Is the Current UK System of Pharmaceutical Price Regulation Working?

Related Lawyers: Lesley Hannah

On 7 December 2016, following a three and a half year-long investigation, the UK Competition and Markets Authority (“CMA”) levied an £84.2 million (over $105 million U.S.) fine on the pharmaceutical manufacturer Pfizer and a £5.2 million fine on its distributor, Flynn Pharma, for excessive pricing of Pfizer’s epilepsy medication Epanutin (phenytoin sodium capsules) following its “de-branding”[1] in September 2012. Thereafter, Pfizer increased the price of the then unbranded drug from £2.83 for a 100mg pack to £67.50 (a 2,300% increase to more than $80 U.S.).

The CMA found that both Pfizer and its distributor Flynn Pharma held a dominant position in their respective markets for the manufacture and distribution of phenytoin sodium capsules, and that they had abused that dominant position by charging excessive and unfair prices after its de-branding.

UK Price Regulation in the Pharmaceutical Industry

The prices of branded[2] prescription drugs have been regulated in the UK since 1957 pursuant to a voluntary agreement between the Association of the British Pharmaceutical Industry (“ABPI”) and the UK Department of Health, which applies to all branded, licensed prescription drugs available on the National Health Service (“NHS”). The arrangement is called the Pharmaceutical Price Regulation Scheme (“PPRS”). The aim of the PPRS, which has regularly been renewed over the past fifty years, is to secure reasonable prices for the NHS while ensuring that a pharmaceutical producer can achieve a fair return on its investment in research and development. When a company that supplies branded drugs to the NHS has not signed up to the voluntary PPRS, the prices it charges to the NHS for its branded product are regulated by The Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008[3] (the “Branded Medicines Prices Regulations”). The PPRS does not apply to non-branded (hereinafter “generic”) version of a drug once it has been de-branded.

The PPRS and the Branded Medicines Prices Regulations regulate branded pharmaceutical prices in different ways. The PPRS regulates the profits that manufacturers are allowed to make on their sales of branded drugs to the NHS, by limiting increases to the overall cost of the branded product.[4] The general rule is that no PPRS member can increase the NHS “list price” of a product regulated by the scheme without the Department of Health's prior approval.[5] Such approval is generally only granted when the PPRS member can show that its estimated profits are likely to fall below a certain level. An allowance is made for the costs of research and development in the calculation of the level of profits permitted in relation to a specific branded prescription drug.
In contrast, the Branded Medicines Prices Regulations control the maximum price of prescription-only branded drugs supplied to the NHS. The initial price of such a drug under the Branded Medicines Prices Regulations is set by the Secretary of State and is generally reduced each year by an amount set out in the Regulations. Increases in price may only be made with the consent of the Secretary of State.

In September 2016, the UK government tabled, for future consideration, a bill on prescription drug pricing reforms which would reform the current system.[6] The aim of the reform is to harmonize the price regulation of all prescription drugs—both branded and generic—and ensure greater savings for the NHS. Currently, the voluntary PPRS delivers greater savings to the NHS than the statutory Branded Medicines Prices Regulations scheme. The reform is important because one of the problems with the current pharmaceutical price regulation provisions is that a pharmaceutical manufacturer or supplier member of the PPRS that produces/supplies both branded and prescription drugs faces no statutory price controls over the unbranded version. The tabled Bill would enable the Secretary of State to regulate the price of generic prescription drugs, even when the manufacturer or supplier is a member of the PPRS and produces both branded and prescription drugs. Over 150 pharmaceutical manufacturers and suppliers are members of the PPRS. Accordingly, if the Bill is passed, it would have a very significant impact on the permissible prices for generics, which currently escape price regulation or control in the UK where they are manufactured by pharmaceutical manufacturers who also produce branded prescription drugs.

**Current UK Competition Act Investigations In the Pharmaceutical Sector**

Pfizer is not the only pharmaceutical manufacturer to be sanctioned by the CMA recently for excessive and unfair pricing of a generic drug in the UK. In December 2016, the CMA also made a provisional finding of excessive pricing and breach of the Chapter II prohibition of the Competition Act 1998 against Actavis UK (formerly Auden McKenzie) in relation to generic hydrocortisone tablets. The company increased the price of its 10mg hydrocortisone tablets from 70 pence in April 2008 to £88 per pack (more than $110 U.S.) by March 2016 (an increase of 12,500%). It also increased the price of 20mg hydrocortisone tablets from £1.07 per pack to £102.74 (more than $125) in March 2016 (an increase of 9,500%).

