IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FERRING PHARMACEUTICALS INC., 100 Interpace Parkway Parsippany, NJ 07054, Plaintiff, v. SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W. Washington, DC 20201, and STEPHEN OSTROFF, M.D., in his official capacity as ACTING COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Defendants.	Civil Action No. _____

COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND OTHER RELIEF

Plaintiff Ferring Pharmaceuticals Inc. ("Ferring") hereby brings this Complaint against Defendants Sylvia Mathews Burwell, solely in her official capacity as Secretary of the Department of Health and Human Services ("HHS"), and Steven Ostroff, M.D., solely in his official capacity as Acting Commissioner of Food and Drugs, head of the Food and Drug Administration ("FDA" or the "agency"), and alleges as follows:

PRELIMINARY STATEMENT

1. This is an action to hold unlawful and set aside FDA's refusal to acknowledge Ferring's statutory right to five years of regulatory exclusivity for its drug PREPOPIK®.

2. To encourage innovation and public access to new medicines, Congress has mandated that a drug containing an active ingredient not previously approved in the United States—a New Chemical Entity ("NCE")—is entitled to a period of regulatory exclusivity. *See* 21 U.S.C. §§ 355(c)(3)(E), (j)(5)(F). This regulatory exclusivity generally precludes FDA from accepting an application for generic versions of the NCE for five years. *Id.*

3. PREPOPIK® is a fixed-dose combination drug product that contains a novel active ingredient, sodium picosulfate, as well as ingredients that FDA had previously approved in other drug applications. Because PREPOPIK® contains a new active ingredient that FDA has not previously approved, it is statutorily entitled to five years of exclusivity.

4. For years, FDA took the position that the Federal Food, Drug and Cosmetic Act ("FDCA") and related regulations limited the grant of five years of exclusivity to drug products comprised *solely* of active ingredients that had not been previously approved. In other words, even if a drug product contained one or more novel active ingredients, it would not be granted five years of exclusivity if the product also contained at least one active ingredient that FDA had previously approved.

5. FDA's position did not comport with the agency's own interpretation of the exclusivity statute in other contexts or with its own implementing regulations. *See* 21 C.F.R. § 314.108(b)(2). And the agency's approach to NCE exclusivity for fixed-dose combination products resulted in an inconsistent application in the awarding of NCE exclusivity.

6. In 2014, after the agency's anomalous position was challenged in a series of citizen petitions, FDA brought its position into line with the statute and regulations and announced that a fixed-dose combination product containing at least one novel ingredient will be entitled to NCE exclusivity.

7. FDA's new position is the correct one. The problem is that the agency has applied the correct construction *only* "prospectively," *i.e.*, to drugs approved after its decision. That line-drawing excluded a few drugs from receiving the benefit of FDA's shift in position. One of them was PREPOPIK®.

8. FDA's decision to continue to apply its *erroneous* construction of the statute to only a handful of approved drugs, while simultaneously announcing its decision to apply the statute *correctly* for all *pending and future* new drug applications, was erroneous, arbitrary, capricious, an abuse of discretion, and not in accordance with law.

9. Ferring thus seeks a declaratory judgment declaring that FDA's determination of the exclusivity period for PREPOPIK® violates the Administrative Procedure Act ("APA"). Ferring also seeks injunctive relief ordering FDA to grant the full five years of exclusivity for PREPOPIK®.

PARTIES

10. Plaintiff Ferring Pharmaceuticals Inc. is a Delaware corporation headquartered at 100 Interpace Parkway, Parsippany, NJ 07054, and the sponsor of NDA 202535, the approved application for PREPOPIK®.

11. Defendant Sylvia Mathews Burwell, who is being sued in her official capacity only, is the Secretary of HHS and is responsible for administering and enforcing the Food, Drug,

and Cosmetic Act, 21 U.S.C. § 321, et seq. Defendant Burwell maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201.

12. Defendant Stephen Ostroff, M.D., who is being sued in his official capacity only, is the Acting Commissioner of Food and Drugs and is responsible for supervising the activities of FDA, an administrative agency within HHS. Defendant Ostroff maintains offices at 10903 New Hampshire Avenue, Silver Spring, MD 20993.

