BIOSIMILARS: “THE PATENT DANCE”
“I Won’t Dance/Don’t Ask Me”

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## 2018-2019 FDA Biosimilar Approvals

<table>
<thead>
<tr>
<th>Biosimilar Drug</th>
<th>Biologic Drug</th>
<th>FDA Approval</th>
<th>Launch Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ontruzant® (Samsung Bioepis / Merck)</td>
<td>Herceptin® (Genentech)</td>
<td>January 20, 2019</td>
<td></td>
</tr>
<tr>
<td>Herzuma® (Celltrion/Teva)</td>
<td>Herceptin® (Genentech)</td>
<td>December 17, 2018</td>
<td></td>
</tr>
<tr>
<td>Truxima® (Celltrion/Teva)</td>
<td>Rituxan® (Roche/Genentech)</td>
<td>November 28, 2018</td>
<td></td>
</tr>
<tr>
<td>Udenyca™ (Coherus)</td>
<td>Neulasta® (Amgen)</td>
<td>November 2, 2018</td>
<td>January 3, 2019</td>
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<tr>
<td>Hyrimoz™ (Sandoz)</td>
<td>Humira® (AbbVie)</td>
<td>October 31, 2018</td>
<td>2023 per settlement</td>
</tr>
<tr>
<td>Nivestym™ (Pfizer)</td>
<td>Neupogen® (Amgen)</td>
<td>July 20, 2018</td>
<td>October 1, 2018</td>
</tr>
<tr>
<td>Fulphila™ (Mylan / Biocon)</td>
<td>Neulasta® (Amgen)</td>
<td>June 4, 2018</td>
<td>July 26, 2018</td>
</tr>
<tr>
<td>Retacrit® (Pfizer / Hospira)</td>
<td>Epogen® / Procrit® (Amgen / J&amp;J)</td>
<td>May 15, 2018</td>
<td>November 12, 2018</td>
</tr>
</tbody>
</table>
The BPCIA “Patent Dance”

- Biosimilar files Application
- Biosimilar application accepted by FDA
- Biosimilar provides confidential info to RPS
- RPS provides patent list to Biosimilar
- Biosimilar provides RPS with patent list and detailed invalidity/noninfringement statement
- RPS provides Biosimilar with detailed statement re infringement and response re validity
- RPS & Biosimilar negotiate final list of patents to litigate
- Biosimilar identifies number of patents that can be asserted
- Simultaneous exchange of patent lists
- RPS files complaint
- Notice of commercialization 180 days before marketing (anytime after FDA acceptance)
- Second Wave of Litigation
To Dance or Not to Dance?

Benefits of Dancing for the Biosimilar*

- Biosimilar controls the number of patents-in-suit
- Biosimilar ensures that certain patents are in the first-wave litigation
- Biosimilar will know the timing of RPS’s complaint
- Early exchange of contentions provides insight into strength of RPS’s infringement and validity positions—but vice versa
- Biosimilar retains the ability to file a declaratory judgment action
- RPS must list all patents or lose right to assert them (“list it or lose it”)**
- RPS’s relief may be limited to a reasonable royalty if it does not comply with strict time restrictions


**See Coggio and Vogel, “Can A Reference Sponsor Forfeit Right To Sue Under The BPCIA?” Law 360 (July 25, 2016)
To Dance or Not to Dance?

Drawbacks of Dancing for the Biosimilar

- Biosimilar must provide confidential information (including manufacturing details) up front (Most asserted patents are process patents.)
- Takes up to 8 months
- Consequences to skipping parts of the dance once started
  - 30-day clock for RPS to file suit is not triggered
  - Biosimilar may be barred from bringing DJ action
- Biosimilar will need to stake out early positions on invalidity and non-infringement that could possibly be used as admissions in litigation
To Dance or Not to Dance?

Drawbacks of Not Dancing for the Biosimilar

- RPS can bring suit on any patent that claims the biological product or its use (42 U.S.C. § 262(l)(9)(C))

- Filing an aBLA is an “act of infringement” under 35 U.S.C. § 271(e)(2)(c)(ii) and covers “any patent that could be identified” in RPS’ § 3A list, which includes process patents

- Thus, RPS can assert all patents without fear of Rule 11 sanctions

- RPS need not list relevant patents § 3A and avoids any “list it or lose it” problems

- Biosimilar’s failure to participate in the dance may be relevant to any RPS motion for a preliminary injunction
## Comparison of the Hatch-Waxman Act and The BPCIA

<table>
<thead>
<tr>
<th>HATCH WAXMAN ACT</th>
<th>BPCIA</th>
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<tbody>
<tr>
<td><strong>Patents identified</strong></td>
<td>Orange Book listing of patents (no process patents), certified against by generic applicant (Para. IV certification)</td>
</tr>
<tr>
<td><strong>Application types</strong></td>
<td>ANDA or § 505(b)(2) “paper NDA”</td>
</tr>
<tr>
<td><strong>FDA stay</strong></td>
<td>Automatic 30-month stay of FDA approval upon filing suit</td>
</tr>
</tbody>
</table>
| **Sponsor exclusivity** | Five-year marketing exclusivity for new active moiety commencing on FDA approval | Twelve-year marketing exclusivity for new biological structures commencing on FDA approval:  
- But if application is filed by same Sponsor or manufacturer of the Sponsor’s product (or a licensor, predecessor-in-interest or a related party), the changed biological structure must also result in:
  - A change in indications, route of administration, dosing schedule, dosing form, delivery system, delivery device or strength, or
  - A change in safety, purity, or potency |
| **Sponsor exclusivity** | Three-year marketing exclusivity for new indication or dosage form | No additional exclusivity for same biological structure |

### HATCH WAXMAN ACT

**ANDA—First to file and to certify under Para. IV (challenging Orange Book patents) receives 180 days of market exclusivity against later-filed ANDAs**
- Can be forfeited under various conditions
- § 505(b)(2)—no 180-day exclusivity

### BPCIA

**Generic exclusivity**
- No exclusivity for biosimilar. First interchangeable biosimilar receives exclusivity against any subsequent interchangeable license application for any condition of use in the Sponsor’s product until the earlier of:
  - One year after commercial marketing by first biosimilar;
  - Eighteen months after court decision (appellate court, if appealed) on all patents or dismissal of action against first biosimilar; or
  - Forty-two months after first biosimilar approval if litigation is still pending, or 18 months after first biosimilar approval if no suit is filed (i.e., where first biosimilar fails to market)

**Pediatric exclusivity**
- Pediatric exclusivity adds 6 months to all exclusivities

**Filing limitation**
-ANDA cannot be filed until 5 years after Sponsor’s FDA approval of new active moiety, but can be filed after 4 years if accompanied by a Para. IV certification
- Biosimilar application can be filed 4 years after Sponsor’s FDA approval