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September 22, 2009

By Hand Delivery

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, Maryland 20852

Re: Docket No. FDA-2009-P-0266

CELGENE'S COMMENTS TO DR. REDDY'S CITIZEN PETITION

Celgene Corporation ("Celgene") provides these comments in response to the above-identified citizen petition submitted by Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's"). At its core, Dr. Reddy's citizen petition requests that the Food and Drug Administration ("FDA") establish a procedure to force an innovator company to sell its proprietary drug product to a generic company for human bioequivalence testing. FDA should deny this request. There is simply no statutory authority for FDA to require the sale of product between competitors. Indeed, in enacting the FDA Amendments Act of 2007 ("FDAAA"), Congress considered and rejected the very procedure that Dr. Reddy's is requesting. Additionally, Dr. Reddy's request wholly ignores the innovator's legitimate liability and safety concerns related to the distribution and use of its drug product for human testing purposes outside of the established risk management program.

BACKGROUND

Dr. Reddy's citizen petition is based on Dr. Reddy's unsuccessful request that Celgene sell its proprietary drug, Revlimid® (lenalidomide), to Dr. Reddy's. According to Dr. Reddy's, Celgene's refusal to sell its product amounted to an inappropriate use of the risk management

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program for Revlimid®. As described in this comment, Celgene acted completely within its rights when it refused to sell its product and in no way used its FDA-mandated risk management plan inappropriately.

On August 12, 2008, Dr. Reddy's sent a letter to Celgene requesting that Celgene sell Revlimid® to Dr. Reddy's for bioequivalence and study testing purposes. Specifically, Dr. Reddy's requested over 1,400 capsules of Revlimid® in various strengths because Dr. Reddy's allegedly was unable to obtain the drug through "normal" distribution channels *(i.e.*, the typical distribution model using drug wholesalers). Dr. Reddy's renewed its request on December 12, 2008, demanding that Celgene provide Dr. Reddy's with Revlimid®. On January 12, 2008, Celgene responded that Celgene has no obligation to supply Revlimid® to Dr. Reddy's and declines to do so.

Celgene developed Revlimid® after years of research and a significant investment. In 2005, Celgene received initial approval for Revlimid® for a subset of myelodysplastic syndromes ("MDS"). After further research and development, Celgene received approval in 2006 for a second indication involving the use of Revlimid® in combination with dexamethasone for the treatment of multiple myeloma patients who have received at least one prior therapy.

Celgene's efforts to discover and bring to market a new drug also resulted in significant intellectual property rights and marketing exclusivity protecting Revlimid®. Both MDS and multiple myeloma are rare diseases, and Celgene received orphan drug marketing exclusivity for both indications. The orphan drug exclusivities expire in 2012 and 2013 for MDS and multiple myeloma, respectively. Celgene also received New Chemical Entity marketing exclusivity for lenalidomide, which expires in 2010. Additionally, Celgene has 12 listed patents for Revlimid® in FDA's *Orange Book*, including compound, formulation, and method of use claims. Celgene's ownership rights in Revlimid® are undisputed.

Revlimid® is an analogue of thalidomide and has been classified as a Pregnancy Category X product. In order to minimize the risk of fetal exposure, FDA approved Revlimid® to be marketed only under a strict Risk Minimization Action Plan ("RiskMAP") developed by Celgene called RevAssist®. RevAssist® was implemented at the commercial launch of Revlimid® in

December 2005. In 2008, pursuant to the FDAAA, FDA deemed Revlimid® to have a Risk Evaluation and Mitigation Strategy ("REMS").[1] REMS programs range from relatively straightforward medication guides to very complex restrictions on labeling and use. RevAssist® is a complex restricted distribution program that tracks the distribution of each Revlimid® capsule from prescription to patient dispensation.

Subsequent to Celgene's denial of Dr. Reddy's request, Dr. Reddy's submitted its citizen petition requesting, among other things, that FDA establish a procedure to require an innovator company to sell its product to a generic company when the product is covered by a REMS program that includes restricted distribution.

The FDA should deny this request for the following reasons:

- The FDAAA does not provide authority for FDA to compel innovator companies to sell or license their intellectual property or products covered by intellectual property to any other company. In fact, Congress expressly rejected statutory authority for precisely what Dr. Reddy's seeks to impose through regulatory fiat in its citizen petition.
- Such compulsion would contravene long-established law in the intellectual property and antitrust arenas. Both bodies of law grant clear authority to any patent holder to refuse to deal with would-be customers or would-be competitors. In the absence of a plain and unambiguous congressional mandate, FDA cannot assume authority that unsettles decades of well-established antitrust and patent law.
- By its own terms, the statute does not apply to a marketing paradigm adopted by a company in its business judgment independent of and unrelated to REMS.
- Dr. Reddy's request wholly ignores the innovator's legitimate liability and safety concerns related to the distribution and use of its drug product for human testing purposes outside of the established risk management program.

