

## **ALLIANCE/IBA MERGER INQUIRY**

### **Summary of a hearing with IBA Molecular held on 8 May 2014**

1. IBA Molecular explained that the activities its UK business had retained following the sale of the Guildford and Dinnington sites (its UK PET business) consisted of its UK Single-Photon Emitting Computerised Tomography (SPECT) business, which imported and distributed mostly molybdenum-based radiopharmaceuticals into the UK from France. These radiopharmaceuticals had longer half-lives than PET radiopharmaceuticals (eg FDG-18) so did not require UK-based production facilities. There was little innovation in SPECT radiopharmaceuticals. IBA itself did not develop new products; instead it distributed other companies' products in different European and international territories.
2. IBA Molecular's UK SPECT business turnover for the current year was budgeted as approximately £[redacted]. Expected profits were budgeted as £[redacted]. Following the sale of its UK PET business, it was working to increase its UK SPECT business's market share.
3. There were a few companies active across Europe in the SPECT market: IBA, General Electric (GE), and Malinkrodt (Covidien). The companies' shares of individual national markets varied, eg IBA was the leader in France, but they were all present in each national market. Conversely, the PET market was very local. IBA was the only global manufacturer of PET products, so its competitors varied from country to country.
4. The SPECT and PET markets also varied in terms of size and growth. IBA's main PET markets in Europe were France, Spain and Italy. The UK PET radiopharmaceuticals market had not seen the growth which had been anticipated some years ago. Growth in the UK PET market was driven by the number of PET scanners in the market, and these were mostly paid for by Government, so growth had been based on Government plans to promote PET scanning. The UK was behind many of its European counterparts in the number of PET scans performed.
5. IBA had invested in its UK PET business based on an anticipation of market growth which had not materialised. It considered it unlikely that the current market conditions would encourage entry into the market. IBA noted that it had been one of the last entrants to the UK market, with its cyclotrons becoming operational in the second half of 2007 and early 2008. It had also

found the licensing process to be challenging. The relatively small size of the UK market (25% of the Italian market) combined with the relatively low level of prices for PET radiopharmaceuticals in the UK meant that IBA had found it very difficult to make either its Guildford or Dinnington sites profitable, even though it had acquired business from another FDG producer that had left the UK market. The PET market across Europe was increasingly challenging. FDG was a commodity product, and suppliers faced increasing regulation and compliance requirements which increased their costs.

6. IBA had to re-bid for the contracts it had acquired from the producer which had left the UK market. It retained three of these contracts: [redacted]. It considered that incumbent suppliers had the advantage of already having an established relationship with the customer when participating in tender processes but noted that most tenders were decided on price. Price was especially important as FDG was an undifferentiated product, so one producer's was the same as another's. Reliability was also important, as an unreliable supplier would not be able to win any contracts, but if competing suppliers could demonstrate a good level of reliability, then price would become the determining factor. As the quality of suppliers had improved, reliability had become less important as a differentiator.
7. IBA had decided to mothball its Dinnington plant because of the loss of a significant contract in Glasgow (to Erigal) and the lack of other business development opportunities. Alliance Medical had won the PET-North NHS scanning contract and had its own FDG supply from Erigal. The Dinnington site (near Sheffield) therefore could not access much of the potential business in the North of England. Apart from its Glasgow contract, it only had a few other small ones, and it knew it would lose one of those (Edinburgh) as that hospital was buying its own cyclotron and would self-supply. IBA considered that there was no other business Dinnington could win, so it had decided to mothball the site. The contracts supplied by Dinnington had been taken over by a number of suppliers including Siemens (PETNET), Erigal and IBA's other site at Guildford. IBA needed to arrange back-up solutions for the Dinnington contracts it had retained and was now supplying from Guildford, [redacted].
8. When the IBA assets were sold to Alliance, the Dinnington site had been mothballed for some time and would have required work to reactivate it. Some equipment from the Dinnington site had been removed to support the Guildford site, but the cyclotron and related core equipment was still there, and IBA inspected the state of the site regularly and ensured it was secure. It would take [redacted] to reactivate the site. This process would involve requalifying as a pharmaceutical production site, reinstalling equipment, producing a number of test batches of FDG and filing the proper administrative and

regulatory documents. There would still be significantly less investment involved in restarting Dinnington than there would be with a greenfield site.

