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**PATENTS**

In this seventh installment in a series of Bloomberg BNA Insights by attorneys at Ropes & Gray LLP addressing PTAB-related subjects, the authors identify successful and unsuccessful strategies for life science patent owners faced with inter partes review challenges.

# Lessons Learned from IPR Proceedings in the Life Sciences

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Since the AIA post-grant review proceedings first became available to patent challengers, there have been over 2,300 petitions for *inter partes* review (IPR) filed with the Patent Trial and Appeals Board (PTAB). Yet, only 183 (8 percent) involve biotech- or pharma-related patents assigned to Technology Center 1600 (life sciences IPRs). In those 183 cases, there have, thus far, been 102 institution decisions (69 granting institution; 33 denying institution) and 19 final written decisions.

The 183 petitions have challenged 3,021 claims, which is roughly half of the 6,189 claims in the patents to which they were directed. To date, the PTAB has instituted trial on 64 percent of the challenged claims. In its final written decisions, the PTAB has invalidated 42 percent of the claims on which the IPR was instituted (or the patent owner canceled those claims.)

Some lessons can be learned from the strategies that patent owners have employed in these life sciences IPRs. The most effective strategy by far for defending a patent is a specific and detailed showing, supported by credible expert testimony and evidence, of crucial dispositive flaws in the invalidity argument. To date, other

strategies that patent owners have employed to defeat challenges to the validity of their claims over the prior art have proven largely ineffective.

## Successful Patent Owners

### Final Written Decisions

The patent owner has successfully defended all of the challenged claims in five of the 19 life sciences IPRs that have resulted in final written decisions. In all five, the key seems to have been a specific and supported attack on a critical flaw in the prior art and the petitioner's and the PTAB's characterization of it. In life sciences IPRs that have reached final written decisions, generic arguments about missing elements from the prior art have been unpersuasive. This is likely because in its institution decision the PTAB had already determined that the prior art disclosed all of the elements of the claim. Instead, successful patent owners have addressed a crucial dispositive and specific issue and have demonstrated how it prevented the prior art from anticipating the claim or rendering it obvious.

In the related IPR2013-00276 and IPR2013-00277, the patent owner argued for 30 pages that the cited art failed to disclose all of the elements of the challenged claims.[1] Similarly, the patent owner's expert witness devoted more than 30 pages of his declaration to demonstrating in a detailed, but unfocused manner, what was missing.[2] Perhaps because the PTAB had already performed a detailed analysis of the prior art and the claim elements in its institution decision,[3] these arguments fell on deaf ears.[4] What carried the day in these IPRs was the patent owner's specific and expert-supported argument and evidence (testimonial and documentary) that an ordinary skilled worker would not—and in fact, *could* not—have combined the prior art.[5]

Similarly, in the related IPR2013-00368, IPR2013-00371 and IPR2013-00372, the patent owner argued that ''modified sustained release'' was different from ''delayed release.''[6] The PTAB specifically credited the patent owner's expert on this point, noting that the petitioner had not explained why the patent owner's expert was incorrect.[7] This argument was likely successful because it illustrated a critical PTAB misunderstanding of one specific aspect of the prior art that had been a basis for the institution decision.[8]

### Institution of Trial Denials

In many of the proceedings in which the PTAB has denied institution of trial, its reasoning has been procedural (e.g., time barred, redundancy, etc.) However, in those cases in which the PTAB's denial was substantive, successful preliminary responses have mostly taken the same specific approach—namely, challenging a dispositive discreet point in the art and the petitioner's characterization of it or its combination. This is true despite the fact that the patent owner cannot submit expert testimony with its preliminary response.

