IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

TEVA PHARMACEUTICALS DEVELOPMENT, INC., Plaintiff, v. AMICUS THERAPEUTICS U.S., INC. Defendant.	Civil Action No.

COMPLAINT

Plaintiff Teva Pharmaceuticals Development, Inc. ("Plaintiff" or "Teva") brings this action against Defendant Amicus Therapeutics U.S., Inc. ("Defendant" or "Amicus") for refusal to provide access to pharmaceutical product samples under the Creating and Restoring Equal Access to Equivalent Samples Act (Section 610 of Division N of the Further Consolidated Appropriations Act, 2020, codified at 21 U.S.C. § 355-2 ("CREATES Act" or "Act")).

NATURE OF THE ACTION

1. Amicus sells GALAFOLD® (migalastat 123 mg capsules), an oral medication used to treat Fabry disease. Amicus obtained marketing approval for GALAFOLD® from the U.S. Food and Drug Administration ("FDA") on August 10, 2018, pursuant to an earlier-filed New Drug Application ("NDA").

2. GALAFOLD® is Amicus' only FDA-approved revenue-generating product. On information and belief, Amicus has priced GALAFOLD® at $315,000 per year for a single

patient. For the year ending December 31, 2020, Amicus' revenue from GALAFOLD® totaled $260.9 million.

3. Teva seeks to develop a generic version of GALAFOLD®. Teva, an experienced product developer, is the leading generic drug manufacturer in the United States. Teva and its affiliates manufacture more than 500 generic prescription and over-the-counter products in more than 2,000 dosage strengths and package sizes, including oral solid dosage forms, injectable products, liquids, ointments and creams.

4. To obtain marketing approval for a generic version of GALAFOLD®, Teva must submit an Abbreviated New Drug Application ("ANDA") to the FDA. The FDA requires such an ANDA to include analytical and bioequivalence testing data comparing GALAFOLD® to Teva's proposed generic product. To perform the required testing, Teva needs to obtain GALAFOLD® product samples from Amicus.

5. Congress has recognized that NDA holders may have a financial incentive to delay providing, or outright refuse to provide, generic product developers with sufficient drug samples to support an ANDA filing. Accordingly, Congress passed the CREATES Act, the stated purpose of which is "[t]o promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products."

6. The CREATES Act provides a timeline and mechanism for a generic product developer (like Teva here) to obtain sufficient quantities of a covered drug product from the holder of an approved NDA, on commercially reasonable, market-based terms. Under Section (b)(2)(iv)(I) of the Act, the license holder must provide those quantities within 31 days after receiving the request from the generic product developer, if the drug product (as here) is not

subject to additional FDA restrictions. Section (a)(10) of the Act further specifies that "sufficient quantities" means "an amount of a covered product that the eligible product developer ***determines allows it***" to conduct testing to support an ANDA, and to fulfill any regulatory requirements relating to approval.

7. Congress added the language bolded above to the final, as-passed version of the CREATES Act after the FDA recommended it do so in March 2019. In comments supporting this proposed amendment, the FDA expressed concern that "[a]s currently written, the bill leaves room for disagreements between the license holder and the eligible product developer as to the quantity of covered product needed by the eligible product developer to develop their product and submit an application. [] Because a license holder's failure to provide sufficient quantities can stymie an eligible product developer's development program and prevent the submission of an application to FDA, this lack of specificity could result in license holders and eligible product developers needing to litigate cases that would otherwise not require litigation, which could slow (or entirely prevent) drug development." The FDA further commented that "[w]e believe these edits will help eliminate opportunities for gamesmanship in this area that could delay or prevent drug development." *See* **Ex. A**, attached, at 2-3.

8. Pursuant to Section (b)(2) of the CREATES Act, a Teva affiliate, Teva Pharmaceuticals USA, Inc. ("TUSA"), submitted an initial request to Amicus seeking to purchase two wallet packs of GALAFOLD® (each containing 14 capsules). This initial request was dated August 5, 2020, and specifically reserved the right to request additional quantities of GALAFOLD® if Teva later determined such quantities were necessary to complete required testing. *See* **Ex. B**, attached. After determining that further product samples would indeed be needed to support an ANDA, Teva sent a second request to Amicus dated March 29, 2021. That

request sought twenty-five additional wallet packs to complete required analytical and bioequivalence testing. *See* **Ex. C**, attached. As of March 29, 2021 Amicus still had not provided the two wallet packs sought in the initial request.

9. Amicus ultimately delivered the two originally-requested wallet packs of GALAFOLD® to Teva on April 27, 2021, more than *six months* after the deadline specified in the CREATES Act for compliance. Amicus then responded to Teva's second request by simply refusing to provide the twenty-five additional packs of GALAFOLD® that Teva sought. Amicus raised a number of specious arguments as to why Teva was not entitled to these twenty-five additional packs, and unilaterally stated that it would furnish only two more wallet packs to Teva. Amicus' refusal to provide the requested quantity of GALAFOLD®, which Teva had determined was necessary to allow Teva to conduct testing to support approval of its planned ANDA, violates the CREATES Act.

