Patent Exclusivity Health Checks for Biologics: Are Your U.S. Patents Ready to Maximize ROI?

THURSDAY, MAY 17, 2018
1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today’s faculty features:

M. Paul Barker, Partner, Finnegan Henderson Farabow Garrett & Dunner, Palo Alto, Calif.

Steven P. O’Connor, Ph.D., Partner, Finnegan Henderson Farabow Garrett & Dunner, Reston, Va.

Sanya Sukduang, Partner, Finnegan Henderson Farabow Garrett & Dunner, Washington, D.C.

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Today’s Agenda

• BPCIA Basics
• Prosecution Considerations
• Pre-Litigation Due Diligence
• Litigation
BPCLA Basics
BPCLA Definition of “Biological Product”

- A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings
“Biosimilar” Products

• “Biosimilar” means:
  — “(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and
  
  (B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.”

  42 U.S.C. § 262(i)(2)
“Interchangeable” Products

• “Interchangeable” means:
  – Biosimilar to RP and
  – Can be expected to produce the same clinical result as the RP in any given patient, and
  – For a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the RP is not greater than the risk of using the RP without such alteration or switch.

  42 U.S.C. § 262(k)(4)
Types of Patents That Can Be Asserted In BPCIA Litigation

- Within **60 days** after receiving copy of Biosimilar application RPS “shall provide”:
  - “A list of patents for which the reference product sponsor believes a claim of **patent infringement could reasonably be asserted**” and
  - “Identification of the patents . . . that the reference product sponsor would be **prepared to license** to the” Biosimilar applicant

42 U.S.C. § 262(l)(3)(A)
Timing Considerations

• 12 year initial data exclusivity
• 6 months pediatric extension
• No new indication extension
• Biosimilar application may be filed 4 years after RP licensed (4.5 years if pediatric extension granted)
• Potential speed of litigation in light of Supreme Court’s decision in Amgen v Sandoz
Prosecution
Several Claims Of Varying Scope That Are Supported, Enabled, And Will Be Literally Infringed By A Single Actor

- Build literal infringement by use of functional discussions, in addition to structural embodiments.

- Cascading disclosure from generic description down to narrower embodiments.

- §112 support for full range of claims.

- Drawings and charts.
Claims Of Varying Scope

• Consider using all three transition terms in application:
  – X comprising...
  – X consisting essentially of...
  – X consisting of . . .
Consider Claim Variety

Method of making

Means-plus-function

Product-by-process

Compound

Method of treatment

Composition/Formulation

Invention
Cannot Rely On Being Able To Amend Claims

Reissue

- New narrow claims
  - New prior art discovered, e.g., in pre-litigation diligence.
  - Old prior art not disclosed during original examination, e.g., to hedge inequitable conduct (see also, supplemental exam).
  - No recapture/broadening issues.

- New dependent claims
  - New prior art; hedge against possible invalidity/unpatentability attack.
  - No recapture/broadening issues.

- New broader claims (general 2-year limit; may have recapture to consider)
  - New products (patent owner or third-party).
  - Unclaimed embodiments or species.
Current Landscape: 
AIA Changes Impacting Patent Reissue

“without any deceptive intention” removed by AIA

35 U.S.C. § 251 -

(a) IN GENERAL.—Whenever any patent is, through error, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

(d) REISSUE PATENT ENLARGING SCOPE OF CLAIMS.—No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.
**AILA Does Not Affect Rules Against Recapture In A Reissue**

**And The 2-year Limit For A Broadening Reissue**

- Recapture test.
- Broadening of claims must be filed within two years.
- Examination is by CRU, not original examiners.
In re Tanaka,
640 F.3d 1246 (Fed. Cir. 2011)

- Board held that it is not reissue "error" under 35 U.S.C. §251 to add a subgeneric claim where all existing claims in the patent are maintained, both broader and narrower than the added claim.

