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Patent Licensing: Advanced Tactics for Licensees Post-AIA

Structuring Contractual Protections and Responding When
Licensed Patents Are Challenged in Post-Grant Proceedings

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1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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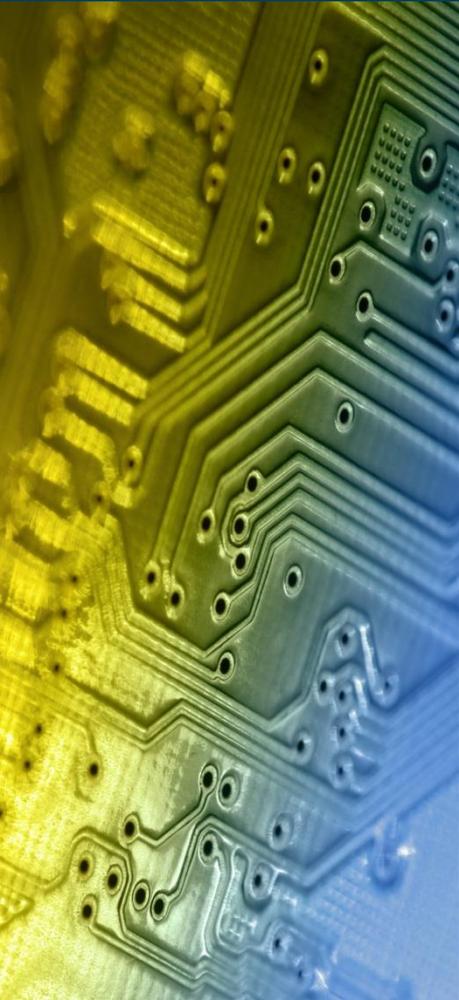
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Patent Licensing: Advanced Tactics for Licensees Post-AIA

William C. Coppola, Senior Patent Counsel, Sanofi-Aventis

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October 16, 2014

Important Considerations of the AIA

DISCLAIMER

The comments and opinions expressed here are solely those of the speakers and do not in any way reflect those of any current or former client of the speaker or any party having any potential or actual business with any current or former client of the speaker. This presentation is provided for informational purposes only and is not legal advice.

Presentation Overview

- § AIA Changes That Impact Licensees
- § Protection Challenges For Licensees
- § Responding To Attempts To Invalidate A Licensed Patent In Post-Grant Proceedings
- § Best Practices And Sample Agreement Provisions

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I. AIA Changes That Impact Licensees

I. AIA Changes That Affect Licensees

- Objectives of Presentation:
 - › Explain some of the more pertinent changes that the AIA has made to Patent Act, from the perspective of a licensee
 - › Provide explanation and helpful suggestions on dealing with the AIA when negotiating with a partner that may help avoid costly litigation

I. AIA Changes That Affect Licensees

A. Post Grant Proceedings

- The AIA provides new trial procedures:
 - › *Inter Partes* Review (IPR)
 - › Post-Grant Review (PGR)
 - › Covered Business Method Review (CBM)
 - › Supplemental Examination
- The role of the ***patent owner*** in these processes is critical

I. AIA Changes That Affect Licensees

- Generally, however, the licensee is ***not*** the patent owner
 - › Licensee may want to retain control over various aspects of the post-grant proceedings, including, *e.g.*,
 - whether such proceedings will be requested (or the risk that they will be requested by a Third Party Petitioner), and if so, for what type of proceeding
 - varying considerations, such as estoppel considerations, for IPR, PGR, CBM, etc.
 - the timing of such proceedings
 - the content of all documents filed in such proceedings
 - important for motions to amend, claim construction positions
 - › Particularly important if licensee is paying prosecution costs

I. AIA Changes That Affect Licensees

Preliminary Response to Petition for *Inter Partes* Review (35 USC § 313)

- › Statute specifically states **patent owner** has right to file preliminary response to petition.
- › Licensee of IP subject to petition does **not** have right to file response.
- › May be desirable for licensee to require control/input in response patent owner (licensor) files with the USPTO.

