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October 29, 2014

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
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# CITIZEN PETITION

This petition is submitted on behalf of Amgen Inc. (Amgen) pursuant to 21 C.F.R. § 10.30 and § 351 of the Public Health Service Act (PHSA). This petition requests that the Food and Drug Administration (FDA) require applications submitted under § 351(k) of the PHSA ("biosimilar applications"), which was added to the PHSA by the Biologics Price Competition and Innovation Act of 2009 (BPCIA), to include a certification by the applicant that the applicant will timely comply with § 351(l)(2)(A) by providing the reference product sponsor with a copy of the biosimilar application and information that describes the process(es) used to manufacture the biosimilar product that is the subject of that application. This certification should be required for all biosimilar applications that have not been accepted for review by the FDA.

## I. INTRODUCTION

The BPCIA is intended to advance the public health and the interests of patients by enabling the expedited approval of biosimilar versions of previously approved reference biological products. Congress sought to achieve that goal through an abbreviated approval pathway that permits a biosimilar applicant to rely on the reference product sponsor's prior demonstration of safety and efficacy but also protects the intellectual property rights and innovation of the reference product sponsor. The statute therefore includes a patent dispute resolution process that proceeds concurrently with FDA's review of the biosimilar application. That process, set out in § 351(l) of the PHSA, ensures that patent disputes relating to the biosimilar product and its manufacturing processes are identified, narrowed, and either resolved through licensing, or through litigation commenced before the biosimilar product is commercialized.

The initiation and orderly conduct of this patent dispute resolution process requires the prompt disclosure of information by biosimilar applicants to the reference product sponsor as required by subsection (l)(2)(A). As recent events demonstrate, this Congressionally-mandated scheme is at risk of being fundamentally undermined unless FDA acts to ensure that biosimilar applicants make the requisite disclosures. Specifically, at least one biosimilar applicant has chosen to disregard its obligations under subsection (l)(2)A), and has done so by relying on the belief that the disclosure mandated by subsection (l)(2)(A) is optional.

Congress chose to create a scheme whereby patents that may be relevant to a biosimilar product and its manufacturing processes are identified through private exchanges of information between the biosimilar applicant and the reference product sponsor. Those exchanges are to commence shortly after FDA accepts a biosimilar application for review and continue concurrently with FDA's review. Specifically, as expressly stated in subsection (l)(2)(A), the biosimilar applicant, within 20 days of the date FDA notifies the biosimilar applicant that its application has been accepted for review, "shall provide to the reference product sponsor a copy of the" biosimilar application along with information fully describing the processes used to manufacture the biosimilar product.[1] That initial disclosure starts a cascade of exchanges under subsections (l)(3) through (l)(5),[2] resulting in the identification of patents for licensing and the identification, if necessary, of one or more patents for an "[i]immediate patent infringement action" under subsection (l)(6).[3] The biosimilar applicant also must provide FDA with notice that a patent infringement action under subsection (l)(6) has been commenced.[4] FDA must then publish in the Federal Register notice of that complaint for patent infringement alerting the public and other potential biosimilar applicants that an infringement action under the statute related to the reference product has commenced.[5]

Non-compliance with subsection (l)(2)(A) vitiates the entire scheme that Congress created. If the biosimilar applicant does not disclose the biosimilar application and manufacturing information, the reference product sponsor may not know that an application referencing its product has been submitted. Even if the reference product sponsor learns of this filing from other sources (e.g., the press), its ability to identify relevant patents is undermined as it may not have the information describing the

[1] 42 U.S.C. § 262(l)(2)(A) (emphasis added).

[2] *Id.* § 262(l)(3)-(5).

[3] *Id.* § 262(l)(6), title

[4] *Id.* § 262(l)(6)(C)(i).

[5] *Id.* § 262(l)(6)(C)(ii).

biosimilar product and its manufacture necessary for meaningful judicial resolution and that should have been exchanged under subsections (l)(2) through (l)(5). This, in turn, prevents or delays the initiation of court proceedings to enforce infringed patents. A patent infringement action commenced by means other than as set out in subsections (l)(2) through (l)(6) also may call into question the biosimilar applicant's obligation to notify FDA, and public notice via the Federal Register may not result.

The timely initiation of patent litigation under (l)(6) also affects the Agency's administration of other portions of BPCIA. Pursuant to subsection (k)(6), the sponsor of the first biosimilar product to be designated an "interchangeable" biosimilar product earns a period of exclusivity that will expire on the earliest of five defined dates: 12 months from actual commencement of marketing, 18 months from approval if there is no patent litigation under (l)(6), or three dates triggered by the initiation of patent litigation under subsection (l)(6).[6] This exclusivity is implemented by the Secretary withholding designation of another biosimilar product as being "interchangeable" until the expiration of the first of these five periods to occur.

Delays in compliance with subsection (l)(2)(A) will delay commencement of, or possibly even eliminate, litigation under subsection (l)(6). That, in turn, delays the expiration of the periods specified in subsection (k)(6)(B), rendering those potential expiration dates inapplicable. That result would frustrate a clearly stated Congressional intent. By not implementing measures to ensure timely compliance with the subsection (l)(2)(A) disclosures, FDA is contributing to that uncertainty to the detriment of the legitimate interests of reference product sponsors, subsequent biosimilar applicants who may wish to seek an interchangeability designation, and the public.

These inevitable consequences of a biosimilar applicant's refusal to comply with its statutorily required disclosure obligations under subsection (l)(2)(A) are contrary to unmistakable Congressional intent. Congress clearly intended for the reference product sponsor to have access to the biosimilar application and manufacturing information

[6] 42 U.S.C. § 262(k)(6) provides that FDA may not grant a subsequent "interchangeable" designation for a period that lasts "until the earlier of—(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product; (B) 18 months after—(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or (ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or (C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or (ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6)" (emphases added).

shortly after the FDA begins its review of the application—that access enables the reference product sponsor to identify and communicate to the biosimilar applicant which of the reference product sponsor's patents would be implicated if the biosimilar product were manufactured or commercialized. The pre-litigation exchange of this information serves to narrow the issues and thereby minimize the burden on the courts. Congress also clearly intended for patent litigation, if necessary, to be initiated before the biosimilar product is marketed, thereby minimizing disruptions to the healthcare delivery system that could otherwise occur without a meaningful opportunity for timely court intervention. Finally, Congress intended to have the FDA inform the public of patent litigations involving the commercialization of biosimilar products that are the subject of biosimilar applications.

