ALLIANCE MEDICAL LIMITED / IBA MOLECULAR UK LIMITED'S FDG MANUFACTURING BUSINESS

INITIAL SUBMISSION TO THE CMA

I. INTRODUCTION AND EXECUTIVE SUMMARY

(a) The Transaction

1. On 16 September 2013, Alliance Medical Molecular Imaging Limited, a wholly owned subsidiary of Alliance Medical Limited ("**AM**"),[1] completed the acquisition of the assets of IBA Molecular UK Limited ("**IBA**") which are used to manufacture fluorodeoxyglucose 18F ("**FDG**") ("**the Transaction**"). The consideration payable was cash of [REDACTED].[2]

2. The Transaction comprised the purchase of a business[3] with a turnover of £2.252m, eight employees and five customers[4] who purchased FDG under fixed price contracts. [REDACTED].[5] Three other customers have contracts with IBA which have expired or will expire over the next nine months or so.[6]

3. IBA owns two plants that are capable of producing FDG, one of which – at Dinnington/Sheffield – was deactivated/mothballed in November 2010. IBA's active plant is at Guildford.[7]

4. It has throughout its existence made losses, even at an EBITDA level.

(b) The Parties

AM's legal structure is set out at Annex 28 to OFT Informal Submission dated 24 January 2014 ("**OFT Submission**").

2 In addition, and as part of the same overall arrangement, a 10-year supply agreement was entered into under which IBA's parent company agreed to supply goods to Alliance Medical Group companies in Italy, Spain and Germany.

3 As noted in para. 1 above, the purchase was structured as an acquisition of assets.

4 InHealth Diagnostic and Imaging Ltd ("**InHealth**"), Cambridge University Hospitals NHS Foundation Trust ("**Cambridge**"), Cobalt, Barts Health NHS Trust ("**Barts**") and Oxford University Hospital Trust ("**Oxford Churchill**").

5 [REDACTED]

6 The InHealth contract has expired, although it is believed still to be making purchases from IBA. The Barts contract expires on [REDACTED] and the Cambridge contract on [REDACTED]. (The Oxford Churchill contract expires on [REDACTED].)

7 AM did not acquire any management, sales or administration people or systems given the nature of the business acquired – IBA Molecular UK operated two businesses within one legal entity and retained eight employees for the other business operating in a market for the provision of SPECT products.

5. Annex 1 comprises brief histories of Alliance Medical Group, AM, Erigal Ltd, IBA Molecular UK Ltd (the vendor) and the IBA FDG business (the target) together with chronologies of significant events in the last five years.

(c) Transaction rationale

6. There are two aspects to AM's acquisition of IBA.

7. First, AM is active not only in the supply of FDG but also – and more significantly commercially – in the downstream market for the supply of PET-CT scans. AM is seeking to compete with a strong incumbent in PET-CT in the South, InHealth.

8. PET-CT scanners are used predominantly for the diagnosis of cancers and are operated by the NHS (foundation trusts and trust hospitals) and third parties (AM, InHealth, Cobalt and some private hospitals). All require reliable supplies of the tracer, FDG, in order to carry out scans. FDG is radioactive and decomposes rapidly: it therefore needs to be produced near to its point of use.

9. The business of manufacturing FDG commercially suffers from poor economics: when demand for PET-CT scanning in the NHS first took off, too much capital was invested in the production of FDG and demand has not grown sufficiently quickly to enable the remaining capital to be operated profitably: GE has exited; Erigal ran into serious financial difficulties, breached the covenants in its loans and was rescued by AM acquiring the remaining 50 per cent. of the shares;[8] and IBA deactivated/mothballed its Dinnington/Sheffield plant.

10. When operators of PET-CT scans – including AM – consider their sources of supply of FDG they therefore place significant weight on:

    (a) the locations of the production facilities (cyclotrons) that will supply FDG to them;

    (b) how they will obtain supplies of FDG if, as commonly occurs, one production facility suffers a planned or unplanned outage; and

    (c) their confidence that their supplier of FDG will remain in business.

[8] This is explained further in Annex 1.

11. Accordingly, FDG customers – including AM – value:

    (a) suppliers with FDG production facilities that are closer to the customer's site;

    (b) suppliers with two FDG production facilities that could be used to meet the customer's requirements ("**dual supply**"), as each plant backs the other one up; and

    (c) suppliers which are financially robust and committed and able to remain active in the supply of FDG.

12. Prior to the Transaction,[9] AM owned two FDG plants in the North and one in the South. The two Northern sites operate as an effective dual supply arrangement in the North. The distance between the Northern sites and the Southern site at the Royal Marsden/Sutton meant that AM had a relatively weaker dual supply offering in the South.

13. As a result of the Transaction:

    (a) AM now owns two FDG facilities in the South – Erigal's at the Royal Marsden/Sutton and IBA's at Guildford – enabling it to offer a credible dual supply of FDG in the South both for self-supply for its PET-CT scanning activities and to third party purchasers of FDG; and

    (b) IBA's Guildford site is now owned by AM, a financially robust, committed supplier of FDG, making it a reliable source of FDG for self-supply and a credible long-term source of FDG for third party purchasers.

14. The Transaction therefore creates a strong new second competitor to PETNET in the supply of FDG in the South and strengthens AM's position in the supply of PET-CT scans in the South because of the improved security of supply of FDG[10] and therefore

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9 Following the acquisition of the remaining 50 per cent. in Erigal.

10 See Board Report, 21 June 2013 (Annex 18 to OFT Submission), slide 6 (describing "*security of supply*" as a core rationale for the Transaction), slide 13 (saying "*We will be in a position to guarantee supply of FDG, unique to the market*" and "*As market prices increase elsewhere we will be in a position to hold prices for our customers, unique in the market*") and "UK Board - Off Site" 18/19th November 2013 (Annex 26 to OFT Submission), slides 29-38. AM's focus on security of FDG supply supporting PET-CT activities is also shared by Guy's & St Thomas' as evidenced by the published documents describing its decision to install its own cyclotron:

gives it a better chance of winning some of the PET-South business which is currently held by InHealth. AM's wish to win new PET-CT scanning business in the South by strengthening its position on back-up supplies of FDG[11] was one of the principal drivers of the Transaction.

15. A second aspect to the rationale for the Transaction is its role in AM's [REDACTED][12] This is described in [REDACTED].

(d) The typical evolution of demand for diagnostic imaging services in Great Britain

16. In assessing the Transaction, AM submits that it is helpful to have in mind the typical evolution in demand for diagnostic imaging services in the UK, as set out in Annex 3. This is informative as the evolution of demand for the older technology of MRI scanning is largely being repeated in the case of newer technology PET-CT scans.

(e) Jurisdiction

17. The CMA has jurisdiction to investigate the Transaction because AM/Erigal and IBA (together, "**the Parties**") overlap in the supply of FDG in the south of Great Britain and together account for a share of supply of 25 per cent. or more.[13]

(f) Executive summary

18. PET-CT scanners are used for diagnosing cancer patients and to inform their treatment. Cancer patients have an expectation – and the NHS has specific targets – around quick diagnosis and treatment for cancer patients (e.g. PET-CT scans must occur within 14 days of referral). The need for speed and reliability around cancer treatment makes it unique (alongside stroke) for the rigour with which commissioners require services to be run. PET-CT scanners only work (for the relevant cancers) where FDG is used to allow the scanners to "see" potential tumours. Therefore, the 100 per cent. reliable supply of FDG is crucial to effectively treating cancer.

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http://www.guysandstthomas.nhs.uk/resources/about-us/board-minutes/2013-board-papers/january/11-trust-risk-register.pdf.

11 An important tender criterion.

12 [REDACTED]

13 The EU Merger Regulation does not apply as the turnover of the target business in the last financial year was £2.147m, i.e. less than €100m. The Transaction has not been notified in any other territory and does not qualify for review under any other merger laws.

19. FDG is produced in cyclotrons which are expensive pieces of capital equipment. Once installed, there are considerable economies of scale in the production of FDG: it is produced in batches and the incremental costs of producing more FDG within a batch are low; and the same cyclotron can be used to produce two or more batches per day. The importance of FDG supply to this new technology led to a large entry of cyclotrons and much more capacity than was required. That capacity sits, in part, within NHS trusts and foundation trusts and, in part, with third party providers. Of the third party providers, GE and IBA's Dinnington/Sheffield plant have exited in response to the over-capacity in the market whilst NHS owned and operated cyclotrons on hospital sites have grown.

20. AM submits that the Transaction is pro-competitive for the reasons set out in the Transaction rationale section above (paragraphs 6 to 16).

21. AM submits that the Transaction has not resulted and may not be expected to result in a substantial lessening of competition, ("**SLC**"), for the following reasons:

    (a) IBA's northern plant, at Dinnington/Sheffield, has been deactivated/mothballed since November 2010. IBA's southern plant at Guildford is located too far away from customers in the North to be a credible supplier, since customers value security of supply ahead of price in making their purchasing decisions. There is therefore no loss of actual competition in the North.

    (b) As to potential competition in the North, the owner of Dinnington would need to start work on re-opening around 15 months before the first supply. It would only make sense to do this on the basis of firm orders, but customers typically award contracts around two months before first supply, creating an insurmountable "*chicken and egg*" or coordination issue.

        The PET North contract will expire on 31 March 2015 and, had IBA retained ownership of Dinnington/Sheffield, it could have sought to partner with a supplier of PET-CT scanning services[14] to obtain a large contract for the supply of FDG. However, the reality is that IBA showed that it could not be

[14] The PET-CT contracts are expected to be awarded in October 2014.

relied on for the long-term in the North by deactivating/mothballing Dinnington/Sheffield and it will therefore not be an attractive supplier either to PET-CT scanning services companies or hospitals seeking reliable long-term suppliers.

There is therefore no loss of potential competition in the North.

(c) IBA's southern plant, at Guildford, had become a very weak competitor for new tenders in the South for three main, inter-related reasons.

(i) Since Dinnington/Sheffield was deactivated/mothballed in 2010, IBA has not had a dual supply offering, which significantly weakened its credibility with customers – who allocate 60 to 80 per cent. weighting in award criteria to security of supply and service issues – and left it commercially vulnerable.

(ii) It was therefore loss-making even at an EBITDA level. IBA had a strong incentive to win new customers to reduce its losses at an EBITDA level and its owners had the expertise to do so as they are active successfully in FDG in other countries. It is therefore particularly significant that IBA has not won any new customers since 2010: all of its sales are to legacy customers. IBA is believed to have asked DoH for financial support, which was refused.

(iii) As a result IBA did not invest properly. An MHRA report from November 2013[15] shows that IBA's Guildford plant required significant expenditure and risked being closed down by the MHRA.

It follows that, if the relevant counterfactual is the pre-merger situation, then IBA had become an ineffective competitor in the South and was becoming progressively weaker.

(d) However, AM submits that a counterfactual should be adopted that is more favourable to AM because, so far as it can establish, the criteria for the exiting firm defence are met:

[15] Annex 4 to OFT Submission.

(i) Exit was inevitable: see (b) and (c) above.

(ii) There was no business reason for a new entrant with no synergies to buy the business:[16] see (b) and (c) above.

(iii) No other purchaser with synergies expressed any interest.[17] If AM had not purchased the assets, they would have left the supply of FDG.[18]

(iv) Had IBA closed its FDG business, its legacy customers would have been bid for by AM/Erigal and PETNET. The same will be true following the Transaction. The Transaction therefore has no effect on competition.

(e) Even if the exiting firm defence is not established, AM/Erigal and IBA were not one another's closest competitors in the South and customers will be protected by strong competition from PETNET:

(i) As noted above, customers value security of supply most highly in making their purchasing decisions (ahead of price). The geographic proximity of the supplier's plant to the customer is therefore an important factor in purchasing decisions. Of the 17 third party tender customers in the South, there is only one for whom IBA and AM/Erigal are the closest geographic competitors: Brighton. In the vast majority of cases, the Transaction will therefore not remove the closest competitor.

(ii) PETNET could readily expand its capacity without needing to invest in a new cyclotron. This is evidenced by the fact that it quoted to provide over 15,000 doses p/a to AM in July 2012 (compared with total third party supply in Great Britain of around 48,700 doses p/a[19]).[20] Erigal would be much more restricted in its ability to do so in the South given the location of its existing site at the Royal Marsden hospital.

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16 Or re-open Dinnington to provide the reliability that customers want.

17 OFT Decision, §74.

18 It may be possible to use the assets to produce other isotopes but there would be no demand for FDG production for the reasons set out in the text.

19 68,000 doses p/a that are produced at the six cyclotrons that are operated to make third party supplies, less 19,400 doses which are the subject of internal transfers from Erigal to AM.

20 See Annex 5 to OFT Submission.

(f) AM/Erigal has also been a weaker competitor in the South in the supply of FDG because it does not offer reliable dual supply: supplies can be shipped from Keele if there is a *planned* outage but usually not if there is an *unplanned* outage. In the South only PETNET truly offered this historically. (IBA had only third party back up arrangements.) Thus, AM/Erigal's historic share of supply of FDG to third parties under competitively tendered contracts in the South is just 1 per cent, indeed if one considers the weekday supply, when the majority of scanning is undertaken, it is less than 0.1 per cent., i.e. the vast majority of the historic supply by AM/Erigal has been of a support nature at weekends.[21]

(g) AM/Erigal's lack of a good self-back-up arrangement for FDG in the South has also meant that it has been a weaker competitor in PET-CT scanning in the South: the PET South business was won by InHealth.

(h) The effect of the Transaction will be:

(i) to create a strong new competitor to PETNET in the supply of FDG in the South, because the merged group will have two southern plants – at Royal Marsden (Sutton) and Guildford – which can credibly offer sufficient "in region" capacity as an alternate to PETNET and back one another up and therefore offer much improved security of supply;[22] and

(ii) to increase competition in the supply of PET-CT scanning services in the South because AM will be a stronger competitor with an assured and reliable supply of FDG in the South, including for back-up purposes.

Both effects will enhance rivalry and benefit customers.

(j) The 11 hospitals and research facilities which operate their own cyclotrons

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21 The share has increased recently because, following completion of the Transaction, AM/Erigal won a contract with King's for around 1,000 doses p/a, which increases its share in the South to around 4.0 per cent. The contract award criteria included a 70 per cent. weighting on quality / security of supply issues.

22 This is directly analogous to AM/Erigal's recent contract with The Christie, Manchester where its dual supply in the North was crucial to winning that new customer.

could supply FDG to third parties.[23] They would need a commercial MHRA licence – which would take around three months[24] – and staff rotas with earlier starts. Cardiff is actively exploring this. AM expects that others will also seek to supply third parties on a commercial basis in order to increase their returns from their cyclotron investments, particularly given ongoing budgetary pressures on the NHS, similarly to the way in which they have operated their central radiopharmacy models which operate under a similar regulatory regime.

