UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GENUS LIFESCIENCES, INC., Plaintiff, v. **ALEX M. AZAR II**, *et al*., Defendants, **LANNETT CO., INC.**, Intervenor-Defendant.	Case No. 1:20-cv-00211 (TNM)

MEMORANDUM OPINION

In the pharmaceutical development arena, Congress created a "winner-take-all" prize. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the first developer of a "new chemical entity" ("NCE")—a drug approved for the first time in the United States—receives a coveted period of exclusivity ("NCE exclusivity"). During that time, competing drugs generally cannot can enter the market.

Three years ago, Genus Lifesciences, Inc., won five-year NCE exclusivity for its new drug, Goprelto. But earlier this year, a competing drug sponsored by Lannett Co., Numbrino, entered the market.

Genus now cries foul. It claims that the U.S. Food and Drug Administration ("FDA") infringed on its exclusivity period when it approved Numbrino. It believes that under the FDCA, it is entitled to a five-year period of complete market exclusivity, barring all approval and submission of applications for competing drugs. FDA and Lannett, on the other hand, claim that everything is aboveboard. FDA explains that while Genus's exclusivity period prohibits FDA

from accepting any new competing drug applications, it does not bar it from approving applications, like Lannett's, that were already in the approval process.

The Court agrees with FDA that Genus's NCE exclusivity does not cover approvals. But it disagrees with the agency's reasoning. The FDCA prescribes timelines for approval of applications like Lannett's based on the type of patent certification in the application. FDA admits that disregarded these timelines. Since the Court finds that FDA misinterpreted the FDCA, the Court's inquiry stops here for now.

I.

A.

Pharmaceutical companies may market new drugs only with FDA approval. *See* 21 U.S.C. § 355(a). Developing and seeking approval of a pioneer drug often involves much time and money. A company's new drug application ("NDA") to FDA must contain "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." *Id.* § 355(b)(1). Most of those reports "rely in large measure on clinical trials with human subjects" and "several phases of clinical testing," often spanning years. *See Abigail All. for Better Access to Dev. Drugs v. Von Eschenbach*, 495 F.3d 695, 697–98 (D.C. Cir. 2007).

To streamline the approval process for some drugs, Congress enacted the Hatch-Waxman Amendments to the FDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984). These amendments created two abbreviated pathways to new drug approval.

First, a company seeking to market a generic drug can submit an abbreviated new drug application ("ANDA"), which "piggy-back[s] on the brand's NDA." *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (citing 21 U.S.C. § 355(j)). "Rather than

providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Id.*

A second streamlined application option, relevant here, is a 505(b)(2) application. *See* 21 U.S.C. § 355(b)(2) (codifying Section 505(b)(2) of the FDCA). A 505(b)(2) applicant must show that its drug meets the "same safety and effectiveness standard[s] as a stand-alone NDA" (*i.e.*, a 505(b)(1) application). Defs.' Mem. at 13, ECF No. 30-1.[1] Yet "unlike a stand-alone NDA, which relies entirely on studies conducted by its applicant, a '505(b)(2) application' may rely on a combination of the applicant's own studies and other sources, such as published reports of studies and the Agency's findings of safety and/or effectiveness for one or more previously approved drugs, to meet the approval requirements." *Id.* (citing 21 U.S.C. § 355(b)(2)).

FDA regulations outline the 505(b)(2) application process. Within 60 days of an applicant submitting an NDA, FDA conducts a filing review to make "a threshold determination that the NDA is sufficiently complete to permit a substantive review." 21 C.F.R. § 314.101(a)(1). This review determines whether the application on its face includes all the required information, is in the correct form, and whether some other drug's exclusivity period blocks approval or submission. *Id.* § 314.101(a)(1), (d)–(e). If FDA files the application, it notifies the applicant and a 180-day review period begins to run. *Id.* § 314.101(a)(2). If, however, it determines that the application is deficient, the applicant must amend and resubmit the NDA before FDA will substantively review it. *Id.* § 314.101(a)(3).

[1] All page citations refer to the pagination generated by the Court's CM/ECF system. Citations to the Joint Appendix, though, use the J.A. pagination assigned by the parties. The Court has cited only the redacted, public versions of the parties' filings. Nothing in this opinion is taken from redacted portions of the filings, although the Court fully reviewed them in reaching its conclusions.

Once FDA files an NDA, it conducts a substantive review of the application to determine whether it can approve the drug. If, during this review, it "determines that [it] will not approve the application or abbreviated application in its present form," it issues a "Complete Response Letter" ("CRL"). *Id*. § 314.110(a). This letter describes the NDA's deficiencies and "recommend[s] actions that the applicant might take to place the application or abbreviated application in condition for approval." *Id*. An applicant receiving a CRL has three options: it may (1) "[r]esubmit the application or abbreviated application, addressing all deficiencies identified in the complete response letter" (which begins a new review cycle period); (2) "[w]ithdraw the application"; or (3) "[r]equest opportunity for hearing." *Id*. § 314.110(b)(1)–(3).

Once FDA determines that an application meets all statutory requirements, it will approve the NDA and send the applicant an approval letter. *Id.* § 314.105. Approval of a 505(b) application—whether an abbreviated or stand-alone NDA—gives the "first-in-time innovator" a "period of exclusivity." *Otsuka Pharm. Co. v. Price*, 869 F.3d 987, 990 (D.C. Cir. 2017) (citing 21 U.S.C. § 355(c)(3)(E)(ii)–(iv)).

The main issue here is the breadth of that exclusivity period.

B.