JURISDICTION AND VENUE

13. Jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331, in that this is a civil action arising under the laws of the United States; 28 U.S.C. § 1346, in that this case involves claims against the federal government; 5 U.S.C. § 702, in that Ferring is seeking judicial review of an agency action from which it has suffered a legal wrong, has been adversely affected, and has been aggrieved; 28 U.S.C. § 1361, in that this is an action to compel an officer of the United States to perform his or her duty; and 21 U.S.C. § 355(q) and other sources of law, in that the conduct complained of constitutes final agency action.

14. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (e) because this is a civil action in which the Defendants are officers of the United States acting in their official capacities and one of the Defendants maintains her office and conducts business in this judicial district. Moreover, a substantial part of the events giving rise to the claims herein occurred within this judicial district.

15. Ferring has standing to bring the present lawsuit because it is suffering and faces additional actual injury as a result of FDA's decisions and because it is within the zone of interest of the relevant statutory provisions.

BACKGROUND

I. The Drug Approval Process

16. The FDCA requires all new prescription drugs to obtain FDA approval before they can be marketed. 21 U.S.C. § 355(a). Manufacturers of brand name (also known as "pioneer" or "innovator") drug products must demonstrate the safety and effectiveness of their products in order to gain FDA approval. Typically, that is done by conducting pre-clinical and clinical studies and submitting the resulting data to FDA in a new drug application ("NDA"). 21 U.S.C. § 355(b)(1).

17. Pioneer drugs may be entitled to a period of non-patent regulatory exclusivity in addition to any available patent protection. After any such periods of regulatory exclusivity expire, FDA may review and approve generic drugs containing the same active ingredient as the pioneer drug.

18. Generic drugs are approved by means of an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j)(1). ANDAs generally do not contain new clinical data. Instead, an ANDA relies on FDA's finding of safety and efficacy for a previously approved pioneer drug (which is termed at that point the "reference listed drug" or "RLD"). 21 U.S.C. § 355(j)(2). In order to obtain approval of a generic drug, an ANDA applicant must show that its proposed drug product is the "same as" the RLD in all key respects (including active ingredient, dosage form, strength, route of administration, and, with certain exceptions, labeling), and that its product is bioequivalent to the RLD. 21 U.S.C. §§ 355(j)(2)(A)(ii)-(v).

II. Five-Year Exclusivity for New Chemical Entities

19. In 1984, Congress amended the FDCA through the Hatch-Waxman Act and put in place an incentive structure designed both to promote the development of innovative drugs and

expedite the approval of generic drugs. *See generally Actavis Elizabeth LLC v. FDA*, 625 F.3d 760, 765 (D.C. Cir. 2010) (recognizing that the exclusivity provisions "struck a balance between expediting generic drug applications and protecting the interests of original drug manufacturers"). As part of that balance, the Hatch-Waxman Act granted successful developers of new drugs protection from generic competition in the form of a five-year exclusivity period. *See* 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii). If a drug approved in an NDA is awarded NCE exclusivity, no application for a generic version of that drug may be submitted for FDA review until five years after the NDA's approval (unless the ANDA contains a challenge to the innovator's patent(s), in which case it may be submitted after four years).

20. The Hatch-Waxman Act also provided for a three-year exclusivity period for changes to a previously approved drug. Thus, three years of exclusivity are granted to a sponsor who submits one or more new clinical studies supporting a change in the conditions of use of an approved product, so long as FDA considers the studies to have been essential to its approval of the change. 21 U.S.C. §§ 355(c)(3)(E)(iii), (j)(5)(F)(iii). Three-year exclusivity is much more limited than five-year NCE exclusivity for reasons beyond the length of the time period: Three-year exclusivity precludes only the *approval* of a generic application, but an ANDA may be *submitted* and reviewed by the agency at any time during the three-year period.

21. NCE exclusivity thus provides a critical incentive for development of novel drugs and advances FDA's goal of protecting and promoting public health. *See* 130 Cong. Rec. H9114 (daily ed. Sept. 6, 1984) (Representative Waxman, the bill's sponsor, explaining that the five-year exclusivity period provided "the drug industry the incentives needed to develop new chemical entities"). The flip side of that statement is just as common-sense: depriving an NCE's sponsor of the full five years of exclusivity stifles innovation.

22. The FDCA sets forth eligibility for the five-year exclusivity period and determines which subsequent applications will be blocked pursuant to that grant of exclusivity:

> If an application submitted under subsection (b) of this section 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) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to **the drug** for which the subsection (b) application was submitted before the expiration of five years from the date of approval of the application under subsection (b)….