22. In summary:

(a) IBA's single site infrastructure (without the benefit of its Dinnington cyclotron), rendered it structurally disadvantaged when seeking to meet NHS customer tender criteria. The NHS do not score IBA's third party back-up as being equivalent to dual supply based back-up which PETNET provides in the South of England and Erigal in the North.

(b) Individual NHS customers place 60 per cent. to 80 per cent. weighting on reliability and quality of supply when they procure FDG for their in-house PET-CT services. The current reprocurement of the national block PET-CT contracts will also demand the same dual supply infrastructure. When the NHS England commissioners evaluate the prospective reliability of commercial service providers, such as InHealth and AM, they will look through to the resilience of the FDG supply. IBA, when evaluated as part of an NHS competitive supply procurement exercise, loses out to the dual supply model - it was structurally inadequate and therefore failing.

(c) The combination of Erigal's Sutton site with IBA's Guildford site results in a supplier in the South with more proximate dual cyclotron capability.

(d) The merger is good for competition in the South as the NHS has a more credible alternative to PETNET led supply. An alternative buyer of the IBA

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23 The hospitals that currently own cyclotrons are Aberdeen, Cardiff, Edinburgh, Glasgow, Guy's and St Thomas', Birmingham, Clatterbridge, Newcastle. The three research facilities currently produce FDG for their own research consumption are Imanova, WBIC (Cambridge) and WMIC (Manchester). See Annex 9 to OFT Submission for a full list of cyclotrons.

24 See slide 26 of the slides at Annex 1 to OFT Submission.

assets (and contracts) would need to add an additional cyclotron to achieve dual supply status for FDG, or reopen Dinnington. The only credible third party with the requisite synergies is GE, but they had already exited the FDG market. The time needed to reopen Dinnington, or build a new cyclotron would be too long to be considered as part of the current national PET-CT long term contracts.

II. MARKET DEFINITION

(a) FDG

(i) Product market

Demand-side analysis

23. FDG is a radioactive isotope which is produced in cyclotrons and is used to carry out PET-CT scans. PET-CT scans are used predominantly for the diagnosis of cancers and to inform the treatment of cancer patients. The Government expects patients that are subject to urgent GP referral for suspected cancer to receive their first definitive treatment within 62 days. PET-CT scans are expected to occur within 14 days of referral.

24. PET-CT scans are carried out by hospitals themselves (including four private hospitals, the Cromwell (BUPA), two HCA hospitals (The Wellington and The Harley Street Clinic) and The London Clinic) or by third party providers (AM, InHealth and Cobalt): see further section (b) below.

25. These hospitals and third party PET-CT scan providers obtain their *primary* supplies of FDG in the following ways:[25]

    (a) Self-supply: eight hospitals have their own cyclotrons (Aberdeen, Cardiff, Edinburgh, Glasgow, Guy's and St Thomas', Birmingham, Clatterbridge and Newcastle[26]); of the five third party providers of PET-CT scans,[27] AM self-

[25] See Annex 9 to OFT Submission for details.

[26] Of these Aberdeen and Newcastle operate "desktop" cyclotrons that have lower production capacity (c. 2,000 doses p/a) than normal cyclotrons (that can readily produce c. 16,000 doses p/a).

supplies.

(b) Third party supply under long-term exclusive contracts: four hospitals have selected a supplier to invest in a cyclotron on their site in return for a long-term exclusive supply contract: Mount Vernon (PETNET), Nottingham (PETNET), Royal Marsden (Sutton) (AM/Erigal) and Preston (AM/Erigal). (Hospitals in this category typically treat large numbers of cancer patients and wish to benefit from the security of supply offered by on-site production of FDG; and they also generally have significant research activities which benefit from the ability to produce onsite isotopes with very short half-lives which cannot be transported other than over very short distances. There have been no examples of the hospitals operating in this way using an alternative to the on-site supplier for the supply of FDG.)

(c) Third party supply under competitively tendered contracts. When this is with a DoH hospital this will typically be subject to the OJEU procurement rules, whereas for contracts with private companies, formal tenders are typically not undertaken, rather a series of commercial dialogues.

26. Cyclotrons are subject to regular outages which may be planned (routine maintenance) or unplanned. Third party PET-CT scan providers and hospitals have a range of options to deal with this.

27. Third party PET-CT scan providers have a strong incentive to ensure that they carry out their scans as scheduled and therefore to ensure that they have an alternative source of supply of FDG in the event of an outage. This is because it is typically costly under the contracts to supply PET-CT scans to fail to carry them out. The supplier is typically not paid for the scan which does not occur as scheduled and the commercial supplier is nevertheless required to perform that scan on another date (without being paid). Third party PET-CT scan providers therefore require their suppliers of FDG to have reliable *back-up* options:

(a) A producer of FDG with two or more cyclotrons, offering a dual supply, can choose to "*self-back up*" if it can supply customers that would have been

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[27] AM, InHealth, Cobalt, HCA and BUPA.

served by the cyclotron which is not operating from one or more of its remaining cyclotrons. This applies to PETNET and AM. As explained further in the geographic market section below, self-back-up can occur over relatively long distances (for example between PETNET's plants at Mount Vernon and Nottingham and the longer distance between Erigal's plants at Royal Marsden (Sutton) and Keele) in the case of *planned* outages, as the firing time can be altered and transport arrangements put in place. Self-back-up in the case of *unplanned* outages typically requires that the back-up provider is located relatively close to the plant which is down (or the customer to be served) because of the limited notice and the need to arrange for both production and transport.[28]

(b) Formal back-up arrangements involve contracts entitling the purchaser to supplies of FDG. AM/Erigal and IBA had a reciprocal back-up arrangement that is described in para. 78 below. So far as AM is aware, PETNET did not have a formal back-up arrangement (although it has a customary arrangement with AM/Erigal about the terms on which spot back-ups will be made as explained in para. (c) below).

(c) Spot back-up arrangements arise when an outage leads to a request for short term supplies. AM/Erigal and PETNET have an arrangement under which each makes spot back-up supplies to the other at a standard price of £[REDACTED] per dose plus transport costs.

28. Hospitals have more flexibility than third party PET-CT scan providers because they are not subject to commercial contract obligations to supply PET-CT scans and they have the relationship with their patients (and can, for example, switch patients to different lists to ensure that they are scanned sufficiently quickly):

(a) Hospitals which produce their own FDG may choose not to schedule PET-CT scans during periods of planned outages and/or to reschedule PET-CT scans during unplanned outages. (Patients requiring urgent scans can, if necessary, be referred to other hospitals during the outage.)

[28] Note, however, that PETNET routinely ships FDG from Nottingham to Mount Vernon and can therefore more readily back-up in the South even for unplanned outages.

(b) Hospitals which produce their own FDG may have a formal contract with a third party supplier to provide FDG in the event of an outage. AM/Erigal is party to such contracts with Edinburgh and Glasgow. AM is not aware of any other such contracts, although PETNET may have one or more.

(c) Hospitals which dual-source FDG from third party providers – Royal Liverpool, Manchester Royal Infirmary[29] and Oxford Churchill[30] – can ask the other supplier to increase its volumes during the outage.

(d) Hospitals facing an outage can request third party providers of FDG to make supplies on a "*spot*" or *ad hoc* basis.

29. Hospitals and third party PET-CT scan providers use FDG only for PET-CT scans. (Other isotopes are sometimes used in PET-CT scanners when scanning for particular cancers[31] but there is no demand-side substitutability between FDG and other isotopes.[32])

30. Research centres use cyclotron and PET-CT scanner technology to develop PET-CT science and new isotopes. They therefore require FDG in a similar form to hospitals and third-party PET-CT scanners, although they typically require fewer doses.

31. The table at Annex 7 to OFT Submission identifies the sources of primary and back-up supplies for the hospitals, third party PET-CT scan providers and research customers.

32. Third party supply under long-term exclusive contracts is separate from third party supply under competitively tendered contracts because:

(a) the terms of the long-term exclusive contracts make the customer's volumes

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29 Both hospitals purchase from the two suppliers of FDG in the North, AM/Erigal and PETNET.

30 Oxford Churchill buys under framework contracts negotiated by the buying group, HTE, as explained in para. 142 below.

31 e.g. Choline is used to scan for prostate cancer and sodium fluoride is used for detection of skeletal abnormalities. There is further detail in (and available contracts are attached to) Response to OFT Questions of 19 February 2014. In summary, IBA does not produce either choline or sodium fluorine and would need to invest in order to do so. Demand for each is small: £ p/a for choline and £ p/a for sodium fluorine. Further information will be included in the response to the MQ.

32 See slide 3 of the slides at Annex 1 to OFT Submission.

uncontestable;[33] and

(b) the former comprise competition for the market, rather than competition in the market.

AM therefore disagrees with the OFT's Decision[34] to treat third party supply under long-term exclusive contracts as part of the relevant product market. (Even if the OFT were correct, the contracts have no significant bearing on the appraisal of the merger as they are not contestable by IBA in the short to medium term.)

Supply-side analysis

33. AM is vertically integrated: approximately 70 per cent. of the FDG it produces is transferred internally and used for PET-CT scans. The OFT/CC Guidelines state that such self-supply will be included in the relevant market if it would be profitable for AM to supply into the merchant market should prices rise: §5.2.20. (The underlying idea is that captive producers should be included in the market to the extent that such inclusion accurately reflects their competitive significance.) In this instance, it would make no sense for AM to supply into the merchant market because it will still need FDG for its PET-CT scanning operations (it could not switch to an alternative input) and if it did not self-supply it would need to buy at prevailing prices. AM's captive supplies are therefore of no competitive significance to third party customers as they will not divert to third party supplies in response to a change in relative prices. The OFT said that if AM lost PET-CT business it would seek to sell into the merchant market the FDG which it had been self-supplying for the lost contracts: Decision §33. /Whether or not this is correct,[35] it is not the test posed by the Guidelines. Self-supply

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33 AM/Erigal's contract with Royal Marsden/Sutton has a [REDACTED] year exclusive purchasing obligation that operates until [REDACTED]. The scope to switch even then will be limited by the fact that AM/Erigal has a 25 year lease for the building from August 2010.
AM/Erigal's contract with Royal Preston Hospital has a [REDACTED]year exclusive purchasing obligation which operates until [REDACTED]. The scope to switch even then will be limited by the fact that AM/Erigal has a 30 year lease for the building from April 2007.
AM understands that PETNET's on-site Nottingham cyclotron has 10 years of exclusivity remaining with Nottingham City Hospital, although this would need to be clarified with PETNET.

34 §38.

35 AM/Erigal has an incentive to agree to supply FDG to InHealth and Cobalt for use in PET-CT contracts if InHealth or Cobalt were to win those contracts, as entering such contracts at this stage would provide AM/Erigal with some down-side protection if AM fails itself to win the PET-CT contract; however there is unlikely to be scope to do so after scanning contracts have been awarded because the provider of the scanning services will put in place long-term contracts for the supply of FDG prior to finalising its price for the PET-CT scanning services. Neither InHealth nor Cobalt has

by AM should therefore be excluded from the market.

34. The eight hospitals which have their own cyclotrons could commence supplies to third parties if they decided to operate their FDG production facility to earn a return rather than simply as a cost-centre (as could the three research sites which produce their own FDG).[36] The licences held by hospitals and research institutions are known as "specials" licences, which enable them to supply today, but on a named-patient basis (as opposed to the simple supply of doses for use by the hospital as it chooses). A full commercial licence could be granted by MHRA in around three months. With the obvious budgetary pressures on hospitals, AM expects that some will seek permission to supply third parties on a commercial basis in order to increase their returns from their cyclotrons, a process which should be straightforward. Around 25 hospitals have obtained licences permitting third party supplies of Technetium, which is also a radioactive isotope.[37] Any such hospital may also need to change the shift pattern of workers at its cyclotron as earlier production may be required to allow time for distribution, but this should be straightforward. Distribution is also straightforward using specialist third party logistics suppliers. Cardiff University School of Medicine is already understood to have considered this option[38] and is understood to be in active talks with Truro hospital about making such supplies. Guy's & St Thomas' has created a trading company, Essentia, to deliver services to acute and primary care providers: the commercialisation of FDG production could be an obvious area for Essentia to develop. AM has no more detailed insight into the strategies of Cardiff, Guy's & St Thomas' or the other hospitals and research institutions and respectfully requests the CMA to clarify their positions directly.

35. A supplier with an installed cyclotron which is currently producing isotopes other than FDG could commence production of FDG. There is therefore scope for supply-side substitution. For example, GE installed a cyclotron in Amersham which it initially used to produce FDG. When the supply of FDG became uneconomic, GE switched to producing other, "*exotic*" isotopes (i.e. isotopes other than FDG and

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yet invited tenders for FDG for use in the contracts that replace the PET-North and PET-South contracts.

36 See fn. 24 above for the lists of hospitals in these categories.

37 The incremental costs of increasing output are low and the potential contribution from supplying third parties on a commercial basis is therefore high.

38 See http://medicine.cf.ac.uk/petic/production-facility/fdg-18-production/.

Technetium which are used in small numbers of scanning procedures or for research and some of which have very short half-lives, sometimes as short as 20 minutes). If the relative returns from producing FDG compared with other isotopes were to change, GE could re-commence supply of FDG. GE's willingness to do so will depend in particular on the relative contributions of FDG and its exotic isotopes activities and any strategic preferences GE may have (e.g. if operating as a supplier of isotopes supports sales of cyclotrons or PET-CT scanners produced by GE). AM has no insight into GE's assessment of these issues and respectfully requests the CMA to clarify the position by inquiries of GE.

Candidate markets

36. AM has identified three candidate markets for assessment.[39]

(a) The primary supply of FDG to third parties under competitively tendered contracts. This may include potential supplies from the eight hospitals and three research institutions with their own cyclotrons and/or GE.

(b) The back-up supply of FDG to third parties.

(c) The build and operation of a cyclotron on a customer's site in return for a long-term exclusive supply contract.

(ii) Geographic market

Primary supply

37. The half life[40] of FDG is 110 minutes. This means that hospitals cannot maintain an inventory of FDG. If they wish to operate a PET-CT scanner, they need a delivery of FDG shortly before scanning commences. If the FDG does not arrive, then the scans will be cancelled, which is both inefficient for the NHS, highly undesirable for patients and expensive in the form of penalties for commercial providers of scanning services. To avoid this, customers have a preference for sourcing from suppliers which are located nearby (and which have nearby sources of back-up supply) to reduce the risk of interruption of supply because of production or transportation

[39] Self-supply by AM and the hospitals/research institutions that have their own cyclotrons appears not to be material to the appraisal.

[40] The length of time in which levels of radioactivity drop by 50 per cent.

problems. This can be seen from the award criteria for the tenders for The Christie Hospital (Manchester), King's (central South London) and Brighton in 2012 and 2013, which allocated just 20-40 per cent. of the weighting to price and the remainder to delivery/reliability/support.[41] Please see Table 1 at para. 111 below which shows the weighting of quality compared to price.