Settlement of *Inter Partes* Review (35 USC § 317)

- › *Inter Partes* Review will be terminated upon the joint request of petitioner and the **patent owner**.
- › Licensee of IP subject to *Inter Partes* Review does not have right to settle. Licensee may consider requiring right to control whether to settle, and terms of settlement.
- › At minimum, licensee may consider requiring that licensor not settle any post-grant review proceeding without express written consent of licensee.

I. AIA Changes That Affect Licensees

Preliminary Response to a Petition for Post-Grant Review (35 USC § 323)

- › Statute specifically states **patent owner** has right to file preliminary response to petition for post-grant review.
- › Licensee does not have the right to file response.
- › Licensee may want to control/provide input of response patent owner files.

Settlement of post-grant Review Proceeding (35 USC § 327)

- › Just as with *inter partes* review, statute specifically states post-grant review proceeding will be terminated upon joint request of petitioner and **patent owner**.
- › Licensee may want right to control whether to settle, and terms of such settlement.
- › At minimum, may want licensor (patent owner) not to settle without express written consent of licensee.

I. AIA Changes That Affect Licensees

Supplemental Examination (35 USC § 257)

- › Permits supplemental examination of issued patent to correct for omissions/errors that may have occurred during prosecution of patent.
- › A patent will not be held unenforceable on the basis of conduct relating to information that:
 - had not been considered;
 - was inadequately considered; or
 - was incorrect in a prior examination of the patent;
- › if the information was considered, reconsidered, or corrected during a supplemental examination of the patent.
- › **Patent owner** only may request supplemental examination.

I. AIA Changes That Affect Licensees

Exception to Supplemental Examination (35 USC § 257 (c)(1))

- › 35 USC § 257 (c)(1) will not apply to:
 - An allegation pled with particularity in a civil action; or
 - An allegation set forth with particularity in a notice received by the patent owner under 21 USC § 355(j)(2)(B)(iv)(II) before the date the of supplemental request to consider, reconsider, or correct information forming the basis for the allegation
 - 21 USC § 355(j)(2)(B)(iv)(II) is the ANDA Paragraph IV certification.
 - Thus, Supplemental Examination will not be effective to resolve an allegation relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination if the allegation is made in a Paragraph IV Certification the patent owner received **prior** to the filing of the petition for Supplemental Examination.

I. AIA Changes That Affect Licensees

Supplemental Examination: 35 USC § 257 (cont.)

- › Due to the § 257(c)(1) exception, it may be desirable for a licensee to have the following rights in license agreement:
 - Licensee controls whether to file Supplemental Examination petition, and to instruct patent owner/licensor accordingly;
 - Licensee controls content of petition and all correspondence with USPTO.
- › Considerations Regarding Supplemental Examination:
 - Thorough review should be made of prosecution history of patent to be listed to determine whether Supplemental Examination is necessary
 - In light of the § 257(c)(1) exception, make any decision on Supplemental Examination ***before any Paragraph IV certifications are received***

I. AIA Changes That Affect Licensees

B. Common Ownership Under Joint Research Agreements

- › Cooperative Research and Technology Enhancement (CREATE) Act of 2004
- › The CREATE Act promoted joint research activities by providing that the prior art of the collaborators could not be used against each other to invalidate inventions arising out of the collaboration
 - Previously, the joint research agreement had to have been in effect prior to the invention; under the AIA, the agreement only needs to be in effect prior to the date of filing
- › CREATE Act in AIA moved from previous location within 35 USC § 103 to 35 USC § 102(c).

I. AIA Changes That Affect Licensees

- An example of a paragraph that may be used in agreement and considers the changes the AIA has made in the Patent Act:

Notwithstanding anything to the contrary in this Agreement, Licensee shall have the right to invoke 35 USC §102 (c) without the prior written consent of the other Party. Where Licensee intends to invoke 35 USC § 102 (c) as permitted by the preceding sentence, it shall notify the other Party and the other Party shall cooperate and coordinate its activities with Licensee with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 USC § 100 (h).

