Neutral Citation Number: [2013] EWCA Civ 1338

Case No: A3/2013/0559

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
Mr Justice Roth
[2013] EWHC 264 (Ch)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 07/11/2013

Before :

LORD JUSTICE RIMER
LORD JUSTICE LEWISON
and
LORD JUSTICE TREACY

- -

Between :

CHEMISTREE HOMECARE LIMITED	**Appellant**
- and -	
ABBVIE LTD	**Respondent**

- -
- -

Mr Thomas de la Mare QC and **Mr James Segan** (instructed by **Matthew Arnold & Baldwin LLP**) for the **Appellant**
Mr George Peretz (instructed by **CMS Cameron McKenna LLP**) for the **Respondent**

Hearing date: 8 October 2013

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Approved Judgment

Lord Justice Rimer :

1. This appeal by the claimant, Chemistree Homecare Limited ('CHL'), is against the order made by Roth J in the Chancery Division on 11 February 2013 dismissing with costs CHL's application for an interim injunction against the defendant/respondent, Abbvie Limited ('Abbvie').

2. By its claim form issued on 4 January 2013, CHL asserted that Abbvie had committed, and was continuing to commit, an abuse of its allegedly dominant position in the United Kingdom market for the drug Kaletra, and had done so by refusing to meet CHL's 'ordinary orders' in accordance with regular commercial practice. CHL sought a declaration, an injunction and damages and on 6 February 2013 it applied to Roth J for an interim mandatory injunction pending trial compelling Abbvie to provide monthly deliveries to it of 570 boxes of Kaletra. Roth J refused the application on the grounds that CHL had no real prospect of showing at trial that Abbvie held a relevant dominant position or, that if it did, it had abused it; and that any loss suffered by CHL by the refusal of such injunction could anyway be compensated in damages so that no interim injunction was appropriate.

3. By this appeal, brought with the permission of Lewison LJ, CHL challenges each ground upon which Roth J refused the injunction. It has to succeed on all three grounds if it is to succeed on the appeal.

4. CHL was represented before Roth J by Mr Colton. Before us, it was represented by Mr de la Mare QC leading Mr Segan. Abbvie was represented before us, as below, by Mr Peretz.

The facts

5. I take these gratefully, in part verbatim, from the judge's account.

6. Kaletra is a protease inhibitor used as one of the elements in combination therapy of antiretroviral ('ARV') drugs used in the treatment of patients with HIV-1, the most common form of HIV. It comprises a mixture of lopinavir and ritonavir. It is manufactured by a company in the Abbvie group based in Holland. Abbvie is registered in England and Wales and supplies Kaletra in the United Kingdom.

7. CHL carries on a pharmacy business and supplies homecare services to NHS hospitals. The homecare service provided by CHL involves it in not just dispensing the drug and delivering it to the patient's home, but also administering it by a nurse or health care professional. Such a service is of obvious value to patients with limited mobility and ARV drugs given to HIV patients are among those for which homecare provision is particularly appropriate. CHL also carries on business as a wholesaler, with a licence for that purpose under the Human Medicines Regulations 2012. It has done so since at least 2009. The judge said that there is an issue in the proceedings as to whether Abbvie either knew or ought to have known of CHL's wholesale trade.

8. CHL was awarded a contract in 2005 for the provision of pan-London HIV pharmacy home delivery services. It opened an account with Abbvie for the supply of Kaletra and another drug expressly for the purpose of fulfilling its obligations under the contract. The contract was renewed in 2008 and again in 2011. CHL's orders for Kaletra

increased over the period of the contracts: by late 2011, it was being supplied with between 330 to over 380 packs a month, rising to over 400 packs by early 2012.

