HUNTON & WILLIAMS LLP
1900 K STREET, N.W.
WASHINGTON, D.C. 20006-1109

TEL 202 • 955 • 1500
FAX 202 • 778 • 2201

February 13, 2009

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: 30-Month Stay Under the QI Program Supplemental Funding Act of 2008

Dear Sir or Madam:

CITIZEN PETITION

This petition is submitted pursuant to section 10.30 of Title 21 of the Code of Federal Regulations on behalf of our client, Medicis Pharmaceutical Corporation ("Medicis").[1] Medicis' New Drug Application ("NDA") for SOLODYN® (minocycline HCl, USP) Extended Release Tablets was initially approved on May 8, 2006. SOLODYN® is a semisynthetic derivative of tetracycline, and is indicated for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients 12 years of age and older. SOLODYN® contains an antibiotic drug that was included in a product that was the subject of a marketing application approved by the U.S. Food and Drug Administration ("FDA") prior to the November 21, 1997 effective date of the Food and Drug Administration Modernization Act ("FDAMA"), Pub. L. No. 105-115, 111 Stat. 2296 (1997) (an "old antibiotic").

On October 5, 2007, Impax, a generic drug manufacturer, submitted an abbreviated new drug application ("ANDA") seeking to market a generic version of SOLODYN® ("ANDA 90-024"). In accordance with and pursuant to the QI Program Supplemental Funding Act of 2008, Pub. L. No. 110-379, 122 Stat. 4075 (2008) ("Antibiotic Act"), which became effective on

[1] Medicis would not object to its petition being consolidated with a similar petition filed on behalf of Mayne Pharma International Pty Ltd. and Warner Chilcott, LLC ("the Warner Chilcott Petition") on January 29, 2009. The docket number assigned to the Warner Chilcott Petition is FDA-2009-P-0038.

October 8, 2008, and FDA's recently issued Draft Guidance for Industry: Submission of Patent Information for Certain Old Antibiotics (Nov. 2008) ("November 2008 Guidance"), Medicis submitted patent information covering SOLODYN® to the FDA's Approved Drug Products with Therapeutic Equivalents ("the Orange Book") on December 3, 2008. Since taking that step, Medicis has learned that at least three additional generic drug manufacturers — Sandoz ("ANDA 90-422"), Mylan ("ANDA 90-911") and Barr/Teva ("ANDA 65-485") — have submitted ANDAs seeking to market generic versions of SOLODYN®. On December 5, 2008, Medicis received notice from Mylan that it had amended its ANDA to provide a paragraph IV certification against the newly listed patent for SOLODYN®. Medicis received similar notices from Sandoz on December 8, 2008, from Impax on December 12, 2008, and from Barr/Teva on December 23, 2008.

On January 13, 2009, Medicis filed suit against Mylan, Barr/Teva, and Sandoz in the United States District Court for the District of Delaware seeking an adjudication that they have infringed Medicis' patent by submitting to the FDA their respective ANDAs for generic versions of SOLODYN®.[2] Because Medicis sued the ANDA applicants within 45 days of receiving notice of the first paragraph IV certification, FDA may not approve any of those three ANDAs for thirty (30) months pursuant to Section 505(j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act").

A. Action Requested

Medicis asks that FDA not approve any of the three ANDAs for generic versions of SOLODYN® whose submitters Medicis has sued for patent infringement within 45 days of receiving notice from them of the submission of a paragraph IV certification. Specifically, we request that FDA:

- stay approval of ANDA 90-422 submitted by Sandoz for 30 months from the date Medicis received notice of the paragraph IV certification from Sandoz, or until an earlier resolution of the patent infringement action;

[2] Although Impax also submitted a paragraph IV certification and notified Medicis of that certification, Impax and Medicis entered into a Settlement and License Agreement dated November 26, 2008. Pursuant to the Settlement and License Agreement, Medicis did not sue Impax for patent infringement within 45 days of receiving notice that it had amended its ANDA to include a paragraph IV certification. As a result, FDA approved Impax's ANDA for generic SOLODYN® on February 3, 2009.

