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Will Recent Excessive Pricing Cases Lay Down Precedent For Future?

by Ian Schofield

The recent upsurge in cases of high drug prices being pursued by competition authorities in Europe could help to lay down some markers for judging what is an "excessive" price in future. At the same time, Brexit could see the UK and the EU begin to drift apart in terms of how they apply competition law to pricing issues.

European competition authorities have traditionally been wary of pursuing cases of "excessive" or "unfair" medicine prices, not least because the burden of proof is high and it is generally accepted that action should be started only in exceptional cases. Change is in the air, though, and the number of investigations undertaken has risen noticeably in recent years.

Decisions over the next year or two in recent cases brought forward by competition authorities are expected to help clarify the criteria for determining whether prices are "excessive," although they may not manage to lay down the "bright-line rules" that regulators and companies would like to see.

Meanwhile, the European competition law landscape is facing something of an upheaval after the UK leaves the European Union on March 29, 2019. The UK has said it plans to keep its competition law aligned with that of the EU, but it is possible that EU law might begin to diverge. If this happens, according to one lawyer, it would leave UK law "frozen in aspic" and be both "inconvenient and costly" for pharmaceutical companies.

What the competition cases currently underway in the drug pricing area have in common is that they involve medicines whose prices were raised sharply after they lost patent protection.

According to Francesca Miotto and Dirk Arts of law firm Allen & Overy, these "appear to be cases where markets have failed to self-correct and regulatory intervention has been deemed not to be possible or appropriate. They also appear to involve conduct that led to very significant increases

in public spending. In this respect, they reflect the application of stringent enforcement screens, whereby intervention is recognized to be justified in exceptional cases only."

One example is the *Aspen Pharmacare Holdings Ltd.* case, which involved price rises on several patent-expired anticancer drugs acquired from *GlaxoSmithKline PLC* in 2009. Following the conclusion of an Italian case against Aspen, which in 2016 was fined by the Italian competition authority for applying "unfair prices with increases of up to 1,500% for life-saving and irreplaceable drugs," the European Commission began its own investigation in May 2017. This was the commission's first such probe in the pharmaceutical sector. (Also see "*'Excessive Pricing' Inquiry Widens As EC's First Antitrust Price Probe Targets Aspen Pharma*" - Pink Sheet, 15 May, 2017.)

The commission was informed that Aspen had engaged in "price gouging" by "imposing very significant and unjustified (excessive) price increases of up to several hundred percent for certain cancer medicines that it acquired after their patent protection had expired," according to Miotto and Arts.

The Aspen case involves "very specific circumstances," they say. It relates to off-patent medicines, whose pricing is not regulated, unlike that of original medicines, and it appears that "market forces have failed to remove or sufficiently erode a monopoly position." There also "appears to be evidence" that Aspen exerted "considerable pressure" to impose the price increases, including threatening to withdraw, or actually withdrawing, the products in certain member states.

Another European competition case at a national level is the landmark *Pfizer Inc./Flynn Pharma Ltd.* case where the companies were fined a total of nearly £90 million by the UK Competition and Markets Authority (CMA) in 2016 for abusing a dominant position and imposing "excessive and unfair" increases on the generic epilepsy drug phenytoin sodium. The case was widely seen as sending a clear message to companies about the need to ensure compliance with competition law.

That case is far from over. In June this year, following an appeal by the companies, the Competition Appeal Tribunal (CAT) ruled that the CMA had not correctly applied the legal test for finding that prices were unfair, as set out in the United Brands case. The CAT said the CMA's overall findings on abuse of dominance were "not well founded as a matter of law and assessment and cannot be upheld." (Also see "*Court Ruling On Pfizer Price Hikes Could Delay Other Investigations, Warns UK Competition Authority*" - Pink Sheet, 8 Jun, 2018.)

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Miotto and Arts told *In Vivo* that it was "clear from the CAT's summary of the judgment that it considers that price control is better left to sectoral regulators, and that cases of excessive pricing should remain rare. If, however, competition authorities decide to pursue such cases (according to the CAT, there is no reason, in principle, why competition law cannot be applied), the CAT stresses that this must be done on the correct legal basis and the analysis of evidence must be sound."

The CMA is also investigating two other cases involving de-branded medicines. In March 2017, it alleged that Actavis UK had breached UK and EU competition law by charging "excessive and unfair" prices for hydrocortisone tablets. It cited price rises of more than 12,000% compared with the price of the branded version that was sold by a different company before April 2008.

In addition, it is pursuing *Concordia International Corp.* over six medicinal products that it said were acquired, de-branded and included in "suspected anti-competitive agreements and/or concerted practices and suspected abuse of dominance."

Lessons For The Future?

A key question is whether, given their very specific nature and circumstances, the outcomes of these cases will lay down any precedent for dealing with future cases of alleged excessive prices.

While they should provide some clearer guidance on how to calculate the benchmark price in pharmaceutical markets, "it remains unclear to what extent these cases, which are unavoidably facts-specific, will actually yield bright-line rules on which market operators can rely when determining their market strategies," say Miotto and Arts.

John Schmidt of law firm Arnold & Porter is inclined to agree. "The current spate of cases will set out relatively clear boundaries as to how you can increase prices in areas where there is a market imperfection that has been manufactured by the company itself," Schmidt said in an interview. "In the Aspen case the company threatened to withdraw from the market unless it got its higher

price. That clearly is red light territory, not only in Italy but probably elsewhere as well. Increasing your prices simply because you can – this will be an issue where there is some other involvement in the process of creating some form of shortage or market imperfection."

