OFFICE OF FAIR TRADING

Completed acquisition by Parexel International Corporation of ClinPhone plc

ME/3736/08

The OFT's decision on reference under section 22(1) given on 29 August 2008. Full text of decision published 4 September 2008.

PARTIES

1. PAREXEL International Corporation (PAREXEL) is a contract research organisation (CRO) based in the United States that provides planning and management related services to pharmaceutical and biotechnology companies. These services include outsourced clinical trial services, clinical trial technology products (under the Perceptive Informatics brand), and consulting and medical communications services.

2. ClinPhone plc (ClinPhone) is a UK public company active in the supply of clinical trial technology, comprising software products and related services. ClinPhone's total and UK turnover was, respectively, £47.3 million and £5.5 million for the year to 29 February 2008.

TRANSACTION

3. PAREXEL acquired the entire issued share capital in ClinPhone through an indirect wholly-owned UK subsidiary for approximately £91million on 14 August 2008. The parties notified the transaction to the OFT on 9 July 2008. The OFT's administrative deadline is 29 August 2008 and the statutory deadline is 8 November 2008.

JURISDICTION

4. As a result of this transaction PAREXEL and ClinPhone have ceased to be distinct enterprises. The parties overlap in the supply of interactive voice recognition services and submit that their combined share of supply does not exceed 25 per cent. However, the OFT believes it is or may be the case, based on third party evidence, that the parties combined share of supply does exceed 25 per cent in the supply of interactive voice recognition services and the share of supply test in section 23 of the Enterprise Act 2002 (the Act) is met. The OFT therefore believes that it is or may be the case that the transaction has resulted in the creation of a relevant merger situation.

MARKET DEFINITION

5. When carrying out clinical trials, pharmaceutical and biotechnology companies are able to carry out the trial in-house or outsource some or all of that trial to a third party CRO such as PAREXEL.

6. Pharmaceutical and biotechnology companies may use bespoke software for their clinical trials, or purchase software under license from independent suppliers (either a CRO or a specialist software supplier such as ClinPhone, sometimes referred to as a Clinical Technology Organisation (CTO)).

Product market

7. The parties overlap in the supply of interactive voice recognition (IVR) services and in providing ancillary technology and integration consulting services in the UK. The parties are also vertically linked in the UK as ClinPhone supply, and PAREXEL purchase, electronic data capture (EDC) software, although PAREXEL does not currently purchase any EDC software from ClinPhone.

8. The parties also overlap outside the UK in the supply of clinical trial management software (CTMS). However, the parties submit there is no UK overlap as ClinPhone currently make no sales in the UK, has never made any sales in the UK and has not sought to make any such sales in the last three years. The OFT therefore does not consider there to be a UK overlap between the parties in CTMS and does not consider CTMS as part of the competitive assessment.

eClinical suite

9. The overlapping products and services all focus on providing clinical trial software and support, and third party competitors indicated that these products form part of an 'eClinical suite' of products, a wide portfolio of clinical trial software and support products that offer very different but complementary functionalities.

10. The OFT considered if there was a wide market reflecting such an eClinical suite of products and containing all of the overlapping products. As the products are not functionally interchangeable the OFT dismisses the possibility of demand-side substitution. On the supply-side, third parties have indicated the main impediment to switching supply between different clinical trial software services is reputation. If a company is active and has a developed reputation in any one or two areas it is therefore relatively straightforward to switch into another area. The OFT notes, however, that there is great variation in the extent of products offered by companies active in the sector. While some companies offer a number of products, others offer only a limited range and are more specialised.

11. Given the mixed evidence in this case, the OFT has taken a cautious approach and considers the market at the narrower level of each product, although competition concerns do not arise on any reasonable market definition. The possibility of consumer harm from the products being bundled as a wider eClinical suite is considered below as part of the non-horizontal competitive assessment.

Interactive Voice Recognition (IVR) Services

12. Interactive Voice Recognition or Response (IVR) is a software programme used to facilitate drug trials by enrolling and randomising patients into different clinical trial groupings, then tracking and managing supplies to those patients. The software is hosted by a licensor and accessed by customers via the telephone.