- stay approval of ANDA 90-911 submitted by Mylan for 30 months from the date Medicis received notice of the paragraph IV certification from Mylan, or until an earlier resolution of the patent infringement action;

- stay approval of ANDA 65-485 submitted by Barr/Teva for 30 months from the date Medicis received notice of the paragraph IV certification from Barr/Teva, or until an earlier resolution of the patent infringement action; and

- stay approval for any other pending ANDA referencing SOLODYN® for which the ANDA submitter makes a paragraph IV certification, and with regard to which Medicis brings a patent infringement action within 45 days of receipt of the certification, for 30 months from the date notice of the certification is received.

B. Statement of Grounds

As noted above, SOLODYN® contains an old antibiotic. In section 125 of FDAMA, Congress directed that the following five statutory provisions added to the FD&C Act by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") would not apply to old antibiotics:[3]

1. Three- and five-year non-patent exclusivity;[4]

2. Patent listing;[5]

3. Patent certification;[6]

[3] FDAMA § 125(d)(2).

[4] FD&C Act §§ 505(c)(3), (j)(5)(D).

[5] *Id.* at §§ 505(b)(1), (c)(2).

[6] *Id.* at §§ 505(b)(2), (j)(2)(A)(vii), (j)(2)(A)(viii).

4. Notice to the NDA holder and patent owner of the filing of an ANDA or section 505(b)(2) application containing a paragraph IV certification;[7] and

5. Thirty-month stay of approval of ANDAs and section 505(b)(2) applications containing a paragraph IV certification if a patent infringement suit is filed within 45 days of notice.[8]

In addition, because, under FDAMA § 125, the patents on old antibiotics could not be submitted to the Orange Book, the first applicant to file a substantially complete ANDA listing an old antibiotic as the referenced listed drug was not entitled to a 180-day period of marketing exclusivity upon approval.

Congress's manifest intent in enacting the Antibiotic Act was to eliminate the inequitable treatment of old antibiotics created by section 125 of FDAMA and, more specifically, to subject old antibiotics to the provisions of the Hatch-Waxman Amendments.[9]

In particular, Congress was concerned that the inequitable treatment of old antibiotics was creating a serious public health crisis, as innovator pharmaceutical companies were scaling back (or altogether abandoning) antibiotic research due to the lack of Hatch-Waxman incentives.[10] Congress eliminated that inequitable treatment by granting drugs that contain old antibiotics certain exclusivities and patent protections.[11]

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[7] FD&C Act §§ 505(b)(3), (j)(2)(B).

[8] *Id.* at §§ 505(c)(3)(C), (j)(5)(B)(iii).

[9] *See* Antibiotic Act § 4 (adding to the FD&C Act new section 505(v)(4), providing that, with some limitations not relevant to 30-month stays, the provisions of the Hatch-Waxman Amendments apply to old antibiotics, notwithstanding section 125 of FDAMA or any other provision of law).

[10] *See* Statement of Senator Burr, Cong. Rec. at S9638 (Sept. 26, 2008) (stating that "as a result of [section 125 of FDAMA], companies have no access to Hatch-Waxman incentives to develop drugs based on [old] antibiotics.").

[11] *See* Antibiotic Act § 4(a).

In addition, the Antibiotic Act permits the sponsors of old antibiotics to submit patent information to the Orange Book.[12] Moreover, for those old antibiotics with patents listed in the Orange Book, we understand that FDA has, in accordance with the Antibiotic Act's Transition Rules, instructed generic drug applicants that ANDAs referencing old antibiotics must contain paragraph IV certifications, and that the applicants must give notice of such certifications to the NDA holders. As a result, that the first four Hatch-Waxman provisions listed above now apply to old antibiotics appears to be uncontroverted. In addition, under the Antibiotic Act's Transition Rules, "first applicants" are entitled to a 180-day period of marketing exclusivity.[13]

It is highly unlikely that Congress, after explicitly providing in the Antibiotic Act that the Hatch-Waxman Amendments apply to old antibiotics notwithstanding section 125 of FDAMA and any other provision of law, intended the Antibiotic Act to apply the first four Hatch-Waxman provisions to old antibiotics, but not the fifth. For the reasons set forth *infra*, it is clear that Congress intended the 30-month stay provision to apply to old antibiotics, and that the best and most natural construction of the Antibiotic Act supports that result.