38. Also, the greater the distance to the delivery point, the higher the transport costs. Transport costs vary by route but as a rule of thumb, AM/Erigal assumes a cost of £[REDACTED] per mile (so a five dose delivery over 100 miles would cost £[REDACTED] for delivery or £[REDACTED] per dose). It is therefore costly to deliver over long distances.[42]

39. The importance of geographic proximity to the customer is evidenced by customers' purchasing decisions.[43] There are 25 sites where FDG is delivered from a third party supplier located offsite.[44] Of these 25 sites, the vast majority have their FDG supplier within 90 minutes (15 out of 25, with three further sites that multi-source having one of their suppliers within 90 mins and virtually all of the remainder choosing a site within a 20 mile radius compared to the closest).[45]

40. Therefore, whilst deliveries of up to four hours are technically possible (and may be made for back-up purposes in cases of absolute necessity), suppliers become progressively and quickly uncompetitive when drive times exceed two hours.[46]

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41 See slide 23 of the slide deck at Annex 1 to OFT Submission. The tender criteria for the three hospitals are attached as Annex 30 to OFT Submission.

42 Delivery over longer distances also uses more production capacity as explained on slide 19 of the slides at Annex 1 to OFT Submission. There are also two relevant regulatory prohibitions: the first prohibits the injection of more than 5 ml of FDG into a patient at any one time (source: ARSAC); this prevents hospitals from injecting the required level of radioactivity by injecting a large physical volume of (much decayed) FDG. The second restriction is that FDG cannot be used if more than four hours has elapsed since the vial was opened. In practice, this means that hospitals running scanning lists in the afternoon as well as the morning require a second delivery of FDG (with the attendant transport costs).

43 The underlying data is attached as Annex 8 to OFT Submission.

44 23 hospitals and research institutions purchase FDG from a third party supplier located offsite (Birmingham, Dundee, Leeds, Royal Liverpool, Manchester - Christie, Manchester Royal Infirmary, St Barts, Brighton, Cambridge, Coventry, BUPA Cromwell, Guildford, HCA (Harley Street Clinic and Wellington sites), Imperial (Hammersmith and Charing Cross sites), King's, The London Clinic, Oxford Churchill, Royal Free, UCLH, Cobalt, Portsmouth, WMIC and WBIC). Of these, two have multiple sites (i.e. HCA and Imperial have two sites each).

45 [REDACTED]

46 For this reason, AM has not included Northern Ireland or the island of Ireland in its analysis. Neither AM nor IBA supplies FDG to the island of Ireland and the Irish supplier would not be a credible competitor for contracts in Great Britain because of the transport time, transport costs and security of supply concerns. (AM does provide scanning services on the island of Ireland using FDG purchased from a third party.)

41. As a result, IBA's Guildford plant is not a credible competitor for customers located in the North and IBA's deactivated/mothballed Dinnington/Sheffield plant would not be a credible competitor for customers located in the South if it were reactivated. It is therefore instructive to split the supply of FDG geographically into the North and South of Great Britain (whilst recognising that centrally located customers would naturally consider plants in both the North and South). This division reflects industry usage and the approach of the NHS/DoH which split its contracts for the purchase of PET-CT scanning services in England into PET-North and PET-South. (The OFT accepted AM's contention that there was a North / South division, whilst sub-segmenting the North.[47])

Back-up supply

42. In the case of a *planned* outage, FDG can be produced and transferred over drive-times of up to four hours, but suppliers become progressively and quickly uncompetitive when drive times exceed two hours. The position is therefore the same as in the case of primary supply.

43. In the case of an *unplanned* outage (which most commonly occurs during synthesis, i.e. over two hours into the production process), FDG is generally[48] sourced (if at all) over quite short distances[49] because the start-up time of the back-up facility cannot be changed at that stage (and early starts are required for longer shipping distances) and the logistics providers cannot readily change the collection point by long distances.

Build and operation of a cyclotron on a customer's site in return for a long-term exclusive supply contract

44. The relevant geographic frame of reference is at least national and probably wider.

45. Any supplier in the UK or abroad with the relevant technical skills would be a credible bidder.

46. It is easy for potential suppliers to identify contracts they may wish to compete for

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47 OFT Decision, §53.

48 Note, however, that PETNET routinely ships FDG from Nottingham to Mount Vernon and can therefore more readily back-up over relatively long distances even for unplanned outages.

49 A supplier facing an unplanned outage would typically contact other local operators to seek to purchase any surplus FDG and, if none is available, to request the other operator to carry out a further firing.

because of the requirement for publicity under EU procurement rules.

(b) PET-CT scanning

(i) Product market

47. PET-CT is a medical imaging technique that produces pictures of the body's internal structures. It combines two different techniques in one scanner, giving clinicians two sets of related information about the body (functional and structural) from one examination. More specifically:

(a) positron emission tomography (**PET**), which works by detecting gamma rays given off by a radioactive tracer that is injected into your body which, for approximately 99 per cent. of PET CT scans in Britain, is FDG.

(b) computed tomography (**CT**), in which a scanner uses x-rays to take a series of two-dimensional cross-section images ('slices') around an axis.

48. The CT scanning produces anatomic imaging, which can be used to more precisely align the functional imaging[50] obtained by PET. Computer processing is then used to construct a three-dimensional image.

49. The Royal College of Physicians produces a document entitled "*Evidence-based indications for the use of PET-CT in the UK 2013*"[51], which sets out an up-to-date summary of the most common uses for PET-CT, divided into oncology applications (such as diagnosing and staging cancer) and non-oncological applications (such as applications in cardiology, neurology and infections).

50. For present purposes, we have restricted ourselves to examining PET-CT services. For many PET-CT applications, however, clinicians can choose alternative approaches to diagnosis.

51. There are four models for PET-CT scanning:

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50 Functional imaging is a method of detecting or measuring changes in metabolism, blood flow, regional chemical composition, and absorption (see further the slides at Annex 1 to OFT Submission).

51 http://www.rcr.ac.uk/docs/radiology/pdf/2013_PETCT_RCP_RCR.pdf (attached as Annex 32 to OFT Submission).

(a) static PET-CT scanners based at a hospital or clinic, which can be:

(i) owned and operated by hospitals themselves;

(ii) owned by the hospital and operated by a private provider (e.g. AM run the scanner owned by North Staffordshire and InHealth run the scanner owned by Portsmouth);

(iii) owned and operated by a private provider;

(b) mobile PET-CT scanners, which are supplied by private providers on hire to a hospital or clinic, in order to meet either a short or long term need; the scanners may be provided either with or (at least in theory) without operational staff.

52. Annex 9 to OFT Submission identifies the PET CT scanners operating in Great Britain.[52]

53. The supply of PET-CT scanning is split into:

(a) scanning performed directly by the NHS using FDG which is either self supplied or supplied by a third party;

(b) scanning provided under third party customer contracts, which are split into those tendered by individual hospitals (mainly NHS but some private) and those delivered as part of the regional "PET North" and "PET South" contracts (April 2008 until originally 31 March 2013, now extended to 31 March 2015).

54. The PET North contract[53] serves nine locations, three of which are static (Sheffield, Leeds and, following a recent switch from a mobile arrangement, North Staffordshire) and six of which are currently served by mobile units (Bradford, Hull, The Royal Liverpool and Broadgreen University Hospitals, Clatterbridge, Newcastle and Middlesbrough).[54]

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52 AM/Erigal used its best endeavours in the preparation of this Annex but it does not have perfect information and it is possible that its work contains some errors.

53 A copy of which is at Annex 10 to OFT Submission along with the sub-contract agreement between AM and Erigal for the supply of FDG.

54 http://www.alliancemedical.co.uk/petnorthnhs#.UrKtxdJdUVB and http://www.alliancemedical.co.uk/sites/default/files/upload/PET_North_Newsletter_Spring_Summer_2012.pdf. The PET North scanners are shown on the map, provided at Annex 11 to OFT Submission.

55. Under the PET North contract, the DoH purchases the PET-CT scanning services at a fixed price (currently £[REDACTED] per scan) from AM as agent for each trust that used those services.[55] The trusts were free to purchase services, but were not obliged to do so. When the contract was originally signed, [REDACTED].[56]

56. The PET South contract was awarded to InHealth. It serves 16 locations, two of which are static (Nottingham and Portsmouth) and the remainder of which are mobile (Basildon, Bournemouth, Cambridge, Canterbury, Colchester, Leicester, Maidstone, Northampton, Norwich, Plymouth, Poole, Sawbridgeworth, Southampton and Musgrove Park/Taunton).[57]

57. Third party contracts usually require the supplier to secure the provision of equipment (static or mobile), qualified technical and support staff, permits and regulatory requirements as well as FDG for each patient that is scanned. For example, the NHS 2013/14 Standard Contract for PET-CET requires the provider to ensure that: "*A reliable and adequate supply of Tracer is available for the performance of Scans*".[58] Ensuring a reliable supply of FDG is therefore crucial to outsourced providers, both to secure PET-CT operation contracts, and to satisfy very strict service levels.

58. The East of England NHS strategic project team (central SPT) announced on 14 February 2014 that it has been appointed to "*to manage the re-procurement of the PET (positron emission tomography) and CT (computerised tomography) scanning services across England (excluding London).*"[59]

59. AM expects that, in awarding the new PET-CT contracts, the NHS Strategic Projects Team will examine carefully the security of supply of FDG from the supplier(s) identified by the tenderers and, specifically, whether the tenderer has a dual supply of FDG. In relation to the South, in the absence of the Transaction, PETNET would be the FDG supplier offering the greatest security of supply as it has two production facilities which are focused on supplying the South. InHealth will presumably compete for PET-CT contracts in both the North and South and will therefore

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55 Clause 12.1 (read with the definition of Referring Health Service Body in Sch. 1).

56 See the extension letter of 14 March 2013, section 2.

57 http://www.inhealthgroup.com/contract-service/nhs-petct-south-service. A map was provided at Annex 12 to OFT Submission.

58 http://www.england.nhs.uk/wp-content/uploads/2013/06/b02-positron-emis-tom.pdf.

59 The announcement is available at http://www.thestrategicprojectsteam.co.uk/another-new-project-for-the-strategic-projects-team-pet-ct.

presumably have a preference for a national supplier of FDG, which would rule out IBA, and result in a competitive process between PETNET and AM/Erigal.

60. The NHS has therefore decided to organise further block contracts (excluding London) for the supply of PET-CT services. The current PET-North and PET-South contracts represent around a third of PET-CT scans. However, it is unclear at this stage how many hospitals will participate: some which currently purchase under the PET-North or PET-South contracts may choose to organise procurements on their own or as part of a group independently of central SPT.

61. The existing contracts expire on 31 March 2015. They cannot be further extended because of the public procurement rules. The new contracts will therefore need to be operational from 1 April 2015. AM understands that the NHS Strategic Projects Team has issued a draft timetable indicating that it will make appointments in October 2014.

(ii) Geographic market

62. The geographic market for the provision of PET-CT scanning services to hospitals is at least national because any supplier in the UK or abroad with the relevant technical skills would be a credible bidder.

(c) Alzheimer's Tracers

63. There are three global companies which are developing diagnostic tests for Alzheimer's: GE (using the tracer, flutemetamol), Eli Lilly (florbetapir) and Piramal (florbetaben).

64. They require supplies of the tracer which is being used in their diagnostic test.

65. The half lives of the three tracers are 110 minutes (i.e. the same as FDG as they are also F18-based).

66. The three companies could produce supplies themselves or purchase them on a "sub-contractor" basis from third parties. In fact, all three have appointed sub-contractors. Both AM and IBA are active in making such supplies on a sub-contracted basis.

(i) Product market

67. All three of the tracers can be produced using a cyclotron and there is therefore supply-side substitution between them, implying that there is a market that is no narrower than the supply on a sub-contract basis of Alzheimer's tracers to the developers of such diagnostic tests.

(iii) Geographic market

68. The three developers have put in place arrangements for supply on a global or multi-country basis. Each has a national supplier in the UK which suggests that the market is no wider than national.

III. COUNTERFACTUAL

69. As noted earlier, IBA has two cyclotrons, one at Dinnington/Sheffield in the North and the other at Guildford in the South.

(a) IBA's deactivated/mothballed northern plant

70. IBA's Dinnington site was mothballed in 2010. Mothballing is cheaper than closure because closure involves significant nuclear decommissioning costs (around £600,000[60]), whereas the costs of mothballing are low (around [REDACTED][61] with a NPV of £[REDACTED]). As a result, a decision to mothball (as opposed to decommission) does not imply that the owner was seeking to preserve the ability to re-open the plant in the future.

71. It would not make economic sense for its owner – whether IBA or any purchaser other than AM – to reopen it. And, in the case of AM, any reopening of the Dinnington plant will only make sense in the context of its wider product strategy in relation to the supply of [REDACTED].

72. The OFT's Decision states at §117 that if Dinnington were to re-open, it would need to sell 6,800 doses p/a to break even at an operating level at average Northern prices. Ignoring the PET-North contact for the time being, the total contestable volume

[60] Source: IBA's accounts included a provision of £1.15m for decommissioning of both sites.
[61] Source: IBA's management accounts provided during due diligence.

within two hours drive of Dinnington is 6,983 doses p/a.[62] This is 183 doses more than the minimum viable operating level and Dinnington might benefit from some growth in customer demand,[63] but:

(a) When AM sought commercial supplies from IBA in Summer 2012, IBA said it "*would take **15 months** to get up and running, which they would only do if they had **firm orders***".[64]

(b) To win any of the forthcoming business, the owner of Dinnington would need to reactivate before competing, because contracts are typically awarded two months before the start of supplies. In IBA's own words, it would not re-open speculatively in the hope of winning business: it would re-open only if it has "*firm orders*". There is a "*chicken and egg*" or coordination problem which Dinnington's owners could not overcome.

(c) It is inconceivable that the new owner would win all of the forthcoming business. Any owner of Dinnington would take this into account in deciding whether it made sense to reopen the plant.

(d) IBA did not have an in-house regional back-up facility in the North (unlike AM/Erigal) and would therefore score less well against award criteria based on security of supply, both for NHS customers and for private PET-CT scan providers – InHealth and Cobalt – who need reliable supplies of FDG in order to provide their service.

(e) Since Dinnington had been mothballed once, customers would inevitably be concerned about whether it would remain operational to service its contracts and the health sector regulator is placing increasing emphasis on assessing the economic viability of suppliers of key services.[65] Also, Dinnington would have no recent track record to enable customers to judge its reliability. If the owner tried to overcome these issues by reactivating and pricing at a lower

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62 The Royal Liverpool & Broadgreen University Hospitals and Manchester Royal Infirmary (954 + 1,518), The Christie NHS FT (3,371) and Warwickshire / Coventry in the HTE tender (1,140).

63 Decision, §119.

64 Annex 14 to OFT Submission..

65 See Monitor's proposed Risk Assessment Framework for providers of Commissioner Requested Services at Annex 3 to OFT Submission.

level, the minimum viable operating level would be higher – and price typically accounts for only 20-40 per cent. of the award criteria.