Doctors have used cocaine hydrochloride ("HCI") topical solutions in nasal and sinus surgeries for decades, but FDA had never approved a drug that used it as an active ingredient. J.A. at 245, ECF No. 52. Beginning in 2008, Lannett began to market an unapproved cocaine HCI topical solution. *Id*. at 1075. The next year, Lannett discussed a proposal with FDA to submit a 505(b)(2) application for its drug. *Id*. at 607. Meanwhile, in 2013, Genus met with FDA to discuss developing a similar drug. *Id*. at 7–8.

In November 2016, Genus submitted an application to FDA for Goprelto, a cocaine HCI topical solution. *Id*. at 93. FDA reviewed the application and found it "sufficiently complete to permit a substantive review" and accepted it for filing. *Id*. at 122. It noted, though, that it had some substantive concerns about Goprelto's trials, labeling, and data, that Genus would need to address before FDA could approve the drug. *Id*. at 122–30. Genus addressed these concerns and FDA approved Goprelto on December 14, 2017. *Id*. at 577.

While FDA was conducting a substantive review of Genus's application, Lannett submitted its 505(b)(2) application for its cocaine HCI topical solution, Numbrino. On November 29, 2017—15 days before approving Goprelto—FDA filed Lannett's application. *Id*. at 840, 847.

During FDA's substantive review of Lannett's application, FDA issued Lannett a CRL, explaining that Lannett would need to submit additional data for it to approve Numbrino. *Id*. at 1182. As Lannett developed a response to this CRL, Genus filed two citizen petitions, urging FDA to rescind its acceptance of Lannett's application or to stop accepting additional submissions from Lannett, given Genus's NCE exclusivity. *See id*. at 1800, 1928. FDA denied both petitions. *See id*. at 1982, 2027. It approved Numbrino in January 2020. *Id*. at 1323.

Genus now brings its arguments here. *See* Compl., ECF No. 1. It claims that FDA's decision to approve Numbrino violated the FDCA and its own regulations. *Id*. at 26–28. It also argues that FDA applied inconsistent standards of review to Genus and Lannett's NDAs. *Id*. at 25–26. Lannett intervened, *see* Min. Order (Feb. 18, 2020), and the parties cross-moved for summary judgment, *see* Pl.'s Mot., ECF No. 24; Defs.' Cross-Mot., ECF No. 30; Lannett's Cross-Mot., ECF No. 31.

After reviewing the parties' motions, the Court requested supplemental briefing on the proper interpretation of the relevant FDCA exclusivity provision, 21 U.S.C. § 355(c)(3)(E)(ii). *See* Order, ECF No. 53. The parties submitted supplemental briefs, *see* Pl.'s Suppl., ECF No. 57; Defs.' Suppl., ECF No. 56; Lannett's Suppl., ECF No. 55, and this matter is now ripe.[2]

II.

The Court reviews FDA's decision to approve Numbrino under the Administration Procedure Act's ("APA") standards of review. Normally, a court will grant summary judgment when there "is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). But Rule 56's standards do not apply to a court's review of a final agency action under the APA. *See Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 89 (D.D.C. 2006). In these cases, summary judgment "serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Id*. at 90 (citing *Richards v. INS*, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977)).

Under the APA, the Court will set aside FDA's decision only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Grant Med. Ctr. v. Hargan*, 875 F.3d 701, 705 (D.C. Cir. 2017) (quoting 5 U.S.C. § 706(2)(A)). Though a court's review of agency action under the arbitrary and capricious standard is "narrow," it must determine whether the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)

[2] The Court has jurisdiction over this case under 28 U.S.C. § 1331 because this action arises under federal law—specifically the Administrative Procedure Act, 5 U.S.C. §§ 701 *et seq*., the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and 28 U.S.C. § 1361.

(cleaned up). If the agency's reasoning is deficient, the "court should not attempt itself to make up for such deficiencies" or "supply a reasoned basis for the agency's action that the agency itself has not given." *Id.* That is not the role of the courts.

The Court reviews FDA's statutory interpretation under the *Chevron* two-step framework. First, the Court considers "whether Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842 (1984). If the statute is unambiguous, that ends the analysis. *See id*. at 842–43. If the statute is "silent or ambiguous," the Court proceeds to step two and must uphold an agency's interpretation if it "is based on a permissible construction of the statute." *Id.* at 843.

III.

A.

Genus claims that FDA should not have approved Numbrino once Goprelto received exclusivity because the FDCA bars submission *and approval* of competing drugs during the exclusivity period. Pl.'s Mem. at 35, ECF No. 25.

Genus undisputedly held "NCE exclusivity" under 21 U.S.C. § 355(c)(3)(E)(ii) ("Romanette ii") as of December 14, 2017. *See* Defs.' Mem. at 10; Pl.'s Mem. at 7. But just how broad is this exclusivity? The parties agree that the answer turns on the plain language of Romanette ii—especially the second sentence of this clause ("Sentence 2"). As the language is not exactly "plain," the Court will diagram the statute for the benefit of the reader. Romanette ii says:

Sentence 1: Submission

If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), *except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A).*

Conditional Clause

Main Clause

Exception Clause

Sentence 2: Approval

The approval of such an application shall be made effective in accordance with this paragraph *except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.*

Main Clause

Exception Clause

21 U.S.C. § 355(c)(3)(E)(ii).

This passage of the FDCA is admittedly difficult to decipher. But that does not necessarily equate to ambiguity.[3] *Cf. Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) ("[A] court cannot wave the ambiguity flag just because it found the regulation impenetrable on first read."). So what does it mean? In short, Romanette ii means that once FDA approves an NCE, no one can *submit* a subsequent 505(b)(2) application to FDA for a competing drug for five years, or four years if the subsequent 505(b)(2) application contains a certification that no patents would be infringed or violated by approval of the new drug. And FDA can *approve* subsequent 505(b)(2) applications as it does for all other 505(b)(2) applications—by referring to the

[3] Recall that the Court defers to the agency's interpretation of statute only if it is ambiguous. *Chevron*, 467 U.S. at 842–43.

application's patent certification and applying the prescribed timeline tied to each type of patent certification.