9. On 28 May 2012, Abbvie opened an inquiry with CHL as to the details of the contracts it had for the supply of its homecare services; and following a CHL request for further supplies, Abbvie sought information as to the prescribers of the drugs supplied by CHL and the hospitals where each prescription was issued, but not of course as to the names of patients. CHL's response was that the request was unlawful, to which Abbvie replied that it was not and that it was making its supply conditional on the provision of the information. CHL's response was that the information was commercially sensitive and it did not provide it.

10. Despite those exchanges, Abbvie fulfilled CHL's orders for July and August 2012. Abbvie, however, re-opened the matter in August when it informed CHL that it appeared from CHL's recent reports that it was providing Kaletra to third parties other than pan-London trusts. It reminded CHL that its account with Abbvie had only been opened on the basis of CHL's agreement to provide homecare services to such trusts. Abbvie asked for details of any agreements to provide homecare services to other trusts. CHL replied that 'that was not [its] understanding at all'. CHL offered a meeting to discuss the matter, which was not taken up, and deliveries of Kaletra continued in September and October (530 and 522 packs respectively).

11. CHL ordered 1,249 packs for November, over twice the previous quantities, and included an order for 660 bottles of tablets as compared to tablets in blister packs, whereas over the previous seven months CHL had ordered only six such bottles. The order was met, but left Abbvie short of supplies in the UK, a shortage met by a diversion of an order due for Ireland, resulting in a shortage there. Drug suppliers plan their stock levels so as to ensure continuity of supply.

12. That turn of events caused concern to Abbvie as to what was going on, which it relayed to CHL. On 17 December, CHL's business development homecare manager sent Abbvie an email acknowledging the increase in the orders. The thrust of the proffered explanation was that the reason for the increased prescriptions over the previous two weeks was because the majority of hospital clinics were closing for Christmas; in addition, CHL had to keep a stock allocation for emergency prescriptions, and it said that a 10% to 15% contingency supply covered this need. Abbvie explained on 18 December that CHL's recent order had caused it to suffer a critical stock position with Kaletra. It asked CHL to indicate its stock in hand at close of business on 18 December and to indicate its month to date sales/deliveries to hospital trusts, unfulfilled orders for the trusts and any projection for further orders from the trusts in December.

13. Heated exchanges followed, with Abbvie expressing concern as to the further orders it had received from CHL not just for Kaletra, but also for another drug, Norvir. On 20 December, CHL emailed Abbvie, saying in substance, and at length, that its orders were based on the requirements placed upon it. Abbvie replied that because of the critical stock position it had recently faced, it wanted a breakdown of, inter alia, CHL's 'sales by trust', being the hospitals covered by the pan-London HIV homecare contract, from which it said it would then be easy for it to calculate CHL's requirements for UK patients. Abbvie provided appropriate spreadsheets for completion by CHL.

14. CHL did not complete the spreadsheets and never has. It instead threatened to apply on 21 December for an injunction but did not do that either. On 23 December, CHL sent a summary of its requirements for Kaletra down to 7 January 2013. That said that its pack requirements would be: (i) 112 for UK prescriptions; (ii) 363 for EU prescriptions; and (iii) 300 for wholesale orders. It showed that less than 15% of the total requirements were for UK prescriptions. The following day, CHL provided a blanked out list of the UK and EU prescriptions, the latter all coming from Lithuania.

15. Abbvie responded by pointing out that this was the first time that CHL had disclosed its wholesale status (over 38% of its requested supplies were for its wholesale trade). It said that it had opened CHL's account on the basis that it was a homecare provider supplying UK trusts against tenders. Its email continued:

> '… We have consistently asked to see such information of your contracts with the NHS and you have provided us with details of your contract with NHS London. We have been supplying you with Kaletra based on this information and your obligations to London trusts.
>
> As this is the first time you have made us aware of your status as a wholesaler we need to clarify the position with respect to our supply chain. We do not supply any wholesalers with Kaletra in mainland UK as Kaletra is a hospital only product. This approach is applied consistently. We use the term "hospital only" to describe a medicine for which the original prescription would have been initiated by a hospital rather than a GP or a pharmacist. We supply homecare providers who are under a contract of supply with an NHS trust. It is not part of our supply chain to provide wholesalers in mainland UK or EU patients as our supply chain already has excellent coverage. Our priority is always to ensure that supply for UK patients is maintained and to ensure that our products reach those UK patients who have been prescribed those medicines. With respect to the EU prescriptions, we already have an existing supply chain in place and are not currently planning on extending it.
>
> In the circumstances, we will review the redacted prescriptions relating to UK prescriptions. …'.