21 U.S.C. § 355(j)(5)(F)(ii) (emphases added).

23. FDA has repeatedly taken the position that the term "**drug**," as used in the FDCA, can mean either "drug substance" (*i.e.*, an active ingredient that is intended to furnish pharmacological activity to a drug product) or "drug product" (*i.e.*, a "finished dosage form … that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients"), depending on context. *See* 21 U.S.C. § 321(g)(1) (offering multiple definitions of "drug"); 21 C.F.R. § 314.3(b) (defining drug substance and drug product). A drug substance, in turn, is comprised of one or more "active moieties," which are the molecules or ions responsible for the physiological or pharmacological action of the drug substance. 21 C.F.R. § 314.108(a).

24. FDA also has long taken the view that the second time the word "**drug**" is used in Section 505(j)(5)(F)(ii), it means drug *substance,* or, more specifically, an active moiety within a drug substance. *See, e.g.*, 54 Fed. Reg. 28872, 28897 (July 10, 1989) (describing what is known as the "umbrella exclusivity policy," in which an innovator's subsequent drug products containing the same active moiety are covered under the "umbrella" of NCE exclusivity awarded to that active moiety); 21 C.F.R. § 314.108(a) (defining active moiety as "the molecule or ion…

responsible for the physiological or pharmacological action of the drug substance"), (b)(2); 21 C.F.R. § 314.50(j).

25. Until recently, however, FDA insisted that the first reference to drug— the "**a drug**" to which the second "**the drug**" refers—meant "drug *product*," not "drug substance." In other words, FDA took the view that if any of the active moieties in the drug product had previously been approved, that product was ineligible for five-year exclusivity. *See* February 2014 Citizen Petition Response, Docket No. FDA-2013-P-0058 (Feb. 21, 2014).

26. It is a settled canon of statutory construction, however, that where Congress uses the same word in close proximity in a statute—here, in the exact same sentence—it must be intended to have the same meaning. This is particularly true where, as here, the word is introduced as "a" thing and later referred back to as "the" thing.

27. Thus, the only permissible interpretation of Section 505(j)(5)(F)(ii) is that a drug *substance* is entitled to five-year exclusivity if it contains no active moiety that has previously been approved.

28. FDA's own regulation regarding new drug product exclusivity is logical only when this statutory interpretation is applied:

> If a **drug product** that contains a **new chemical entity** was approved after September 24, 1984, in an application submitted under section 505(b) of the act, no person may submit a 505(b)(2) application or abbreviated new drug application under section 505(j) of the act for a drug product that contains the same active moiety as in the new chemical entity for a period of five years from the date of approval of the first approved new drug application.

See 21 C.F.R. § 314.108(b)(2) (emphasis added). For purposes of this provision, FDA defined "**new chemical entity**" to mean "a **drug** that contains no active moiety that has been approved by FDA in any other application submitted under 505(b) of the Act." *Id*. § 314.108(a) (emphasis added).

29. When read together with the operative exclusivity provision, the term "**drug**" as used in the definition of "new chemical entity" simply cannot mean "drug product," as suggested by FDA. Otherwise, FDA's new drug product exclusivity regulation would nonsensically read: "If a **drug product** that contains a **drug product** . . . ." Accordingly, a new chemical entity eligible for exclusivity must be a drug substance (*i.e.*, active ingredient) that contains no previously approved active moiety.

30. Both the statute and the regulations thus support the conclusion that NCE exclusivity requires a substance-by-substance analysis. A drug product contains one or more drug substances, which contain one or more active moieties. If ***any*** drug substance in the product is novel, that is contains no previously approved active moiety, the product must be awarded NCE exclusivity. This is true even if the product also contains other previously-approved drug substances.

31. FDA, however, saw it differently. Instead, for years, it continued to take a legally and textually indefensible position on fixed-combination drug product exclusivity.

II. Ferring's PREPOPIK®

A. Approval of Ferring's NDA for PREPOPIK®

32. PREPOPIK® is a fixed-combination drug product designed for cleansing the colon as a preparation for colonoscopy in adults. The product contains the novel active ingredient sodium picosulfate, which had never before been approved in an NDA, as well as the active ingredients magnesium oxide and anhydrous citric acid, both of which have been previously approved in other NDAs.

