

Inside Views: Excessive Pricing And Sham Patent Litigation: The Pfizer And AbbVie Decisions

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By Frederick M. Abbott*

Competition law is a critical tool in seeking to maintain some semblance of reasonable pricing in the pharmaceutical market. It is particularly important as legislators around the world appear extremely hesitant to address pharmaceutical pricing in meaningful ways, regrettably influenced by well-funded lobbying.

Two recent competition law decisions discussed below illustrate the importance of and challenges to regulating the pharmaceutical sector. In the first, the UK Competition Appeal Tribunal (CAT) partially upheld and partially reversed and remanded (pending briefing) a decision by the Competition and Markets Authority (CMA) fining Pfizer and Flynn close to £90 million for abuse of dominant position in the excessive pricing of an anti-epilepsy drug. The CAT decision is problematic because it creates unnecessary and unwarranted hurdles to findings of excessive pricing in the UK. In the second decision, the US Federal Trade Commission succeeds in proving that AbbVie engaged in abuse of monopoly power by engaging in sham patent litigation against two generic producers in order to delay market entry of competitive products. The Federal District Court found that AbbVie's patent lawyers by "clear and convincing" evidence had knowingly pursued patent infringement claims without chance of success for no other purpose than to delay market entry.

1. *Flynn Pharma & Pfizer v. Competition and Markets Authority (CMA)*, in UK Competition Appeal Tribunal, [2018] CAT 11, Case Nos: 1275-1276/1/12/17, 7 June 2018[1]



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In December 2016, the UK Competition and Markets Authority (CMA) fined Pfizer and Flynn £89,361,425 for abuse of dominant position by excessive pricing of a pharmaceutical product used to treat epilepsy. The drug in question was phenytoin sodium capsules. This is an older generic drug formulation that continues to be used by about 48,000 individuals in the UK, as switching to newer treatments, or even different manufacturers of the same formulation, has been determined to present significant risk to patients. The National Health Service (NHS) in the UK is essentially a captive market for the capsules produced by Pfizer.

Pfizer engaged in a complex strategy more or less unique to the British regulatory system that involved so-called "debranding" or generisizing that took phenytoin sodium capsules out of Britain's price control system. Pfizer transferred its marketing authorization, but not its trademark ("Epanutin"), for the drug to a middle-person, Flynn, which became responsible for supplying the drug, and which took a distribution cut of the newly elevated (i.e. excessive) prices. Evidence showed that Pfizer had expressly engaged Flynn because of concerns that there would be a political backlash when the scale of its price increases became public, and Flynn would take the heat and defend the new prices before regulatory authorities and the media. There was no other reason for Pfizer to engage with Flynn, since Flynn would supply exactly the same Pfizer product from exactly the same factory to the NHS. Pfizer had undertaken this supply up until it engaged Flynn. There was no change involved other than massive profits for Pfizer/Flynn, and prices escalating from £2 million to £50 million per year to the UK healthcare system.

On June 7, 2018, the Competition Appeal Tribunal (CAT) rendered a decision partially upholding, and partially reversing and remanding the decision of the CMA. The CAT upheld the CMA determination that Pfizer and Flynn had a dominant position on the market for phenytoin sodium capsules. The product market is narrow because of the requirements of prescription continuity. The CAT reversed the CMA's finding of excessive pricing on grounds that the CMA did not employ a sufficient number of alternative methodologies. It did so almost wholly based on the opinion of Advocate General Wahl to the Court of Justice of the European Union (CJEU) in the *Latvian Copyright* case.[2] In that opinion, AG Wahl expressed significant skepticism regarding excessive pricing doctrine, notwithstanding that Article 102 of the Treaty on the Functioning of the

European Union (TFEU) expressly addresses abuse of dominant position through unfair prices. In his view, competition authorities should always pursue multiple analyses of factual elements just to make sure that something is not overlooked, and as a "sanity check".

Importantly, while the CJEU referred with approval to certain of AG Wahl's recommended approaches to deciding the *Latvian Copyright* case,^[3] it did not adopt his multiple analyses strategy. Instead, it confirmed its two-step analytic approach for determinations of excessive pricing under the *United Brands (1978)*^[4] case, which included approval of a cost-price analysis as a means of identifying excessive prices, which is the approach that was used by the CMA. The CJEU has previously held that its second prong, unfairness, can be determined either through unfairness "in itself" or unfairness "when compared to competing products", and that these elements are not cumulative. It did not tinker with this approach in the *Latvian Copyright* case. In fact, if there was any change in CJEU doctrine in the *Latvian Copyright* case, it was to relax the standards for findings of excessive pricing and unfairness by holding that there is no minimum threshold differential when undertaking cross-market comparisons.

