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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-02031
Patent No. 6,407,213

PATENT OWNER'S PRELIMINARY RESPONSE

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Genentech, Inc. ("Patent Owner" or "Genentech") submits this Preliminary Response to the Petition that Boehringer Ingelheim Pharmaceuticals, Inc. ("Petitioner" or "Boehringer") filed challenging certain claims of U.S. Patent No. 6,407,213 ("the '213 patent") (Paper 2).

I. INTRODUCTION

On December 1, 2017, the Board instituted four IPRs in which Celltrion, Inc. (IPR2017-01373 and IPR2017-01374) and Pfizer, Inc. (IPR2017-01488 and IPR2017-01489) have challenged numerous claims of the '213 patent (based on a total of 32 separate grounds). Patent Owner's responses in those proceedings are due on February 15, 2018.

More than three months after Celltrion and Pfizer filed their now-instituted petitions, Boehringer filed the present Petition (and a second petition in IPR2017-02032). The Board should deny institution of the Boehringer petitions under 35 U.S.C. § 325(d) for at least two reasons.

First, Boehringer copied Grounds 1-3 and 5 of this Petition from IPR2017-01374 (Celltrion) and IPR2017-01488 (Pfizer), and copied Grounds 1-5 of IPR2017-02032 from IPR2017-01373 (Celltrion) and IPR2017-01489 (Pfizer)—without seeking joinder with those earlier-filed proceedings. Boehringer thus asks the Board to institute its IPRs on the ***same*** grounds ***already instituted*** in the Celltrion and Pfizer proceedings—but on a schedule trailing those proceedings by

several months. This redundancy would waste the Board's and Patent Owner's resources, and also would unfairly allow Boehringer to preview the parties' arguments before having to address them itself. Given this resulting waste and prejudice, institution of Grounds 1-3 and 5 of this Petition (and Grounds 1-5 of IPR2017-02032) should be denied.

Second, Boehringer's remaining Grounds 4 and 6 in this proceeding are based on a 1986 article by Jones et al. (Ex. 1033) ("Jones") and a 1988 article by Riechmann et al. (Ex. 1069) ("Riechmann"). But those grounds are not "new" at all. To the contrary, both references are discussed in the '213 specification, and during prosecution of the '213 patent, Patent Owner brought both references to the Patent and Trademark Office's ("PTO") attention on several occasions and specifically overcame an obviousness rejection based on Riechmann. As such, because the PTO has already found the challenged '213 claims patentable over both cited references, the Board should reject Boehringer's invitation to second-guess this prior patentability determination by denying institution of Grounds 4 and 6.

Patent Owner therefore respectfully requests that the Board exercise its discretion and deny institution of all grounds pursuant to Section 325(d).

II. BACKGROUND

A. The Invention of the '213 Patent

In the early 1990s, the field of therapeutic antibodies was still in its infancy. Although scientists had known since the 1970s how to obtain antibodies from animals (*e.g.*, mice) that would bind to specific targets, those antibodies generally could not be used in humans because, over time, the body's own immune system would attack and inactivate them (known as an "immunogenic" response). (Ex. 1001 at 1:52-58.)

Beginning in the late 1980s, a few scientists created "humanized" antibodies that incorporated the binding site from a non-human antibody into a human antibody framework—which they hoped might address the immunogenicity problem by reducing the amount of non-human amino acid sequences in the antibody. But those early humanized antibodies suffered from reduced binding affinity and/or still produced an immunogenic response. (*Id.* at 2:21-35, 3:50-55.)

The '213 inventors, Drs. Paul Carter and Leonard Presta, at Genentech developed a new "consensus human sequence" approach to humanizing antibodies that solved the prior art binding and immunogenicity problems of other humanized antibodies. (*Id.* at 11:32-38.) That "consensus" approach involved a single human amino acid sequence that could be used for ***any*** humanized antibody of a particular immunoglobulin subclass or subunit structure (*e.g.*, light chain κ1). (*Id.* at 16:20-

22 ("All of the humanized antibody models of this invention are based on a single three-dimensional computer graphics structure hereafter referred to as the consensus structure.").) Drs. Carter and Presta also identified specific amino acids important to maintaining binding affinity. (*Id.* at 20:32-35.)

