

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GRAY SQUARE PHARMACEUTICALS, LLC,
Petitioner,

v.

POZEN, INC.,
Patent Owner.

Case IPR2016-00191
Patent 7,332,183 B2

Before DONNA M. PRAISS, JO-ANNE M. KOKOSKI, and
JEFFREY W. ABRAHAM, *Administrative Patent Judges*.

ABRAHAM, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Gray Square Pharmaceuticals, LLC¹ (“Petitioner”), filed a Petition seeking *inter partes* review of claims 1 and 2 of U.S. Patent No. 7,332,183 B2 (Ex. 1001, “the ’183 patent”). Paper 1 (“Pet.”). Pozen, Inc. (“Patent Owner”) filed a Patent Owner Preliminary Response to the Petition. Paper 9 (“Prelim. Resp.”). After considering the Petition and Preliminary Response, we determine that Petitioner has not established a reasonable likelihood of prevailing with respect to any of the challenged claims of the ’183 patent. See 35 U.S.C. § 314(a). Accordingly, we deny the Petition, and do not institute *inter partes* review.

II. BACKGROUND

A. *Related Proceedings*

Patent Owner states that there are currently no judicial or administrative matters that would affect, or be affected by a decision in this case. Paper 6, 3. Petitioner identifies several previously-filed district court and Federal Circuit matters involving the ’183 patent. Pet. 3.

B. *The ’183 Patent*

The ’183 patent, titled “Multilayer Dosage Forms Containing NSAIDs and Triptans,” is directed to the treatment of migraine and other pain relief. Ex. 1001, 1:1–15. The ’183 patent discloses pharmaceutical tablets containing naproxen and a triptan, wherein substantially all of the triptan is

¹ As of the November 12, 2015 filing date of the Petition, Petitioner operated under the name Graybar Pharmaceuticals, LLC. Pet. 3. Petitioner changed its name to Gray Square Pharmaceuticals, LLC on January 6, 2016. Paper 7.

found in one layer, and substantially all of the naproxen is found in a second, separate layer. *Id.* at 1:66–2:6. The layers are in a “side-by-side arrangement such that the dissolution of the naproxen occurs independently of the dissolution of triptan.” *Id.* at 2:7–9. According to the ’183 patent, a bilayer tablet dosage form having separate layers of naproxen and triptan has “surprisingly better properties” than other tablet arrangements. *Id.* at 2:9–11, 1:60–65 (noting advantages in terms of release properties, stability, and pharmacokinetic profile that “could not have been predicted a priori”).

C. Challenged Claims

Petitioner challenges claims 1 and 2 of the ’183 Patent, which are reproduced below:

1. A multilayer pharmaceutical tablet comprising naproxen and a triptan and, wherein:
 - a) substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer; and
 - b) said first layer and said second layer are in a side by side arrangement such that the dissolution of said naproxen occurs independently of said triptan.
2. The tablet of claim 1, wherein said naproxen is in the form of naproxen sodium at between 200 and 600 mg.

D. References

Petitioner relies on the following references:

Plachetka, U.S. Patent No. 6,060,499, issued May 9, 2000 (“Plachetka,” Ex. 1007).

Desai, U.S. Patent No. 5,756,125, issued May 26, 1998 (“Desai,” Ex. 1009).

Ouali et al., U.S. Patent No. 6,183,779 B1, issued Feb. 6, 2001 (“Ouali,” Ex. 1011).

Elger et al., U.S. Patent No. 4,844,907, issued July 4, 1989 (“Elger,” Ex. 1012).

Devane et al., U.S. Patent No. 6,730,325 B2, issued May 4, 2004 (“Devane,” Ex. 1013).

E. The Asserted Grounds

Petitioner asserts the following grounds of unpatentability:

References	Statutory Basis	Claims Challenged
Plachetka and Ouali	§103	1 and 2
Plachetka and Elger	§103	1 and 2
Devane and Elger	§103	1 and 2
Plachetka and Desai	§103	1 and 2

Petitioner also relies on the declaration of Dr. Arthur H. Kibbe, Ph.D. Ex. 1002 (“Kibbe Declaration”).

III. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct.

890 (mem.) (2016) (No. 15-446). Claim terms generally should be given their ordinary and customary meaning, except “1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Thorner v. Sony Computer Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). “To act as its own lexicographer, a patentee must ‘clearly set forth a definition of the disputed claim term’ other than its plain and ordinary meaning.” *Id.* (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)).

An extraneous limitation should not be read into the claims from the specification. *E.g.*, *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988). An extraneous limitation is one the presence of which in a claim is unnecessary for the purpose of making sense of the claim. *See, e.g.*, *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994); *Renishaw PLC, v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998).

Petitioner proposes constructions under a broadest reasonable interpretation for “side-by-side arrangement” and “naproxen.” Pet. 26–28. We determine that no express claim construction of these terms is required for purposes of this decision.

Patent Owner proposes a construction under the broadest reasonable interpretation for “dissolution of said naproxen occurs independently of said triptan.” Prelim. Resp. 21–24. Patent Owner contends that this phrase means “the naproxen and triptan are in an immediate release form in the first and second layer such that their dissolution occurs at approximately the same rate as if the drugs were given separately.” *Id.* at 21–22. In support of

this construction, Patent Owner points to the statement in the Specification that “[t]he layers should be arranged such that the individual therapeutic agents ***dissolve independently*** of one another, ***i.e., dissolution should occur at approximately the same rate as would occur if the drugs were given separately.***” *Id.* at 22 (quoting Ex. 1001, 2:46–49) (emphasis in Prelim. Resp.). Patent Owner also argues that the Specification “makes clear that the active ingredients need to release immediately for migraine relief” (*id.* at 22–23 (quoting Ex. 1001, 9:19–25, 10:11–16)), and that the Applicants made it clear during prosecution that the claims cover a single dosage form having two immediate release layers (*id.* at 23–24 (citing Ex. 1004, 7)).

Petitioner does not propose an express construction for this phrase, but, as discussed in more detail below, considers ingredients in a bilayer tablet that dissolve “at the same time” to dissolve “independently.” *See, e.g.*, Pet. 20, 21.

Based on our review of the Specification, we are persuaded that Patent Owner acted as its own lexicographer by defining “dissolve independently” in the Specification. Specifically, as noted by Patent Owner, the ’183 patent explains that

The layers should be arranged such that the individual therapeutic agents dissolve independently of one another, i.e., dissolution should occur at approximately the same rate as would occur if the drugs were given separately. In this context, “approximately the same rate” indicates that the time for complete dissolution of agent when drugs are given in the combination tablet should require the same amount of time $\pm$ 10% as when the same amount of agent is given alone.

Ex. 1001, 2:46–54.

Patent Owner’s proposed interpretation, however, goes beyond the Specification’s definition, and requires that the naproxen and triptan are in

an immediate release form. Although the Specification does refer to a bilayer tablet as providing “more rapid release of each component” than other tablet configurations, and states that “[r]apid or immediate release . . . is advantageous” (*id.* at 10:5–12), the Specification does not include the term “immediate release” in its definition of “dissolve independently.” Further, the Specification appears to differentiate between independent and immediate release by stating that a bilayer tablet can provide “*independent and immediate release* of each component.” *Id.* at 3:61–64 (emphasis added). Because the claim expressly requires only that the two components dissolve independently, and defines that term without reference to immediate dissolution, we see no reason to import a limitation from the Specification into the claim and require that the naproxen and triptan be in immediate release form. *See In re Paulsen*, 30 F.3d at 1480; *Renishaw PLC*, 158 F.3d at 1249.