16. The outcome was that Abbvie reiterated its position not to supply Kaletra other than for UK homecare provision, which CHL asserted was unlawful. CHL ordered 1,368 packs in December, of which Abbvie supplied 540. It responded to CHL's order of 800 packs for January 2013 by saying that this seemed above the level required for CHL's UK homecare contracts.

17. CHL's proceedings followed on 4 January 2013. The evidence on the interim application amounted to a witness statement for CHL from Mr Hundal, and witness statements in answer from Mr Ellis, of Abbvie. The particulars of claim served on 24 January showed that CHL's case rested exclusively on an assertion of an abuse of a dominant position by Abbvie under EU and UK competition law. Demonstration of dominance was essential since it is not a breach of competition law for a non-dominant supplier to refuse to supply a customer. The judge said that as the application was for an interim injunction, CHL had to show that it had a real prospect of success at trial and

that the grant, as opposed to the refusal, of the injunction carried the least risk of injustice between the parties. The principles were the same even though what was being sought was a mandatory rather than a prohibitory injunction.

Abuse of a dominant position

18. Article 102 of the Treaty on the Functioning of the European Union provides, so far as material, that 'Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States'. Section 18 of the United Kingdom's Competition Act 1998 provides, so far as material, that '… any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the United Kingdom.'

19. To succeed on a claim for such an abuse, a claimant must establish that the defendant is an 'undertaking', that there is a market in which it is in a 'dominant position', that the defendant has engaged in an 'abuse' of that position, and that the abuse 'may affect trade' to the relevant geographic extent according to whether the claim is under Article 102 or section 18. There is no issue that Abbvie is an 'undertaking' but the other ingredients of the claim are in issue.

The judge's judgment

(a) The product market

20. The judge dealt first with the 'dominance' issue, observing that the first task is to identify the relevant market. The claim was that Abbvie is in a dominant position in the market for Kaletra in the UK and the judge said it is generally the case that the geographic market for prescription medicines is national. There was no issue as to that, but there was an issue as to whether, as CHL claimed, Kaletra was the relevant product market. If it was, Abbvie accepted that it was dominant in the Kaletra market; if it was not, Abbvie was not dominant in any relevant market and CHL accepted that its application could not succeed.

21. The judge said that the dominance question fell to be answered by reference to considerations of demand substitution, that is the range of products viewed by the customer as substitutes for the product at issue. It was agreed that supply substitution was not relevant. The judge referred to the explanation of the principles of demand substitution in the European Commission's Notice on the definition of the relevant market for the purposes of Community competition law, Official Journal, (97/C 372/03), and it is convenient to set out the paragraphs he quoted:

> '17. The question to be answered is whether the parties' customers would switch to readily available substitutes or to suppliers located elsewhere in response to a hypothetical small (in the range 5% to 10%) but permanent relative price increase in the products and areas being considered. If substitution were enough to make the price increase unprofitable because of the resulting loss of sales, additional substitutes and areas are included within the relevant market. This would be done until the set of products and geographical areas is such

> that small, permanent increases in relative prices would be profitable….
>
> 18. A practical example of this test can be provided by its application to a merger of, for instance, soft-drink bottlers. An issue to examine in such a case would be to decide whether different flavours of soft drinks belong to the same market. In practice, the question to address would be whether consumers of flavour A would switch to other flavours when confronted with a permanent price increase of 5% to 10% for flavour A. If a sufficient number of consumers would switch to, say, flavour B, to such an extent that the price increase for flavour A would not be profitable owing to the resulting loss of sales, then the market would comprise at least flavours A and B. The process would have to be extended in addition to other available flavours until a set of products is identified for which a price rise would not induce a sufficient substitution in demand.'