Here, Romanette ii means that FDA's approval of Goprelto provided Genus with a five-year *submission* bar. But FDA could approve Lannett's already-submitted application for Numbrino on the normal timeline prescribed for 505(b)(2) applications.

How does the Court reach this conclusion? First, note that Romanette ii on its face never says that a "505(b)(2) application may not be *approved* before the expiration of five years." It bars submissions. 21 U.S.C. § 355(c)(3)(E)(ii) ("[N]o application . . . may be *submitted* under subsection (b)[.]" (emphasis added)). The only mention of approval is that the "approval of such an application shall be made effective in accordance with this paragraph." *Id.* As FDA and Lannett note, this is significant. *See* Defs.' Mem. at 27; Lannett's Mem. at 19, ECF No. 31-1.

Congress showed in the surrounding exclusivity provisions that it "could have easily expressly barred approvals . . . but it chose not to" in Romanette ii. Lannett's Reply at 12, ECF No. 44; *see, e.g.*, 21 U.S.C. § 355(c)(3)(E)(iii) ("[T]he Secretary may not make the approval of an application submitted under subsection (b) . . . effective before the expiration of three years from the date of the approval of the application under subsection (b)[.]"); *id.* § 355(c)(3)(E)(iv) (same). "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (cleaned up).

Nor has the D.C. Circuit held, as Genus suggests, *see* Pl.'s Mem. at 35, that Romanette ii imposes a five-year bar on approvals. In *Otsuka Pharmaceutical Co.*, the D.C. Circuit noted in the statutory background section of its opinion that "Romanette ii confers an exclusivity period

of five years, during which 'no [abbreviated] application which refers to the [first-in-time] drug' may be approved." 869 F.3d at 990 (alterations in original). But that case was not about how to interpret Romanette ii—it involved determining the scope of two other exclusivity provisions in the FDCA. As FDA argues, *see* Defs.' Mem. at 30, this statement is dictum—meant only to provide context for the other two exclusivity provisions. *See In re Grand Jury Investigation*, 916 F.3d 1047, 1053 (D.C. Cir. 2019) ("[A] statement not necessary to a court's holding is dictum."). And this dictum does not provide the Court a basis to ignore the statute's unambiguous text.[4]

So what is the scope of Romanette ii? A closer look at the statute's text and structure is in order.

B.

Romanette ii begins with a conditional clause: "If an application submitted under subsection (b) for a drug, no active ingredient . . . of which has been approved in any other application under subsection (b), is approved after September 24, 1984[.]" 21 U.S.C. § 355(c)(3)(E)(ii). All parties agree that Goprelto was such an application, since it was (1) for a drug using cocaine HCI, which FDA had not approved in any other 505(b) application, and (2) approved by FDA in 2017. *See* Defs.' Mem. at 10; Pl.'s Mem. at 7.

The main clause follows. In sum, it says that no one may submit a subsequent abbreviated application—a 505(b)(2) NDA—to FDA within five years of FDA's approval of the first-in-time drug (*i.e.*, the approved "application under subsection (b)"). *See* 21 U.S.C. § 355(c)(3)(E)(ii). An exception clause follows this main clause: certain applications may be

[4] Genus also relies on a parenthetical in the *Otsuka* district court opinion, which describes 21 U.S.C. § 355(c)(3)(E)(ii) as "directing that . . . no subsequent application . . . may be submitted (or approved) for five years." *Otsuka Pharm. Co. v. Burwell*, 302 F. Supp. 3d 375, 384–85 (D.D.C. 2016); *see* Pl.'s Mem. at 11, 35, 38. But as with the *Otsuka* D.C. Circuit opinion, the district court opinion was about the scope of two *other* exclusivity provisions—21 U.S.C. § 355(c)(3)(E)(iii) and 355(c)(3)(E)(iv). *See Otsuka Pharm Co.*, 302 F. Supp. 3d at 391. The opinion's reference to Romanette ii was in passing, in the background section, not necessary to—or even part of—the analysis, and therefore is dictum. *See id.* at 384–85.

submitted after only four years—505(b)(2) applications that "contain[] a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A)." *Id.*

So what is this "certification of patent invalidity or noninfringement"? This is what FDA calls a "Paragraph IV certification." *See* 21 C.F.R. § 314.50(i)(1)(i)(A)(4). Recall that abbreviated 505(b)(2) applications rely on previously conducted investigations and studies assessing the safety and effectiveness of one or more previously approved drugs to meet FDA's approval requirements. 21 U.S.C. § 355(b)(2). Sometimes, drugs for which those studies were conducted already have patents associated with them. To ensure that no 505(b)(2) application is infringing on a patent, the FDCA mandates that every 505(b)(2) application "shall"—along with all the information required for a stand-alone NDA—"also include a certification . . . with respect to each patent which claims the drug for which" the 505(b)(2) applicant submitted studies and reports. *Id.* The certification must state one of four things: (i) "that such patent information has not been filed"; (ii) "that such patent has expired"; (iii) "the date on which such patent will expire," or (iv) "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(b)(2)(A)(i)–(iv). A Paragraph IV certification refers to this last option. 21 C.F.R. § 314.50(i)(1)(i)(A)(4).

