United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Amy J. St. Eve	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	09 C 4572	**DATE**	12/11/2009
CASE TITLE	Winston Labs vs. Sebelius et al.		

DOCKET ENTRY TEXT

Defendants' Motion to Dismiss [11] is denied.

■[For further details see text below.] Notices mailed by Judicial staff.

STATEMENT

For the following reasons, the Court denies Kathleen Sebelius, as Secretary and Senior Officer of the United States Department of Health and Human Services, and Margaret Hamburg, M.D.'s, as Commissioner and Senior Officer of the United States Food and Drug Administration ("FDA") (collectively, "Defendants"), Motion to Dismiss.

BACKGROUND

In its complaint, Plaintiff Winston Laboratories, Inc. ("Winston Labs") seeks declaratory and injunctive relief challenging the FDA's denial of Winston Labs' application for a fee waiver pursuant to the small business waiver provision of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 379h(d)(1)(D). (R. 1-1, Complaint, ¶ 1.)

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Courtroom Deputy Initials:	KF

I. FDCA

Pursuant to the FDCA, any person who submits a new drug application to the FDA on or after September 1, 1992 is subject to a user fee. 21 U.S.C. § 379h(a)(1)(A). The FDCA, however, provides for fee waivers or reductions in certain instances. Pursuant to 21 U.S.C. § 379h(d)(1)(D), the FDA "shall grant to a person who is named as the applicant in a human drug application a waiver from or a reduction of one or more fees assessed to that person under subsection (a) where the Secretary finds that . . . (D) the applicant involved is a small business submitting its first human drug application to the Secretary for review." Specifically, the FDCA provides that, "the Secretary shall waive under paragraph (1)(D) the application fee for the first human drug application that a small business *or its affiliate* submits to the Secretary for review." 21 U.S.C. § 379h(d)(4)(B) (emphasis added). For the purposes of paragraph (1)(D), "the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates, and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce." 21 U.S.C. § 379h(d)(4)(A). The FDCA further provides that, "[i]n determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and *any affiliate of the applicant*." 21 U.S.C. § 379h(d)(2) (emphasis added). The FDCA defines "affiliate" to mean "a business entity that has a relationship with a second business entity if, directly or indirectly--

> (A) one business entity controls, or has the power to control, the other business entity; or
> (B) a third party controls, or has power to control, both of the business entities."

21 U.S.C. § 379g(11). The FDCA further states that, "After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay--

> (i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and
> (ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business."

21 U.S.C. § 379h(d)(4)(B).

II. Winston Labs

The FDA premised its denial of Winston Labs' fee waiver request on Winston Labs' relationship with two other pharmaceutical companies. Winston Labs is a Delaware corporation incorporated in 1998. (R. 1-1, Complaint, ¶¶ 7, 33.)[1] Dr. Joel Bernstein and his immediate family members own approximately 60% of Winston Labs. *Id.* at ¶ 33. Northbrook Testing Co., Inc. ("Northbrook") was an Illinois corporation that dissolved in 1984. *Id.* at ¶ 31. Prior to its dissolution, Dr. Bernstein was President of Northbrook and owned a majority of its shares. *Id.* GenDerm Corporation ("Genderm") was an Illinois corporation incorporated in 1983. *Id.* at ¶ 32. In 1997, GenDerm's stock was sold to Medicis Pharmaceutical Corporation ("Medicis"), and GenDerm merged into Medicis. *Id.* Dr. Bernstein was a minority shareholder and Chairman and CEO of GenDerm prior to its merger with Medicis. *Id.* At no time did Winston Labs ever control, or have the power to control, Northbrook or GenDerm. *Id.* at ¶ 34. At no time did a third party, including Dr. Bernstein, control or have the power to control, both Winston Labs and Northbrook, or Winston Labs and GenDerm. *Id.* at ¶ 35.

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[1] The factual section of this opinion is based on allegations contained in Winston Labs' complaint.

