Generics Perspective:
Role of Intellectual Property

Roman Lapka,
Director Intellectual Property, Zentiva a.s.
CEE IP legislation: fully harmonized, practice converging

- **IP laws**
  - Patents, SPC, utility models, trademarks, copyright
- **Pharma law**
  - Data exclusivity 8+2+1
- **Civil, criminal & company laws**
  - Enforcement of IP rights
- **Practice: diminishing country differences**
  - *convergence factors*
    - EP, community SPC, community pediatric SPC, community TM, community data exclusivity, EPLA?, community patent?
  - *divergence factors*
    - Local patents, local SPC, local DE
    - Enforcement
CEE specifics

• „patent window“
  – Discrepancy between harmonized patent laws and reality
    • Limited retroactivity of law
    • Applicants differ in their attitude to apply for patents

• High generic penetration
  – Branded generics
  – Low prices
  – Strong local players, some of them became strong regional players
  – Vertical and horizontal integration – relatively independent
  – GxP compliant

• Problematic reinforcement of law
  – Courts, police, custom
    • Missing laws, inexperienced staff, unwillingness, corruption
Zentiva: who we are

• No 1 generic player in 5 aggregated markets
• Number one in Czechia, Romania and Slovakia
• Fastest growing company in Poland and Russia
• New acquisition in Turkey
Our IP mission: not to infringe third parties IP rights
Dominant Position in Czech, Romanian and Slovak Markets; number 3 in Turkey

Clear Generics Leader in Czech Republic…

Market Share (Value of Generics market)

- **Zentiva**: 50%
- **Ivax**: 8%
- **Krka**: 7%
- **Menarini**: 5%
- **Ratiopharm**: 4%

… and Slovakia

Market Share (Value of Generics market)

- **Zentiva**: 59%
- **Ratiopharm**: 10%
- **Gedeon Richter**: 8%
- **Krka**: 6%
- **Menarini**: 6%
## Focused on Attractive Branded Generics Markets

<table>
<thead>
<tr>
<th>Zentiva Core Markets</th>
<th>Czech Rep</th>
<th>Slovakia</th>
<th>Poland</th>
<th>Russia</th>
<th>Germany</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Value Penetration(^{(1)})</td>
<td>34%</td>
<td>24%</td>
<td>40%</td>
<td>34%</td>
<td>21%</td>
</tr>
<tr>
<td>Branded Prescribing(^{(2)})</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Payment(^{(2)})</td>
<td>Predominantly National Health Insurance</td>
<td>Predominantly National Health Insurance</td>
<td>Predominantly National Health Insurance</td>
<td>Predominantly cut-of-pocket</td>
<td>Predominantly National Health Insurance</td>
</tr>
<tr>
<td>Co-payment Practice(^{(2)})</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Pricing(^{(2)})</td>
<td>Reference</td>
<td>Reference</td>
<td>Reference</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>Pharmacist Substitution(^{(2)})</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Predominantly No</td>
</tr>
<tr>
<td>Therapeutic Categories(^{(3)})</td>
<td><img src="image1" alt="Therapeutic Category Pie Charts" /></td>
<td><img src="image2" alt="Therapeutic Category Pie Charts" /></td>
<td><img src="image3" alt="Therapeutic Category Pie Charts" /></td>
<td><img src="image4" alt="Therapeutic Category Pie Charts" /></td>
<td><img src="image5" alt="Therapeutic Category Pie Charts" /></td>
</tr>
</tbody>
</table>

---

\(CVS\): \(\text{Alimentary}\) | \(\text{CNS}\) | \(\text{Respiratory System}\) | \(\text{G.U. System & Sex Hormones}\) | \(\text{Musculo-Skeletal System}\) | \(\text{Anti-Infectives}\) | \(\text{Other}\)

---

\(^{(1)}\) Generic Value Penetration
\(^{(2)}\) Branded Prescribing, Payment, Co-payment Practice, Pricing, Pharmacist Substitution
\(^{(3)}\) Therapeutic Categories
Integrated, Scaleable and Low Cost Business Processes

Best in Class Cost and Efficiency

Efficiency through

- Rigorous process management
- Leading IT infrastructure

Efficiency with low cost environment allows for most competitive pricing while retaining leading margins
Business concept
Primary care & prevention

Promotion to doctors
Generating prescription

Promotion in pharmacies
Generating orders

Promotion to consumers
Generating demand
Business strategy

• **Company goals**
  – CZ, SK, RO, TR markets – keep the highest possible market share
  – CEE region – to be a leading player

• **R&D and M&S goals**
  – Full product availability
  – Price competitiveness
  – High share of new products
  – First to market
  – To be a market leader in all chosen molecules
Research and development

