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Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

CITIZEN PETITION

We submit this petition under sections 505(b) and 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") and section 10.30 of Title 21 of the Code of Federal Regulations on behalf of our clients Mayne Pharma International Pty Ltd. ("Mayne"), and Warner Chilcott (US), LLC, Warner Chilcott Laboratories Ireland Ltd., and Warner Chilcott Company, Inc. (collectively "Warner Chilcott"). Mayne holds new drug application ("NDA") 50-795 for DORYX® (doxycycline hyclate) delayed-release tablets and U.S. Patent 6,958,161 ("the '161 patent"). Warner Chilcott markets DORYX pursuant to an exclusive license from Mayne.

FDA considers DORYX to be an "old" antibiotic because it contains an active ingredient (doxycycline hyclate) first approved prior to November 21, 1997, the date on which the FDA Modernization Act of 1997 ("FDAMA") harmonized the approval path for non-antibiotic drugs and antibiotics. The recently enacted QI Program Supplemental Funding Act ("QI Act")[1] made old antibiotics such as DORYX subject to the patent listing, patent certification, and 30-month stay provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the "Hatch-Waxman Amendments"[2] and codified, in relevant part as amended, at FDCA sections 505(c) and 505(j). This Citizen Petition addresses the question of whether the 30-month stay provisions of the Hatch-Waxman Amendments apply

[1] Pub. L. No. 110-379, 122 Stat. 4075 (2008). "QI" stands for "Qualifying Individual" and is a reference to provisions of the QI Act not relevant here that provide financial assistance to low-income Medicare beneficiaries.

[2] Pub. L. No. 98-417, 98 Stat. 1585 (1984).

FDA-2009-P-0038

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to a pending abbreviated new drug application ("ANDA") seeking approval of a generic version of an old antibiotic for which the holder of the NDA timely lists patents in accordance with the transition rules of the QI Act.

As explained below, the plain language of the QI Act directs that the 30-month stay provisions of the Hatch-Waxman Amendments apply to pending ANDAs if the following conditions are met: the holder of the NDA for the old antibiotic timely lists a patent for the drug, the ANDA applicant makes a certification against the listed patent under FDCA section 505(j)(2)(A)(vii)(IV) (a "paragraph IV certification"), and the patent and/or NDA holder brings a patent infringement action within 45 days of receipt of notice of the paragraph IV certification. Those conditions have been met here. In accordance with the transition provisions of the QI Act,[3] Warner Chilcott (as agent for Mayne) submitted information on the '161 patent to FDA for listing in the Orange Book for DORYX. Five pending ANDA applicants with ANDAs referencing the DORYX NDA amended their ANDAs to include paragraph IV certifications to the '161 patent and provided notice to Mayne and Warner Chilcott. Mayne and Warner Chilcott initiated (or, in the case of Actavis, will initiate) infringement actions in federal district court within 45 days of receipt of notifications of the paragraph IV certifications. The QI Act is clear that a 30-month stay now applies to FDA approval of the ANDAs.

I. Actions Requested

We request that FDA sets out its views on the applicability of the 30-month stay provisions of the Hatch-Waxman Amendments to ANDAs that were pending at the time that the holder of an NDA for an old antibiotic submitted patents to FDA for listing in the Orange Book in accordance with the QI Act, and confirm that under FDCA section 505(v) a 30-month stay will apply to the pending ANDAs where the patent or NDA owner brings an infringement action within 45 days of receipt of notification of a paragraph IV certification for the ANDAs. With respect to DORYX, we specifically request that FDA:

- stay approval of ANDA 90-431 submitted by Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan") for 30 months from the date notice of the paragraph IV certification from Mylan was received, or until an earlier resolution of the patent infringement action;

- stay approval of ANDA 90-505 submitted by Impax Laboratories, Inc. ("Impax") for 30 months from the date notice of the paragraph IV certification from Impax was received, or until an earlier resolution of the patent infringement action;

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[3] QI Act, § 4(b).