In the absence of action by FDA to implement subsection (l)(2)(A), the risk of non-compliance is real and substantial. The very first biosimilar application was accepted for review by FDA on July 7, 2014. Under the explicit terms of subsection (l)(2)(A), the sponsor of that biosimilar application, Sandoz Inc. (Sandoz), was required to provide the reference product sponsor, Amgen, with a copy of the application and manufacturing information by July 27, 2014. Sandoz, however, notified Amgen that it had decided not to provide the application and manufacturing information to Amgen within the statutorily-mandated timeframe. Sandoz explained its view that the entire subsection (l) process is optional and can be used, if desired, at the discretion of the biosimilar applicant. Having disposed of subsection (l), Sandoz offered to voluntarily disclose its application to Amgen but only on condition that Amgen accept limitations and restrictions nowhere found in the BPCIA. If Amgen was unwilling to accept Sandoz's terms, Sandoz invited Amgen to file a lawsuit to get the information Sandoz had opted to withhold from Amgen. This pernicious conduct is extraordinary, not only because of the unequivocal and precise statutory obligation at issue, but because Sandoz represented to a Federal Court just one month earlier that it would comply fully with all of its obligations under subsection (l) if FDA accepts another biosimilar application that Sandoz is pursuing. As it stated then:

> This is a situation where Sandoz fully intends to comply with all statutory obligations—at the appropriate time when those obligations accrue—while availing itself of a statutory remedy to resolve an existing patent dispute with Amgen.[7]

[7] Non-confidential Reply Brief of Sandoz, *Sandoz Inc. v. Amgen, Inc. et al.*, Appeal No. 14-1693 at 19 (filed June 13, 2014), http://1.usa.gov/1rIXKwb (emphasis added); *see also id.* at 9 ("After a subsection (k) filing, Sandoz will comply with its obligations under the BPCIA, and Amgen will have every opportunity to bring suit against Sandoz under 35 U.S.C. § 271(e).").

Sandoz has now flatly refused to do just that: comply with its statutory obligations. Without FDA action to ensure compliance with subsection (l)(2)(A), the proper and intended operation of the BPCIA scheme will be subject to the whims of biosimilar applicants.

Plainly, an administrative mechanism is necessary to prevent future biosimilar applicants from engaging in similar behavior and thereby circumventing the disclosure requirements set forth in subsection (l)(2)(A). Unless FDA acts to ensure that biosimilar applicants comply with the statutory obligations set out in the BPCIA, particularly those in subsection (l)(2)(A), applicants will be incentivized to ignore their obligations and thereby undermine the intended operation of the biosimilar approval scheme established by Congress. This poses unnecessary risk to stakeholder confidence in the biosimilar pathway, and will operate to the great detriment of biosimilar applicants, reference product sponsors, the courts, and the public. To avoid potential adverse consequences, FDA should adopt practices that will foster uniform and predictable enforcement of the statute to further its plainly stated objectives.

## II. ACTION REQUESTED

Amgen requests that FDA adopt policies and practices in their acceptance and review of biosimilar applications that will provide for the orderly implementation and efficient functioning of the BPCIA. Specifically, Amgen requests that FDA take action to ensure that biosimilar applicants will comply with the statutory obligation set out in § 351(l)(2)(A) of the PHSA. To that end, before accepting an application for review under § 351(k), FDA should require that such applications contain a certification from the biosimilar applicant that it will comply with subsection (l)(2)(A) by providing to the reference product sponsor a copy of the application accepted for review and information that fully describes the manufacture of the proposed biosimilar product within 20 days after being informed by FDA that its biosimilar application has been accepted for review. This certification should be required for all biosimilar applications that have not been accepted for review by the FDA.

A certification requirement for biosimilar applications can be implemented without an appreciable burden on FDA. Enforcement of the certification requirement can be achieved through existing practices and procedures.

## III. STATEMENT OF GROUNDS

### A. The Statutory Scheme And Purpose

The BPCIA was the result of several years of legislative deliberation. Similar to the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman),

the BPCIA process balances the interests of biosimilar applicants, the reference product sponsor and the public: increased choice in biological medicines and the need to protect the intellectual property rights and innovation of the reference product sponsor. Its purpose is to increase availability of biological products by establishing an abbreviated pathway that permits approval based on the biosimilar applicant's demonstration of a high degree of similarity of the biosimilar product to a previously approved reference product, instead of the full complement of data, including a *de novo* demonstration of safety and effectiveness of the biosimilar product. At the same time, the BPCIA seeks to protect the intellectual property rights of reference product sponsors and provides significant periods of data exclusivity for the innovator.

Both objectives are equally important. On the one hand, the streamlined approval process for biosimilar products in subsection (k), which relies on the safety and efficacy data previously developed by the reference product sponsor, facilitates delivery of potentially lower cost versions of approved biological products to the market. On the other, the patent provisions in subsection (l) ensure in part that the necessary incentives to invest in research and development of new life-saving biological products will continue to exist. Both objectives—fostering competition and preserving the incentive to innovate—advance the public health.

The new statutory pathway thus provided a substantial benefit to a diverse group of stakeholders, including developers of biosimilars, by creating an abbreviated approval framework for FDA approval of biological products that are "biosimilar" to a previously licensed originator product (i.e., the "reference product") at a substantially reduced cost and effort. In providing this benefit for sponsors of biosimilar products, however, the BPCIA also imposes attendant obligations and limitations. More specifically, in exchange for allowing biosimilar applicants to rely on the prior licensure of a reference product, a license secured at significant expense and effort of another company, Congress mandated that biosimilar applicants make specific disclosures, participate in a specific sequence of exchanges of information, participate in negotiations, and provide certain notices in accord with specific timelines.

This process, laid out in explicitly mandatory language in § 351(l) of the PHSA, was designed to run concurrently with FDA's review of a biosimilar application under § 351(k). Timely identification of patent disputes implicated by the biosimilar product and its processes of manufacture is a central purpose of the Act—the BPCIA patent provisions were included to enable patent disputes to be identified at the beginning of FDA's review of biosimilar application under § 351(k) and to be resolved before the biosimilar product is approved by FDA or put before the courts before the first commercialization of the approved biosimilar product.

