UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

DR. REDDY'S LABORATORIES INC.,

Plaintiff,

v.

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, AMARIN CORPORATION PLC

Defendants.

COMPLAINT

Plaintiff Dr. Reddy's Laboratories Inc. ("DRL") brings this antitrust lawsuit against Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation plc (collectively "Amarin" or "Defendants"), by and through its counsel, and alleges as follows:

INTRODUCTION

1. This is an action under the Sherman Act and New Jersey law arising out of Amarin's anticompetitive conduct to delay and prevent generic competition to its branded Vascepa (icosapent ethyl) product. Since it first began marketing Vascepa in 2012, Amarin has embarked on an anticompetitive strategy to insulate Vascepa from generic competition. This is understandable: Vascepa is Amarin's only product, and one for which Amarin has been steadily

increasing prices since its launch. However, Amarin's anticompetitive conduct has delayed generic entry while Amarin overcharges payers and patients.

2. Specifically, DRL has developed its generic icosapent ethyl drug product, prevailed twice in patent litigation with Amarin, and obtained the necessary regulatory approval to market its generic drug. Consequently, there was nothing preventing DRL from launching a generic icosapent ethyl drug product except for Amarin's illegal conduct to foreclose the supply of a critical input to manufacturing—the icosapent ethyl active pharmaceutical ingredient ("API"). Absent Amarin's anticompetitive conduct, DRL would have launched its generic drug product to compete with Amarin's branded Vascepa in August 2020.

3. In particular, after prevailing in patent litigation in district court in March 2020, DRL promptly began preparations for launch, only to discover that Amarin had foreclosed all the suppliers of the icosapent ethyl API who have sufficient capacity to support a commercial launch in a timely manner. First, [redacted]. Indeed, as DRL later discovered, Amarin had entered into a de facto exclusive agreement [redacted]. As a point of comparison, the entire U.S. market for Vascepa is estimated to require only 450 metric tons / year of icosapent ethyl API.

4. [redacted]. But for Amarin's de facto exclusive agreement [redacted], DRL would have been able to obtain the necessary icosapent ethyl API [redacted] and launch its generic icosapent ethyl product as soon as August 2020, when it received the necessary regulatory approval.

5. Second, when [redacted], DRL contacted all potentially viable suppliers of icosapent ethyl API in an attempt to obtain enough supplies to launch as soon as possible. However, DRL's efforts were again thwarted. Since as early as 2012, Amarin had entered into exclusive or de facto exclusive agreements with the only icosapent ethyl API suppliers with sufficient capacity to support a commercial launch of generic icosapent ethyl drug product without having to first expand their capacity. These suppliers are Novasep Holding SAS ("Novasep," including its subsidiary Finorga SAS), Nisshin Pharma Inc. ("Nisshin"), BASF Group ("BASF"), and Chemport Inc. ("Chemport"). Amarin's agreements with these suppliers have a minimum purchase requirement in exchange for exclusivity, and at least some of these agreements also require Amarin to pay the suppliers in cash if it cannot satisfy the minimum purchase requirement in order for the suppliers to maintain exclusivity with Amarin. [redacted]. DRL also reached out to other suppliers who have not entered into exclusive or de facto exclusive contracts with Amarin, but these suppliers all have limited capacity or have not made the requisite regulatory filings, and, thus, they could not supply DRL for the next 1-2 years at the earliest.

6. Amarin's hoarding of icosapent ethyl API supplies is contrary to industry practice, cannot be justified by any legitimate business reason, and can only be explained as part of an

anticompetitive strategy to prevent and delay generic competition to its branded Vascepa. It is industry practice for a branded drug manufacturer to have only one to two API suppliers, even though more may be available, because it is costly to qualify and ensure quality control at the suppliers. Thus, Amarin retaining five API suppliers when there is no indication of supply issues makes no economic sense, and the fact that these contracts are exclusive or de facto in nature is even more suspect. In fact, the evidence suggests that Amarin had sufficient or an excess of API supply. Amarin reportedly stated in December 2018, [redacted], that it had enough API supply for at least two years, totaling $1 billion worth in Vascepa sales. Given Amarin's existing API supplies, it has no legitimate business reason [redacted]. Accordingly, the only explanation for Amarin's various supply agreements is that it has been paying API suppliers to not supply to generic competitors, including DRL, either through literal exclusive agreements or through agreements that allow Amarin to effectively acquire all available supplies of the respective API suppliers.

7. Amarin's exclusive or de facto exclusive agreements, [redacted], foreclosed a substantial part of the market for the supply of icosapent ethyl API. Because of Amarin's conduct, DRL's launch is delayed despite DRL's best efforts to find an alternative API supplier, as the other API suppliers all have limited capacity or have not made the requisite regulatory filings and, thus, could not support a timely launch by DRL. Accordingly, Amarin's various exclusive or de facto exclusive agreements with icosapent ethyl API suppliers have delayed generic competition from DRL. This delay is particularly egregious because there was no legal or regulatory hurdle preventing DRL from launching as of August 2020, and DRL has been prepared to launch as soon as the requisite icosapent ethyl API became available.

8. But for Amarin's locking up of the icosapent ethyl API supply, DRL would have been ready, willing, and able to launch in August 2020, upon receiving regulatory approval. Instead, Amarin's [redacted] and the other icosapent ethyl API suppliers have delayed DRL's launch by a minimum of 10 months, and delayed a launch that will cover the demand for which DRL had set forth resources and planned to meet absent Amarin's anticompetitive conduct by more than a year. In particular, had Amarin not entered into a de facto exclusive agreement [redacted], DRL would have been able to obtain the necessary icosapent ethyl API [redacted] to launch in August 2020. However, Amarin's conduct [redacted] from supplying any meaningful quantity of icosapent ethyl API for DRL to launch in a timely manner.[1]

9. In addition, because Amarin has foreclosed a substantial share of the supply for icosapent ethyl API, DRL was forced to incur additional significant costs to qualify an additional alternative API supplier that had not, amongst other things, made the requisite regulatory filings. DRL cannot commercially market its generic icosapent ethyl drug product using this alternative API supplier until more than a year after when DRL would have launched but for Amarin's anticompetitive conduct.

10. DRL seeks in this action to obtain an order requiring Amarin to cease its unlawful exclusive or de facto exclusive agreements, including [redacted], to recover DRL's lost profits from the delayed launch, treble damages, and an award of DRL's costs and attorneys' fees.

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[1] [redacted] has delayed DRL's launch by more than a year.

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