The text of the Antibiotic Act is absolutely unambiguous on this point. It states:

> 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 drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(a).[14]

The provision for 30-month stays, FD&C Act § 505(j)(5)(B)(iii), is one of "the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984." The old antibiotic in SOLODYN® is a "drug subject to paragraph (1)." Nothing in paragraphs (1), (2), or (3) – the Transition Rules – bars or limits the application of section 505(j)(5)(B)(iii) to SOLODYN®. Therefore, Medicis, the sponsor of SOLODYN®, is entitled to a 30-month stay with respect to each ANDA with a paragraph IV certification as to which Medicis files a patent infringement action within 45 days of Medicis's receipt of notice of such a certification.

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[12] *See generally* November 2008 Guidance.

[13] *See* Antibiotic Act § 4(b)(3).

[14] FD&C Act § 505(v)(4), added by Antibiotic Act § 4(a).

Indeed, Congress intended the requirements for patent listings, certification and notice, 180-day marketing exclusivity, and the opportunity for a 30-month stay to work together as part of an integrated statutory process and well-balanced structure of incentives. The provisions for 180-day exclusivity and for a 30-month stay plainly are intended to be closely interrelated.[15] Without the risk of a 30-month stay, the reward of 180 days of marketing exclusivity would be unduly generous.

For these reasons alone, it is difficult to imagine why Congress would allow old antibiotics to be listed in the Orange Book and would require generic drug manufacturers to jump through the hoops of patent certification and notice if such patents were listed, if the NDA holder would not be entitled to a 30-month stay if it sues within 45 days of receiving the notice. Likewise, it is hard to understand why Congress would provide the huge incentive of 180 days of marketing exclusivity to the "first applicant" who risks patent litigation,[16] if the NDA holder would not be entitled to a 30-month stay if it promptly commences such litigation.[17] Indeed, given Congress's intent to spur innovation through passage of the Antibiotic Act,[18] providing the former incentive without the latter would make no sense.[19]

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[15] *See, e.g.*, *In re Cardizen CD Antitrust Litig*., 332 F.3d 896, 901 (6th Cir. 2003) ("In order to encourage generic entry, and to compensate for the thirty-month protective period accorded the patent holder, the first generic manufacturer to submit an ANDA with a paragraph IV certification receives a 180-day period of exclusive marketing rights, during which time the FDA will not approve subsequent ANDA applications.").

[16] *See* Antibiotic Act § 4(b)(3).

[17] FDA and the courts have repeatedly noted that the 180-day marketing exclusivity is "an incentive to the first generic drug manufacturer to expose itself to the risk of patent litigation." *See Torpharm Inc. v. Thompson*, 260 F.Supp.2d 69 (D.D.C. 2003) (Federal Defendants' Memorandum in Opposition to Plaintiff's Motion for Preliminary Injunction, March 5, 2003, at 10) (*citing Mova Pharm Corp. v. Shalala*, 140 F.3d 1060, 1064 (D.C. Cir. 1998)).

[18] S*ee* Statement of Senator Burr, *supra* note 10.

[19] To the extent one is of the view that providing incentives to already approved drugs will not spur innovation, we simply note that providing incentives to already filed ANDAs will not spur risk taking, either. As such, that view cannot rationally explain why Congress would provide generic manufacturers with 180 days of marketing exclusivity, but would not provide innovators with a 30-month stay. Congress may well have recognized that firms organized to develop and market antibiotics

Finally, as explained *infra*, there is no conflict between the Antibiotic Act providing innovators such as Medicis with a 30-month stay and the amendments to the Hatch-Waxman Act contained in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") that preclude 30-month stays for so-called later listed patents.

1. The MMA is Not Applicable

a. Thirty-Month Stays Under the Hatch-Waxman Amendments of 1984

Under the Hatch-Waxman Amendments, an ANDA must contain, with respect to the listed drug, one of the four certifications described in section 505(j)(2)(A)(vii). If the ANDA contains a paragraph IV certification that the patent for the listed drug is invalid or will not be infringed by the sale of the generic drug, the ANDA submitter must so notify the innovator and/or patent holder within 20 days after the filing of the ANDA.[20] If the patent holder files a patent infringement lawsuit against the submitter of the ANDA within 45 days of receiving the notice of a paragraph IV certification, FDA is generally prohibited from approving the ANDA for a period of 30 months, subject to an order by the court in which the infringement lawsuit is pending.[21]

Under the original Hatch-Waxman Amendments, multiple 30-month stays of approval of a particular ANDA were possible. Specifically, if the NDA holder submitted a newly issued patent to the Orange Book during the initial 30-month stay, *e.g.*, at month 28, the ANDA submitter was required to amend the ANDA to certify to the newly listed patent; and, if the certification was a paragraph IV certification, the ANDA submitter was required to provide notice thereof to the NDA holder. The notice presented the NDA holder with the possibility of another 30-month stay if it filed patent infringement litigation on the so-called later listed patent within 45 days of receiving the notice.