III. Relevant Events

Winston Labs filed a fee waiver request under the small business waiver provision of the FDCA on May 21, 2008 for new drug application ("NDA") 22-403 for Civanex cream. *Id.* at ¶ 4. NDA 22-403 was Winston Labs' first human drug application submitted to the FDA for review. *Id.* at ¶ 38. In a letter dated December 1, 2008, the FDA denied Winston Labs' waiver request. *Id.* at ¶ 25; Ex. D. The letter stated that "for purposes of determining whether to grant a small business waiver, FDA considers all affiliates, even those that are no longer in existence." *Id.* at Ex. D, p. 2. The FDA concluded that due to Dr. Bernstein's prior relationship with GenDerm and Northbrook, the FDA considered both GenDerm and Northbrook to be affiliates of Winston Labs. *Id.* Accordingly, because GenDerm and Northbrook had "previously submitted NDAs for review by the FDA" and "the application for NDA 22-403, Civanex Cream 0.075%, [was] not the first human drug application submitted by Winston or its affiliates to the FDA," the FDA denied Winston Labs' request for a small business waiver of the user fee. *Id.*

On December 9, 2008, Winston Labs requested the FDA to reconsider its denial of Winston Labs' request for a small business user fee waiver. *Id.* at p. 27. On February 2, 2009, the FDA denied the request for reconsideration. *Id.* at ¶ 28. The FDA stated that "because Dr. Bernstein *controlled* both Winston and Northbrook," Northbrook is an affiliate of Winston Labs under the FDCA, and that "because Dr. Joel Bernstein *had* the power to control both Winston and GenDerm, GenDerm is considered an affiliate of Winston for the purposes of the Act." *Id.* at Ex. F, pp. 3-4 (emphasis added).

On April 8, 2009, Winston Labs appealed the FDA's denial of its fee waiver request to the FDA User Fee Appeals Officer. *Id.* at ¶ 29. In a letter dated June 18, 2009, the FDA upheld its denial of Winston Labs' request for a fee waiver. *Id.* at ¶ 30; Ex. H. The User Fee Appeals Officer found that although there was not sufficient evidence to determine whether GenDerm and Winston Labs were affiliates, the evidence demonstrated that Northbrook and Winston Labs were affiliates and that Northbrook previously submitted an NDA to the FDA. *Id.* at Ex. H, p. 11. Accordingly, the User Fee Appeals Officer upheld the denial of Winston Labs' request for a small business fee waiver. *Id.* at ¶ 30; Ex. H.

LEGAL STANDARD

I. Motion to Dismiss Standard

"A motion under Rule 12(b)(6) challenges the sufficiency of the complaint to state a claim upon which relief may be granted." *Hallinan v. Fraternal Order of Police of Chicago Lodge No. 7,* 570 F.3d 811, 820 (7th Cir. 2009). Pursuant to Rule 8(a)(2), a complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a)(2). As the Seventh Circuit recently explained, this "[r]ule reflects a liberal notice pleading regime, which is intended to 'focus litigation on the merits of a claim' rather than on technicalities that might keep plaintiffs out of court." *Brooks v. Ross,* 578 F.3d 574, 580 (7th Cir. 2009) (quoting *Swierkiewicz v. Sorema N.A.,* 534 U.S. 506, 514, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002)). This short and plain statement must "give the defendant fair notice of what the claim is and the grounds upon which it rests." *Bell Atlantic v. Twombly,* 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) (quoting *Conley v. Gibson,* 355 U.S. 41, 47, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957)). Also, under the federal notice pleading standards, a plaintiff's "factual allegations must be enough to raise a right to relief above the speculative level." *Twombly,* 550 U.S. at 555. Put differently, a "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal,* 129 S.Ct. 1937, 1949 (2009) (quoting *Twombly,* 550 U.S. at 570); *see also Limestone Dev. Corp. v. Village of Lemont, Ill.,* 520 F.3d 797, 803 (7th Cir. 2008) (amount of factual allegations required to state a plausible claim for relief depends on complexity of legal theory). "[W]hen ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus,* 551 U.S. 89, 127 S.Ct. 2197, 2200, 167 L.Ed.2d 1081 (2007).

