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Veering Off the Well-Trodden Path? European Merger Control and the Pharmaceutical Industry

Gavin Bushell (Baker & McKenzie) · Friday, October 30th, 2015

We have recently celebrated the 25th anniversary of the EU Merger Regulation, which came into force on 21 September 1990.

Since that date, we have seen an exponential growth in merger control notifications at the European level – at least up until the financial crisis that began in 2008.

The good news is that, to the end of September 2015, there have been 247 notifications this year. We appear to be on track for approximately 330 notifications in total for 2015. This almost reaches the level of notifications in 2008 (348) – albeit somewhat off the all time high of 2007 (402).

But what does this mean to the pharmaceutical industry? It has been at the vanguard of the resurgence in M&A since the financial crisis – alongside telecoms. I thought I would take a moment to reflect on the state of merger control enforcement in this sector at the European level.

EUMR Statistics show a higher rate of intervention in pharmaceutical cases

It is well known that the pharmaceutical industry has demonstrated a relatively high level of consolidation over the last 25 years though it remains a rather fragmented sector.

Of the 5,973 total cases notified to the European Commission to the end of September 2015, 131 have been assigned with the NACE Code C.21 – relating to the manufacture of pharmaceutical products and preparations (NACE is the statistical classification of economic activities in the European Union).

Statistically, this means that cases with this NACE code represent approximately 2.2% of all notified cases. This is hardly surprising given the importance of the pharmaceutical industry to the European and global economies. But what else can the statistics tell us?

Well, I spent a little time looking into the numbers. Of these 131 cases, 94 were cleared without any form of intervention (approximately 72% of all pharmaceutical cases). 32 cases involved intervention in the form of remedies (approximately 24% of all pharmaceutical cases).

The good news is that there have been no prohibitions in the sector. The eagle-eyed or at least those with long memories will point out that two cases were abandoned – this was because the deals collapsed (*American Home Products/Warner-Lambert* and *Merck/Schering*) rather than

because of a risk of prohibition.

But how does the rate of intervention in pharmaceutical cases compare with the overall statistics for all notified cases? If we look at the rate of intervention in all cases, the percentage of total cases cleared by the Commission with remedies either in Phase I or Phase II is only approximately 6.1% (365 cases). This compares to 24% in the pharmaceutical industry.

This indicates that the level of intervention in pharmaceutical cases is significantly higher than across the economy as a whole. Generally, 89% of all cases are cleared in Phase I or Phase II without remedies (compared to 72% in pharmaceutical cases as noted above). Perhaps this is not surprising given the push in pharmaceutical M&A to seek ever increasing synergies in R&D cost savings and returns for stakeholders. These types of pharmaceutical deals give rise to overlaps that are more likely to require remedies.

Of the 32 pharmaceutical cases cleared with remedies, only three involved remedies in Phase II. That is to say that 90% of pharmaceutical cases involving remedies are cleared in Phase I. This includes very large transactions with multiple overlaps (e.g. *Astra/Zeneca, Pfizer/Pharmacia, Pfizer/Wyeth, Novartis/Alcon, Teva/Ratiopharm,* and *Teva/Cephalon*).

The percentage of pharmaceutical cases cleared with remedies in Phase II is largely similar to all Phase II conditional clearances – 2.2% (3 cases) of all pharmaceutical cases. This compares to 1.9% (114 cases) of all economy cases. Notably, there are no pharmaceutical cases that have entered Phase II and been cleared without remedies. This suggests that taking the time to argue why molecule-level product market definition is inappropriate is a fruitless task.

So what does this picture tell us? What is the relevance of this when advising our clients?

Well, my suggestion would be that – whilst each case naturally turns on its facts – in the pharmaceutical industry we are more likely to be engaged in transactions that will result in some form of regulatory intervention. But – at least at the European level – there would appear to be a clear roadmap for dealing with these substantive issues.

The practical learning point should be that a proactive antitrust assessment and remedy strategy should figure largely in the upfront deal planning of any pharmaceutical transaction.

How to remedy concerns in a pharmaceutical case in Europe?

As we all know, there is a clear preference in Europe for structural rather than behavioural remedies.

In the pharmaceutical industry, this typically means the divestment of one of the parties' drug products in the overlapping area(s). Through the 32 intervention cases I highlighted above, we have seen the development of a reliable and – at sometimes – flexible template for resolving the concerns of the Commission.

Earlier this year, I had the privilege in representing Abbott Laboratories in the sale of its EPD-DM business to Mylan. That transaction was cleared in Phase I by the Commission in January subject to remedies in five discrete areas. The public version of that decision was made available last month.