- stay approval of ANDA 91-043 submitted by Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc., and URL Pharma, Inc. (collectively, "Mutual") for 30 months from the date notice of the paragraph IV certification from Mutual was received,[4] or until an earlier resolution of the patent infringement action;

- stay approval of ANDA 90-192 submitted by Sandoz, Inc. ("Sandoz") for 30 months from the date notice of the paragraph IV certification from Sandoz was received, or until an earlier resolution of the patent infringement action;

- stay approval of ANDA 90-134 submitted by Actavis Elizabeth LLC ("Actavis") for 30 months from the date Mayne received notice of the paragraph IV certification from Actavis was received, or until an earlier resolution of the patient infringement action; and

- stay approval of any other pending ANDA referencing DORYX for which the ANDA applicant makes a paragraph IV certification, and with regard to which Mayne and Warner Chilcott bring a patent infringement suit within 45 days of receipt of the certification, for 30 months from the date notice of the certification is received.

II. Brief Statement of Grounds

A. Background

1. The Hatch-Waxman Amendments

In 1984, Congress created an abbreviated pathway to market for generic drug products when it enacted the Hatch-Waxman Amendments to the FDCA. The courts have recognized that, in enacting the Hatch-Waxman Amendments, Congress sought to strike a delicate balance between facilitating generic drug entry and maintaining incentives to spur pharmaceutical innovation.[5] At the center of the careful balance struck by Congress is a detailed regime for the identification and resolution of patent disputes prior to generic drug market entry.

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[4] Mutual sent several notices of its paragraph IV certification, many of which pre-dated the listing and publication of the '161 patent. Mayne and Warner Chilcott request that FDA stay approval of ANDA 90-134 for 30-months from the receipt date of the first notice sent after the '161 patent was listed on December 3, 2008 and published in the Orange Book on December 5, 2008. *See* Section II.A, *infra*, for a description of the patent listing and certification rules in the Hatch-Waxman Amendments and the QI Act.

[5] *See, e.g., Abbott Labs. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990) ("Facing the classic question of the appropriate trade-off between greater incentives for the invention of new (continued...)

Potential patent disputes are identified prior to generic drug market entry through a system of patent listing and certification. The Hatch-Waxman Amendments require that NDAs include a list of patents that claim the drug substance, drug product, or method of use of the new drug covered by the NDA.[6] FDA lists these patents in its publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book). When an applicant submits an ANDA to market a generic version of an approved reference listed drug in the Orange Book, the ANDA must include one of four certifications concerning the listed patents.[7] The certification relevant to this petition is the fourth one, known as a "paragraph IV" certification, in which the ANDA applicant asserts that a listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."[8]

Once an ANDA applicant has asserted that a listed patent is invalid or not infringed, provisions for notice to the patent and NDA holders and for deeming the patent certification an act of infringement make it possible for patent infringement actions to be filed, and the patent disputes potentially resolved, before generic market entry. ANDA applicants are required promptly to notify each NDA and patent holder of the paragraph IV certification.[9] This notice must include a "detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."[10] Submitting an ANDA with a paragraph IV certification is a constructive act of patent infringement.[11] Accordingly, upon

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products and greater affordability of those products, Congress struck a balance between expediting generic drug applications and protecting the interests of the original drug manufacturers.") (citation omitted); *Mylan Pharms. Inc. v. Thompson*, 268 F.3d 1323, 1326 (Fed. Cir. 2001) ("These provisions of the Hatch Waxman Amendments emerged from Congress' efforts to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.") (internal quotation omitted).

[6] Hatch-Waxman Amendments, § 102 (codified at FDCA § 505(b)(1) (subsequently amended) and (c)(2)); 21 C.F.R. § 314.53(b).

[7] Hatch-Waxman Amendments, § 101 (codified at FDCA § 505(j)(2)(A)(vii)).

[8] Hatch-Waxman Amendments, § 101 (codified at FDCA § 505(j)(2)(A)(vii)(IV)).

[9] Hatch-Waxman Amendments, § 101 (codified as amended at FDCA § 505(j)(2)(B)(ii)).

[10] Hatch-Waxman Amendments, § 101 (codified as amended at FDCA § 505(j)(2)(B)(iv)).

[11] 35 U.S.C. § 271(e)(2)(A); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

receipt of notice of the paragraph IV certification, the patent holder may bring an infringement action.

