

ALLIANCE IBA MERGER INQUIRY

Summary of a hearing with Siemens PETNET Solutions held on 15 May 2014

1. Siemens PETNET Solutions (PETNET) reaffirmed its previous statement to the Office of Fair Trading (OFT) that it welcomed competition and did not regard rationalisation of the market as a positive development, but that it had not expressly objected to Alliance's acquisition of IBA's UK PET Radiopharmaceutical business.
2. PETNET explained that Siemens manufactured both SPECT (gamma) and PET scanners, and that its core business was the provision of these scanners and after-sales maintenance and support. Part of that support was the provision of radiopharmaceutical FDG, manufactured by Siemens' PETNET business, to Siemens' scanner owners. However, PETNET was happy to sell FDG to customers which used other manufacturers' (eg GE and Philips) scanners, and some customers who bought Siemens scanners purchased their FDG from sources other than PETNET. PETNET regarded FDG as a generic product. It had only branded the FDG it produced as 'Metatracer' for marketing licence purposes. There was a standard recipe for FDG in the EU Pharmacopeia which all manufacturers had to adhere to.
3. Siemens also manufactured cyclotrons used to produce F-18 and could supply the radiochemistry equipment needed to create FDG and other tracers. The production and sale of cyclotrons was a low-volume business. The only part of the supply chain which neither Siemens nor PETNET were involved in was the provision of the actual scanning services.
4. For the current financial year, PETNET did not anticipate that its UK PET scanner sales business would be more than double the size of its FDG provision. Siemens did not sell many cyclotrons in the UK as it was a limited market.
5. PETNET noted that in the Republic of Ireland there was only one commercial provider of FDG and this meant that the price of FDG in the Republic of Ireland was much higher than in Great Britain, which PETNET did not think was good for the Irish market.
6. PETNET supplied FDG for two reasons. First, it helped to support Siemens' PET scanner business and the overall PET scanning market by ensuring that

customers had access to FDG at a reasonable price. Second, the provision of FDG was a profitable business in its own right. Siemens' competitors in the UK scanner market (eg GE, Philips) did not currently produce FDG, though GE had done so for a short time (18 months) from 2008/09 but had then exited.

7. Production of FDG accounted for around 90% of PETNET's revenue. It also produced other tracers, most recently an Alzheimer's tracer under licence from Eli Lilly. Siemens' scanner business and PETNET operated wholly separately. Customers buying scanners from Siemens would do so separately from buying FDG from PETNET. To Siemens' recollection there had never been a single tender from a customer for both scanners and tracers. Where possible, Siemens and PETNET would try to promote their own FDG to scanner customers, but it did not actively bundle the two products together. Again, PETNET considered that its production of FDG contributed to keeping the cost of FDG affordable, which meant that customers were more likely to buy scanners in the first place.
8. Most of the profitability of Siemens' scanner business was derived from its after-sales maintenance, not the initial sales of the scanners. PETNET thought that the profitability of the after-sales maintenance business was probably higher than that of its FDG business.
9. Siemens acquired PETNET in 2005/06 from a US-based firm, CTI Molecular, and had inherited operations at the Mount Vernon and Nottingham hospitals. At Nottingham, it had also inherited a partnership arrangement with InHealth to set up a PET scanning centre with on-site production of radiopharmaceuticals. Under this arrangement, Nottingham University Hospital acted as the overall landlord and had provided land for InHealth to build the centre, which contains a scanning facility operated by InHealth and a radiopharmaceutical production unit (RPU) operated by PETNET. This arrangement had remained unchanged since its inception. What had changed in the meantime was that the NHS had implemented a national contract for PET scanning, including mobile scanning. InHealth had won some of this business (predominantly for the Midlands and the South of England), and PETNET had a separate agreement with InHealth to supply tracers to its mobile scanning business, which PETNET did from the RPU at Nottingham. The contract for scanning services for the North of England had been won by Alliance, and PETNET acted as a small minority supplier of tracers to Alliance. Until recently, the scanner at Nottingham had been a Siemens scanner, but Nottingham had just switched to a GE scanner.
10. Under the Nottingham partnership agreement, PETNET was not exclusively required to supply InHealth with tracers, and InHealth was not required to buy

a minimum of tracers from PETNET. This meant that it was necessary for PETNET to ensure that its prices were competitive, so that InHealth would not seek to buy its radiopharmaceuticals elsewhere. As it happened, InHealth sourced the majority of its tracer requirements from PETNET. PETNET and InHealth had discussions about how many doses InHealth would need to purchase, which allowed PETNET to plan and ensure that it had the production capacity, but ultimately, InHealth would only pay for the number of doses it actually purchased.