II. Review of Agency Statutory Interpretation

The Administrative Procedure Act, 5 U.S.C. § 701, *et seq.*, sets out the standards for reviewing federal agency action. An agency may articulate its policies through its adjudicative process or through regulations. *See Bullwinkel v. FAA*, 23 F.3d 167, 171 (7th Cir. 1994) (citing cases). "Considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984); *Ali v. Achim*, 468 F.3d 462, 468 (7th Cir. 2006). Under 5 U.S.C. § 706, the Court may overturn an agency's interpretation of law only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *see Chao v. Gunite Corp.*, 442 F.3d 550, 556 (7th Cir. 2006).

In analyzing an agency's interpretation of a statute, the Court first applies traditional tools of statutory construction to the language of the statute to determine its plain meaning. *Chevron*, 467 U.S. at 843 n.9. The agency's interpretation of the statute must not conflict with the plain meaning of the statute. *Sullivan v. Everhart*, 494 U.S. 83, 88-9, 110 S. Ct. 960, 108 L. Ed. 2d 72 (1990); *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291-292, 108 S. Ct. 1811, 100 L. Ed. 2d 313 (1988). "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43.

If Congress' intent is not clear, the Court determines whether the agency's answer is based on a permissible construction of the statute. *See Chevron*, 467 U.S. at 843; *Ali*, 468 F.3d at 468; *see also Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512, 114 S. Ct. 2381, 129 L. Ed. 2d 405 (1994); *Paragon Health Network, Inc. v. Thompson*, 251 F.3d 1141, 1145 (7th Cir. 2001). The Court may look to the legislative history of the statute to determine whether the agency's interpretation is permissible. *See Chevron*, 467 U.S. at 845; *Harrell v. United States Postal Serv.*, 445 F.3d 913, 924 (7th Cir. 2006); *Square D Co. v. Comm'r*, 438 F.3d 739, 745 (7th Cir. 2006). The Court must uphold an agency's permissible interpretation even if it differs from the construction the Court would have given the statute if the question initially had arisen in a judicial proceeding. *See Ali*, 468 F.3d at 468 (citing *Chevron*, 467 U.S. at 843 n. 11).

ANALYSIS

This case involves a challenge to the FDA's interpretation of the small business fee waiver provision of the FDCA. The parties agree that the *Chevron* analysis governs Defendants' Motion to Dismiss. Defendants contend that the Court should uphold the FDA's denial of Winston Labs' fee waiver request and dismiss Winston Labs' complaint because: (i) the FDA's decision was consistent with the plain language of the FDCA, and (ii) even if the relevant language of the FDCA is ambiguous, the FDA's decision was based on a permissible construction of the statute and therefore warrants deference. (R. 12-1, Memorandum in Support of Defendants' Motion to Dismiss ("Memorandum"), pp. 8-14.) Winston Labs argues that: (i) the FDA's ruling was contrary to the plain language of the statute, and (ii) even if the Court proceeds to step two of the *Chevron* analysis, the FDA's interpretation of the statute is unreasonable and not entitled to deference. (R. 18-1, Plaintiff's Response in Opposition to Defendants' Motion to Dismiss ("Response"), pp. 6-12.) Because Defendants have not established that giving effect to the plain language of the FDCA requires dismissal of Plaintiff's action, or that the statute is ambiguous and therefore the FDA's interpretation warrants deference, the Court denies Defendants' Motion to Dismiss.