Nor are we persuaded by Patent Owner’s arguments that statements made during prosecution of the application that issued as the ’183 patent support a construction requiring naproxen and triptan to be in an immediate release form. In context, the reference to immediate release made during prosecution appears in a sentence directed towards distinguishing the claimed invention over a prior art reference based on the fact that the prior art reference combined different formulations *of a single drug* in a single dosage form, whereas the rejected claims combined *two separate drugs* in a single dosage form. Ex. 1004, 7. Thus, although we do not disagree with Patent Owner’s assertion “that the claims cover a single dosage form configuration having two immediate release layers” (Prelim. Resp. 23), Patent Owner has not directed us to evidence sufficient to demonstrate the

claims are limited to only those tablet configurations having two immediate release layers. *See Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013) (discussing clear and unmistakable disavowals during patent prosecution).

Based upon this record, we find that the broadest reasonable interpretation of the phrase “dissolution of said naproxen occurs independently of said triptan” is a dissolution profile such that complete dissolution of naproxen and triptan when the drugs are given in the combination tablet requires the same amount of time $\pm$ 10% as when the same amount of naproxen or triptan is given alone.

B. Obviousness over Plachetka and Ouali

Petitioner argues that the subject matter of claims 1 and 2 would have been obvious in view of Plachetka and Ouali. Pet. 28–40.

Plachetka discloses a method of treating migraine headaches comprising co-timely administration of an NSAID, such as naproxen or naproxen sodium, and a 5-HT agonist, such as sumatriptan. Ex. 1007, 1:13–41. Plachetka discloses many dosage forms that can be used to co-administer naproxen and sumatriptan (*id.* at 12:56–13:5), including a single tablet formulation (*e.g.*, *id.* at 10:65–67, 11:22–25, 12:4–13).

Ouali discloses a composition for the oral administration of an NSAID, such as naproxen, and a prostaglandin. Ex. 1011, Abstract, 4:44. Ouali teaches that NSAIDs exhibit some undesirable side effects, such as gastrointestinal bleeding, ulceration, and perforation, and refers to several prior art references disclosing attempts to reduce these undesirable gastrointestinal effects through co-administration of an NSAID and a

prostaglandin. *Id.* at 1:34–39, 55–64. According to Ouali, however, “prostaglandins are unstable compounds and degrade readily in the presence of NSAIDs, thus requiring a stabilizing agent . . . which can, in turn, lessen the activity of an NSAID.” *Id.* at 1:65–2:3. Ouali thus seeks to provide a composition in which the prostaglandin is stabilized and the efficacy of the NSAID is maintained. *Id.* at 2:14–23. In one preferred embodiment, the stabilized prostaglandin and NSAID are combined into a bilayer tablet. *Id.* at Abstract, 4:22–35; Fig. 1.

Petitioner argues that Ouali teaches or otherwise renders obvious the “first layer and said second layer are in a side by side arrangement such that the dissolution of said naproxen occurs independently of said triptan” limitation in claim 1. Pet. 34–36, 38. According to Petitioner, Ouali combines naproxen sodium with prostaglandin and its stabilizing agent into a bilayer tablet “*precisely because* they dissolve independently from each other.” *Id.* at 35 (citing Ex. 1002 ¶ 61). Petitioner points to Ouali’s teaching that it was known that prostaglandins degrade in the presence of NSAIDs and that stabilizing agents lessen the efficacy of the NSAID, and contends that Ouali uses a bilayer tablet configuration “to avoid the deleterious affects [sic] on each chemical’s release by virtue of their interaction when they dissolve *at the same time*—i.e., ‘independently’.” *Id.* at 35–36 (citing Ex. 1011, 1:65–2:3; Ex. 1002 ¶¶ 61–62). Petitioner thus argues that, in view of Ouali, a person of ordinary skill in the art would have known that bilayer tablets allowed for the independent dissolution of the ingredients in each layer. *Id.* at 36 (also stating, “it was not an unexpected or surprising result that bilayer tablets yield independent dissolution of the ingredients in each respective layer”).