So Sentence 1's exception clause means this: if a later application for a competing drug includes a certification that any patents covering drugs referred to in the studies and reports submitted by the applicant are invalid or will not be infringed by the new drug, *then* FDA can accept the 505(b)(2) application of a competing drug after four years.

Sentence 2 is where the parties most vehemently disagree. It starts with the phrase: "The approval of such an application[.]" 21 U.S.C. § 355(c)(3)(E)(ii). What does "such an application" refer to?

Genus contends that this phrase refers to the subject of Sentence 1—all subsequent 505(b)(2) applications. Pl.'s Mem. at 37. FDA and Lannett, on the other hand, construe this phrase as part of a larger "patent clause," governing only later applications that have a Paragraph IV certification. Defs.' Mem. at 30; Lannett's Mem. at 10–11. Since Lannett's application for a competing drug did not have a Paragraph IV certification, they argue Sentence 2 does not apply here at all. *See* Lannett's Reply at 10.

The Court agrees, on this point, with Genus. "The term 'such,' when used as an adjective, . . . nearly always operates as a reference back to something previously discussed." *Takeda Pharms., U.S.A., Inc. v. Burwell*, 78 F. Supp. 3d 65, 99 (D.D.C. 2015). That, of course, is of limited help since Sentence 1 refers to three applications: the first-in-time application with exclusivity, the subsequent 505(b)(2) application, and a subset of subsequent applications with Paragraph IV certifications.

But rules of statutory interpretation clear up this confusion. Under the "Last-Antecedent Canon," a "pronoun, relative pronoun, or demonstrative adjective generally refers to the nearest reasonable antecedent." *See* Antonin Scalia & Bryan A. Garner, *Reading Law* 144 (2012). This rule would generally support FDA's reading. The nearest antecedent to "such an application" is the application referred to in Sentence 1's exception clause.

But there is an exception to this rule: a pronoun or demonstrative adjective "that is the subject of a sentence and does not have an antecedent in that sentence ordinarily refers to the *subject* of the preceding sentence. And it almost always does so when it is the word that begins the sentence." *Id*. at 146 (emphasis added); *see, e.g.*, *Loftus v. United States*, 46 F.2d 841, 847 (7th Cir. 1931) ("The phrase 'such offender' . . . refers to the subject of that sentence which immediately precedes that phrase, which is 'any person violating this act.'").

This exception applies here. Since Sentence 2 begins with the phrase "approval of such an application," there is no antecedent in that sentence for "such" to reference. Instead, "such an application" refers to the *preceding* sentence and, more specifically, the *subject* of the preceding sentence. The subject of the preceding sentence is in the main clause: an "application which refers to the drug for which the subsection (b) application was submitted and for which the investigations . . . were not conducted by or for the applicant." 21 U.S.C. § 355(c)(3)(E)(ii). In other words, any later competing 505(b)(2) application. For the Court to read "such an application" the way FDA and Lannett do, it would have to locate the subject of Sentence 1 in the exception clause. That defies the rules of grammar.

A second rule of statutory interpretation supports this reading. Under the Presumption of Consistent Usage canon, "[a] word or phrase is presumed to bear the same meaning throughout a text." *See* Scalia & Garner, *supra*, at 170. Though "such an application" may not share the same meaning throughout the FDCA (given that the adjective "such" refers to different antecedents depending on the context), identical phrases in close proximity are, in particular, presumed to share the same meaning. *Brown v. Gardner*, 513 U.S. 115, 118 (1994) (explaining that the presumption of consistent usage is "surely at its most vigorous when a term is repeated within a given sentence").

The phrase "such an application" appears not only in Romanette ii, Sentence 2, but also in Sentence 1's exception clause. *See* 21 U.S.C. § 355(c)(3)(E)(ii). Sentence 1 creates a five-year submission bar for 505(b)(2) applications, "except that *such an application* may be submitted under subsection (b) after the expiration of four years" if it includes a Paragraph IV certification. *Id*. (emphasis added). There, the phrase "such an application" cannot reasonably be read to refer to anything besides any subsequent 505(b)(2) application—the subject of

Sentence 1. That Congress chose to use the same phrase again in the next sentence, without further clarification, suggests that it meant to refer to the same type of application in both instances.

The structure of Romanette ii confirms this reading. The two sentences in Romanette ii follow the same pattern. Sentence 1, addressing submission of any subsequent 505(b)(2) application, says that no subsequent 505(b)(2) application can be submitted within five years of the first-in-time application. *Id.* It then provides a timing exception for applications with Paragraph IV certifications. *Id.* Sentence 2 explains that *approval* of subsequent 505(b)(2) applications will be made effective "in accordance with this paragraph." *Id*. It then provides another timing exception for applications with Paragraph IV certifications: "except that, if an action for patent infringement is commenced . . . the thirty-month period referred to in subparagraph (C)"—which refers to Paragraph IV certifications—"shall be extended." *Id*.

The parallel structure of these two provisions confirms that Congress did not narrow the sweep of "such an application" in Sentence 2 to mean only Paragraph IV certification applications. Sentence 1 applies to submissions and Sentence 2 applies to approvals—with both sentences providing timing exceptions for applications with Paragraph IV certifications.

