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Questcor/Synacthen: Antitrust, Political Analysis Reveals Significant Risk that FTC Will Investigate U.S. Patent Rights Acquisition; Likelihood of Challenge to Turn on Competitive Landscape of Long Release ACTH Drugs

Conclusion

Deal Overview. On June 11, 2013, Questcor reached an agreement to acquire the U.S. rights to Synacthen and Synacthen Depot (Synacthen) from Novartis. The transaction was not HSR-reportable, and Synacthen's U.S. rights transferred to Questcor concurrently with the execution of the License Agreement. Questcor's sole product is HP Acthar Gel ("Acthar"), a naturally derived adrenocorticotropic hormone (ACTH) therapy. Synacthen is a synthetic ACTH drug, which, although not FDA-approved, is indicated in other jurisdictions for largely the same conditions as Acthar. Acthar is the only long release ACTH drug available in the U.S., and The Capitol Forum is unaware of any firms planning to enter this market. In addition, Synacthen, in markets in which it's approved, is sold at a price point significantly lower than Acthar.

Questcor Possibly Acquired its Sole Potential U.S. Competitor. Questcor agreed to acquire the rights to Acthar's closest, and possibly only, potential competitor, which, if it had fallen into the hands of a competitor, could have significantly undercut Acthar on price. Since acquiring Acthar in 2001, Questcor has increased the price of the drug from $40 a vial to over $28,000 a vial today. A competing bidder for Synacthen's U.S. rights had proposed bringing Synacthen to the U.S. at "a few hundred dollars a vial."

FTC Scrutiny Highly Likely. As a result, we expect that the FTC will pay significant attention to this transaction, although we have not been able to confirm that the agency has opened an investigation. We also expect there to be significant political pressure on the FTC to investigate the deal.

The Capitol Forum reached out to the Questcor and Novartis seeking comment—Novartis declined comment, while neither Questcor's IR nor corporate counsel responded prior to time of publication.

Timing is unpredictable. Past FTC investigations into non-reportable and already-consummated pharmaceutical deals have taken an average of about 2 years. However, the significant potential cost to taxpayers and consumers of inaction could drive a more aggressive timeframe.

We expect the FTC to investigate the transaction formally, and below are the risks and drivers attendant to the deal once such an investigation is initiated (if it hasn't started already):

Factors determining whether FTC will launch an investigation:

• **Compelling effects story.** Acthar is the only FDA-approved long release ACTH therapy. Synacthen Depot may be Acthar's closest substitute, as well as the most likely timely entrant to the long release ACTH market.

• **Senate's antitrust subcommittee likely to pressure FTC to investigate deal.** Senator Klobuchar, the subcommittee's chairwoman, is on record as criticizing Acthar's pricing, and we expect significant Congressional pressure on the FTC to commence an investigation into the Synacthen deal.

• **Proposed FTC rule indicates significant agency interest in deals like Questcor/Synacthen.** A proposed 2012 FTC rule would have made the transfer of "all commercially significant rights" the standard for determining HSR reportability in pharmaceutical deals, and would have rendered the Questcor-Synacthen deal reportable, and subject to the HSR waiting period

Risks and drivers if the FTC launches an investigation

Deal risks include:

• **The FTC has defined narrow, single-product markets in the past:** Given past practice, the FTC may define a market or markets in which Acthar is the only product and Synacthen is the only reasonably interchangeable competitor.

• **Barriers to entry are high, and entry won't be timely:** Barriers to entry in the long release ACTH market are high, and it does not appear that any firm is currently developing a competitor to Acthar.

• **Divestiture as a remedy is highly unlikely:** Because Questcor is acquiring a single drug, the FTC and Questcor are unlikely to agree on a divestiture.

Deal drivers include:

• **Challenges to the FTC market definition:** A proposed market definition of (1) long release ACTH drugs or (2) therapies for the treatment of infantile spasms may be overly narrow or inconsistent with the facts.

• **Uncertainty regarding entry could damage a potential FTC case:** If currently FDA-approved cosyntropin products are viewed as market participants or potential timely entrants, a potential FTC case could be complicated.

• **Deal could be reviewed by Mergers I:** The FTC's Mergers I Division is viewed as less aggressive than Health Care—if the Directors assign the case to Mergers I, the deal could be less likely to face a serious challenge.