- FC: Reversed and remanded.
  - "adding dependent claims as a hedge against possible invalidity of original claims "is a proper reason for asking that a reissue be granted." In re Handel, 50 CCPA 918, 312 F.2d 943, 946 n. 2 (1963)."
  - "the omission of a narrower claim from a patent can render a patent partly inoperative by failing to protect the disclosed invention to the full extent allowed by law."
Instead Of Reissue, Keep Continuation Pending…

  - PTAB denied Petitioner’s request to file a motion to stay the prosecution of the continuation patent application.
    - “Patent Owner will not be permitted to obtain in a patent any claims that are not patentably distinct from any claim that is canceled as a result of this proceeding. But whether any of the claims in the ’497 patent will be canceled is an issue that is not yet decided and will not necessarily be decided until a final written decision is entered in this case and appeals from it are exhausted. To bar Patent Owner from prosecuting claims now that may be patentably indistinct from the claims under review thus would be premature. It is sufficient, under the current circumstances, for Patent Owner to continue to take reasonable steps to apprise the Examiner of the status of this proceeding.”
Consider, In Keeping Continuation Application Pending:

Take into account cases: “unreasonable and unexplained delay.”

- Tafas v. Doll, 559 F.3d 1345 (Fed. Cir. 2009)
- In re Bogese, 303 F.3d 1362 (Fed. Cir. 2002)
- Symbol Tech., Inc. v. Lemelson Medical, Educ. & Research Foundation, 422 F.3d 1378 (Fed. Cir. 2005)

No recapture issues.

Broadening limited only by requirements of 35 USC § 112(a).
**Health Check On TD Issues**

Term

- 35 USC 154(a)(2): *Grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed....*

Terminal Disclaimers (TD)

- 37 CFR 1.321(a): *Any patentee may disclaim or dedicate to the public...any terminal part of the term, of the patent granted.*
- 37 CFR 1.321(b): *An applicant may disclaim or dedicate to the public...any terminal part of the term, of a patent to be granted.*
- May overcome obviousness-type double patenting (ODP).
**Gilead Decision**

*Gilead Sci., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014)

- Commonly owned, same inventors, similar written descriptions
- Unrelated and have different expiration dates
- After ’483 issued, **Gilead filed TD in ’375 application over ’483**; did not file TD for ’483 over ’375
- District court concluded that ’375 patent could not be ODP reference for ’483
- Federal Circuit disagreed; held that **patent that issues after but expires before another patent can qualify as an ODP reference for that other patent**

![Diagram showing timeline of patents and TD filings]
Health Check On PTA Issues

Patent Term Adjustment (PTA)

• 35 USC 154(b)(1)(A) and (B): [I]f the issue of an original patent is delayed due to the failure of the [USPTO]...the term of the patent shall be extended 1 day for each day [of USPTO delay].

• 35 USC 154(b)(2)(C)(i): The period of adjustment...shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.
Effect Of PTA On ODP?

*AbbVie Inc. v. Kennedy Inst.*, 764 F.3d 1366 (Fed. Cir. 2014)

- Commonly owned; identical written descriptions; ’766 claims genus and ’422 claims species; Different priority dates and ’442 had PTA.
- Held ’442 invalid for ODP over ’766
- “Patents claiming overlapping subject matter...filed at the same time still can have different patent terms due to [PTA].”

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Patent Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-8-92</td>
<td>Parent filed</td>
<td>’766</td>
</tr>
<tr>
<td>8-1-96</td>
<td>Filed</td>
<td>’766</td>
</tr>
<tr>
<td>8-7-01</td>
<td>Issued</td>
<td>’766</td>
</tr>
<tr>
<td>10-8-12</td>
<td>Expires</td>
<td>’766</td>
</tr>
<tr>
<td>8-1-96</td>
<td>Parent filed</td>
<td>’442</td>
</tr>
<tr>
<td>9-12-05</td>
<td>Filed</td>
<td>’442</td>
</tr>
<tr>
<td>12-7-10</td>
<td>Issued</td>
<td>’442</td>
</tr>
<tr>
<td>8-21-18</td>
<td>Expires</td>
<td>’442</td>
</tr>
</tbody>
</table>
Post-Grant Proceedings
IPR Challenges On Biologic Patents

