Healthcare & Life Sciences - United Kingdom

Considering the "multi-headed beast" in pharmaceutical product market definition

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Introduction

The Court of Appeal has ruled on the correct approach to market definition in relation to pharmaceutical products, in the context of a dispute between a pharmaceutical manufacturer and a wholesale trader.(1) The Court of Appeal strenuously rejected the notion that a patented medicine should be regarded as being a market on its own merely because the pharmacist holding a prescription for that product had no choice as to whether to purchase that product or another. Since the market had to be defined more broadly – to include products that the physician might have selected as alternatives – the wholesaler failed to show that the supplier was dominant, and therefore could not claim that a refusal to supply was an abuse of dominance. The Court of Appeal agreed with the manufacturer that the choice of drug is decided by a "multi-headed beast comprising the patient, the prescriber and the budget holder, who is the ultimate payer".

Facts

Pharmaceutical company Abbvie Ltd supplied its HIV therapy Kaletra direct to hospitals, without the use of wholesalers. Abbvie also supplied the medicine to Chemistree Homecare Limited to enable Chemistree to provide homecare services to patients treated in clinics covered by the pan-London HIV consortium.

The pan-London HIV consortium awarded Chemistree a contract to supply homecare services for HIV patients in 2005 and subsequently renewed it in 2008 and 2011. Chemistree ordered Abbvie's 'third agent' HIV medicine Kaletra as part of those arrangements. Its orders for Kaletra increased over the period of the contracts, with particularly significant increases in 2012. By November 2012 it was ordering more than three times the volumes ordered at the beginning of that year. Such increased volumes seemed more than would be credibly needed to supply its homecare services. Abbvie requested Chemistree to provide evidence of need. After some prevarication, Chemistree eventually admitted that only 15% of its orders were required for the homecare contract, with 40% being ordered for its wholesale activities (which Abbvie had not authorised and which had not been previously disclosed by Chemistree) and 45% for the satisfaction of European Economic Area (EEA) prescriptions. Abbvie declined to supply Kaletra to Chemistree other than was required for its homecare services contract.

Chemistree claimed that Abbvie's refusal was an abuse of its alleged dominance in the relevant market, and applied for an interim injunction in the High Court, pending trial. Justice Roth, an experienced competition law judge, refused the application, finding that there was no arguable case that Abbvie was dominant with Kaletra, or that – even assuming dominance – it would be an abuse for it to decline the additional supply to Chemistree.

Chemistree appealed to the Court of Appeal against this refusal to grant interim measures. In order to succeed on appeal, it needed to show a real prospect of success at trial that Abbvie was dominant with Kaletra, and that Abbvie's conduct was abusive. It also had to show that an injunction to require Abbvie to supply it with Kaletra at average 'pre-peak' levels was appropriate on the balance of convenience.

Pharmaceutical supply chains

Just as in other industrial sectors, pharmaceutical suppliers are permitted to design their supply chains in the way that suits their products and their business model. As the Office of Fair Trading stated in its report on medicines distribution, it was:

> "*concerned to ensure that competition will remain in the wholesale sector so that each manufacturer will be able to select the method of distribution it would prefer, as well as the wholesalers and/or [logistics service providers] that it would prefer to use*."(2)

The freedom of companies to design their supply chain as they wish has also been recognised by the advocate general of the European Court of Justice (ECJ) in *GSK Greece*:

> "*GSK was free to design its own distribution system in Europe. It decided on a strategy which incorporated... wholesalers because it considered it more economically efficient and advantageous. It could have opted instead for a vertically integrated system for the distribution of its medicines... It was at liberty to restructure its distribution networks, as long as it respected normal commercial practice*."(3)

Using this freedom, pharmaceutical companies in the United Kingdom have taken different approaches to the design of their supply chain, and many have made changes as a result of increasing pressure from parallel exports following the currency disturbance between sterling and the euro. Companies have chosen from among the following models:

- the traditional open wholesale model;
- a limited number of wholesalers, including some examples of exclusive arrangements;
- direct-to-pharmacy models, with or without a logistics service provider; and
- direct-to-patient models (ie, homecare).

Some companies employ more than one model, with one part of the portfolio delivered through wholesalers and another directly to the pharmacy.