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are likely to use at least a portion of gains from 30-month stays to fund research and development of new antibiotic products.

[20] *See* FD&C Act § 505(j)(2)(B)(ii).

[21] *See id.* at § 505(j)(5)(B)(iii).

b. Thirty-Month Stays Under the Hatch-Waxman Amendments, as amended by the MMA

Congress had not anticipated that the Hatch-Waxman Amendments would allow multiple 30-month stays against a single ANDA. Unhappy with this development, Congress in the MMA amended the stay provision.

The MMA prevents multiple 30-month stays against a single ANDA by providing that patents filed with FDA *after* an ANDA or 505(b)(2) application is submitted are not eligible for a 30-month stay.[22] Thus, for ANDAs with paragraph IV certifications to a patent submitted to FDA on or after August 18, 2003,[23] a 30-month stay may be available for litigation related to that patent only if the patent was submitted to FDA before the date on which the ANDA (excluding an amendment or supplement) was submitted. Put another way, "the MMA precludes 30-month stays for *later listed* patents, that is, those patents submitted to FDA on or after the date the ANDA . . . was submitted. As a result of the MMA, ANDAs . . . will, in most cases, be subject to no more than one 30-month stay."[24]

As explained more fully *infra*, old antibiotics are not subject to the "later listed patent" limitation added by the MMA. Even if they were, the SOLODYN® patent that was listed pursuant to section 4(b)(1) of the Antibiotic Act is not a later listed patent. This conclusion follows from the fact that the Antibiotic Act recalculates the submission date of a covered ANDA from the day it was originally filed to the first day on which the first possible application containing a paragraph IV certification could have been submitted, which, by logical necessity, will always be after the date the patent information for the old antibiotic was submitted to the Orange Book. Thus, in the instant circumstances, Medicis filed its patent information on December 3, 2008; and Sandoz, Mylan, and Barr/Teva necessarily filed their respective ANDAs with paragraph IV certifications after that date.

Congress's decision to recalculate the date of submission of an ANDA that references as the listed drug a drug containing an old antibiotic is not surprising given that, prior to the

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[22] *See* FD&C Act § 505(j)(5)(B)(iii).

[23] *See* MMA § 1101(c)(3).

[24] *See* Guidance for Industry: Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, *available at* http://www.fda.gov/cder/guidance/6174dft.pdf (emphasis in original).

Antibiotic Act, patent information for SOLODYN® and other drugs containing old antibiotics was not required – or permitted – to be submitted with the original NDA (or application under FD&C Act § 507), could not be listed in the Orange Book, and could not have been the subject of a paragraph IV certification. Accordingly, the MMA's prohibition of 30-month stays for later listed patents does not apply to SOLODYN® or other drugs listed pursuant to section 4(b)(1) of the Antibiotic Act.

c. The Antibiotic Act

The Antibiotic Act provides that, "[n]otwithstanding section 125, or any other provision, of [FDAMA], or any other provision of law, and subject to the limitations [placed on patent and non-patent exclusivities elsewhere in the Antibiotic Act], the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply" to old antibiotics.[25] As an initial matter, the phrase "notwithstanding section 125, or any other provision, of [FDAMA]" makes it perfectly clear that FDAMA no longer stands as a barrier to an old antibiotic receiving a 30-month stay. Moreover, as explained *infra*, the phrase "or any other provision of law" makes it clear that the MMA does not stand as a barrier, either.