In so arguing, Petitioner equates dissolving “at the same time” to dissolving “independently.” *See, e.g.*, Pet. 34–38. As noted above, however, the broadest reasonable construction of “dissolution of said naproxen occurs independently of said triptan” is a dissolution profile such that complete dissolution of naproxen and triptan when the drugs are given in the combination tablet requires the same amount of time $\pm 10\%$ as when the same amount of naproxen or triptan is given alone. Based on our review of the record, including the declaration submitted by Petitioner, we are persuaded that Petitioner fails to identify sufficient evidence demonstrating that Ouali discloses or suggests bilayer tablets having a dissolution profile such that complete dissolution of the ingredients when given in the combination tablet requires approximately the same amount of time as when the ingredients are given alone.

For example, Petitioner does not direct us to any test results comparing dissolution rates of Ouali’s ingredients combined in a multilayer tablet with dissolution rates of those same ingredients on their own. Additionally, Petitioner fails to explain adequately how Ouali’s disclosure that “prostaglandins degrade readily in the presence of NSAIDs” constitutes a teaching that prostaglandins and NSAIDs, when administered in a bilayer tablet, would require the same amount of time to dissolve as if the two ingredients were administered alone. Furthermore, Petitioner does not direct us to any evidence in Plachetka that cures this deficiency.

We note that the declaration provided by Dr. Kibbe simply mirrors the statements made in the Petition, without providing additional analysis or references to prior art disclosures that explain adequately why a person of ordinary skill in the art would have known that the time required for

dissolution of the prostaglandins and NSAID when administered in Ouali's bilayer tablet formulation is approximately the same as the amount of time required for the dissolution of these ingredients when they are administered alone. *Compare* Ex. 1002 ¶¶ 61–62 *with* Pet. 35–36.

Nor are we persuaded by Petitioner's conclusory statement that independent dissolution of ingredients in a bilayer tablet is an inherent property of that formulation. Pet. 38 (citing Ex. 1002 ¶ 68, Ex. 1011). Neither Petitioner nor Dr. Kibbe supports this conclusion with evidence sufficient to demonstrate that the property of independent dissolution is necessarily present in bilayer tablets. *Akamai Technologies, Inc. v. Cable & Wireless Internet Services*, 344 F.3d 1186, 1192 (Fed. Cir. 2003).

Therefore, on this record, Petitioner has not established sufficiently that Plachetka and Ouali disclose or suggest every element of claim 1 or claim 2, and we determine that Petitioner does not show a reasonable likelihood of prevailing on its assertion that claims 1 and 2 are obvious in view of Plachetka and Ouali.

C. Obviousness over Plachetka and Elger

Petitioner argues that the subject matter of claims 1 and 2 would have been obvious in view of Plachetka and Elger. Pet. 40–47.

Elger discloses a pharmaceutical composition in the form of a bilayered tablet containing a narcotic analgesic and an NSAID, such as naproxen. Ex. 1012, Abstract, 2:16–25. Elger recognizes that prior art tablets containing narcotic analgesics and NSAIDs “exhibit serious incompatibility, poor crushing strength and long disintegration problems.” *Id.* at 1:35–40. Elger teaches that its inventors were able to overcome these

problems by (1) separating the ingredients into a multi-phase, layered tablet, (2) removing stearic acid and/or stearate salts from the composition, and (3) adding at least one self-lubricating, direct compression aid. *Id.* at 3:26–43.

With regard to the independent dissolution limitation of claims 1 and 2, Petitioner contends that Elger teaches “a bilayer tablet with two active ingredients where each ingredient dissolves at approximately the same time, i.e., independently.” Pet. 21. Additionally, Petitioner argues that it would have been obvious to a person of ordinary skill in the art to include naproxen and triptan in first and second layers in a side by side arrangement such that the dissolution of naproxen occurs independently of triptan because Elger teaches that a bilayer tablet formulation allows for reduced release times for the ingredients in each layer, including incompatible ingredients that otherwise require long disintegration times. *Id.* at 42–44, 47.