9. [REDACTED]
10. IBA's owners, SK Capital (SK), had undertaken all the negotiations with Alliance and the decision to sell the IBA UK PET business to it. IBA had not been involved. SK had taken this decision based on its view of the financial viability of the UK PET business and its obligations to its shareholders. The agreement to sell the UK PET business to Alliance also included an agreement for IBA Molecular to supply Alliance with radiopharmaceuticals in a number of other European countries. [REDACTED]
11. At the time of the sale to Alliance, IBA considered that its production of FDG was reliable. The UK market simply had not grown as anticipated, and it had not grown quickly enough to support the investments made by the participating companies. Production sites were left with significant unused capacity. This had led to the participants chasing increased volumes and lowering their prices, which had led to sites becoming less profitable or unprofitable. IBA did not consider that the NHS's purchasing arrangements had caused the problem, it was the fact that the UK FDG market was approximately one-third the size of the UK's total production capacity.
12. It was noted that the fact that some UK hospitals self-supplied made the overcapacity of the commercial supply even worse. Vertical integration between suppliers of FDG and suppliers of PET scans was not a feature of other markets around the world.
13. IBA's Guildford and Dinnington sites had the same infrastructure and staff numbers. Guildford had been producing [REDACTED], which was not enough for it to break even, so IBA had been working on growing the Guildford business and considered that it would reach the break-even point in two years at the earliest if it were able to retain its existing business and gain new contracts. These new contracts would require the introduction of at least two new PET scanners. IBA bid for the contract to supply one new PET scanner at King's College Hospital in London but did not win it. Another new scanner which had been planned at the Royal Free had not yet been introduced. As neither of these opportunities had materialised, and there were no others on the horizon, IBA had previously looked at various alternatives for Guildford (which were similar to those it had considered for Dinnington, such as operating a commercial radiopharmacy). However, these alternatives had only been in the very early stages of development and were not taken forward.

14. IBA mothballed Dinnington in 2010. At that time, it decided to keep Guildford open as the site had an infrastructure that allowed IBA to keep it running, and some production was transferred from Dinnington to Guildford which boosted its viability. IBA was also working on the production of new tracer molecules, including Florbetaben, which it hoped to produce at Guildford in the future. IBA wanted to retain Guildford as part of a global network of facilities, so that it would be able to conclude multi-country arrangements with major pharmaceutical companies to distribute their new products as widely as possible. [X]
15. IBA considered that its major competitors were approximately as efficient as it was. It surmised that profitability in the UK tracer production industry was close to zero. IBA's view was that the closure of Dinnington had not adversely affected the viability of the Guildford site, which provided a good service to InHealth. Since January 2011, Guildford had bid for seven contracts. The closure of Dinnington had not affected Guildford's ability to bid for new business. [X] Since its acquisition by SK, IBA had changed its approach to bidding to a cost-plus approach, which meant that it would only bid for new business on the basis that the business would be profitable if it won, so, for example, it would adjust its bids to reflect the costs (eg transport) of fulfilling a particular tender.
16. IBA had continued to invest in and maintain the Guildford site to the level necessary to maintain compliance with regulatory standards, but it had not added extra capacity. In the case of Dinnington, IBA considered that for it to have reopened the site, it would have needed guaranteed volumes. The amount of business required to reopen Dinnington would depend on the number of doses, the price of the doses, the level of use of the cyclotron, the location of the customers and consequent transport costs. [X] Alliance had approached IBA in September 2012 about IBA supplying it with FDG, but these discussions had not been successful, so IBA's management escalated them to SK.
17. [X]
18. IBA had not had discussions with InHealth and its other customers about the possibility of mothballing Guildford and exiting the UK PET market or about how the two businesses could cooperate to ensure Guildford remained open. IBA had previously spoken to the Department of Health about the closure of Dinnington and how the Department might assist in keeping it open.
19. IBA's view was that the sale to Alliance had been a better option than mothballing. The decision to sell to Alliance had been SK Capital's, [X]. SK had neither sought nor had discussions with other potential purchasers.