In its Pfizer/Flynn decision, the CAT acknowledges that the opinion of the AG Wahl does not carry the weight of the CJEU, but thought it was "eminently sensible". That seems a long way from explaining why it overturned the findings of the CMA as if it were following a new mandate from the CJEU.

Despite the fact that the CMA had conducted an in-depth analysis to arrive at a reasonable cost-plus benchmark price for Pfizer's phenytoin sodium capsules, and despite the fact that the Pfizer/Flynn price increases were facially excessive, the CAT said that the CMA could have further explored alternative methodologies, such as comparison with other products or companies that it opined might comport more with the "real world". The fact that there were no directly competitive products did not dissuade the CAT.

With respect to unfairness, the second prong of the *United Brands* analytic approach, the CAT principally faulted the CMA on two accounts. First, even though the CMA had expressly noted that Pfizer supplied the identical product in other European markets at substantially lower prices than the UK, and that Pfizer had offered no objective explanation for the dissimilarities, the CAT suggested that the CMA had not explored this sufficiently. This despite that the CMA had not relied on cross-market comparisons for its

decision, since it had decided that Pfizer's prices were unfair in themselves, and thus did not need to show that they were unfair in relation to competing products. The CAT also said that the CMA had not adequately taken into account the economic value of having the product available to the NHS and patients, even though the CMA had addressed that in finding that there was no additional economic value to supplying exactly the same product from exactly the same factory, and to an already captive market.

The CAT rejected the thorough investigation and analysis by the CMA in reliance on speculation that *even more* approaches might eventually turn up some evidence in favor of Pfizer and Flynn, in the face of evidence that Pfizer's executives knew exactly what they were doing in overcharging NHS and its patients (which one of its executives mused might be perceived as "taking the opportunity to fleece the NHS"), and burdening the British healthcare system. As stakeholders in that system pointed out, the dramatic increase in the price of the old-line generic treatment would cause cutbacks in other areas of British healthcare.

Among the routes open to the CMA there appears to include an appeal of the CAT decision, or a reopening of the investigation to pursue the additional lines of analysis mandated by the CAT. Either approach likely has some merit. No doubt on further investigation Pfizer and Flynn will again be determined to have engaged in excessive pricing. On the other hand, an appeal (which could include a reference to the CJEU – Brexit considerations aside) might clear the jurisprudential underbrush that the CAT has unnecessarily added to excessive pricing investigations. A third option is for the CMA to decide that pursuing the case would involve an unwarranted use of internal resources. That would be an unfortunate result from the standpoint of British and global competition policy.

The decision of the CMA is about 550 pages, and the decision of the CAT about 150 pages, and this brief discussion does not fully capture the details. A more detailed exposition is forthcoming in IIC – International Review of Intellectual Property and Competition Law, Max Planck Institute for Innovation and Competition [online first; hardcopy Issue 7, Sept. 2018].

2. *Federal Trade Commission (FTC) v. AbbVie*, Civ. No. 14-5151 (ED Penn. 2018)

On June 29, 2018, a US Federal District Court judge in Pennsylvania rendered a civil award of \$448 million in favor of the US Federal Trade Commission (FTC) against AbbVie for

abusing its monopoly power in the market for topical testosterone replacement therapies (TTRTs). Earlier, on September 15, 2017, the same judge found AbbVie to have engaged in sham patent litigation against Perrigo and Teva. AbbVie initiated patent infringement proceedings against Perrigo and Teva in response to Paragraph IV filings by those companies seeking early entry into the market for generic versions of Androgel 1%. The FTC had proved that AbbVie could not reasonably have believed that it would succeed in the patent infringement actions because it had limited the scope of its patent claims to a single form of "penetration enhancer" (i.e. isopropyl myristate) in response to an examiner's objections during the patent prosecution process, and AbbVie knew that the accused infringers' generic products used different penetration enhancers (i.e. isostearic acid (Perrigo) and isopropyl palmitate (Teva)). AbbVie's patent infringement claims were "objectively baseless".^[5] The District Court had denied the FTC's motion for summary judgment regarding abuse of monopoly power because of genuine issues of material fact, and the more recent judgment addresses those outstanding issues.

