

FORECLOSURE: A CASE STUDY FROM THE PHARMACEUTICAL INDUSTRY

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The patented protection of intellectual property rights is fundamental if the incentive to innovate is to be maintained. In this paper, Conor Flanagan examines the contentious issue of foreclosure in the pharmaceutical industry. Genzyme, as the sole providers of an essential medical treatment, held considerable power with regards to price setting. Although Conor recognizes that the firm in question foreclosed on the downstream market, this was acceptable given their right to extract monopoly profit from a patented product. By distinguishing between static and dynamic efficiency, he concludes that the firm in question was incorrectly convicted, to the detriment of societal welfare.

Introduction

This essay analyses a supposed foreclosure in the pharmaceutical industry and its subsequent investigation by the United Kingdom's Office of Fair Trading (OFT). Section I reviews the terms and concepts that are essential to understanding the case. Section II gives the background to the case, defines the relevant markets, assesses market power and finds that foreclosure did take place. Section III argues that there was no obvious anti-competitive motive for the foreclosure. Section IV sifts through the welfare implications of the foreclosure and the OFT's investigation. While static efficiency may have been harmed, the benefits to dynamic efficiency mean the foreclosure is justifiable in welfare terms. The OFT's erroneous finding of abuse may itself have caused significant harm. The essay concludes with a discussion of the broader implications of the case.

I. Foreclosure and Margin Squeeze

‘Foreclosure refers to a dominant firm’s denial of proper access to an essential good it produces, with the intent of extending monopoly power from that segment of the market to an adjacent segment’ (Rey and Tirole, 2007: 2148).

There are a number of exclusionary strategies a firm can use to achieve foreclosure such as bundling, tying, refusal to supply and exclusive distribution. A practice known as a margin squeeze is of interest in this case:

‘A price [or margin] squeeze arises when a [firm], with market power in the provision of an ‘essential’ upstream input prices it, and/or its downstream product or service in such a way and for a sufficiently long period to deny an equally or more efficient downstream rival a sufficient profit to remain in the market’ (Crocioni and Veljanovski, 2003: 30).

There are two criteria which must be satisfied in order to judge that a margin squeeze has occurred. Firstly, it should not be of a temporary or short-term nature but of long enough duration to have an exclusionary effect. Secondly, it should have the effect of making equally or more efficient downstream competitors unprofitable (Crocioni and Veljanovski, 2003).

An imputation test can determine if the second criterion is met. The EU employs two versions of the test to determine if a margin squeeze has taken place:

‘The dominant company’s own downstream operations could not trade profitably on the basis of the upstream price charged to its competitors by the upstream operating arm of the dominant company’ (EU Commission, 1998 quoted from Crocioni and Veljanovski, 2003: 50).

‘The margin between the price charged to competitors on the downstream market for access and the price which the [upstream firm] charges in the downstream market is insufficient to allow a reasonably efficient service provider in the downstream market to obtain a normal profit’ (ibid: 50).

II. Case Study: Genzyme and the Market for Enzyme Replacement Therapy¹

Enzyme replacement therapy (ERT) is the preferred treatment for Type I Gaucher Disease², a rare enzyme disorder affecting approximately 180 people in the U.K. Cerezyme, produced by Genzyme, is the only ERT drug on the market.

There are two relevant product markets in this case.³ The first is the upstream market for drugs to treat Gaucher Disease. Other methods can be used to treat Gaucher Disease, but they are relatively ineffective and are authorised to be used only when ERT is unsuitable. Genzyme faces no current competition in the upstream market on the demand side. The entrance of new suppliers, either now, or in the short- to medium term, is not particularly likely. Genzyme holds patents for the substance itself, and over the production process. Furthermore, the production methods and knowledge that other biotechnology and pharmaceutical firms have developed are not easily transferable. In addition to this, potential entrants will not be incentivised to enter, as Genzyme was. They are unlikely to be afforded the benefits of an ‘Orphan Medicinal Product’⁴ classification now that a treatment exists. With no current competitors and significant barriers to entry Genzyme’s degree of dominance is such that it could be classed as a monopolist in the upstream market.

The second relevant market is the downstream market for home treatment.⁵ There are already a number of firms that supply a similar style of home treatment to patients suffering from other illnesses. The conversion costs would not be so high as to block entry. Cerezyme is an essential facility for firms wishing to take part in this market. A firm that could not access Cerezyme could not offer a service. Once firms have access to Cerezyme, the downstream market offers some scope for competition.