I. AIA Changes That Affect Licensees

C. Inventor Declarations (35 USC § 115)

- The AIA allows assignee to file a substitute statement in lieu of an inventor's declaration or oath when:
 - › inventor is unable to submit the oath; or
 - › inventor is unwilling to do so and has an obligation to assign the invention to “assignee”

I. AIA Changes That Affect Licensees

- Consider confirming that all employees/consultants of third party potential licensor have executed an agreement, *e.g.* an employment agreement, that at minimum, obligates employee to assign all inventions and works to third party licensor
- Should employee/inventor disappear, become uncooperative or otherwise refuse to execute a declaration for any inventions in which Licensee would have rights, third party licensor (inventor's employer) can submit the substitute statement, and commence prosecution of the application
- Licensee may want right to instruct the third party licensor to file the substitute statement in order to avoid any delay in prosecution, and thus loss of grant

I. AIA Changes That Affect Licensees

D. Derivation Proceedings (35 USC § 135)

- › AIA introduces derivation proceeding in order retain the one year grace period for filing applications in the US after public disclosure.
- › Statute specifically states that "applicant" of the later filed application has right to request a derivation proceeding.
- › Thus, when negotiating in-licensing agreements, potential licensee may want:
 - Control over whether to request such a proceeding;
 - Control of content of all papers applicant files with the USPTO in the proceeding should a proceeding be commenced;
 - Licensor to agree licensor's employees/inventors will cooperate in the filing and prosecuting of such a proceeding.

I. AIA Changes That Affect Licensees

E. Citation of Prior Art and Written Statements (35 USC § 301)

- › Written statements of the **patent owner** filed in a proceeding before a Federal Court or USPTO are citable prior art in certain post grant proceedings:
 - Reexamination proceeding ordered by the Director (35 USC § 304);
 - *Inter Partes* Review proceeding (35 USC § 314);
 - Post-Grant Review proceeding (35 USC § 324).

- Licensee may consider requiring input/control of all documents filed with USPTO during prosecution of patents covering any invention in-licensed, or more importantly in a collaboration, in which applications may likely cover a potential product that results from the collaboration in order to control what is stated in the prior art.

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II. Protection Challenges For Licensees

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***Medtronic v. Mirowski Family Ventures*, 134 S.Ct. 843 (2014)**

- Unanimous reversal of the Federal Circuit
- Patentee maintains the burden of proof on infringement even in declaratory judgment actions by licensees in good standing
 - › Patentee ordinarily has the burden of proving infringement
- Licensees may be further emboldened in challenging licensed patents
- The Court reinforced that licensees may be the only parties with the economic motivation to challenge questionable patents

II. Protection Challenges for Licensees

FTC v. Actavis, Inc., 133 S.Ct. 2223 (2013)

- Question before the Court was whether Hatch-Waxman Act settlements are generally legal as long as they don't exceed the scope of the patent
- Federal Trade Commission urged that all “pay-for-delay” settlements should be blocked
- Other side urged “scope of the patent” test
 - › Settlements are fine as long as they...
 - Don't exceed the substance of the patent
 - Don't extend the duration of the patent
 - Result from sham litigation
 - Protect patents obtained through fraud

II. Protection Challenges for Licensees

FTC v. Actavis, Inc., 133 S.Ct. 2223 (2013) (cont.)

- Settled in Sept. 2006
- › Claim construction had been fully briefed
- › Discovery was underway
- FTC alleged that terms of the settlement were not arms length and exceeded the value of the services provided
- The Supreme Court rejected both positions, holding that reverse payment settlements are not presumptively anticompetitive
- › “Rule of Reason” applies
- Decision arguably opens the door for all patent license agreements to be challenged in a similar fashion