In the just-issued judgment, the District Court determined that AbbVie had subjectively intended to directly interfere with Perrigo and Teva's business. The Court applied a high standard of proof, i.e., by clear and convincing evidence "that defendants had actual knowledge that the patent infringement suits here were baseless".^[6] The bad actors within AbbVie were its patent lawyers. The District Court found:

"It is a compelling inference that they knew the law concerning the prosecution history estoppel and related principles and understood that prosecution history estoppel barred the infringement suits against Teva and Perrigo. They decided to file these lawsuits anyway. Since these experienced patent attorneys filed objectively baseless infringement lawsuits, it is reasonable to conclude that they intended the natural and probable consequences of acts they knowingly did. This leads ineluctably to an inference that the subjective intent of the decision-makers was to file sham lawsuits. We find by clear and convincing evidence that these attorneys had actual knowledge that the infringement lawsuits they initiated in 2011 against Teva in the United States District Court for the District of Delaware and against Perrigo in the United States District Court for the District of New Jersey were baseless and that they acted in bad faith. The only reason for the filing of these lawsuits was to impose expense and delay on Teva and Perrigo so as to block their entry into the TTRT market with lower price generics and to delay defendants' impending loss of hundreds of millions of dollars in AndroGel sales and profits. They had no expectation of prevailing in the lawsuits."^[7]

The District Court determined that the relevant product market was made up of all TTRTs, that AbbVie held between a 71.5% and 60%+ share of the market during the relevant period (April 2011-Dec. 1014), and that AbbVie was able to maintain that market share with a profit margin of over 65% during the relevant period. This dominant position was supported by significant barriers to entry into the TTRT market, including regulatory barriers. According to the Court: "In sum, we find that the FTC has proven that defendants had a dominant share of the TTRT market in the relevant period and that significant barriers existed for entry into that market. This sham litigation delayed the entry of much less expensive competitive generic products into the TTRT market to the detriment of consumers and protected the defendants against loss of hundreds of millions of dollars in sales and profits." [8]

The award of \$448 million is an equitable remedy of "disgorgement" of profits intended to "deter violations of antitrust law and to prevent the unjust enrichment of defendants". [9] It reflects AbbVie's financial gains flowing from the sham patent litigation based on the delay in market entry of Perrigo's generic product. The District Court determined that Teva decided to stay out of the relevant generic market for business reasons that were not sufficiently associated with AbbVie's conduct. This trial court judgment may yet be appealed.

Concluding observation: In the face of general inaction by political branches to contain pharmaceutical prices, the ability of competition authorities to pursue actions that impose penalties sufficient to deter industry excess is important to protecting the public interest. Competition authorities may not always be free from political pressures that arise from well-funded political lobbying, but they typically enjoy a reasonable freedom to operate. Competition enforcement actions are often complex and time-consuming, and involve expenditure of considerable administrative resources. This is not the most efficient way to enhance public welfare. But, for the time being, it is among the most effective methods for containing pharmaceutical and other healthcare costs. The fundamental objective of competition law is protection of the public interest, which includes protection against excessive pricing. It is well past time for competition authorities to look beyond the "Chicago-school" mantra that competitive markets correct themselves. That mantra has limited relevance to the pharmaceutical sector in which government granted exclusivities, regulatory requirements and the needs of patients create an environment that demands a contextual economic approach in which deliberate exploitation of the public can be effectively addressed.

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[1] Available at: <http://www.catribunal.org.uk/237-9616/1274-1-12-16-IR-Flynn-Pharma-Limited-and-Another.html> [hereinafter "CAT Decision"].

[2] Opinion of Advocate General Wahl, Case C-177/16, 6 April 2017.

[3] Autortiesību un komunikēšanās konsultāciju aģentūra/Latvijas Autoru apvienība v Konkurences padome, CJEU, Case C-177/16, 14 Sept. 2017.

[4] Case 27/76, United Brands Co. & United Brands Cont'l B.V. v. Comm'n of the European Cmtys., 1978 E.C.R. I-207.

[5] FTC v. AbbVie, Civ. No. 14-5151, 2017 WL 4098688 (E.D. Penn), The district court found:

"Here, any reasonable person who reads the prosecution history of the '894 patent can reach no other conclusion than that the defendants have purposefully and not tangentially excluded isopropyl palmitate and isostearic acid as penetration enhancers equivalent to isopropyl myristate.

The patent lawsuits against Teva and Perrigo were without question objectively baseless." 2017 WL 4098688, at *11.

[6] Federal Trade Commission (FTC) v. AbbVie, Civ. No. 14-5151 (ED Penn. 2018), at page 37.

[7] Id. at pages 52-53.

[8] Federal Trade Commission (FTC) v. AbbVie, Civ. No. 14-5151 (ED Penn. 2018), at page 77.

[9] Id., at page 95.



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