The '213 challenged claims are directed to humanized variable domains or humanized antibodies containing certain specified amino acid substitutions identified using the inventors' novel consensus sequence approach.

B. Prosecution History

The '213 patent is a continuation-in-part of an application filed on June 14, 1991. (Ex. 1001, coversheet.) During prosecution, Patent Owner presented, and the PTO considered, a number of references describing humanized antibodies, including each of the references relied upon by Boehringer in its petitions.

For example, the '213 specification discussed both Jones and Riechmann at length, including by explaining that the references describe "substitut[ing] rodent CDRs or CDR sequences for the corresponding segments of a human antibody." (Ex. 1001 at 2:20-28.) The specification further contrasts Jones's approach of "substituting CDRs from rodent antibodies for the human CDRs in human frameworks [which was] sufficient to transfer high antigen binding affinity," with Riechmann's disclosure that it was "necessary to additionally replace one . . . framework region (FR) residue[]." (*Id.* at 2:53-61.)

Moreover, during prosecution, Patent Owner raised Jones in overcoming a written description rejection (Ex. 1002 at 370), and overcame an obviousness rejection based on Riechmann (*id.* at 253-54 (Examiner asserting that Riechmann teaches "altering the sequence of the antibody to restore packing or to increase binding affinity"); *id.* at 372-74 (Patent Owner addressing rejection based in part on Riechmann); *id.* at 508-11 (Examiner no longer raising Riechmann rejection).) The Examiner ultimately allowed the challenged claims to issue over Jones and Reichmann.

During prosecution of the '213 patent, the Examiner also raised U.S. Patent No. 5,530,101 ("the '101 patent") (which Boehringer relies upon in IPR2017-02032) as a Section 102(e) reference and initially rejected several '213 claims based on it. (*E.g.*, Ex. 1002 at 739-40.) In response, Patent Owner explained how the Examiner had misconstrued the teachings of the '101 patent and submitted a joint affidavit from Drs. Carter and Presta to antedate the '101 patent. (*Id.* at 793, 802-07.) The Examiner allowed the claims to issue over the '101 patent after accepting that antedation evidence. (*Id.* at 813.)

C. Other IPR Petitions Involving the '213 Patent

In August 2016, Mylan Pharmaceuticals, Inc. challenged the '213 patent in two separate IPRs (IPR2016-01693 and IPR2016-01694), which the Board terminated after settlement in March 2017. (IPR2016-01693, Paper 24 (Mar. 3,

2017); IPR2016-01694, Paper 23 (Mar. 3, 2017).) In May 2017, Celltrion and Pfizer each filed "copy-cat" petitions of the two original Mylan petitions. (IPR2017-01373 (Celltrion); IPR2017-01374 (Celltrion); IPR2017-01488 (Pfizer); IPR2017-01489 (Pfizer).)

As shown in the table below, the copy-cat Celltrion IPR2017-01373 and Pfizer IPR2017-01489 proceedings assert identical grounds based on six references, including a 1989 article ("Queen 1989"), a PCT application published on July 26, 1990 ("Queen 1990"), the Protein Data Bank Database ("PDB Database"), a 1990 article ("Tramontano"), a 1987 reference book ("Kabat 1987"), and a March 1989 publication ("Hudziak"):

Ground	**Claims and Basis**	
	IPR2017-01373 (Celltrion)	**IPR2017-01489 (Pfizer)**
1	Claims 1, 2, 12, 25, 29, 63, 66, 67, 69, 71-81 **Queen 1989** **PDB Database**	Claims 1, 2, 12, 25, 29, 63, 64, 66, 67, 71-81 **Queen 1989** **PDB Database**
2	Claims 1, 2, 4, 12, 25, 29, 62-67, 69, 71-81 **Queen 1990** **PDB Database**	Claims 1, 2, 4, 12, 25, 29, 62-64, 66, 67, 69, 71-81 **Queen 1990** **PDB Database**
3	Claims 65, 75-77, 79 **Queen 1989** **PDB Database** **Tramontano**	Claims 65, 75-77, 79 **Queen 1989** **PDB Database** **Tramontano**
4	Claims 65, 75-77, 79 **Queen 1990**	Claims 65, 75-77, 79 **Queen 1990**