FDA's substantive review of a biosimilar application under § 351(k) begins in lockstep with the patent process of § 351(l). Under subsection (l)(2)(A), within 20 days after FDA notifies a biosimilar applicant that its application has been accepted for review, the applicant "shall provide to the reference product sponsor a copy of the application . . . and such other information that describes the process or processes used to manufacture the biological product."[8] The statute protects the confidentiality of this information, imposing substantial restrictions on who may receive the information and how it may be used, and presuming irreparable harm for any breach of these confidentiality provisions.[9] The information disclosed by the biosimilar applicant at this stage is the predicate for a cascade of exchanges between that applicant and the reference product sponsor designed to identify patent disputes, if any, to be resolved through licensing or litigation.[10] If warranted, those exchanges will induce litigation within a fixed period defined in the statute.[11]

The early identification of information about the biosimilar product and its processes of manufacture are critical to orderly operation of the statutory scheme. The disclosure mandated by § 351(l)(2)(A) serves two purposes. It enables the reference product sponsor to learn of the existence of a biosimilar application shortly after it has been accepted for review by the FDA. It also provides the reference product sponsor with information to identify patents implicated by the biosimilar product, its intended use, or its processes of manufacture: information that is known to the biosimilar applicant at the filing date of the application, but unlikely to be otherwise available to the reference product sponsor. The process of identifying and listing of patents, in turn, allows the parties to articulate their positions on each patent, and to then work together to identify which of the disputed patents may be licensed or require immediate litigation. Importantly, because the initial disclosures of the necessary information about the biosimilar product and its manufacture are to have been made by this point pursuant to subsection (l)(2)(A), the subsection (l) process may proceed without disturbing FDA's review of the biosimilar application under subsection (k).

Another aspect of the BPCIA underscores the Congressional intent that patent disputes be initiated before a biosimilar product is approved and launched. Subsection (l)(8)(A) states that once a biosimilar product has been licensed by FDA, the biosimilar applicant "shall provide notice to the reference product sponsor not later than 180 days

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[8] 42 U.S.C. § 262(l)(2)(A) (emphasis added).

[9] *See id.* § 262(l)(1)(A-H).

[10] *See id.* § 262(l)(3)(A), (3)(B), 3(C), (4), (5).

[11] *See id.* § 262(l)(6), (8), (9); *see also* 35 U.S.C. § 271(e)(2)(C).

before the date of the first commercial marketing" of the biosimilar product.[12] This notice enables the reference product sponsor to seek a preliminary injunction to prevent the launch of the biosimilar product until claims of patent infringement have been resolved by the courts.[13] This, too, reflects Congress's intent to protect the intellectual property of the reference product sponsor and related patent owners and avoid the disruption associated with the marketing of infringing biosimilar products.

The public—not just the reference product sponsor and the biosimilar applicant—has an interest in the timely provision of information mandated by subsection (l)(2)(A). The prompt provision of this information sets the course for exchanges of information and, if necessary, "immediate" patent litigation under subsection (l)(6)(A). Congress made clear there is a public interest in the timely resolution of patents disputes under the biosimilar scheme—it expressly requires the FDA to publish a notice in the Federal Register of any "immediate" patent litigation that has been commenced under the BPCIA scheme. Among other purposes, this notice serves (1) to inform other, prospective biosimilar applicants of the existence of litigation, and thus, patents of the reference product sponsor that may pertain to biosimilar versions of that product and (2) provide notice to other biosimilar developers of litigation for which the outcome may affect when other biosimilar applicants will be eligible for an FDA interchangeable designation for their products.[14]

The statutorily-mandated disclosure and subsequent exchanges of information also further the public interest by operating to narrow the scope of disputes requiring judicial intervention to resolve. Specifically, the subsection (l) procedures function to identify those patents available for licensing and those patents in need of immediate court intervention after the subsection (k) application is accepted for review. They also ensure that when patent infringement litigation is necessary to resolve a defined dispute, it is commenced quickly after FDA acceptance of a biosimilar application and with as minimal a burden on the courts as possible. And, of course, the public benefits by having these patent disputes resolved promptly, whether through licensing or promptly initiated litigation, and ideally before the biosimilar product is marketed.

Although the FDA has begun accepting biosimilar applications for review, it has not yet taken any steps to implement subsection (l) or ensure compliance with it. However, as noted above, at least one applicant, Sandoz, has erroneously concluded the entire subsection (l) process is optional and, therefore, has refused to make the disclosures mandated by subsection (l)(2)(A) pursuant to the BPCIA. Such a reading of

[12] 42 U.S.C. § 262(l)(8)(A) (emphasis added).

[13] *See id.* § 262(l)(8)(B).

[14] *See id.* § 262(k)(6)(B), (C); *see also supra* n.6; *infra* n.44.

the BPCIA is unsound. As discussed below, reading subsection (l)(2)(A) as being permissive, and not mandatory, is contrary to the text, structure, and history of the statute; will create uncertainty for biosimilar applicants, reference product sponsors, and the public; and, most importantly, would frustrate Congressional intent by precluding the timely and focused patent litigation necessary to ensure the proper functioning of the overall statutory scheme.

The linkage in the PHSA between FDA's review under subsection (k) and the private exchange of patent information under subsection (l) cannot be ignored. Simply stated, the dual objectives of the BPCIA cannot be achieved without the early disclosure mandated by the statute. Unless biosimilar applicants honor their initial disclosure obligations under subsection (l)(2)(A) as mandated by Congress—within 20 days of FDA's acceptance of the biosimilar application—the timely identification and assertion of relevant patents will not occur.

### B. History, Text, and Structure of the BPCIA

Although the BPCIA did not become law until March 23, 2010,[15] issues related to biosimilars had been debated by legislators, regulators, consumer groups, innovators, and generic manufacturers for well over a decade. For instance, section 123 of the Food and Drug Administration Amendments Act of 1997 (FDAMA), directed the Secretary of Health and Human Services to "take measures to minimize differences in the review and approval of" new drugs and biological products.[16] Shortly thereafter, Senator Hatch began meeting with stakeholders to discuss "generic biologics" at a conceptual level.[17] In 2002, Senator Rockefeller proposed to fund a study by the Institute of Medicine regarding the feasibility of "generic biologics."[18] The first bills to propose enabling legislation were introduced by Congressman Waxman and Senator Schumer in 2006 and reintroduced in 2007.

Notably, the Waxman/Schumer proposals included patent dispute provisions that would have been optional for biosimilar applicants.[19] A competing version was

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[15] Pub. L. No. 111-148, § 7002, 124 Stat. 119, 804-21 (2010).

[16] Pub. L. No. 105-115, § 123(f), 111 Stat. 2296, 2324 (1997).

[17] *See FDA, USP Should Set Generic Biologics Standards, Sen. Hatch Proposes*, The Pink Sheet at 16, (Aug. 12, 2002) ("Hatch has been talking about generic biologics as a concept since 1999, when he held a series of meetings with industry and consumer groups to discuss Waxman/Hatch reform.").

[18] S. 2677, 107th Cong. § 103 (2002).