As noted in the Warner Chilcott Petition, the Antibiotic Act does not state that the provisions of the Hatch-Waxman Amendments, *as amended*, shall apply, but, instead, provides that "the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984" – *i.e.*, the session law as originally enacted and prior to any codification or amendment – shall apply. Of course, Congress was well aware of the numerous amendments to the Hatch-Waxman Amendments over the last 25 years, including the significant changes made by the MMA. Indeed, in the Antibiotic Act's Transition Rules, where Congress wanted to modify the FD&C Act's rules governing "first applicants," a term not used in the Hatch-Waxman Amendments of 1984 (but instead added to the FD&C Act by the MMA in 2003), Congress carefully cited not "the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984" (*i.e.*, the original session law prior to codification and later amendments) but, rather, "paragraph 5(B)(iv) of such section 505(j)" (*i.e.*, the statute in its then currently codified and amended form).[26]

[25] *See* FD&C Act § 505(v)(4), added by section 4 of the Antibiotic Act.

[26] *See* Antibiotic Act § 4(b)(3).

Having specifically cited in the Transition Rules a Hatch-Waxman provision as amended by the MMA, Congress's decision not to cite in new section 505(v)(4) of the FD&C Act "the Drug Price Competition and Patent Term Restoration Act of 1984, as amended by the MMA," or some equivalent reference to the statute as previously amended, must be considered deliberate.[27]

Indeed, to make it perfectly clear that changes to the Hatch-Waxman Amendments of 1984, including the MMA, were not meant to apply, Congress included in section 505(v)(4), as added by the Antibiotic Act, the phrase "or any other provision of law," after the phrase "[n]otwithstanding section 125 [of FDAMA]." Consequently, the 30-month stay provision enacted as part of the original Drug Price Competition and Patent Term Restoration Act of 1984 (and not the 30-month stay provision as amended by the MMA in 2003) applies to old antibiotic drug products such as SOLODYN®. As explained *supra*, the original provision does not preclude a 30-month stay for a later listed patent, *i.e.*, a patent submitted to FDA on or after the date the ANDA was submitted.

2. Even Under the MMA, if Applicable, Medicis is Entitled to a 30-Month Stay

a. ANDAs Amended to Contain Paragraph IV Certifications Pursuant to the Antibiotic Act Should be Treated as Having Been Submitted After the Patent Information Was Filed

Even if, contrary to the foregoing analyses, old antibiotics were subject to the "later listed patent" language added by the MMA, the SOLODYN® patent listed in the Orange Book pursuant to section 4(b)(1) of the Antibiotic Act is not a later listed patent. As explained *infra*, the Antibiotic Act recalculates the submission date of a covered ANDA to the first day on which the first possible application containing a Paragraph IV certification could have been submitted. By necessity, that date will always follow the date the patent information was submitted to the Orange Book: it is impossible to file an ANDA with a paragraph IV certification until after patent information has been submitted to the Orange Book.

Under section 4(b)(3) of the Antibiotic Act, each generic applicant that submits a timely Paragraph IV amendment to an ANDA that was substantially complete on October 8, 2008,

[27] *See, e.g., Russello v. United States*, 464 U.S. 16, 23 (1983) ("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.").

"shall be deemed to be a first applicant (as defined in paragraph (5)(B)(iv) of such section 505(j))".[28] The term "first applicant" has a very specific meaning under the definition set forth in section 505(j)(5)(B)(iv)(II)(bb) of the FD&C Act, *i.e.*, it means "an applicant that, on the first day on which a substantially complete application containing a [paragraph IV certification] is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [paragraph IV certification] for the drug."[29] That is, the term "first applicant" is defined in terms of a specific submission date. Here, under section 4(b)(3), the submitters of the pending ANDAs for generic SOLODYN® are all being deemed to be applicants that, on the first day on which a substantially complete paragraph IV application is or was submitted, submitted substantially complete applications containing paragraph IV certifications.

Thus, on the basis of the unique situation presented by the Antibiotic Act, and by operation of its Transitional Rules, all of the paragraph IV applicants are deemed to have submitted their ANDAs on the first day on which the first possible ANDA containing a paragraph IV certification could have been submitted. That day had to have been after the day on which Medicis submitted its patent information. Indeed, it would have been impossible to submit a paragraph IV certification before that day. From the operation of the Antibiotic Act's Transitional Rules, it necessarily follows, therefore, that, as to the three ANDAs at issue, the patent as to which Medicis submitted information with respect to SOLODYN® is not a later listed patent.