Celgene elaborates on each of these points below.

[1] Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16313 (March 27, 2008).

In addition to Dr. Reddy's proposal, Dr. Reddy's citizen petition includes unfounded and inappropriate allegations that Celgene has engaged in a "company-wide campaign" against generic competition. Celgene also addresses those allegations below.

ARGUMENT

I. Compelling An Innovator To Sell Its Product To A Generic Company Is Contrary To Established Law.

A. Congress Specifically Considered And Rejected Dr. Reddy's Proposed Approach To Providing ANDA Applicants With Drug Samples Subject To Restricted Distribution Schemes For Bioequivalence Testing.

The FDAAA provides that FDA can require manufacturers of certain drugs to submit a REMS program to manage a known or potential serious risk to ensure that the benefits of a drug outweigh its risks. Revlimid® is subject to a deemed REMS consisting of a complex restricted distribution program, called RevAssist®. RevAssist® requires, among other things, patient counseling, patient consent, two forms of birth control, and periodic pregnancy testing. All prescribers and patients must register in the program, and dispensing pharmacies are contracted to dispense according to the program only after patient counseling, consent, and verification of pregnancy testing. Furthermore, prescription authorization and confirmation numbers must be obtained before Revlimid® can be dispensed.

Dr. Reddy's requests that FDA adopt procedures that would suspend the effective and proven restricted distribution measures and would compel the sale of drug for purposes of bioequivalence testing by generic manufacturers. However, Dr. Reddy's own citizen petition recognizes that Congress considered and subsequently rejected provisions that would have provided a mechanism for FDA to mandate that holders of approved New Drug Applications ("NDA") provide samples of drugs to sponsors of Abbreviated New Drug Applications ("ANDA") for purposes of bioequivalence testing.

Specifically, in a previous draft of the FDAAA, the bill included the following provisions:

> (6) BIOEQUIVALENCE TESTING – Notwithstanding any other provisions in this subjection, the holder of an approved application that is subject to distribution restrictions required under this subsection that limit the ability of a sponsor seeking approval of an application under subsection 505(b)(2) or (j) to purchase on the open market a sufficient quantity of drug to conduct bioequivalence testing shall provide to such a sponsor a sufficient amount of drug to conduct bioequivalence testing if the sponsor seeking approval under section 505(b)(2) or (j) -
>
> (A) agrees to such restrictions on distribution as the Secretary finds necessary to assure safe use of the drug during bioequivalence testing; and
>
> (B) pays the holder of the approved application the fair market value of the drug purchased for bioequivalence testing.
>
> (7) LETTER BY SECRETARY – Upon a showing by the sponsor seeking approval under section 505(b)(2) or (j) that the sponsor has agreed to such restrictions necessary to assure safe use of the drug during bioequivalence testing, the Secretary shall issue to the sponsor seeking to conduct bioequivalence testing a letter that describes the Secretary's finding which shall serve as proof that the sponsor has satisfied the requirements of subparagraph (6)(A).

H.R. 2900, 110th Cong. § 901(b) (2007). Neither paragraph (6) nor (7) from H.R. 2900 is included in the final bill. Although Dr. Reddy's dismisses this fact as inconsequential, the omission of this language from the final version of the bill is compelling evidence that Congress did not intend to create any such mechanism. Authoritative legislative history can confirm an interpretation that is otherwise grounded in the text and structure of the statute itself. *See United States v. Gayle*, 342 F.3d 89 (2d Cir. 2003) ("As a general matter we may consider reliable legislative history where . . . the statute is susceptible to divergent understandings and, equally important, where there exists authoritative legislative history that assists in discerning what Congress actually meant.").

Here, to the extent that there is ambiguity as to whether FDCA § 505-1(f)(8), which is the provision relied upon by Dr. Reddy's, requires an NDA holder subject to a restricted distribution REMS to provide drug product to an ANDA sponsor for purposes of bioequivalence testing, the legislative history is more than "reliable" - it is dispositive. As Dr. Reddy's admits, paragraphs

(6) and (7) do not appear in the final version of the FDAAA. Congress, therefore, specifically removed them from the enacted version of the bill. Congress' rejection of the very language that would have achieved the result Dr. Reddy's urges in its citizen petition weighs decisively against Dr. Reddy's position. *See INS v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987) ("Few principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language.") (internal quotation marks and citations omitted); *Chickasaw Nation v. United States*, 534 U.S. 84, 93 (2001) (courts "ordinarily will not assume that Congress intended to enact statutory language that it earlier discarded in favor of other language") (internal quotations omitted); *Fmali Herb, Inc. v. Heckler*, 715 F.2d 1385, 1389 (9th Cir. 1983) ("[M]embers of Congress considered incorporating an explicit geographic element in the exception to pretesting under section 321(s), but declined to do so. We are very hesitant to imply such a limitation when Congress failed to adopt a bill that would have included the same restriction.").