Dominance in pharmaceutical markets

A refusal to supply cannot be an infringement of competition law if the supplier is not dominant in the relevant market. At EU level, the definition of 'pharmaceutical market' was addressed by the EU General Court in *AstraZeneca* and was confirmed by the ECJ.(4) It held in that case that the relevant market included products that are substitutable from the viewpoint of the physician in terms of indication, seriousness or stage of disease, mode of delivery, patient population and so forth. Physician choices are influenced by features such as:

- efficacy and safety;
- suitability for the relevant patient;
- whether the product is a first-line or second-line medication;
- method of delivery;
- side effects and contraindications; and
- the scope of authorisation.

The central influence exerted by the physician in the definition of the relevant market was stressed throughout the judgment of the General Court(5) and the ECJ agreed. Similarly, in the earlier UK case *Genzyme* – which concerned a pharmaceutical supplier's relations with a homecare service provider – the Competition Appeal Tribunal found that it was:

> "*self evident that there is a group of consumers, namely those suffering from Gaucher disease, who have a constant need for effective treatment for that disease*. Similarly the clinicians responsible for these patients have a constant need to treat that disease. *A treatment that does not treat Gaucher disease is of no use to a patient suffering from that disease, nor to the clinician responsible for the treatment of that patient. It follows, on the basis of the case law... that the relevant product market for the purpose of [abuse of dominance] consists of effective treatments for Gaucher disease*."(6) (emphasis added)

Refusal to supply intermediaries

Where suppliers reserve distribution for themselves or appoint a limited number of wholesalers, it is inevitable that they will decline to sell to other would-be intermediaries. This is legitimate even for dominant suppliers, since no one has a right to insist on participating in the supply chain of another company and sharing in the

margin. This is the case even where the object or effect is to limit parallel trade, so long as the dominant supplier respects the ordinary orders of long-term customers. 'Ordinary orders' are those that are consistent with previous business relations and the requirements of patients in the domestic market.(7)

Because even dominant companies have the right to select their trading partners, a refusal to supply is typically abusive only where it unfairly removes or limits competition. This might occur, for example, where a dominant supplier integrates forward into a downstream market and refuses to supply a downstream company that requires such supply as an input to produce another product or service in that downstream market. It might also occur where a dominant supplier refuses to supply a customer unless it refrains from purchasing from a rival supplier.

Appeal

Relevant market

Chemistree's appeal turned on the definition of the relevant market occupied by Abbvie with its medicine Kaletra. To succeed on appeal, it first had to show that it had a real prospect of showing at trial that Abbvie was dominant with Kaletra. It was common ground that in order to do so, Chemistree would have to show that the relevant market was for Kaletra alone. In the High Court, Chemistree accepted that, under the clinical guidelines issued by the London HIV consortium, Kaletra was one of eight alternative third agents that were substitutable for the treatment of HIV. There were therefore significant levels of substitutability as regards those patients starting therapy. The High Court judge rejected Chemistree's argument that there were no substitutable products for patients who were already on Kaletra, because there was not:

> "*even the beginnings of an indication as to what share of total purchases of Kaletra in the United Kingdom come into this category nor is there any evidence as to what share of total purchases of Kaletra in the United Kingdom are accounted for by new patients... as compared to stable patients*."

In the Court of Appeal, Chemistree argued that, in defining the relevant pharmaceutical market in the case of a refusal to supply, it was necessary to focus on the position of the indirect customer – the pharmacist – and not on the choices facing the physician. It argued that if a pharmacist were required to satisfy a prescription for Kaletra, he or she had no opportunity to substitute another product. He or she therefore required Kaletra, and that product alone, from the wholesaler or supplier. This in turn required the wholesaler to purchase the specific product (in this case, Kaletra) without regard to other therapies that would have been available to the physician. Such an approach would lead to each medicine being its own relevant market, in combination only with generic substitutes, for any purpose connected with the relationship between supplier and wholesaler. Chemistree claimed that this placed Abbvie in a dominant position with Kaletra insofar as the wholesaler was concerned.

Abbvie argued that the 'pharmacist as customer' concept was wrong in law and had not been put to the High Court. The better approach, it argued, was that the customer was "a multi-headed beast comprising the patient, the prescriber and the budget holder, who is the ultimate payer."(8) This enabled all elements that drive demand, both price and non-price, to be taken into account and required no departure from the prior jurisprudence and practice of courts and competition authorities.