FDA's own actions support this reading of the text of the Antibiotic Act. FDA maintains a list of drug products for which an ANDA containing a Paragraph IV certification has been received by the Office of Generic Drugs ("OGD"). This list includes the name of the drug product, the dosage form, the strength (that is the subject of Paragraph IV certification), the reference listed drug, and the date on which the first substantially complete generic drug application was submitted to the Agency.[30] Unlike the submission dates for other drugs on the list, the submission date for old antibiotics (whose patent information was submitted to the Orange Book following the enactment of the Antibiotic Act) is identified with the entry "PIV received prior to 2/5/2009."[31] Tellingly, the listed submission date is not the date the first

[28] Antibiotic Act § 4(b)(3) (emphasis added).

[29] FD&C Act § 505(j)(5)(B)(iv)(II)(bb).

[30] *See* Paragraph IV Patent Certifications, *available at* http://www.fda.gov/cder/ogd/ppiv.htm.

[31] *See, e.g., id.* at Doxycycline Hyclate and Minocycline Hydrochloride.

ANDA was received by OGD; but, rather, as noted *supra*, the submission date is linked to the submission of the paragraph IV certification. Again, given its importance, it bears repeating that a paragraph IV certification necessarily occurs only after patent information has been submitted to the Orange Book; it cannot possibly occur before then.

Section 505(j)(5)(B)(iii) of the FD&C Act – the 30 month stay provision – requires FDA to assign and compare two dates: (1) the date on which information on the patent was submitted to the Orange Book under section 505(b)(1) or (c)(2), and (2) the date on which the substantially complete ANDA at issue was submitted. The Transitional Rules under the Antibiotic Act answer the second question in a very specific way. Those Rules deem all generic applicants (whose applications were substantially complete prior to October 8, 2008) who certify under Paragraph IV within the 120-day grace period to have submitted their ANDAs on the same day – *i.e.,* the day on which the first possible substantially complete ANDA with a Paragraph IV certification could have been submitted. That day logically must have been after the patent information had been submitted to the Agency; it simply cannot be any other way. Thus, even if the MMA were to apply, the patent on SOLODYN® at issue is not a later listed patent, i.e., the Medicis patent had been submitted to the Orange Book before the ANDAs were deemed "submitted" to the Agency.

As discussed *supra*, by deeming all such ANDA applicants to be "first applicants" – as defined 505(j)(5)(B)(iv) – the transitional provision re-sets the submission date for these applications. Resetting the submission date is critical to being able to apply the FD&C Act, as amended by the MMA, to applicants covered by the transitional provisions of the Antibiotic Act. More than one provision of the MMA – including the 30 month stay provision – is directly dependent upon the *submission date* of a particular ANDA. To be able to align the MMA with the transitional provisions of the Antibiotic Act, the submission dates of each "first applicant" under section 4(b)(3) must be carried forward.

Resetting these submission dates is critical to the prospective application of the forfeiture provisions of the MMA to those ANDA applicants who meet the terms of section 4(b)(3) of the Antibiotic Act. In fact, without a reset of the submission dates for these "first applicant" ANDAs, an ANDA applicant could face immediate forfeiture of its exclusivity, based on circumstances the applicant could not have anticipated when it originally submitted the ANDA (well prior to the enactment of the Antibiotic Act). For example, the "failure to market" forfeiture provision under section 505(j)(5)(D)(i)(I) states that the first applicant forfeits its exclusivity if it fails to enter the market "30 months after the date of submission of

the application of the first applicant."[32] As with the 30 month stay provision discussed above, this provision requires the agency to determine the "date of submission" of the "first applicant." Were the agency to revert to an applicant's pre-Antibiotic Act submission date, an ANDA applicant who meets the terms of section 4(b)(3) may be in a position of having already forfeited its exclusivity, even though section 4(b)(3) on its face gives that applicant "first applicant" status.

Similarly, the "failure to obtain tentative approval" forfeiture provision is dependent upon the date of submission and filing of the first applicant's ANDA.[33] Unless the submission date of a 4(b)(3) ANDA is reset – under the terms of section 4(b)(3) – an ANDA applicant may have forfeited its exclusivity based on events or conduct prior to the enactment of the Antibiotic Act, when the applicant could not have anticipated that the pace of its ANDA submission and review were matters of legal consequence.