The NHS operates and makes agreements on a national basis. The patients

¹ This section draws heavily on the Decision of Director General of Fair Trading (27/03/2003) ‘Exclusionary Behaviour by Genzyme Limited’, Office of Fair Trading, No. CA98/3/03, hereafter OFT (2007)

² There are two other, more serious, types of Gaucher disease for which there is no treatment. From this point on, Type I Gaucher Disease is referred to as Gaucher Disease

³ To allow a structured and clearly bounded analysis of market power, potential abuses and welfare effects, it is necessary to determine the relevant markets, from both a geographic and product market point of view.

⁴ See Section IV for further discussion of this classification.

⁵ Home treatment involves provision by a nurse, refrigerated storage and delivery of Cerezyme.

are U.K. residents receiving services at home. This is sufficient to define the United Kingdom as the relevant geographic market.

Following a complaint by Healthcare at Home (HH), the OFT launched an investigation into Genzyme's behaviour. Genzyme supplies the NHS with Cerezyme at a price regulated by the Pharmaceutical Price Regulation Scheme. The NHS pays the same price for the drug whether it carries out the treatment themselves, or if Genzyme, or one of their agents carries out the treatment at a patient's home. Home treatment is, in effect, bundled with the drug at no additional cost.

HH provided home treatment on behalf of Genzyme until 2003, when the contract that it had successfully bid on expired. It was paid a fixed fee by Genzyme. When the contract ended, Genzyme appointed one of its subsidiaries to provide home services instead. HH wanted to stay in the market and so tried to buy Cerezyme from Genzyme. Genzyme charged HH the same price that it charged the NHS for Cerezyme and home treatment, leaving HH unable to cover costs, let alone make a profit.

This pricing policy, which prevented HH from effectively competing with Genzyme in the downstream market, would undoubtedly lead to Genzyme 'failing' both imputation tests discussed above. The price that Genzyme charged HH for Cerezyme, combined with Genzyme's bundling of home treatment with Cerezyme to the NHS, ensured no firm buying Cerezyme at that price could be profitable. Genzyme also fulfilled the first criteria for a margin squeeze, as there was nothing to indicate that their pricing policy was of a transitory nature. Genzyme did indeed employ a margin squeeze, by means of bundling, to foreclose on the downstream market. The OFT investigation found this to be an abuse of market power.

III. Motives for Foreclosure: Did Genzyme have Anti-Competitive Intentions?

It has been established that Genzyme foreclosed on the downstream market. What has not been explained is why? Did Genzyme have an anti-competitive motive or intent? The traditional view, that foreclosure is motivated by a desire to extend monopoly power, was to some extent rebuked in the 1970s by the Chicago School (Crocioni and Veljanovski, 2003; Rey and Tirole; 2007). They argued that since there is only one final product, there is only one monopoly profit. It does not pay to extend a monopoly. Any extra profit extracted downstream will be at the expense of profit upstream. Foreclosure is benign and pro-competitive. A monopolist could only profitably foreclose on a market if it was more efficient

that anyone else in the market.

Later work rightfully asserted that the results of the Chicago model are contingent on two assumptions (Crocioni and Veljanovski, 2003). The first assumption is strict complementarity of the upstream and downstream inputs.⁶ The second is a competitive downstream market. Anti-competitive foreclosure could be rational if these assumptions were relaxed. Crocioni (2007) argued that the assumptions behind the Chicago model do hold in the case of Genzyme. A fixed amount of Cerezyme is needed to provide a fixed amount of home treatment. The downstream market is, as discussed above, competitive, or at least has the potential to be so.

Crocioni (2007) also discussed the concept of ‘dynamic’ foreclosure. A firm may engage in ‘dynamic’ foreclosure not to extend its monopoly downstream, but to prevent firms from eventually threatening its upstream monopoly. It is hard to see how Genzyme’s foreclosure could be of a ‘dynamic’ nature. The skills and knowledge developed by firms in the downstream industry are not the same skills and knowledge that would be needed to overcome the upstream entry barriers.

The OFT developed a more complex argument derived from this concept of ‘dynamic’ foreclosure. It argued Genzyme could increase the upstream barriers to entry by foreclosing on the downstream market. Potential entrants into the upstream market need authorisation to sell their product. To get this authorisation, entrants need to test their product on patients. Genzyme, with its control of the downstream market, controls access to patients. They could prevent potential entrants from testing their products and thus entering the market by refusing to supply patients with any drugs but their own. What the OFT overlooked was that these patients need not be tested in the U.K. Authorisation is a European Union matter. Genzyme does not operate in the downstream market, and hence does not have the ability to control access to patients in every country where it sells Cerezyme. It would be possible for a firm to use the results of tests in a different jurisdiction to gain authorisation to compete in the U.K. market.