	PDB Database **Tramontano**	**PDB Database** **Tramontano**
5	Claims 4, 62, 64, 69 **Queen 1989** **PDB Database** **Kabat 1987**	Claims 4, 62, 64, 69 **Queen 1989** **PDB Database** **Kabat 1987**
6	Claims 30, 31, 42, 60 **Queen 1989** **PDB Database** **Hudziak**	Claims 30, 31, 42, 60 **Queen 1989** **PDB Database** **Hudziak**
7	Claims 30, 31, 33, 42, 60 **Queen 1990** **PDB Database** **Hudziak**	Claims 30, 31, 33, 42, 60 **Queen 1990** **PDB Database** **Hudziak**

In the other two copy-cat proceedings, Celltrion IPR2017-01374 and Pfizer IPR2017-01488 assert similar grounds based on seven references, including a European patent application published on December 19, 1990 ("Kurrle"), Queen 1990, a 1983 publication ("Furey"), a 1987 publication ("Chothia & Lesk"), a 1985 publication ("Chothia 1985"), and Hudziak:

Ground	**Claims and Basis**	
	IPR2017-01374 (Celltrion)	**IPR2017-01488 (Pfizer)**
1	Claims 1, 2, 25, 29, 63, 66, 71, 75, 76, 78, 80, 81 **Kurrle**	Claims 1, 2, 25, 29, 63, 66, 67, 71, 72, 75, 76, 80, 81 **Kurrle**
2	Claims 1, 2, 4, 29, 62-64, 80, 81 **Queen 1990**	Claims 1, 2, 4, 29, 62-64, 80, 81 **Queen 1990**
3	Claims 1, 2, 4, 25, 29, 62-64, 66,	Claims 1, 2, 4, 25, 29, 62-64, 66,

	67, 69, 71, 72, 75, 76, 78, 80, 81 **Queen 1990** **Kurrle**	67, 69, 71, 72, 75, 76, 78, 80, 81 **Queen 1990** **Kurrle**
4	Claim 12 **Queen 1990** **Kurrle** **Furey**	Claim 12 **Queen 1990** **Kurrle** **Furey**
5	Claims 65, 73, 74, 77, 79 **Queen 1990** **Kurrle** **Chothia & Lesk** **Chothia 1985**	Claims 73, 77 **Queen 1990** **Kurrle** **Chothia & Lesk**
6	Claims 30, 31, 33 **Queen 1990** **Hudziak**	Claim 74 **Queen 1990** **Kurrle** **Chothia 1985**
7	Claim 42 **Queen 1990** **Kurrle** **Hudziak** **Furey**	Claims 65, 79 **Queen 1990** **Kurrle** **Chothia & Lesk** **Chothia 1985**
8	Claim 60 **Queen 1990** **Hudziak** **Chothia & Lesk**	Claims 30, 31, 33, 42 **Queen 1990** **Hudziak**
9		Claim 42 **Queen 1990** **Hudziak** **Furey**
10		Claim 60 **Queen 1990** **Hudziak**

		Chothia & Lesk

On December 1, 2017, the Board instituted IPRs on all grounds recited in the four Celltrion and Pfizer petitions. (IPR2017-01373 (Paper 16); IPR2017-01374 (Paper 15); IPR2017-01488 (Paper 27); IPR2017-01489 (Paper 27).) Patent Owner's response in those proceedings is due on or before February 15, 2018.

In September 2017, Samsung Bioepis also filed copy-cat petitions of the Mylan/Celltrion/Pfizer petitions (IPR2017-02139 and IPR2017-02140). Unlike Boehringer, however, Samsung filed motions seeking to join its petitions with the earlier-filed Pfizer proceedings. (IPR2017-02139, Paper 3; IPR2017-02140, Paper 3.) Samsung's motions remain pending.