Petitions filed

Source: Finnegan research as of April 22, 2018; 321 petitions filed.
**IPR Challenges On Biologic Patents**

**Institution decisions**

- **Denied**: 81 (40%)
- **Instituted**: 124 (60%)

*Compare to overall institution rate of 68% (4236/6256) (USPTO stats as of Feb. 28, 2018)*

*Source:* Finnegan research as of April 22, 2018; 205 institution decisions. Does not include additional outcomes such as settled prior to institution decision (31), dismissed (4), adverse judgment requested (2), institution decision pending (77).
## Institution Rate By Type of Claim In IPRs

### Institution Rate

<table>
<thead>
<tr>
<th>Type</th>
<th>Institution Rate</th>
<th>Reference Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>apparatus/kit/device</td>
<td>40% (4/10)</td>
<td></td>
</tr>
<tr>
<td>compound</td>
<td>52% (12/23)</td>
<td></td>
</tr>
<tr>
<td>composition/formulation</td>
<td>50% (19/38)</td>
<td></td>
</tr>
<tr>
<td>method of treatment</td>
<td>62% (38/61)</td>
<td></td>
</tr>
<tr>
<td>method of making</td>
<td>73% (16/22)</td>
<td></td>
</tr>
<tr>
<td>method of using</td>
<td>64% (25/39)</td>
<td></td>
</tr>
<tr>
<td>product-by-process</td>
<td>50% (1/2)</td>
<td></td>
</tr>
<tr>
<td>product</td>
<td>50% (9/18)</td>
<td></td>
</tr>
<tr>
<td>system</td>
<td>80% (4/5)</td>
<td></td>
</tr>
</tbody>
</table>

Account for ¾ of claims challenged

**Source:** Finnegan research as of April 22, 2018; 205 institution decisions. There may be one more than one type of claim per petition. Does not include additional outcomes such as settled prior to institution decision (31), dismissed (4), adverse judgment requested (2), institution decision pending (77).
IPR Final Written Decisions On Biologic Patents

All instituted claims unpatentable, 38, 67%

All instituted claims survived, 11, 19%

Mixed, 7, 12%

Motion to amend granted, 1, 2%

Excluding mixed results and including motion to amend as a “win” for the patent owner, the patent owner win rate in Final Written Decisions is 24% (12/50).

Compare to overall rate for patent owners 23% (338/1470) (Finnegan, aiablog.com, as of Feb. 1, 2018)

Source: Finnegan research as of April 22, 2018; 124 instituted IPRs. Does not include additional outcomes such as settled (14), adverse judgment requested (8), FWD pending (45).
Survival Rate By Type Of Claim In IPR Final Written Decisions

Source: Finnegan research as of April 22, 2018; 57 Final Written Decisions on the merits. There may be one more than one type of claim per petition. Chart does not include outcomes for apparatus-kit/device (0%, 0/3); product-by-process (0%, 0/1); product (1 mixed result); or system (2 all instituted claims unpatentable, 2 mixed).
PGR Challenges On Biologic Patents

Petitions filed

<table>
<thead>
<tr>
<th>Year</th>
<th>Petitions filed</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>1</td>
</tr>
<tr>
<td>2016</td>
<td>0</td>
</tr>
<tr>
<td>2017</td>
<td>0</td>
</tr>
<tr>
<td>2018</td>
<td>2</td>
</tr>
</tbody>
</table>
PGR Challenges On Biologic Patents

• Only 1 institution decision so far: granted.
• Grounds in petition: §§102, 103, 112a, 112b.
• Statutory disclaimer of all claims but 1.
• Instituted grounds: §§102 and 103 only.
• FWD - all instituted claims unpatentable under §102(a)(1).
• Claim was an apparatus claim:
  – 1. An apparatus to identify at least one component from a plurality of components in a fluid mixture, the apparatus comprising:....