(f) As well as covering operating costs, any owner would need to recover capital costs. IBA's former owners estimated those costs at more than £[REDACTED] to reactivate the site in addition to any cost to acquire it in the first instance.[66]

73. The vendor's evidence to the OFT was that "*a business case **was not looked at** to reactivate [IBA's site at] Dinnington given the **lack of business opportunity** and **associated capital costs** required to reactivate the site.*"[67] The question of re-opening was therefore not finely balanced: it was so clear-cut that the owners did not even bother to test the business case.

74. AM notes that:

(a) the OFT seemingly discounted evidence from the vendors when it was oral[68] and not written, but it is hardly surprising that some decisions were not documented as the target business was a small, loss-making activity; and

(b) the OFT noted that *senior* management of the vendor said they had no intention of re-opening Dinnington, but *local* managers said they would consider doing so and described the evidence as "*mixed*": Decision, §116. AM submits that the views of senior management would determine what the company in fact did. The only business case for re-opening that local managers could credibly take to senior management was one in which they had "*sufficient committed volume*", yet they would never achieve this for the reasons given above.

75. The successors to the PET-North and PET-South contracts for PET-CT scanning will operate from 1 April 2015. The supplier(s) of PET-CT scans in the PET-North area will require 12,959 doses p/a from 1 April 2015.[69] If IBA won all or much of this volume, it might provide a business case for re-opening. However, there was no prospect of IBA doing so:

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66 OFT Issues Paper, §112. (This issue is presumably repeated in Decision §114, but it has been redacted as against AM.)

67 See OFT Issues Paper, §50.

68 OFT Decision, §77.

69 See OFT Issues Paper, §116.

(a) There is less than "***15 months***" until the start date of 1 April 2015 and IBA is nowhere near receiving a "***firm order***", nor is there any prospect of it doing so: it would therefore not have been able to reopen Dinnington/Sheffield in time.

(b) Anyway, no rational company seeking to bid for the contract to supply PET-CT scanning services would partner for (probably) up to 10 years with someone who had: (i) previously exited the North by mothballing Dinnington; (ii) is believed to have asked the NHS for financial support to enable it to remain in the market and been turned down; (iii) lost money on a cash basis – let alone earnings – every single year. There would be too much risk of being left without FDG supplies.

(c) Nobody would bid for the PET-North contract and only later arrange FDG supplies: bidders need certainty on FDG pricing to price the PET-CT service. As a result, these volumes would probably be uncontestable for a further period of at least five years.

(d) If IBA thought it could profitably re-open Dinnington based on winning contracts on the expiry of the PET-North contract on 1 April 2015, it could have kept the business rather than selling. The "*opportunity*" was known about at the date of the Sale & Purchase Agreement.

76. There was therefore no realistic prospect of IBA winning sufficient business at sufficiently high prices to make the re-opening of Dinnington/Sheffield viable. The counterfactual is therefore that it remained deactivated/mothballed.

(b) IBA's weak southern plant

77. AM/Erigal and IBA have competed historically in the South to an extent. However, in the absence of the Transaction, there would have been little, if any, effective competition in future for three reasons.

78. First, on deactivating/mothballing Dinnington/Sheffield in 2010, IBA was left without a second cyclotron to act as a back-up for Guilford in the event of maintenance or a supply outage. This left IBA in a very challenging position because contracts are awarded as to 60 to 80 per cent. weighting on security of supply and service issues.

As a result, in an attempt to address the security of supply issues discussed in this submission, IBA sought to agree formal support and eventually agreed the following with Erigal:

(a) Erigal agreed to act as IBA's back-up supplier.[70]

(b) with IBA having already taken the decision to mothball their Dinnington site, IBA was in a particularly weak bargaining position. Erigal was concerned to ensure that IBA did not obtain a cost advantage through a contracted third party back-up arrangement. Accordingly, Erigal required a price which approximated to the cost that IBA would have incurred had it not closed Dinnington.

(c) in particular, it was determined that:

(i) IBA could call on Erigal to supply up to [REDACTED] per cent. of its customer contract requirements; and

(ii) if IBA did call for back-up supply for an individual customer but did not take the full [REDACTED] per cent. of the volume, it had to pay Erigal the profit on the portion of the [REDACTED] per cent. that it did not take.

(d) IBA can name Erigal as its back up supplier where it seeks to tender for new customers.

(e) the back up arrangement was stated to be reciprocal, but commercially Erigal believed it would be providing back up to IBA far more than the other way around (for example, because Erigal could always self-back-up from one of its other sites before needing to seek external back up from IBA).

(f) as a result, IBA has paid Erigal an average of £[REDACTED] per annum since the closure of Dinnington.

79. IBA has called for back up supply for its customer contracts with Cambridge, Cobalt, St Barts, Oxford Churchill and InHealth.

[70] AM believes that PETNET were approached but declined to quote.

80. The back up arrangement became intra-group on completion of the Transaction and was replaced with a new simplified contract (even though it was now intra-group a formal contract was required under Erigal's banking arrangements).[71]

81. Secondly, it has for a long time been loss making at an EBITDA level and there was little prospect of that changing. IBA is understood to have asked DoH (AM believes it approached John Warrington, a Deputy Director) for funding in the form of consideration for the purchase of Dinnington, which DoH is believed to have refused. Whilst IBA may have offered a more positive face to the market, parent company support was the only thing keeping IBA active in FDG. Customers seeking long-term supply would have no reason to contract with someone who was evidently not committed to the market and who on closer review were clearly in financial difficulty within the UK. Customers seeking long-term supplies of FDG would have no reason to buy from a supplier whose commitment to the market, even in the short-term, was, at best, uncertain, following the mothballing of Dinnington/Sheffield.[72]

82. Thirdly, as a result, IBA had not invested properly in maintaining its Guildford plant. This is evident from the results of an MHRA inspection in November 2013 which identified an unusually long list of serious concerns, a number of which were particularly concerning to MHRA as they had not been rectified from earlier visits.[73] The resolution of these concerns requires money – estimated to be c. £[REDACTED]– and management commitment, neither of which was forthcoming from IBA. In AM's view, IBA had failed properly to invest in the Guildford plant and was risking it being shut down by the MHRA. AM respectfully requests the CMA to contact the MHRA to obtain its views on how matters would have progressed had the plant not been bought by AM.

83. If the relevant counterfactual is the pre-merger situation, then IBA had become an ineffective competitor in the South. If IBA were sold to another purchaser, the position would not have been any better: IBA's parent company was an international operator with extensive FDG activities; it was therefore as well-placed as anyone else

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71 Copies of the agreements in place immediately prior to and after completion of the Transaction are attached at Annex 15 to OFT Submission.

72 For this reason, IBA would not have become short of capacity had it remained in the market under its former owners.

73 The MHRA's letter is attached at Annex 4 to OFT Submission.

(other than AM) to turn IBA into a sustainable operator, but it failed to do so.

(c) IBA's financials

84. AM commissioned PWC to carry out financial due diligence on IBA.[74]

85. As at 31 December 2011, IBA had £17m of unutilised trading losses.[75]

86. PWC reported that "*The business continues to leak cash*" and estimated the run-rate EBITDA loss at £[REDACTED] to £[REDACTED][76] (compared with FY12 total UK business turnover of £[REDACTED][77]).

87. The financial position of the IBA FDG business is such that it would minimise its losses if it mothballed its Guildford plant. In 2012 (for which AM has data) IBA achieved sales revenue of less than £2.3m.[78] The costs of material, transport of FDG to customers, engineers operating the cyclotron and electricity necessary to operate it totalled a little more than £2.2m in the same period. This leaves a direct contribution of less than 2%. However, these are not all the costs that IBA incurs when running the Guildford plant. It also incurs costs of maintaining the facility in a shape that allows it to be used to produce FDG of £0.3m (not to be confused with depreciation of the asset) and the overheads that can be associated with IBA's FDG business in the UK of almost £0.6m. Both these costs would be avoided if IBA mothballed the Guildford plant. These costs meant that running the Guildford plant loses IBA over £0.8m in cash per year. When compared to the cost of mothballing the Guildford plant of about £30k per year[79], it is clear that IBA would save almost £0.8m of cash per year if it deactivated the Guildford plant.

88. Whilst the balance sheet shows net assets of £4.3m,[80] this is an accounting (rather than economic) figure which flows from the original sum invested in the two cyclotrons. It is evident from its conduct in deactivating/mothballing

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74 PWC's report is at Annex 16 to OFT Submission.
75 Slide 37.
76 Slide 6.
77 Slide 9.
78 £2.3m is composed of £2.147m revenues from the sale of FDG and £0.105m of transport revenue obtained as a result of IBA being able to pass some limited costs of transport onto its customers.
79 AM estimates that IBA would need to spend the same amount per year on mothballing the Guildford plant as it spends on mothballing the Dinnington plant which is around £30k.
80 Slide 23.

Dinnington/Sheffield and failing properly to maintain Guildford that IBA's former owners saw no prospect of generating cash flow from the IBA business.

89. Contracts are awarded by competitive tender and relatively few are expected in the next three years – other than for supply of FDG for the replacements for the PET-North and PET-South contracts – and so it is not likely that IBA would be able to turn its business around.[81]

(d) AM/Erigal's relatively weaker position in the South

90. AM/Erigal has been a relatively weaker competitor in the South in the supply of FDG because it does not have a close alternative site for self-back-up: supplies can be shipped from Keele if there is a *planned* outage but usually not if there is an *unplanned* outage. Keele currently provides approximately 16-17,000 doses, predominantly to the North, and is both capacity constrained to supply scale support into the South and financially enjoys slightly higher prices and shorter relative supply distances to customers in the North. Thus, AM/Erigal's historic share of supply of FDG to third parties under competitively tendered contracts in the South is just 1 per cent, indeed if one considers the weekday supply, when the majority of scanning is undertaken, it is less than 0.1 per cent., i.e. the vast majority of the historic supply by AM/Erigal has been of a support nature at weekends.[82]

91. AM/Erigal's lack of a good self-back-up arrangement in the South has also meant that it has been a relatively weaker competitor in PET-CT scanning in the South: the PET South business was won by InHealth (with PETNET as primary supplier and IBA as secondary supplier).[83]

(e) Historic market shares and bids are therefore not informative

92. For the reasons developed in this section, an analysis of historic market shares and an

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81 In the South, IBA's current contracts have expired [REDACTED] or, with one exception, are expiring over the next nine months or so (although IBA would need to win these to stay still: they are not a source of growth). In addition, the current PET South contract expires on 31 March 2015 (for PET-CT scanning services); and the HTE contract for FDG expires on 19 August 2015. Annex 13 to OFT Submission shows expected contracts in the North.

82 The share has increased recently because, following completion of the Transaction, AM/Erigal won a contract with King's for around 1,000 doses p/a, which increases its share in the South to around 4.0 per cent.

83 For further detail please see Annex 9 to OFT Submission.

analysis of the outcomes of older bids is relatively uninformative about current competitive dynamics: by the time of the Transaction, IBA was no longer a credible independent competitor and looking at sales won when it was a credible competitor are therefore misleading. For completeness, in section IV below, AM includes historic shares split into the three candidate market definitions identified in para. 36 above.

(f) Pricing of FDG in the counterfactual

93. If AM is correct in its submission that the relevant counterfactual is exit by IBA, then the counterfactual is the same as the post-merger situation.

94. In the remainder of this section, AM considers the position if (contrary to AM's analysis) the counterfactual is that IBA remained in the market.

(i) If IBA remained an independent supplier

95. Once IBA deactivated/mothballed Dinnington/Sheffield, it increasingly lost credibility in the market for the reasons developed in section (b) above. Once it lost the ability to self-back-up, it was in a weak position in competing for new customers because contract award criteria typically allocate 60 to 80 per cent. weighting to security of supply and service issues. This led IBA to *quote* low prices in an attempt to retain business for its Guildford cyclotron to make some contribution to its high fixed costs of operating. However, this strategy failed. IBA has not won any new customers since it deactivated/mothballed its Dinnington/Sheffield plant in 2010 and has lost some of its existing customers, as evidenced by the bid study at section IV(c) below. AM understands that IBA quoted the lowest prices in the recent tender for The Christie, Manchester but lost because it could not offer acceptable security of supply. The tender award criteria are on slide 15 of the slidedeck presented at the initial meeting with CMA staff.

96. Therefore, if the counterfactual is that IBA remained in the market *pursuing its pre-merger pricing strategy*, its influence on market prices would have been very limited: once the impact of Dinnington's closure became clear,[84] NHS tender customers were

[84] When the Barts and Cobalt contracts were awarded in 2011, Dinnington had only recently been deactivated/mothballed and its operation presumably resulted in IBA having better performance data to

simply not willing to buy from a supplier which would probably not be around to perform the contract and had no self-back-up arrangements. As to non-NHS customers: Cobalt have switched supplier for reasons other than the price of FDG and InHealth was very unlikely to switch to IBA because PETNET provided a better option in terms of security of supply, scanner prices, availability of back up and proximity to customers. Market prices would have continued to be determined by competition between PETNET and AM/Erigal as customers perceived them to offer much better security of supply and to be more committed to the market.

97. Overall on a typical site in the South of say 1,000 scans p/a with an FDG cost of, say, £[REDACTED] per dose, the hospital will spend approximately £[REDACTED] per annum on PET-CT scans of which £[REDACTED] relates to FDG out of a total budget, for a medium-sized hospital, of say £300m. The decision for a trust to switch either PET-CT or on a non-PET-South trust must have the benefits outweigh the risk of that switch. Price alone does not do this and accordingly IBA was structurally deficient in being able to compete.

98. The OFT reached a different conclusion in §102 of its Decision. AM submits that the OFT was wrong for the reasons given above. Unfortunately, the OFT did not address in its Decision the evidence – which was before it and was emphasised heavily by AM in its response to the Issues Paper – about why customers – and, specifically, the procurement teams – in fact attribute more weight when awarding contracts to suppliers with self-back-up arrangements. Had the OFT accepted AM's submission on this issue, there would have been no reason to make a phase 2 reference.

(ii) If a third party bought IBA

99. If (contrary to AM's expectations), IBA were sold to a third party, the new owner would have needed to make (at least) two changes to IBA's business: (a) it would have needed somehow to improve IBA's position on security of supply (which would

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quote to the customers. Indeed, the deadline for submission of tenders on Barts was 29 November 2010. http://euroalert.net/en/contracts.aspx?idl=921562.

have required investment[85]); and (b) it would have needed to raise IBA's prices. It would have to do this on a speculative basis to put it into a potentially competitive position in the face of prevailing strong competition from PETNET and AM/Erigal, with the outcome of the national contract awards determined and more customers leaving the business. It would make no business sense whatsoever to buy a business that was loss-making even at an EBITDA level (and make investments to improve the security of supply position, such as opening or re-opening a second site or installing a second cyclotron at Guildford) and persist with a strategy that simply consumed cash.