As step one in the *Chevron* analysis, if "the statute speaks clearly 'to the precise question at issue,' [a court] 'must give effect to the unambiguously expressed intent of Congress.'" *Barnhart v. Walton*, 535 U.S. 212, 218 (2002) (citing *Chevron*, 467 U.S. at 842-843). *See also Miles v. S.C. Johnson & Son*, 2002 U.S. Dist. LEXIS 22695 (N.D. Ill. Nov. 22, 2002) (*Chevron* "deference is appropriate, however, only if 'the intent of Congress is unclear.' If, on the other hand, 'a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect.'") (internal citations omitted). In their Motion to Dismiss, Defendants posit that the plain terms of the FDCA

require the Court to "read [the] definition [of affiliate] to include all entities related horizontally or vertically to an applicant." (R. 19-1, Motion to Dismiss, p. 8.) Specifically, Defendants argue that Winston Labs is not entitled to a fee waiver pursuant to the plain language of the statute because Winston Labs is an affiliate of Northbrook, a now defunct entity which previously submitted an NDA to the FDA and which was defunct at the time Winston Labs submitted the application at issue in this suit.[2]

Here, while the language of the statute at issue is clear, it does not warrant the interpretation set forth by Defendants. The FDCA requires the FDA to "waive . . . the application fee for the first human drug application that a small business *or its affiliate* submits to the Secretary for review." 21 U.S.C. § 379h(d)(4)(B). The FDCA defines "affiliate" to mean "a business entity that *has* a relationship with a second business entity if, directly or indirectly – (A) one business entity *controls*, or *has the power to control*, the other business entity; or (B) a third party *controls*, or *has power to control*, both of the business entities." 21 U.S.C. § 379g(11) (emphasis added). As noted in Winston Labs' response, "[t]he relevant terms 'has' and 'controls' as used in the definition of 'affiliate' denote present control or present power to control." (R. 18-1, Response, p. 2) (emphasis in original). Defendants assert that the FDA found that "Winston and Northbrook are affiliates" because "Dr. Bernstein *was*, at relevant times, the owner and CEO of both entities, and thus *controlled* or *had the power to control* them both." (R. 12-1, Memorandum, p. 9) (emphasis added; internal citations omitted). The FDA's reasoning is contrary to the plain language of the statute which defines "affiliate" in the present tense. Defendants have not established that Winston Labs controls, or has the power to control, Northbrook, or that a third party controls, or has the power to control, both Winston Labs and Northbrook. Indeed, Northbrook was dissolved in 1984 – almost 25 years before Winston Labs submitted its application to the FDA. Accordingly, Northbrook's submission of an NDA to the FDA does not affect Winston Labs' waiver request.

Defendants make several conclusory arguments in support of their construction of the relevant FDCA provisions. First, Defendants contend that "a small business is ineligible for a fee waiver for an NDA submitted in 2008 if a now-dissolved affiliate submitted an NDA in 1990. There is simply no basis in the Act for reaching a different result if the earlier-submitted NDA was submitted by an affiliate." (R. 12-1, Memorandum, p. 10.) Defendants further argue that a contrary result would "ignore the Act's specific requirement that the FDA take into account the prior actions of affiliates." *Id.* Defendants' arguments, however, are unpersuasive. This is not a case that presents conflicting interpretations of an undefined term. Congress specifically defined the term "affiliate" in the text of the FDCA employing a present sense definition. If Congress intended the term "affiliate" to include dissolved, defunct or previously existing corporate entities, Congress could have included such a definition of "affiliate" in the text of the FDCA. *See* 21 U.S.C. § 379g(11); *United States v. Wilson*, 503 U.S. 329, 333 (1992) ("Congress' use of a verb tense is significant in construing statutes"). While Defendants argue that the use of a verb tense does not "mandate" a result contrary to the intended application of a statute, they provide no persuasive support to establish that adopting the present sense definition of "affiliate" renders such a result. Indeed, Defendants recognize that the Dictionary Act provides that, "[i]n determining the meaning of any Act of Congress, unless the context indicates otherwise . . . words used in the present tense include the future as well as the present." 1 U.S.C. § 1. Despite this guidance, Defendants take the untenable position that the Court should read present tense words to include the *past* as well as the present. *See, e.g., In re Kmart Corp.*, 2006 Bankr. LEXIS 542, *27 (Bankr. N.D. Ill. Apr. 11, 2006) (enforcing the present sense definition of the statutory phrase "is authorized" and noting that "pursuant to § 1 of the Dictionary Act . . . 'in determining the meaning of any Act of Congress, unless the context indicates otherwise … words used in the present tense include the future as well as the present …'; they do not include the past . . . [n]othing in the context of the statute here indicates otherwise") (citing 1 U.S.C. § 1).