Deal Overview

Questcor Pharmaceuticals announced its acquisition of the U.S. rights to market Novartis' Synacthen and Synacthen Depot (Synacthen) products, as well as rest of world rights (excluding 13 European jurisdictions) on June 11, 2013. Because the acquisition of U.S. rights was structured as an IP transfer, with Novartis retaining certain manufacturing rights to Synacthen, the transaction was not reportable under the HSR Act and closed concurrently with the execution of the License Agreement.

In consideration for the U.S. and non-U.S. rights to Synacthen, Questcor will pay Novartis between $135 million and $300 million, depending on conditions regarding timing of FDA approval and Synacthen net sales.

According to the U.S. rights agreement, Novartis may terminate Questcor's Synacthen License under certain circumstances, all related to Questcor's failure to seek FDA approval for Synacthen. This condition is notable in that it may prevent Questcor from having acquired the rights to Synacthen simply to prevent the drug from coming to market as a competitor to Acthar in the U.S.

A Capitol Forum review of the License Agreement contained within Questcor's 6/30/2013 10-Q did not reveal notable antitrust language beyond boilerplate information-sharing clauses.

Questcor is an Anaheim, California-based biopharmaceutical company that derives nearly all of its revenue from the marketing of a single drug--H.P. Acthar Gel (repository corticotropin injection) (Acthar). Acthar is FDA-approved for 19 indications, although Acthar derives substantially all of its revenue from uses for the treatment of (i) proteinuria in Nephrotic Syndrome (40% of paid Rx), (ii) Multiple Sclerosis ("MS") relapse (30%), (iii) infantile spasms (10%), and (iv) certain rheumatology conditions (18%).

Synacthen (tetracosactide) (aka cosyntropin) is a corticotropic preparation that displays a very similar pharmacological profile to natural ACTH. Synacthen Depot is available in more than 40 jurisdictions, and is indicated to treat largely the same conditions as Acthar, including (i) proteinuria in Nephrotic Syndrome, (ii) MS relapse, (iii) infantile spasms and (iv) certain rheumatology conditions. However, Synacthen is not FDA-approved, nor have clinical or pre-clinical trials begun on the drug.

Deal Risks

Compelling effects story. In 2001, Questcor acquired the rights to Acthar for $100,000, as well as a 1 percent royalty on annual sales over $10 million. After acquiring Acthar, Questcor increased the price of the drug from $40 to $700 a vial, and has continued to increase the price of the drug in subsequent years. In 2007, Questcor increased the price of a vial of Acthar from $1,650 to more than $23,000, and as of today, the price of one vial of Acthar has risen to over $28,000. Given that the typical infantile spasms ("IS") patient requires 3½-4½ vials during the course of treatment, the price of treatment for the average Acthar patient is now over $100,000. The rapid escalation in price for a therapy widely used for IS (which, if not treated, can result in severe developmental disability), has resulted in significant negative press for Questcor.

Synacthen, by contrast, wholesales in jurisdictions in which it is approved for a mere fraction of Acthar's price. Retrophin, a firm the New York Times identified as a competing bidder for Synacthen, hoped to market Synacthen in the U.S. "for a few hundred dollars a vial." As Synacthen likely won't be brought to market in the U.S. for around 3-5 years (if at all), Questcor will not have to make decisions on Synacthen pricing for quite some time. However, given already-existing criticism of Questcor's Acthar pricing strategy, there may be significant FTC, Congressional and media expectation that Questcor will eventually market Synacthen at a price much higher than a competitor would have.

In short, some will view this transaction as Questcor acquiring Acthar's most likely (and only) possible competitor, effectively foreclosing competition from an equally effective, but much less expensive drug. Whether this story is consistent with the facts is yet to be determined, but if it is, the FTC will have a compelling story to tell.

Political Pressure against the deal is likely. Given past statements of Senator Amy Klobuchar, chair of the Senate Judiciary Committee's Antitrust, Competition Policy, and Consumer Rights subcommittee, we expect significant Congressional pressure on the FTC to thoroughly investigate and potentially challenge Questcor's Synacthen acquisition. A Capitol Forum source revealed that both Senator Klobuchar and Senator Al Franken have expressed concern about the deal, and that Senator Klobuchar plans to write a letter to FTC Chairwoman Edith Ramirez expressing her concerns. Congressional pressure may have more influence on FTC action in investigations of already-consummated mergers compared to investigations of non-consummated mergers subject to the HSR Act-mandated waiting period.