So the first phrase of Sentence 2 means "approval of subsequent competing 505(b) applications." Then what? The parties agree on the meaning of the next phrase, "shall be made effective." *See* Lannett's Suppl. at 3; Pl.'s Suppl. at 5. Congress used this phrase throughout Section 355 and generally had it precede a statement about a specific timeframe. For instance, directly after Romanette ii, in 21 U.S.C. § 355(c)(3)(E)(iii) and (iv), the statute provides that the Secretary "may not make the approval of" a different type of application "effective before the expiration of three years" after the approval of the first-in-time drug. Or consider 21 U.S.C.

§ 355(c)(3)(C), which says that another application's "approval shall be made effective immediately." *See also, e.g.*, 21 U.S.C. § 355(c)(3)(C)(ii)(II) ("[T]he approval shall be made effective on the date specified by the district court in a court order[.]"); *id.* § 355(j)(5)(B)(iii) ("[T]he approval shall be made effective upon the expiration of the thirty-month period[.]").

So when Romanette ii says that "such an application shall be made effective," the reader expects the next phrase to state a timeframe. It does not—at least at first blush. Instead, it says "in accordance with this paragraph." *Id.* § 355(c)(3)(E)(ii). So what does "this paragraph" mean?

"Congress often drafts statutes with hierarchical schemes—section, subsection, paragraph, and on down the line." *NLRB v. SW Gen., Inc.*, 137 S. Ct. 929, 938–39 (2017). Throughout the FDCA and, particularly in Section 355, "Congress used that structure . . . and relied on it to make precise cross-references. When Congress wanted to refer only to a particular subsection or paragraph, it said so." *Id.* at 939 (describing the Federal Vacancies Reform Act); *see, e.g.*, 21 U.S.C. § 355(a) (referring to applications filed under "subsection (b) or (j)"); *id.* § 355(b)(2) (referring to applications submitted "under paragraph (1)").

The word "paragraph," then, is a legislative term of art, meaning the third level of a statute—*i.e.*, a "subdivision of a subsection." *See* M. Douglass Bellis, *Statutory Structure and Legislative Drafting Conventions* 8 (Fed. Jud. Ctr. 2008), https://www.fjc.gov/sites /default/files/2012/DraftCon.pdf. In Section 355, "paragraphs" are marked by Arabic numbers. *See, e.g.*, 21 U.S.C. § 355(b)(2) (referring to applications submitted "under paragraph (1)"). Subparagraphs and clauses—the next two levels of the statute—are noted by capitalized letters and romanettes, respectively.

The sentence at issue appears in Section 355, subsection (c), paragraph (3), subparagraph (E), clause (ii). So when Romanette ii says "in accordance with this paragraph," it refers the reader back to 21 U.S.C. § 355(c)(3). That paragraph, in turn, provides timelines for approval of applications filed under Section 355(b)(2), depending on the type of patent certification included.

More specifically, Romanette ii instructs FDA to refer to the timelines prescribed in 21 U.S.C. 355(c)(3)(A)–(C). Section 355(c)(3) begins with this instruction:

> The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A)[.]

Immediately following this instruction, Subparagraphs (A), (B), and (C) provide three timelines—all tied to an application's "certification made under subsection (b)(2)(A)." If the applicant certified that "such patent information has not been filed" or that "such patent has expired," (*i.e.* "a certification described in clause (i) or (ii) of subsection (b)(2)(A)"), then "approval may be made effective immediately." *Id.* § 355(c)(3)(A). A Paragraph III certification—providing "the date on which such patent will expire," *id.* § 355(b)(2)(A)(iii)—may not be approved until "the date certified" that the patent will expire. *Id.* § 355(c)(3)(B). Finally, an application with a Paragraph IV certification "shall be made effective immediately unless . . . an action is brought for infringement of the patent that is the subject of the certification." *Id.* § 355(c)(3)(C). Then approval is not effective until "the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order." *Id.*

So Romanette ii's instruction that "approval" be "made effective in accordance with this paragraph" means that FDA should refer to the subsequent 505(b)(2) application's patent certification to determine the timeline for approval of that application.

This makes sense. But even clearer language in the parallel provision of Section 355 bolsters this reading. As Genus and FDA recognize, the FDCA contains a substantially identical provision to Romanette ii that applies to ANDAs. *See* Pl.'s Reply at 34 n.8, ECF No. 38; Defs.' Mem. at 30 n.12; 21 U.S.C. § 355(j)(5)(F)(ii) ("ANDA Clause"). This clause, though, has a slight variation in its language. Rather than say that approval "shall be made effective in accordance with *this paragraph*," 21 U.S.C. § 355(c)(3)(E)(ii) (emphasis added), it says approval "shall be made effective in accordance with *subparagraph (B)*," *id*. § 355(j)(5)(F)(ii) (emphasis added).

Section 355(j)(5)(B) (*i.e.*, "Subparagraph (B)"), in turn, directly mirrors the language of Section 355(c)(3). *Compare id*. § 355(j)(5)(B), *with id*. § 355(c)(3). It directs FDA to reference the patent certification contained in the application to find the timeline for approval. It then provides three clauses—21 U.S.C. § 355(j)(5)(B)(i)–(iii)—that provide the same timeframes as 21 U.S.C. § 355(c)(3)(A)–(C). The ANDA clause—by referencing Subparagraph (B)—certainly was directing the reader to a different portion of the statute to find the timeline for approval. So why should the Court read the reference to "this paragraph" in 21 U.S.C. § 355(c)(3)(E)(ii) any differently?