The EPD-DM business focused on distributing branded ex-originator products with expired patents. Mylan is a U.S. producer of generic pharmaceuticals. The Commission's investigation found that for the majority of the products no competition concerns arose.

However, for five products the Commission identified concerns, in particular, where it found there to be high combined market shares of the parties on narrow markets (typically molecule level), a lack of substitutable products, and a low likelihood of entry. The markets where the Commission identified potential concerns were mebeverine in Germany and the UK, pygeum africanum in France, betahistine in Ireland, and delorazepam in Italy.

Obtaining clearance in Phase I was achievable however because of the template. So what does that template typically include? And what do I mean by flexibility? Well the Mylan remedy package included:

• the relevant marketing authorizations, including all relevant dossiers, and importantly no limitation as to the use of the information contained in the dossiers (the Commission wanted to encourage the purchaser not only to develop the existing businesses but potentially to use them to enter other markets in contiguous countries);

• all licenses, permits and authorisations;

• customer contacts and historical information of orders;

• the assignment of supply contracts or at least a best efforts obligation to obtain the assignment of the supply contracts entered into by Mylan (here we see some flexibility being built into the remedy design to acknowledge that third parties' consents and involvement are required – yet still allowing the remedy to survive despite the execution risk arising from third party consents);

• all advertising, marketing, sales, publicity and presentational materials;

• a non-exclusive and transitory manufacturing or supply arrangement for a period of up to two years after closing, on a reasonable cost-plus basis to be agreed with the Purchaser and the monitoring trustee, and/or reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the products (again showing some flexibility and optionality in order to cater for the needs of the Purchaser without imposing a rigid obligation on the notifying party); and

• an option for the Purchaser to hire one or more personnel, who work for the Divestment Businesses and who would be considered necessary to maintain the viability, marketability and competitiveness of it. Again, this optionality shows some flexibility in the remedy design.

So the template was readily deployed, market-tested, and successfully negotiated and accepted within the limited 10-15 working day remedy window of Phase I. Notably, no upfront buyer condition was required – increasingly prevalent in general economy mergers where there are doubts as to the deliverability of a divestment or the identity of a purchaser. This contrasts with the position of the U.S. FTC which routinely requests such a condition.

I should note however that the Mylan remedy package also included a specific purchaser requirement: to have an existing footprint in the sale of generics in the relevant countries.

Such clauses do limit the potential pool of purchasers. Where there is a sufficiently large enough pool of generic companies in the relevant countries, it can usually be accepted. You may query whether however this term could be renegotiated *ex-poste facto* in the absence of a purchaser being found to avoid a fire-sale.

It is true that we have seen some flexibility from the Commission to extend the divestment period in the light of difficult financial markets. But the renegotiation of key terms relating to the purchaser criteria seems unlikely, absent a material change in circumstances.

In a medical device case last year, I was able to convince the Commission to accept a divestment purchaser's sub-contractor, which had originally been outside of the scope of the Commission's purchaser requirements – but only because the market structure had changed since the approval decision. This experience would appear to be an outlier.

But what about manufacturing facilities?

So we have a workable template for remedies in pharmaceutical cases in Europe. Whilst the *Mylan/Abbott EPD-DM* remedy package constitutes a "structural" remedy – because the businesses were being divested – it did not include the relevant drug manufacturing facilities.

The Commission has broadly accepted that this is not a requirement. This is because most purchasers have their own facilities and there is a prevalence of manufacturing and outsourcing agreements in the industry. Short-term transitional manufacturing agreements and optional technical assistance to help the purchaser start up production, normally suffice to assuage concerns in this area.

Where concerns do persist, however, the Commission may require a concomitant divestiture of assets. We saw this recently in cases such as *Merck/Sigma-Aldrich* (albeit a case relating to solvents and inorganics), and *Pfizer/Hospira*, where the final remedies were improved to include – at the purchaser's request – the technology transfer of a product's manufacturing to a facility of the purchaser's choice.

Remedies for innovation competition?

And *Pfizer/Hospira* brings me on to the issue of innovation competition. It is notable in that it is the second large case this year in which the Commission extracted a remedy from the parties in respect of a pipeline product (the other case being *Novartis/GSK Oncology*).

It is clear that there is a new focus in the last year – since the induction of Competition Commissioner Margrethe Vestager last November – on promoting innovation and not just concentrating on price effects in the context of merger review.

In the January 2015 approval of the €16 billion acquisition of GSK's oncology portfolio by Novartis, the Commission extended its assessment beyond those pipeline products already in Phase III clinical trials. It broke new ground in fully assessing the impact of the deal on innovation competition, including an analysis of the impact the deal would have had across the overall clinical research programme for ovarian and skin cancer. This signalled a closer degree of scrutiny and potentially a lower threshold for intervention in pharma cases.

