Hot and Hostile: Recent Developments in SPCs and Patent Term Extensions
Pharma Session 3

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• Takeshi S. Komatani, SHUSAKU•YAMAMOTO (JP)
What is Protected?

Similarities and differences by jurisdiction

What is – or is not – a new product?
EU – Article 1: Definitions

‘medicinal product’ means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

‘product’ means the active ingredient or combination of active ingredients of a medicinal product;
EU – Article 3: Conditions for obtaining a certificate

a) the product is protected by a basic patent in force;

b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

c) the product has not already been the subject of a certificate;

d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.
EU – Article 4: Subject matter

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.
US – Patent Term Extension

• Available 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 = \( \frac{1}{2} \) (testing phase) + approval phase - any time applicant did not act with due diligence
  - Not to exceed 5 years from patent expiration, or 14 years from NDA approval – whichever comes first
US – Requirements for PTE

• Term of the patent has not expired before an application for PTE is submitted
• Patent has never previously received PTE
• Product has been subject to a regulatory review period before its commercial marketing or use
• Permission for the commercial marketing or use of the product is the first permitted commercial marketing or use of the product
JP – Article 67 et seq: Requirements

- Article 67(2): Period during which it is not possible for a person to work the patent invention due to the need to ... ensure safety, etc. or any other disposition*
  - *[human or veterinary] “pharmaceuticals,” “in vitro diagnostics,” “regenerative medicine products,” and “agricultural chemicals”
  - But “medical devices” are excluded

- Only Patent Owner can file for PTE
  - Licensee who obtained regulatory approval in Japan cannot file
  - However, Patent Owner can file based on an approval which was obtained by its licensee

- Application for Patent Term Extension
  a) Copy of the regulatory approval;
  b) Copy of the IND (including IND filed with foreign authority, if any); and
  c) License agreement (if any)

Extension = (Date of Registration or First date of clinical trial, whichever later) -> (Approval Date)
Not to exceed 5 years from patent expiration
Scope of Protection

Recent Developments

New indications, formulations, or other?

Impact on PTE/SPC for biologics?
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JP – Article 68bis: Scope

If the term of a patent right is extended (including if the term is deemed to have been extended pursuant to Article 67-2, paragraph (5)), the patent right is not effective against any act other than the working of the patented invention for the product that was the subject of a disposition designated by Cabinet Order as referred to in Article 67, paragraph (2) which constituted the grounds for the registration of the extension (when the specific use of the product is prescribed in the disposition, the product as it is used for that usage).
JP – Article 67ter (historical review)

• 1\textsuperscript{st} Regime (before 2011): First Approval Rule
  – The regulatory approval must be the first approval received with respect to the Product (active ingredient) and Use (indication/effect).

2011 Supreme Court Decision (Pacif capsule case)

• 2\textsuperscript{nd} Regime (2011-2015): All Technical Feature Rule
  – Condition 1: All the technical features of the relevant claims must be identified in the newly approved drug.
  – Condition 2: No drug that possesses all technical features of the broadest claim of the relevant patent had been approved for the same indication.

2015 Supreme Court Decision (VEGF(Bevacizumab) case)

• 3\textsuperscript{rd} Regime (2016- ): Approval Based Rule
  – Any PTE is granted as long as the approval on which it is based on can be distinguished from any existing approvals.
  – Distinction is based on any substantive marketing approval conditions including ingredients, quantity, dosage regimen, effect and efficacy
### JP – Model Cases

<table>
<thead>
<tr>
<th>Broaddest Claims</th>
<th>First Approval</th>
<th>Second Approval</th>
<th>Third Approval</th>
<th>Fourth Approval</th>
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<tbody>
<tr>
<td><strong>Compound X</strong></td>
<td><strong>Anticancer Injection 5mg daily</strong></td>
<td><strong>Anticancer Injection 10mg daily</strong></td>
<td><strong>Anticancer Tablet 5mg daily</strong></td>
<td><strong>Anticancer Injection 50mg Once/week</strong></td>
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<td>Patent A Compound X</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; - 3&lt;sup&gt;rd&lt;/sup&gt;: YES</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;/2&lt;sup&gt;nd&lt;/sup&gt;: NO 3&lt;sup&gt;rd&lt;/sup&gt;: YES</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;/2&lt;sup&gt;nd&lt;/sup&gt;: NO 3&lt;sup&gt;rd&lt;/sup&gt;: YES</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;/2&lt;sup&gt;nd&lt;/sup&gt;: NO 3&lt;sup&gt;rd&lt;/sup&gt;: YES</td>
</tr>
<tr>
<td>Patent B A pharmaceutical composition for treating cancer</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; - 3&lt;sup&gt;rd&lt;/sup&gt;: YES</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;/2&lt;sup&gt;nd&lt;/sup&gt;: NO 3&lt;sup&gt;rd&lt;/sup&gt;: YES</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;/2&lt;sup&gt;nd&lt;/sup&gt;: NO 3&lt;sup&gt;rd&lt;/sup&gt;: YES</td>
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<tr>
<td>Patent C Injectable comprising compound A</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; - 3&lt;sup&gt;rd&lt;/sup&gt;: YES</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;: NO 2&lt;sup&gt;nd&lt;/sup&gt;/3&lt;sup&gt;rd&lt;/sup&gt;: YES</td>
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<td>1&lt;sup&gt;st&lt;/sup&gt;/2&lt;sup&gt;nd&lt;/sup&gt;: NO 3&lt;sup&gt;rd&lt;/sup&gt;: YES</td>
</tr>
<tr>
<td>Patent D A pharmaceutical composition characterized in once/week regimen</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; - 3&lt;sup&gt;rd&lt;/sup&gt;: NO</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; - 3&lt;sup&gt;rd&lt;/sup&gt;: NO</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; - 3&lt;sup&gt;rd&lt;/sup&gt;: NO</td>
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JP – *Debio Pharm v. Towa*
IPHJC-J, Jan. 20, 2017

**Before the Decision:**
Product: Product (API)
Usage: (Indication)

**After the Decision:**
Product: ingredients (*NOT LIMITED TO API*), quantity,
Usage: dosage regimen, effect and efficacy will be limiting factor when interpreting the extended scope of the claims + equivalent thereof

—–>even a generic drug may not be covered by the extended scope!
JP - *Debio Pharm v. Towa* (Impact)

• Elplat case (oxaliplatin)

• Patented Claim in suit
  – Pharmaceutically stable formulation ... **consisting of:**
  – an aqueous solution of oxaliplatinum ....
  – Specification describes “no other additives are contained”

• Innovator’s formulation
  – Elplat i.v. infusion (i.e. consisting of oxaliplatinum and water (for infusion))

• Generic’s formulation
  – comprising oxaliplatinum, water and **conc. glycerin**

→ **outside the scope of extended scope**
US – Scope of Protection

Rights in extended term limited to:

• Patent claiming a product: any use approved for the product before the expiration of the term of the patent

• Patent claiming a method of using a product: any use claimed by the patent and approved for the product before the expiration of the term of the patent

• Patent claiming a method of manufacturing a product: the method of manufacturing as used to make the approved product
Implications/Predictions

Third-party SPCs

SPC manufacturing waiver

Is the value of a PTE/SPC changing?
Thank you for your attention!