OFFICE OF FAIR TRADING

Completed acquisition by IVAX International GmbH of 3M Company's distribution business for certain asthma products

The OFT's decision on reference under section 22 of the Enterprise Act 2002, given on 20 October 2003

PARTIES

IVAX International GmbH (IVAX) manufactures and supplies pharmaceutical products including products for treating asthma. For the financial year to 31 December 2002, IVAX's UK turnover was approximately (see note 1).

3M Company (3M) also manufactures and supplies pharmaceutical products including those for the treatment of asthma. In the financial year to 31 December 2002, 3M's turnover was US$16.3 billion. The turnover of the part of 3M's business being acquired was (see note 1).

TRANSACTION

IVAX has acquired 3M's distribution business for certain asthma treatments operating in the UK, Ireland, Germany, France, the Netherlands, Norway, Sweden, Finland and Denmark for (see note 1).

The transaction was notified by IVAX on 31 July 2003. The 40 working day administrative deadline expired on 16 September 2003. The merger was completed on 1 October 2003 and the statutory deadline expires on 31 January 2004.

JURISDICTION

As a result of this transaction, the distribution businesses of IVAX and 3M for asthma treatments have ceased to be distinct. The parties overlap in the supply of salbutamol sulfate (salbutamol) and beclomethasone dipropionate (BDP) inhalers in the UK and the share of supply test in section 23 of the Enterprise Act 2002 (the Act) is met. The OFT believes that it is or may be the case that a relevant merger situation has been created for the purposes of section 22(1)(a) of the Act.

RELEVANT MARKET

Product market

Asthma treatments comprise molecules that relieve or prevent the symptoms of asthma, which are administered through an inhaler, orally in tablet or liquid form, or by injection.

In terms of the molecule, the parties overlap in the supply of salbutamol (a short-acting beta$_2$ agonist) used to relieve the symptoms of asthma, and BDP (a corticosteroid) used to prevent the symptoms of asthma. In this respect, salbutamol and BDP are not substitutes for each other but, for some patients, may be complementary treatments. The parties have, in the past, both supplied BDP treatments but the IVAX and 3M chloroflurocarbon (CFC) BDP based inhalers are in the process of being withdrawn (see note 2) and so the merger itself gives rise to no competition concerns in this sector which is not considered further.

The parties have indicated that other reliever molecules such as terbutaline are clinically substitutable for salbutamol. However, from a demand perspective, salbutamol (unlike terbutaline) is available in generic form and doctors are incentivised to prescribe generic treatments. Moreover terbutaline is substantially more expensive and it is therefore unclear to what extent terbutaline is an effective demand side substitute for salbutamol.

In terms of the method of delivery, there are various types of salbutamol inhalers including CFC or hydrofluoroalkane (HFA) metered dose inhalers (the so-called 'click and breathe' form of delivery); CFC or HFA breath actuated inhalers; and dry powder inhalers (see note 3). A reliever molecule can, theoretically (but not always), be administered through all these different types of inhalers, although not all combinations are commercially available. At its narrowest, the parties are currently the only suppliers of salbutamol in the form of HFA breath actuated inhalers.

On the demand side, the type of inhaler prescribed depends on various factors including the age of the patient, their physical co-ordination, the size of the inhaler and the side effects the patient might experience. Prescription policy and practice within the UK suggests that patients experiencing asthma symptoms for the first time are likely to be prescribed a salbutamol metered dose inhaler (not least because this is the cheapest form of delivery). It is not clear in what circumstances a patient would switch from a metered dose inhaler to some other form of delivery but an inability to co-ordinate the click and breathe delivery or patient preference might be factors. Since all these inhalers are supplied under prescription, patients will pay the standard prescription charge unless they are exempt. Patients are thus not aware of cost prices and are likely to be price insensitive. It is unclear to what extent prescribing doctors are price or budget sensitive as they will prescribe the treatment that is clinically most appropriate, although they are incentivised to control prescription costs by the Primary Care Trust. The parties have stated that for patients with poor co-ordination, a metered dose inhaler with a spacer, a breath actuated inhaler, or a dry powder inhaler may be prescribed as an alternative to a metered dose inhaler. Generally, however, there appears to be little switching between different types of inhaler once a patient is

prescribed a particular type to which they are suited. The evidence available to the OFT (including evidence on prices) has not enabled us to conclude with any certainty that dry powder inhalers or metered dose inhalers with spacers are demand side substitutes for breath actuated inhalers.

On the supply side, manufacturing processes vary for the different inhalers and it is unlikely that a supplier of one type could quickly and with minimal cost switch to producing another, particularly for breath actuated inhalers where the parties hold patents for the only products licensed and approved by the Medicines and Healthcare Products Regulatory Agency (MHRA). It is noted that this merger does not involve the transfer of any manufacturing capability.

On the basis of the evidence available, the OFT takes the cautious view that the appropriate frame of reference in this case appears to be the distribution of salbutamol HFA breath actuated inhalers.

Geographic market

National regulations governing the manufacture, distribution and prescription of asthma treatments as well as variations in price and medical practice between countries suggest that a national market is the most appropriate frame of reference at the distribution level.

HORIZONTAL ISSUES

The prices of these pharmaceutical products are regulated by the Pharmaceutical Price Regulation Scheme (PPRS) which seeks to set the 'list price' at which they will be supplied to wholesalers (but does not prevent wholesalers from seeking to negotiate volume discounts). The PPRS is a voluntary scheme between the Department of Health (DoH) and the pharmaceutical industry which aims to control profits on branded prescription medicines sold to the NHS (generic drugs are not covered). The DoH, through the Prescription Pricing Authority, also administers the Drug Tariff which sets the price paid by the DoH to pharmacies for these products.