IV. HISTORIC MARKET SHARES AND BID STUDY

(a) Historic market shares by volume

100. In para. 36 above, AM identified three candidate market definitions.

101. First, primary supply of FDG to third parties under competitively tendered contracts is detailed in the table at Annex 9 to OFT Submission. In summary:

(a) in the North, AM/Erigal supplies [REDACTED] per cent., PETNET supplies [REDACTED] per cent. and IBA supplies [REDACTED] per cent.

(b) in the South, AM/Erigal has historically[86] supplied just five doses per week on weekdays; it has made more supplies on Saturdays, taking its total share up to around [REDACTED] per cent. By contrast, PETNET supplies [REDACTED] per cent. and IBA supplies [REDACTED] per cent. (a figure which is bolstered by the InHealth contract, but which is falling steadily as IBA loses contracts).

102. There is therefore no change in shares in the North and only a small change ([REDACTED] per cent.) in historic shares in the South.

103. Secondly, back-up supply of FDG to third parties. As discussed in section II(a)(i) above, third party PET-CT scanning providers need to be able to demonstrate convincing back-up arrangements in order to have a chance of winning contracts and

[85] IBA deactivated/mothballed Dinnington/Sheffield in order to reduce its rate of losses. It is not evident why a third party buyer of IBA would reverse that decision, increasing the rate of losses even at an EBITDA level.

[86] Since completing the Transaction, AM has won a contract with King's, increasing its share in the South to around 4.0 per cent.

AM/Erigal and IBA had a formal reciprocal back-up arrangement (which has now been internalised as a result of the Transaction). In addition, back-up supplies may be made on a "*spot*" basis. However,[87] the back-up volumes supplied are relatively small and share data will not add meaningfully to the data provided above. In FY 2013, AM/Erigal supplied 336 doses to IBA under a formal back-up agreement (this reflects supplies on, typically, one or two days per month), 210 back up doses to Edinburgh under a formal back-up arrangement and 117 doses to Guy's and St Thomas' on a spot back-up basis.

104. Thirdly, the build and operation of a cyclotron on a customer's site in return for a long-term exclusive supply contract. There have been four such contracts. AM/Erigal won the contracts at Royal Marsden (Sutton) and Preston. PETNET won the contracts at Nottingham and Mount Vernon. The historic pre-merger shares by customer wins are therefore: AM/Erigal, [REDACTED] per cent.; PETNET, [REDACTED] per cent.; IBA, [REDACTED]. By volume the pre-merger shares are: AM/Erigal [REDACTED] per cent. ([REDACTED]doses out of 9,322); PETNET [REDACTED] per cent. ([REDACTED]out of 9,322) and IBA, zero. The Transaction does not change the historic shares. (IBA did not compete for any of the four contracts. It was not then active in the supply of FDG.)

(b) Historic market shares by value

105. The total value of contestable third party supply of FDG in Great Britain is around £[REDACTED]. This is calculated as 68,000 doses p/a that are produced by the six cyclotrons which are used to make third party supplies, less [REDACTED]doses which are the subject of internal transfers from Erigal to AM[88] and [REDACTED]doses supplied by operators of on-site cyclotrons to their on-site customer under long-term exclusive contracts = [REDACTED] doses at an indicative weighted average price in Great Britain of £[REDACTED] per dose.

106. Customers now generally require prices for delivered FDG (rather than ex-works,

87 The prices for back-up supplies are typically higher than those for primary supplies, as evidenced by the increase in prices agreed with Edinburgh when they switched from making primary purchases from AM/Erigal to requiring back-up cover.

88 AM's policy is to self-supply FDG in order to maintain security of supply (a crucial part of its competitive proposition in the supply of PET-CT scanning services). There is therefore no likelihood of its purchasing FDG from third parties (and, indeed, doing so would simply reduce utilisation rates at its own cyclotrons whereas high utilisation rates are required given the high fixed costs).

with delivery being paid for separately). Variations in delivery costs, quality of back-up arrangements and service support mean that prices differ between customers. However, the product itself – FDG – is homogeneous and AM submits that value data is relatively uninformative as it will be distorted by passed through delivery costs (and chronological issues about the dates of contract awards).

(c) Historic market shares by capacity

107. Prior to the merger, there were six operative cyclotrons making third party supplies of FDG: AM operated three, PETNET two and IBA one.

108. In addition, eight cyclotrons are currently owned by hospitals for self-supply of FDG; and four are operated by research institutions for self supply (Imanova operates two).[89] Of the cyclotrons operated by hospitals, two – at Aberdeen and Newcastle – are lower capacity "*desktop*" cyclotrons capable of producing around 2,000 doses p/a.

109. Further, GE has a cyclotron at Amersham that has withdrawn from the production of FDG on economic grounds.

110. The 17 standard cyclotrons can readily produce around 16,000 doses p/a and could produce more, e.g. by adding a third firing each day.[90] It should be noted that AM/Erigal's site at Keele is the only site understood to be currently running at close to full capacity and that the capacity of the site at Sutton has slightly lower capacity due to its location in the hospital at around [REDACTED]doses, Sutton currently provides approximately [REDACTED]doses. [REDACTED].

(d) Bid study

111. Table 1 below identifies the 14 contract awards in the last three years that AM is aware of,[91] including two it learnt of from the OFT's Decision.

Table 1: bid study (2011-14)

Customer	Date	Volume	Incumbent(s)	Winner	Quality: Price

89 See Annex 9 to OFT Submission for details.

90 See slide 25 of the slides at Annex 1 to OFT Submission.

91 AM believes that its recent information is reliable, but it has much more limited knowledge about older tenders as they were dealt with by its then joint venture, Erigal, rather than AM itself.

		(approx no. of doses p/a)			**ratio**
Cobalt	January 2011		IBA	IBA	N/A
Barts	May 2011		Unknown	IBA	60 : 40
London Clinic	December 2012	700	PETNET	PETNET	N/A
Edinburgh (back-up volumes only)	2013	Back-up only	AM/Erigal	AM/Erigal	N/A
BUPA Cromwell (NB award made without a formal tender)	2013	550	PETNET	PETNET	N/A
Brighton University Hospital	January 2013	900	PETNET	PETNET	60 : 30
Dundee	February 2013	676	AM/Erigal	AM/Erigal	70: 30
Liverpool Royal Infirmary & Manchester Royal Infirmary (joint tender)	April 2013	954 + 1,518	AM/Erigal and PETNET (Liverpool) and AM/Erigal, IBA and PETNET (Manchester)	AM/Erigal and PETNET	80: 20
Glasgow (back-up volumes only)	June 2013	Back-up only	AM/Erigal	AM/Erigal	N/A
The Christie, Manchester	July 2013	3,371	IBA	AM/Erigal	65 : 35
HTE tender (for Warwickshire-Coventry, UCLH, the two HCA hospitals and Oxford Churchill)	August 2013	1,140 + 3,000 + + 2,600 + 2,872	See note (2)	See note (2)	See Note 2 (below)
King's College, London	October 2013	1,000	-	AM/Erigal	70 : 30
Royal Free	January 2014	1,000	-	PETNET	80 : 20
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Notes:

1. The date of the tender submission for Barts (row 2) was 29 November 2010, at around the time of the de-activation/mothballing of Dinnington/Sheffield.

2. The HTE tender involved suppliers quoting prices to supply the hospitals participating in the buying group and the hospitals are free to purchase from one or more of the suppliers. This is therefore not a "normal" tender in which the business is awarded to one (or more) suppliers. However, PETNET is believed to have "won" in the sense that it is now the leading supplier to the hospitals participating in the HTE buying group, including to Warwickshire-Coventry which had previously purchased from AM/Erigal. Oxford Churchill has continued to purchase from IBA.

112. AM highlights the following points which arise from the bid study.

(a) IBA does not appear to have won any new customers during the period.[92] This is important because IBA was losing money even at an EBITDA level throughout this period and therefore had a strong incentive to win new business so long as it made at least some contribution.

(b) IBA lost [REDACTED] Manchester Royal Infirmary (where it was joint incumbent)). This corroborates AM's case that IBA had become a weak competitor following the deactivation/mothballing of Dinnington/Sheffield and IBA's financial difficulties: see section III above.

(c) PETNET won all of the contracts in the South after Dinnington was deactivated/mothballed,[93] apart from[94] King's (which was awarded after AM/Erigal completed the acquisition of IBA).

(d) There is relatively little switching. This is consistent with the evidence that customers place relatively greater weight on service / security of supply or other non- price factors than on price, since the position on security of supply is generally unchanged from one tender to the next unless capacity is withdrawn as IBA did or a supplier under-performs.

V. EXITING FIRM

(a) The history of the negotiations leading to the Transaction

113. [REDACTED].

114. [REDACTED].

115. [REDACTED].

116. [REDACTED].

92 AM does not know the identity of the incumbent supplier at Barts prior to the May 2011 award.

93 See note 1 to the Table for a discussion of the chronology in the case of the Barts contract which commenced in May 2011.

94 In addition, Oxford Churchill buys from IBA under the HTE framework agreement, although PETNET "won" the contract as explained in note 2 to the Table.

117. As has already been noted, it was clear to AM management that it needed to have a secure supply chain given the structural market challenges and financial difficulties of both Erigal and IBA. It was in this context that AM sought and obtained written confirmation from DoH about taking control of its supply chain in order to provide its own and the DoH security of supply of the product: see paragraph 237 below.

118. In March/April 2013 a compromise arrangement was agreed between AM, M2i and RBS, the bankers for Erigal, to split the business and the debt obligations between the former co-owners, however there were a number of regulatory matters that needed to be concluded leading to the resultant transactions completing in August 2013.

119. During the period of review and negotiation a far deeper understanding of the FDG and isotope market was sought and gained by the senior management of AM. Previously they had "merely been a customer" and concerned as to security of supply and price. It was clear that Erigal would not have the capacity to supply the needs of AM in the South in the event of it being successful in winning the PET-South contract and further [REDACTED] in the DoH became apparent.

120. [REDACTED].

121. The asset purchase came with eight people and five contracts which in aggregate lost money even at an EBITDA level, the people, essentially technicians AM valued to support the expansion into the South and the burden of the contracts was accepted as part of the mid-term strategy.

(b) Inevitability of exit

122. For reasons developed in section III above, AM believes that exit by IBA was inevitable: the business was losing money, there was no prospect of turning it around given its lack of self-back-up and doubts on the part of customers about its future, and keeping it open required significant capital expenditure. However, the knowledge of the vendor's position lies with the vendor and not AM. AM therefore respectfully requests the CMA to gather that evidence directly from the vendors.

(c) Alternative purchasers

123. The vendor has confirmed that it was not aware of any other party who was interested

in acquiring the target or any of its assets.[95]

124. The vendor is sophisticated and active internationally in the supply of FDG: if it believed that anyone else would have been willing to buy the target, it would have explored that possibility.

125. The fact that someone undertook preliminary due diligence *before SK Capital* acquired IBA[96] is not relevant: if that party was interested in buying the target, it could have approached SK Capital, but it evidently did not.

126. AM believes that it would have made no business sense for a purchaser to buy IBA for the production of FDG[97] at any price unless it had synergies arising from existing FDG production (most obviously the creation of a "dual supply" structure) or PET-CT scanning. Without synergies, a purchaser would have faced the same (insurmountable) problems as IBA and would have continued to make losses at an EBITDA level (i.e. the business was not viable even for a purchase price of £1).

(d) What would have happened to IBA's sales on exit?

127. As noted in para. 2 above, contracts to supply four out of IBA's five customers have expired or will expire over the next nine months or so (and Cobalt has already decided to switch to PETNET from June 2014). If IBA had exited from the FDG market, it would presumably have performed its remaining obligations[98] under its legacy FDG contracts to avoid a claim for damages (probably by calling on its back-up supplier, AM, to do so).

128. AM and PETNET would then have been able to compete for those contracts on any re-tender (assuming that the customer did not switch to self-supply), with AM being a relatively weaker competitor to PETNET for the existing IBA customers in the South. The same situation will arise after the Transaction: the customers will retender the contracts and AM and PETNET can compete for them. The Transaction therefore makes no difference (except that it maintains capacity in the market, increases competition in FDG in the South and assures AM of its ability to provide PET-CT

95 OFT Decision, §74.
96 OFT Decision, §80.
97 There may be a business case to use the cyclotrons to produce exoteric isotopes, as GE did with its Amersham cyclotron on exiting from the supply of FDG.
98 Itself or by appointing a sub-contractor if its contracts permitted.

scans to its customers, particularly in the South, which will increase the competition faced by InHealth).

129. [REDACTED].

VI. COMPETITIVE CONSTRAINTS

(a) Actual competition: PETNET

130. PETNET is a strong competitor. It is a wholly owned subsidiary of Siemens Medical Solutions USA, Inc., which is a leading producer of PET-CT machines and of cyclotron equipment. PETNET operates the world's largest network of PET radiopharmacies, with over 50 locations worldwide. It delivers[99] more than 800,000 doses to more than 2,800 imaging centres worldwide, each year. PETNET also has the largest global network of integrated manufacturing operations. It offers the full array of PET tracers covering both research and clinical applications, meaning it is well positioned to meet the growing demand for PET imaging services.

131. In the UK, PETNET operates as a division within Siemens plc as an integrated part of its healthcare business with a common management team, "free" use of shared services and the benefit of a much large commercial team that Siemens UK provides. Core to the UK business of Siemens is the provision and maintenance of equipment and the FDG business is an effective complement to that business. [REDACTED]. To put some context on this, a typical scanner would represent £1-1.5m of capital expenditure, maintenance costs for that would be some £100,000 per annum for the life of the scanner typically 7-10 years, (with an incremental margin of around 80 per cent. on that maintenance).

132. PETNET is believed currently to be making reasonably full use of its British cyclotron capacity (Mount Vernon and Nottingham) using two-firings per working day[100] but is not currently capacity constrained.[101] It could readily expand should a business case exist. This is evidenced by discussions which AM had with PETNET when AM was considering how it could secure its supplies of FDG when Erigal had

99 http://www.healthcare.siemens.com/molecular-imaging/petnet-solutions/access-offered)

100 For this reason, PETNET is sometimes said to be operating near to full capacity. However, for the reasons given in the body of the paragraph, this is true only on a two-firings per working day strategy and PETNET has itself said that it could raise its capacity significantly.