13. The parties submitted to the OFT that any market for clinical IVR software should include voice, touch-tone or internet recognition software used in other applications and paper-based solutions. The OFT was unable to find any support amongst third parties for inclusion of either of these as part of

a wider market alongside IVR and does not therefore consider them to be part of the relevant product market.

14. The parties also submitted that IVR constitutes both telephone and internet applications. The OFT's investigation, however, has found most third parties distinguish between telephone applications, known as IVR, and web-based applications, known as Interactive Web Response (IWR).

15. On the supply-side, competitors have indicated switching supply between IVR and IWR is straightforward, although one competitor suggested there would be a substantial amount of investment required to switch. The OFT notes that the majority of suppliers appear to provide both IVR and IWR.

16. On the demand-side, third parties generally considered the products to be substitutes, although some customers indicated they were used as complements. There was general consensus among third parties that the products are functionally interchangeable, essentially providing the same service through different applications. IVR is simply a more established technology. Importantly, third parties indicated that customers can choose between them and switching to the other would occur in the event of a price rise in one of the products.

17. On the balance of evidence of both demand- and supply-side substitution, the OFT considers IVR and IWR to form part of the same product market (hereafter, IV&WR).

18. The OFT investigation has also found that customers, predominantly large and sophisticated pharmaceutical or biotechnology companies, can and, in some cases do, supply IV&WR internally. Third parties stated that a shift to develop and supply IV&WR in-house would occur in reaction to any price rise levied by independent suppliers. However, the OFT does not have sufficient information to conclude that all customers (including smaller customers) have the ability to supply internally. Further, suppliers appear to have the ability to discriminate between customers as tendering and bidding for individual projects is common.

19. Given uncertainty over the extent of internal supply capabilities amongst customers, the OFT has taken a cautious approach and does not consider in-house supply to form part of the relevant product market.

Technology consulting and integration

20. The parties submit they overlap in the provision of technology consulting and integration services but only as ancillary services to the supply of their software products. The parties do not consider themselves to be active in any market or markets for the provision of technology consulting or integration services as stand-alone business.

21. Even if the parties' activities in this area are considered distinct, the parties submit their activity in the market would be minimal. There are no distinguishing features, according to the parties between the services they provide, which is simply the integration of data between new software systems (supplied by the parties) and customers' legacy systems, and those offered in relation to other types of software provided by large IT companies such as IBM, Accenture, and EDS.

22. Nevertheless, past European Commission cases[1] in IT services have delineated the market more narrowly. Therefore taking the narrowest approach, consulting services for pharmaceuticals and biotechnology companies, and development integration services for pharmaceutical and biotechnology companies, the parties combined share of supply in the UK would be less than 1 per cent. Given the negligible activity of the parties in this area and the absence of third party concerns the OFT does not consider this overlap further.

Electronic Data Capture

23. EDC software is used by pharmaceutical, biotechnology and life-science organisations to collect clinical trial data in electronic form in the computer system at the clinical site, rather than at a central data management point. ClinPhone is active as a licensor of an EDC product and PAREXEL is a licensee of this type of software, although ClinPhone does not currently license its software to PAREXEL. In order to deliver some of its CRO services, PAREXEL uses EDC products licensed from competitors of ClinPhone (these are solely for PAREXEL's use and PAREXEL does not resell them). Following the merger, PAREXEL would be able to source such software internally from ClinPhone.

[1] See, for example, Comp/M. 4871 *KPN/ Getronics*, European Commission, September 2007.

24. However, the parties submit that ClinPhone's share of UK (or global) EDC supply is less than 5 per cent and PAREXEL is only a minor customer of EDC software (the parties estimate PAREXEL sources less than 2 per cent of all EDC sales worldwide). Given the parties' small presence as supplier and customer the OFT does not consider EDC supply further.

Geographic market

25. In past cases relating to software, and medical software in particular, it has been noted that software can be developed anywhere in the world[2]. The OFT notes that many of the parties' competitors are based in the US and have no UK base. Competitors all considered themselves to be competing on a global basis. However, one competitor indicated that the importance of reputation means that US or European companies can develop software in countries with lower labour costs but it is unlikely that a rival company can emerge from these countries.