To permit patent claims to be resolved before generic market entry, the Hatch-Waxman Amendments provide for a stay on the approval of the ANDA for the generic product if the patent holder brings suit against the ANDA applicant within 45 days of receipt of the paragraph IV notice. FDA cannot approve the ANDA for a period of 30 months while the litigation is pending, subject to modification by the court.[12]

In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA")[13] amended the Hatch-Waxman Amendments to add a restriction on the ability of a patent or NDA holder to obtain a 30-month stay. The MMA restricts the 30-month stay to cases in which the NDA holder lists the pertinent patent before the ANDA is submitted to FDA.[14] Thus, when a patent is listed with FDA after an ANDA has already been submitted, no 30-month stay is available, even if the ANDA applicant submits a paragraph IV certification against the new patent.

Prior to the MMA, it was possible for multiple 30-month stays to apply to an ANDA if, after one 30-month stay was in place, a new patent issued and was listed. If an ANDA applicant submitted a paragraph IV certification to this new patent, and if that certification prompted a timely patent infringement suit, the ANDA would be subject to another 30-month stay. Congress enacted the new restriction in the MMA to limit the ability of patent and NDA holders to obtain multiple 30-month stays.[15]

2. Old Antibiotics Before the QI Act

Historically, antibiotics were not subject to the Hatch-Waxman Amendments. FDA approved non-antibiotic drugs under section 505 of the FDCA and antibiotic drugs under section 507 of the FDCA. The Hatch-Waxman Amendments applied only to drugs approved under section 505, and consequently did not apply to antibiotics.[16]

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[12] Hatch-Waxman Amendments, § 101 (codified as amended at FDCA § 505(j)(5)(B)(iii)).

[13] Pub. L. No. 108-173, 117 Stat 2066 (2003).

[14] MMA § 1101 (codified at FDCA 505(j)(5)(B)(iii)).

[15] *See* H.R. Rep. No. 108-391, at 835-36 (2003).

[16] *See* 65 Fed. Reg. 3623 (proposed Jan. 24, 2000) (describing the history of antibiotic regulation).

Congress eliminated the different approval mechanisms for non-antibiotic drugs and antibiotic drugs when it enacted FDAMA on November 21, 1997.[17] Section 125 of FDAMA repealed FDCA section 507 and provided that antibiotic drug applications that had been approved under section 507 would be considered to have been submitted, filed, and approved under section 505. Because the Hatch-Waxman Amendments apply to drugs approved under FDCA section 505, the FDAMA provisions bringing antibiotics under section 505 made antibiotics subject to the Hatch-Waxman rules going forward.

Notwithstanding this prospective harmonization of the approval mechanism for non-antibiotic and antibiotic drugs, FDAMA section 125(d) maintained a distinction between antibiotics that were the subject of marketing applications received by FDA before November 21, 1997 ("old antibiotics"), and those that FDA received on or after that date.[18] Marketing applications for "old antibiotics" were exempted from the patent listing, patent certification, and marketing exclusivity provisions of the Hatch-Waxman Amendments.[19] Further, FDA interpreted FDAMA section 125(d)(2) to provide that any drug that contained an active moiety that was first approved as an old antibiotic was ineligible for exclusivity and patent listing under the Hatch-Waxman Amendments. Thus, even after FDAMA, new products containing "old" antibiotic active moieties were not subject to the patent listing, patent certification, and marketing exclusivity provisions of the Hatch-Waxman Amendments.

3. The QI Act

The enactment of the QI Act on October 8, 2008 brought old antibiotics into the Hatch-Waxman fold. The QI Act contains a Section 4 entitled "Incentives for the Development of, And Access To, Certain Antibiotics." Section 4(a) adds a new subsection (v) to FDCA section 505. The new FDCA section 505(v) sets forth marketing exclusivity rules that apply to certain old antibiotics.[20] Section 505(v)(4) then provides that

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[17] Pub. L. No. 105-115, 111 Stat. 2296 (1997).

[18] FDAMA § 125(d)(2).

[19] *See* 65 Fed. Reg. at 3624-25.

[20] Section 505(v)(1) provides that the sponsors of NDAs for previously approved old antibiotics may obtain three years of non-patent exclusivity under the Hatch-Waxman Amendments for the approval of a new condition of use for the drug. Section 505(v)(2) contains other provisions that establish marketing exclusivity periods for drug products containing an antibiotic that was the subject of one or more applications received by FDA under section 507 but not approved by FDA under that section.

> notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law . . . the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 [the Hatch-Waxman Amendments] shall apply [to an old antibiotic].[21]

Thus, the QI Act applies the original Hatch-Waxman Amendments to old antibiotics, without reference to the MMA or the amended provisions of the Hatch-Waxman Amendments as now codified in the FDCA.

The QI Act contains transition rules to permit patent listing and certification for old antibiotics that were approved prior to the QI Act.[22] The transition rules provide that sponsors of NDAs for old antibiotics that were approved on or before the date the QI Act was enacted (October 8, 2008), had 60 days from the enactment of the QI Act (until December 5, 2008) to submit eligible patents to FDA for listing in the Orange Book.[23] FDA, in turn, was required to publish these newly submitted patents in the Orange Book within 90 days after enactment of the QI Act (by January 6, 2009).[24] Sponsors of pending "substantially complete" ANDAs must certify to the listed patents not later than 120 days after enactment of the QI Act (by February 5, 2009) in order to be deemed "a first applicant" eligible for 180-day exclusivity against subsequent ANDA filers.[25]

4. DORYX and the Delayed-Release Doxycycline Hyclate ANDAs

DORYX is the brand name for a novel delayed-release formulation of doxycycline hyclate that Warner Chilcott markets and sells under an exclusive license from Mayne. Under Warner Chilcott's license with Mayne, Warner Chilcott is also the exclusive licensee of Mayne's patent covering the formulation of DORYX, the '161 patent, which was issued on October 25, 2005, and expires on December 15, 2022. DORYX is a tetracycline-class oral antibiotic that is widely prescribed for the adjunctive treatment of severe acne, and that is also indicated for (1) rickettsial infections, (2) sexually transmitted infections, (3) respiratory tract infections, (4) specific bacterial infections, (5) ophthalmic infections, (6) anthrax, including inhalational anthrax (post-exposure), (7) alternative treatment for selected infections when

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[21] QI Act § 4(a) (to be codified at FDCA 505(v))(emphasis added).

[22] QI Act § 4(b).

[23] QI Act § 4(b)(1).

[24] QI Act § 4(b)(2).

[25] QI Act § 4(b)(3); *see also* FDCA § 505(j)(5)(B)(iv).

penicillin is contraindicated, (8) adjunctive therapy in acute intestinal amebiasis, and (9) prophylaxis of malaria.

Mayne originally obtained FDA approval for DORYX in 1985 in a delayed-release capsule formulation. These capsules are no longer marketed. FDA approved the NDA for 75 mg and 100 mg delayed-release tablets on May 6, 2005. FDA approved a 150 mg delayed-release tablet on June 20, 2008, but the paragraph IV notifications Mayne and/or Warner Chilcott have received to date reference only the 75 mg and 100 mg tablets.

DORYX's key feature is the delayed-release formulation. Specially-coated pellets of doxycycline are compressed into tablets. The tablets dissolve in the stomach, but the specially-coated pellets of doxycycline in DORYX pass through the stomach intact, dissolving and releasing the doxycycline in the small intestine, where it is absorbed with fewer gastrointestinal side effects. DORYX's main advantage over other available doxycycline products is that it produces a lower incidence of stomach upset and nausea, a common side effect of doxycycline hyclate.

FDA has classified DORYX as an "old antibiotic" because it contains an active moiety (doxycycline) first approved before November 21, 1997.[26] Given this classification, Mayne and Warner Chilcott could not submit the '161 patent to FDA for listing in the Orange Book prior to enactment of the QI Act. Upon enactment of the QI Act, and in accordance with the transition rules of the new law, Warner Chilcott (as agent for Mayne) timely submitted the '161 patent to FDA for listing on December 3, 2008 and FDA listed the '161 patent in its Orange Book entry for DORYX on December 5, 2008.

Under the terms of the QI Act, sponsors of pending ANDAs referencing DORYX have until February 5, 2009 to certify to the '161 patent in order to be deemed a "first applicant" eligible for 180-day exclusivity. Thus far, Mayne and Warner Chilcott have received notice of paragraph IV certifications from five ANDA applicants—Mylan, Impax, Mutual, Sandoz, and Actavis.