We are not persuaded by Petitioner’s arguments. Once again, Petitioner’s argument is based, at least in part, on its understanding that dissolving “at the same time” is equivalent to dissolving independently. As noted above, however, the broadest reasonable construction of “dissolution of said naproxen occurs independently of said triptan” is a dissolution profile such that complete dissolution of naproxen and triptan when the drugs are given in the combination tablet requires the same amount of time $\pm 10\%$ as when the same amount of naproxen or triptan is given alone. Based on our review of the record, including the declaration submitted by Petitioner, we determine that Petitioner fails to identify sufficient evidence demonstrating that Elger discloses bilayer tablets having a dissolution profile such that complete dissolution of the ingredients when given in the combination tablet requires approximately the same amount of time as when the ingredients are

given alone.

For example, Petitioner does not direct us to any test results comparing dissolution rates of Elger's ingredients combined in a multilayer tablet with dissolution rates of those same ingredients on their own. Petitioner also fails to explain adequately how Elger's disclosure of tablets exhibiting reduced release times for the ingredients in each layer constitutes a teaching that narcotic analgesics and NSAIDs, when administered in a bilayer tablet, would require the same amount of time to dissolve as if the two ingredients were administered alone. Additionally, as was the case with Petitioner's contentions based on the combination of Plachetcka and Ouali, Petitioner does not direct us to any evidence in Plachetka that cures this deficiency. We further note that the declaration provided by Dr. Kibbe simply mirrors the statements made in the Petition, without providing additional analysis or references to prior art disclosures that explain adequately why a person of ordinary skill in the art would have known that Elger's bilayer tablets allowed for the independent dissolution of the ingredients in each layer. *Compare* Ex. 1002 ¶¶ 71–77 with Pet. 41–43.

Nor are we persuaded by Petitioner's statement that "[a] bilayer formulation of two active ingredients was known to be equivalent, and interchangeable, with a patient taking the two ingredients separately, but at the same time." Pet. 45. As support for this statement, Petitioner cites to paragraph 81 of the Kibbe Declaration, which simply repeats the statement without adding any explanation. Such unsupported conclusory statements are entitled to little weight. *Rohm and Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997). Furthermore, this statement, even if true, does not constitute sufficient evidence demonstrating a dissolution profile such

that complete dissolution of two ingredients when they are given in a combination tablet requires the same amount of time $\pm 10\%$ as when the same amount of ingredients are given alone.

Therefore, on this record, Petitioner has not established sufficiently that Plachetka and Elger disclose or suggest every element of claim 1 or claim 2, and we determine that Petitioner does not show a reasonable likelihood of prevailing on its assertion that claims 1 and 2 are obvious in view of Plachetka and Elger.

D. Obviousness over Devane and Elger

Petitioner argues that the subject matter of claims 1 and 2 would have been obvious in view of Devane and Elger. Pet. 47–50.

Devane discloses a multiparticulate, modified release composition having a first and second component, wherein the active ingredient in the first and second components can be the same or different. Ex. 1013, Abstract, 4:10–16. Devane teaches that a multilayer tablet is a suitable dosage form (*id.* at 10:41–42), and includes naproxen and sumatriptan among the list of drugs that the claimed invention may be used to deliver (*id.* at 6:30–32, 6:45–47).

Petitioner again relies on Elger as disclosing or suggesting the independent dissolution limitation of claims 1 and 2. *See* Pet. 49–50. Petitioner's argument is no more persuasive here than it was when presented in combination with Plachetka. Additionally, Petitioner does not direct us to any evidence in Devane that cures the deficiencies of Elger. Thus, for the same reasons presented above, based on this record, Petitioner has not established sufficiently that Devane and Elger disclose or suggest every

element of claim 1 or claim 2, and we determine that Petitioner does not show a reasonable likelihood of prevailing on its assertion that claims 1 and 2 are obvious in view of Devane and Elger.

E. Obviousness over Plachetka and Desai

Petitioner argues that the subject matter of claims 1 and 2 would have been obvious in view of Plachetka and Desai. Pet. 51–59.