[19] H.R. 6257, 109th Cong. (2006) (proposed § 351(k)(16)(E): "A comparable biological product applicant may not be compelled, by court order or otherwise, to initiate the procedures set forth in this paragraph. The decision as to whether to invoke the procedures set forth in this paragraph is left entirely to the

introduced early in 2007 that would have vested control over the patent dispute process with the reference product sponsor.[20] Later that year, a compromise proposal developed by the Senate HELP committee adopted the mandatory form of the patent dispute scheme, starting with the requirement that the biosimilar applicant "shall provide" a copy of the application and information regarding the manufacturing processes for the proposed biosimilar product to the reference product sponsor.[21] Subsequent proposals in the both the House and Senate likewise made clear that the biosimilar applicant's participation in the patent dispute resolution process was not optional.[22]

As enacted, section 351(l)(2) states that, within 20 days of FDA's acceptance of a biosimilar application, the biosimilar applicant "shall provide to the reference product sponsor a copy of the application . . . and such other information that describes the process or processes used to manufacture the biological product."[23] What follows is a carefully mapped-out sequence of events, under which relevant patents are identified and both parties exchange legal positions within tight limitations:

- Upon receiving a copy of the application and manufacturing information, the reference product sponsor has 60 days in which it must provide the biosimilar applicant with a list of patents that would be infringed by the manufacture, use, import or sale of the biosimilar and indicate which of those patents it would be prepared to license.[24]

- Upon receiving the patent list, the biosimilar applicant has 60 days in which to (1) provide a detailed statement, on a claim-by-claim basis, of its opinion that the patents are invalid, unenforceable, or will not be infringed; (2) agree that

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discretion of the applicant or prospective applicant."); S. 4016, 109th Cong. (2006) (same); H.R. 1038, 110th Cong. (2007) (proposed § 351(k)(17)(E): "An applicant or prospective applicant for a comparable biological product under this subsection may not be compelled, by court order or otherwise, to initiate the procedures set forth in this paragraph. Nothing in this paragraph requires an applicant or a prospective applicant to invoke the procedures set forth in this paragraph."); S. 623, 110th Cong. (2007) (same).

[20] *See* S. 1505, 110th Cong. (2007) (proposed § 351(k)(8)(B)(i): "A patent owner may—(I) request information from the person that submits an application for a biosimilar under paragraph (1) to ascertain whether such person's product or processes would infringe on a patent of the patent owner").

[21] *See, e.g.*, S. 1695, 110th Cong. (2007) (proposed § 351(l)(2)(A): "shall provide").

[22] *See, e.g.*, H.R. 5629, 110th Cong. (2008) (proposed § 351(l)(4)(A)(i): "shall provide"); H.R. 1548, 111th Cong. (2009) (same); S. 1679, 111th Cong. (2009) (same).

[23] 42 U.S.C. § 262(l)(2)(A) (emphasis added).

[24] *Id.* § 262(l)(3)(A)(i), (ii).

commercial marketing will not commence before the patent(s) expire; and/or (3) respond to any indications of willingness to license.[25]

- Upon receiving that response, the reference product sponsor then has 60 days in which to provide a detailed statement, on a claim-by-claim basis, of its opinion as to why the patents are valid, enforceable, and infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application.[26]

- After the detailed statements have been exchanged, the reference product sponsor and the biosimilar applicant must negotiate in good faith for 15 days to agree on a list of patents, if any, to be included in an "immediate patent infringement action."[27]

- If they cannot reach an agreement, the list of patents that must be included in an immediate patent litigation is decided by an exchange of lists in which the biosimilar applicant determines the number of patents that each side can list.[28]

- If the biosimilar applicant contends that zero patents should be listed, the reference product sponsor may list one patent.[29] Notably, this provision demonstrates the biosimilar applicant cannot entirely avoid patent litigation if relevant patents have been identified and disputed.

- The reference product sponsor and the biosimilar applicant must then engage in a simultaneous exchange of lists of patents to be included in an immediate patent litigation.[30]

- Within 30 days of an agreement or the exchange of lists, the reference product sponsor must bring an infringement action with respect to the patents on the exchanged lists.[31]

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[25] *Id.* § 262(l)(3)(B)(i)-(iii).

[26] *Id.* § 262(l)(3)(C).

[27] *Id.* § 262(l)(4)(A), (B).

[28] *Id.* § 262(l)(5)(A), (B)(ii)(I).

[29] *Id.* § 262(l)(5)(B)(ii)(II).

[30] *Id.* § 262(l)(5)(B)(i)(I), (II).

[31] *Id.* § 262(l)(6)(A)-(C).

- Within 30 days of being served with the complaint, the biosimilar applicant must notify FDA that it has been sued, under this provision of the statute, and FDA must publish a notice of the complaint in the Federal Register.[32]

- The biosimilar applicant must give the reference product sponsor at least 180 days notice prior to the date of first commercial marketing of its licensed biosimilar product.[33]

- Upon receiving the biosimilar applicant's notice of commercial marketing, the reference product sponsor is entitled to seek, during the notice period, a preliminary injunction to prevent commercial manufacture or sale until the court has resolved the patent disputes related to any patents that were not listed for the immediate patent litigation.[34]

- Finally, if a preliminary injunction is sought, both sides must "reasonably cooperate to expedite" discovery as is needed in connection with the preliminary injunction motion.[35]

In this scheme, Congress provided the reference product sponsor with several key rights and protections including: (1) requiring that a biosimilar applicant provides the reference product sponsor with information necessary for a meaningful patent assessment and efficient resolution;[36] (2) ensuring that the reference product sponsor can designate at least one patent for "immediate" patent litigation;[37] (3) enabling the reference product sponsor to commence immediate litigation on the listed patents;[38] (4) guaranteeing that the reference product sponsor will receive at least six months advance notice of the commercial launch of the licensed biosimilar product;[39] and (5) allowing the reference product sponsor to seek a preliminary injunction to enable orderly judicial resolution of the patents that were not listed for "immediate" litigation.[40] None of these rights can be exercised effectively or as Congress intended if the

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[32] *Id.* § 262(l)(6)(C).

[33] *Id.* § 262(l)(8)(A).

[34] *Id.* § 262(l)(8)(B), (9)(A).

[35] *Id.* § 262(l)(8)(C).

[36] *Id.* § 262(l)(1), (2)(A), (3)(B); (7).

[37] *Id*. § 262(l)(5)(B)(ii)(II).

[38] *Id.* § 262(l)(6)(A),(B); *see also* 35 U.S.C. § 271(e)(2)(C).