D. The Redundant Boehringer Petitions

Boehringer filed its two petitions on August 31, 2017—*i.e.*, over seven months after Genentech filed its December 2016 Patent Owner's Preliminary Response in the original Mylan proceedings, over three months after Celltrion and Pfizer filed their petitions, and without any explanation as to why it could not have filed its petitions earlier. As shown in the chart below, Boehringer asserts the following grounds of unpatentability in this proceeding:

Ground	Claims and Basis
1	Claims 1, 2, 25, 29, 63, 66, 71, 75, 76, 78, 80, 81 **Kurrle**

2	Claims 1, 2, 4, 29, 62-64, 80, 81 **Queen 1990**
3	Claims 1, 2, 4, 25, 29, 62-64, 66, 67, 69, 71, 72, 75, 76, 78, 80, 81 **Kurrle** **Queen 1990**
4	Claims 1, 2, 4, 25, 29, 62, 64, 66, 69, 71, 73, 75-78, 80, 81 **Jones**
5	Claims 73 and 77 **Queen 1990** **Kurrrle** **Chothia & Lesk**
6	Claim 63 **Jones** **Riechmann**

(Paper 2 at 4.)

III. ARGUMENT

Under 35 U.S.C. § 325(d), the Board may exercise its discretion to deny institution where "the same or substantially the same prior art or arguments previously were presented to the Office." *Id.*; *see Harmonic Inc. v. Avid Tech., Inc*., 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding."); *Cultec, Inc. v. Stormtech LLC*, IPR2017-00777 (Aug. 22, 2017) (Paper 7) (designated as informative) (exercising discretion to deny institution where same prior art and arguments were presented to the PTO).

Where a petitioner raises substantially the same prior art or arguments that were previously raised to the examiner or the Board, the patent owner's interests in avoiding harassment and the Board's interests in conserving resources often outweigh the petitioner's desire to be heard. *See Hospira, Inc. v. Genentech, Inc*., IPR2017-00739, Paper 16 at 16-18 (July 27, 2017) (designated as informative) (explaining considerations under Section 325(d)); *Unified Patents, Inc. v. Berman*, IPR2016-01571, Paper 10 (Dec. 14, 2016) (designated as informative) (same); *Neil Ziegmann N.P.Z., Inc. v. Stephens*, IPR2015-01860, Paper 13 at 6-14 (Sept. 6, 2017) (expanded PTAB panel) (explaining the rationale and purpose of § 325(d)).

As detailed below, four of Boehringer's six asserted grounds (1-3 and 5) duplicate grounds that the Board has already instituted in the Celltrion and Pfizer proceedings, and the remaining two grounds (4 and 6) assert prior art that the PTO already considered when issuing the claims. Because the Board's and Patent Owner's interests in avoiding duplicative challenges far outweigh any interest Boehringer has in retreading these grounds, and because Patent Owner would be prejudiced if Boehringer is permitted to proceed separately on the same grounds at

issue in other proceedings, institution of all grounds should be denied pursuant to Section 325(d).[1]

A. The Board Should Deny Institution of Grounds 1-3 and 5 Because the Board is Already Considering Those Same Grounds in the Ongoing Celltrion and Pfizer IPRs.

As shown in the chart below, four of Boehringer's grounds (1-3 and 5) are essentially identical to those already instituted in the Celltrion and Pfizer IPRs (the few minor differences are underlined):