*The other 2 bio-related PGRs, PGR2018-00033 and PGR2018-00059 are awaiting an institution decision.*
IPRs DO NOT VIOLATE THE CONSTITUTION

• *Oil States Energy Services, LLC v. Greene’s Energy Group, LLC*, 584 U.S. ___ (U.S., April 24, 2018)
  - 7-2 affirmed the Federal Circuit.
      - “Inter partes review involves the same basic matter as the grant of a patent. So it, too, falls on the public-rights side of the line.”
      - “The Constitution does not prohibit the Board from resolving it outside of an Article III court.”
      - “Because inter partes review is a matter that Congress can properly assign to the PTO, a jury is not necessary in these proceedings.”
    - Concurring: BREYER, Ginsburg, Sotomayor
    - Dissent: GORSUCH, Roberts
      - “Today’s decision may not represent a rout but it at least signals a retreat from Article III’s guarantees.”
FINAL WRITTEN DECISION MUST ADDRESS ALL CLAIMS IN PETITION

- *SAS Institute Inc. v. Iancu, Director, USPTO*, 584 U.S. ___ (U.S., April 24, 2018)
  - 5-4 reversed and remanded to the Federal Circuit.
    - Majority: GORSUCH, Roberts, Kennedy, Thomas, Alito
      - "when §318(a) says the Board’s final written decision ‘shall’ resolve the patentability of ‘any patent claim challenged by the petitioner,’ it means the Board must address every claim the petitioner has challenged."
    - Dissent: GINSBURG, Breyer, Sotomayor, Kagan
  - Dissent: BREYER, Ginsburg, Sotomayor, and Kagan (except as to Part III-A)
PTAB’s Post-SAS Guidance

• PTAB issued formal guidance on April 26, 2018

• PTAB will comply with Supreme Court interpretation of §318(a) by issuing Final Written Decisions that address the patentability of every claim and every ground set forth in the petition.

• While the PTAB noted that institution is still discretionary, if it decides to institute, from now on it will institute on all challenged claims and all grounds (all-or-nothing approach).
Pending IPRs

- If trial was instituted on less than all claims, or less than all grounds, then “the panel may issue an order supplementing the institution decision to institute on all challenges raised in the petition.”
  - Already seeing several instituted IPRs with orders retroactively instituting on all challenged claims/all grounds.

- If the panel enters an order supplementing the institution decision, “the panel may take further action to manage the trial proceeding.”
  - e.g., additional time and/or briefing, discovery, oral argument
IMPLICATIONS

• SAS will mean big shift in PTAB practice.
• May impact the PTAB’s statutory 12-month timeline.
• May see more remands from the Federal Circuit for insufficient reasoning by PTAB.
• The scope of IPR petitioner estoppel may be clarified since there will be no difference between claims in the petition and claims addressed in the Final Written Decision.
Pre-Lit/Due Diligence
Health Check

- Best mode requirement (still law)
- Derivation
- Compliance with §112(b)
- Priority assertions
- Eligibility for prior art exceptions (AIA §102(b)(a), (B), and (C))
- Double patenting
- Improper inventorship may be grounds for invalidating a patent, or grounds for a finding of inequitable conduct (if the requisite intent is found)
Remedial Measures from Inventorship issues in Health Check

- Correct inventorship, as needed
  - 35 U.S.C. §116 for applications
  - 35 U.S.C. §256 for patents

- Reissue to correct misjoinder (MPEP 1412.04)

- File continuation-in-part to combine full disclosures of both applications and claims of both applications and with inventor nomination of both.
Health Check: Implications of Ownership

- Real-party-in-interest in AIA post-grant proceedings (statutory requirement and impacts estoppel)
- § 102(b)(2)(C) common ownership exception to prior art
- § 102(c) Common ownership under joint research agreements
- Double patenting
- Loose ends with employees/former employees
- Need to tie down ownership to smoke out pre-existing obligations to assign; in U.S., co-owners have no accountability absent an agreement to contrary.
Common Inventors But Not Common Ownership

In re Hubbell, 709 F.3d 1140 (Fed. Cir. 2013)

• Inventors Hubbell and Schense at CalTech
  – Research resulted in ‘509 application (earliest priority April 3, 1997), patent assigned to CalTech.