In a 2008 speech on the Senate floor, Senator Klobuchar harshly criticized Questcor:

"The mother that testified I will never forget her story about how she, her little baby, was sick in the hospital suddenly having spasms and these could actually affect his brain. His name is Trevor and he's in the hospital and she tries to get the drug that helps with this, Acthar, and she finds out it is about $2,000 per vial. But then what happened? Once it was sold to Questcor and her baby needed this drug the price of the drug skyrocketed to $23,000 per vial, which is a 14-fold increase. So, this mom and the dad are at the hospital with their little baby, Trevor, and the drug has gone up to $23,000 per vial. That is a 14-fold increase… What do you think will happen? Will the insurance company that used to pay for it when it was $2,000 per vial say, oh no problem? They had to negotiate for five days with the insurance company. They had to get their neurologist involved and she had to write a letter that it would affect the baby's life and this baby could be mentally retarded without the drug… Eventually, after five days she got the drug approved."

The Acthar price increase brings to mind Lundbeck's 2005 acquisition of Indocin IV (see below), a treatment for PDA, another very rare condition affecting infants. After acquiring the drug from Merck, Lundbeck immediately raised the price of Indocin IV from $108.88 to $1,500. After challenging Lundbeck's acquisition of a competing PDA drug, former FTC Chairman Jon Leibowitz stated that Lundbeck's "profiteering on the backs of critically ill premature babies is not only immoral, it is illegal." Notably, in her floor speech criticizing Questcor's pricing, Senator Klobuchar singled out one additional company by name: Lundbeck.

Proposed FTC rule indicates significant agency interest in deals like Questcor/Synacthen. In August 2012, the FTC Commissioners voted 5-0 to approve a notice of proposed changes to the premerger notification rules that would define the standard for determining HSR reportability in pharmaceutical deals as whether a seller had transferred "all commercially significant rights" to the acquirer. Current FTC practice holds that if a licensor retains certain manufacturing rights to a drug, the transaction is not viewed as reportable—this proposed new rule reflects the FTC's understanding that the right to manufacture is less important than the right to commercialize in the pharmaceutical industry.

Under the proposed rule, the Questcor-Synacthen deal would be reportable, and subject to the HSR waiting period, as it includes the transfer of "all commercially significant rights" to Synacthen to Questcor. The fact that the FTC has specifically proposed rules to make deals such as the Synacthen acquisition reportable clearly demonstrates their interest in such transactions, and could indicate their interest in further investigating the transaction, given that if the proposed rule were in place, the Synacthen deal would have been subject to HSR reporting requirements.

The FTC has defined narrow, single-product markets in the past. In reviewing pharmaceutical mergers, the FTC may define a relevant market as consisting of drugs in an individual therapeutic category, or as narrowly as a specific active ingredient or mechanism of action by which the drug interacts with the body. The FTC has also defined markets based on a drug's method of administration (injectable, liquid, tablets, etc.), frequency of dosage, and strength of dosage.

The leading case on pharmaceutical market definition, ***FTC v. Lundbeck***, (D.Minn 2010) could bolster an FTC effort to define a narrow relevant product market. In Lundbeck, the FTC alleged that Lundbeck, the marketer of the only patent ductus arteriosis ("PDA") drug on the market, had violated Section 7 by acquiring the rights to the only pipeline drug (likely entrant) seeking indication for PDA. At trial, the FTC alleged a relevant product market of FDA-approved treatments for PDA.

However, the district court rejected the FTC's argument, finding that the two drugs did not exhibit significant cross-elasticity of demand, as neonatologists chose one drug or the other due to factors unrelated to cost, such as "perceived differences in the drugs' safety, differences in side effects, or the presence or lack of long-term studies." Although the FTC came out on the losing end in Lundbeck, given that the court endorsed a narrow approach to market definition, the decision could actually provide ammunition (and motivation) for an FTC challenge to Acthar's Synacthen acquisition.

The FTC, in identifying participants in a relevant market, examines (1) existing competitors, (2) firms that are in the process of entering the market (pipeline), and (3) firms that are capable of entering the market in a timely manner (whether or not they have plans to do so). The FTC has challenged pharmaceutical mergers that increase the likelihood that an acquirer would "forego or delay" the launch of an acquired drug that is not a current participant in the market, because it lacks FDA-approval (see **Watson/Robin Hood**, **Perrigo/Paddock**). Given the facts of this case, the FTC may have a strong argument that Questcor would be motivated to "forego or delay" the launch of Synacthen, especially relative to a different buyer.

