purpose of fulfilling its contract with the NHS to supply that drug (on a homecare basis) in the Greater London area. In 2012, Abbvie became suspicious that not all of the Kaletra it supplied to Chemistree was being used to fulfil that NHS contract. Consequently Abbvie began to ask questions of Chemistree about its sales.

By November 2012, Chemistree’s orders had increased to around three times their pre-2012 levels. Meeting the November order caused Abbvie to suffer a shortage of Kaletra across the UK, requiring it to divert supplies from elsewhere in the EU. Abbvie again sought information from Chemistree in relation to the intended use of the increased volumes of Kaletra ordered. Chemistree refused to provide all of the information sought and asserted that the extra supplies were needed to satisfy the additional demands over the Christmas period.

In January 2013, Chemistree provided a summary of its requirements as involving 100 units for “UK Prescriptions”, 360 units for “EU Prescriptions” and 300 units for “Wholesale Orders”. This was the first time Abbvie was informed about sales outside of Chemistree’s NHS homecare contracts. Abbvie took the position that it would only provide Chemistree with the supplies needed to meet its NHS contracts.

Proceedings

On 4 January 2013, Chemistree issued a Claim Form alleging that there had been a refusal to supply amounting to a breach by Abbvie of Article 102 TFEU. Chemistree also applied for an interim mandatory injunction to require Abbvie to supply it with 570 units of Kaletra per month until trial. Roth J refused the application and Chemistree appealed the decision to the Court of Appeal.

Judgement of the High Court

Roth J applied the well-known test in *American Cyanamid*. He commented that, having regard to the potential harm to Abbvie of the grant of the injunction, the fact that it would be a mandatory rather than a prohibitory injunction was not of any significance. The first issue was whether Abbvie was arguably dominant in any relevant product market (as it was not disputed that Chemistree had a real prospect of successfully arguing that the geographic scope of the market was the UK). The Judge considered that there were a number of therapeutically equivalent products and, crucially, that the evidence before him did not provide a basis for a finding that Kaletra was a “must-have” drug for such a substantial proportion of patients that Kaletra arguably constituted a separate relevant product market. He emphasised that the burden was on Chemistree to establish some evidential foundation for its case on dominance and it had failed to do so. The application therefore failed at the first step of showing an arguable case on dominance.

Roth J went on, however, to consider whether, were Abbvie dominant, there would have been an arguable case of abuse. He noted that that the Court of Justice of the European Union (“CJEU”) case law established that “...refusal by an undertaking occupying a dominant position on the market of a given product to meet the orders of an existing customer constitutes abuse of that dominant position under [Article 102] where, without any objective justification, that conduct is liable to eliminate a trading party as a competitor” (Joined Cases C468/06 to C478/06, *Sot. Lelos v GlaxoSmithKline*, paragraph 34) and that a dominant undertaking cannot discontinue supplies to a longstanding customer who abides by regular commercial practice if the orders placed by that customer are in no way out of the ordinary (Case 27/76 *United Brands v Commission*, paragraph 49). However he noted that Article 102 TFEU had never been held to oblige a supplier to adopt a particular manner of distribution of its own products. As Abbvie’s policy was not to supply Kaletra to wholesalers in the UK it was not abusive for it to refuse to supply Kaletra to Chemistree for that purpose. He distinguished *Lelos* on the basis that in that case GSK had a practice and policy to distribute through wholesalers and in those circumstances GSK could not then take action to limit the supply in an attempt to prevent parallel imports.

Chemistree argued that it was Abbvie’s policy and practice to supply wholesalers as Abbvie had in fact been supplying Chemistree, who was acting as a wholesaler, for

a number of months. The Judge rejected that argument. He agreed with Abbvie's submission that Chemistree's conduct in not disclosing its Kaletra wholesale activities was "disingenuous" and thus Abbvie's supplies to it for that purpose could not be said to amount to a regular commercial practice. The fact that some or all of those wholesale supplies might have been parallel exports did not alter that analysis.