Accordingly, Dr. Reddy's proposed process for compelling the sale of drug product subject to a restricted distribution program to generic manufacturers for bioequivalence trials is impermissible under the FDAAA and, indeed, was specifically considered and rejected by Congress.

B. Compelling Sales Would Also Contravene Antitrust And Intellectual Property Law And Policy.

Antitrust and intellectual property law has long recognized the right of innovators to decide whether and how to deal with other commercial firms. Absent a plain and unambiguous statement from Congress, FDA should not assume the authority to override this long-established principle.

It is well-settled in antitrust jurisprudence that the Sherman Act "does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal." *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). This is no longer regarded simply as a recognition that law, particularly antitrust law, cannot become relevant to every commercial dispute or negotiation. As the Supreme Court unanimously recognized in *Verizon Communications, Inc. v.*

Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 (2004), the Sherman Act's objective of promoting vigorous, dynamic competition requires courts to recognize that firms, even monopolists, are not required to create competition against themselves by dealing with others.

The *Trinko* Court also acknowledged that the imposition of forced-sharing obligations on a company raises administrative concerns and requires public bodies like the courts or the FDA to act outside of their normal roles. The Court noted that even if compulsory sharing were not generally anticompetitive, courts (or, for that matter, any overseer) would not be well-suited to mediate commercial disputes: "[e]nforced sharing also requires antitrust courts to act as central planners, identifying the proper price, quantity, and other terms of dealing – a role for which they are ill suited." *Id.* at 408. Moreover, that same process of negotiation would bring together firms that might otherwise be rivals, which often does greater violence to the Sherman Act than a world where rivals compete vigorously. *Id.*

After reviewing the legal and regulatory context in which the alleged monopolist had purportedly refused to assist its competitors, the *Trinko* Court agreed that the district court was correct in dismissing the antitrust claims. Similarly, any attempt by a court or regulator to compel Celgene to sell or license its patented products and processes to another entity must also fail. To be sure, Celgene is not a monopolist, but even if it were, the FDA should accord the same importance to the incentive to innovate and Celgene's business judgment as the Supreme Court attributed to all firms in *Trinko*.

Trinko is but one among many holdings recognizing that compulsory dealing is inconsistent with the purposes of the antitrust laws. Courts have held for over a century that even a monopolist's refusal to license its competitors within the scope of its patents should not give rise to antitrust liability. *See Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 429 (1908); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 457 (1940); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195 (2d Cir. 1981); *Miller Insituform, Inc. v. Insituform of N. Am., Inc.*, 830 F.2d 606, 609 (6th Cir. 1987); *Data General Corp. v. Grumman Systems Support Corp.*, 36 F.3d 1147 (1st Cir. 1994). The Federal Circuit has only strengthened this law, holding in two separate cases that a patentholder's refusal to deal is beyond Section 2 of the Sherman Act. In the first case, *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999), the

court stated in no uncertain terms that "the antitrust laws do not negate the patentee's right to exclude others from patent property." In *In re Independent Service Organizations Antitrust Litigation*, 203 F.3d 1322 (Fed. Cir. 2000), the court held that a unilateral refusal to license or sell patented products was beyond Section 2 in the absence of sham litigation, tying, or fraud on the Patent & Trademark Office. Indeed, the court expressly noted that "the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws. We therefore will not inquire into his subjective motivation for exerting his statutory rights, even though his refusal to sell or license his patented invention may have an anticompetitive effect . . . ." *Id.* at 1327.

Thus, in the absence of express statutory authority to require Celgene and other innovators to deal with generic applicants, FDA should conclude that Congress did not vest it with authority to go beyond the power of courts and agencies under the antitrust laws and require intellectual property holders to do business with other firms. There is no evidence that Congress intended or effected such a radical departure from mainstream antitrust law and bedrock intellectual property rights. Indeed, the legislative history indicates that Congress specifically recognized these rights. Thus, the better course would be for FDA to interpret its authority under § 505-1(f)(8) consistent with the antitrust and patent laws.