Mayne and Warner Chilcott have filed (or in the case of Actavis, will soon file) patent infringement actions against the ANDA applicants.[27] These patent actions were (or will

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[26] *See* 65 Fed. Reg. at 3627.

[27] Mayne and Warner Chilcott filed patent infringement actions against, Mylan, Impax, and Mutual in the United States District Court for the District of New Jersey on December 23, 2008. Mayne and Warner Chilcott filed a patent infringement action against Sandoz in the United States District Court for the District of New Jersey on January 15, 2009. A patent infringement action against Actavis will be filed within the next few days.

be) filed within the 45-day period that the Hatch-Waxman Amendments provide a patent owner to bring suit and trigger the 30-month stay. In letters dated December 23, 2008, and January 15, 2009, Warner Chilcott (as agent for Mayne) provided FDA notice of the pending patent actions and stated that 30-month stays on FDA approval of the ANDAs now apply. The infringement actions remain pending.

B. Discussion

Under the plain terms of the QI Act, the pending ANDAs referencing DORYX are now subject to a 30-month stay on FDA approval, pending resolution of the patent infringement actions. The express text of the QI Act is clear on this point. The result also makes sound policy sense. An alternate approach would deprive NDA sponsors of one of the core features of Hatch-Waxman even though they had no ability to list patents prior to the QI Act.

1. The Plain Language of the QI Act Requires Application of the 30-Month Stay Provisions of the Original Hatch-Waxman Amendments.

The plain language of the QI Act applies the Hatch-Waxman Amendments to patents listed under the QI Act without regard to the later changes to the Hatch-Waxman 30-month stay provisions instituted under the MMA.[28] As indicated above, under the MMA only patents listed with FDA before an ANDA is submitted can provide the basis for a 30-month stay. However, FDCA section 505(v)(4) as added to the FDCA by the QI Act provides that:

> Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any [antibiotic drug approved before November 21, 1997] or any [antibiotic drug submitted before November 21, 1997, but not approved, for which

[28] MMA § 1101, *codified at* FDCA §§ 505(c)(3)(C), (j)(5)(B)(iii) (each providing that, if a generic applicant makes a paragraph IV certification any FDA approval of the application is immediately effective unless, within 45 days of proper notice, an action is brought for the "infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary . . . before the date on which the application (excluding an amendment or supplement to the application) . . . was submitted").

> the sponsor elects to be eligible for marketing exclusivity periods described in the QI Act].[29]

Congress's use of this "notwithstanding" clause could not be more clear. The provision plainly applies the Hatch-Waxman Amendments, including the 30-month stay provisions, "notwithstanding . . . any other provision of law," including the MMA.[30]

The MMA restriction is indisputably not a "provision[] of the Drug Price Competition and Patent Term Restoration Act of 1984." It was enacted 19 years after the Hatch-Waxman Amendments. The MMA is thus an "other provision of law" under the QI Act, and the QI Act instructs that the Hatch-Waxman Amendments govern notwithstanding the MMA or any "other provision of law." It would violate the plain language of the QI Act to apply the Hatch-Waxman Amendments as they have been revised by the MMA, an "other provision of law."

In applying the Hatch-Waxman Amendments to old antibiotics "notwithstanding . . . any other provision of law," the QI Act references the Hatch-Waxman Amendments in their original, unamended form. The Act provides that the "Drug Price Competition and Patent Term Restoration Act of 1984"—not the "Drug Price Competition and Patent Term Restoration Act of 1984, as amended"—shall apply to old antibiotics. Furthermore, the QI Act references the "Drug Price Competition and Patent Term Restoration Act of 1984" itself, and not the codification of the Hatch-Waxman Amendments in the FDCA. Had Congress wanted the MMA's restriction on 30-month stays to apply to old antibiotics, it could have specified as much. FDA cannot add "as amended" where Congress chose not to do so.

When Congress wanted the QI Act to apply the Hatch-Waxman Amendments as amended by the MMA, it specifically indicated as much by referencing the codified version of the FDCA instead of the original Hatch-Waxman Amendments. Section 4(b)(3) of the QI Act provides that each ANDA applicant that amends a pending ANDA to certify to a patent listed

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[29] QI Act § 4(a) (adding FDCA § 505(v)(4)) (emphasis added).