Indeed, FDA's own regulations support this reading. Under the heading "Submission of and timing of approval of a 505(b)(2) application or ANDA," FDA's regulations explain the following about Romanette ii's submission bar:

> If a drug product that contains a new chemical entity was approved after September 24, 1984, in an NDA submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act, no person may submit a 505(b)(2) application or ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act for a drug product that contains the same active moiety as in the new chemical entity for a period of 5 years from the date of approval of the first approved NDA, except that the 505(b)(2) application or ANDA may be submitted after 4 years if

> it contains a certification of patent invalidity or noninfringement described in § 314.50(i)(1)(i)(A)(4) or § 314.94(a)(12)(i)(A)(4).

21 C.F.R. § 314.108(b)(2). The very next paragraph describes Romanette ii's instruction for approval of 505(b)(2) applications:

> The **approval of a 505(b)(2) application** or ANDA **described in paragraph (b)(2) of this section** [*i.e.*, 21 C.F.R. § 314.108(b)(2)] will occur **as provided in § 314.107(b)(1) or (2),** unless the owner of a patent that claims the drug, the patent owner's representative, or exclusive licensee brings suit for patent infringement against the applicant during the 1-year period beginning 48 months after the date of approval of the NDA for the new chemical entity and within 45 days after receipt of the notice described at § 314.52 or § 314.95, in which case, approval of the 505(b)(2) application or ANDA will occur as provided in § 314.107(b)(3).

Id. § 314.108(b)(3) (emphasis added). Note, first, that FDA's regulation itself interprets Romanette ii's reference to "such an application" as "approval of a 505(b)(2) application . . . described in paragraph (b)(2) of this section." *Id*. In other words, any subsequent 505(b)(2) application. The regulation does *not* limit its approval instruction to 505(b)(2) applications that have Paragraph IV certifications.

Second, the regulation points FDA to a *different* regulation to determine the timeline for approval of these subsequent 505(b)(2) applications: 21 C.F.R. § 314.107(b)(1) or (2). Section 314.107(b) says that:

> As described in paragraphs (b)(1) and (2) of this section, the status of patents listed for the listed drug(s) relied upon or reference listed drug, as applicable, must be considered in determining the first possible date on which a 505(b)(2) application or ANDA can be approved.

Section 314.107(b)(1)(i) then explains that a "505(b)(2) application or ANDA may be approved . . . [i]mmediately, if the applicant certifies . . . that:

> (A) The applicant is aware of a relevant patent but the patent information required under section 505(b) or (c) of the Federal Food, Drug, and Cosmetic Act has not been submitted to FDA; or
> (B) The relevant patent has expired; or
> (C) The relevant patent is invalid, unenforceable, or will not be infringed, except as provided in paragraphs (b)(3) and (c) of this section, and the 45–day period

> provided for in section 505(c)(3)(C) and (j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act has expired; or
> (D) There are no relevant patents.

Clauses (ii) and (iii) provide the timelines for 505(b)(2) applications with Paragraph III and Paragraph IV certifications. *See id*. § 314.107(b)(1)(ii)–(iii).

See the parallels? FDA's regulations explain that subsequent competing 505(b)(2) applications are barred from submission for five (or four) years *and* that those same applications are approved according to the type of patent certification in the application.

So even if the Court were to proceed to "*Chevron* step two" and defer to FDA's reasonable interpretation of Romanette ii, the result would be the same. The Court does not defer to the litigation position in the agency's briefs, but only to an "agency interpretation" that "was promulgated in the exercise of [delegated] authority"—*i.e.*, rules and regulations. *Miller v. Clinton*, 687 F.3d 1332, 1341 (D.C. Cir. 2012). Here, the FDA's promulgated regulations support the Court's interpretation of Romanette ii, even if FDA's litigation position does not.

C.

The parties agree with this analysis—to a point. In supplemental briefing, all admit that "this paragraph" indeed means 21 U.S.C. § 355(c)(3), *not* specifically 21 U.S.C. § 355(c)(3)(E)(ii). *See* Pl.'s Suppl. at 5; Lannett's Suppl. at 3; Defs.' Suppl. at 7 (accepting, but not explicitly affirming the Court's interpretation).

But that is where the agreement ends. Despite the Court's interpretation and FDA's own regulations, the parties do *not* think that the Court should use the timelines prescribed in Subparagraphs (A), (B), and (C) to determine when FDA should have approved Numbrino. Here's why.

FDA and Lannett suggest Subparagraphs (A), (B), and (C) *cannot* apply to Numbrino because Lannett did not submit a patent certification with its 505(b)(2) application. Defs.' Suppl. at 7; Lannett's Suppl. at 2. FDA, specifically, notes that Paragraph 3's directives apply only to "an application filed under subsection (b) ***which contains a certification*** required by paragraph (2) of such subsection." Defs.' Suppl. at 7 (emphasis in original). So since "Lannett's application does not contain a patent certification, none of the approval timelines in subparagraphs (A)–(C) of Paragraph 3 is applicable." *Id.*

This is perplexing, since FDA implies that a patent certification is an optional part of a 505(b)(2) application. It is not. The FDCA explains that a 505(b)(2) application "*shall* also include . . . a certification" that the "patent information has not been filed," that the patent "has expired," that the patent "will expire" on a specific date, or that the patent "is invalid or will not be infringed." 21 U.S.C. § 355(b)(2)(A)(i)–(iv); *see* Pl.'s Suppl. at 6 ("Every drug sponsor submitting a 505(b)(2) application . . . includes as part of its application patent certifications under Paragraph (b)(2) and applicable regulations.").

The FDA's regulations agree:

> A 505(b)(2) application must contain the following: . . . .
>
> If, in the opinion of the applicant and to the best of its knowledge, there are no patents described in paragraph (i)(1)(i) of this section, a certification in the following form:
>
> In the opinion and to the best knowledge of (name of applicant), there are no patents that claim the drug or drugs on which investigations that are relied upon in this 505(b)(2) application were conducted or that claim a use of such drug or drugs.