Rey and Tirole (2007) present a model in which foreclosure is motivated by a wish to retain, rather than extend, the upstream monopoly. Unless all transactions are fully observable, an upstream monopolist might not be able to credibly commit to supplying each downstream buyer with a quantity sufficient to produce the monopoly output. Although the upstream firm has monopoly power, it cannot achieve a monopoly outcome. If the upstream monopoly were

⁶ This means the proportion of upstream inputs needed to produce the downstream output is fixed.

efficiency enhancing, then this type of foreclosure would be pro-competitive.

The upstream monopolist can solve the commitment problem by excluding all but one firm from the downstream market. This can be done by integrating downwards and refusing to supply other firms. An alternative way to solve the commitment problem is to deal exclusively with a single downstream firm. Genzyme's actions were in keeping with the behaviour of a firm trying to solve the commitment problem. Prior to the margin squeeze strategy, Genzyme dealt exclusively with HH. Once it is recognised that a margin squeeze and a refusal to supply are different means to the same end (Crocioni, 2007), it becomes clear that the downstream market was always foreclosed. All that changed was the method of foreclosure.

Why the switch from exclusive distribution to vertical integration? One can only speculate. Perhaps Genzyme learned over the course of the contract that the size of the market combined with the transaction, contracting and potential reputation costs meant that compared to exclusive distribution, vertical integration was a preferable method of foreclosing the market. The onus is on the competition authority to prove guilt, not the accused to establish innocence. In this case there was nothing to suggest that Genzyme's foreclosure had an anti-competitive motive.

IV. Welfare and Efficiency: Consequences of Foreclosure

Foreclosure is problematic from a welfare standpoint because it eliminates downstream competition. Competition's value is not intrinsic, but rooted in its ability to improve efficiency and welfare. There are three types of efficiency to be considered: allocative, productive, and dynamic.

The chief problem associated with a monopoly is its allocative inefficiency. With prices above, and quantity below their competitive level, there is a deadweight loss. However, if demand is perfectly inelastic, the demand curve is vertical and there is no dead weight loss (Motta, 2004). Furthermore, the less elastic demand is, the smaller the deadweight loss would be. In the Genzyme case, it is reasonable to assume downstream market demand to be extremely inelastic. The drug and home treatment are complementary goods and the latter is by far the cheaper of these. When two goods are complementary, the cheaper of the two is more inelastic. The greater the price differential between the complements, the greater is the difference in elasticities. This downstream inelasticity is compounded by the upstream inelasticity of Cerezyme. Pharmaceuticals, such as Cerezyme are, by their very nature, highly inelastic. Health insurance, particularly government administered insurance such as in the

U.K. market, decreases the incentive for agents to consider prices, further adding to inelasticity. Consequently the loss of allocative efficiency resulting from the foreclosure would be very small.

The incentives of society and the firm are aligned with regard to productive inefficiency. A common solution to productive inefficiency is to outsource onto a competitive market. If productive inefficiency were a major concern for Genzyme, it would not have integrated vertically, as it did. If productive inefficiency was not a major worry amongst the informed decision makers within Genzyme, then it should not be a major concern for society either.

Although the effect on static efficiency may be low, the foreclosure does lead to a transfer of surplus from consumers to Genzyme. This may be undesirable from a static consumer surplus perspective. However, it is desirable from a dynamic efficiency standpoint. Dynamic efficiency is concerned with innovation. Patents allow those who innovate a temporary monopoly over the fruits of their research. Without them, firms would be less willing to take on the risks, investment and fixed costs associated with innovation. Others could free ride on their research, which is non-excludable, driving down profits and leaving the innovating firm unable to recover their fixed costs. A balance has to be struck between fostering competition and creating the incentives for innovation. In trying to solve this trade-off, there are five circumstances in which a competition authority should give more weight to static than dynamic considerations (Crocioni, 2007). In the Genzyme case, two of these circumstances are of particular relevance: first, if the downstream market is large compared to the upstream market; second, if imposing an obligation to supply is relatively easy, low cost and unlikely to cause distortions.

Setting the price at which Cerezyme would be available to downstream firms would be complicated and costly when compared to the size of the downstream market, which is small, both relative to the upstream market, and in absolute terms. The circumstances of this case imply the OFT should have weighed the dynamic considerations much more heavily than static considerations, which were small to begin with.

Even from a legal standpoint, refusing to supply intellectual property rights is an abuse only in exceptional circumstances, such as in *Magill* (Whish, 2003). In this case, it was ruled that television broadcasters were obligated to supply a magazine, *Magill*, with the right to print T.V. listings. The circumstances were said to be exceptional because the innovation needed to develop T.V. listings was not worthy of legal protection (Motta, 2004). These circumstances certainly do not apply in the Genzyme case, because the innovation in question is undoubtedly worthy of legal protection.