[39] 42 U.S.C. § 262(l)(8)(A).

[40] *See, e.g.*, *id.* § 262(l)(5)(B)(ii)(II), (6)(A), (6)(B), (8)(A), (8)(B).

biosimilar applicant flouts its obligation to make the first, key disclosure under subsection (l)(2)(A).

The multi-step process reflected in subsection (l) ensures that patent disputes involving biosimilars are resolved or litigated in an efficient and timely manner, thus "providing certainty to the applicant, the reference product manufacturer, and the public at large."[41] The scheme benefits both the reference product sponsor and the biosimilar applicant. It also benefits courts by reducing unnecessary disputes over patents that may not have to be litigated and the public by ensuring any disputes are identified and court intervention is sought before commercial marketing of the biosimilar product begins. In sum, the statutory scheme implemented by the BPCIA serves a compelling public interest, which will be frustrated if the predicate event the statute defines to commence the process is not performed by biosimilar applicants.

### C. The Patent Dispute Resolution Process Mandated By Congress Is Not Optional Or Discretionary For Biosimilar Applicants.

Amgen owns several BLAs, including one for NEUPOGEN® (filgrastim). Coincident with the deadline for Sandoz to provide Amgen with its subsection (l)(2)(A) disclosure, Sandoz informed Amgen that FDA had accepted for review an application under § 351(k) for a biosimilar filgrastim product designating Amgen's NEUPOGEN® (filgrastim) as the reference product. At that time, Sandoz also stated that it was opting not to provide Amgen with a copy of the biosimilar application or any manufacturing information based on its belief that the subsection (l) process is a matter of choice vested in the biosimilar applicant. That belief ignores the plain statutory language and cannot be reconciled with the purpose and objectives of the statutory scheme established by Congress.[42]

The structure of subsection (l) clearly demonstrates that Congress intended and expected biosimilar applicants to participate in the patent dispute resolution process by making the disclosures set out in subsection (l)(2)(A), thereby enabling "immediate" litigation of at least one of the patents identified by the reference product sponsor as potentially being infringed by commercial marketing of the biosimilar product. As discussed above, the statute is designed to ensure that the biosimilar applicant and the reference product sponsor have made informed decisions that narrow, streamline and

[41] 155 Cong. Rec. E687-88 (daily ed. Mar. 17, 2009) (statement of Rep. Eshoo).

[42] In a series of letters, Sandoz offered to provide Amgen some of the information specified in subsection (l)(2)(A), but conditioned that access on Amgen accepting a number of conditions and restrictions not found in the statute. Sandoz also explicitly maintained that its willingness to provide a disclosure of any information was entirely voluntary on its part, and pointed Amgen to the option of filing a declaratory judgment patent litigation.

prioritize patent disputes so that, if court intervention is required, the disputes can be expeditiously raised. That structure can function as intended only if the disclosures under subsection (l)(2) are made in a timely manner as specified in the statute.

Indeed, if the biosimilar applicant simply refuses to provide a copy of the application and information about the manufacturing of its product within the prescribed time period, the biosimilar applicant substantially undermines the ability of the reference product sponsor to determine which patents may be implicated by the commercial manufacture, use, sale or import of the biosimilar product. In turn, the reference product sponsor cannot provide the list required under subsection (l)(3)(A). That, in turn, precludes the exchange of contentions and negotiations contemplated by subsections (l)(3)(B) and (l)(4), the exchange of patent lists contemplated by subsection (l)(5), and the institution of an immediate patent litigation under subsection (l)(6). All of these provisions quickly become nullities if biosimilar applicants are free to simply ignore the requirements of § 351(l)(2)(A).

Moreover, because a failure to comply with subsection (l)(2)(A) can have the effect of circumventing or forestalling immediate litigation under subsection (l)(6), the biosimilar applicant may inappropriately avail itself of a period of interchangeable exclusivity under § 351(k)(6) of the PHSA to which Congress did not intend. Under the latter provision, FDA cannot make a determination that a second or subsequent biosimilar product is eligible for an interchangeability determination until the earliest of certain deadlines, several of which are linked to the termination of litigation commenced under subsection (l)(6).[43] This aspect of the statute will be open to abuse if the first biosimilar applicant is able to delay or avoid litigation under subsection (l)(6) by ignoring subsection (l)(2)(A).[44]

Subsection (l) also vests important rights in the reference product sponsor designed to protect intellectual property interests. For example, in subsection (l)(5)(A), if the biosimilar applicant and the reference product sponsor do not agree on which patents should be litigated, the biosimilar applicant may dictate the number of patents that must be the subject of "immediate" patent litigation under subsection (l)(6). This discretion, however, is limited by a corollary right vested in the reference product

[43] *See* 42 U.S.C. § 262(k)(6)(B)(i)-(ii), (C)(i)-(ii).

[44] For example, § 262(k)(6)(B)(i) sets one of the dates which can terminate a period of interchangeable biological product exclusivity to be the date that is 18 months "after a final court decision on all patents in suit in an action instituted under subsection (l)(6) . . . ." If the litigation specified in § 262(l)(6) is timely commenced, this period may expire earlier than other periods specified in § 262(k)(6), such as that in § 262(k)(6)(A) (i.e., one year after the first commercial marketing of the first interchangeable biosimilar product). By delaying its disclosure obligation under § 262(l)(2)(A), the biosimilar applicant can delay the commencement of litigation under § 262(l)(6), and consequently, the termination of that litigation.

sponsor. Specifically, in subsection (l)(5)(B)(ii)(II), Congress specified that if the biosimilar applicant lists zero patents for immediate litigation, the reference product sponsor can nevertheless "list 1 patent." By expressly enabling the reference product sponsor to override an attempt by the biosimilar applicant to avoid immediate patent litigation, Congress made clear that the patent dispute resolution process is not a matter solely within the discretion of the biosimilar applicant.[45]

Likewise, it is simply inconceivable that Congress intended to allow biologic applicants to "opt out" entirely from a process that begins with the phrase "the subsection (k) applicant . . . shall provide . . ."[46] and then proceeds to lay out at least sixteen additional steps framed in mandatory terms.[47] As courts routinely recognize, "'[t]he word 'shall' generally indicates a command that admits of no discretion on the part of the person instructed to carry out the directive.'"[48] Indeed, that biosimilar applicants have no "right" to opt out of the disclosures required by subsection (l)(2)(A) is confirmed by the very next clause of the statute, which states that biosimilar applicants "may provide" additional information in response to requests received from the reference product sponsor.[49] The juxtaposition of "shall provide" and "may provide" is dispositive. When Congress uses "shall" and "may" to refer to parallel obligations, the former "is as mandatory as a statute can be."[50]

The legislative history also forecloses reading subsection (l) as an optional pathway to be invoked or disregarded at the exclusive discretion of the biosimilar

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[45] In the Hatch-Waxman context, FDA has stated that it "must exercise its discretion in a consistent and equitable manner that does not undermine . . . [the] legislative balance designed to facilitate the availability of generic drug products that meet the statutory requirements for approval while protecting innovator intellectual property rights." Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, to Gary L. Veron, Esq., Sidley Austin LLP, Response to Citizen Petition, Docket No. FDA-2010-P-0614, at 18 (May 25, 2011).