Although it was "unnecessary" to do so, Roth J also specifically considered the issue of parallel exports. He set out paragraphs 76 to 77 of the *Lelos* case and stated: *"That suggests that even for a supplier that actively supplies wholesalers it may not be an abuse to refuse suppliers which are out of proportion to those quantities previously sold to those wholesalers to meet domestic requirements. Therefore, in the particular context of pharmaceutical medicines it may indeed be legitimate to restrict supplies in such a way that parallel exports would be restricted: see in that regard, Whish, Competition Law (7th Edition, 2012) at p.712."*

Roth J concluded that, even if Abbvie were dominant, there would be no reasonable prospect of its conduct being found to be abusive pursuant to Article 102 TFEU. The Judge was also unimpressed by Chemistree's case on the risk of injustice limb of the *American Cyanamid* test. As regards Chemistree's UK homecare business, he held that there was no effective refusal to supply and therefore no loss. He further found that any loss of profits on wholesale supplies could be remedied in damages and that there was insufficient evidence to suggest that Chemistree would face any problem in sourcing Kaletra for any homecare supplies that it might make in the EU: if it needed Kaletra in Germany, there was no reason why it could not obtain a supply from the relevant Abbvie entity in that country.

Judgment of the Court of Appeal

Chemistree contended that Roth J was wrong to find that Abbvie was not dominant. It was argued that pharmacists, not doctors, were the relevant purchasers of Kaletra and that the combined effect of the distinct therapeutic advantage of Kaletra for certain patients and Abbvie's exclusivity of supply of Kaletra meant that Abbvie was dominant. The Court of Appeal rejected these submissions, holding that it was the prescribing doctor, either alone or consultation with the patient, that made the decision as to whether or not Kaletra should be used and it was that part of the buying chain which was sensitive to increases in price. The pharmacist merely acted as a middle man and its role in the economic chain was irrelevant to the determination of the relevant product market. Although Kaletra might have been a "must have" drug for certain patients there was insufficient evidence before the court to enable any conclusions to be drawn as to impact of this on the relevant product market. As a consequence the Court of Appeal concluded that Roth J was right to find that Abbvie was not in a dominant position and as a result it did not need to consider any of the other grounds of appeal raised by Chemistree.

Comment

Roth J's reasoning poses a real obstacle to claimants seeking pharmaceutical supplies for parallel export. The Judge appears to have reasoned as follows:

1. A pharmaceutical supplier may justifiably adopt a policy of not making sales intended for wholesale.
2. An existing retail sales customer that then seeks additional supplies in order to feed a wholesale/export operation is not acting in accordance with "regular commercial practice" and making "ordinary orders".
3. The pharmaceutical supplier may refuse to meet the additional orders on this basis without having to provide any independent justification for the restriction on parallel exports that its policy creates.

Roth J's judgment also seems to have been significantly influenced by the fact that Chemistree was "disingenuous" as to the purpose for which it was purchasing Kaletra. Roth J noted that:

"Moreover, in the present case I have quoted at some length from the series of emails sent by the claimant when the defendant started to query the reason for the sharp increase in its level of orders, which show that the claimant repeatedly put forward as the explanation only exceptional circumstances relating to the domestic hospital homecare services in the run-up to the Christmas period, with not a word about wholesale or overseas demand."

If Chemistree had informed Abbvie from the outset that it was purchasing some of the Kaletra to export as a wholesaler, and Abbvie had continued to supply for a time, Chemistree could arguably have established a "regular commercial practice" which could in turn have rendered a refusal to supply for that purpose abusive.

George Peretz appeared for Abbvie before the High Court and the Court of Appeal.*

The comments made in this case note are wholly personal and do not reflect the views of any other members of Monckton Chambers, its tenants or clients.

* Ronit Kreisberger has acted for Pfizer, Teva and Roche in abuse of dominance claims made by Chemistree.