33. FDA approved PREPOPIK® in July 2012. The agency's approval was based in part on two randomized, controlled clinical studies that demonstrated PREPOPIK®'s non-inferiority compared to other, previously approved colon cleanser products.

34. FDA did not require factorial studies[1] to evaluate the individual components of PREPOPIK®, however. Sodium picosulfate, although a novel active ingredient, was not suitable as a single-ingredient drug for use as a colon cleanser; its therapeutic benefit is realized only in combination with the other components. FDA thus determined that single-ingredient clinical trials would raise "serious ethical concerns." NDA 202535, Summary Review at 40.

B. FDA's Determination of the Exclusivity Period for PREPOPIK®

35. Ferring invested a significant amount of time and resources to develop and study PREPOPIK®. And under the governing statute and FDA's implementing regulations, its innovation should have been rewarded: the five-year NCE exclusivity period should have attached to sodium picosulfate, the drug substance not previously approved by FDA. *See supra.*

36. Ferring developed PREPOPIK® with the expectation that sodium picosulfate would be awarded NCE exclusivity. Indeed, Ferring requested five years of exclusivity at the time it submitted its NDA for PREPOPIK®. *See* NDA 202535, Statement of Claimed Exclusivity.

37. But FDA did not award Ferring five years of NCE exclusivity, because PREPOPIK® contained magnesium oxide and anhydrous citric acid—two ingredients containing active moieties that had previously been approved by FDA. As a result, the agency awarded

[1] Factorial studies assess the effect attributable to drug substances in combination; they are used to evaluate the individual contribution of each substance to the overall efficacy of the drug product.

PREPOPIK® only three-year exclusivity, based on the new clinical studies supporting its approval.

38. Other manufacturers of combination drug products got better news. Some manufacturers secured the benefit of a five-year exclusivity period by first obtaining FDA approval of a novel active moiety in a single-ingredient product and *subsequently*—meaning after either some period of years, or even just hours—obtaining approval of fixed-combination products that contain the same new active moiety.

39. For example, VALTURNA®—a fixed-combination product containing two previously approved ingredients, aliskiren hemifumarate and valsartan—received five-year exclusivity under the umbrella exclusivity policy, because FDA had approved the same sponsor's single-ingredient aliskiren hemifumarate NDA two years before. Other examples are even more dramatic. FDA "first" approved an NDA for the single-ingredient product NESINA® (alogliptin), and awarded it NCE exclusivity. *See* Letter from Curtis Rosebraugh, FDA, to Takeda Pharmaceuticals U.S.A., Inc. (Jan. 25, 2013) (stating that FDA was "approving the single entity [product] first, before approving the combination products"). *Later that same day*, FDA approved two NDAs containing alogliptin in fixed combination with other, previously approved ingredients—and awarded those products NCE exclusivity.

40. Thus, three products approved on the same day all received the benefit of NCE exclusivity, because the novel ingredient was "first" approved in a single-ingredient NDA. If the order of the approvals of the alogliptin products had been reversed, ***none*** of the three products would have been awarded NCE exclusivity, because each would have contained a previously approved active ingredient. This approach to awarding five-year exclusivity unnecessarily and arbitrarily hinges on the order in which the innovator sponsor's applications are approved. *See*

Abbott Labs v. Young, 920 F.2d 984, 989 (D.C. Cir. 1990) (finding "farfetched" and "fail[ing] to serve any conceivable statutory purpose" an interpretation that would base the degree of exclusivity protection a drug receives on the sequence in which a sponsor's applications are approved).

41. Unlike the sponsors of VALTURNA® and NESINA®, however, Ferring could not similarly game the timing of agency approval for PREPOPIK®. Ferring could not create a novel, single-ingredient version of PREPOPIK® to get approved before the combination product: the new active moiety in PREPOPIK® is not suitable as a single-ingredient drug, and indeed, FDA determined that single-ingredient clinical trials for sodium picosulfate would raise "serious ethical concerns."

42. Thus, because Ferring's combination product contained only *one* new drug component and not *all* new drug components—and because Ferring could not otherwise manipulate the timing of its application to secure exclusivity—FDA denied Ferring the full five-year NCE exclusivity to which the company was entitled. Instead, the agency granted Ferring only three years' exclusivity, based on the fact PREPOPIK® contained an ingredient that had been previously approved.