[46] 42 U.S.C. § 262(l)(2)(A) (emphasis added).

[47] *See, e.g.*, *id.* § 262(l)(1)(B)(i) ("shall provide"), 262(l)(2) ("shall provide"), 262(l)(3)(A) ("shall provide"), 262(l)(3)(B)(ii) ("shall provide"), 262(l)(3)(B)(iii) ("shall provide"), 262(l)(3)(C) ("shall provide"); 262(l)(4)(A) ("shall engage in"); 262(l)(4)(B) ("shall apply"); 262(l)(5)(A) ("shall notify"); 262(l)(5)(B) ("shall simultaneously exchange"); 262(l)(6)(A) ("shall bring an action"); 262(l)(6)(B) ("shall bring an action"); 262(l)(6)(C)(i) ("shall provide"); 262(l)(C)(ii) ("shall publish"); 262(l)(7) ("shall provide"); 262(8)(A) ("shall provide"); 262(8)(C) ("shall reasonably cooperate").

[48] *Cook v. FDA*, 733 F.3d 1, 7 (D.C. Cir. 2013) (quoting *Ass'n of Civilian Technicians, Montana Air Chapter No. 29 v. Fed. Labor Relations Auth.*, 22 F.3d 1150, 1153 (D.C. Cir. 1994)).

[49] 42 U.S.C. § 262(l)(2)(B) (emphasis added).

[50] *Zivotofsky v. Sec. of State*, 571 F.3d 1227, 1243-44 (D.C. Cir. 2009); *see also, e.g.*, *Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012), *aff'd sub nom. Cook v. FDA*, 773 F.3d 1 (D.C. Cir. 2013) (citing *Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 346 (2005)).

applicant. Prior, rejected drafts of the BPCIA had used permissive language when describing the initial disclosures to be made by biosimilar applicants.[51] Very early drafts had explicitly stated that the entire patent dispute resolution process was optional for the biosimilar applicant and that the biosimilar applicant could not be compelled to participate.[52] Congress rejected all of those proposals in favor of an explicitly mandatory process. That rejection reinforces the already obvious conclusion that section 351(l) was intended to be mandatory.[53]

Amgen is aware that some biosimilar applicants, like Sandoz, have argued that the BPCIA process was not intended to be an exclusive mechanism for resolving patent disputes relating to biosimilar applications. This theory is flatly inconsistent with the statutory language that expressly regulates patent litigation relating to the biological products seeking approval pursuant to § 351(k). It also fails to account for the practical reality that there are jurisdictional limits on declaratory judgment patent actions prior to a qualifying act of infringement.[54] Indeed, much of the BPCIA process exists specifically to avoid that jurisdictional problem by enabling the parties to identify and resolve their disputes, or if not resolved, initiate patent litigation[55] before commercial marketing of the biosimilar product commences.[56] Allowing biosimilar applicants to simply pick and choose whether—and, if so, how—to comply with subsection (l) would plainly frustrate Congress's intent.[57]

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[51] *See, e.g.*, H.R. 1427, 111th Cong. (2009) (proposed § 351(k)(18)(A)(i): "At any time, including at the initial stages of development, an applicant or a prospective applicant under this subsection may send a written request for patent information to the holder of the approved application for the reference product."); S. 726, 111th Cong. (2009) (same).

[52] *See supra* n.19.

[53] *See, e.g.*, *Russello v. United States*, 464 U.S. 16, 23-24 (1983) ("Where Congress includes limiting language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended." (citing *Arizona v. California*, 373 U.S. 546, 580-581 (1963))); *Nat'l Pub. Radio, Inc. v. FCC*, 254 F.3d 226, 231 (D.C. Cir. 2001) (same).

[54] Indeed, at least one court has found that declaratory judgment was not available unless and until the statutorily mandated exchanges of information and legally operative notice of commercial marketing was provided pursuant to 351(l). *See Sandoz Inc. v. Amgen Inc.*, No. 13-2904, 2013 U.S. Dist. LEXIS 161233, at *6-7 (N.D. Cal. Nov. 12, 2013), *appeal docketed* as No. 14-1693 (Fed. Cir., Dec. 13, 2013) (finding that a declaratory judgment action brought by Sandoz disputing patents owned by Roche was both barred by the provisions of the BPCIA and lacked the "real and immediate injury or threat of future injury" required for a declaratory judgment action) (quotation marks omitted).

[55] *See, e.g.*, 42 U.S.C. § 262(l)(6).

[56] *See, e.g.*, *id.* § 262(l)(8)(B), (9)(A).

[57] As the Supreme Court noted in the Hatch-Waxman context, the statutory scheme for resolving patent disputes prior to product launch "will not work, of course, if the holder of the patent pertaining to the

It has also been suggested that subsection (l)(1)(A) can be read in a manner that would make the entire BPCIA process optional. Specifically, some have pointed to the language in subsection (l)(1)(A) which states that (l)(1)(B) to (H) apply "[u]nless otherwise agreed to by" the biosimilar applicant and the reference product sponsor.[58] This strained reading ignores that it is expressly specifying the confidentiality provisions of the BPCIA (i.e., those in subsection (l)(1)(B) to (H)). Such a reading also cannot be logically reconciled with at least seventeen (17) other mandatory requirements in subsection (l)(2) through (8)(A), which are not rendered "permissive" just because the parties can, by agreement, alter the confidentiality provisions in subsection (l)(1).

In reality, the flexibility given to the parties to craft alternative confidentiality provisions underscores that Congress intended for the rest of § 351(l) to be mandatory. By including default confidentiality provisions to govern when the parties cannot reach an agreement, Congress precluded either side from stalling and/or evading the BPCIA process by refusing to enter into a confidentiality agreement. In such situations, the default confidentiality provisions written into the statute ensure that the disclosures, negotiations, and litigation called for in subsections (l)(2) to (6) can proceed within their respective deadlines. Notably, none of that is possible if the biosimilar applicant fails to provide the initial disclosure required by subsection (l)(2)(A).