[30] *See Cisneros v. Alpine Ridge Group*, 508 U.S. 10, 18 (1993) (explaining that the use of a "notwithstanding" clause "clearly signals the drafter's intention that the provisions of the 'notwithstanding' section override conflicting provisions of any other section."); *Liberty Maritime Corp. v. United States*, 928 F.2d 413, 416 (D.C. Cir. 1991) (observing, in interpreting similar "notwithstanding" language, that "'[a] clearer statement is difficult to imagine.'") (quoting *Crowley Caribbean Transport, Inc. v. United States*, 865 F.2d 1281, 1283 (D.C. Cir. 1989)); *Crowley Caribbean Transport* 865 F.2d at 1283 (citing "the broad language" of the "notwithstanding" clause and rejecting as "most implausible" the contention that "the Cargo Preference Act is not among the 'other Acts'" covered by that exemption) (quoting *Illinois Nat'l Guard v. FLRA*, 854 F.2d 1396, 1403 (D.C. Cir. 1988)).

under the QI Act will be considered "a first applicant" as that term is defined in FDCA section 505(j)(5)(B)(iv). The definition of "a first applicant" was added to the Hatch-Waxman scheme by the MMA.[31] Had Congress similarly wanted the MMA's restriction on 30-month stays to apply to patents listed for old antibiotics, it knew how to make its intention clear by referencing the codified version of the FDCA, just as it did when specifying that the "first applicant" definition from the MMA would apply to eligible ANDAs. Instead, Congress clearly stated in the plain language of the QI Act, that the Hatch-Waxman Amendments would apply as they were enacted in 1984. Where Congress includes limiting language in one section of a statute but omits it from another, "it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."[32]

The QI Act applies the "Drug Price Competition and Patent Term Restoration Act of 1984"—the Hatch-Waxman Amendments—to old antibiotics, "notwithstanding" any "other provision[s] of law," such as the MMA. Where, as here, the plain language of the statute is clear, the agency must "give effect to the unambiguously expressed intent of Congress."[33]

2. Applying the 30-Month Stay to All Old Antibiotics Makes Sound Policy Sense.

If the QI Act is read—contrary to its plain terms—to incorporate the MMA restriction on the 30-month stay on FDA approval to cases in which a patent is listed prior to the submission of an ANDA, then no holder of an NDA for an old antibiotic could obtain a 30-month stay for a patent that it newly lists under the QI Act transition provisions against a generic manufacturer with an ANDA pending with FDA. Such a result would render FDCA section 505(v)(4) as added by the QI Act effectively meaningless for old antibiotics with pending ANDAs, and would make little sense in light of the purposes of the new law or the MMA.

New FDCA section 505(v)(4) provides that "the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any" old antibiotic (emphasis added), whether or not there is a pending ANDA for the drug. Even if one could set aside the plain language reference to the original Hatch Waxman Amendments, the effect of this provision would be significantly and materially altered, if applied so as to deprive the NDA/patent holders

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[31] MMA § 1102(a)(1).

[32] *Russello v. United States*, 464 U.S. 16, 23 (1983) (internal quotation omitted).

[33] *Chevron, U.S.A., Inc. v. Natural Res. Def. Counsel*, 467 U.S. 837, 842-43 (1984); *see also Zuni Pub. Sch. Dist. No. 89 v. Dep't of Educ.*, 127 S. Ct. 15534, 1543 (2007)("Under this Court's precedents, if the intent of Congress is clear an unambiguously expressed by the statutory language at issue, that would be the end of our analysis.")(citing *Chevron*, 467 U.S. at 842-43).

an opportunity for a 30 month stay with respect to pending ANDAs, even though the relevant patent information was timely listed in accordance with the QI Act.. The 30-month stay is a core component of the Hatch-Waxman scheme.[34] If the 30-month stay is stripped away, there is little left of the Hatch-Waxman Amendments to apply to an old antibiotic NDA such as DORYX.[35] Such a result would be especially anomalous in the context of the Hatch-Waxman scheme, because Congress so carefully constructed the statute to effect a balance between speeding generic market entry and providing incentives for new pharmaceutical research.[36]