• Hubbell and Schense left CalTech to join ETHZ
  – Research resulted in ’685 patent (earliest priority August 27, 1998), patent assigned to ETHZ and Universitat Zurich, and issued first.

• Examiner rejected ’509 application based on ODP over ’685 patent and Board affirmed.

• FC: Affirmed.
  – No common ownership or JRA, so terminal disclaimer not available.
  – No two-way obviousness analysis: Hubbell partially responsible for delay that caused ’685 patent to issue first.
Is There A Need For Supplemental Examination To Clear The Path To Enforceability?

35 U.S.C. § 257(a): “A patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent[.]

the “patent shall not be held unenforceable on the basis of ... information ...considered, reconsidered, or corrected during a supplemental examination of the patent.” (§ 257(c))

Does not apply against allegations already raised in district court or ANDA notice para. IV before date of filing request (§257(c)(2)(A)), or any defenses raised in ITC litigation/district court litigation unless SE and any reexam ordered there from is finished before the date on which the action is brought (§257(c)(2)(B)).
Burden On Patent Owners For Supplemental Examination

• Steep fee;

• Patent owner admissions;

• Limit to number of items that a patent owner may raise in a request for supplemental examination.
Looking For Additional BPCIA Patents On Inventions Beyond The Biologic Itself
I.S.O. Additional BPCIA Patents

- Patent claims tracking the results of clinical trials that will be included in the generic manufacturer’s label.

- Biologic combination therapy patents.

- New indications that are novel and nonobvious over the indications disclosed in the original biologics patent(s).

- Improved formulations patents, particularly for those formulations designed for large-scale randomized Phase III clinical trials.
Preparing For Challenges At The PTAB And District Court
U.S. Filings

Factors Influencing Biosimilar Applicant’s Decision to File IPR

- 12 year exclusivity period for reference product
- Biosimilar application can be filed 4 years after BLA approval
- Cost and timeline of litigation vs IPR

<table>
<thead>
<tr>
<th>ISSUE</th>
<th>PGR/IPR</th>
<th>DISTRICT COURT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burden of proof</td>
<td>Preponderance of the evidence</td>
<td>Clear and convincing evidence</td>
</tr>
<tr>
<td>Cost</td>
<td>$$</td>
<td>$$ $$</td>
</tr>
<tr>
<td>Presumption of Validity?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Time</td>
<td>statutory 12-month deadline from institution (may be extended to 18 months; so far, very rare to extend)</td>
<td>Pharma litigation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>D. Del. 31.8 months*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>D. NJ 34.8 months*</td>
</tr>
<tr>
<td>Claim construction</td>
<td>Broadest reasonable Interpretation (BRI)</td>
<td>Phillips/Markman framework: analyze claims, specification, and prosecution history to determine how claims would be understood by one of ordinary skill in the art</td>
</tr>
<tr>
<td>Decision maker</td>
<td>Patent Trial and Appeal Board (APJs)</td>
<td>District court judge or jury</td>
</tr>
<tr>
<td>Success rate for challenger/alleged infringer</td>
<td>49% (claims from TC1600)** (plus an institution rate of 62% (377/608)*** and institution decisions are not appealable)</td>
<td>pharma litigation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bench trial win rate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>D. Del. 33.1%*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>D. NJ 39%*</td>
</tr>
</tbody>
</table>