11. PETNET's overall strategy for its FDG business was to remain an active participant in the market where there was now increasing interest in other types of tracers (eg ones for Alzheimer's). FDG was the 'workhorse' of PET scanning because it could be used as a tracer for many types of cancer and was used for over 90% of scans. However, there were certain cancers which FDG was less good at detecting, and niche tracers were being developed for these, but FDG remained the primary tracer product, and PETNET intended to continue to produce it.
12. PETNET was looking to use its existing facilities more efficiently, ie producing more FDG from its existing cyclotrons and had aspirations to expand, [X]. PETNET was currently making some improvements to its Mount Vernon facility in order to maintain compliance with GMP and MHRA standards.
13. Currently, PETNET's existing cyclotrons were not running at full capacity. It anticipated that the UK PET market would continue to grow [X]. Every PET scan run required a dose of FDG, so growth in the number of scans (and scanners) would require the production of more doses of FDG and other tracers.
14. PETNET considered that the addressable market for FDG included, in its broadest sense, the FDG that Alliance sourced from Eriegal, its in-house producer. PETNET supplied 5% of Alliance's (mobile scanner) FDG requirements, but the requirement for scanning providers (both Alliance and InHealth) to source their FDG requirements from more than one producer had been mandated by the NHS in the contracts in order to ensure security of supply. However, how much FDG a scanning provider sourced from a given supplier was up to the scanning provider. Naturally, Alliance sourced the vast majority of its requirements from Eriegal.
15. PETNET did not serve the Scottish and Northern Irish markets as these were too far away from its production facilities. In the case of Wales, there was an NHS cyclotron at Cardiff which provided that hospital's needs. PETNET regarded its potentially addressable market as the majority of fixed sites in England and InHealth's and Alliance's mobile scanning fleets. It therefore saw

England as a single geographic market although there would be contracts which would be harder for it to win than others, either because the potential customer self-supplied or because the customer had a relationship with another supplier which was local.

16. As it had two production facilities, in most cases PETNET was able to back up its own supply of FDG in the event of a production failure at one of its sites. PETNET's understanding was that the NHS had wanted the (independent) scanning providers to source FDG from more than one company in case one of the FDG suppliers went out of business.
17. Where NHS hospitals had their own cyclotrons, PETNET's view was that they would continue to use these to supply themselves with FDG and with isotopes with shorter half-lives, such as Carbon-11, and for research work. It did not think it likely that NHS hospitals would seek to enter the market for the commercial supply of FDG and compete with PETNET to supply other hospitals. More NHS hospitals might seek to build their own cyclotrons, but these would be the larger research centres and teaching hospitals, which would use the cyclotrons for the range of activities noted above. As the cost of FDG was quite competitive, it would not be economic for most hospitals to build their own cyclotrons and labs just to supply themselves with FDG. PETNET did not consider that the number of cyclotrons in the UK would greatly increase in the years to come. Hospitals which used their cyclotrons to make other tracers would limit the amount of FDG they could produce. Also, the NHS's staffing model militated against producing FDG for early morning appointments, so, for example, PETNET supplied some early morning doses of FDG to a hospital which had its own cyclotron. Hospitals which wanted to enter the commercial market would also need to develop marketing and sales operations, and PETNET had seen little evidence in the academic and National Health Service world for going down this route. A sudden rise in the price of FDG might make hospitals reconsider whether or not to self-supply, or in the case of those which already had cyclotrons, to seek to supply others. PETNET did not think that a rise of 10% would be large enough to trigger such a move. It did not know what size an increase would be but considered that if a customer felt that an increase was unjustified, it would consider its options.
18. PETNET could not self-back-up the FDG it supplied from its Nottingham site to [§<], as its Mount Vernon facility was simply too far away, but it was able to supply Plymouth from either Nottingham or Mount Vernon and could send back-up supplies from Nottingham to London in the event of a failure at Mount Vernon. In PETNET's opinion, having two facilities in the same part of the country for back-up purposes was not necessary.