II. Protection Challenges for Licensees

- ***General Protecht Group v. Leviton Mfg.*, 651 F.3d 1355 (Fed. Cir. 2011)**
 - There is a strong presumption that continuations are impliedly included in license agreements unless there is a positive manifestation in the papers to the contrary
 - This issue should be negotiated and clearly reflected in drafting
- ***Intel Corp. v. Negotiated Data Solutions, Inc.*, 703 F.3d 1360 (Fed. Cir. 2012)**
 - Unless the stated intent of the parties is to the contrary, reissue patents are within the scope of a broad and unrestricted grant of a license
 - Holding to the contrary would run the risk of allowing the licensor to pull the rug out from under the licensee by filing for a reissue

II. Protection Challenges for Licensees

***Relume Corp. Trust v. GE Lighting Solutions*, 2013 U.S. Dist. LEXIS 182537 (D. Del. Dec. 30, 2013)**

■ Background:

- › December 1999 – RCT and Ecolux settle patent infringement suit through a Settlement Agreement including the following provisions:
 - (2) Relume...grants to Ecolux a paid-up, royalty free... under the '645 and '909 patents ... and any ... reissues thereof ...
 - (5) Relume ... covenants, represents and warrants that it will not assert against Ecolux, its ... successor-in-interest, assigns... any claim for infringement
 - (14) This Agreement shall inure to the benefit of, and be binding upon, the parties and their respective affiliates, successors and assigns.
- › Ecolux transferred the Agreement to GE when GE acquired Ecolux

II. Protection Challenges for Licensees

***Relume Corp. Trust v. GE Lighting Solutions*, 2013 U.S. Dist. LEXIS 182537 (D. Del. Dec. 30, 2013) (cont.)**

■ Issue

- › RCT argued that Section 14 was narrow and did not permit the assignment of the Section 2 license to a reissue patent through acquisition
- › GE contended that Section 14 applied to the entirety of the Agreement

■ Holding

- › Section 14's broad "successors and assigns" clause properly applies to the Reissue patent license granted under Section 2
- › The Court rejected RCT's argument that Section 2 does not contain the "successors" and "assigns" language that is, for example, in Section 5, and thus Section 14 does not apply

II. Protection Challenges for Licensees

***Relume Corp. Trust v. GE Lighting Solutions*, 2013 U.S. Dist. LEXIS 182537 (D. Del. Dec. 30, 2013) (cont.)**

■ Lessons Learned

- › Be specific in the rights you are granting
- › If you don't want a future third party to end up with a license, either expressly limit the same, or build in the ability to approve future successors or assigns, while maintaining the right to terminate the license

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III. Invalidation Of A Licensed Patent In Post-Grant Proceedings

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- A licensee wishing to invalidate a licensed patent may be hesitant to do so if a traditional “No Challenge” clause appears in the license
- “Neither Licensee nor any of its affiliates shall pursue, or cause, aid, or encourage a third party to pursue, any Patent Challenge ...”
(Validity / Enforceability / Scope / Infringement / Ownership)
- **General Rule**: Not Enforceable
 - › Courts follow *Lear v. Adkins* (S.Ct. 1969) and reject the enforceability of "no-challenge" clauses in license agreements
 - › If license agreement entered into at the time litigation threatened, but prior to initiation, clause still unenforceable
- **General Exception**: Litigation Settlements
 - › Courts (specifically the Federal Circuit) enforce "no-challenge" clauses in license agreements or consent judgments used to settle litigation

III. Invalidation Of A Licensed Patent In Post-Grant Proceedings

- Licensee Strategy: Alternatives to a “No Challenge” Clause
 - › Shorter License Term
 - License term renews only if there is no dispute or litigation between the parties, or only if Licensee has not challenged the licensed patent
 - › Notice and Information Procedures
 - Licensee must give Licensor advance notice of challenge and information regarding challenge
 - › Set a Higher Upfront License Fee/Declining Royalty Structure (disincentive to Licensee patent challenge)
 - › Royalty Step-Up if Unsuccessful Challenge
 - › Payment of Attorneys’ and/or Experts’ Fees Upon Challenge
 - › Licensee Considerations
 - Include an express right to challenge
 - Make explicit that Licensee makes no admission of validity or enforceability of the patent(s)