The Capitol Forum's expectation is that the FTC would approach an investigation of the Questcor-Novartis agreement with a narrowly-defined proposed relevant market of long release ACTH treatments, in which Acthar is the only current participant, and Synacthen the most likely potential entrant. Alternately, the FTC may allege a market consisting of drugs FDA-approved for the treatment of infantile spasms ("IS"). Both proposed markets appear plausible, although a fact-intensive examination of medical evidence and doctors' prescribing practices will be key in proving or disproving the plausibility of these proposed markets (see below).

Barriers to entry are high, and entry will not be timely. Acthar was approved by the FDA in 1952, and has long lacked any type of intellectual property-based market exclusivity. However, Questcor, in numerous investor presentations and calls, has claimed that its specialized knowledge of ACTH extraction, purification, and concentration creates high barriers to entry for potential competitors, whether they were to submit a New Drug Application (generally 5 years for FDA approval) or pursue a generic/biosimilar approach (generally 2-3 years for FDA approval).

• A 2008 Questcor investor presentation contains a slide titled "High Barriers to Entry," which notes that Acthar is the result of a "complex, multi-step manufacturing process involving extensive proprietary know-how," that would be "tremendously difficult to reproduce by competitor or generic company."

• In a Q1 2012 Earnings Call, Questcor's CSO David Young suggested that bringing a generic or biosimilar to Acthar would "be almost impossible given the guidances." Young also noted that "we don't have a great idea of [competitors] coming in now but even if something was to come in soon, it would take many, many years before it gets approved."

• In that same call, in referring to the potential introduction of an ACTH-based competitor to Acthar, Don Bailey, Questcor CEO, stated that "we don't think the business economics work at all"

• In a Q2 2012 Earnings Call, Young described approval of a generic version of Acthar Gel as "extremely unlikely." While describing the emergence of a competitive ACTH product as "a possibility," he noted that approval of any such NDA would take "a minimum of five years," and that Questcor was "not aware of any [such] effort underway."

• In a 2013 investor presentation, Questcor CEO Don Bailey claimed that the "the trade secrets surrounding Acthar would make it very difficult for somebody to duplicate" and "very difficult to reverse engineer."

While Questcor made these statements in the context of reassuring investors concerned with potential competition, and not during an antitrust review, the FTC will likely view this volume of documents and statements regarding Questcor's belief of high barriers to entry as definitive on the topic.

When the FDA approved an IS indication for Acthar in October 2010, it granted Questcor a seven-year orphan drug exclusivity period, "during which the FDA is prohibited from approving any other adrenocorticotropic hormone (ACTH) formulation for IS unless the other formulation is demonstrated to be clinically superior to Acthar." If introduced to the U.S. market, it is unlikely that Synacthen could meet this standard. However, Synacthen could pursue a non-IS indication and, if approved, could be prescribed off-label for use to treat IS. But as things stand, Synacthen would be unlikely to receive an FDA indication for IS until October 2017.

The FTC will likely find that even if a firm overcame the high barriers to entry in the market, entry would not be sufficiently timely to deter the competitive effects of Questcor's Synacthen acquisition. The FTC has consistently identified the timing for acquiring an ANDA (an application for generic drug approval) as at least two years, which is a timeframe they consider insufficiently timely to deter potential competitive effects. Given that no firm is currently pursuing a generic (or biosimilar) version of Acthar or an NDA for a new ACTH formulation, the FTC, reflecting past precedent that for a new entry to be timely it must occur within a two year window, would likely determine that entry would be neither sufficient nor timely enough to offset the competitive effects of Questcor's Synacthen acquisition.

Divestiture as a remedy is highly unlikely. Typically the FTC will insist on divestitures or the licensing of certain IP rights as a remedy in horizontal pharmaceutical mergers that create competitive concerns. However, these remedies are highly unlikely in this transaction, as Questcor is licensing a single drug. As a result, FTC action in this deal would appear to be an all-or-nothing proposition, as Questcor cannot divest its rights to Synacthen (or its flagship drug, Acthar) while enjoying any benefit from its acquisition of Synacthen's rights.

In that same respect, the FTC's frequently narrow and oftentimes conclusory market definitions tend to be accepted by merging parties in large pharmaceutical mergers, who will accept divestitures rather than endanger the entire transaction by engaging in a protracted fight over market definition. Here, as Questcor won't divest Synacthen, market definition will be key, and Questcor will have every incentive to fight an FTC market definition it views as overly narrow and conclusory.