Refusal to supply

Chemistree also had to show a real prospect that if Abbvie was dominant in a relevant product market, it had abused that position. It argued that Abbvie's choice of a direct-to-hospital model, together with a refusal to sell to wholesalers other than for homecare services, amounted to a prohibition on cross-border trade within the European Economic Area and, as such, was an infringement of competition law. It did not accept that this point had already been settled by the ECJ in *GSK Greece*, where the court ruled that pharmaceutical suppliers could confine supplies to the ordinary orders of long-term customers. Chemistree argued that this approach did not apply where the dominant supplier had acted to eliminate, and not merely reduce, trade between EEA member states.

Chemistree also argued that Abbvie was not entitled to audit Chemistree's need for Kaletra volumes because Chemistree was entitled, and required, to treat EEA prescriptions with equal priority to UK prescriptions.

Abbvie relied on the case law on refusals to supply mentioned above, and also referred to the warning in the opinion of Advocate General Jacobs when he reviewed such case law in *Oscar Bronner*:(9)

> "*The right to choose one's trading partners and freely to dispose of one's property are generally recognised principles in the laws of the Member States, in some cases with constitutional status. Incursions on those rights require careful justification*."(10)

Judgment

The Court of Appeal heard the case on October 8 2013 and delivered its judgment almost exactly one month later, on November 7 2013.

In dismissing the appeal, Lord Justice Rimer, with whom Lord Justices Lewison and Treacy agreed, focused on the definition of the relevant market, particularly whether the 'pharmacist as customer' approach was correct. He rejected the concept as being of any relevance to the definition of the market. Chemistree's role in the supply chain was irrelevant for these purposes, because it was not a 'relevant' customer:

> "*[Chemistree] is of course an Abbvie customer, but it is not in the business of buying for its own consumption, or for the pleasure of admiring the boxes of unsold Kaletra on its shelves. It is a middle man buying exclusively to serve the needs of the end consumer, the patient*."(11)

The court had much closer regard to the position of the patient and the physician in generating demand:

> "*The cost of Kaletra is ultimately borne by the patient or budget holder, and the choice as to whether or not it is to be used for any particular patient is the result of a decision made by the prescribing doctor, either alone or in consultation with the patient. It is that part of the buying chain that either will, or will not react, to a [small but significant price increase] or other deterioration in the perceived qualities of Kaletra as compared with other drugs*."(12)

Rimer also agreed with the High Court judge that it was impossible, without evidence, to determine whether the cohort of stable patients (who arguably were captive to Kaletra) was significant to market definition:

> "*As regards the consideration that there may be a section of captive patients... who will not switch despite the increase in price, the position is that even if there are, the relevant question is whether there are others at the margins who can switch. It is they who count*."(13)

Having rejected Chemistree's case on dominance, the Court of Appeal did not rule on abuse, so the High Court judge's findings were upheld.

Comment

This judgment is of broad significance. It reaffirms the established principle that in pharmaceutical markets, the decision as to whether a particular drug is to be used for a patient rests with the prescribing doctor, either alone or in consultation with the patient. That is the essential step in the definition of the product markets; the position of the wholesaler or any other intermediary has no role in that task.

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Endnotes

(1) *Chemistree Homecare Limited v Abbvie Ltd*, Court of Appeal (Civil Division) [2013] EWCA Civ 1338, November 7 2013.

(2) Office of Fair Trading, "Medicines Distribution", December 2007, Paragraph 6.14.

(3) Opinion of Advocate General Colomer in Joined Cases C-468/06 to C-478/06, *Sot Lelos kai Sia EE v GlaxoSmithKline AEVE*, Paragraph 111.

(4) Case C457/10 P, *AstraZeneca v European Commission*, December 6 2012.

(5) Case T321/05, *AstraZeneca v European Commission*, July 1 2010.

(6) Case 1016/1/1/03, *Genzyme Limited v Office of Fair Trading*, March 11 2004, Paragraph 202.

(7) *GSK Greece*, Paragraph 73.

(8) Court of Appeal judgment, at Paragraph 40.

(9) Case C-7/97, *Oscar Bronner GmbH & Co KG v Mediaprint Zeitungsund Zeitschriftenverlag GmbH & Co KG*, opinion delivered on May 28 1998.

(10) *Id*, at Paragraph 56.

(11) Court of Appeal judgment, at Paragraph 46.

(12) *Id*.

(13) *Id*, at Paragraph 44.