Depriving Mayne and Warner Chilcott of a 30-month stay would also essentially penalize them for listing the patent "late," even though the only reason for that "late" listing was the lack of any statutory basis to list patents for old antibiotics before enactment of the QI Act. Such a result is simply inconsistent with the specific terms of the QI Act. With respect to pending ANDAs, the NDA holder would not receive the benefit of the core component of the Hatch-Waxman provisions—the 30-month stay. In the meantime, those same ANDA applicants would benefit substantially from those Hatch-Waxman provisions, because they could file a paragraph IV certification and earn eligibility for a period of 180-day exclusivity against later filed ANDAs containing paragraph IV certifications under the transition provisions of the QI

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[34] *Ben Venue Labs., Inc. v. Novartis Pharm'l Corp.*, 146 F.Supp.2d 572, 578 (D.N.J. 2001) ("This 30-month stay is to allow the patent infringement action to be litigated in court, and to give assurances to innovator companies that generic manufacturers will not immediately proceed to market after receiving approval of their ANDA's.").

[35] Other core features of the Hatch-Waxman scheme such as the availability of non-patent exclusivity for NDAs are addressed separately in the QI Act and thus not addressed by the new FDCA section 505(v)(4). For example, the QI Act separately provides a narrow mechanism for an old antibiotic to obtain three years of exclusivity for a new condition of use. *See* 21 U.S.C. § 355(v)(1) and (3) (added by the QI Act).

[36] *See* H. Rep. 98-857(II), p. 7 (Judiciary Comm.) ("The proponents of the legislation urged its adoption as the best possible compromise between two competing economic interests."); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003) (noting that the Hatch-Waxman Amendments was "a compromise between two competing sets of interests"); *Mylan v. Thompson*, 268 F.3d 1323, 1326 (Fed. Cir. 2001) (citation omitted) (noting that Hatch-Waxman "emerged from Congress's efforts to balance two conflicting policy objectives: to induce brand name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market").

Act. Congress has given no indication that it intended such an anomalous outcome with differential treatment to NDA and ANDA sponsors.[37]

Moreover, the underlying rationale for the MMA limitation on 30-month stays does not apply in the circumstances presented here. The MMA change to the 30-month stay provisions was designed principally to prevent NDA and patent holders from sequencing the issuance and listing of patents to obtain multiple 30-month stays against a single ANDA.[38] Here, there was no delay in listing the '161 patent. As soon as the QI Act was enacted thereby permitting the patent to be listed, it was listed.[39]

In sum, it is contrary to the QI Act's plain language and to basic principles of fairness to conclude that Congress carved out a subset of old antibiotics that had pending ANDAs when the QI Act was passed and denied them, and only them, the benefit of the Hatch-Waxman compromise.

III. Environmental Impact

The actions requested in this petition are subject to categorical exclusion under 21 C.F.R. §§ 25.31(g).

IV. Economic Impact

An economic impact statement will be submitted at the request of the Commissioner.

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[37] *Cf. Glaxo Group Ltd. v. Apotex, Inc.*, 272 F. Supp. 2d 772, 779 (N.D. Ill. 2003) (rejecting generic manufacturer's argument that, under the FDCA as amended by FDAMA, it is entitled to exercise its Hatch-Waxman right to manufacture, use or sell a generic version of an old antibiotic if done for the purpose of submitting an ANDA but that the innovator is not entitled to exercise its Hatch-Waxman right to protect its patent before the generic drug actually goes to market).

[38] *See, e.g.*, H.R. Conf. Rep. 108-391, p. 835-36 (2003).

[39] The existence of the '161 Patent has, of course, long been fully public. So there is no element of unfair surprise raised by treating the ANDAs to DORYX, in a sense, as if the '161 Patent was listed at the time the ANDAs were filed with FDA.

V. Certification

Each of the undersigned certifies as follows:

I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following dates: the date the QI Act was enacted (October 8, 2008), the date the '161 patent was submitted for listing in connection with DORYX (December 3, 2008), and the dates Mayne and/or Warner Chilcott subsequently received paragraph IV notifications, the first having been received in December 2008.. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: my law firm expects to receive from the client identified below my signature payments in the ordinary course of business at our standard rates for our legal services rendered. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

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January 29, 2009