21 C.F.R. § 314.50(i)(1)(ii). Applications with this certification are viewed as Paragraph I certifications (*i.e.*, a certification "that such patent information has not been filed") and are approved immediately in accordance with 21 U.S.C. § 355(c)(3)(A) and 21 C.F.R.

§ 314.107(b)(1)(i)(D). *See* Pl.'s Suppl. at 7 n.3. It is unclear why here in litigation, FDA takes a position so clearly in opposition to its regulations. *See Nat'l Envtl. Dev. Ass'ns Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014) ("It is axiomatic . . . that an agency is bound by its own regulations." (cleaned up)).

Indeed, even in its supplemental brief, FDA fails to emphasize the critical language of Section 355(c)(3). Paragraph 3 applies to "an application filed under subsection (b) ***which contains a certification*** required by paragraph (2) of such subsection." 21 U.S.C. § 355(c)(3) (emphasis in FDA's brief, underlining added). True, not every application filed under "subsection (b)" requires a certification. For instance, stand-alone applications filed under 505(b)(1) would have no need to include a patent certification since they do not rely on anyone else's studies or reports. But "paragraph (2)"—that is, 505(b)(2)—applications *require* that certification. *See id.* § 355(b)(2)(A).

As FDA and Lannett acknowledge, Lannett did not submit a patent certification. Instead, FDA's assessment form for Lannett's Numbrino application checks a box under "Patent Certification/Statements" that says, "No patent certifications are required (e.g., because application is based solely on published literature that does not cite a specific innovator product)." J.A. at 1788. Strangely, though *every other option* for "Patent Certification/Statements" on the form provides a statutory or regulatory basis for that option, this one option cites *no* regulatory or statutory basis. *Id.*[5] It is thus unclear on what basis FDA could justify accepting a 505(b)(2) application without a certification. If, as Lannett and FDA claim, there were no patents covering the studies relied on for Numbrino, Lannett should have, at least, filed a certification saying there were "[n]o relevant patents." *See* 21 C.F.R. § 314.50(i)(1)(ii).

[5] It is also unclear what the distinction is between this option and the seventh option on the form: "21 CFR 314.50(i)(1)(ii): No relevant patents." J.A. at 1788.

Nor does the Court agree with Lannett's alternative interpretation of the phrase "shall be made effective in accordance with this paragraph." According to Lannett, Congress did not really mean to refer the reader to Paragraph 3. Lannett's Suppl. at 3. It says that "this paragraph" refers only to Section 355(c)(3)(C). *Id*. Indeed, it needs to argue this because of how it defines "such an application" at the beginning of Sentence 2. If "such an application" means, as Lannett says, a "505(b)(2) application with a Paragraph IV certification," then it would make little sense for Congress to broadly direct the reader back to all of Section 355(c)(3), which includes timelines for applications with *all* types of certifications.

Lannett's argument faces another problem, though. If Congress wanted to refer to Subparagraph (C), it would have done so. In Romanette ii, Sentence 2 itself, Congress homes in on Subparagraph (C), citing it in the exception clause. *See* 21 U.S.C. § 355(c)(3)(E)(ii). It would be odd for Congress to refer to this subparagraph as "this paragraph" at the beginning of the sentence, only to refer to it again as "subparagraph (C)" a few words later.

Genus disagrees with the Court for a different reason. While it affirms that "this paragraph" refers to Paragraph 3, it notes that Paragraph 3 contains more than just Subparagraphs (A)–(C). Pl.'s Suppl. at 7. FDA must also consider Subparagraphs (D)–(E), it argues, when trying to determine Numbrino's approval timeline, since Paragraph 3 states that "[t]he approval . . . shall be made effective on the *last* applicable date." *Id*. at 7–9 (citing 21 U.S.C. § 355(c)(3)). Romanette ii (in Subparagraph E), it argues, "also contains an 'applicable date' for approvals: Five years." *Id.* at 8.

Under this reading, Genus argues Romanette ii would block Numbrino's approval for five years. But three clues suggest this clause lacks the applicable timeline for approval. *First*, if Congress wanted FDA to apply the five- or four-year submission bar timeline to approvals of

subsequent 505(b)(2) applications, there is no reason for it to refer to Paragraph 3. It would have just said "approvals shall be made effective in accordance with *this clause*" or "clause (ii)." Genus provides no reasoned explanation for why it would refer to the timeline in Romanette ii through such a round-about way as Genus proposes.

Second, reading the prefacing text of Paragraph 3 as applying only to Subparagraphs (A)–(C) matches the parallel provisions in the ANDA section of the statute. Recall that the equivalent ANDA provision of Romanette ii refers the reader to the timelines "in accordance with subparagraph (B)." 21 U.S.C. § 355(j)(5)(F)(ii). Subparagraph (B) and the next three clauses (i)–(iii) provide the approval timeline for an ANDA, depending on the type of patent certification in the application. *Id.* § 355(j)(5)(B). Notably, the ANDA exclusion clauses do *not* appear under Subparagraph (B). They appear in their own subparagraph—Subparagraph (F). *See id*. § 355(j)(5)(F). In other words, the parallel ANDA provisions show that Congress did not mean to sweep Subparagraph (E) exclusions into the timelines provided under 21 U.S.C. § 355(c)(3).