Separately, it has been suggested that, because the BPCIA specifies one "remedy" for the biosimilar applicant's non-compliance with the disclosure requirement, the disclosures specified in subsection (l)(2)(A) are somehow made optional. However, the inclusion of a remedy or a penalty in a statute "does not nullify the mandatory provision" being enforced.[59] The fact that Congress included a supposed remedy at subsection (l)(9)(C) cannot justify reading subsection (l)(2)(A) to mean anything other than what it says: biosimilars "shall" (i.e., "must") make the requisite disclosures.

Moreover, this argument based on subsection (l)(9)(C) fails because it rests on the false premise that a declaratory judgment action is capable of rectifying the harms caused by the biosimilar applicant's failure to timely comply with the (l)(2)(A) disclosures. It is not. As discussed above, the subsection (l) process is intended to identify the disputed patents for "immediate" litigation. Subsection (l)(9)(A) states that, if the process proceeds as intended, a declaratory judgment action regarding patents not listed for immediate litigation may be brought when the biosimilar applicant provides

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pioneer [product] is disabled from establishing in court that there has been an act of infringement." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

[58] 42 U.S.C. § 262(l)(1)(A).

[59] *Washingtonian Publishing Co. v. Pearson*, 306 U.S. 30, 50-51 (1939).

advance notice of commercial marketing.[60] That default rule is modified by the two provisions that immediately follow. If the biosimilar fails to comply with its obligations, then subsection (l)(9)(B) still authorizes the reference product sponsor to bring a declaratory judgment—but not the biosimilar applicant.[61] And, if the biosimilar applicant fails to comply with the foundational disclosure requirement in subsection (l)(2)(A), then subsection (l)(9)(C) again authorizes the reference product sponsor—still not the biosimilar applicant—to bring a declaratory judgment action.[62] These provisions stand as a penalty for the biosimilar applicant's noncompliance, but they cannot be presumed to remedy all harms caused by the biosimilar applicant's failure to comply with its statutory obligations under subsection (l).

Indeed, subsection (l)(9)(C) does not provide a meaningful remedy for a reference product sponsor in the scenario where the biosimilar applicant simply refuses to comply with subsection (l)(2)(A). The filing of a biosimilar application is not a public event,[63] which means a reference product sponsor may not be aware that an application referencing its product has been filed. Even if the reference product sponsor discovers that an application has been filed, absent the disclosure required by subsection (l)(2)(A), the reference product sponsor is left to guess if and when a lawsuit would be appropriate and which patents should be brought in such an infringement action. The reference product sponsor may not otherwise come to learn which, if any, of the reference product sponsor's patented processes, formulations or uses are being used by the biosimilar applicant. While some of this information might become available or more visible after FDA licensure of the biosimilar product, the entire point of subsection (l) is to enable court intervention through patent litigation, including preliminary injunction, before the approved biosimilar is commercialized. Delaying that litigation until the reference product sponsor, by chance, learns of infringing conduct is no remedy at all.

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[60] 42 U.S.C. § 262(l)(9)(A).

[61] *Id.* § 262(l)(9)(B).

[62] *Id.* § 262(l)(9)(C).

[63] Notably, under at least one prior version considered by Congress, such a filing would have been public. *See* S. 1505, 110th Cong. (2007) (proposed § 351(k)(8)(A): "When an application for a biosimilar is submitted, the Secretary shall publish a notice in the Federal Register identifying—(i) the sponsor of the application of the reference product upon which the application for the biosimilar relies; and (ii) the name of the sponsor of the application for the biosimilar, or an agent designated by such sponsor to receive communications regarding patents."). Congress replaced that provision with subsection (l)(2)(A), which further underscores the conclusion that Congress intended to force the biosimilar applicant to reveal the existence of a pending application, and provide a copy of it and information regarding the manufacturing processes for the proposed biosimilar product to the reference product sponsor.

To make the point more concrete, a reference product sponsor is entitled to assert patents relating to the manufacture of the biosimilar product, but biosimilar manufacturing details are typically maintained as trade secrets. An interpretation of the BPCIA that would make compliance with subsection (l)(2)(A) optional would reward the biosimilar applicant by improving the chances that its infringing manufacturing conduct would go undetected. The biosimilar applicant would be emboldened to hide, frustrate and delay detection of the very information meant to bring clarity to whether a patent dispute exists. The reference product sponsor may have no way of knowing whether its manufacturing patents are being infringed short of commencing a lawsuit and using discovery during litigation to determine which may be relevant. A scheme that compels inefficient and potentially unnecessary litigation and discovery is contrary to the intent of Congress. Indeed, it would be illogical to read subsection (l)(9)(C) as being the sole remedy for non-compliance with (l)(2)(A) since it forces reference product sponsors to engage in potentially unnecessary litigation and discovery simply to obtain, later in time, the information that subsection (l)(2)(A) expressly requires the biosimilar applicant to provide at the start of the process in order to narrow and limit the litigation that is actually necessary.

In addition, the availability of a declaratory judgment cannot remedy the biosimilar applicant's gamesmanship with respect to the exclusivity periods described in subsection (k)(6). Nor can it remedy the increased burden on the courts that would be caused by not having the patent litigation narrowed as intended by subsection (l).

As is abundantly clear, the statute compels early and thorough disclosure of information about the biosimilar product and its manufacturing process, exchange of the legal claims and positions, negotiation, and if licensing is not achievable, litigation. These provisions all work together to enable the reference product sponsor to promptly identify and assert its patents concurrently with FDA's review of the application under § 351(k) and to seek preliminary injunctive relief before the biosimilar applicant commences marketing of the licensed biosimilar product. Once the biosimilar product is actually marketed, the interests of the reference product sponsor are severely prejudiced. Further, the BPCIA process is intended to mitigate the risk of the disruption that would be created were a finding of patent infringement to result in the withdrawal of a marketed biosimilar product.

### D. FDA Should Establish A Policy Requiring Biosimilar Applicants To Certify Compliance With Subsection (l)(2)(A).

FDA should ensure that the biosimilar application process is fairly and faithfully implemented. To do so, FDA should implement reasonable measures to confirm that biosimilar applicants will comply with their obligation, under subsection (l)(2)(A), to

provide the reference product sponsor with a copy of the biosimilar application and manufacturing information for the biosimilar product. Amgen submits that the most efficacious way to do so would be to require biosimilar applications to include a certification from the biosimilar applicant that it will comply with subsection (l)(2)(A) by making the disclosures required therein within 20 days of being informed that the application has been accepted for review by FDA.

