M&A RARX/UCBJF: HSR Pull-and-Refiles Create Timing Risk

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Takeaways

- Although the FTC recently granted early termination to Achillion/Alexion, there are key differences between that transaction and the pending Ra Pharma/UCB deal that may increase the relative risk profile of the latter with respect to a FTC second request.
- Both deals entail the the overlapping of pipeline assets and/or on-market drugs targeting the same disease space. In the recently approved Achillion/Alexion merger, Achillion's danicopan's applicability to just 10% of the PNH population may have worked in favor of the deal. In contrast, the Ra Pharma/UCB transaction entails overlaps related to drugs targeting a specific condition, generalized myasthenia gravis, or gMG. Ra Pharma's zilucoplan can be marketed and prescribed to a significant 80% of the gMG patient population.
- Overall, there is little risk that the FTC would block Ra/UCB. There is uncertainty, however, about whether the merging companies can successfully use multiple HSR pull and refiles to avoid a second request. "It is reasonable to surmise that multiple pull and refiles are indicative of a complicated analysis where a second request will end up being necessary," said Patrick Souter, counsel at Gray Reed.
- UCB and Ra have said they expect to close their transaction by the end of the first quarter.

The FTC's approval of Alexion's acquisition of Achillion Pharma on Friday, Jan. 24, indicates positive read-throughs for the Ra Pharma/UCB transaction. However, certain key differences between the two deals may increase the relative risk profile of Ra/UCB with respect to an FTC second request. UCB and Ra have already filed their HSR paperwork multiple times.

The Ra/UCB transaction has key similarities to the recently approved Achillion/Alexion and Spark/Roche mergers. In all three of these transactions, both the target and acquirer have pipeline assets or on-market drugs targeting the same disease space but adopt a different treatment method or biological approach to treat the underlying disease.

In Ra Pharma/UCB, both companies have pipeline assets targeting a specific condition, generalized myasthenia gravis, or gMG, but adopt two different biological approaches to target the disease. As Reorg analyzed previously, UCB's rozimab essentially attacks autoantibodies, while Ra Pharma's zilucoplan addresses the complement system.

The myasthenia gravis patient population can be divided into two subpopulations: 1) MuSK-antibody patients (15% of myasthenia gravis population) where the complement system is not activated, and therefore Ra Pharma's zilucoplan is not effective; and 2) the acetylcholine receptor antibody-positive patients (about 80% of myasthenia gravis population) for which both rozmab and zilucoplan could work as an effective combination treatment. In other words, Ra Pharma's zilucoplan can be marketed and prescribed to a significant 80% of the gMG patient population.

In contrast, in the recently approved Achillion/Alexion deal, even though both companies had on-market and pipeline assets targeting the PNH disease space, Achillion's danicopan was viewed as an "add-on" treatment for a small subset of the PNH population. This small subset of the PNH population is estimated at under 10%.

While it is difficult to pinpoint the exact contours of the FTC's assessment framework for both of these deals, the applicability of Achillion's danicopan to just 10% of the PNH population may have worked in favor of the deal. However, as Reorg analyzed previously, in addition to UCB and Ra, several other companies are actively developing new drugs to treat gMG.

Even though some industry merger reviews have been surprising in terms of duration and required divestitures, the FTC thus far has not battled any recent pharma deals in court. Overall, there is little risk that the FTC would block Ra/UCB, which is further evidenced by the companies' expectation to close their transaction by the end of the first quarter of this year.

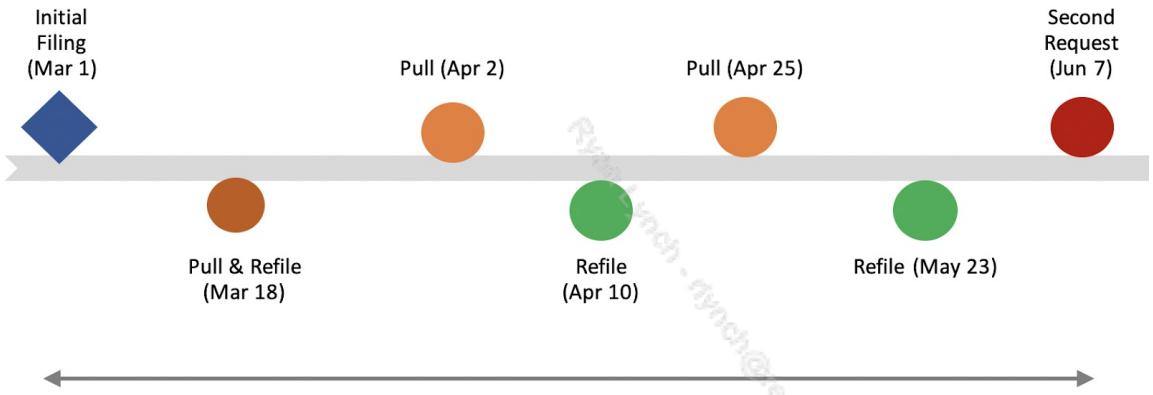
Instead, there is uncertainty about whether the merging companies can convince the FTC not to issue a second request. "It is not uncommon that the pull and refile is done for the primary purpose of avoiding a second request," said Patrick Souter, counsel at Gray Reed and professor of healthcare studies at Baylor University School of Law. "It is reasonable to surmise that multiple pull and refiles are indicative of a complicated analysis where a second request will end up being necessary." UCB and Ra did not respond to requests for comment.