As noted *supra*, the FDA itself appears to have recognized these very issues as it uses the recalculated submission date in the Paragraph IV Patent Certification Listing. Thus, even the agency has recognized that for ANDAs that meet the terms of section 4(b)(3), the pre-Antibiotic Act submission dates for these applications are no longer determinative. Rather, these applications must be viewed as having a unique "transitional" submission date for purposes of being able to apply the MMA, in its entirety, to these applications. This transitional submission date allows for rational application of the forfeiture provisions of the MMA, as well as appropriate application of the 30 month stay provision of the MMA to pioneer applicants – like Medicis – who both timely listed their patents with FDA and brought suit within 45 days of receipt of each "first applicant" paragraph IV notice.

b. Patents Listed Pursuant to the Antibiotic Act Should be Treated as Having Been Filed in the Original NDA

The Antibiotic Act's Transitional Rules, found in section 4(b)(1), permit NDA holders to list patents that are for drug products containing old antibiotics and that were issued before

[32] FD&C Act § 505(j)(5)(D)(i)(I)(aa)(BB).

[33] *See, e.g.*, FDA Determination of Acarbose Exclusivity at 9-10 (May 7, 2008) (interpreting the term "filed" in this provision to mean "submission" to maintain consistency with the failure to market provision), *available at* http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&o=090000648055265c.

the October 8, 2008 enactment date. Section 4(b)(3) requires ANDA submitters whose applications were filed and substantially complete as of October 8, 2008 to amend their applications to include a paragraph IV certification for products listed pursuant to section 4(b)(1). Section 4(b)(1) states that patent information "required to be filed with [FDA] under subsection (b)(1) or (c)(2)" of section 505 of the FD&C Act in order to be listed for a "drug to which subsection (v)(1) . . . applies" shall be filed with FDA.[34] As previously stated, section 505(b)(1) of the FD&C Act requires an NDA submitter to include in the application patent information covering the drug product that is the subject of the NDA. Section 505(c)(2) imposes a similar requirement on holders of approved NDAs who were unable to submit the patent information with their application either because (1) the NDA was submitted prior to the September 24, 1984 enactment of the Hatch-Waxman Amendments and the information was, therefore, not required to be submitted when the NDA was filed, or (2) the patent was issued after the NDA was approved.[35] Section 4(b)(1) is functionally similar to the transitional provision in section 505(c)(2).

In enacting section 4(b)(1) of the Antibiotic Act, Congress recognized that, absent the now-repealed FDAMA provisions, patent information for old antibiotic drugs would have been "required to be filed with [FDA] under subsection (b)(1) or (c)(2)."[36] By now requiring patents on drugs containing old antibiotics to be listed, section 4(b)(1) effectively fills a statutory gap created by FDAMA.

Indeed, FDA's November 2008 Draft Guidance confirms this interpretation. The Draft Guidance states that "the sponsor of an NDA approved on or before October 7, 2008, for a drug . . . containing an antibiotic drug that was the subject of an application approved under section 507 of the FD&C Act (as in effect before November 21, 1997) must submit this patent information."[37] With respect to the paragraph IV certification requirement in Section 4(b)(3), the Draft Guidance states that "Section 4(b)(3) . . . contemplates submission of patent certifications by applicants of pending ANDAs that reference drugs for which patent

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[34] Section (v)(1) applies to "Antibiotic drugs approved before November 21, 1997." *See* Section 4(a) of the Antibiotic Act, which creates section 505(v)(1) of the FD&C Act.

[35] *See* FD&C Act § 505(c)(2).

[36] Antibiotic Act § 4(b)(1).

[37] November 2008 Guidance 3 (emphasis added).

information must be listed under section 4(b)(1)."[38] Thus, treating the SOLODYN® patent that was listed pursuant to section 4(b)(1) as if it had been filed in the original NDA (and so as not being later listed) avoids any statutory tension created by the MMA's prohibition on 30-month stays for later listed patents.