III. Invalidation Of A Licensed Patent In Post-Grant Proceedings

- Through post-grant proceedings, the AIA makes challenging patents more attractive to third parties (and licensees)
 - › Rather than bringing a costly declaratory judgment proceeding in District Court, a party may instead seek IPR, PGR, or CBM review
 - › Chance of invalidating patent claims is significantly higher with an IPR or CBM than in District Court
- Forum selection provisions become important for the licensee who may wish to challenge a licensed patent
 - › Licensors may attempt to require that challenges be handled by arbitration or in District Court
 - › In this instance, a Licensee should include the Patent Trial and Appeal Board (PTAB) as a forum
 - › Forum selection provisions omitting PTAB as a forum for challenges may be held unenforceable if litigated

III. Invalidation Of A Licensed Patent In Post-Grant Proceedings

- Negotiation leverage of post-grant petitions
 - › To gain an advantage in a licensing negotiation...
 - › Consider preparing an IPR or CBM petition
 - › Show the petition to the Licensor prior to filing
 - IPRs/PGRs/CBMs are very real threats to validity of patent

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IV. Best Practices And Sample Agreement Provisions

IV. Best Practices And Sample Agreement Provisions

A. Post Grant Proceedings (Filed by a Third Party Regarding a Licensed Patent)

In the event that Licensor becomes aware that a Third Party has filed a Post Grant Proceeding with respect to any Licensed Patent, Licensor will notify Licensee in writing to that effect within 10 days of becoming aware of such filing. Once such a Post Grant Proceeding has commenced, Licensor shall provide Licensee:

(A) with a copy of any action, communication, letter, or other correspondence issued by the relevant patent office or the Third Party within at least 10 days of receipt thereof;

(B) with a copy of any proposed response, amendment, paper, or other correspondence to be filed with the relevant patent office no more than 30 days prior to filing the same in any patent office worldwide, unless otherwise agreed by patent counsel for both parties. Licensee shall have the right to provide suggestions and recommendations regarding the content of the response, amendment, paper, or other correspondence by no later than 15 days prior to its filing. Licensor shall accept any suggestions or recommendations Licensee provides;

IV. Best Practices And Sample Agreement Provisions

A. Post Grant Proceedings (Filed by a Third Party Regarding a Licensed Patent) (cont.)

(C) with a copy of any response, amendment, paper, or other correspondence as filed with the relevant patent office no more than 10 days after Licensor receives confirmation from the relevant patent office that the response, amendment, paper, or other correspondence has indeed been filed; and

(D) Licensor agrees not settle any Post Grant Proceeding a Third Party files with respect to a Licensed Patent without the prior written approval of Licensee, not to be unreasonably withheld or delayed.

IV. Best Practices And Sample Agreement Provisions

B. Post Grant Proceedings (Filed by Party Regarding a Licensed Patent)

Should a Party desire to file a Post Grant Proceeding with respect to a Licensed Patent, the Party shall so notify the other Party. The Parties shall then consult with each other and consider each other's input with respect to whether such a post grant proceeding should be filed; provided, however, Licensee shall have final decision authority with respect to the filing of such a proceeding. Should such a proceeding be filed, Licensor shall provide Licensee:

(A) with a copy of any action, communication, letter, or other correspondence issued by the relevant patent office within at least 10 days of receipt thereof;

(B) with a copy of any response, amendment, paper, or other correspondence to be filed with the relevant patent office no more than 30 days prior to filing the same in any patent office worldwide, unless otherwise agreed by patent counsel for both parties. Licensee shall have the right to provide suggestions and recommendations regarding the content of the response, amendment, paper, or other correspondence by no later than 15 days prior to its filing. Licensor shall accept any suggestions or recommendations Licensee provides;

IV. Best Practices And Sample Agreement Provisions

B. Post Grant Proceedings (Filed by Party Regarding a Licensed Patent) (cont.)

- (C) with a copy of any response, amendment, paper, or other correspondence as filed with the relevant patent office no more than 10 days after Licensor receives confirmation from the relevant patent office that the response, amendment, paper, or other correspondence has indeed been filed; and
- (D) Licensor shall not settle such a Post Grant Proceeding without the prior written approval of Licensee, not to be unreasonably withheld or delayed.