101 OFT Decision, §106.

breached its banking covenants and its future was uncertain. In Summer 2012, AM asked Ian Brown, general manager of PETNET in the UK, whether PETNET could meet AM's requirements and was told in July 2012 that PETNET could supply over 15,000 doses p/a if required (compared with total third party supply in GB of around 48,700 doses p/a[102] of which PETNET already supply some 22,000 doses p/a).[103]

133. AM believes that PETNET would have supplied the 15,000 or more doses by a third firing of its two existing cyclotrons rather than by investing in a further cyclotron because the commencement date for supplies – around nine months later – did not leave enough time to construct and license a new FDG plant from scratch. In an internal AM presentation of 21 July 2012 discussing the scope to replace Erigal as AM's supplier of FDG,[104] AM stated: "*They [PETNET] have indicated that they can supply this [the 15,000 doses p/a], by either increasing production of [or] reduce production of other tracers).*"

(b) New entry

134. The eight hospitals and three research institutions which own their own cyclotrons for self-supply are potential entrants into third party supply.[105] They have already invested in the cyclotrons and incur operating costs in producing FDG for their own consumption. Since the variable costs of additional production within a batch are low, any third party business won by these hospitals or research institutions would make a contribution: in effect, it would reduce the costs of operating what is, for them, a cost-centre.[106]

135. The main barrier to entry[107] is that they would need to obtain a variation to the licences issued by the MHRA to permit commercial supplies.[108] So far as AM can judge, there is no reason why MHRA would refuse to grant such a consent given that third parties are authorised to supply FDG.

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102 68,000 doses p/a that are produced at the six cyclotrons that are operated to make third party supplies, less 19,400 doses which are the subject of internal transfers from Erigal to AM.

103 The correspondence is at Annex 5 to OFT Submission.

104 Attached as Annex 17 to OFT Submission.

105 Aberdeen and Newcastle operate "desktop" cyclotrons with more limited capacity than standard cyclotrons and are therefore more restricted in their scope to compete for third party business.

106 In marked contrast to third party commercial suppliers who seek to operate their cyclotrons as profit centres.

107 In addition, they would need to start their shifts earlier to allow time for delivery to third party customers.

108 See slide 26 of the slides at Annex 1 to OFT Submission.

136. Cardiff University School of Medicine has considered entry[109] and is understood to be in active discussions with Truro hospital about making third party supplies of FDG.

137. There are precedents for hospitals commercialising an in-house production facility of radioisotopes, as this has occurred in the case of Technetium in around 25 instances.

138. As long ago as October 2005, DoH envisaged that NHS cyclotron facilities might operate commercially, making supplies of FDG to third parties (other hospitals or research institutions).[110]

(c) Buyer power

139. Hospitals have buyer power because they can threaten to invest in their own cyclotron and, if they do so, they are lost from the third party supply market for the operational life of the cyclotron, i.e. 25 years. Both Edinburgh and Glasgow installed their own cyclotrons on cyclotrons, which started operating over the last 12 months, because[111] they required sufficient volumes to make self-supply viable and they were not willing to accept AM's best price for supply. Hospitals are aware of the costs of operating a cyclotron and those costs operate, in effect, as a "*silent bidder*" (i.e., following the Transaction, as a third option or "*quotation*" for the customer) in any competitive tender requesting prices for third party supply.[112] For example, Glasgow and Edinburgh have recently installed their own cyclotrons: the transport costs increased prices to those sites to a level which made self-supply more economic in their minds and they have both been lost to third party suppliers (other than for back-up volumes).

140. Similarly, customers requiring FDG for research purposes – even in quite small volumes – can invest in a cyclotron, as WMIC, WBIC, Newcastle and Birmingham have done.[113]

141. Hospitals – including smaller hospitals – can also benefit from the NHS's central

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109 See http://medicine.cf.ac.uk/petic/production-facility/fdg-18-production/.

110 See http://www.inahta.org/upload/HTA_resources/PET_A_framework_for_development_of_PET_services_in_England.pdf at p. 27 (Table 3(c)).

111 They also use their on-site cyclotrons for research purposes.

112 As explained on slide 32 of the slide deck at Annex 1 to OFT Submission.

113 Where hospitals purchase FDG both for clinical and research purposes, they can bundle the purchases together as The Christie, Manchester and Imperial, Hammersmith have done: see Annex 9 to OFT Submission.

buyer power. As noted above, the DoH has entered two block contracts under which hospitals can purchase PET-CT scans (inclusive of FDG) at prices fixed in the agreement. Under the agreement for the North,[114] which AM supplies, DoH consent was required for any sub-contracting. DoH accordingly reviewed and approved the terms (including as to price) of the sub-contract for the supply of FDG between AM and Erigal. In that context, the DoH sought successfully to reduce the price payable for FDG saying that the price in the South was slightly lower. Indeed, the contract as a whole was agreed on the basis of open book accounting principles, evidencing the customer's buyer power.

142. Hospitals can also benefit from joint purchasing arrangements. For example, HTE Health Trust Limited has negotiated framework prices at which UCLH, the two HCA hospitals (Wellington and Harley Street Clinic), Coventry and Oxford Churchill can purchase from FDG suppliers. There is no obligation on the hospitals in question to purchase under the framework agreements but they will do so when it is in their interests and they have largely[115] purchased from PETNET for routine (i.e. Monday to Friday) deliveries.[116] Similarly, NHS SBS provides a comparable service for Liverpool and Manchester.

143. A similar structure is being set up in the North by the North of England Commercial Procurement Collaborative, which is organising a framework contract.

VII. NO SLC IN FDG

(a) No loss of potential competition from IBA's Dinnington site

144. For the reasons given in section III(a) above, there is no likelihood of IBA's Dinnington site being restarted.

(b) The Transaction strengthens FDG and PET-CT competition in the South

(i) Introduction

114 Annex 10 to OFT Submission.

115 Oxford Churchill has purchased weekday deliveries from IBA under the framework agreement.

116 The price charged by PETNET for Saturday deliveries is believed to be less attractive to customers, as evidenced by the fact that two of the hospitals – Oxford Churchill and UCLH – make some direct purchases from AM on Saturdays.

145. Prior to the Transaction:

(a) AM's share of third party contestable supply[117] was [REDACTED] per cent. This low share was because AM bid and failed (not because it chose not to bid): in fact, it bids for every FDG contract it is aware of and, importantly, all, or almost all, NHS hospital contracts are made public and subject to formal tenders under public procurement rules.[118]

(b) IBA has not won any new customers anywhere since January 2011 and has lost some, despite having a very strong incentive to price low to win volume. The incentive arises because IBA was losing money at a cash level (i.e. ignoring charges for depreciation etc.) and it was therefore costing its private equity owners money to stay open (contrary to the normal private equity model of using strong cash flows to cover interest payments). Since variable costs of FDG production are low and IBA had capacity – not least because of contract losses – it clearly needed to increase its volumes at prices which covered variable costs to stem its losses. The owners acted on this incentive, as evidenced by the low price they quoted for The Christie, Manchester (but still lost). IBA's inability to win new customers despite the huge incentive to do so demonstrates that it was a weak rival.

146. Prior to the Transaction neither IBA nor AM/Erigal had a compelling proposition for customers in terms of the reliability of their supply. Security of supply (e.g. through "dual supply") is crucial in the supply of FDG: FDG is an essential input for scans for cancer patients (without it, scans cannot take place as there is no substitute); cyclotrons cannot produce FDG without some planned and unplanned downtime; and FDG cannot be stored as it must be used within a few hours of production.

147. Prior to the Transaction, AM's security of supply involved shipping from Keele or Preston (which are, respectively, 3 hours 6 minutes and 4 hours and 2 minutes drive from Sutton) and IBA's arrangement involved a contract with AM. By contrast, PETNET had another facility at its Mount Vernon site from Nottingham, 2 hours 8 minutes drive away and routinely ships from North to South.

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117 Where most if not all competition occurs on a merger control time-frame.

118 Only non-NHS organisations, such as InHealth and Cobalt, have the flexibility to award FDG supply contracts informally outside of public procurement processes.

148. The OFT found that customers were indifferent to how their suppliers arranged for security of supply. Whilst customers do not mind how it is provided, many place significant weight in their award criteria on the quality of security of supply arrangements: see the tender criteria for The Christie, Manchester. In that case, which is typical, the service reliability criteria included categories for "*secondary production sites*" and "*expected delivery delays for unplanned production interruptions*".

149. Suppliers with dual supply arrangements score better against such criteria. For example, the Award Notice sent by The Christie, Manchester stated "*Expected delivery delay for unplanned production disruptions Erigal [Alliance Medical] exceeded The Christie requirement having an advantage of two identical production facilities being equidistant from The Christie Hospital, communicating through the night and, if necessary switching production and delivery between facilities.* "

150. The advantage of dual supply arrangements for customers has two components. The first concerns the operational and coordination efficiencies of having primary and back-up supply under the control of a single firm, as noted in the Award Notice for The Christie.

    (a) Where back-up is required as a result of an unplanned interruption at a cyclotron, a supplier will generally only be able to source back-up supplies from another supplier where that supplier has, for some reason, produced more than was required for its own customers. The availability of these extra doses is unpredictable and cannot be guaranteed. However, arranging internal back-up supplies is much easier as there is inevitably better communication through the night (e.g. by advising other plants of *potential* problems rather than waiting until they materialise) and greater willingness to undertake an additional production run at one cyclotron to cover the short fall caused by another going out of operation.[119]

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[119] This is illustrated by the 11 occasions between December 2013 and February 2014 where AM required back-up (self or third party). The internal batch reports for these 11 occasions are attached as Annex 4 of AM's Response of 10 March 2014 to the OFT's Issues Paper. Of these batch reports:
(a) On 3 December 2013, there was a problem with Sutton (AM). The batch report says: "*Shipping delayed - Guildford [IBA] have covered so no delays expected.*" IBA therefore backed-up AM/Erigal (prior to the hold separates), avoiding delays or failures to deliver, clearly illustrating the benefit of the Transaction.
(b) On 31 January 2014, Keele's cyclotron failed part way through the first batch and was hard down. The report says "*PETNET cannot help. Preston doing three batches. Only impact is*

(b) If one of the cyclotrons is down for a lengthy period – as happened when Guildford shut for four weeks in September 2013 – or has regular problems[120] the owner can reorganise production schedules and shifts at other cyclotrons to maintain supply. It is unrealistic to expect that a third party will be willing or able to cover this.

151. The second advantage of self-back-up for customers is that it eliminates the double marginalisation that arises when purchasing back-up services from a third party.[121]

152. The remainder of this section considers the implications of the Transaction for the relevant product markets identified above.

(ii) The primary supply of FDG to third parties under competitively tendered contracts

153. The customers in this category comprise:

North Staffs delay 1 hour." Without self-back-up the impact on customers would have been much greater.

(c) On 26 February 2014, Keele's second batch had a low yield. There was "*No spare available from PETNET or AMMIL*" but Preston covered some customers with Keele running a third batch for another. Without self-back-up, these customers would have had no supply or later supply.

120 Shortly after the Transaction, AM did this for the benefit of its customers, InHealth, when Sutton produced a spare vial "just in case" the IBA facility had problems: see the email at slide 24 of Annex 1 of AM's Response of 10 March 2014 to the OFT's Issues Paper.

121 This can also be analysed as a straightforward demand side efficiency that is explicitly recognised in the OFT/CC Merger Guidelines and that explains very clearly why we believe firms that self-back-up are stronger competitors than those that cannot. This efficiency (sometimes known as a "Cournot effect") concerns the fact that primary supply and back-up supply are very clearly economic complements.

The OFT suggested in its Decision at §226 that they are substitutes, but this is incorrect: a supplier requires a source of primary supply and a source of back-up supply. If the primary supply fails, the supplier will switch to its back-up supply but this substitution in use does not make the two substitutes for one another when the supplier is arranging its sources of supply. More formally, if the demand for primary supplies increases, so too does demand for back-up supplies, indicating that the two are indeed complements.

As the OFT/CC guidelines puts it (§5.7.17): "*Bringing products that are complements under common ownership may allow the merged firm to obtain the positive effect of a fall in the price of one on sales of the others. Achieving this effect through a merger may result in lower prices for all products in the bundle, because it may become profit-enhancing for the firm which sells all the complements to sell them at a lower combined price than the sum the customer would have paid to assemble the same package from different suppliers before the merger.*"

This effect can occur through better prices (as the OFT/CC describe) and/or through improved service quality for any given price.

In this particular case the effect is highly material for two reasons:

(a) There is a high direct contribution margin for FDG supply (of around [REDACTED] per cent). In particular the primary supplier backing up in-house does not have to pay the profit mark-up that it would if it obtains FDG from a third party (an effect analogous to the elimination of so called double marginalisation in vertical effects); and

(b) Almost all customers require back-up.

(a) InHealth (various sites) and Cobalt (Cheltenham) (which both provide PET-CT scans in the South); and

(b) the following hospitals: St Barts, Birmingham, Brighton, Cambridge, Coventry/Warwickshire, Cromwell (BUPA), HCA (Harley St Clinic and The Wellington) Imperial (Charing Cross Hospital and Hammersmith Hospital), King's, London Clinic, Oxford Churchill, Royal Free (a new customer, tender awarded recently to PETNET) and UCLH.[122]

154. At the time of the Transaction, IBA had five customers: InHealth (although the contract has expired and PETNET supplied two-thirds of InHealth's requirements), St Barts, Cambridge, Cobalt (Cheltenham) [REDACTED] and Oxford Churchill. It was also an actual or potential competitor for the other hospitals identified above.

155. AM has investigated whether AM/Erigal and IBA were one another's closest competitors for customers in the South by identifying drive times to the customer. It is evident from the tender documents referred to in para. 111 that security of supply is the customer's primary concern in appointing a supplier of FDG (ahead of price). Other things being equal, a supplier with a shorter drive time is a more reliable supplier. (Formally, the product which is supplied – FDG – is homogeneous, but the suppliers are differentiated because of their different geographic locations and back-up arrangements. Put another way, the customer is not simply buying homogeneous FDG but is buying a differentiated service of secure/reliable deliveries of FDG to enable PET-CT scans to occur as scheduled.)

156. In that context, Table 2 below identifies for each of the contestable third party customers in the South the closest supplier of FDG, the second closest and the third closest.

[122] There is no scope for competition for Royal Marsden (AM) or Mount Vernon (PETNET) as both are subject to long-term exclusive contracts granted in return for the supplier constructing an FDG plant on site.