26. Past cases[3] have also found a key requirement in marketing and selling a new system, and for customers, the requisite installation (and maintenance) expertise, to be a local presence. However, the need for a local presence has not arisen in this case. Many of the customers in the industry are international pharmaceutical and biotechnology companies that undertake clinical trials globally using the IV&WR provided by US and European companies.

27. The parties submit that the market for IV&WR services is global. Further, third parties have noted that the competitive assessment at a UK and global level would likely be much the same: the same companies are active in similar competitive environments. In the absence of competition concerns on any basis it is not necessary to conclude on the precise scope of the geographic frame of reference. For the purposes of the competitive assessment, however, the OFT has taken a cautious approach and considered the market at a UK level.

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[2] See *Completed acquisition by iSOFT Group plc of Torex plc*, OFT, March 2004. (*iSOFT/Torex*)

[3] Ibid.

HORIZONTAL ISSUES

28. The parties have estimated the total market size for IV&WR services in the UK in 2007 to be £[20-30] million. PAREXEL and ClinPhone, with sales of £[0-3] million and £[3-7.5] million, respectively, have an estimated combined share of supply of just over [15-25] per cent with a merger increment of just [0-10] per cent. According to the parties' estimates, three competitors have a share of supply of between five and ten per cent. The remainder of the market (at minimum just under half) is fragmented and made up of companies supplying less than 5 per cent of the market.

29. A number of competitors disputed the parties' figures considering them to be higher than those estimated. One competitor estimated that combined the parties supplied over half the UK market. The parties were also considered by some customers to be close competitors. However, competitors also indicated that the majority of combined activity was attributable to ClinPhone and the merger increment was small, which is corroborated by the parties' share estimates. ClinPhone was perceived as the leading player in the industry. The OFT understands that ClinPhone has focused on IV&WR to a much greater extent than most competitors who provide these services as ancillary to their core offerings. Some third parties even considered PAREXEL to have limited activity in the area.

30. Despite the indications from competitors that the parties combined share of supply is higher and from some customers that the parties are close competitors, third parties did not generally consider the parties to have any ability to raise prices.

31. The OFT investigation revealed a general perception amongst market participants that the market was highly competitive with a number of alternative suppliers beyond the parties. One large pharmaceutical customer, for example, identified twelve alternative suppliers.

32. Customers stated they regularly use more than one supplier for different projects at the same time and readily switch suppliers. The eClinical industry is characterised by competitive tenders and bidding for each project. One competitor indicated that bidding against other suppliers can occur at three different stages: for each project, in order to obtain preferred

provider status (through framework agreements), and bidding as a preferred provider against other preferred providers.

33. The majority of third party respondents had no horizontal concerns. One customer indicated only a limited number of alternative suppliers but all other customers contacted did not consider this to be a problem. Competitors also indicated a number of alternative suppliers which they compete with regularly.

34. Given the above analysis, the OFT does not consider that it is or may be the case that the merger has resulted, or may be expected to result, in a substantial lessening of competition in the supply of IV&WR services.

NON-HORIZONTAL ISSUES

35. The parties are active in the supply of a wide range of products related to clinical trial support. ClinPhone provides electronic Patient Reported Outcomes (ePRO), Patient Recruitment Solutions, as well as IVR services, EDC, CTMS and technology consulting. These products can be provided together as an integrated eClinical suite.

36. The OFT has considered if the parties would have the ability to force customers into a combined product solution (in other words, a bundle of products) and prevent them from sourcing individual products from multiple suppliers. One competitor raised concerns in this area, although this was based on the assertion that the parties have market power in both IV&WR services and CTMS. Neither of these are borne out by the OFT's horizontal assessment as discussed above. Indeed, the parties would have no product in which they could leverage market power (such as a 'must-stock' product). Further, the OFT notes there is independent demand for each of the products from customers.

37. The parties may engage in a strategy of mixed bundling (offering the products individually and as part of a combined product solution) but they currently engage in this practice anyway and the OFT does not believe the merger would substantially increase the incentives to do so, particularly given the small merger increment in IV&WR services. Many of the parties' competitors also offer both a combined package and individual products

separately to varying degrees and with a variety of products making up competing eClinical suites.