22. Those paragraphs reflect the so-called 'SSNIP test' (small but significant non-transitory increase in price). The judge said that, whilst it was conceptually possible for a single patented drug to be dominant in a market and to constitute a distinct market of its own, it was rare. That is because other medicines may be therapeutically equivalent even if their precise formulation or mode of operation is different. Everything depends, however, on the facts.

23. In this case, Mr Hundal, in paragraph 48 of his witness statement, had advanced three arguments as to why Kaletra was not interchangeable or substitutable with other medication. His first argument was that there was no 'generic equivalent' to Kaletra, which the judge said was true, as of all patented medicines, but that it did not follow that each such medicine constituted a distinct product market. His third argument, that Kaletra 'provides a unique function', was not pursued in argument. The argument before the judge turned principally on Mr Hundal's second point, namely that once patients have been prescribed and stabilised on Kaletra, the prescribing consultants are generally reluctant to change their treatment regime. Mr Hundal continued:

> 'Prescribing consultants are routinely monitoring the bloods of HIV affected patients. Blood levels are always monitored before a further prescription is issued to ensure viral load and CD4 counts which need to be within the recommended ranges; deviation could trigger changes in drug, dosage or both. Once patients are thought mainly stabilised there is often very little change in treatment regime. By their very nature the service [CHL] provides is most suited to patients on stable regimes whom the hospital trust reasonably expects to stay on such a regime for a long period of time and hence they will supply 4-6 months worth of medication as a single instalment.'

24. Abbvie's response to that evidence was to put in evidence what the judge described as two material documents. The first was the British HIV Association Guidelines for the treatment of HIV-1 positive adults with antiretroviral therapy 2012. The judge explained that section 5 was devoted to so-called 'therapy naïve' patients (those starting therapy), and recommended that they started their AR therapy on a combination of two drugs of a particular type, referred to as 'the backbone', plus a third agent. Section 5

included a tabulated list of preferred and alternative third agents. There were four preferred agents, of which two were ritonavir-boosted protease inhibitors ('PI/rs'); and four alternatives, of which two were also PI/rs, and one of which was Kaletra. In summary, the table was to the effect that Kaletra is one of eight 'third agents' listed in the Guidelines, which listed it as one of four alternative such agents, the other four being listed as 'preferred'.

25. The second document produced by Abbvie was a series of slides produced in April 2011 by the London HIV Consortium. The title of the slide presentation was 'Improving the cost of antiretrovirals (ARVs) in London, Summary of ARV prescribing messages for London'. The slide headed 'Agreed prescribing messages for London (continued)' said:

> '• For second line [that is, third agent] and subsequent therapy, where it is clinically appropriate to do so
>
> - Atazanavir should be used
>
> - Consider switching to atazanavir for patients on protease inhibitors when clinically appropriate.
>
> - Reserve use of the more expensive drugs (raltegravir) to agreed clinical indications.'

26. One of the subsequent slides, entitled 'Second line therapy (Protease inhibitors)', said:

> 'Use of least expensive PI (atazanavir) where it is clinically appropriate
>
> Atazanavir NOT clinically appropriate in the following scenario
>
> • Not supported by PI resistance profile
>
> • Clear clinical contraindication – drug-drug interactions e.g. PPI
>
> • History of renal stones.'