Genus argues that this difference in structure was intentional. Pl.'s Suppl. at 12. It submits that, since ANDAs can never be submitted before approval of a drug with NCE exclusivity (there would be no pre-existing drug to copy), "the ANDA [NCE exclusivity] provision's bar on submissions functions automatically to bar approvals for five years." *Id*. So there was no need for Congress to "generally subject ANDA approvals to the limits of the ANDA NCEE provision[;] . . . the 5-year submission bar ***already*** provided a 5-year approval bar." *Id*. at 13 (emphasis in original).

Perhaps so. But this explanation still does not grapple with the statutory language in Paragraph 3—which is the *third* reason Subparagraph (E) does not provide the applicable

timeline. Paragraph 3—before reaching Subparagraphs (A)–(C)—says that "approval . . . shall be made effective on the last applicable date determined *by applying the following to each certification* made under subsection (b)(2)(A)." 21 U.S.C. § 355(c)(3) (emphasis added). Subparagraphs (A)–(C) then provide three timelines for approval based on each application's patent certification. *Id.* § 355(c)(3)(A)–(C). Subparagraphs (D) and (E)—though they appear at the same "subparagraph" level—clearly address different aspects of 505(b) applications, "[c]ivil action[s] to obtain patent certainty" and exclusivity periods. *Id*. § 355(c)(3)(D)–(E).

Finally, even if Genus were correct that Subparagraph (E) should be considered as part of "this paragraph," it still would not provide the result Genus wants. Nothing in Romanette ii bars *approvals* for five- or four-year periods. So even if FDA considered Subparagraph (E) in its search for the applicable timeline under "this paragraph," Romanette ii of Subparagraph (E) would not provide a later "applicable date."

D.

Along with its statutory construction arguments, Genus raises a policy reason for why Romanette ii should be read to block approval during the exclusivity period. Congress created exclusivity periods to incentivize innovation and to reward "drug makers who develop drugs containing an active ingredient that is not a component of an existing FDA-approved drug." Pl.'s Mem. at 10. And Congress, it claims, intended Romanette ii to be the "'FDCA's broadest grant of marketing exclusivity . . . commensurate with the degree of innovation required to' [obtain it]." *Id*. (citing *Otsuka Pharm. Co.*, 869 F.3d at 990, 993).

But, it reasons, how could Romanette ii be "FDCA's broadest grant of marketing exclusivity," if it does not bar approvals? Other surrounding provisions in the FDCA unequivocally prohibit approval of competing applications. *See, e.g.*, 21 U.S.C.

§ 355(c)(3)(E)(iii). If the Court interprets those provisions to "reach more broadly than" Romanette ii, the Court would "undermine Congress's intent." Pl.'s Mem. at 39 (emphasis omitted).

But in most cases, Romanette ii *does* provide NCE exclusivity holders with a broader grant of exclusivity than other provisions. As Genus itself recognizes, "a bar on 'submission' is even broader than a bar on FDA 'approvals'—it means the second-in-time applicant cannot even *begin* the lengthy FDA review process, and so cannot be ready for approval on the day after the exclusivity period ends, as frequently occurs under other forms of exclusivity." *Id.* at 12.

This case is a rare exception—likely one that Congress did not even contemplate.[6] Indeed, "FDA is not aware of another set of 'dueling' 505(b)(2) applications since 1984." J.A. at 1925. That is because, generally, NCE exclusivity protects development of "novel, heretofore unknown molecule[s]." Defs.' Mem. at 32. It would be a strange coincidence for two companies at the same time to develop the same NCE and apply to FDA.

Here, Genus and Lannett both submitted applications for a drug using cocaine which "has been known and used for various purposes as a drug for well over a century." *Id.* Their dueling applications set an unexpected stumbling block for Genus—since Lannett submitted its application before Genus's approval date, Romanette ii's broad exclusivity provision did not apply.

Perhaps this is a loophole. But it is not the Court's loophole to close. A court's role is "to interpret the language of the statute enacted by Congress, not to improve upon it." *Eagle Pharms., Inc. v. Azar*, 952 F.3d 323, 340 (D.C. Cir. 2020) (cleaned up).

[6] As Genus points out in supplemental briefing, there are contextual clues that Congress may have *assumed* that approval would always follow the five-year submission bar. Pl.'s Suppl. at 9–10. Even so, the Court cannot ignore what Congress actually said: Romanette ii's exclusivity period extends only to submission, not approval, of competing drug applications.

* * *

So what does all this mean for this case?

First, it means that Genus is mistaken that its NCE exclusivity bars submission *and* approval of subsequent 505(b)(2) applications. Romanette ii bars submission of competing 505(b)(2) applications but does not bar their approval.

More, it means that FDA also misapplied Romanette ii. Despite the language of the statute, FDA claims that "Romanette ii does not require FDA to approve Lannett's application within the timelines prescribed in Paragraph 3." Defs.' Suppl. at 4. The Court disagrees. The plain language of Romanette ii and Paragraph 3 makes approval of a subsequent 505(b)(2) application effective based on that subsequent application's patent certification. Based on FDA's own representations, it did not consider the timelines prescribed in Paragraph (3) when it approved Numbrino.

IV.

"Under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end[.]" *PPG Indus. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995). FDA correctly determined that Genus's exclusivity period did not bar it from approving Numbrino. But by misinterpreting the approval clause of Romanette ii, it failed to provide a reasoned explanation to this Court for when Lannett's application could properly be approved under the FDCA. The Court will thus deny summary judgment for FDA and Lannett and grant it, in part, to Genus on Count III. A separate Order will issue.

2020.09.15
16:14:49 -04'00'

Dated: September 15, 2020

TREVOR N. McFADDEN, U.S.D.J.