20. If the site had been mothballed, it would have been necessary to speak to the other two commercial tracer producers in order to ensure that continuity of service to customers was maintained. The approach to mothballing varied, but it would be necessary to address each customer's contracts individually as their terms would vary. IBA had not undertaken this process in respect of Guildford.
21. Public hospitals with their own cyclotrons tended to entirely self-supply and were effectively out of the market as far as commercial tracer producers were concerned. If more hospitals obtained cyclotrons and self-supplied, then the market available to commercial producers would shrink. IBA was not aware of any public hospitals seeking full market authorisation from the MHRA. If a hospital did obtain market authorisation, then it would be able to supply tracers in competition with existing commercial providers. Some hospitals had acquired cyclotrons so they could manufacture research molecules, which commercial producers would not produce, alongside their current tracer requirements.
22. The contestable commercial market consisted of the NHS contracts and various competitive tenders. Bodies which self-supplied, either NHS hospitals or Alliance, which obtained its tracers from Erigal, were not part of the contestable market. Hospitals sometimes used the threat of self-supply in negotiations, but very few, if any, new hospital cyclotrons had been installed in recent years.
23. IBA explained that when Dinnington had been mothballed, it had transferred the supply of tracers to one hospital, the Christie, to its Guildford site at the same price in order to retain the contract, even though this had been financially challenging for IBA.
24. The market could be divided geographically into the South of England, which ended at Birmingham; the North, which went from Birmingham to the Scottish border, and Scotland. Back-up production sites could be located further away from customers than main production facilities. [X]
25. IBA Guildford's closest competitor in the South had been the PETNET cyclotron at Mount Vernon Hospital, [X]. Dinnington's closest competitors were Erigal at Keele and PETNET at Nottingham. IBA's sites had been newer than their competitors and this had given them a reliability advantage when they first entered. IBA understood that GE had exited the market because it had been unable to sustain regular supplies of FDG. Since 2007, differences in market participants' reliability had very much reduced, so that there was now little difference between them. FDG production was a market where little differentiation between competitors was possible.

26. Once customers were satisfied with the reliability of a producer, including its back-up arrangements, their focus would move to price. Assuming reliable back-up could be secured, there was therefore little advantage in having two or more sites in the same region according to IBA's global strategic approach for its business.
27. Following the closure of Dinnington and the acquisition by SK Capital, IBA Guildford had continued to work to retain its existing contracts and gain new business, but it had been pessimistic about the chances of growing its business. IBA considered that if it had still owned Guildford; then it would have had a good chance of retaining the Cobalt contract.
28. The average working life of a cyclotron was 25 years, which was also the life of the central components. Other parts, such as the targets, tubing etc, would need to be renewed at regular intervals (eg every two, five or ten years).
29. When contracts were renegotiated, there had been a tendency for prices to come down even though the costs of production had been increasing. It was difficult to get customers to understand the cost pressures which affected producers.
30. IBA had begun the process of setting up its Guildford and Dinnington sites in late 2004/early 2005. Dinnington had become operational in August 2007 and Guildford in February 2008. Setting up these sites in the UK had taken longer because of a lack of experience about the regulatory hurdles. IBA now considered that it would take around [X] to set up a new site. The set-up costs, including regulatory costs, would be around £[X]. Reactivating Dinnington would take [X]. Installing the equipment would take [X], and the remaining time would be needed to deal with the regulatory requirements. When a mothballed site was reactivated, any pre-existing equipment had to be requalified. IBA had never reactivated a mothballed cyclotron.
31. Operating two sites in the same region did not create any economies of scale at a site level since each site would need the same number of workers and managers in the same roles. There were some economies as far as purchasing was concerned, but these were small.
32. The minimum efficient capacity of a radiopharmaceutical production unit depended on the price per dose which could be obtained and the proximity of the customers it served. [X] Hospitals with cyclotrons might make only one batch of FDG a day and use the cyclotron to make other research materials the rest of the time. Theoretically, hospital cyclotrons could produce two or three batches a day (20,000 doses a year). Hospitals would need to get the

same market authorisation as commercial producers if they wanted to supply each other. [X]

33. It was possible for cyclotrons to make many batches of tracers a day, but for IBA in the UK the demand from its customers in the UK meant that no more than three had been viable. If the NHS invested more heavily in PET scan equipment, then there would be greater demand for FDG-18 and suppliers would produce more.