27. On that evidence, which CHL did not answer, CHL conceded that it could not be said that Kaletra faced no substitutability as regards those patients starting therapy. It submitted to the judge that the position was, however, different as regards stable patients, namely those already on therapy. The submission was that the London HIV Consortium presentation showed that switching of drugs should only take place when it was clinically appropriate and that there will be some patients for whom Kaletra remained the appropriate third agent. The judge said of that:

> '35. I have no doubt that this submission is correct. There will be some patients for whom Kaletra is a "must-have" medicine and for whom, therefore, a 10%, or perhaps even significantly higher, increase in price will not lead to any switch to another medicine. But there is 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, or therapy naïve patients, as compared to stable patients. Without at least some information along those lines, it seems to me that it is impossible to argue that a small but significant increase in the price of Kaletra will not cause a sufficient degree of switching to one of the other PI/rs such that this increase will not be profitable for [Abbvie]. Mr Colton submitted that [Abbvie] is better placed to provide such information than [CHL]. That may be so, but the burden is on [CHL] to establish some evidential foundation for its case on dominance. It cannot, in my judgment, be entitled to interim relief on a merely speculative basis in the hope that some evidence giving it a serious question to be tried or real prospect of success will emerge on eventual disclosure.
>
> 36. Moreover, [CHL] does know how much of its own purchases of Kaletra are used for UK homecare services as compared to its wholesale business or in meeting foreign subscriptions. Depending on what that information showed, it might provide some basis for saying that homecare treatment, and thus, on Mr Hundal's evidence, acquisition for stable patients accounts for a very large share of [CHL's] own acquisitions. But [CHL] has not provided even that information.'

28. The judge's conclusion was that whilst there was a real prospect that ritonavir based PIs used in ARV may constitute a distinct product market, the evidence disclosed no real prospect of its being shown that Kaletra constituted a relevant product market by itself. It followed that as there was no serious question to be tried on the issue of dominance, the application failed. The judge nevertheless also expressed his views on the question of abuse and whether any interim relief would anyway be appropriate, and a summary of his conclusions on those issues is as follows.

(b) Abuse

29. The judge said the refusal by an undertaking in a dominant position to supply an existing customer could be an abuse and that such an 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. But, said the judge, Article 102 had never been held to oblige a supplier to adopt a particular manner of distribution of its own products. The policy and practice of Abbvie was that it did not supply wholesalers in Britain at all. Its case was that it was not until it received CHL's email of 23 December 2012 that it learnt that CHL was trading as a wholesaler. CHL's response to that stance was that Abbvie should have realised the position earlier, or could have pursued its earlier inquiries of CHL more vigorously.

30. The judge disagreed with CHL's stance in that respect. He regarded its conduct as having been disingenuous. He held that:

> '43. … If an undertaking supplies a customer on the basis that the supply is for retail sale and has a policy of not supplying wholesalers, the fact that, unknown to the supplier, its customer is reselling some of the products on the wholesale market does not mean that the customer's orders for the purpose of wholesale constitute "ordinary

> orders" within the principles to which I have referred or mean that the undertaking cannot adhere to its policy and practice of not supplying wholesalers once it finds out what has been going on. …'

31. The judge held that CHL therefore had no real prospect of showing that, if Abbvie *was* dominant in the relevant product market, it had abused that position.

(c) Interim relief

32. The judge said that Abbvie was willing to continue to supply Kaletra to CHL in order to meet the needs of its domestic homecare business and so CHL faced no loss under that head of its activities. As for its wholesale business, it would face a loss but it was purely financial and could be compensated in damages. The same applied to what CHL had described as its mail order dispensing services used to deliver medication against prescriptions sent from hospitals and clinics in the EU. As for CHL's alleged overseas homecare service business, the evidence was sparse, but the judge said there was no reason why CHL could not obtain supplies from the company in the Abbvie group serving the relevant country. Such supplies might be more expensive, but any loss occasioned by that would again be financial loss.

33. In the result, as the answer to the first consideration identified by Lord Diplock in *American Cyanamid Co v. Ethicon Ltd* [1975] AC 396, at 408C, was that CHL could be adequately compensated at trial for the loss sustained by Abbvie's refusal to meet its supply demands over and above those for its domestic homecare service market, there was no case for an interim injunction.