** Source: Finnegan, aiablog, as of Feb. 1, 2018.
*** USPTO stats, as of Feb. 28, 2018.
Timeline Of PTAB Proceedings

* Trial Proceeding Timeline

- **Petition Phase**
  - Petition Filed
  - PO Preliminary Response
  - Decision on Petition
  - PO Response & Motion to Amend Claims
  - PO Discovery Period

- **Trial Phase**
  - Petitioner Reply to PO Response & Opposition to Amendment
  - Petitioner Discovery Period
  - PO Reply To Opposition to Amendment
  - PO Discovery Period
  - Hearing Set on Request
  - Oral Hearing
  - Final Written Decision

* Time period set by Statute
* No more than 12 mos.
Tactical Advantages Favoring The Challenger At PTAB

• Challenger generally has time to plan attack, secure experts, and prepare detailed and compelling expert written reports.
• Low burden of proof for petitioner.
• PTAB weighs factual disputes at institution stage in favor of petitioner
• Strict limits on discovery.
• Motions to amend so far not granted very often.
• Petitioner estoppel not discouraging filings; Patent Owner estoppel is harsh.
Preemptive Thinking During Prosecution

• Develop a strong prosecution record
  – Can you establish defensible objective indicia of non-obviousness during prosecution?
  – Will a robust expert declaration be helpful?
• Develop multiple layers of patent protection
  – Composition
  – Method of use
  – Formulations
  – Methods of manufacturing
  – Delivery devices
• Can you maintain a continuation application pending?
Locate A Good Expert

• Experts are often the most important witnesses.

• Identify and retain multiple experts early
  – Patent Owner only has 3 months to submit a Patent Owner Preliminary Response
  – Challenger generally has time to plan attack, secure experts, and prepare detailed and compelling expert written reports.

• Will you use the same expert in an IPR and litigation?
  – May depend on how expert holds up in the IPR

• A good expert is not necessarily the most qualified expert.
  – A good expert must be a good witness.
Litigation
The Patent Dance

Biosimilar files Application → ? → Biosimilar Application accepted by FDA

20 days → Biosimilar provides confidential info to RPS → 60 days → RPS provides patent list to Biosimilar → 60 days → Biosimilar provides RPS with patent list and detailed statement

15 days → RPS provides Biosimilar with detailed statement → 60 days

Agreement reached → yes → RPS files complaint → no → Biosimilar identifies number of patents that can be asserted

30 days → RPS files complaint

Biosimilar identifies number of patents that can be asserted → 5 days → Simultaneous exchange of patent lists → 30 days → RPS files complaint

180 days before Biosimilar commercialization must notify RPS

42 U.S.C. § 262(l)
Questions Presented:

• Whether § 262(l)(2)(A)’s requirement that an aBLA applicant provide its aBLA and related manufacturing information to the reference product sponsor (RPS) may be enforced by an injunction under Federal law.

• Whether the § 262(l)(8)(A) notice of commercial marketing from a biosimilar applicant is legally effective if given before the FDA licenses the biosimilar product.
Disclosure of the aBLA

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application

42 U.S.C § 262(l)(2)(A)
Disclosure of the aBLA: Supreme Court Decision

The sole federal remedy for an applicant’s failure to disclose its aBLA and manufacturing information is a declaratory-judgment action:

- Failure to disclose under § 262(l)(2)(A) is NOT an act of infringement under § 271(e)(2)(C)(ii), so § 271(e)(4) is irrelevant.
- “When an applicant fails to comply with § 262(l)(2)(A), § 262(l)(9)(C) authorizes the sponsor, but not the applicant, to bring an immediate declaratory-judgment action for artificial infringement as defined in § 271(e)(2)(C)(ii) . . . . The remedy provided by § 262(l)(9)(C) excludes all other federal remedies, including injunctive relief.”
(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

42 U.S.C § 262(l)(8)(A)
180-Day Notice: Supreme Court Decision

180-day notice of commercial marketing can be provided before or after FDA approval.