Table 2: Ranking suppliers by drive-time for contestable third party customers in the South[123]

Customer	Closest supplier of FDG (and drive-time)	Second closest supplier of FDG (and drive-time)	Most distant supplier of FDG (and drive-time)
St Barts	1= PETNET Mt Vernon (45 mins) & AM/Erigal Marsden (45 mins)		IBA Guildford (63 mins)
Birmingham	AM/Erigal Keele (64 mins)	PETNET Nottingham (71 mins)	IBA Guildford (135 mins)
Brighton	AM/Erigal Marsden (59 mins)	IBA Guildford (69 mins)	PETNET Mt Vernon (90 mins)
Cambridge	PETNET Mt Vernon (79 mins)	AM/Erigal Marsden (106 mins)	IBA Guildford (113 mins)
Cobalt (Cheltenham)	AM/Erigal Keele (97 mins)	PETNET Mt Vernon (104 mins)	IBA Guildford (119 mins)
Coventry/Warwickshire	PETNET Nottingham (57 mins)	AM/Erigal Keel (71 mins)	IBA Guildford (123 mins)
Cromwell (BUPA)	PETNET Mt Vernon (37 mins)	AM/Erigal Marsden (38 mins)	IBA Guildford (53 mins)
Guildford (Royal Surrey County Hospital)[124]	IBA Guildford (14 mins)	AM/Erigal Marsden (38 mins)	PETNET Mt Vernon (46 mins)
HCA (Harley St Clinic)	PETNET Mt Vernon (37 mins)	AM/Erigal Marsden (49 mins)	IBA Guildford (62 mins)
HCA (The Wellington)	PETNET Mt Vernon (38 mins)	AM/Erigal Marsden (50 mins)	IBA Guildford (63 mins)
Imperial (Charing Cross Hospital)	AM/Erigal Marsden (35 mins)	PETNET Mt Vernon (39 mins)	IBA Guildford (48 mins)
Imperial (Hammersmith Hospital)	PETNET Mt Vernon (31 mins)	AM/Erigal Marsden (43 mins)	IBA Guildford (56 mins)
King's	AM/Erigal Marsden (38 mins)	PETNET Mt Vernon (53 mins)	IBA Guildford (62 mins)
London Clinic	PETNET Mt Vernon (38 mins)	AM/Erigal Marsden (50 mins)	IBA Guildford (63 mins)
Oxford Churchill	PETNET Mt Vernon (53 mins)	IBA Guildford (77 mins)	Am/Erigal Marsden (85 mins)
Royal Free	PETNET Mt Vernon (39 mins)	AM/Erigal Marsden (56 mins)	IBA Guildford (69 mins)
UCLH	PETNET Mt Vernon (39 mins)	AM/Erigal Marsden (51 mins)	IBA Guildford (63 mins)

Source of drivetime data: Google Maps

123 There is no scope for competition for Royal Marsden (AM) or Mount Vernon (PETNET) as both are subject to long-term exclusive contracts granted in return for the supplier constructing an FDG plant on site.
Sales to InHealth under the PET South contract are not included because of the range of delivery locations.

124 This refers to Guildford hospital which is an Alliance operated site.

157. It follows from Table 2, that of the 17 customers, there is only one[125] for whom IBA and AM/Erigal are the closest geographic competitors (Brighton); in the majority of cases, the Transaction will not remove the closest competitor.

158. In addition, in considering the effect of the Transaction on competition in the supply of FDG in the South:

(a) AM/Erigal did not have a close alternative site for self-back-up: supplies can be shipped from Keele if there is a planned outage but usually not if there is an unplanned outage. The merged group will have two southern plants – at Royal Marsden (Sutton) and Guildford – which can credibly back one another up, including for unplanned outages: a dual supply offering. The effect of the Transaction will be replace two relatively weaker competitors to PETNET in the supply of FDG in the South with one strong one, which will increase competition and benefit customers.

(b) Five of the 17 hospitals are members of a buyers' group, HTE Health Trust Limited, which increases their bargaining strength against AM/Erigal and PETNET.

(c) Whilst IBA had <u>historically</u> been a strong competitor for the five customers it supplied – which is why it won the contracts in the first place – and would have competed for at least some of the others, it had become a very weak rival and would have remained so in the absence of the Transaction: see section III above.

(d) Hospitals can always install their own cyclotrons or purchase from other hospitals or research institutions which have already done so (or GE): see section VI above.

<u>(iii) The back-up supply of FDG to third parties</u>

159. The existing back-up supply arrangements are described in para 27 above.

160. The Transaction does not change the position in the North: AM/Erigal and PETNET remain the third party options for back-up supply.

[125] Guildford is an AM scanner and therefore not contestable.

161. In the South, the Transaction removes IBA as an independent source of back-up supply. However, IBA provided formal back-up arrangements only to AM/Erigal (an arrangement which became intra-group following the Transaction).

162. In terms of spot supplies in the South (which typically involve sites which are close to the site which has suffered the outage):

(a) For hospitals and third party PET-CT scanning suppliers seeking spot back-up supplies, the merged group will continue to face close competition from PETNET's Mount Vernon site.

(b) AM/Erigal has an incentive to continue to supply PETNET on the customary terms applied between them as AM/Erigal wishes to continue to benefit from supplies from PETNET if AM/Erigal requires them. (The volumes involved in spot supply of back-up FDG are small but they can be crucial to maintaining uninterrupted supply.)[126]

(iv) The build and operation of a cyclotron on a customer's site in return for a long-term exclusive supply contract

163. AM is not aware of any proposed tenders falling within this category.

164. If tenders were to be organised, AM/Erigal (in conjunction with a cyclotron manufacturer, e.g. GE or others) and PETNET would be credible competitors and the contract would provide an opportunity for new entry into third party supply, whether by another British hospital or research institute or an overseas producer of FDG or cyclotrons.

165. It is most unlikely that IBA would have been a credible tenderer for this type of contract had AM/Erigal not purchased it because of the uncertainties about the length of time it would remain in the market: see section III above.[127]

[126] PETNET routinely ships FDG from Nottingham to Mount Vernon and can therefore more readily self-back-up in the South even for unplanned outages.

[127] It should be noted that since IBA Molecular was purchased from IBA, IBA Molecular would not be in a position to provide the cyclotron itself as part of an intra-group supply.

(c) Effect of the Transaction on prices

166. For the reasons developed in this submission, the Transaction will not result in higher prices than the counterfactual.

167. The counterfactual is discussed in section III above. As explained there, if the relevant counterfactual is exit by IBA or IBA remaining in the market and continuing with its (wholly unsuccessful) strategy, then the counterfactual is one in which prices are set by competition between PETNET and AM/Erigal. If IBA had remained in the market under new third party ownership, it was inevitable that its prices would rise because nobody would continue to operate IBA in a way which made losses for the indefinite future even at an EBITDA level: the business would simply continue to consume cash.

168. In preparing its internal documents considering the Transaction, AM assumed that prices would rise following the Transaction. Specifically, in its business case for the Transaction, AM assumed that prices would rise by [REDACTED] per cent. per year from 2014 to 2017.[128]

169. The assumption was not based on any detailed analysis of the market or researched projections and AM did not carry out sensitivity testing. This is because the main drivers for the Transaction were the benefits in terms of [REDACTED] PET-CT scanning, rather than the supply of FDG to third parties.

170. However, the assumption reflected a belief that prices would rise, particularly in the South, because suppliers would not continue indefinitely with strategies that meant that they lost money even at an EBITDA level (and therefore had to pay to remain in the market).

VIII. NO RISK OF VERTICAL FORECLOSURE IN FDG

(a) The OFT's vertical theories of harm

[128] See the FDG Acquisition Paper, tab "IBA" (Annex 18 to OFT Submission), row 3. Other documents refer to prices "harmonising" with those charged by AM/Erigal and to prices "hardening".

171. The OFT examined a vertical theory of harm in which AM's presence in both the upstream supply of FDG-18 and downstream supply of PET-CT scanning may provide them with the ability and incentive to undermine the competitiveness of downstream rivals so as to increase its own presence in the downstream supply of PET-CT scans and reduce the downstream competitive constraints it faces (so-called "input foreclosure". (The OFT's Decision noted that any such effects would only be present in the South, the area where it found horizontal unilateral effects.)

172. The OFT noted that, in theory, these effects could occur through:

(a) increasing prices of FDG-18 to competitors so as to raise their costs, making competitors less competitive in bidding for contracts;

(b) disrupting primary or back-up supply to competing downstream providers; or

(c) totally refusing to supply primary or back-up.

173. There is no potential for AM to disrupt or refuse back-up supply to PETNET, given the ability of PETNET to self-back-up in the South.

174. The OFT also examined a theory regarding so-called "customer foreclosure". This concerns the scenario in which, if AM was successful in gaining business downstream through input foreclosure, at the expense of competing PET-CT suppliers, its ability to 'self-supply' this additional business downstream may reduce the number of customers that PETNET can supply. If the supply of PETNET was reduced sufficiently through such a strategy, the theory would be that PETNET may be marginalised such that it can no longer achieve the economies of scale necessary to remain a strong competitor in the supply of FDG-18.

175. Below we comment in turn on each of the elements of analysis set out in the CMA's merger guidelines, namely: ability, incentive and effect.

(b) Ability to implement input foreclosure

176. It is important to note at the outset that the business at stake with respect to

foreclosure theories is small. Total primary supplies to PET-CT commercial competitors at the point of the merger totalled only 6,000 doses, with the prospect of even that contract being lost. This represents supply to only 30 per cent. (i.e. 6,000 of 20,000) of the scans provided by rival commercial PET CT providers in the UK.

177. For those NHS trusts who own and operate their own PET CT scanners, it is difficult to envisage circumstances in which AM could have a theoretical ability to foreclose FDG-18 supply in order to encourage those customers to switch scanning contracts to them, as customers would be fully aware of any such behaviour and reputational damage would be quickly and readily transmitted across the NHS. The customers would switch to PETNET.

178. Below we look at each of the areas of analysis that the CMA considers in assessing ability to implement input foreclosure, namely: the ability to avoid a price increase by switching away from FDG-18, the cost of the input relative to the cost of the final product and pass-through of cost increases to customers.

179. These factors apply to each of the types of vertical theory set out above. We therefore consider the foreclosure mechanisms together in commenting on them.

(i) Availability of alternatives

180. Although there is no immediate alternative to the use of FDG-18, customers would be able to switch to PETNET which has a [REDACTED] per cent share of supply to third parties under competitively tendered contracts in the South, appetite and desire for additional volume, current spare capacity and the ability readily to expand its capacity using its existing cyclotrons.

181. The OFT's Decision said that some customers who multi-source their FDG-18 supplies for security of supply reasons may be faced with no alternative but to seek supplies from AM post-merger. However, the two of the three hospitals which dual source – Royal Liverpool and Manchester Royal Infirmary – are in the North and are unaffected by the Transaction. This leaves InHealth which accounts for large volumes of FDG and could obtain attractive terms by the potential to sole source (or could play off two suppliers by threatening to switch the balance between the suppliers which prior to the merger was in reality an empty threat as AM did not have

the capacity in the South and IBA was a structurally deficient supplier) and Oxford Churchill.

182. We also believe that the actions of downstream customers are relevant in considering the ability of AM to foreclose supply of FDG-18. If customers believed that AM might have such ability post-merger, they would surely have been keen to secure long- term supply arrangements on their pre-merger terms after the acquisition.

183. AM offered such arrangements to both InHealth and Cobalt. InHealth did not take up the offer. Neither did Cobalt as they were seeking to secure an equipment-plus-FDG arrangement with Siemens/PETNET.

184. In our view these actions are entirely inconsistent with the vertical theory and should be accorded more evidential weight than assertions that may be put forward by rivals who may understandably fear increased competition if the merger proceeds.

(ii) The cost of the input as a proportion of total costs

185. FDG-18 accounts for [REDACTED]per cent. of the direct marginal costs of supplying a PET-CT scan. Assuming an illustrative price rise of FDG-18 of [REDACTED] per cent., this would equate to an increase in costs of between [REDACTED] per cent.

186. As scanning direct marginal costs represent around [REDACTED] per cent. of the price of a scan, and assuming full pass through of cost increases, this equates to a price increase of a PET-CT scan of only around [REDACTED] per cent. (This same percentage range applies to a typical PET-CT scan contract taken as a whole, given that there are no capacity constraints that mean additional costs are incurred in supplying FDG for an additional contract.) Bigger price differences already exist in the market.

187. If PETNET attempted to benefit from any FDG-18 price increase by AM by increasing its own price, the PETNET price rise would be likely to be smaller than any AM price rise as is the nature of an accommodating response (as the OFT notes in its Decision). The maximum price increase for the affected PET-CT scans would therefore be even lower than the figures for AM's customers set out above.

188. We believe that it is not plausible that the levels of price increase for PET-CT scans described above could result in significant harm to competition in the market for PET-CT scans, especially bearing in mind the pricing benefits that vertical integration brings (described further below).

(iii) Pass-through of cost increases

189. PET-CT scan price increases at the low levels described above assume full pass-through of the hypothetical FDG-18 price rises. Competitive pressure to win PET-CT scan contracts (especially given AM's greater competitiveness looking ahead) and the terms of existing contracts are likely, in AM's view, to mean that any FDG-18 price rises would not be passed on, certainly not in full. This would reduce the extent to which rivals' customers switch their PET-CT scan requirements to AM, thereby negating part of any foreclosure rationale.

190. The OFT's Decision states that that rivals could nevertheless be damaged, as their absorption of part or all of any FDG-18 price increase – even at these very low levels of increase – may still be sufficient to undermine their competitiveness. While we accept that rivals may feel they would be harmed in this scenario, competition itself could only be harmed if the loss in downstream rivals' profits was sufficient either significantly to reduce their ability or incentive to invest or to threaten their very survival. In turn this could only happen if they were unable or unwilling to take any steps to mitigate the effects, such as becoming more efficient. It is difficult to believe that such steps would not be possible given the small scale of the effects to be mitigated.

191. These scenarios for harm to competition also seem to us inconsistent with InHealth's and Cobalt's considered decisions not to secure their forward FDG supply terms, as described above.

192. We note also that the OFT Decision contains no evidence suggesting that the viability of rivals or their investments are in practice threatened, despite the fact that rival companies had ample opportunity to provide it during the OFT inquiry.

193. Regarding total input foreclosure the Merger Assessment Guidelines state that: "*in evaluating the ability of the merged firm to engage in total input foreclosure, [the*

OFT and the CC] may consider how easily the merged firm can commit not to re-enter the input market." In this regard we note that marginal costs of FDG-18 production are relatively low in relation to price and that there are strong incentives to maximise production in order to cover fixed costs. In these circumstances we submit that total foreclosure would not be a credible strategy.

(c) Incentive to implement foreclosure

194. Although absolute direct contribution margins for PET-CT scans are higher than for FDG-18, the significance of this to harm to competition depends on the level of switching from which AM could benefit and on the likelihood of switching at that level affecting rivals seriously enough to undermine or remove them as competitors. (We note also that higher downstream margins give AM a strong incentive to pass-through vertical efficiencies, as discussed further below.)

195. A pressure on downstream rivals to increase prices by [REDACTED] per cent. (which is an upper level given that it assumes 100 per cent. pass-through) in bidding for PET-CT contracts would be on a par with many other variables that need to be managed in such bids (including, for example, how to price for cost increases over the life of a contract). As a result, it is difficult to envisage that price pressures at this level could induce significant levels of switching to AM.

196. The OFT reported that the greater concern raised by third parties was foreclosure through disruption to supply as opposed via price increases. As PET-CT scans have to be rescheduled in the event of no FDG-18 supply, it argued that such a strategy may impose costs on the PET CT scan provider but without loss of FDG business for AM.

197. Aside from the fact that deliberate disruption to supply goes against everything AM works to achieve, AM believes that it has no incentive to pursue such a strategy for the following five reasons:

(a) First, contracts can be designed, and are designed, to incentivise reliable service delivery.[129]

[129] See, e.g., the compensation scheme for Glasgow General Hospital: see Annex 5.