PARTIES

10. Teva Pharmaceuticals Development, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interspace Parkway, Parsippany, NJ 07054.

11. On information and belief, Defendant Amicus Therapeutics U.S., Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3675 Market Street, Philadelphia, PA 19104.

JURISDICTION AND VENUE

12. Teva's claim for failure to provide access to pharmaceutical product samples arises under the CREATES Act, 21 U.S.C. § 355-2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and 21 U.S.C. §355-2(b)(1).

13. This Court has personal jurisdiction over Amicus because Amicus maintains a principal place of business in this district, conducts continuous and systematic business activities in this district, and has committed acts in this district giving rise to Teva's claims.

14. Venue is proper in the Eastern District of Pennsylvania under 28 U.S.C. § 1391 because Amicus resides in this district and a substantial part of the events giving rise to Teva's claims occurred in this district.

BACKGROUND

15. Amicus is the holder of NDA 208623 for GALAFOLD®, migalastat 123 mg capsules. The FDA approved this NDA under 21 U.S.C. §355(c) on August 10, 2018. GALAFOLD® is a "covered product" under 21 U.S.C. §355-2(a)(2), and Amicus is a "license holder" under 21 U.S.C. §355-2(a)(5).

16. GALAFOLD® does not appear on the drug shortage list in effect under 21 U.S.C. §356(e), which the FDA makes accessible at https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

17. GALAFOLD® is not subject to a Risk Evaluation and Mitigation Strategy ("REMS") under 21 U.S.C. §355-1, with Elements to Assure Safe Use ("ETASU") under 21 U.S.C. §355-1(f), as demonstrated by the list of drugs subject to a REMS that the FDA makes accessible at https://www.accessdata.fda.gov/Scripts/cder/Rems/index.cfm.

18. Teva seeks to develop a generic version of GALAFOLD® for approval pursuant to an ANDA under 21 U.S.C. §355(j). Teva is thus an "eligible product developer" under 21 U.S.C. §355-2(a)(4).

19. On August 5, 2020 Teva's affiliate, TUSA, sent Amicus a CREATES Act request seeking to purchase two wallet packs of GALAFOLD®. *See* **Ex. B**. Under 21 U.S.C. §355-2(b)(2)(iv)(I), Amicus was required to deliver these packs within 31 days after receiving the request. But Teva did not receive them until April 27, 2021, far beyond the timeline prescribed by the CREATES Act.

20. Meanwhile, on March 29, 2021, Teva sent Amicus a second request under the CREATES Act, seeking to purchase twenty-five additional wallet packs of GALAFOLD®. *See* **Ex. C**. In that request, Teva explained that it needed these twenty-five additional wallet packs to conduct testing in support of its planned ANDA, including analytical and bioequivalence testing. Teva also noted that it had attempted to obtain GALAFOLD® through normal commercial channels, but the product was simply not available through those channels. Teva still needs twenty-five additional wallet packs of GALAFOLD® to conduct testing in support of its planned ANDA, but these additional packs remain unavailable through normal commercial channels.

21. Teva's determination that twenty-five additional wallet packs of GALAFOLD® are required to conduct bioequivalence testing is consistent with the FDA's assessment of the amount of drug product typically needed for bioequivalence testing. On December 22, 2016, the FDA sent a letter to several Senators in Congress. That letter provided information in response to questions Congress had raised about behavior by brand name drug manufacturers, including the withholding of samples needed by generic applicants for bioequivalence testing. *See* **Ex. D**, attached. The FDA stated that "[t]he total amount of RLD [reference listed drug] product

required to conduct bioequivalence studies, in vitro dissolution tests, and maintain retention samples necessary to support a generic drug application is typically between 1,500 and 5,000 units (e.g. tablets or capsules) of the product. This range reflects factors such as the type of bioequivalence studies recommended for the product, the number of doses required, the number of strengths being tested, the need for retention samples, the number of required in vitro tests, and whether the product is available in a variety of packaging configurations or not." **Ex. D** at 2.

22. Teva's March 29, 2021 CREATES Act request sought 350 capsules of GALAFOLD®. Together with the first request, the total number of capsules Teva has sought from Amicus is 378. That is far less than the 1,500 capsules the FDA has identified to Congress as the low end of the range typically required for bioequivalence studies.

23. The FDA has also issued a draft Product Specific Guidance on Migalastat Hydrochloride (Nov. 2019), available at https://www.accessdata.fda.gov/drugsatfda_docs/psg/PAG_208623. This Guidance requires: (1) comparative dissolution testing on 12 dosage units each of the test and reference products; and (2) a single dose, two-treatment, two-period crossover *in vivo* bioequivalence study. In addition, ANDA sponsors are required to maintain reserve samples of all reference products used in bioequivalence tests. The FDA Guidance on this issue, available at https://www.fda.gov/media/141218/download, specifies that Teva would have to retain a minimum of 30 single-dose units (*i.e.*, capsules) of the GALAFOLD® reference product. This requirement alone requires three wallet packs to fulfill, at 14 capsules per pack.