Ground	IPR2017-02031 (Boehringer)	IPR2017-01374 (Celltrion)	IPR2017-01488 (Pfizer)
1	Claims 1, 2, 25, 29, 63, 66, 71, 75, 76, 78, 80, 81 **Kurrle**	Claims 1, 2, 25, 29, 63, 66, 71, 75, 76, 78, 80, 81 **Kurrle**	Claims 1, 2, 25, 29, 63, 66, 67, 71, 72, 75, 76, 80, 81 **Kurrle**
2	Claims 1, 2, 4, 29, 62-64, 80, 81 **Queen 1990**	Claims 1, 2, 4, 29, 62-64, 80, 81 **Queen 1990**	Claims 1, 2, 4, 29, 62-64, 80, 81 **Queen 1990**
3	Claims 1, 2, 4, 25, 29, 62-64, 66, 67, 69, 71, 72, 75, 76, 78, 80, 81 **Queen 1990** **Kurrle**	Claims 1, 2, 4, 25, 29, 62-64, 66, 67, 69, 71, 72, 75, 76, 78, 80, 81 **Queen 1990** **Kurrle**	Claims 1, 2, 4, 25, 29, 62-64, 66, 67, 69, 71, 72, 75, 76, 78, 80, 81 **Queen 1990** **Kurrle**
5	Claims 73, 77	Claims 65, 73, 74, 77,	Claims 73, 77

[1] For this preliminary response, Patent Owner has only presented argument under Section 325(d). Should the Board institute any aspect of this Petition, Patent Owner will present arguments on the merits at that time.

	Queen 1990 **Kurrle** **Chothia & Lesk**	79 **Queen 1990** **Kurrle** **Chothia & Lesk** **Chothia 1985**	**Queen 1990** **Kurrle** **Chothia & Lesk**

Specifically, Boehringer's Grounds 1-3 and 5 raise the same prior art (Kurrle (Ex. 1071), Queen 1990 (Ex. 1050), and Chothia & Lesk (Ex. 1062)), and challenge the same claims as Celltrion IPR2017-01374 and Pfizer IPR2017-01488 (claims 1, 2, 4, 25, 29, 62-64, 66, 67, 69, 71-73, 75-78, 80, 81). The only difference is that, for certain grounds, Celltrion and Pfizer have asserted invalidity of ***additional*** claims that Boehringer has not challenged.

Thus, because Boehringer's Grounds 1-3 and 5 are wholly redundant of the already-instituted grounds in the Celltrion and Pfizer IPRs, instituting an IPR on those same grounds in this proceeding would unnecessarily waste both the Board's and Patent Owner's resources. *See R.J. Reynolds Vapor Co. v. Fontem Holdings 1 B.V.*, IPR2017-01118 and IPR2017-01119, Paper 8 at 4 (Oct. 4, 2017) (denying institution where "[t]he asserted art is identical to that presented in the earlier *inter partes* reviews"); *Hospira*, IPR2017-00739, Paper 16 at 18 (recognizing interests "in conserving the resources of the Office and granting patent owners repose on issues and prior art that have been considered previously" (citation omitted)).

Denying institution also is necessary to protect Patent Owner from the significant prejudice that would result if Boehringer's later-filed petition is instituted. Over the last eighteen months, Boehringer could have sought to join the earlier-filed Mylan, Celltrion, and/or Pfizer petitions, including after the Board instituted the Celltrion and Pfizer decisions on December 1, 2017. But Boehringer declined to do so (offering no explanation for its delay), and the time for joinder has now passed. *See* 37 C.F.R. § 42.122 (providing that "[a]ny request for joinder must be filed . . . no later than one month after the institution date of any inter partes review for which joinder is requested"); *see also Google Inc. v. Personal Web Techs., LLC*, IPR2014-00980, Paper 10 at 4-5 (Oct. 30, 2014) (denying untimely motion for joinder).

By failing to seek joinder, Boehringer essentially asks for an unfair tactical advantage—one that would allow it to preview all of Patent Owner's arguments and evidence in the Celltrion and Pfizer IPRs (Patent Owner's Responses are due on February 15, 2018) well before they are presented in this proceeding. The Board should not allow Boehringer to engage in that sort of gamesmanship, particularly when coupled with the inherent inefficiency that would result by proceeding on the same grounds already instituted in the Celltrion and Pfizer IPRs. Patent Owner therefore requests that the Board deny institution of Grounds 1-3 and 5 for these reasons as well.

B. The Board Should Deny Institution of Grounds 4 and 6 Because the PTO Already Considered the Cited References During the '213 Original Prosecution.