19. PETNET used flat pricing for its contracts which did not take into account the amount of cyclotron activity required to provide a finished dose to customers located further from its production sites or to be used later in the day, ie a dose to be used at 10.00am would not cost less than a dose to be used at 4.00pm. On transport pricing, PETNET simply passed the courier costs through to its customers, so if a courier charged PETNET £100, then PETNET would charge the customer £100. The cost of a dose supplied from Nottingham was not higher than one supplied from Mount Vernon. PETNET did not take production costs and factors such as distance into account when bidding for new contracts except in relation to the actual transport costs.
20. PETNET had recently won the contract to supply [X] with FDG. [X] had told PETNET that one of the key issues which had been taken into account when awarding PETNET the contract was reliability. [X]'s facility [X] was also geographically equidistant from PETNET's sites at Nottingham and Mount Vernon. Siemens had been involved in negotiations with [X] about supplying a scanner to it prior to the FDG tender, which had proved successful. The sale of the scanner to [X] took place before and was completely separate from the bidding process to supply FDG. PETNET again noted that Siemens did not expect its scanner customers to buy their FDG from PETNET, and PETNET was happy to supply customers who used GE and Philips scanners.
21. PETNET thought that most customers considered both reliability and price when awarding contracts. It did not think that customers did so in a sequential way which meant that they, for example, first took account of reliability and then considered price. PETNET did not think that it would have won the [X] tender if its price had been double that of its competitors, no matter how important [X] considered reliability to be. PETNET considered that on average customers tended to weight price and reliability fairly equally. More experienced customers perhaps gave greater priority to reliability as they better understood the problems that could arise when deliveries did not arrive.
22. Customers asked about suppliers' back-up arrangements, and PETNET considered that being able to self-back-up would be a comfort to customers and would be perceived as being better than arrangements which involved other suppliers. PETNET's experience was that the emphasis on price versus reliability could vary depending on whether the tender was being assessed by a finance person, who would focus on price, or a clinician, who would focus on reliability.
23. Prior to the acquisition by Alliance of the IBA UK PET business in September 2013, PETNET had regarded Erigal as the stronger competitor in FDG supply as Erigal had the effective in-house supply arrangement with Alliance and also had the network of three production sites at Preston, Keele and Sutton

(Royal Marsden). IBA had been more limited geographically to the South-East and had lost its contract to Eriegal to supply the Christie Hospital in the North-West.

24. As far as the South-East was concerned, prior to the acquisition, PETNET, Alliance and IBA had all had one site in the area, but PETNET and Alliance (Eriegal) had their in-house back-up capabilities with their sites at Nottingham and Keele respectively, while IBA had closed its other site so was dependent on other producers for back-up. On this basis, PETNET considered Alliance to have been the stronger competitor in the South-East. The closure of IBA's site at Dinnington and PETNET's awareness (as a back-up supplier for IBA) of production problems at IBA's Guildford site had let PETNET to consider that IBA had been weakening as a competitor in early 2013.
25. PETNET's sites only had to back each other up in emergency situations. It conducted maintenance at the facilities at weekends so they could operate Monday to Friday. Both sites' reliability levels were in the high 90% range and overall reliability in terms of delivering doses to customers was above 99.5%. As it was rare for PETNET to ask another supplier to provide back-up, it did not have fixed arrangements in place but would simply contact other suppliers about producing the required dose and providing the necessary transport. If back-up was required it was handled by operational staff and there was no negotiation around price. Providers knew that there was a patient waiting to be scanned and would do their best to ensure that the scan took place.
26. PETNET's view was that FDG prices had been slowly falling, [X]. It did not know whether the Alliance/IBA merger would affect this.
27. PETNET did not know whether or not it would be able to cover the whole of the IBA Guildford site's customers if it were to close, but PETNET thought it would be able to produce [X] additional [X] doses per year from its existing facilities.
28. As PETNET did not provide scanning services, it was not competing in the latest round of tendering for NHS block contracts. [X] FDG prices needed to remain sustainable and a price war would not be helpful as this may result in price erosion to an unsustainable level. In such a case, other suppliers may leave the market and furthermore the market could be seen as being 'broken', such that no new entrants would want to come in.
29. Incumbency was only an advantage when tendering if the FDG supplier had been performing well, since the customer would know the supplier 'warts and all'. It was always possible for customers to dual source and try out new

suppliers without severing ties with their current one. This practice might increase in the future.

