M&A AGN/ABBV: European Commission Likely to Examine Innovation Effects, Potential Overlaps in Crohn's Disease Treatment, Other Pipeline Drugs

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Takeaways

- According to two pharmaceutical industry experts with knowledge of AbbVie and Allergan's businesses, the transaction will likely warrant scrutiny from the European Commission regarding overlaps in three areas where the parties compete, including treatments for Crohn's disease, exocrine pancreatic insufficiency and abnormal uterine bleeding.
- In addition to potential overlaps, the European Commission will likely examine the transaction for potential harms to innovation in drug development, according to Pablo Figueroa, an antitrust attorney at the Spanish law firm Garrido Abogados.
- The companies have yet to file their notifications with the commission. A spokesperson for the commission told Reorg M&A that a gap of one to two days may sometimes exist between the filing of the companies' notifications and the posting of the case to the commission's webpage.

The European Commission will likely conduct an extended review of AbbVie and Allergan's tie-up, according to pharmaceutical industry experts and a European antitrust practitioner.

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Some of these products may have already been identified by the companies for planned divestiture. As AbbVie Chief Legal Officer Laura Schumacher previously told investors at the time of the deal's announcement, the companies have identified several products which they expect to "divest promptly" for U.S. antitrust clearance.

According to the first industry expert, Allergan's brazikumab, a pipeline drug designed for the treatment of Crohn's disease, is very similar in application to several AbbVie products, including the company's Skyrizi product, which is in Phase 3 clinical development in Europe and has been approved for the treatment of plaque psoriasis in the U.S. In addition to Skyrizi, Allergan's brazikumab may also be considered a rival to AbbVie's upadacitinib, which is also under review by the European Medicines Agency. "While different in composition, these are largely used for the same treatments," said the industry expert, who declined to be named due to potential conflicts of interest.

Despite these products being in the pipeline instead of already on the market, the European Commission is likely to consider them in its review. In Phase 2 clinical development before the European Medicines agency, Allergan's brazikumab is in earlier development than its AbbVie counterparts. Yet while historically the commission has left Phase 2 development drugs out of its antitrust analysis of pharmaceutical mergers, the commission has recently taken an interest in such products in its investigations, according to Pablo Figueroa, an antitrust attorney at the Spanish law firm Garrido Abogados.

"When certain pipeline products have entered an advanced clinical stage of trials, they are analyzed as existing drugs by the European Commission," Figueroa said. "That includes Phase 3 and, in recent cases, Phase 2 clinical stages." Figueroa has represented several pharmaceutical companies in past transactions before the commission.

In addition to these, the companies also carry overlaps between Allergan's Zenpep and AbbVie's Creon, which are commercialized treatments for pancreatic insufficiencies, according to the first and

a second industry expert. While AbbVie CEO Gonzalez noted that Zenpep was among expected divestitures for U.S. approval, AbbVie's Creon is not sold in Europe, according to AbbVie's 2018 annual report. It is unlikely, therefore, that the European Commission will similarly require divestiture of this product for approval.

It is worth noting that the commission typically defines the geographic market for commercialized drugs - like Zenpep and Creon - on a nation-specific basis, while defining the geography for pipeline drugs - like brazikumab and Skyrizi - on a European-wide or global basis, according to Figueroa. "They tend to use a wider geographical scope for pipeline products than the actual projected sale of the drugs," Figueroa said. "It is case-dependent, whether they define it as European-wide or worldwide."

The second industry expert noted that regulators may also take issue with potential overlaps between Allergan's Esmya and AbbVie's Orlissa, both of which are used to treat abnormal uterine bleeding in women. According to the expert, however, the two have slightly different applications and may not directly compete in Europe. Allergan's Esmya is not FDA-approved in the U.S.

In addition to potential overlaps, the European Commission will likely examine the transaction for potential harms to innovation in drug development, according to Figueroa. "This is peculiar because it is very hard to predict the effects on innovation in a transaction," Figueroa said. "The commission uses proxies for innovation that are questionable, such as R&D expenditure and patent citations."

"What has changed lately - and this is a trend you can see that goes beyond pharma into other innovation-intensive industries, in transactions such as Bayer/Monsanto and Dow/DuPont - is that, where before the EC's analysis as to innovation was reduced to pipeline products, they now try and ascertain the effects of the transaction in terms of innovation effects," Figueroa said. "The EC has repeatedly required substantial divestitures recently on the basis of this theory of harm."

Both the European Commission and the FTC have typically reached a negotiated settlement with merging parties in pharmaceutical deals that carried antitrust concern. Over the last 20 years since 1999, the European Commission has reviewed 143 mergers in the pharmaceutical industry, according to the commission's website. Of these, the majority were cleared outright, while a smaller portion were eventually approved in Phase 1 with remedial conditions. None of the deals during this time went to Phase 2 investigation.

According to Figueroa, these numbers can be explained by the merging parties' desire to stay out of Phase II investigation. Companies in past pharmaceutical mergers have been willing to make extremely large levels of divestiture to avoid Phase 2 and receive approval in Phase 1, Figueroa said, citing recent cases such as Johnson & Johnson's tie-up with Actelion and GSK's recent purchase of Pfizer's consumer health division.

"Once the commission institutes a Phase 2 investigation, you are in the first place in unpredictably long timing," Figueroa said. "Second, it really becomes unpredictable what the commission's ultimate decision will be. So I'm not surprised that companies are willing to make large concessions in Phase 1."

AbbVie and Allergan have yet to file their notifications with the European Commission. A commission spokesperson noted that a gap of one to two days often exists between the companies' submission of their notifications and the commission's public disclosure of such notifications.

The FTC could not be reached for comment regarding the companies' HSR filings, which the parties at the time of their announcement stated they plan to make within 30 days of their merger agreement.

Neither AbbVie nor Allergan could be reached for comment in time for this story's publication.

Reorg M&A's previous coverage of this transaction can be found **HERE**.

--Matt Tracy