38. As companies in the sector have differing ranges of products within their competing eClinical suites, competitors indicated they often sub-contract a specific element from a competitor to offer the full range the client seeks. No competitor or customer has expressed concerns over foreclosure or refusal to supply, in line with the horizontal assessment.

39. On this basis, the OFT does not consider this transaction to raise any competition concerns in relation to tying, bundling or portfolio effects.

Barriers to entry and expansion

40. Any strategy pursued by the parties to further engage in (mixed) bundling may serve to deter entry. However, competitors are also offering a range of products together and the OFT considers this more likely to be an industry trend driven by customer needs, rather than attempts to tie, exclude, foreclose or cross-subsidise. In the absence of competition concerns it is not necessary to determine the extent of barriers to entry in this case.

Buyer power

41. The parties submitted to the OFT that in the eClinical industry market power resides with the pharmaceutical and biotechnology customer. Customers are large firms and sophisticated purchasers able to play suppliers against each other and exercise consider buyer power. Buyers can use the option to self-supply (even if this is not included in the market, the precedent that one customer sets by self-supplying provides leverage to those sourcing externally), alongside the threat of switching to alternative suppliers, as a benchmark comparator and a source of negotiating power. All competitors confirmed the parties' assertion that customers are large sophisticated buyers with a great deal of buyer power.

42. Some customers also agreed with the parties, believing they can negotiate significant discounts based both on the scale of what they purchased and the scope (negotiating discounts based on sourcing additional products from the same firm, rather than sourcing them independently). While the OFT acknowledges there appears to be a significant amount of buyer

power in this sector, it is not necessary to determine the extent of this in the absence of competition concerns.

Coordinated effects

43. The OFT did not receive any evidence to suggest coordination pre-merger, that either of the parties were disrupting collusion, or that the merger will significantly increase the ability or incentives for coordination in any of the markets assessed. The products are highly differentiated and shares of supply indicate significant asymmetry between suppliers. There is little, if any, transparency (with bidding, competitive tendering and auction processes commonplace). Further, customers appear to have significant countervailing buyer power which could defeat any attempts to coordinate. The OFT therefore do not see any realistic likelihood of coordinated effects arising from the merger.

THIRD PARTY VIEWS

44. Third party responses were received from three customers and five competitors, some of whom are also customers. One competitor asserted that the parties had a majority share of supply in IV&WR services and CTMS, and thus sufficient market power to force customers into a combined solution, neither of which were borne out by the competitive assessment. One customer indicated a limited number of alternative suppliers, which was also not supported by the competitive assessment.

ASSESSMENT

45. The parties overlap in the supply of IV&WR services and technology consulting in the UK. The parties' activity in the latter is minimal. ClinPhone is also a supplier, and PAREXEL a purchaser, of electronic data capture (EDC) software. However, ClinPhone has a minimal share of supply, and PAREXEL is a minimal customer, in this sector.

46. In IV&WR services, third parties suggest the parties are close competitors and have shares of supply higher than the [15-25] per cent estimated by the parties. Despite this, third parties generally consider the market to be highly competitive with a range of alternative suppliers. Further, there

appears to be significant multiple sourcing and switching in the sector. Any attempt to increase prices would be met with such switching.

47. Third parties also confirmed that much of the combined activity in IV&WR would be attributable to ClinPhone and the merger increment is low.

48. The OFT does not consider that the merger raises competition concerns in relation to tying, bundling or portfolio effects relating to an integrated eClinical suite. There is no product in which the parties could leverage market power, competitors also offer competing eClinical suites, and customers can retaliate by sourcing products independently from more than one supplier.

49. There also appears to be some evidence of countervailing buyer power. Customers are mainly large sophisticated pharmaceutical and biotechnology companies that source a range of products in the eClinical industry and with the potential to supply internally. However, in the absence of competition concerns, it has not been necessary to determine the extent of any countervailing buyer and, for similar reasons, the extent of barriers to entry.

50. No evidence has been presented to the OFT to suggest that the proposed merger would create or strengthen coordinated behaviour in the industry.

51. Consequently, the OFT does not believe that it is or may be the case that the merger has resulted, or may be expected to result, in a substantial lessening of competition within a market or markets in the United Kingdom.

DECISION

52. This merger will therefore not be referred to the Competition Commission under section 22(1) of the Act.