- “Product licensed” in § 262(l)(8)(A) modifies “commercial marketing” rather than “notice.”
- Use of term “licensed” merely reflects fact that, on “date of first commercial marketing,” the product must be licensed.
- § 262(l)(8)(A) has only one timing requirement, unlike neighboring § 262(l)(8)(B)’s two timing requirements (after notice and before commercial marketing), showing Congressional intent.
- “Accordingly, the applicant may provide notice either before or after receiving FDA approval.”
“On remand, the Federal Circuit should determine whether California law would treat noncompliance with § 262(l)(2)(A) as ‘unlawful.’ If the answer is yes, then the court should proceed to determine whether the BPCIA pre-empts any additional remedy available under state law for an applicant’s failure to comply with § 262(l)(2)(A) . . . . The court is also of course free to address the pre-emption question first by assuming that a remedy under state law exists.”
State Law Claims: Fed. Cir. Decision on Remand

State law claims are not permitted under the BPCIA.

- The Federal Circuit “address[ed] the pre-emption question first by assuming that a remedy under state law exists.”
- Sandoz did not waive its preemption defense even though it was not raised below, *inter alia*, given the “especially compelling” “interest of justice [] at stake.”
- Both field and conflict preemption exist so as to bar any state law remedies:
  - Biosimilar litigation is “hardly a field which the States have traditionally occupied.”
  - “[S]tate laws imposing those penalties ‘would interfere with the careful balance struck by Congress.’”
What Does this all Mean?

• Biosimilar applicants dictate the pace of litigation.
  – Can significantly shorten nearly 8 months of “patent dance.”

• Biosimilar applicants can collapse two phases of litigation into one:
  – By providing 180-day notice as soon as the aBLA is filed.
What Patents Are Eligible For BPCIA Litigation?

- Within **60 days** after receiving copy of Biosimilar application RPS “shall provide”:
  - “A list of patents for which the reference product sponsor believes a claim of *patent infringement could reasonably be asserted*” and
  - “Identification of the patents . . . that the reference product sponsor would be *prepared to license* to the” Biosimilar applicant

42 U.S.C. § 262(l)(3)(A)
Generate Your Own Orange/Purple Book

- Identify all patents that may reasonably be asserted
  - Not only your own, but those you have exclusively licensed in

- Assess strengths and weaknesses

- While you are required to list all patents that may reasonably be asserted you do not have to sue on all of them
  - Are there strategic reasons to not assert all patents?
Patent Infringement Issues Relevant To BPCIA Claims

• What is your strategy if the biosimilar applicant discloses its aBLA?
  – Likely dictated, to an extent, by BPCIA “patent dance”

• What is your strategy if the biosimilar applicant is unwilling to disclose its aBLA?
  – File a DJ on:
    – All patents?
    – Some patents?

• Do you have a good faith basis to assert infringement if aBLA not provided?
Patent Validity Issues Relevant To BPCIA Claims
Are Us Patent Claims Subject To Litigation Under The BPCIA Definite Under The Current Standards?

**In Court:** *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120 (U.S. 2014)

standard: “a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with **reasonable certainty.**”

**In the USPTO (including PTAB):** *In re Packard*, 751 F.3d 1307 (Fed. Cir. 2014) (per curiam)

MPEP §2173.05(e): “A claim is indefinite when it contains words or phrases whose meaning is unclear.”

“If the scope of a claim would be **reasonably ascertainable** by those skilled in the art, then the claim is not indefinite.”
Health Check: Indefiniteness: What to Look For

- Analyze key patents and relevant claims to search for any potential ambiguities.

- Looking for claim language that could raise questions about clarity and “reasonable certainty” under 35 U.S.C. §112(b), e.g., relative terms, words of degree, ranges without end points at both ends, inconsistently used terms, undefined terms.

- More than one method to measure a parameter, different methods may provide different results, and no direction as to which method to use.

