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Patent protection strategies in Russia

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Outline

• Overview of Russian & Eurasian patent systems
• Strategies to secure strong patent protection
• Patent term extension, data protection
• Appeal & Invalidation, IP Court

(Examples: life sciences)
Protecting inventions in Russia: options

- Russian national patent and Eurasian regional patent
- Russian patent
  - covers Russia
- Eurasian patent
  - covers 8 contracting states:
    - Russia
    - Azerbaijan
    - Belarus
    - Tajikistan
    - Kazakhstan
    - Turkmenistan
    - Armenia
    - Kyrgyzstan

Russian Patent System

- Russian Patent Office (RPO), Moscow
  - Website: http://www.rupto.ru

- Legislation:
  - Civil Code of the Russian Federation, part IV
    (in particular, Chapter 72 “Patent Law”)
  - Administrative Regulations
Eurasian Patent System

- Eurasian Patent Organization (inter-governmental)
- Eurasian Patent Office (EAPO), Moscow
  Website: http://www.eapo.org

- Legislation:
  - Eurasian Patent Convention (EAPC)
  - Regulations under EAPC
  - Rules of compiling, filing and considering

Eurasian Patent System

- inventions only
- single application to EAPO, single patent covering 8 EA states
- language: Russian
- once granted, patent is validated in chosen EA states
- non-EA applicants: via Eurasian Patent Attorney
Russian vs. Eurasian Patent

- RU and EA patents for the same invention may co-exist
- Choosing of RU and/or EA route depends on business interests
- Life of RU and EA patents: more similarities than differences
- Costs: considerably lower official fees in Russia

Russian vs. Eurasian Patent: official fees

- Examples:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>RU</th>
<th>EA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filing application</td>
<td>1650 RUR (45 USD) for up to 25 claims 250 RUR (7 USD) for each extra claim</td>
<td>25500 RUR (710 USD) for up to 5 claims 3200 RUR (90 USD) for each extra claim</td>
</tr>
<tr>
<td>Request for substantive examination</td>
<td>2450 RUR (70 USD) 1st claim 1950 RUR (55 USD) claims 2-10 3100 RUR (85 USD) claims 11-…</td>
<td>25500 RUR (710 USD) 1st claim 19000 RUR (630 USD) 2nd claim 9500 RUR (265 USD) 3rd, 4th, 5th claim</td>
</tr>
<tr>
<td>Amendments (substantive examination stage)</td>
<td>only 2350 RUR (65 USD) for each new independent claim</td>
<td>6400 RUR (180 USD) any amendment + 19000 RUR (630 USD) 2nd (new) independent claim 9500 RUR (265 USD) 3rd, 4th, ... (new) independent claim 2200 RUR (60 USD) increase in number of claims by 1</td>
</tr>
</tbody>
</table>
**General information**

- **Patent term** for inventions: 20 years from the filing date of the original application (international filing date for PCT)
- **Patent term extension** is available (see later)
- **Invention** (RU): technical solution relating to product or process (EA): man-made or man-modified object or process
- **Patentability criteria**: novelty, inventive step, industrial applicability
- **Scope of protection** is defined solely by set of claims

**General information 2**

- 6-month **grace period** in case of disclosure before filing the application
- **Divisional application** may be any time filed before registration
- **PPH** is available

<table>
<thead>
<tr>
<th>RPO</th>
<th>EAPO</th>
</tr>
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<tbody>
<tr>
<td>- Japanese PO</td>
<td>- Japanese PO</td>
</tr>
<tr>
<td>- Chinese PTO</td>
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<tr>
<td>- United States PTO</td>
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<td>- Korean IPO</td>
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<td>- Finnish PO</td>
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<td>- Spanish PTO</td>
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<td>- Danish PTO</td>
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</table>
### Cannot be patented:

<table>
<thead>
<tr>
<th>Russia</th>
<th>Eurasia</th>
</tr>
</thead>
<tbody>
<tr>
<td>• methods for cloning humans</td>
<td>• inventions commercial use of which needs to be prevented for the purposes of protecting public order and morality, including protection of life and health of humans and animals or protection of plants, or to avoid serious damage to the environment</td>
</tr>
<tr>
<td>• methods for modifying generic integrity of human germline cells</td>
<td></td>
</tr>
<tr>
<td>• use of human embryos for industrial and commercial purposes</td>
<td></td>
</tr>
<tr>
<td>• other solutions contradicting public interests, principles of humanity and morality</td>
<td></td>
</tr>
</tbody>
</table>

### Not protected as inventions

<table>
<thead>
<tr>
<th>Russia</th>
<th>Eurasia</th>
</tr>
</thead>
<tbody>
<tr>
<td>• discoveries</td>
<td>• discoveries</td>
</tr>
<tr>
<td>• scientific theories and mathematical methods</td>
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</tr>
<tr>
<td>• solutions concerning solely the outward appearance of manufactured articles and intended to satisfy aesthetic requirements</td>
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</tr>
<tr>
<td>• computer programs;</td>
<td>• algorithms and computer programs;</td>
</tr>
<tr>
<td>• solutions concerning solely presentation of information.</td>
<td>• presentation of information;</td>
</tr>
<tr>
<td>• topographies of integrated circuits</td>
<td>• topographies of integrated circuits;</td>
</tr>
<tr>
<td>• rules and methods of games and for intellectual or business activity;</td>
<td>• plant varieties and animal breeds</td>
</tr>
<tr>
<td>• varieties of plants, breeds of animals and biological methods of obtaining thereof with the exception of microbiological methods and products obtained by the use of such methods</td>
<td>• projects and plans for structures and buildings and for land development;</td>
</tr>
<tr>
<td></td>
<td>• methods of economic organization and management;</td>
</tr>
<tr>
<td></td>
<td>• symbols, schedules and rules;</td>
</tr>
<tr>
<td></td>
<td>• methods for performing mental acts</td>
</tr>
</tbody>
</table>
“Medical” claims: acceptable formats