30. The current PETNET management had not been involved with the setting up of its Nottingham facility, but the initial agreement had been signed in 2004, scanning of patients had begun in late 2006 and FDG had been supplied at Nottingham in late 2006/early 2007. Based on other sites it had opened on the Continent, PETNET considered that two to three years was usually how long it would take to get a new FDG production site built and operational. [X]
31. There were few economies of scale in having two or more sites located in the same region. The advantages would be derived from having one larger site, which was why PETNET was looking at expanding its existing facilities. Additional sites would require additional staff to run them as even if located close by each site would need its own technicians, production specialists, quality control staff etc. A larger site would not require so many extra staff.
32. Assuming current market conditions, PETNET considered that a single cyclotron site would need to produce 10,000 or slightly more doses a year to break even.
33. It would be possible to increase the number of FDG production runs at each of PETNET's sites [X].
34. PETNET considered that the in-house NHS cyclotrons had really only affected the markets in Scotland and Wales. The investment in eight commercial cyclotrons had been based on an expectation of greater NHS funding for PET and greater growth in the UK PET market than had occurred. A rationalisation had already begun with GE leaving the market and IBA closing its site at Dinnington. The current level of six cyclotrons (three Alliance, one IBA and two PETNET) had been maintained for the past three years or so. Since 2010 NHS investment in PET scanning had grown, and the market and PETNET's business had grown with it. PETNET expected that the numbers of PET scans would not decline as the service had become established in the NHS, and it hoped that the numbers would continue to increase, but it was not clear how fast the market would grow and much would depend on the current NHS scanning tendering process. Therefore, it was difficult to say how many competitors the market could support.
35. PETNET did not know whether IBA's UK PET business was viable, and if not, whether it could have been made viable. Leaving their ownership aside, PETNET believed that the current market could support six commercial cyclotrons. It did, however, think that six cyclotrons at six different sites would be less viable than, say, two suppliers with three cyclotrons each or three

suppliers with two cyclotrons each, which would be able to share some (though by no means all) costs between the sites. A single cyclotron with one RPU would not be very attractive to an entrant to the market from outside the UK. Issues such as proving reliability and arranging back-up would need to be addressed as would the need to obtain a secure contract at a known price. The current size of the market and its current level of production capacity meant that any new entrant would face considerable risks.

36. Neither PETNET nor Siemens had been approached by SK Capital to gauge its interest in purchasing either the IBA assets or the contracts they served. PETNET would have been interested to consider whether buying the IBA site at Guildford would have been a viable alternative to its plans to expand its Mount Vernon site, but it suspected that it might not have been very attractive and was also sensitive to the potential issues that such an acquisition might create with regard to the competition authorities.
37. PETNET was concerned that the Alliance/IBA acquisition would lead to the market becoming a duopoly and this could create substantive problems and perceived problems about how the market operated, particularly if FDG prices began to rise or if one of the two suppliers won the lion's share of the market and the other supplier's viability was challenged. The merged Alliance/IBA would have four cyclotrons to PETNET's two, and if the market developed in a way which led to PETNET losing a significant part of the overall market share, it could be seen as very much the number two in the market and its viability could be threatened.
38. When GE exited the FDG market, PETNET believed that its supply contracts were all novated to IBA and there was no real opportunity to tender for them. A similar situation had occurred when IBA had closed its Dinnington site, but PETNET had managed to win some business as a result of the closure, notably Newcastle which IBA could no longer supply from Guildford.
39. PETNET had briefly considered buying Dinnington but had decided against doing so as the site was located in the wrong part of the country in that it was too close to Nottingham, and the majority of scans in that area were carried out by Alliance who were sourcing FDG from Erigal. PETNET had not had conversations with IBA about supplying back-up as it understood that Alliance and IBA had come to a contractual back-up agreement.
40. If Guildford were to close in the wake of the acquisition, it would make little difference to the FDG contracts currently supplied by that site as all of them were up for renewal in the short term, and PETNET would be able to bid for these through the usual tender processes. [X]

41. PETNET expected that the NHS would wish to know how the scanning suppliers were intending to source their FDG. It expected to speak to both InHealth and Alliance as the tender process progressed. Alliance was a customer of PETNET and Siemens as it respectively purchased FDG and scanners from them. It was also likely that some NHS hospitals and other independent scanner providers would bid for the contracts, which would give PETNET other opportunities to supply FDG. The NHS's decision to move from two to an increased number of regional lots would also allow for more participants in the scanning market and different purchasing arrangements. If Alliance were to win a significant share of that business, it would be likely to wish to source its FDG from Erigal and the IBA site, which would take away a very significant part of PETNET's current business.