In the recently approved Achillion/Alexion transaction, the two companies presumably engaged in several months of pre-HSR discussions with the FTC in order to smooth the regulatory review process ahead of time. In contrast, approximately two weeks after announcing their deal UCB and Ra made initial HSR filings, putting the FTC on the clock.

This difference in strategy assumes significance as Ra/UCB have had to engage in multiple pull and refiles since their Oct. 10, 2019, merger announcement compared with a single HSR filing and early termination for Achillion/Alexion.

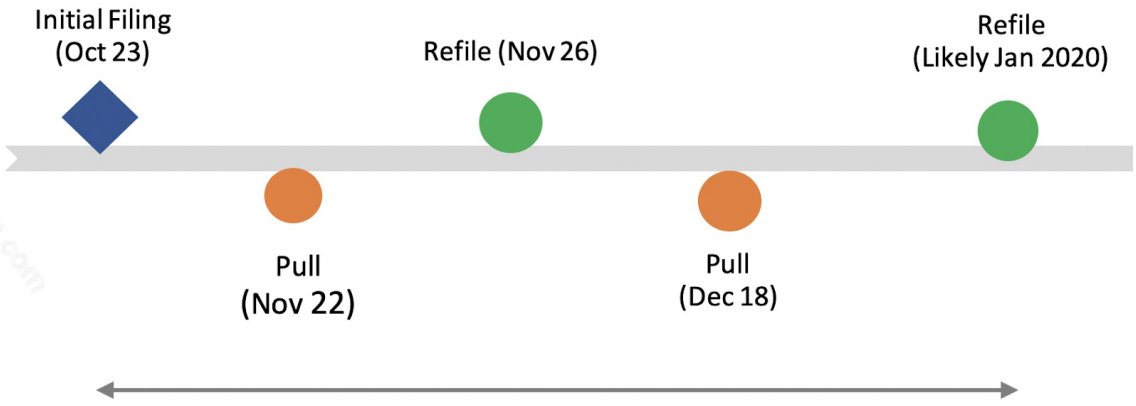
However, both UCB and Ra may derive some level of comfort from the successful approval of Spark/Roche. The latter transaction engaged in three pull and refiles, which led to a second request from the FTC. Despite that, the agency eventually approved the merger without conditions.

Figure 1: Spark/Roche Timeline (2019)



(Source: Reorg M&A)

Figure 2: Ra Pharma/UCB Timeline (2019-20)



(Source: Reorg M&A)

Reorg's review of regulatory filings reveals that the Spark/Roche transaction was under FTC review for approximately three months from the date of first filing until it received a second request. In the case of Ra/UCB, the merger has been under review for roughly three months as well. UCB has indicated that it intends to refile in January 2020. Assuming that the companies have already refiled for the second time in January, another subsequent refile later in the year would not bode well with respect to a potential second request and subsequent extension of the merger review timeline.

Compared with a second request, there can be cost savings if companies withdraw their HSR paperwork and refile. The first pull and refile does not create any additional cost for the merging companies, as long as their transaction does not materially change. Subsequent pull and refiles require additional payment equal to the initial filing fee. By comparison, companies can expect to pay millions of dollars to comply with a second request. In 2014, the average estimate was $4.3 million.

"There's a big debate among antitrust lawyers about pulling and refiling," said Jay Levine, co-chair of the antitrust and consumer protection group at law firm Porter Wright. While some antitrust attorneys advocate pulling and refiling in the hopes of avoiding a second request or at least reducing the scope of an extended inquiry, other attorneys would rather begin working on the second request as soon as possible, he said.

Pharma transactions often involve complexities such as spinoffs or licensing deals, and the multiple pull and refiles by Ra/UCB could indicate changes to the structure of their deal, Levine noted.

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

--Shrey Verma and Ryan Lynch