24. In its March 29, 2021 CREATES Act request, Teva offered to purchase the GALAFOLD® it seeks from Amicus on commercially reasonable, market-based terms, as defined in 21 U.S.C. §355-2(a)(1).

25. Teva's March 29, 2021 CREATES Act request was addressed to Bradley L. Campbell, president of Amicus Therapeutics U.S., Inc. and thus a named corporate officer of the license holder for GALAFOLD®. Amicus received Teva's request by email on March 29, 2021, and via certified mail by April 13, 2021. *See* certified mail return receipt, attached as **Ex. E**.

26. Teva's March 29, 2021 CREATES Act request provided contact information, including telephone, email and office address, for a primary point of contact (Scott M. Lassman), and a shipment address for the requested quantity of GALAFOLD®. *See* **Ex. C**.

27. Amicus did not respond to Teva's March 29, 2021 CREATES Act request until April 30, 2021 – eighteen days after receiving it by certified mail, and more than a month after receiving it by email. Amicus thus did not comply with the required 14-day response period under 21 U.S.C. §355-2(b)(3)(C)(i), and it did not "offer" to sell GALAFOLD® to Teva. Quite the opposite: in its belated response, Amicus refused to provide the requested quantity of GALAFOLD®, raising a number of specious arguments as to why Teva was not entitled to that amount. Instead, Amicus stated it would only furnish two additional wallet packs of GALAFOLD®. Those are not "sufficient quantities" under 21 U.S.C. §355-2(b). For at least these reasons, Amicus' response does not constitute an offer to sell "sufficient quantities" of GALAFOLD® to Teva at commercially reasonable, market-based terms.

28. Amicus has not delivered any GALAFOLD® in response to Teva's March 29, 2021 CREATES Act request.

29. Amicus has failed to provide sufficient quantities of GALAFOLD® to Teva, and in fact has refused to do so, apparently in an effort to delay potential generic competition to GALAFOLD®.

COUNT I
Failure to Provide a Covered Drug Product
In Violation of 21 U.S.C. § 355-2(b)

30. Teva incorporates each of the preceding paragraphs 1-29 as if fully set forth herein.

31. GALAFOLD® is a covered product that is not subject to a REMS with ETASU.

32. As of the date of the filing of this action, Teva has not obtained sufficient quantities of GALAFOLD® on commercially reasonable, market-based terms.

33. On March 29, 2021, Teva submitted a written request to Amicus to purchase sufficient quantities of GALAFOLD®. This request was sent to Bradley L. Campbell, president of Amicus Therapeutics U.S., Inc. and a named corporate officer of Amicus Therapeutics U.S., Inc.; was made by certified mail with return receipt requested; specified Scott M. Lassman as the primary point of contact for Amicus to direct communications related to the sale of GALAFOLD® to Teva, including email, telephone and office addresses; and specified an address to which the GALAFOLD® was to be shipped upon reaching an agreement to transfer it. *See* **Ex. C**, attached. This request was delivered to Amicus via certified mail, return receipt requested, by April 13, 2021. *See* **Ex. E**, attached.

34. As of May 14, 2021, the deadline under the CREATES Act, Amicus had not delivered to Teva sufficient quantities of GALAFOLD® on commercially reasonable, market-based terms. Nor has Amicus delivered such quantities to Teva at any time since May 14, 2021.

PRAYER FOR RELIEF

WHEREFORE, Teva prays for judgment against Defendant Amicus Therapeutics U.S., Inc. and requests the following relief:

A judgment that Amicus has failed to provide sufficient quantities of GALAFOLD® to Teva, in violation of 21 U.S.C. §355-2;

An immediate order under 21 U.S.C. §355-2(b)(4)(A)(i) and (b)(4)(C) directing Amicus to provide Teva without delay sufficient quantities of GALAFOLD® on commercially reasonable, market-based terms, including the quantity sought by Teva in its March 29, 2021 CREATES Act request;

An award to Teva of its reasonable attorney's fees and costs for this action;

An award to Teva of a monetary amount sufficient to deter Amicus from failing to provide eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, under 21 U.S.C. §355-2(b)(4)(A)(iii); and

An award of all such other relief as this Court deems just and proper.

Dated: July 13, 2021

Respectfully submitted,

By:/s/ *Adam S Tolin*

Adam S. Tolin (Bar Number 91424)
atolin@shb.com
SHOOK, HARDY & BACON L.L.P.
Two Commerce Square
2001 Market St., Suite 3000
Philadelphia, PA 19103
Tel: 215-278-2555
Fax: 215-278-2594

John D. Garretson
jgarretson@shb.com

Lauren E. Douville
ldouville@shb.com
Lydia C. Raw
lraw@shb.com
SHOOK, HARDY & BACON L.L.P.
2555 Grand Blvd.
Kansas City, MO 64108
Tel: 816-474-6550
Fax: 816-421-5547

Attorneys for Plaintiff
Teva Pharmaceuticals Development, Inc.