(b) Secondly, AM's reputation would suffer. The cause of the supply disruption would be easy for the PET CT scan provider to communicate and for FDG rivals to use to their advantage in promoting their services.

(c) Thirdly, it would encourage some customers – whether NHS or private – to take FDG-18 supply in-house. When this occurs the loss of FDG-18 business is, to all intents and purposes, irreversible. This is because, once the fixed costs of self-supply have been incurred, the incremental costs of in-house supply will be below market rates for the lifetime of the equipment which is around 25 years.

(d) Fourthly, behaviour of this sort would strongly incentivise rival PET CT scan providers using AM's FDG-18 to establish closer and stronger relationships with other FDG-18 suppliers, including sponsoring new entry if necessary. Such moves would ultimately be at AM's expense.

(e) Finally, AM is reliant on other FDG suppliers for back-up for its own PET-CT scanning business. Volumes are small, but also important to it. If AM were to start misbehaving in this way, then there is a possibility of retaliation or encouragement of other FDG suppliers to behave similarly in a way that would damage AM.

198. The OFT worried that customers may have a more elastic response to service disruption than to prices and that therefore the levels of switching away from downstream rivals may be higher than would be associated with a [REDACTED] per cent. price rise. We see no reason why this should be the case and no evidence was put forward to support it.

199. The OFT concluded that AM's Transaction rationale to win new PET-CT scanning business in the South "*speaks to AM's incentives to engage in foreclosure*". We strongly disagree with this interpretation. An intention to win new business through becoming a stronger competitor as a result of vertical integration is a perfectly valid and pro-competitive business objective that, of itself, says nothing about incentives to

foreclose. AM does not need a foreclosure strategy to achieve its objective in this regard and there is no evidence to suggest that AM has ever considered such a strategy (the reverse being the actual case as AM/Erigal has supplied spot business to PETNET a part of which will have been for InHealth sites for example). Indeed, any such strategy would put at risk one of the Transaction's main objectives by damaging AM's reputation, as discussed above.

(d) Effect of foreclosure on competition

200. AM submits that there could be no significant effect on competition in PET CT scans for two reasons.

201. First, as discussed above, we believe that, even if such a strategy were attempted, the levels of switching would be too low to put rivals at risk and the underlying volume of business at issue is modest in any case.

202. Secondly, the Transaction will increase the degree of rivalry in the PET-CT scanning services market as a result of the elimination of double marginalisation and the more competitive FDG back-up capability. If the CMA were to believe that there may be strong incentive to increase rivals' costs or degrade service quality (in order to win scanning business) it would also follow that AM would be strongly incentivised to pass through to customers the double marginalisation and back-up benefits (to the same end). The two are sides of the same coin. As the CMA recognises in its guidelines, this is why all of the elements in vertical effects need to be considered in the round, taking full account of the offsetting effects that are inherent in the theory, and the likely responses of rivals (e.g. PETNET/Siemens is vertically integrated).

203. The elimination of double marginalisation is significant in this case given that FDG direct contribution margins are around [REDACTED] per cent.

(e) Customer foreclosure

204. The theory put forward by the OFT was that, should AM manage to foreclose its downstream rivals it could bring supply of FDG-18 to its new downstream customers in-house. This may reduce PETNET's business and may mean they would no longer be able to achieve sufficient economies of scale to be viable.

205. This is not, in our view, a credible theory of harm given that AM has only a [REDACTED] per cent. share of PET CT scans in the UK, most of them already supplied by AM's FDG-18. Nor is it consistent with the contracting structure of the block contracts which are awarded for a relatively long period, indications are for 10 years in the current round of re-commissioning and with consequences of non-performance which start with penalties but would ultimately result in the DoH taking the scanning service in house rather than to "switch" it to a different commercial provider.

(f) Summary on vertical foreclosure

206. There is no evidence that AM has engaged in vertical foreclosure behaviour in the past, despite its ownership of Erigal and the weak position of IBA.

207. Moreover, AM's actions in offering InHealth and Cobalt favourable contract extensions are also not consistent with the theory.

208. Nor is there any evidence in AM's internal documentation that supports an anti-competitive interpretation of its stated objective of becoming a stronger competitor to InHealth in the South, as opposed to a straightforward pro-competitive interpretation.

209. Finally we note that the Transaction offers significant benefits from vertical integration that need to be fully incorporated in the overall assessment.

IX. NO COORDINATED EFFECTS IN FDG

210. Coordinated effects between AM/Erigal and PETNET in the market for the supply of FDG are unlikely for three reasons.

211. First, the market is a tendered market in which small numbers of contracts come up for competition each year. This means that contracts are relatively large as a proportion of the overall market value, varied in size and infrequent. It would be very difficult to identify a coordination strategy that the FDG suppliers could adopt. The suppliers would also find it difficult to discipline a supplier deviating from a collusive agreement as the varied size of the contracts and infrequent nature of their award

would make it difficult to enact effective and appropriate punishment. Finally, in a market where economies of scale are significant and contracts relatively large, there would be very little incentive to coordinate as losing a contract would be potentially fatal to the coordinating supplier. Coordination could therefore not be sustained.

212. Secondly, the ability to coordinate on price is significantly restricted by the fact that customers typically allocate only around 20-40 per cent. weighting to price, with 60-80 per cent. depending on security of supply, factors which are largely determined by historic investment decisions, particularly whether and where to invest in cyclotrons.

213. Thirdly, AM's strategy, and therefore its incentives, is very different from PETNET's and neither is focused on FDG as a free-standing profit centre. AM is a vertically integrated supplier of FDG and PET-CT scanning services and is developing (highly confidentially) the strategy described in [REDACTED]: it needs to ensure that its PET-CT scanners have the necessary FDG (to ensure that it is paid under its PET-CT services contracts) and to ensure that the market as a whole perceives FDG supply to be reliable (as this will support the long-term growth of PET-CT scanning in Great Britain from its current very low level compared with other advanced countries[130]). By contrast, PETNET supplies tracers and cyclotrons and is part of Siemens group. Siemens manufacturers PET-CT scanners and has an incentive to promote the sale of its PET-CT scanners over those of other providers of imaging equipment, including by ensuring the ready availability of FDG for use on PET-CT scanners [REDACTED]. Since AM and PETNET have different strategies and neither AM nor PETNET is focused on FDG as a free-standing profit centre (both are interested in other markets which may be affected by FDG sales) it is most unlikely that there will be a stable coordinated outcome in FDG which both would have an incentive to adhere to.

X. ALZHEIMER'S TRACERS

214. The three global companies which are developing Alzheimer's diagnostic tests using radioactive tracers have appointed their sub-contracted suppliers of tracers in the UK: GE has appointed AM/Erigal, Eli Lilly has appointed PETNET and Piramal has

130 See slide 13 of the slides at Annex 1 to OFT Submission.

appointed IBA. Prices under the contracts are fixed.[131] There is further detail in (and available contracts are attached to) Response to OFT Questions of 19 February 2014.

215. There is therefore no actual competition at present for the supply of Alzheimer's tracers on a sub-contracted basis.

216. Competition could arise on the award of a fresh contract. GE's contract with AM/Erigal expires in [REDACTED]. and Piramal's contract with IBA expires in [REDACTED].

217. Following the Transaction, AM and PETNET would compete strongly for such business for the reasons discussed in relation to FDG.

218. The three customers purchase on a global or multi-country basis, giving them buyer power over AM and PETNET in the UK: if the UK terms quoted are not satisfactory, the customer can threaten to switch in other territories.

219. GE could self-supply its tracers if it wished using its cyclotron.

220. There is potentially very large global demand for a reliable test for Alzheimer's and many companies are working on a wide-range of different technologies, including blood tests, genetic tests, and the use of biomarkers.

221. If testing using radioactive tracers succeeds and establishes itself as a standard diagnostic procedure, the demand for tracers will presumably be significant which is likely to facilitate new entry by third parties and to support investment for self-supply by the developers.

222. If, on the other hand, testing using radioactive tracers fails to establish itself as a standard, then the (presently small) demand for tracers from GE, Eli Lilly and Piramal will collapse.

223. It is not clear how the market will evolve and any competition analysis is therefore highly speculative and uncertain.

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131 OFT Decision, §126.

XI. RIVALRY ENHANCING EFFICIENCIES: INCREASED COMPETITION IN THE SUPPLY OF FDG IN THE SOUTH

224. The provision by AM of self-back-up supplies in the South (i.e. dual supply) will increase competition in the supply of FDG in the South.

225. Prior to the acquisition of IBA, AM/Erigal's ability to self-back-up in the South was limited because of the distance from its closest northern site, Keele. (By contrast, PETNET, which supplies FDG to InHealth, routinely ships significant volumes of FDG from Nottingham to Mount Vernon despite the distance, and can therefore readily use Nottingham as a back-up facility, by producing and shipping more if necessary.)

226. The absence of reliable self-back-up in the South explains why, other than the long-term exclusive Royal Marsden contract, AM/Erigal had little third party FDG business in the South: it made only occasional deliveries on a Saturday to UCLH and Oxford Churchill (totalling 313 doses p/a).

XII. CUSTOMER BENEFITS: INCREASED COMPETITION IN THE SUPPLY OF PET-CT SCANS IN THE SOUTH, SECURITY OF SUPPLY [REDACTED]

(a) Increased competition in the supply of PET-CT scans in the South

227. One of the main drivers of the Transaction was for AM to rely on its newly established security of FDG supply to be a more effective competitor in PET-CT scanning in the South and in particular to win a reasonable share of the PET-CT scanning business that had been covered by the PET South contract.[132] This is evidenced by the business case for the Transaction.[133]

228. AM believes, based on the evolution of demand for diagnostic services (see Annex 3) that there is a propensity of individual trusts to convert previously outsourced arrangements to self supply, particularly at the time of contracts ending. For AM to be successful in competing strongly in the South, AM believes that security of supply

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132 Prior to the Transaction, AM had none of the business covered by the PET South contract.

133 See Annex 18 to OFT Submission.

and security of back up supply will be key drivers to improve service to customers and increase competitiveness. Reliable back-up supplies are crucial because a failure to carry out scheduled PET-CT scans impacts severely on patient care and is very costly under the terms of PET-CT scanning contracts.[134]

229. AM will be better able to compete for such business because it will have a secure source of FDG in the South, including for back-up purposes, as explained in section (b) below.

230. This benefit was only available through the Transaction: the security of supply arises by bringing production of FDG in-house avoiding the risks and uncertainties of relying on supplies from third parties who may decide at any time to exit given the unattractive economics of the supply of FDG.

231. The benefit arises immediately on the Transaction, and will be of particular significance around the expiry of the PET South contract on 31 March 2015.

232. Customers will benefit from this increased competition in the form of lower prices, higher quality, greater choice or greater innovation.[135]

(b) Security of supply

233. Around 98 per cent. of clinical PET-CT scans occur for patients of NHS hospitals. The balance of clinical supply is for patients of private hospitals.[136]

234. Whilst the shift to Foundation Trusts has meant that purchasing decisions in the NHS have generally been devolved, there has to date been a high level of central NHS/DoH involvement in the purchasing of PET-CT services and, through those purchases, in FDG price (the PET North contract was priced on an open-book basis and the DoH challenged the FDG costs used by AM).

235. The NHS/DoH is very concerned about security of supply because, without a delivery

134 When a PET-CT scanning service provider misses a scheduled scan, it loses the fee from that scan and must subsequently provide the scan at no cost.

135 Enterprise Act 2002, s. 30(1). (The Transaction therefore enhances rivalry in the supply of PET-CT scanning services: this could be analysed as a customer benefit in a market other than FDG or as a rivalry enhancing efficiency; AM believes that the formal categorisation should not affect the substantive analysis.)

136 In addition, small volumes are supplied for research purposes.

of FDG, it is not possible for a hospital to operate its PET-CT scanner. When supplies fail, very vulnerable patients (often suffering from cancer or with suspected cancer) are turned away, their treatment is delayed (with potentially serious consequences) and expensive equipment and staff is unutilised. If cancer waiting times are not met, the hospital could face financial consequences which can be significant.

236. AM believes that IBA approached the NHS/DoH to seek a subsidy to continue to operate its FDG businesses and was refused.

237. Before entering both the Erigal acquisition and the Transaction, AM briefed the NHS/DoH. If the NHS/DoH had objected, AM would not have proceeded with either deal. Following discussions, the DoH wrote a letter to AM on 25 February 2013 supporting the acquisition of IBA under the heading "*Securing surety of FDG[18] supply for the NHS by Alliance Medical Limited*".[137] The letter reflects the considered view of the senior team within the NHS which has a good understanding of the way in which the overall market operates and of procurement within it. AM submits that it is of more probative weight than claims on the OFT's market test that the Transaction will reduce security of supply by reducing the number of independent suppliers in the South.

238. Securing security of supply is a relevant customer benefit in the form of "*lower prices, higher quality or greater choice of goods or services*".[138]

239. The Transaction results in security of supply because:

(a) AM will be able to self-supply all of its primary and back-up requirements of FDG for its downstream PET-CT scanning activities in the South as well as the North. It accounts for around 27 per cent. of all PET-CT scans in Great Britain. This will improve the reliability of AM's PET-CT scanning services across Great Britain, benefiting hospitals purchasing those services and patients using them.

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137 A copy is at Annex 3 to OFT Submission. Contact details for the author of the letter, Professor Erika Denton, National Clinical Director for Imaging at the Department of Health are included at Annex 19 to OFT Submission.

138 S. 30(1)(a)(i).

(b) [REDACTED]

240. The detailed and verifiable evidence to support AM's claims is contained in its internal documents at Annex 18, Annex 20 and Annex 26 to OFT Submission, read with the DoH's letter of support for the Transaction.

(c) [REDACTED]

241. [REDACTED]

XIII. CONCLUSION

242. The market for FDG in the UK is small and cash generation for the competitors in the market overall is low relative to the level of invested capital. Prior to the Transaction, IBA was a loss-making, structurally weak competitor, losing customers and would inevitably have exited from the market. The available market to IBA in the North, historically and prospectively, was such that reopening Dinnington was not feasible and in the South the inevitable loss of customers was weakening its position further.

243. Historically, AM/Erigal has also been a relatively weaker competitor in the South due to proximity of back up. To be successful as a competitor for both FDG and PET-CT scanning services in the South prospectively it required a second production site in the region. To build and license its own would take approximately 12-18 months, which would put it outside of the re-commissioning window for the largest part of the available South market for a period of up to another 10 years and running a second site on a relatively limited scale would simply be loss making and hence uninvestable.

244. The IBA assets are the only ones capable of accommodating the necessary cyclotrons to support [REDACTED] and increase capacity for FDG in the UK

245. Accordingly the acquisition increases the ability of AM to compete in the South providing credible competition to both PETNET for FDG and InHealth for PET-CT therefore enabling at least the possibility of switching. AM will improve quality compared to IBA and price competitiveness, whilst providing increased security of supply for the market in all of the UK. In addition it enables the development of a solution to [REDACTED].

246. AM therefore respectfully requests the CMA to approve the Transaction.