The appeal

(a) Product market

34. Mr de la Mare submitted that the judge fell into two errors in his application of the SSNIP test. First, he had regarded the prescribing doctor as the relevant 'customer' rather than the pharmacist. Second, he had failed to have regard to the evidence showing that prescriptions for Kaletra were being written on the ground of clinical need rather than cost such that there was no potential for the party purchasing it – dispensing chemists – to substitute a different drug.

35. As to the first point, the submission was that it is the pharmacists rather than the doctors who are the relevant purchasers of the drugs, and therefore are the relevant customers. Kaletra is a prescription only drug and so, save in exceptional cases, it will be dispensed by pharmacists; and it is the pharmacists who buy Kaletra from Abbvie. As such a purchaser, the pharmacist has no choice but to buy Kaletra to meet the prescriptions written by the doctors. The pharmacists are in the business of meeting the prescriptions. They cannot react to a SSNIP in respect of Kaletra by buying an alternative drug in order to meet a Kaletra prescription. Either they buy Kaletra at whatever its price or they do not. As their business is to meet doctors' prescriptions, including for Kaletra, they have no choice but to buy Kaletra; and as Abbvie is the sole UK supplier of Kaletra, it must be dominant in the market for Kaletra.

36. As to the second point, Mr de la Mare submitted that whilst the SSNIP test is a useful tool in identifying the relevant product market, it is but the starting point. Every case

turns on its facts. The question in this case is as to the competitive constraints that arise in the pharmaceutical market. He accepted that the fact that a particular medicine may be patented does not by itself give its supplier significant market power, since there may be rival products serving the same therapeutic end. Where, however, a particular patented medicine is indispensable, or is in the 'must have' class for a particular cohort of patients, different considerations will or may arise, and that medicine may have market power or dominance over that cohort. He said it is important to remember that doctors prescribing medicines are ethically and legally driven by the paramount consideration of which medicine is to the best therapeutic advantage of their patients. The ultimate question for them is whether a particular product is therapeutically superior to other products; and it is only when alternative products are therapeutically comparable and substitutable that considerations of cost come into play. Where, however, therapeutic advantage carves out a particular cohort of patients for whom, for any reason, a particular product is a necessary one, that product becomes a 'must have' product.

37. Mr de la Mare's proposition was ultimately that the combined effect of exclusivity of supply of a particular product linked with the distinct therapeutic advantage of that product to a particular cohort of patients is a feature that arguably gives rise to significant market power, or dominance, at least as regards pharmacists. There was no dispute that Kaletra is an exclusive product. Moreover, the London Consortium guidelines, through which Mr de la Mare took us, show that for a cohort of patients it is arguably a 'must have' product for therapeutic reasons. That 'must have' status is sufficient to displace the basic instruction from the London Consortium that atazanavir, a cheaper drug, should be dispensed. In other words, doctors have concluded that notwithstanding that atazanavir is cheaper, they must, on clinical grounds, regardless of cost, prescribe Kaletra in cases where it will be of clinical advantage to the patient. The guidelines show that Kaletra should be prescribed for those patients even though atazanavir is a cheaper alternative. He submitted that there is no reason to assume other than that those guidelines are working and that Kaletra is not being so prescribed. He submitted that there is an arguable inference that Abbvie had deliberately targeted the niche 'must have' market, where it was seeking higher margins, at the cost of competitiveness in cases in which the cheaper atazanavir provided an alternative.

38. In sum, the guidelines reflect a push for the prescription of atazanavir when appropriate, on the ground that it is the cheapest drug, and Mr de la Mare also referred to Abbvie's evidence that following the publication of these guidelines prescriptions of Kaletra fell in favour of atazanavir. He asserted that this switch was because, as CHL asserts, atazanavir is cheaper. What remains, he said, is a cohort of patients who are being prescribed Kaletra on the grounds that it is for them the most clinically appropriate 'must have' drug. If the guidelines are working, Kaletra will only be prescribed for that particular cohort, and its higher price reflects that Abbvie has already recognised that and that it is at least arguable that it is enjoying a position of dominance in a market in which Kaletra alone is the product market. He said that the judge's paragraph 35, which I have quoted, failed to recognise that.