43. FDA's decision thus reduced exclusivity for PREPOPIK® by two years. It also meant that generic manufactures could submit ANDAs containing the same active ingredients during that shortened exclusivity period. Unlike a five-year exclusivity period, a three-year exclusivity period allows *submission* of ANDAs and only precludes FDA from *approving* those applications. On January 12, 2015, Ferring received noticed from Par Pharmaceutical, Inc. ("Par") that it had filed an ANDA seeking permission to market a purported generic version of

PREPOPIK®. Par was permitted to file its ANDA as a direct result of FDA's unlawful decision to assign PREPOPIK® a reduced exclusivity period.

C. Ferring's Challenge to FDA's Exclusivity Determination

44. FDA's denial of five-year exclusivity for PREPOPIK® did not comport with the statute, regulation, or common sense.

45. Accordingly, in January 2013, Ferring submitted a Citizen Petition requesting that FDA amend the exclusivity period for PREPOPIK® from three to five years. *See* 21 C.F.R. § 10.25.

46. Two other companies submitted similar Citizen Petitions asking FDA to award five-year exclusivity for drugs that similarly combined novel and previously-approved ingredients. Gilead Sciences, Inc. submitted a Citizen Petition in January 2013 for STRIBILD®. And Bayer HealthCare Pharmaceuticals, Inc. submitted a Citizen Petition in April 2013 for its NATAZIA®.

D. FDA Abandons Its Erroneous Position On Exclusivity

47. FDA issued a consolidated response to the three companies' Citizen Petitions in February 2014. FDA defended its previous interpretation of the statute, arguing that it was "permissible to interpret the same word in two ***different clauses*** to mean different things"—ignoring that here, the same word was used not only in the same ***clause*** but in fact in the same ***sentence***. February 2014 Citizen Petition Response at 11 (emphasis added). And yet FDA conceded that its previous position—that a drug product did not qualify for five-year NCE exclusivity unless *all* the ingredients were new—"may result in drug development strategies that are suboptimal from a public health perspective." Response at 15. FDA also observed that fixed-combination products were "becoming more prevalent" and that combination therapies

were "'an important treatment modality'" in certain "critical therapeutic areas." *Id.* at 14-15, 2. Moreover, FDA explained, "international organizations and the U.S. medical community" have "identified the benefits of fixed-combinations over several single-entity drug products." *Id.* at 15.

48. FDA also agreed with Ferring, Bayer, and Gilead that the agency's position on exclusivity "may place undue importance on the order in which . . . NDAs are approved." *Id.* at 16. And the agency acknowledged that the strategy of seeking approval of a single-ingredient product before a fixed-combination product "may not be available if a new active moiety does not clinically lend itself to approval in a single-entity drug." *Id*. FDA thus concluded that changing its position "is desirable as a matter of policy." *Id*. at 17.

49. Accordingly, FDA issued a draft guidance document abandoning its previous position on exclusivity. FDA explained that "a drug substance containing no previously approved active moiety would be eligible for 5-year NCE exclusivity even when such a drug substance is approved in a fixed-combination with another drug substance containing one or more previously approved active moieties." *Id.* at 17. PREPOPIK® satisfies this standard: sodium picosulfate is a drug substance whose single active moiety has not previously been approved by FDA, notwithstanding that the active moieties in magnesium oxide and anhydrous citric acid have previously been approved.

50. FDA refused, however, to apply its new interpretation to PREPOPIK® (or to Bayer or Gilead's drugs). Instead the agency declared that it would apply its new interpretation—that is to say, the *correct* interpretation—only prospectively. By "prospectively," FDA meant that it would apply this interpretation only after it finalized its draft guidance document and only to products approved after the date of finalization.

51. FDA attempted to justify its line-drawing with a few different contentions: (1) its prior position was "longstanding"; (2) the new position represented a departure; (3) if the new position were applied to products for which ANDAs had already been filed, it could impose a burden on the ANDA sponsor, who relied on FDA's prior interpretation in developing its products; and (4) awarding five years of exclusivity to PREPOPIK® would not necessarily encourage the development of a novel drug.

52. None of those factors, individually or collectively, suffices to explain or justify FDA's decision to deny PREPOPIK® the five years of exclusivity to which it was entitled.