Defendants are correct that the Court must consider the statutory text at issue in the context of the statue

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[2] The Court notes that Northbrook, an Illinois corporation that was dissolved in 1984, submitted its NDA to the FDA prior to the introduction of the user fee requirement. (R. 1-1, Complaint, ¶ 31.)

as a whole. The Seventh Circuit has stated that, "[w]hen we interpret a statute, we look first to its language. If that language is plain, our only function is 'to enforce it according to its terms.' The plain meaning of a statute is conclusive unless 'literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters.' Therefore, our interpretation is guided not just by a single sentence or sentence fragment, but by the language of the whole law, and its object and policy." *United States v. Ketchum*, 201 F.3d 928, 933 (7th Cir. 2000) (internal citations omitted). *See also Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Lauer*, 49 F.3d 323, 326-27 (7th Cir. 1995) ("We look first to the text for an answer. We look beyond the express language of a statute only where such language is ambiguous, or where a literal interpretation would lead to absurd results or thwart the goals of the statutory scheme."). As described above, however, here the language of the statute is clear and Defendants present no evidence to indicate that limiting "affiliate" to the literal definition contained in the statute is contrary to the goals of the FDCA. Instead, Defendants argue that Winston Labs' "interpretation would create a loophole that is inconsistent with both the language and purpose of the small business fee waiver. There is no policy reason to permit an individual owner or business, through re-shuffling the corporations it controls, to secure successive small business fee waivers." (R. 19-1, Reply in Support of Defendants' Motion to Dismiss ("Reply") p. 2.) The Seventh Circuit, however, has recognized that the FDCA's "overriding purpose" is to "protect the public health." *See U.S. v. Genedo Pharmaceutical, N.V.*, 485 F.3d 958, 964 (7th Cir. 2009). Defendants have presented no evidence or legislative history to support their claim that enforcing the plain language of the statute and the present-sense definition of the term "affiliate" is contrary to that goal, or that Congress would consider Winston Labs' obtainment of a fee waiver an "abuse" of the FDCA. Accordingly, under *Chevron* step one, Defendants have not established that Plaintiff cannot succeed on its claim.

In addition, because the *Chevron* step one analysis reveals that the language of the FDCA user fee provision and the definition of "affiliate" are clear for the reasons stated above, the Court need not reach the question pursuant to *Chevron* step two of whether the FDA's decision was based on a permissible construction of the statute. *See Bloomington Nat'l Bank v. Telfer*, 916 F.2d 1305, 1310 (7th Cir. 1990) (where statute is found to not be ambiguous or silent on an issue, *Chevron* deference to agency's determination is not required and court must give must give effect to the expressed intent of Congress); *Miles*, 2002 U.S. Dist. LEXIS 22695 (where "Congress' intent to establish uniform, national labeling and packaging requirements for hazardous substances is clearly stated in the statutes' legislative histories," the court "must effectuate that intent, regardless of the [agency]'s views"); *Clark v. Chicago*, 2000 U.S. Dist. LEXIS 21515 (N.D. Ill. June 27, 2000) (where the "ADA clearly expresses Congress' intent that employment claims be governed exclusively by Title I . . . under *Chevron*, the regulation to the contrary promulgated by the Attorney General is entitled to no weight"). Accordingly, the Court need not defer to the FDA's interpretation of the term "affiliate" as it relates to application of the small business waiver provision of the FDCA.

CONCLUSION

For the foregoing reasons, the Court denies Defendants' Motion to Dismiss.