From both an economic and legal perspective, there was nothing

illegitimate about Genzyme extracting a regulated monopoly profit. The patent endowed Genzyme with this right. The OFT was wrong to consider the ‘substantial profits’ resulting from the foreclosure to be proof of an abuse of market power. The very purpose of a patent is to ensure an innovator is rewarded for their innovation. Foreclosure is not intrinsically harmful. It can improve dynamic efficiency by: ‘compensating the bottleneck for its investment or activity’ (Rey and Tirole, 2007: 2201).

Cerezyme would never have been developed without the incentive of a patent. By taking away the benefits of this patent *ex post* two hands of government, working independently, held up Genzyme. This may benefit consumers in the short run, but ultimately will hurt dynamic efficiency not just in this market, but also in the other sectors of the economy where innovation and patents are important. The harm that a competition authority can do to dynamic efficiency by committing a type 1 error, a ‘false positive’, is far greater in an emerging market,⁷ such as the upstream market, where innovation is important. Although the government did not make a ‘conscious’ decision to hold up Genzyme, it did show an inability to live up its obligations and enforce the patent. In future this will lessen the government’s ability to credibly commit to protecting patents, deterring firms from investing in the risky process of innovation. It is imperative for competition authorities to tread lightly when dealing with cases in emerging markets.

Cerezyme was classified as an ‘Orphan Medicinal Product’ by the E.U.⁸ This granted Genzyme benefits above and beyond that of a normal patent⁹. By wrongly punishing the producer of an ‘orphan’ drug the OFT discouraged innovation where it was most needed, in an area already lacking in incentives. It is a telling indictment of the OFT’s investigation that its report makes no reference to consumer harm when discussing the supposed abuse and the penalty to be imposed.

When considering the welfare implications of this case, it is certainly relevant to consider the costs of the investigation. The market for Cerezyme is small and the market for downstream provision smaller still. Even if there were efficiency gains to be made, they would have to be quite large to overcome the costs to society of the investigation, and the legal proceedings that followed.

Although there is scope for downstream competition, how desirable is it

⁷ Crocioni (2007) discusses both emerging markets and the cost of errors by competition authorities when dealing with them, in great detail.

⁸ This classification is designed to encourage innovation in the treatment of rare diseases, where a low potential user base inherently limits profits.

⁹ Such as extended marketing exclusivity, research grants and fee exemptions

really? Markets do not function without costs. They have transaction and contracting costs. These costs can be significant when a market is as small as the downstream market in this case. The NHS was opposed to downstream competition. It opposed Genzyme's strategy, not because it prevented competition, but because it wanted a single provider of home treatment for all drugs (OFT, 2007). Genzyme itself obviously did not want downstream competition either. Who did apart from HH?

A final potential welfare concern is that assets were stranded with HH as a result of the foreclosure. However, it should be remembered that HH did willingly take on this risk when it signed the contract with Genzyme. The competition authority should not provide ex post insurance for a firm after a risky contract it signs does not go in their favour. This will only encourage inefficient decision-making and moral hazard. Furthermore, there may be a potential for the assets to be converted for use in providing home treatment for other drugs.

Conclusion

Genzyme foreclosed on the downstream market with the intention of re-capturing its monopoly profit. It did this first via dealing exclusively with HH, and then by vertically integrating and initiating a margin squeeze. It is clear the OFT's finding of abuse was wrong and harmful to both total welfare and long-run consumer surplus, once dynamic welfare is considered.

This case demonstrates foreclosure can have positive effects.¹⁰ Competition authorities should treat foreclosure with a rule of reason, not per se rules. Different means (exclusive distribution, bundling, and margin squeeze) to the same end (foreclosure) should be treated consistently. When nothing but the method of foreclosure changes, intervention by a competition authority is unwarranted.

Competition authorities should also be cautious when using imputation tests. They are a poor substitute for a test that considers the change in consumer surplus or welfare resulting from a foreclosure. Although they may reveal the existence of a margin squeeze, and thus foreclosure, they say little about the possible benefits of the foreclosure. Imputation tests do tests have

¹⁰ As well as serving to reward firms for innovating and snuffing out markets whose existence is not welfare enhancing, it also can reduce monitoring costs, uncertainty relating to associating a product with a poor quality downstream service/good and other costs associated with a competitive market (Rey and Tirole, 2007).

value, but they are no *deus ex machina*.

Competition authorities should be careful when dealing with intellectual property rights, especially in emerging markets. Errors can cause great harm beyond that of the market in question. Property rights are the natural solution to expropriation and a fundamental right (Motta, 2004). Competition authorities should be wary of revoking them. To do so creates uncertainty for firms considering investing in innovation. Rules need to be developed regarding the obligation to supply essential facilities, which result from innovation, and are under patent. By removing ex post uncertainty, such rules would encourage innovation and improve welfare.

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