This signal was confirmed on the announcement of the approval of Pfizer's acquisition of Hospira

on 4 August 2015, subject to remedies. The remedies included the divestiture of a late pipeline biosimilar product (infliximab – used to treat autoimmune diseases such as rheumatoid arthritis and Crohn's disease) that was under development by Pfizer, and the sterile injectable voriconazole (used to treat invasive fungal infections) that Hospira was just bringing to market.

Commissioner Vestager commented that the decision *"…is not just about keeping prices low for patients and healthcare services. We have also made sure that the merger… does not stand in the way of the research and development of medication that could have huge benefits for society"*. It seems that the promotion of biosimilars – essentially genericized medicines – may also tick the innovation box.

What is notable is that the U.S. FTC's Order in the *Pfizer/Hospira* case covered various products including voriconazole, but did not include the biosimilar infliximab – suggesting a potential divergence between the EU and U.S. agencies.

I understand that since the 2004 *Genzyme/Novazyme* case, there is a general reluctance in the U.S. FTC to intervene on innovation competition grounds. Recent indications from conversations with Commission officials – as well as the track record in these two recent cases – suggest that the Commission is indeed breaking new ground – and in contradiction to the position of the U.S. FTC and the intentions of the EU.-U.S. Best Practices in Cooperation in Merger Investigations.

In particular, the indications are that the Commission is moving away from its Horizontal Merger Guidelines to go considerably beyond the standard two-to-three year horizon to map out future market developments.

There is also the suggestion that there may be a working presumption of harm where a pipeline overlap exists, because incentives can be expected to change post-merger – to facilitate R&D cost savings (*"Why else would you be doing this deal?"*). This represents a departure from prior cases before the Commission such as *Teva/Cephalon* and *Watson/Actavis*.

My own personal view is that protecting innovation competition is important, but that caution is required. Requiring a divestment of a pipeline product may have an impact on the development of the pipeline product itself. So intervention should be limited to those cases where a proper investigation reveals a likelihood of real harm.

The analysis is inherently speculative. Products often fail in clinical trials. A careful fact-based analysis should be undertaken. The assessment should not be straight-jacketed by a simple legal presumption that harm must arise simply because of an overlap in pipeline products, which are presumed to be destined to come to market.

This is particularly the case given the inherent difficulty for the notifying parties to provide pre-existing or contemporaneous documentary evidence to support the argument that their incentives to bring products to market will not be changed by the proposed merger.

I would encourage the Commission to look to then Chairman Muris's public statement in the *Genzyme/Novazyme* case, where he noted *"neither economic theory nor empirical research supports an inference regarding [a] merger's likely effect on innovation (and hence patient welfare) based simply on observing how the merger changed the number of independent R&D programs. Rather, one must examine whether the merged firm [is] likely to have a reduced incentive to invest in R&D, and also whether it was likely to have the ability to conduct R&D more*

successfully”.

Bottom line: facts, not presumptions, should control the EUMR analysis and intervention should be limited to cases where the Commission has clear and compelling evidence that there will likely be harm from a reduction in R&D and products not being brought to market – which it must prove (rather than the parties being required to overturn a simple presumption).

The burden should remain upon the Commission until the likely effect of harm is established – and only then should the burden shift to the parties. In addition, the horizon for review should not be extended unreasonably beyond two-to-three years.

The potential redeployment of R&D funds post-merger into other pipeline areas should also be taken into account in a holistic assessment aimed at ensuring overall patient welfare.

Only time will tell where in Europe this road will take us, but for the here and now, my practical advice for any client is to ensure that in any pharmaceutical merger assessment, that all pipeline products (and not just those in Phase III) are cleared mapped out and understood.

Clients will also be well-advised to ensure that internal document creation guidelines are in place, and are adhered to, so as to ensure that no inadvertent hostages to fortune are created for a future merger review. Today it seems that only the internal documents really seem to matter in the overall assessment – particularly where economic assumptions and analysis are highly disputed.

Concluding remarks

The pipeline of M&A transactions appears to be healthy. Naturally, a certain number of transactions do not pass through all the various phases or obtain authorisation to go to market. Trial by Commission has a valid role to play in that process.

There is no presumption that mergers are inherently pro-competitive. But the conditions in Europe should favour the facilitation of global M&A and the completion of transactions. Intervention should be limited to those cases where a likelihood of significant harm is sufficiently foreseeable. Increasing clarity for merging parties on how to obtain EUMR authorisation is welcome.

Pharmaceutical mergers, at the heart of the economy in Europe and the health of its citizens, should merit a clean, clear, even if clinical, trial.

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