39. In response to Mr de la Mare's submission that it is the pharmacists who are the relevant customers, Mr Peretz noted that this was a new argument that was not advanced to the judge, but he submitted that it was anyway wrong. He said the key to the identification of the relevant product market is the consideration of competitive

constraint, namely whether 'other products alleged to form part of the same market act as a competitive constraint on the conduct of the allegedly dominant firm' (see *Genzyme Ltd v. Office of Fair Trading* [2004] CAT 4; [2004] CompAR 358, at paragraph 195, quoting with approval from *Aberdeen Journals Ltd v. The Director General of Fair Trading supported by Aberdeen Independent Ltd* [2002] CAT 4; [2002] CompAR 167, at paragraph 97). In this case, the relevant inquiry is as to the extent to which competition from equivalent or similar drugs has a competitive effect on the supply of Kaletra: do such constraints have the effect of keeping its supplier up to the mark in terms of price, therapeutic effect, presentation, pack size, pill size, precise formulation and other considerations? The point of competition is to benefit the consumer – in this context, the patient - and it is in his interests that the relevant market is competitive. It is his perspective that is critical when considering an inquiry as to whether a supplier is or is not dominant in a particular product market.

40. Mr Peretz recognised that, in the pharmaceuticals market it is perhaps oversimple to identify the patient as the consumer. He will commonly have no notion of the relative therapeutic merits or of the cost, so far as relevant, of particular drugs, or as to which drug is the best for him. The choice will be made by the prescriber of the particular drugs, who will know what is best for him; and to the extent that cost is relevant (as it will be between substitutable drugs), he will also know their relative cost. The consumer in such a case is therefore best regarded as what Mr Peretz called a multi-headed beast comprising the patient, the prescriber and the budget holder, who is the ultimate payer. It will not, however, include the pharmacist who is simply an intermediary whose task is to supply the prescribed drug.

41. The inquiry as to competitive constraints is not answered by asking whether pharmacists do or do not have any choice but to buy Kaletra if they are to meet prescriptions for Kaletra. They only have to meet prescriptions for Kaletra if the doctors prescribe it, with the ultimate burden of the cost of such prescriptions falling either on the patient or the budget holder. The relevant question is, therefore, whether the doctors have a choice as between Kaletra and other drugs, and to the extent that price plays its part in the choice between Kaletra and other drugs, Abbvie will have an interest in competing on price. Intermediaries such as CHL will of course have to buy and supply whatever the doctor prescribes, but its role in the supply chain is irrelevant to the competition considerations. The purpose of the competitive process is not to protect the economic interests of the middle man in the supply chain.

42. Mr Peretz submitted further that if Mr de la Mare's submission were right, it would follow logically that every patented medicine would represent a distinct product market, on the basis that the pharmacist had no choice but to buy it in order to supply it to the consumer. The judge correctly rejected this as a notion, and Mr Peretz added that there was no reported case in which the proposition advanced by Mr de la Mare had been given any credence. If the proposition were right, the market analysis in *Genzyme* would have been unnecessary.

43. As regards Mr de la Mare's broader submissions, Mr Peretz made the point that although much weight was placed by CHL on the assertion that Kaletra was a more expensive drug than other drugs available as a third agent, there is no evidence before the court as to this. The only evidence touching on the point was that one of the slides described atazanavir as the 'least expensive' second line therapy (protease inhibitors), a class including Kaletra. But there was no evidence as to the cost of Kaletra vis-à-vis

other third agents. It would have been open to CHL to adduce evidence of the cost of Kaletra relative to other drugs had it wished to, since it buys both Kaletra and other drugs used in the treatment of HIV patients. It had, however, adduced no such evidence. The evidence to be derived from the guidelines was, the judge held, essentially that Kaletra was one of eight substitutable third agents in combination with whichever backbone was used; and CHL had conceded before the judge that Kaletra was so substitutable, at least as regards therapy naïve patients.