Moreover, because, prior to the Antibiotic Act, patent information relating to old antibiotics could not be submitted to the Orange Book, and ANDAs and 505(b)(2) applications were not required (or able) to certify to patents for drugs containing old antibiotics, the paragraph IV certifications submitted pursuant to section 4(b)(3) would be the first such certifications against the patent covering SOLODYN®. Thus, SOLODYN's patent is not later listed. SOLODYN® is, therefore, exempt from the MMA's prohibition on 30-month stays for later listed patents. Accordingly, sections 4(b)(1) and 4(b)(3) of the Antibiotic Act should be harmonized with the notice and 30-month-stay provisions of section 505(j)(2)(B)(iii) and section 505(j)(5)(B)(iii), respectively, in such a way that innovators will have notice of all paragraph IV certifications referencing patents listed pursuant to section 4(b)(1) and 45 days to determine whether to sue for patent infringement.

Support for this harmonized reading of the MMA and the Antibiotic Act's Transitional Rules is found in the preamble to FDA's June 18, 2003 regulations, which were promulgated prior to the MMA to address the issue of multiple 30-month stays.[39] In the preamble to the 2003 regulations, FDA interpreted section 505(j)(2)(B) as providing at least one opportunity for a 30-month stay against the first paragraph IV certification submitted to FDA in a given ANDA or 505(b)(2) application. Specifically, the Agency stated:

> We believe that Congress considered the first paragraph IV certification, notice and the opportunity for a single 30-month stay, to be an inter-connected process. . . . In the final rule we keep these provisions operating together, as much as possible, requiring that certifications be made and notification provided in

[38] *See id.* at n.3.

[39] *See* Final Rule, Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,675, 36,693 (June 18, 2003).

> such a way that there always will be one full opportunity for a 30-month stay.[40]

Thus, the preamble illustrates that the Agency has previously recognized the need to balance the innovator company's interest in having an opportunity for fair adjudication of its patent infringement claims prior to approval of a generic drug and the generic company's interest in avoiding multiple 30-month stays against the same ANDA. Under the Antibiotic Act, that same balance was intended by Congress to apply, and so should apply, to old antibiotics as well.

In sum, FDA has previously acknowledged that Congress intended the requirements for patent listings, certification and notice, and the opportunity for a 30-month stay to work together as part of an integrated statutory process.[41] Treating patent information submitted under section 4(b)(1) of the Antibiotic Act as having been submitted with the original NDA, and not as causing the patents to become later listed patents, strikes a fair balance – and the congressionally intended balance – between innovator and generic interests by providing innovators with the opportunity for adjudication of patent infringement claims before the approval of an ANDA, while achieving the MMA's purpose of preventing multiple 30-month stays against the same ANDA.

The above-described interpretation implements the plain meaning of the Antibiotic Act's Transitional Rules and FDA's goal, stated in the 2003 preamble quoted *supra*, of giving integrated operational effect to the paragraph IV certification, notice, and 30-month stay provisions. This interpretation allows these provisions to operate together as Congress intended in the Hatch-Waxman Amendments. Any other reading of the Transitional Rules would be contrary to congressional intent and sound public policy, and would lead to inconsistent and unfair results. Given the regulatory significance of these provisions with respect to the continued innovation and availability of important antibiotic drugs, it is critical

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[40] 68 Fed. Reg. at 36,688.

[41] *See* Report of the Judiciary Committee, Part II of House Report No. 98-857(ii) Aug. 1, 1984, at 15 (noting that Hatch-Waxman authorizes "flexible schedule of ANDA approval-effectiveness dates" that is contingent on notice to the patent holder, initiation of a patent infringement suit within 45 days of the notice, and the availability of a 30-month stay).

that FDA provide clear guidance on how the Agency plans to implement the Transitional Rules and other provisions of the Antibiotic Act.[42]

C. Environmental Impact

Information on the economic impact of the action requested by this petition will be submitted if requested by the Commissioner.

D. Economic Impact

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

E. Certification

I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the comment 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 date: January 13, 2009, the date Medicis filed suit against Mylan, Sandoz, and Barr/Teva for patent infringement. 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: Medicis. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of thispetition.

Sincerely,

Sheldon T. Bradshaw

[42] It would be appropriate and desirable, in the interest of the Agency and regulated firms, for the Agency to set forth its interpretation of the Antibiotic Act with respect to the issues presented in this petition in regulations adopted through notice-and-comment rulemaking.

cc: Mary Ann Holovac
Elizabeth Dickinson
Kim Dettlebach