Boehringer bases Ground 4 on Jones, and Ground 6 on Jones in combination with Riechmann. Boehringer fails to acknowledge in its Petition that Patent Owner already presented these references during prosecution and after fully considering them, the PTO allowed the claims. In particular, Patent Owner discussed both references at length in the '213 patent specification. (Ex. 1001 at 2:20-26 (explaining that Jones and Riechmann describe "substitut[ing] rodent CDRs or CDR sequences for the corresponding segments of a human antibody"); *id.* at 2:53-61 (explaining in Jones, "substituting CDRs from rodent antibodies for the human CDRs in human frameworks [was] sufficient to transfer high antigen binding affinity," and in Riechmann it was "necessary to additionally replace one . . . framework region (FR) residue[]").)

Patent Owner also addressed Jones and Riechmann in responding to PTO office actions during prosecution. For example, in overcoming a written description rejection, Patent Owner pointed to Jones as describing an antibody candidate for humanization using the invention of the '213 patent. (Ex. 1003 at 370.) And Patent Owner overcame obviousness rejections that the Examiner raised based on Riechmann. (Ex. 1002 at 253-54, 386-87, 416-17 (Examiner asserting that Riechmann teaches "altering the sequence of the antibody to restore

packing or to increase binding affinity"); *id.* at 372-74, 431-35 (Patent Owner addressing rejection based in part on Riechmann); *id.* at 508-11 (Examiner no longer raising Riechmann rejection).) *See also Application of Flint*, 330 F.2d 363, 365 n.1 (C.C.P.A. 1964) ("[W]ithdrawal of a reference upon which a rejection is based unequivocally withdraws that rejection.").

Because both Jones and Riechmann are "the same prior art . . . previously . . . presented to the Office," the Board should exercise its discretion under Section 325(d) and deny institution of Grounds 4 and 6. *See also Neil Ziegmann, N.P.Z.*, IPR2015-01860, Paper 13 at 19 ("[T]he use of the word 'or' in 'prior art or arguments' indicates that the presence of previously presented prior art or arguments is sufficient to invoke Section 325(d).").

C. *Inter Partes* Review Proceedings Violate the Constitution.

The Board should terminate this proceeding because it violates Patent Owner's constitutional rights. Because patents are private property rights and disputes concerning their validity were traditionally decided by courts, patent validity must be litigated in an Article III court, not before an executive branch agency. *McCormick Harvesting Mach. Co. v. C. Aultman & Co.*, 169 U.S. 606, 609 (1898). Adversarial challenges to an issued patent—like *inter partes* reviews—are also "Suits at common law" for which the Seventh Amendment guarantees a jury trial. U.S. Const. amend. VII; *Markman v. Westview*

Instruments, Inc., 517 U.S. 370, 377 (1996). Moreover, even if *inter partes* review is constitutional in other circumstances, it is unconstitutional for patents—like the '213 patent—that issued before passage of the America Invents Act.

The Supreme Court is currently considering the constitutionality of *inter partes* reviews in *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, No. 16-712. Patent Owner presents this constitutional challenge now to preserve the issue pending the Supreme Court's decision.

IV. CONCLUSION

Boehringer's Petition raises grounds that the Board is already addressing in other proceedings, and that rest on prior art that the PTO already considered during prosecution. Allowing Boehringer to raise those redundant arguments in a new IPR proceeding would waste the Board's and Patent Owner's resources, and present Boehringer with an unfair tactical advantage. Genentech therefore respectfully requests that the Board exercise its discretion to deny institution of all grounds pursuant to Section 325(d).

Respectfully submitted,

Date: January 5, 2018

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Patent Owner's Preliminary Response, contains 3,372 words as measured by the word processing software used to prepare the document, in compliance with 37 C.F.R. § 42.24(d).

Respectfully submitted,

Dated: January 5, 2018

/David L. Cavanaugh/
David L. Cavanaugh
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CERTIFICATE OF SERVICE

I hereby certify that, on January 5, 2018, I caused a true and correct copy of the following materials:

- Patent Owner's Preliminary Response
- Certificate of Compliance

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