44. More specifically, Mr Peretz said that the answer to CHL's unproved price difference point ignored the fact that when engaging in an exercise of market definition it is necessary to focus on the marginal customer, the person who is in a position to switch and can thereby keep the supplier up to the mark. The relevant question is whether there are enough marginal customers to act as a competitive constraint. It is that to which the SSNIP test is directed. Would sufficient customers at the margins switch away so as to make the price rise not worth the candle? As regards the consideration that there may be a section of captive patients – or Mr de la Mare's cohort – 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.

45. Applying those points to this case, there is no evidence of the extent of the captive patients. Roth J assumed there were some, as he said in his paragraph 35, but he also pointed out the lack of evidence of the proportion of patients in that category. It is known that Kaletra is one of a group of third agents. There is, however, no evidence that it has special qualities exclusively serving particular needs. Even if it is accepted that there are such captive patients, the key question is still whether there is or is not a sufficient number of marginal patients who would be prepared to switch from Kaletra if in some manner Abbvie fails to keep it up to the competitive mark. Even if, as CHL asserts, there is a price difference between Kaletra and other third agents, that does not show by itself that the products are occupying different markets. In the field of pharmaceuticals, as in other product areas, many comparative dynamics will be in play apart from price, and it is oversimple to point just to the alleged price differential between Kaletra and other drugs and deduce that they respectively constitute different product markets.

Discussion and conclusion on the product market issue

46. I agree with Mr Peretz on 'the pharmacist is the customer' issue. The fact that such a point does not appear to have been taken in earlier cases does not mean that it must be wrong. New points often prove to be good, and were it otherwise the law would not develop as it needs to and does. The point that CHL is, however, either the, or a, relevant customer in the relevant competition inquiry is misconceived. CHL 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. 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 SSNIP or other deterioration in the perceived qualities of Kaletra as compared with other drugs. The extent to which it does or does not so react will have a direct effect on the quantities of Kaletra that CHL will in turn need to buy and provide, but CHL's role in the economic chain is irrelevant to

the inquiry as to the identification of the relevant product market. I am not surprised this point was not taken before the judge. It is a mistaken one that I would reject.

47. As to the more general issue whether CHL has shown that there is a serious issue to be tried that the relevant product market is Kaletra alone, I also agree with Mr Peretz. Mr de la Mare advanced CHL's case with conviction, enthusiasm and persuasiveness, but he was working with the same material as was before the judge, who is particularly experienced in the specialised field of competition law. The judge understood the evidence correctly and recognised, or at least was prepared to assume, that there will be a cohort of captive patients for whom Kaletra is a 'must have' drug. However, for the reasons he explained in paragraph 35, that did not by itself, and without at least some evidence identifying their share of the Kaletra market in the UK and also the share of the Kaletra market occupied by therapy naïve patients, enable any conclusions to be drawn as to the impact on Kaletra's role in the market of a small but significant price increase.

48. In my judgment, given the exiguous nature of the evidence that CHL chose to adduce in support of its claim, that was a correct conclusion. The problem with CHL's case is that it was based on evidentially unsupported theory. For the reasons the judge gave, as cogently developed before us by Mr Peretz, this was not a case in which it could be said that CHL had shown that there is a serious issue to be tried that the relevant product market is Kaletra. The burden was on CHL to make good that assertion. The judge concluded that it had failed to do so. I agree with him.

49. That being so, this appeal must fail. It is unnecessary also to consider the other two grounds upon which the judge also found against CHL.

50. I would dismiss CHL's appeal.

Lord Justice Lewison :

51. I agree.

Lord Justice Treacy :

52. I also agree.