- Method claims, including methods of treatment
- Use claims, including “1st” and “2nd medical use”
- Advice: good to have a product claim
  - drawing a product claim from “use of known product”
    claim is possible by rewording generic concept
- Example:
  from “Use of enzyme X as colon cancer marker...”
  to  “Colon cancer marker being enzyme X...”

Life of Russian/Eurasian Patent

Applying

Formal examination

Search

Substantive examination

Refusal

Appeal

Grant

Maintenance

IP Court
Application prosecution

- **Formal examination**
  - RU: multiple dependency claims cannot depend from multiple dependency claims

- **Substantive examination**: 2-3 Office Actions:
  1) evaluation of unity of invention
     - RU unity requirement: interrelated or variant inventions
     - EA unity requirement: PCT-like (Rule 13 of the Regulations under the PCT)
  2) evaluation of compliance with 3 patentability requirements

Application prosecution 2

- RU: “industrial applicability” assessment: is the scope of claims realistic/justifiable in the light of the available experimental data?
  - “lack of support” objection is raised if scope of claim exceeds scope of experimental data or is not reflected in experimental data
  - more experimental data and/or limitation of claims is requested
  - arguing back may suffice

- Example: claiming protein with 95% identity to “confirmed” one may be justified solely by prior art

- **Inventive step**: non-obviousness, typically evaluation of superiority over closest analog (prototype)
Patent term extension (RU)

- Available for **medicament, pesticide or agrochemical** that requires marketing authorization (MA)
- Extension = time between filing date and date of receipt first MA minus 5 years
- Cannot exceed 5 years
- PTE is not automatic: has to be applied for by patent holder to the Russian Patent Office (“filing PTE request”)
- Extended are relevant claims, not whole claim set

Patent term extension (RU) 2

For **medicaments**, eligible claims are directed to:

- compound, group of compounds of general structure, crystal forms, polymorphs, etc.
- composition, combination, formulation, dosage form, etc.
- use in formats:
  - use of A for treatment of Y or
  - use of A for manufacturing medicament for treatment of Y
- kit (substance + device/package/instructions, etc.)
- method for treatment
Patent term extension 3

- **Notification of PTE grant** is enclosed to letters patent
  - extended patent term expiry date, relevant claims

- **Eurasia**: PTE available in all states, except Tajikistan
  - procedure, terms, documents - according to national legislations
  - validity term of Eurasian patent may be extended in chosen EA states

Data exclusivity protection

- Russian law “On circulation of medicaments”, Article 18(6) prohibits *obtaining, disclosure and use, for the purposes of registration, of information on preclinical and clinical studies provided by the applicant for registration, without his consent during 6 years since the registration*.

- 6-year term, does not prohibit registration as such

- No regulations yet

- Consequence: no accelerated examination procedure for generics (Article 26)
Appeal/invalidation

Contesting
- Decision to Refuse Granting (appeal)
- Decision to Grant (invalidation)

Russia:
- to Chamber of Patent Disputes (CPD)
  - appeal: within 6 months from Decision
  - invalidation: any time during patent term

Eurasia:
- appeal: to EAPO within 3 months from Decision
- invalidation:
  - within 6 months from grant – to EAPO
  - after that – separately to each chosen EA state

Appeal

- Amending claims is possible
  - deletion of claims, conversion of dependent into independent
  - correction of technical errors (misprints, omissions, etc.)
  - deletion of non-essential features;
  - inclusion of disclaimers;
  - including features disclosed in original application materials

Russia
- possible to submit further supporting data
- claims may only be amended once

Eurasia
- possible to change subject-matter
Invalidation

Reasons for invalidation:

Russia
- non-compliance with patentability conditions
- claim features missing in description on filing date
- more than one application for the same invention, with the same priority date
- incorrect indication of authors & patent holders

Eurasia
- non-compliance with patentability conditions
- claim features missing in description on filing date
- incorrect indication of authors & patent holders

Invalidation 2

- Invalidation may be full or partial
- Full invalidation: patent is cancelled from the filing date
- Partial invalidation: claims are limited

Russia
- like appeal, but no inclusion of features from specification

Eurasia
- only deletion of claims or conversion of dependent to independent

- Eurasia: patent holder may also abandon or limit patent in chosen EA states
IP Court

• Location: Moscow
• Recently established (2013)
• Specialized court for dealing with IPR disputes, such as:
  - Infringement of patent rights
  - Contesting decisions of CPD
• First hearing was on Aug 6, 2013
• Court staff: Presiding judge + 17 judges + technical experts

Thank you for your attention!

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