Where profits earned by a manufacturer on branded medicines exceed an agreed cap, the excess profit is returned to the NHS; similarly if the manufacturer does not achieve its profit level then it may increase the price of certain selected products if the DoH agrees. Price increases in one branded medicine may be offset by price decreases elsewhere in the manufacturer's portfolio – the scheme focuses on profits across the company, rather than the price (and profits earned) from a particular treatment. These arrangements do not mean, however, that it is necessarily always in a supplier's interest to charge the maximum allowable price or to seek to remedy a financial shortfall by increasing the price on a given product to the maximum extent allowed under the scheme. The scheme sets price ceilings rather than a fixed price for each product. It is reasonable to assume that suppliers will take into account the effect on their sales levels, and therefore on their profits, that a price change would have. In theory, therefore, a merger involving companies supplying products that are close substitutes for one another will affect pricing incentives because, in setting prices, each supplier no longer has to be concerned about sales foregone to the other.

In practice, however, it appears that once a price is set when a product is introduced, it is not often reduced subsequently (except as part of the offsetting arrangement discussed above). This might be, for example, because suppliers perceive that, once a price reduction is made, it is difficult to reverse under the terms of the scheme. In this case, it seems unlikely therefore that the merger would significantly affect the prospects for price reductions. There does seem a reasonable prospect, however, that the transaction will increase the incentive for the parties to seek price increases where these are allowed under the scheme for the reasons set out above.

Market shares

As noted above, current government directions indicate that CFC propelled inhalers are to be phased out by the end of December 2003. Therefore, as of January 2004, the parties will become the sole supplier of salbutamol (HFA) breath actuated inhalers in the UK. IVAX only entered this sector of the market in 2001 (see note 4); prior to that date 3M had been the sole manufacturing supplier to the UK. By 2002, IVAX represented 60-70 per cent (see note 5) of the supply of salbutamol HFA breath actuated inhalers in the UK; figures from the parties suggest that for the year to July 2003 this had further increased to 80-90 per cent (see note 5). It appears that in the context of the supply of salbutamol HFA breath actuated inhalers, the parties have been effective competitors.

Barriers to entry and expansion

The costs of setting up a distribution business, including advertising costs, particularly for an 'own brand' supplier (which repackages the products of other manufacturers) are considered to be low. However, such businesses would need access to breath actuated inhalers. The salbutamol molecule itself is available as a generic and a number of companies are developing HFA breath actuated inhalers to be used with this particular molecule. Both IVAX and 3M have invested heavily to develop breath actuated inhalers and it is apparent that the technical difficulties and the costs of developing these products and gaining appropriate licences are significant. From evidence obtained by the OFT, it appears unlikely that new entry will occur within the near future.

Buyer power

Within the supply chain the immediate customers of distributors such as the parties are predominately pharmaceutical wholesalers, who sell on to the independent or vertically dependent retailers (pharmacists and supermarkets with in-store pharmacies). As noted above, larger wholesalers are able to benefit from volume discounts. It is arguable that the DoH possesses buyer power due to the range of products it purchases from the companies. Any existing countervailing buyer power that the DoH does have through the PPRS may be weakened as a result of the transaction by the removal of one of the only two suppliers of salbutamol HFA breath actuated inhalers (see note 1)

THIRD PARTY VIEWS

Customers and competitors generally expressed few concerns about the merger with wholesalers and retailers (pharmacies) noting that they were required to stock a full range of asthma treatments to meet doctors' prescriptions (see note 4).

ASSESSMENT

The merged entity will have a monopoly in the supply of salbutamol HFA breath actuated inhalers. On the evidence available to it, the OFT is unable to conclude with any certainty that other asthma treatments would operate as a constraint on the parties post-merger. New entry appears to be costly and may take some time. This may not be sufficient to allay concerns that the parties could raise prices post merger. Although prices are regulated by the DoH through the PPRS, the merger changes the incentives of the parties by means of lessening the competitive constraint faced by IVAX. Moreover, the transaction lessens any existing countervailing buyer power that DoH might have and could lead to increased prices to the DoH in respect of the supply of salbutamol breath actuated inhalers.

In these circumstances, the OFT believes that it is or may be the case that the creation of the relevant merger situation has resulted or may be expected to result in a substantial lessening of competition within a market or markets in the United Kingdom for goods or services.

UNDERTAKINGS IN LIEU

Having concluded that the transaction should be referred to the Competition Commission, we have considered whether there might be some undertakings in lieu of reference, pursuant to section 73 of the Act, which would address the concerns we have outlined above. IVAX has indicated that it is willing to offer a behavioural undertaking not to increase the price of their salbutamol HFA breath actuated inhalers until a new supplier enters this sector. The competition concern relates to the ability of the merged company to increase the price of these products. Given the particular structure of this sector, the proposed undertaking would address that concern.

DECISION

This merger will therefore be referred to the Competition Commission unless IVAX gives suitable undertakings pursuant to section 73 of the Act to address the competition concern outlined above.

NOTES

1. Information excised at parties' request.
2. Current government directions require that the supply of CFC propelled inhalers be phased out in the UK by the end of December 2003 – manufacture of these products for the UK market has already ceased.
3. Dry powder inhalers do not need a chemical propellant.
4. Information excised at request of third parties.
5. Figure replaced by a range at the parties' request.