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Patents And LOEs Poised To Be Hot Q2 Topics

by Jessica Merrill

Novartis and Johnson & Johnson will be the first two big pharmas to release second quarter financial results, and both have faced recent patent case developments for top-selling drugs.

Johnson & Johnson has an opportunity to maintain the exclusivity of its top-selling drug Stelara (ustekinumab) longer than expected, while *Novartis AG* may be facing the opposite situation with its top-selling drug Entresto (sacubitril/valsartan). The loss of exclusivity (LOE) timelines for those drugs are essential to the companies' sales and earnings outlooks, and investors will be anxious to get more clarity from their management teams during second quarter earnings calls.

Novartis and J&J are the first of the big pharma companies scheduled to present Q2 financial results, with Novartis slated to release its earnings report on 18 July, followed by J&J on 20 July.

New developments have unfolded in ongoing patent litigation in the US for both companies since they reported first quarter sales and earnings, and those have an impact on investor sentiment.

J&J reached two patent settlements with biosimilar manufacturers in May and June that will delay the launch of biosimilar versions of Stelara until 2025, potentially giving the company valuable extra time to cash in on the anti-inflammatory therapy's blockbuster-sized revenues. Stelara generated $9.72bn in 2022.

Investors and management had been anticipating Stelara biosimilars would enter the market late in 2023, and the imminent LOE was expected to be an overhang for J&J next year particularly.

During J&J's first quarter sales and earnings call in April, the company warned investors it may not hit the mid-term pharma revenue growth goal the company set in 2021 – to reach $60bn in pharmaceutical revenues by 2025. Management cited unfavorable currency trends and lower-

than-expected sales of some drugs like Imbruvica (ibrutinib). The $60bn target set in 2021 would be $57bn, taking into account currency fluctuations, the firm said. (Also see "*J&J Hedges On 2025 Pharma Revenue Outlook*" - Scrip, 18 Apr, 2023.)

Maintaining Stelara revenue could help bridge any gap, however. In May, J&J reached a patent settlement agreement with *Amgen, Inc.*, the first to file a biosimilar application with the US Food and Drug Administration, which agreed to launch its biosimilar version of ustekinumab on 1 January 2025. (Also see "*Stelara Settlement Gives Amgen US Ustekinumab Entry Date*" - Generics Bulletin, 24 May, 2023.) Then, in June, *Alvotech* and its US commercial partner *Teva Pharmaceutical Industries Ltd.* also settled litigation with J&J, agreeing to a biosimilar launch date "no later than 21 February, 2025." (Also see "*Alvotech And Teva Follow Amgen With US Stelara Settlement*" - Generics Bulletin, 12 Jun, 2023.)

Whether similar arrangements will continue to play out with other biosimilar developers remains uncertain, but reaching an agreement for a date-certain launch can be appealing to a biosimilar manufacturer when a drug is protected by numerous patents and litigation is expensive.

Investors will be eager to hear more from management about the outlook for the Stelara LOE and what the developments will mean for 2023 and 2024 financial targets. Analysts were encouraged about what the prospects for J&J's financials going forward.

"We believe that a later US Stelara LOE should go a long way towards closing the gap between J&J's 2025 pharma revenue target of $57bn and consensus of $54.8bn," Wells Fargo analyst Larry Biegelsen said in a 9 July analyst note. The bank increased its Stelara sales forecast by $260m in 2023, $2.4bn in 2024 and $1.2bn in 2025.

A Win And Loss For Novartis

Novartis, on the other hand, will be pressed by investors on the LOE expectations for the heart failure drug Entresto, which generated $4.64bn in 2022 and has outpaced Cosentyx (secukinumab) to become the company's top-selling drug in recent quarters.

On 7 July, a US district court in Delaware invalidated a key US patent covering Entresto that had been scheduled to expire in July 2025. The decision was a victory for the generic manufacturers that were defendants in the case, including *MSN Laboratories Pvt. Ltd.*, *Hetero Drugs Ltd.*, and *Macleods Pharma USA*. (Also see "*ANDA Sponsors Knock Out Key US Entresto Patent, Mylan Falls To Infringement*" - Generics Bulletin, 11 Jul, 2023.) As many as 18 generic drug manufacturers have submitted applications for generic Entresto, which is a small molecule tablet.

The timing for potential generics remains uncertain, however. A generic launch ahead of an appeal may be unlikely. And, in a different district court case filed in West Virginia against *Mylan Pharmaceuticals Inc.*, the court ruled in favor of Novartis that Mylan's proposed generic would

infringe two different patents covering Entresto that expire in May 2027 and November 2027.

Novartis said it would continue to defend the intellectual property protecting Entresto and that it had previously entered into settlement agreements with several abbreviated new drug application (ANDA) filers that would be able to launch a generic version of Entresto at an agreed upon, yet undisclosed, date.

J.P. Morgan analyst Richard Vosser, in a 10 July note, said the loss of the Delaware court case could lead to generic competition in 2024.

"We believe the generics manufacturers will likely have to wait until 1) the outcome of Novartis' petition to the FDA to stay approval until Feb. 2024, with a verdict from the FDA likely in 3Q and 2) the outcome of a Novartis appeal, which, if unsuccessful, could see generics launch by mid-2024," he said.

Bank of America Securities analyst Graham Perry predicted that generics would be unlikely to launch before 2025, given that Novartis will appeal the court decision and any generic launch before would be considered "at risk," meaning generic manufacturers could be liable for damages if Novartis won the appeal.

"Novartis has won one case and lost another in the Entresto patent litigation with overall generic risk increased a little, in our view, but generic launch ahead of Novartis and consensus modelling of 'not before 2025' still seems unlikely," Perry said.

The evolving situation for Stelara and Entresto puts a spotlight on just how challenging it can be to predict the timeline for a drug LOE. The way big pharmaceutical manufacturers have successfully extended the life of many blockbuster franchises through widespread patenting is a complaint of industry critics who have pushed for stronger drug pricing legislation.

Now, new Medicare policies that are being implemented as part of the Inflation Reduction Act could curb some of that brand life elasticity by putting in place certain timelines for drug price negotiations – at least for drugs reimbursed by the US government.

The law allows small molecule drugs nine years on the market before facing Medicare price negotiations and allows biologic drugs 13 years. A recent analysis in the *Journal of Managed Care and Specialty Care* showed that many top-selling drugs have substantially longer commercial lives. The 10 drugs identified in the analysis as being likely to face first negotiations in 2026 will have had an average commercial life span of 15 years in 2026. (Also see "*First Drugs That Could Be Picked For Price Negotiation Showcase Longevity Of Some Brands*" - Scrip, 30 Mar, 2023.)