Deal Drivers

Challenges to the FTC market definition include:

(1) Long release ACTH treatments. If the FTC were to proceed with this market definition, Acthar would be the only current participant, and Synacthen the most likely potential entrant. This market appears plausible, given that Synacthen, which includes the entire functionally significant portion of naturally derived ACTH (the first 20 amino acids), is pharmacologically very similar to Acthar. In addition, the indications for which Synacthen is approved in many-non-US jurisdictions very closely mirror the indications for which Acthar is FDA-approved. Given these facts, the argument that Synacthen and Acthar are "reasonably interchangeable," appears strong. In addition, a

Capitol Forum review of recent Questcor earnings calls reveals that the only potential Acthar competitor identified by analysts and Questcor management is Synacthen, which management addressed as a potential competitor in both its Q1 and Q2 2012 earnings calls. This is further evidence that both the company and the investment community view Synacthen as Acthar's closest, and possibly only, substitute.

However, the plausibility of a long release ACTH treatment market is not a bulletproof case. Synacthen and Acthar differ in several significant ways—Synacthen is synthetic while Acthar is naturally occurring (this means dosing is slightly different as well), the two drugs contain different amino acids and peptides, and, while in the same class, the two drugs may have different pharmacological profiles. This argument would be supported by prior Questcor public statements—David Young, Questcor's Chief Science Officer, for example, has specifically identified Synacthen as "unlikely to be compared to Acthar" owing to "different amino acid sequence and a different pharmacology profile from Acthar," and described Synacthen as "a different molecule" and "a completely different peptide."

In a press release announcing the Synacthen acquisition, Young suggested that Questcor would develop Synacthen for "conditions different than Acthar" as well as "conditions where Synacthen would potentially provide a clinical benefit over Acthar." Taken at face value, this statement demonstrates that Questcor views Synacthen as a product that differs from Acthar significantly.

Given these differences, Questcor will contend that Synacthen and Acthar are not substitutes, and do not exhibit significant cross-elasticity of demand. And given Acthar's low shares in all indications except IS, and Synacthen's potential counterindication for use in infants (see below), even if a market of long release ACTH treatments exists, Acthar/Synacthen's combined market share in indications such as MS and Nephrotic Syndrome is so low as to moot any potential competition concerns. The FTC's approach will entail a fact-intensive investigation of medical literature and prescribing practices, and will likely hinge on doctors' views as to whether Acthar and Synacthen are sufficiently pharmacologically similar as to be "reasonably interchangeable."

(2) Drugs FDA-approved for the treatment of infantile spasms. The only therapeutic category for which Acthar has a significant market share is treatment of IS, where it controls roughly 40% of the market. Infantile spasms are a very rare condition affecting infants that, left untreated, can result in severe cognitive impairment. The only other FDA-approved therapy for IS is Sabril (vigabatrin) (Lundbeck)—while other therapies such as prednisone and topiramate may be used off-label for the treatment of IS, Acthar and Sabril are the two dominant players in the IS market. Furthermore, The Capitol Forum was unable to identify any pipeline drugs seeking an FDA indication for the treatment of IS, which, given the relatively small market size of therapies for IS, is unsurprising.

Sabril was approved by the FDA for treatment of IS in 2009, while Acthar received an FDA indication for IS in 2010. Despite their shared indication, Acthar and Sabril exhibit significant differences, and may not be particularly close substitutes or display significant cross-elasticity of demand. For one, Sabril is administered orally, whereas Acthar is injected. Sabril has the potential to cause vision damage in infants, and carries an FDA "black box" warning, while Acthar carries no such warning. And Sabril is particularly effective in infants with tuberous sclerosis, and is preferred to Acthar in such cases.

Given these facts, the FTC could define an even narrower product market definition, such as injectable therapies for IS, or ACTH-based treatments for IS, that include Acthar and Synacthen (as a potential competitor) but exclude Sabril. These market definitions would show Acthar with a monopoly market share, while identifying Synacthen as the closest, and only, potential competitor.

However, while Synacthen is indicated for IS in Australia and New Zealand, in other jurisdictions in which it's approved, including the UK and Canada, Synacthen lacks an IS indication. This is likely due to the presence of benzyl alcohol in Synacthen, which may be toxic to children. In fact, consumer information for Synacthen in Canada and the UK specifically state that Synacthen is not suitable for use in children under three. Notably, in its press release announcing the Synacthen acquisition, Questcor did not mention Synacthen's indications for IS. Furthermore, Questcor CSO David Young has noted that Synacthen "contains benzyl alcohol, which is toxic to children," and, as a result, "might face substantial safety and distribution issues in the U.S."