Because the decisions against Pfizer, Flynn Pharma and Actavis are not public, the exact basis on which the CMA found the price rises to be excessive and therefore an abuse of dominance is unknown. In a press release,[7] Flynn Pharma contended that the CMA's decision was based on “wholly flawed understanding of the UK pharmaceutical market,” and warned that the decision may have “unintended consequences on future investment in, and availability of, generics”. Flynn Pharma asserted that the CMA's decision was based on “an entirely novel theory as to the level of margin that can be made by a generic company”. It appears that Flynn Pharma's position related to the CMA's use of the PPRS pricing model as a benchmark in determining Pfizer and Flynn's pricing to be excessive.[8] Both companies have now confirmed they will appeal the CMA's decision. Flynn Pharma's application to the Competition Appeal Tribunal (“CAT”) for interim relief from the price reductions imposed by the CMA was denied on 19 January 2017.[9]

**What Is An “Excessive” Price?**

The leading European case on excessive pricing is United Brands v Commission,[10], in which it was ruled that a price is unlawfully excessive when “It has no reasonable relation to the economic value of the product supplied”. This could then constitute an abuse of a dominant position when a dominant undertaking has made use of the opportunities arising out of its dominant position “in such a way as to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition”. The Court of Justice of the European Union (“ECJ”) declared in that decision that the questions to be asked in determining whether there is an abuse of dominance is “whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products.” Various methods of determining the product's relationship to its economic value could be used, including: a cost/price analysis; comparing the dominant firm's prices with that of others in the market; or comparing undertakings across the market generally. To date, the European Commission has not focused on cases of excessive pricing, and the current European Commissioner for Competition, Margrethe Vestager, has recently declared that this is an example of where national competition authorities should be active, particularly regarding the pharmaceutical sector.[13]
The Napp Pharmaceutical Experience

Considering again the regulatory experience in the UK, the difficulty of assessing what constitutes an excessive price was discussed by the UK's Competition Appeal Tribunal in Napp Pharmaceutical Holdings Ltd.[14] There, Napp had been selling the same morphine drug both to hospitals and pharmaceutical wholesalers. The wholesale price was more than ten times the price charged to hospitals. The UK's Office of Fair Trading ("OFT") (the CMA's predecessor) had determined that this factor, together with the size of Napp's profit margin relative to other drugs, supported the OFT's conclusion that the price for the drug, where it was sold wholesale, was excessive because it significantly exceeded what a competitive price would have been.

Relying on the ECJ's United Brands decision, the CAT approved the OFT's starting point in determining whether Napp's prices were excessive, being that “(i) prices are higher than would be expected in a competitive market, and (ii) there is no effective competitive pressure to bring them down to competitive levels, nor is there likely to be”[15]. The OFT then analyzed the prices Napp had set in the community relative to the price of the drug charged to hospitals or the export market, both sectors in which Napp faced competition. The OFT also considered the gross profit margin on sales of the drug compared to others Napp sold to hospitals, and compared it to the gross profit margins of the company's next most profitable competitor. The CAT remarked that these types of calculation were among the approaches that may reasonably be used to establish excessive prices.

Napp's defenses included the argument that its original investment in the product should be accounted for in the assessment of whether a price was excessive, but could not put forward evidence showing the amount of that original investment. In any event, given the investment took place in the 1980s, both the OFT and the CAT concluded that the investment would have been recouped long ago. Napp also argued that when a company was regulated by the PPRS, it would be erroneous to consider one of its products and find the pricing of that individual product excessive, given the PPRS' emphasis on a company's return of capital. However, the CAT found that in assessing whether there is an abuse of dominance in a particular market, it would not consider the reasonableness or otherwise of a company's profits in other unspecified markets.

Analysis

The entry of independent generic drug manufacturers into pharmaceutical markets generally results in significant price decreases. However, it would appear from the recent infringement findings in the UK that sophisticated pharmaceutical manufacturers are taking advantage of the lacuna in price regulation of generic products when they are members of the PPRS, and they may be deliberately de-branding their products then increasing prices for the generic version for their own commercial gain. The tabled Bill may help to address these issues by introducing price regulation for de-branded prescription drugs manufactured or supplied by companies who are members of the PPRS who are currently able to avoid pricing regulation on their de-branded prescription drugs. In this year's infringement decision by the UK's CMA against Pfizer, Pfizer claimed that its Epanutin product was loss-making before it was de-branded, although it is not clear how it calculated the profitability of the drug and whether it took research and development costs into account. Pfizer is a participant in PPRS, and therefore also subject to pricing regulation as regards its branded prescription drugs (but not its generic prescription drugs).

The UK's CMA also has three other ongoing investigations into the pharmaceutical sector. These concern so-called reverse payment, or "pay-for-delay" agreements which defer competition from independent generic drug manufacturers, and potentially deprived the NHS of the significant price falls that generally result from generic competition. In the case of paroxetine, when independent generic entry eventually took place at the end of 2003, average paroxetine prices dropped by over 70% in 2 years.

Footnotes

[1] “De-branding” of pharmaceutical products means removing the brand name from a product and relaunching the product as a “generic,” a term more widely used in the U.S.
Under the PPRS, a “branded” medication is “any medicinal product for which a marketing authorization has been granted and to which the proprietor applies a brand name which enables that product to be identified without reference to the generic title...” para 3.16 PPRS 2014.

As amended by The Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013.

Para 6.1, PPRS 2014.

Para 7.1, PPRS 2014

The Health Service Medical Supplies (Costs) Bill (the "Bill"), HL Bill 81


Para 37(c) Flynn Pharma Limited and Flynn Pharma (Holdings) Limited v Competition and Markets Authority [2017] CAT 1.


Para 250, Ibid.

Para 249, Ibid.


Case No 1001/1/1/01 Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading [2002] CAT 1, para 392.

Ibid, paras 390-1.

*Lesley Hannah is a senior associate and Jessica Phillips is an associate in the London office.*

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