Desai is directed to “multilayer controlled release preparations containing a layer of compressed delayed and immediate release granulates of naproxen and a layer of naproxen sodium.” Ex. 1009, 3:21–24. According to Desai, this type of dosage form immediately releases the naproxen sodium to achieve a desired therapeutic plasma level in less than 1 hour, and subsequently releases the naproxen granulates to maintain therapeutic blood levels for a duration of 24 hours. *Id.* at 3:24–30. Desai teaches that its composition can be prepared in the form of a bilayer tablet. *Id.* at Fig. 1.

With regard to the independent dissolution limitation of claims 1 and 2, Petitioner argues that, as Desai recognizes, naproxen was known to have a low water solubility. Pet. 52 (citing Ex. 1009, 1:33–35), 58. In view of this, Petitioner contends that

[b]ecause naproxen and the triptan, when formulated together, are competing for solvent, then the slow dissolution rate of naproxen could slow the dissolution rate of the triptan. (Ex. 1002, Kibbe Decl. ¶89). When naproxen and the triptan are formulated in separate layers, however, they no longer compete with each other as much for the solvent (which is principally water), and therefore, the triptan would go into solution faster. (*Id.*).

Id. at 52. Petitioner also argues that Desai's bilayer formulation provides for immediate release of naproxen sodium, which provides for faster pain relief. *Id.* at 58. Thus, Petitioner concludes that it would have been obvious to a person of ordinary skill in the art to include naproxen and triptan in first and second layers in a side by side arrangement such that the dissolution of naproxen occurs independently of triptan. *Id.* at 58–59.

We are not persuaded by Petitioner's argument. As noted above, the broadest reasonable construction of "dissolution of said naproxen occurs independently of said triptan" is a dissolution profile such that complete dissolution of naproxen and triptan when the drugs are given in the combination tablet requires the same amount of time $\pm 10\%$ as when the same amount of naproxen or triptan is given alone. Based on our review of the record, including the declaration submitted by Petitioner, we determine that Petitioner fails to identify sufficient evidence demonstrating that Desai discloses bilayer tablets having a dissolution profile such that complete dissolution of the ingredients when given in the combination tablet requires approximately the same amount of time as when the ingredients are given alone.

For example, Petitioner does not direct us to any test results comparing dissolution rates of Desai's ingredients combined in a multilayer tablet with dissolution rates of those same ingredients on their own. Additionally, Petitioner fails to explain adequately how Desai's disclosure of multilayer controlled release preparations that provide both immediate and delayed release of naproxen sodium and naproxen constitutes a teaching that these two ingredients, when administered in a bilayer tablet, would require the same amount of time to dissolve as when the two ingredients are

administered alone. Furthermore, Petitioner does not direct us to any evidence in Plachetka that cures this deficiency.

We also note that the declaration provided by Dr. Kibbe simply mirrors the statements made in the Petition, without providing additional analysis or references to prior art disclosures that explain adequately why a person of ordinary skill in the art would have known that Desai's bilayer tablets allowed for the independent dissolution of the ingredients in each layer. *Compare* Ex. 1002 ¶¶ 100–101 *with* Pet. 57–58.

Therefore, on this record, Petitioner has not established sufficiently that Plachetka and Desai disclose or suggest every element of claim 1 or claim 2, and we determine that Petitioner does not show a reasonable likelihood of prevailing on its assertion that claims 1 and 2 are obvious in view of Plachetka and Desai.

IV. ORDER

For the reasons given, it is hereby
ORDERED that the Petition is *denied*.

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Patent 7,332,183 B2

PETITIONER:

Zachary Silbersher
Sergey Kolmykov
Kroub, Sibersher & Kolmykov PLLC
zsilbersher@kskiplaw.com
skolmykov@kskiplaw.com

PATENT OWNER:

Dominick A. Conde
Brendan M. O'Malley, Ph.D.
FITZPATRICK CELLA, HARPER & SCINTO
PozenIPR@fchs.com

Stephen M. Hash, Ph.D.
Jeffrey S. Gritton
BAKER BOTTS LLP
PozenIPR@bakerbotts.com