- Breadth alone is not indefiniteness.
Remedial Measures Emanating from Health Check

- Consider expert declaration to support what a POSITA would understand.
- Consider expert declaration explaining the degree of precision available (or lack thereof) in the relevant art at the relevant time.
- Consider reissue possibilities.
- Consider continuation possibilities.
Do The BPCIA Claims Possess Written Description Support Under The Current Standards?

**In Court:** AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285 (Fed. Cir. 2014)

“the written description requirement with respect to particularly claimed subject matter is met if the specification shows that the stated inventor has in fact invented what is claimed, that he had possession of it.”

**In the USPTO:** MPEP 2163.02
Support for the Claimed Subject Matter in Disclosure

“the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.”
In Health Check, Apply Teachings from Ariad Pharmaceuticals v. Eli Lilly
598 F.3d 1336 (Fed. Cir. 2010) (en banc)

• Enablement and written description are separate requirements.

• Question of fact how much disclosure is required; no bright-line rule: “the level of detail required ...varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.”

• Obviousness not enough: “a description that merely renders the invention obvious does not satisfy the requirement”
Written Description: What to Look For in the Health Check?

- Result without means of achieving (just a hope or plan);
- Broad claim with little support in specification such as a genus claim or functionally described structure with few or no species described in specification;
- Unsupported claim limitations;
- Attempts to cherry pick the original disclosure to specifically claim narrow subject matter later discovered to be valuable;
- Substantial claim amendments made during prosecution;
- Priority chain support; and
- Could a POSITA conclude with “reasonable certainty” that patentee had “possession” of claimed invention?
Remedial Measures Emanating from Health Check: Written Description

- Consider expert declaration to support what a POSITA would understand.
- Consider inherency arguments.
- Consider amending claims.
  - Reissue;
  - Continuations;
  - Motion to amend in post-grant proceeding.
**Are The BPCIA Claims Enabled Under The Current Standards?**

**In Court:** Claims are not enabled when, at the effective filing date of the patent, one of ordinary skill in the art could not practice their full scope without undue experimentation. *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1380–81 (Fed. Cir. 2012).

**In the USPTO:** MPEP 2164.01 Did the “disclosure, when filed, contain[] sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention[?]” “The standard for determining whether the specification meets the enablement requirement...: is the experimentation needed to practice the invention undue or unreasonable? ... In re Wands, 858 F.2d 731, 737, ...(Fed. Cir. 1988).”
Health Check for Enablement: What to Look For?

- Are claims objectively enabled?
- Routine v. undue experimentation;
- Proper/improper use of post-filing evidence? (can only reflect state of art at time of filing);
- Priority date assertions;
- Claims enabled throughout scope?
Remedial Measures For Enablement from the Health Check

• Consider expert declaration to support what a POSITA would understand.

• Consider reissue possibilities.

• Consider continuation possibilities.
What Is The Situation With Patent Term Extension?
35 U.S.C. § 156

- 35 U.S.C. § 156 provides for patent term extensions for a patent that claims a product, a method of making a product, or a method of using a product that has been subject to premarket regulatory review before it is approved for commercial marketing in the United States.

- Extension = ½ (testing phase) + approval phase - any time applicant did not act with due diligence

  - Not to exceed 5 years from patent expiration, exclusive of any regulatory review period occurring before the patent issues §156(g)(6) or not to exceed 14 years from NDA approval § 156(c)(3), whichever comes first.
PTE and ODP

- ODP does not trump PTE *(Gilead does not apply)*: *Kowa Co., Ltd. v. Amneal Pharms., LLC*, 1:14-cv-02758

THANK YOU

M. Paul Barker
Finnegan
Stanford Research Park
3300 Hillview Avenue
Palo Alto, CA 94304-1203
+1 650 849 6620
paul.barker@finnegan.com

Sanya Sukduang
Finnegan
901 New York Avenue, NW
Washington, DC 20001-4413
+1 202 408 4377
sanya.sukduang@finnegan.com

Steven P. O’Connor, Ph.D.
Finnegan
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190-5675
+1 571 203 2718
steven.oconnor@finnegan.com