A brief summary of illustrative substantive institution denials demonstrates this point:

- In IPR2013-00023, the PTAB agreed with the patent owner that the petitioner's reliance on inherency was unfounded and unsupported.[9]
- In IPR2014-00331, the PTAB agreed with the patent owner that one claim element—the automated seed sampler system—was lacking in the prior art.[10]
- In IPR2014-00398, the PTAB found the patent owner's claim construction argument to be persuasive and dispositive.[11]
- In IPR2014-00651, the PTAB agreed with the patent owner that the petition attempted to ''gloss over'' the distinction between the claimed compound (hydroxypropyl methylcellulose) and the prior art compound (hydroxyethyl cellulose).[12]
- In IPR2014-00842, the patent owner successfully argued that ''[i]dentifying patients that do not respond (or respond poorly) to a particular type of therapy does not suggest whether or how to treat these patients.''[13]
- In IPR2014-00885, the PTAB agreed with the patent owner that the motivation to combine the obviousness references was missing.[14]
- In IPR2014-01126, the PTAB was persuaded that the disclosure of a genus with a large number of species failed to anticipate a single species within the genus.[15]

## Unsuccessful Patent Owner Strategies

The two most glaring unsuccessful patent owner strategies have been (1) amending claims and (2) arguing objective indicia of nonobviousness.

### Claim Amendments

Patent owners may file a motion to amend after conferring with the board.[16] However, any proposed claim amendment must respond to a ground of unpatentability involved in the trial and it must not enlarge the scope of the claims of the patent or introduce new subject

[1] *See Ariosa Diagnostics v. Verinata Health, Inc.*, IPR2013-00276, Paper 20 (P.T.A.B Jan. 16, 2014).
[2] *See Ariosa Diagnostics v. Verinata Health, Inc.*, IPR2013-00276, Ex. 2003 (P.T.A.B Jan. 16, 2014).
[3] *See Ariosa Diagnostics v. Verinata Health, Inc.*, IPR2013-00276, Paper 11 (P.T.A.B Oct. 25, 2013).
[4] *See Ariosa Diagnostics v. Verinata Health, Inc.*, IPR2013-00276, Paper 43 (P.T.A.B Oct. 23, 2014).
[5] *Id.*
[6] *See Amneal Pharms., LLC v. Supernus Pharms., Inc.*, IPR2013-00368, Paper 94 (P.T.A.B. Dec. 9, 2014).
[7] *Id.*
[8] *See Amneal Pharms., LLC v. Supernus Pharms., Inc.*, IPR2013-00368, Paper 8 (P.T.A.B. Dec. 17, 2013).
[9] *Monsanto Co. v. Pioneer Hi-Bred Int'l, Inc.*, IPR2013-00023, Paper 32 (P.T.A.B. Apr. 11, 2013).
[10] *E.I. Du Pont De Nemours & Co. v. Monsanto Tech. LLC*, IPR2014-00331, Paper 21 (P.T.A.B. July 11, 2014).
[11] *Lenroc Co. v. Enviro Tech Chemical Services, Inc.*, IPR2014-00382, Paper 12 (July 24, 2014).
[12] *Endo Pharms., Inc. v. Depomed, Inc.*, IPR2014-00651, Paper 12 (P.T.A.B. Sep. 29, 2014).
[13] *Phigenix, Inc. v. Genentech, Inc. and Immunogen, Inc.*, IPR2014-00842, Paper 10 (P.T.A.B Dec. 9, 2014).
[14] *Mylan Pharms. Inc. v. Gilead Scis., Inc.*, IPR2014-00885, Paper 15 (P.T.A.B Dec. 9, 2014).
[15] *Actavis, Inc. v. Research Corp. Techs., Inc.*, IPR2014-01126, Paper 22 (P.T.A.B. Jan. 9, 2015).
[16] 37 CFR § 42.121.