IV. Best Practices And Sample Agreement Provisions

C. Additional Comments: Post Grant Proceedings

- May also need language in any “prosecution” provisions, such as, *e.g.*:

The Parties hereby agree that for the purpose of this Agreement, “Prosecution” shall not include Post Grant Proceedings.

- May also include the following definitions, if necessary:

“Post Grant Proceedings” means all any and all proceedings before any national patent authority that involves the review, examination, analysis or any combination thereof, of any issued Patent. Particular examples of Post Grant Proceedings include, but certainly are not limited to, post grant review proceedings, *inter partes* review proceedings, supplemental examination, patent interference proceedings, opposition proceedings, and reexamination.

IV. Best Practices And Sample Agreement Provisions

D. Biosimilar Applications

If either Party receives a copy of an application submitted to the FDA under subsection (k) of Section 351 of the Public Health Service Act (“PHSA”) (a “Biosimilar Application”) naming a Product as a reference product or otherwise becomes aware that such a Biosimilar Application has been filed (such as in an instance described in Section 351(1)(9)(C) of the PHSA), either Party shall, within ten (10) Business Days, notify the other Party. Licensee shall then seek permission to view the application and related confidential information from the filer of the Biosimilar Application under Section 351(l)(1)(B)(iii) of the PHSA. If either Party receives any equivalent or similar certification or notice in any other jurisdiction, either Party shall, within ten (10) Business Days, notify and provide the other Party copies of such communication. Regardless of the party that is the “reference product sponsor” for purposes of such Biosimilar Application:

(i) Licensee shall have the sole right to designate pursuant to Section 351(l)(1)(B)(ii) of the PHSA the outside counsel and in-house counsel who shall receive confidential access to the Biosimilar Application;

IV. Best Practices And Sample Agreement Provisions

D. Biosimilar Applications (cont.)

(ii) Licensee shall have the sole right to list any patents, including Licensor Patents, Licensee Patents and Joint Patents, insofar as they claim or cover the applicable Product as required pursuant to Section 351(l)(1)(3)(A), Section 351(l)(5)(b)(i)(II), or Section 351(l)(7) of the PHSA, to respond to any communications with respect to such lists from the filer of the Biosimilar Application, and to negotiate with the filer of the Biosimilar Application as to whether to utilize a different mechanism for information exchange other than that specified in Section 351(l) of the PHSA; and

IV. Best Practices And Sample Agreement Provisions

D. Biosimilar Applications (cont.)

(iii) Licensee shall have the sole right to identify Patents or respond to communications under any equivalent or similar listing in any other jurisdiction. If required pursuant to Applicable Law, Licensor shall prepare such list and make such response at Licensee's direction. Licensor will provide to Licensee, within (15) days of Licensee's request, all information, including a correct and complete list of Licensor and Joint Patents that is necessary or reasonably useful to enable Licensee to make such lists of Patents that cover the Product, and cooperate with Licensee's reasonable requests in connection therewith, including meeting any submission deadlines, in each case, to the extent required or permitted by Applicable Law. Licensee shall reasonably consult with Licensor prior to identifying any Licensor Patents to a Third Party as contemplated by this Section. Licensee shall consider in good faith advice and suggestions with respect thereto received from Licensor, and notify Licensor of any such lists or communications promptly after they are made. If Licensee does not proceed under this Section, then Licensor shall have the right to proceed in place of Licensee under this Section with the roles of the Parties reversed.

IV. Best Practices And Sample Agreement Provisions

- Final Thoughts
 - › Understand that the AIA can impact dramatically impact strategic and practical decisions about licensing
 - › Do the hard work when drafting
 - › Keep up to date with current case law



Questions?

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Thank you!