53. Moreover, even if FDA *had* adequately justified its decision to apply the correct statutory interpretation of the NCE exclusivity provision only "prospectively," the agency nevertheless provided no rational justification for applying its "prospective" position only to drug products that had not yet been approved. The five-year exclusivity period at issue is implicated—if at all—only when an ANDA or 505(b)(2) NDA seeks to rely upon the innovator drug. After all, it is only when a second sponsor seeks to submit its own application that the statutory and regulatory exclusivity provisions apply. If no generic application has been submitted—as was the case with PREPOPIK® at the time of FDA's revised interpretation—then exclusivity remains "prospective." Even if the agency believes that it can permissibly apply the correct statutory interpretation only "prospectively," that "prospective" application should not hinge on the date of approval of the innovator product, but the date of submission of the generic product.

E. FDA Refuses to Reconsider its Exclusivity Determination for PREPOPIK®

54. Ferring requested that FDA reconsider its denial of the Citizen Petition and decision not to grant PREPOPIK® five years of exclusivity. As Ferring explained, FDA's

position treats similarly situated applicants differently, artificially draws a line in the sand between applicants whose NDAs were approved before FDA made its decision and those whose applications were pending or not yet submitted, and otherwise constitutes arbitrary and capricious conduct.

55. FDA denied Ferring's request for reconsideration. That same day, the agency finalized its guidance document outlining the agency's new, prospective-only application of the five-year exclusivity provision.

56. FDA's decision on Ferring's Citizen Petition and request for reconsideration constitutes a final agency action that is reviewable by this court. 21 C.F.R. § 10.45(d).

57. In light of the above, Ferring has exhausted all of its available administrative remedies.

Count I
(Administrative Procedure Act: Violation of the FDCA and Applicable Regulations)

58. Ferring re-alleges, reasserts, and incorporates by reference herein each of the foregoing allegations of the Complaint as though set forth fully herein.

59. FDA's decision to deny Ferring five years of regulatory exclusivity was unlawful and in violation of the FDCA and the agency's own regulations, policies and procedures.

60. FDA's decision to deny Ferring five years of regulatory exclusivity constitutes final agency action for which Ferring has no other adequate remedy within the meaning of 5 U.S.C. § 704.

61. FDA's decision to deny Ferring five years of regulatory exclusivity was not in accordance with federal law and therefore violates 5 U.S.C. § 706(2)(A).

62. FDA's decision to deny Ferring five years of regulatory exclusivity constitutes agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, in violation of 5 U.S.C. § 706(2)(C).

63. Both Ferring and the public will be irreparably harmed unless FDA is ordered to revoke its decision.

Count II
(Administrative Procedure Act: FDA's Conduct Was Arbitrary, Capricious, an Abuse of Discretion and Contrary to Law)

64. Ferring re-alleges, reasserts, and incorporates by reference herein each of the foregoing allegations contained in the Complaint, as though set forth fully herein.

65. The APA prohibits FDA from implementing the FDCA in a manner that is arbitrary, capricious, or an abuse of discretion. 5 U.S.C. § 706(2)(A).

66. FDA's decision to deny Ferring five years of regulatory exclusivity was not based on reasoned decision or rational basis, and therefore was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law in violation of 5 U.S.C. § 706(2)(A).

67. FDA's decision to deny Ferring five years of regulatory exclusivity was premised on agency determinations that treated similarly situated entities differently. FDA's conduct thus was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law in violation of 5 U.S.C. § 706(2)(A).

68. FDA's decision to deny Ferring five years of regulatory exclusivity violates FDA's own regulations and governing statute, in violation of the APA.

69. FDA's decision to deny Ferring five years of regulatory exclusivity constitutes final agency action for which Ferring has no other adequate remedy within the meaning of 5 U.S.C. § 704.

70. Both Ferring and the patient population will be irreparably harmed unless FDA is required to revoke its decision.

71. Ferring is without an adequate remedy at law because of the unique nature of the harm.

PRAYER FOR RELIEF

WHEREFORE, Ferring respectfully prays for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that FDA's decision to deny Ferring five years of regulatory exclusivity was arbitrary, capricious, and contrary to law under the APA and the FDCA;

B. Temporary, preliminary and/or permanent injunctive relief requiring FDA to rescind its decision to deny Ferring five years of regulatory exclusivity;

C. An order awarding Ferring costs, expenses and attorneys' fees pursuant to 28 U.S.C. § 2412; and

D. Such other and further relief as the Court deems just and proper.

Dated: June 1, 2015

Respectfully submitted,

HOGAN LOVELLS US LLP

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