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matter.[17] The amended claims must be supported by the written description in the specification.[18] Additionally, the patent owner must ''show patentability [of the amended claims] over the prior art in general, and not just over the references applied by the petitioner against the original patent claims.''[19]

To date, a motion to amend has successfully saved the claims from invalidity in one life sciences IPR.[20] And, in that IPR, the petitioner did not challenge the substitute claims.[21] The remaining eight life sciences cases in which the PTAB has ruled on motions to amend have resulted either in denial of the motion or in granting the motion to cancel claims but denying the motion to substitute new claims. The denials have had varying bases, including non-narrowed claim scope,[22] unresponsiveness to a ground of unpatentability at issue,[23] unpatentability of the amended claims[24] and lack of written description support.[25]

## Objective Indicia of Nonobviousness

In both institution decisions and final written decisions, the patent owner's arguments regarding objective indicia of nonobviousness have failed in life sciences IPRs. At the institution stage, the board rarely addresses objective indicia. The few times it has done so, it has found the evidence of record—which cannot include declaratory evidence—insufficient to prevent the petitioner from meeting its burden.[26]

In final written decisions, the PTAB has not yet found any objective indicia arguments persuasive. For example, in IPR2013-00117 more than half of the patent owner's response was devoted to objective indicia of nonobviousness.[27] However, the PTAB held that there was no nexus between any of the objective indicia and the claimed invention.[28] In other IPRs, the PTAB has found the evidence of objective indicia to be not credible and/or to be unpersuasive.[29] Indeed, even in the five decisions validating all claims on which the PTAB had instituted trial, the objective indicia analysis was moot in light of the substantive analysis.

## Conclusion

Although the sample size for life sciences IPRs is small, especially in comparison to those in other technologies, the PTAB's life sciences decisions have shown important trends. Unfocused, generic litigation-style responses comparing the claim elements to the prior art have been ineffective. So too have reliance on claim amendments or objective indicia of nonobviousness. By contrast, patent owners who have prevailed before the PTAB have made focused and evidence-supported arguments demonstrating specific flaws in the invalidity arguments.

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[17] *Id.*

[18] *Id.*

[19] *Toyota Motor Corp. v. Am. Vehicular Scis. LLC*, IPR2013-00419, Paper 32 (P.T.A.B. Mar. 7, 2014).

[20] *Int'l Flavors & Fragrances Inc. v. U.S.*, IPR2013-00124, Paper 12 (P.T.A.B. May 20, 2014).

[21] *Id.*

[22] *Illumina, Inc. v. Trustees of Columbia Univ.*, IPR2012-00006, Paper 128 (P.T.A.B. Mar. 6, 2014).

[23] *Illumina, Inc. v. Trustees of Columbia Univ.*, IPR2012-00007, Paper 140 (P.T.A.B. Mar. 6, 2014).

[24] *Ariosa Diagnostics v. Isis Innovation Ltd.*, IPR2012-00022, Paper 166 (P.T.A.B. Sep. 2, 1014).

[25] *Smith & Nephew, Inc. v. Convatec Techs., Inc.*, IPR2013-00102, Paper 87 (P.T.A.B. May 29, 2014).

[26] *See Apotex Inc. v. Alcon Pharms., Ltd.*, IPR2013-00012, Paper 43 (P.T.A.B. Mar. 19, 2013); *Phigenix, Inc. v. Immunogen, Inc.*, IPR2014-00676, Paper 11 (P.T.A.B. Oct. 29, 2014).

[27] *Gnosis S.p.A. v. Merck & CIE*, IPR2013-00117, Paper 37 (P.T.A.B. Oct. 16, 2013).

[28] *Gnosis S.p.A. v. Merck & CIE*, IPR2013-00117, Paper 71 (P.T.A.B. June 20, 2014).

[29] *See Illumina, Inc. v. Trustees of Columbia Univ.*, IPR2012-00006, Paper 128 (P.T.A.B. Mar. 6, 2014); *Illumina, Inc. v. Trustees of Columbia Univ.*, IPR2012-00007, Paper 140 (P.T.A.B. Mar. 6, 2014); *Illumina, Inc. v. Trustees of Columbia Univ.*, IPR2013-00011, Paper 130 (P.T.A.B. Mar. 6, 2014); *Smith & Nephew, Inc. v. Convatec Techs., Inc.*, IPR2013-00102, Paper 87 (P.T.A.B. May 29, 2014).