FDA has the requisite authority. Subsection (l)(2)(A) explicitly imposes key disclosure obligations on biosimilar applicants. FDA has the power to remind parties of existing statutory duties without going through any particular level of formality.[64] Similarly, FDA has broad authority to determine the manner in which parties present themselves or their viewpoints to the agency.[65] Thus, either as a matter of interpretative or procedural authority, FDA has the power to require that biosimilar applicants certify compliance with subsection (l)(2)(A).

In fact, Congress ensured that FDA would have its entire regulatory toolkit available to implement the BPCIA. Thus, the PHSA contains explicit authority to establish regulations governing "the approval, suspension, and revocation of biologics licenses,"[66] which obviously extends to "application[s] for licensure of a biological product" under subsection (k).[67] FDA has exercised that authority to establish regulations governing all applications "under section 351," which also obviously extends to biosimilar applications.[68] Such applications must be submitted "on forms prescribed for such purposes" and "shall not be considered as filed until all pertinent information and data have been received by" FDA.[69] The reference to "pertinent information" is broad and means that FDA may refuse to file an application based on "administrative incompleteness."[70]

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[64] *Ass'n of Am. Physicians & Surgs. v. Sebelius*, 901 F. Supp. 2d 19, 34 (D.D.C. 2012) ("'An interpretive rule simply states what the administrative agency thinks the statute means, and only 'reminds affected parties of existing duties.'" (quoting *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1307 (D.C. Cir. 1991))).

[65] *Sentara-Hampton Gen. Hosp. v. Sullivan*, 980 F.2d 749, 759 (D.C. Cir. 1992) ("interpretative rules may affect the way parties act or alter the manner in which parties present themselves or their viewpoints to the agency") (quotation marks omitted).

[66] 42 U.S.C. § 262(a)(2)(A).

[67] *Id.* § 262(k)(1).

[68] 21 C.F.R. § 601.2(a).

[69] *Id.* FDA has modified Form FDA 356h "to support the information required under section 351(k)." 77 Fed. Reg. 8880, 8881 (Feb. 15, 2012).

[70] FDA, CBER, *SOPP 8404: Refusal to File Procedures for Biologic License Applications*, Ver. 3 (Jan. 26, 2011), http://1.usa.gov/1wyheGw; *see also* FDA, CDER, *MAPP 6025.4: Good Review Practice:*

In addition to its rulemaking authority, FDA has authority to issue guidance regarding "the licensure of a biological product" under subsection (k).[71] FDA's authority to issue biosimilar guidance is explicitly linked to its authority to issue guidance under section 701(h) of the Federal Food, Drug, and Cosmetic Act (FDCA).[72] In the drug and device contexts, the Agency routinely uses its authority under section 701(h) of the FDCA to issue guidance dictating the contents of premarket applications.

To date, FDA has implemented certain provisions of the BPCIA, and now must take action to ensure that subsection (l) also is implemented in a way that accords with Congress's intent and purpose. FDA need only adopt a procedural policy that requires biosimilar applications to include a statement from the applicant that the applicant will comply with subsection (l)(2)(A) within 20 days after receiving notice that the application has been accepted for review. This requirement could be implemented in any number of ways at FDA's discretion, including, for example, by modifying Form FDA 356h to include a simple certification. Regardless of how FDA may choose to implement such a requirement, a ministerial change to ensure that § 351(l)(2)(A) of the PHSA is not ignored by biosimilar applicants is warranted.[73]

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*Refuse to File*, 3 n.5 (Oct. 11, 2013), http://1.usa.gov/1tb6cVh ("For BLAs, § 601.2(a) states that a BLA 'shall not be considered as filed until all pertinent information and data have been reviewed by FDA.' CDER interprets this provision to permit it to refuse to file a BLA under the same conditions that it can refuse to file an NDA.").

[71] 42 U.S.C. § 262(k)(8)(A). FDA has used that authority to issue guidance on a host of topics related to biosimilars. FDA, *Information for Industry (Biosimilars*) (Sept. 9, 2014), http://1.usa.gov/1wAiQzJ.

[72] 42 U.S.C. § 262(k)(8)(A) (referencing 21 U.S.C. § 371(h)).

[73] The need for FDA to take steps to implement section 351(l) has been highlighted for FDA in several settings. Biotechnology Industry Organization, *Comments on the Food and Drug Administration Pathway for Biosimilar and Interchangeable Biological Products*, FDA-2010-N-0477, at 33 (Dec. 23, 2010), http://bit.ly/ZZUWzj; Biotechnology Industry Organization, *Comments on Options for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications*, FDA-2011-N-0326, at 2 (June 9, 2011), http://bit.ly/1vcLAZM; Biotechnology Industry Organization, *Comments on Biosimilars: Questions and Answers Regarding Implementation of BPCIA of 2009*, FDA-2011-D-0611, at 13-14 (Apr. 16, 2012), http://bit.ly/1vcMjds; Letter from the American Council on Education, the Association of American Medical Colleges, the Association of American Universities, the Association of Public and Land-grant Universities, the Association of University Technology Managers, and the Council on Governmental Relations to Commissioner of Food and Drugs Margaret A. Hamburg (Nov. 5, 2012), http://bit.ly/1uODsjx.

## IV. CONCLUSION

For the foregoing reasons, Amgen requests that FDA take action to implement subsection (l)(2)(A) of section 351 of the PHSA in a manner that is consistent with the statute's text, structure, and history. The Agency should establish a policy of requiring biosimilar applications to include a certification from the biosimilar applicant that it will comply with subsection (l)(2)(A) by making the statutorily-mandated disclosures within the statutorily-specified timeframe. This certification should be required for all biosimilar applications that have not been accepted for review by the FDA.

## V. OTHER REQUIRED INFORMATION

### A. Environmental Impact

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

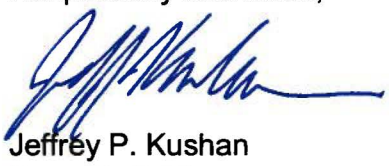
### B. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), an economic impact statement will be submitted upon request of the Commissioner.

### C. Certification

The undersigned certify that, to our 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) the undersigned have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to them. The undersigned further certify that the information upon which the action requested herein is based first became known to Amgen Inc. on or about July 25, 2014 (non-compliance of Sandoz, Inc. with the explicit requirements of 42 U.S.C. § 262(l)(2)(A)). The undersigned state that they expect to receive payment to file this petition only from Amgen Inc. The undersigned verify under penalty of perjury that the foregoing certification is true and correct as of the date of the submission of this petition.

Respectfully submitted,



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