However, despite these warnings, there is evidence that Synacthen is used off-label in other jurisdictions for the treatment of infantile spasms. And it is important to understand that if Synacthen were approved by the FDA for any indication, US doctors would then be free to use Synacthen off-label for the treatment of IS. By way of example, Acthar didn't receive an FDA indication for IS until 2010—prior to that point it had been used off label—but nevertheless retained a substantial market share in the US for treatment of IS prior to FDA approval.

Uncertainty regarding entry could damage a potential FTC case. Questcor may argue that currently marketed formulations of injectable cosyntropin are either current competitors in a potential ACTH-based drug market, or, at least, possible timely entrants. In the event these drugs were included, the market would be significantly less concentrated, comprising four drugs (with Synacthen a fifth). The FTC will examine the plausibility of developing and bringing to market depot (sustained release) versions of these drugs—the answer to this query will have an important impact on market definition and composition.

Three firms have FDA approval to market an injectable cosyntropin, a synthetic form of ACTH that is chemically the same as Synacthen (tetracosactide). Amphastar received FDA approval for its branded cosyntropin product (Cortrosyn) in 1970. In March, 2008, Sandoz (Novartis' generic pharmaceutical division) began marketing a generic cosyntropin, with Mylan following suit in December 2009.

However, the only FDA indication for these cosyntropin products is diagnostic testing of adrenal insufficiency (Addison's Disease)—the drugs lack the additional indications Acthar and Synacthen carry for IS, Nephrotic Syndrome, Multiple Sclerosis, and rheumatoid conditions. This is because these cosyntropin formulations dissolve more or less immediately after injection, while Acthar's gel and Synacthen's Depot formulations result in a sustained release of ACTH. Likewise, Acthar and Synacthen Depot are not indicated for diagnostic use.

Despite their single indications, there is evidence that, especially outside the US, cosyntropin products are used off-label to treat a variety of diseases, including Multiple Sclerosis and IS. In Japan, for example, where Acthar is generally not available, cosyntropin is used generally interchangeably with the naturally extracted ACTH. Cosyntropin is significantly less expensive than Acthar, with pricing generally at around $100 per vial.

Questcor could argue that the Amphastar, Sandoz, and Mylan cosyntropin products are current participants in the ACTH market, as well as potential entrants to the long release market, while the cosyntropin products' lack of depot formulations, which generally renders them suited only for diagnostic use, would seem to counsel towards their exclusion from a market composed of Synacthen and Acthar. The plausibility and likelihood of developing depot formulations of currently marketed cosyntropin products will likely be an important issue in the FTC's review. However, the fact that Acthar did not acquire the rights to Mylan's generic cosyntropin from Novartis would seem to indicate that Questcor likely does not view cosyntropin as a substitute for Acthar.

Deal could be reviewed by Mergers I. We expect that either Mergers I or Health Care will take the lead at the FTC in a potential investigation of this transaction. Mergers I is viewed as less likely to challenge the deal than Health Care—a source suggested that even if Mergers I determines that Acthar has a monopoly in a relevant market, given that Synacthen isn't a competitor in the US, the shop won't view the Synacthen acquisition as altering the current market structure. Health Care, still smarting from its loss in Lundbeck, is viewed as more likely to challenge the acquisition, given its stronger enforcement history and expertise in the pharmaceutical industry. Whether the deal ends up in front of Mergers I or Health Care is the decision of the FTC Bureau of Competition Director, and that decision could have a serious impact on the outcome of a potential investigation.

Timing. Because Novartis retained certain manufacturing rights to Synacthen, Questcor's acquisition of Synacthen was not reportable under the HSR Act. As such, the deal closed concurrently with the execution of the License Agreement. As a result, from a timing perspective, any potential FTC investigation will not proceed according to the traditional HSR timeline, which begins with an initial 30-day waiting period and continuing with a decision by the FTC to either close the investigation, or issue a Second Request. Instead, stakeholders should expect any FTC investigation to proceed according to an extended timeline, as the FTC will be unburdened by the HSR Act's calendar. In two notable prior non-reportable pharmaceutical industry acquisitions (Novazyme/Genzyme and Ovation/Abbott), the FTC took around two years to conduct its investigation and decide to move to challenge or close its investigation.