II. An Innovator's Refusal To Sell Its Product To A Generic Company For Reasons Independent Of The Existence Of A REMS Would Not Violate The Statute.

As described above, Dr. Reddy's reading of the statute contravenes the legislative history and established antitrust and intellectual property principles. However, even under Dr. Reddy's interpretation, the facts involving Celgene's direct distribution system demonstrate that the new statute has no application to whether Dr. Reddy's or any other person can obtain Revlimid®. Celgene, since it began selling Revlimid®, lawfully established direct distribution for Revlimid®. Many situations exist where a company may make a voluntary decision to limit its use of typical distribution channels, such as wholesalers, independent from any REMS requirement. For example, a very small patient population may render wholesalers unnecessary because a company could supply the product on an as-needed basis. A product subject to voluntary

marketing limitations, such as direct distribution, could not be accessed through "normal channels," nor would Dr. Reddy's proposal provide access.

Celgene distributes Revlimid® only directly to retailers for sale only to patients with a prescription. Direct distribution to pharmacies is not required by REMS.[2] Sale to patients only upon a valid prescription, though required by virtue of the fact that Revlimid® is a prescription drug, is not a REMS requirement. The REMS requirements for Revlimid® relate primarily to the certification of prescribers and dispensers, evidence of safe use conditions, and patient monitoring in order to minimize the risk of pregnancy exposure.

Dr. Reddy's primary complaint is that there are no wholesalers from which to purchase Revlimid® samples. They also complain that they cannot obtain Revlimid® samples from either Celgene's pharmacy retailers (which would involve dispensing without a prescription) or from Celgene (which is entitled under antitrust law and intellectual property law to refuse unilaterally to deal with competitors). In other words, Dr. Reddy's is complaining about Celgene's direct distribution system, and not about Celgene's use of REMS. Accordingly, the statute is inapplicable on its face.

III. An Innovator Company May Have Legitimate Business And Safety Reasons For Declining To Sell A Product Subject To A REMS To A Generic Competitor.

In addition to proprietary rights, Dr. Reddy's request would require an innovator company to ignore the safety concerns that necessitated restricted distribution in the first place, as well as related liability considerations. An innovator company would be required to relinquish its risk management of a product by providing a substantial quantity of the drug to a third party for human testing purposes. Dr. Reddy's proposal fails to acknowledge that many REMS, including those for Thalomid® and Revlimid®, are complex programs specifically designed to ensure patient safety with respect to drugs that pose heightened safety risks. Innovator companies work diligently to establish appropriate risk management plans (*e.g.*, REMS) that address these heightened risks and allow patients to safely receive the benefits of a

[2] Indeed, the statutory provision governing REMS does not even include distributor certification or similar supply chain requirements as a potential element to assure safe use, which underscores that such restrictions are voluntary and outside the scope of REMS authority. *See* 21 U.S.C. § 355-1(f).

new drug product, such as Revlimid®. Having a strong risk management program that is appropriately executed also benefits the innovator company by decreasing its liability risks.

In an environment where an innovator company can be held liable for a patient's use of a generic drug,[3] Dr. Reddy's demand that an innovator company disregard proprietary rights, business considerations, and liability concerns and provide its product to a third party (with less at stake if the product is mishandled) is unreasonable. This is particularly true considering that a non-REMS product that is distributed under a direct distribution model (*i.e.*, one that does not include wholesalers) would not be subject to the same requirement.

The innovator company not only has a right, but a duty, to consider the impact of the sale of its product to a third party on the safety of the human subjects who will be administered the product and the associated liability risks. The innovator's concerns regarding the safety of individuals receiving and handling the product, and protection of its own interests, are independent from FDA's role, despite FDA's willingness to use its enforcement discretion to allow a sale. Similarly, FDA's approval of a generic's study protocol would not alleviate the need for an Institutional Review Board to conduct its own independent assessment of safety concerns for the very same protocol.[4]

Although Dr. Reddy's proposal provides for FDA to review and approve the generic company's proposed safety procedures, such a process would not allay the innovator's risks. Product liability lawsuits still arise based on products reviewed and approved by FDA as safe and effective, and the innovator's liability issues would still remain after FDA's review and approval of the generic's procedures. FDA would only be able to provide its best judgment based on the information submitted by the generic company. It would be impossible for FDA to guarantee the safety of the generic's testing. FDA needs to carefully consider how it would actively monitor the generic's testing just as it monitors the implementation of REMS programs

[3] *See, e.g.*, *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (Cal. Ct. App. 2008) (holding that an innovator company could be liable for injuries due to the use of a generic product).