- 3 R&D sites (Prague, Luleburgaz, Hlohovec)
- Active ingredient and formulation development
- Vertical and horizontal integration
- 250 staff
- 150 projects ongoing
- Efficient management
- Business strategy integrated into product portfolio
- High quality registration documentation
Typical time frame of product development

API dev

DF dev

Brand launch

- 4-5

Pat exp

12-15 y
How do we work in IP field

- **Corporate patent dept**
  - Detailed patent search
  - Decisions
  - Coordination
  - Own patent applications

- **Global external PF**
  - Complex cases (EP, more countries)
  - Legal advise & coordination
  - Case performance

- **Local attorney**
  - Country specific cases

- **Local Zentiva office**
  - Information
  - Liaison officer
Strategy differs

Third party IPR

- Patent status
  - Granted
  - Application
    - EP within 9 m
    - EP after 9 m
    - National

- Patent type
  - Product other
    - Process
    - Use

- Product relevance
  - Blockbuster
  - Less important

- Patentee
  - Originator

- Geography
  - EU
  - Non EU
Decision tree – patent application

Application

Product, e.g. polymorph
- Different form
  - Own application
    - Third party observation
      - Wait
        - Be prepared for granting
  - Third party observation
    - Wait
      - Be prepared for granting

Process
- Different process
  - Own application
    - Third party observation
      - Wait
        - Be prepared for granting
  - Third party observation
    - Wait
      - Be prepared for granting

Use
- Opposition
- Wait
  - Be prepared for granting
- Third party observation
„Blocking“ patents, „ever-greening“

- **Aim:** to block competitors
- **Characteristics:** low inventive step
  - Salts
  - Solvates
  - Derivatives
  - Precursors
  - Metabolites
  - Polymorphs
  - Enantiomers
  - Sometimes
    - Galenic preparations
    - New processes
    - 2nd indication

**Examples:**
- Citalopram
- Perindopril
Opposition: grounds & evaluation

- Lack of novelty
  - 2/3 of cases
  - Easy to prove if published material available
- Lack of inventive step
  - 20-30 % of cases
  - No obvious answer what constitutes an inventive step
- Insufficient disclosure
- Overall success rate 50-60 %
- Frequently unpredictable, differing country by country
- Time consuming and expensive, not enough time till product launch
- Safe procedure, no risk
Third party observation

- Used by Zentiva only after proper assessment of consequences
- Sometimes risk that applicant modifies its application
- Straightforward
- Cheap and quick
- No statistics of success rate available
- Unsafe process, no legal status of observer
Non infringement

- Limited experience of the legal system in CEEC
- No direct connection between infringement and patent validity
- Passive and risky approach
- Quick
- Legal system only partly supportive to IPR holders
- Prior use
Patent free (different) solution

• Preferred way if possible
  – New synthetic process, polymorph, hydrate, etc
    • Developed by Zentiva
    • Different manufacturer
  – Different drug formulation developed by us

• Problems:
  • Product properties defined too broadly and by irreproducible methods
  • Product by process claims
  • Too similar solution (risk of equivalence)
Future trends in patents

• Harmonization of Substantive Patent Law Treaty
  – Standards of patentability
  – Scope of inventive step
  – Interpretation of claims
• Strengthen enforcement in case of infringement
• Increase in filing of patents
• Increase of litigations
• Abuse of monopoly
• More power of international organizations
  – One application, international agency, international court
• Economic arguments prevail over public policy
Globalization through convergence: A personal view

• IP protection same/similar everywhere – same generic entry in all countries
  – Patents litigated only once (EPLA)
  – Same court practice combating piracy
  – Easier life for global players both research oriented and generic
  – IPR do not block pharma industry development

• Non IP issues
  – Convergence in treatment trends / drug consumption
  – Pricing / reimbursement: convergent and divergent trends
  – Harmonization of registration requirements
  – OTC switches
The future of EU pharma market

• Long-lasting high generic penetration
  – Switch from branded market to substitution market?

• Sales and marketing – decisive factor of success
  – Affordable price to health system
  – Broad service to customers

• Research based companies
  – Rare, expensive to treat illnesses
  – Biotech drugs
  – High price
  – Full reimbursement
  – Specialists oriented

• Global generic companies
  – Common illnesses – treatment & prevention
  – Low price, full reimbursement – high patients’ penetration
  – Primary care oriented
  – Massive production – low production cost
Thank you for attention

Dr. Roman Lapka
Director IP
Zentiva a.s.
U kabelovny 130
102 37 Prague
Czech Republic
tel: +420 267 242 280
fax: +420 272 701 331
mob: +420 602 135 849
mail: roman.lapka@zentiva.cz