It's not yet clear when these ongoing cases will be resolved. "Pfizer/Flynn will, I suspect, produce some results next year," Schmidt says. "There is a question as to whether it goes to the Court of Appeal. The CAT has refused to give leave to do this, but companies can go directly to the Court of Appeal and seek leave to appeal. We will hear whether they have done that; it may well happen. If it goes to the Court of Appeal, will we get a judgment next year? We may not."

As for the commission's case against Aspen, Schmidt says: "Pharma cases usually take a number of years to resolve. This is a little easier as it only involves one company, unlike the pay for delay cases that have taken five, six or seven years to come to a decision. My feeling is that they will probably take longer than next year to finalize the decision – the fact that they haven't had many excessive pricing cases means they will want to get it right."

Extension To Patented Drugs?

Although these cases have concerned off-patent medicines, it is not clear whether the lessons learned will have any bearing on issues around the prices of patented products.

Miotto and Arts say that the significance of the current cases would be limited to situations involving off-patent medicines. "The benchmark price and unfairness assessment is arguably more complex where patent-protected medicines are involved, given how costly and complex the R&D process and uncertain the market returns are, and the heightened risk that enforcement action at this stage in a medicine's life cycle may negatively affect innovation incentives."

Nonetheless, there is evidence that competition authorities may well have patented drugs in their sights too. Action in this area seems to be spearheaded by the Netherlands.

In March this year, the Dutch Authority for Consumers and Markets (ACM) published a working paper on "Reconciling competition and IP law: the case of patented pharmaceuticals and dominance abuse." In a nutshell, it states that despite the general caution over applying EU competition law to patented pharmaceuticals, there is "growing evidence that the enforcement of competition law in a patent context can both be justified and carried out in a manner that is compatible with IP law."

Miotto and Arts say the paper indicates that the ACM "sees no objection in principle to a finding of excessive pricing in cases where the relevant drug is still patent protected and even suggests a possible framework for deciding which excessive pricing cases involving patented medicines to pursue."

The paper was produced by a special pharmaceutical task force set up by the ACM. Schmidt says this is "a sign that they are taking pharma cases on and are continuing to monitor pharma cases … The interesting point here is that they are looking at the spate of current cases, but they are also looking at those that are not purely in the realm of patent expired products where, for whatever market imperfection reason, prices go up by multiples. They are saying we can also get involved in cases where there is ongoing patent protection. Simply the fact that a product is still under protection doesn't exempt it from the application of competition law."

Brexit

Of course, the shadow of Brexit falls on competition law as it does on countless other aspects of the life sciences sector. What will happen to UK competition law once the country leaves the EU – and what will become of any "live" cases still ongoing as of March 29, 2019?

Much will depend on what Brexit deal is are eventually implemented. If a withdrawal agreement is passed, a transition period will kick in until the end of 2020, during which time EU law (including any new legislation) will continue to apply in the UK, as will the jurisdiction of the Court of Justice of the European Union (CJEU).

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What if, though, the UK leaves without a deal? "The UK has said it will take into account EU law up to the Brexit date on a no-deal exit, but it is not clear how they will take into account EU law developed after that – and that will be pretty important," says Angus Coulter of law firm Hogan Lovells. "We will be consciously separating ourselves from European law – this is an area with a lot of live cases, and as that law changes we may find that we are in a different place. Whenever I have spoken to people at the CMA, there is really no appetite here in the UK to change our competition law away from what Europe is doing."

What is more likely, Coulter says, is that Europe will move away, "and there may be big changes

in areas where we are not expecting them. I think that almost certainly if the two systems come apart in this area of excessive pricing, or more generally, it will not be driven by the UK. It will be driven by the EU continuing to evolve and us being frozen in aspic because of Brexit."

This, he says, could be "inconvenient and costly" for companies. "If you are a big pharmaceutical company, and if you do the same thing across the EU including the UK, you may find it is legal in one country and not in another. The way to avoid that might then be for the company to say that it will have to do something different in the UK. But given the international nature of these products and almost all the companies involved, this will be very hard. Certainly, it is a real example of a potential Brexit issue for industry."

Schmidt says that after Brexit "the law will not change significantly in the short term. The UK has been the thought leader and initiator of new cases in the excessive pricing area, and the CMA will want to continue doing that. It will continue to be seen as a strong independent thought leader whether inside the European competition network or outside."

However, in the medium to longer term the CMA could take a different approach to how it looks at some of the cases and how it applies some of the EU case law, "because then it will no longer be strictly bound by EU precedent, depending on the Brexit deal," Schmidt adds. "If the EU takes a case that will no longer relieve the CMA from its jurisdiction, it could be investigated in parallel by the UK after Brexit or the transitional period. It may want to show that it can work as an equal partner to the EU."

And what of the future of individual cases that straddle Brexit? As for the GSK paroxetine case, for example, Coulter says: "The questions have gone to the CJEU, but they have not been answered yet. We have heard that the CJEU will answer them come what may, even if it doesn't do so before Brexit. It is not clear what impact that will then have after Brexit, because those views will be directly relevant if they are accepted as precedents."

In the Aspen case, he points out that once the European Commission takes over a case, EU national competition authorities are not able to. However, "after Brexit the CMA could do it itself. I don't know whether there is a UK element to the case, but if there is the CMA would almost certainly take it up. This is an area they are interested in, they know the Italian authorities definitely had a case, and they have the European Commission work to build on."

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