[4] *See* 21 C.F.R. § 314.94(a)(7)(iii).

to ensure appropriate compliance.[5] Such monitoring is particularly important when the generic company is taking the drug product out of the country to perform its tests in a foreign jurisdiction where the human subjects may be more vulnerable to protocol and safety violations.

IV. Dr. Reddy's Reference To Third-Party Allegations Are Inaccurate And Irrelevant.

Dr. Reddy's devotes a substantial portion of its citizen petition to unfairly vilifying Celgene. Dr. Reddy's attempts to support its attacks by citing to third-party allegations in an unrelated lawsuit that does not even involve Dr. Reddy's and to the fact that Celgene submitted a citizen petition regarding thalidomide. There is no merit to these attacks, and they have no place in the citizen petition process.[6]

First, the allegations regarding the patent infringement litigation between Barr Laboratories and Celgene are irrelevant to any issue related to Dr. Reddy's petition. Moreover, Dr. Reddy's does not have any first-hand knowledge of the case, and their speculation is useless. Suffice it to say that Celgene has vigorously denied any counterclaims, and the parties are currently litigating the issues in court. Celgene is confident in its position.

Second, as FDA acknowledged in its interim response to Celgene's thalidomide citizen petition, the petition raises complex safety, labeling carve-out, and orphan drug issues regarding generic thalidomide. These issues are important to the public safety and present FDA with legitimate, substantive issues that Celgene had a lawful right to bring to FDA's attention through the citizen petition process. Notably, Dr. Reddy's has not provided any comments to Celgene's thalidomide citizen petition docket explaining why the citizen petition is inappropriate, nor even provided such an explanation in Dr. Reddy's current citizen petition. In sum, Dr. Reddy's accusation is irrelevant to the issue at hand.

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[5] The Office of Inspector General estimated that FDA inspected only 1% of clinical trial sites during the fiscal year 2000-2005 period. Department of Health and Human Services, Office of Inspector General, "The Food and Drug Administration's Oversight of Clinical Trials," Report No. OEI-01-06-00160 (September 2007) at 18.

[6] *See* 21 C.F.R. § 10.20(c)(5) (stating that defamatory, scurrilous, or intemperate matter should not be submitted to the Division of Dockets Management).

Finally, Dr. Reddy's complains of Celgene's refusal to provide Revlimid® samples to Dr. Reddy's. However, Dr. Reddy's could not have expected any other response because, even under Dr. Reddy's proposed procedures, its request was materially deficient. Remarkably, Dr. Reddy's failed to meet even the most basic precaution of receiving safety assurances from FDA.

CONCLUSION

In sum, Dr. Reddy's has requested that FDA adopt procedures that require an innovator company to sell its drug product to a direct competitor for human testing purposes when the product is covered by a REMS with restricted distribution requirements. Ordering the compulsory sale of product between competitors would be an extreme measure contrary to established law. Tellingly, Congress considered exactly the same requirement, but did not enact it. For FDA to now adopt the very procedure that Congress rejected would be untenable. Not only does Dr. Reddy's procedure lack authority, but it also fails to address any of the important liability and business concerns a drug innovator must consider. It is clear for all of these reasons that Dr. Reddy's citizen petition should be denied.

VERIFICATION

I. Section 505(q) Does Not Apply.

Dr. Reddy's argues that its citizen petition is subject to FDCA § 505(q) regarding citizen petitions.[7] However, § 505(q) applies only to citizen petitions that request FDA to take action that could delay approval of a pending ANDA or 505(b)(2) application.[8] Contrary to Dr. Reddy's argument, Dr. Reddy's citizen petition does not request that FDA delay approval of a pending ANDA or 505(b)(2) application. It merely requests that FDA establish a procedure to require an innovator company to sell drug product to a generic company in certain situations. Recognizing the futility of its argument, Dr. Reddy's cites to a pending ANDA for a generic

[7] Among other things, § 505(q) requires certain citizen petitions and related comments to include certifications and verifications, respectively. Additionally, FDA is required to take final agency action on a citizen petition subject to § 505(q) within six months of the date the petition was submitted.

[8] FDA Draft Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (January 2009) at 7.

version of Thalomid®. However, Dr. Reddy's provides no explanation as to how its citizen petition seeks to delay approval of that ANDA. There is no explanation. Dr. Reddy's citizen petition is not subject to § 505(q).

II. Verification Under 505(q) If FDA Determines That Section 505(q) Applies.

However, if FDA interprets § 505(q) to apply, the following verification is provided pursuant to that section:

I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about June 10, 2009. 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: Celgene Corp. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

Respectfully submitted,

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