

Generics Perspective: Role of Intellectual Property

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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

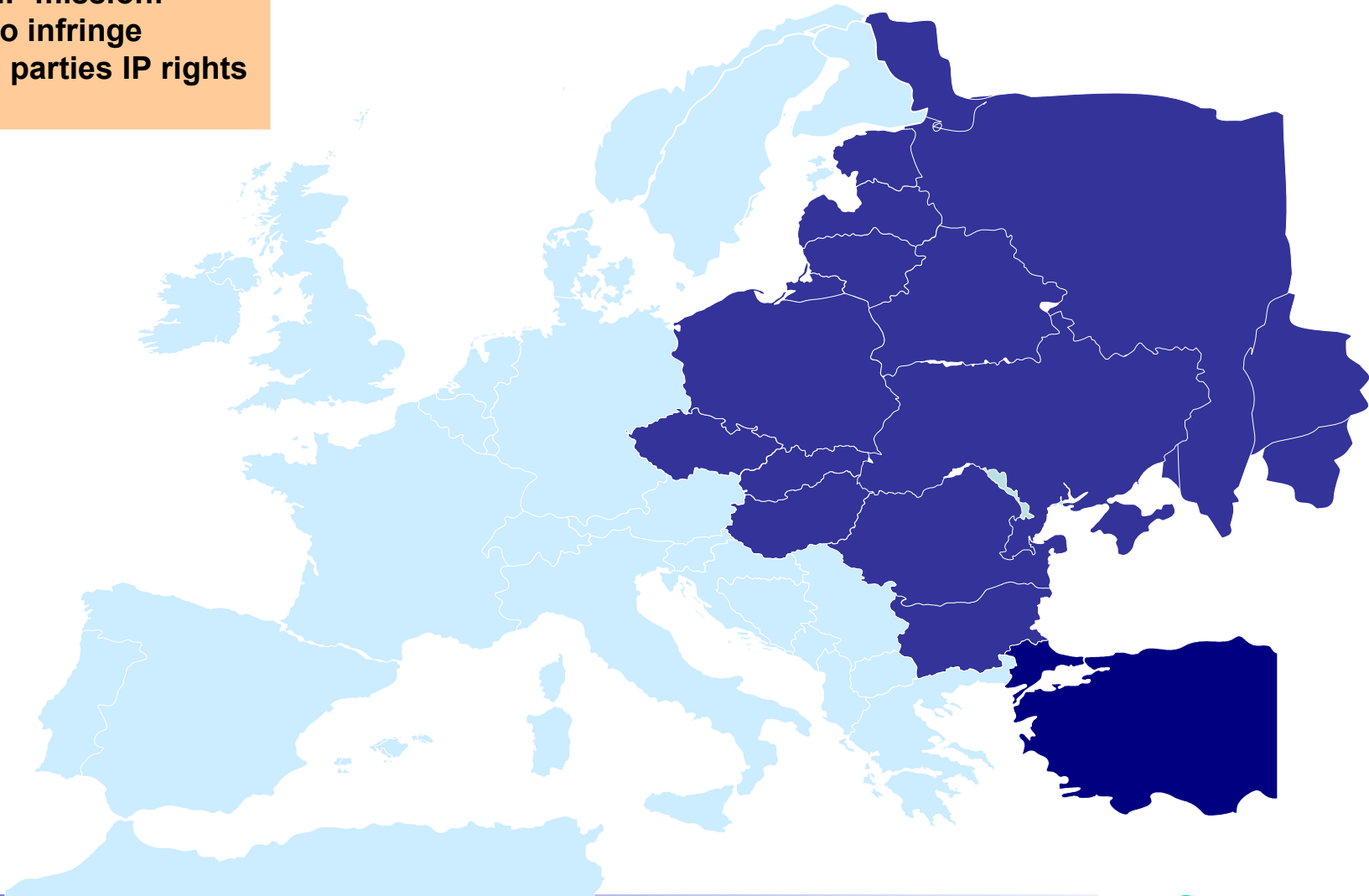
CEE specifics

- „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**

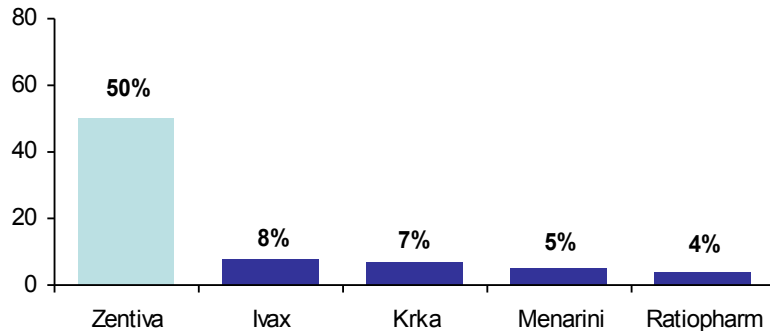
**Our IP mission:
not to infringe
third parties IP rights**



Dominant Position in Czech, Romanian and Slovak Markets; number 3 in Turkey

Clear Generics Leader in Czech Republic...

Market Share (Value of Generics market)
%

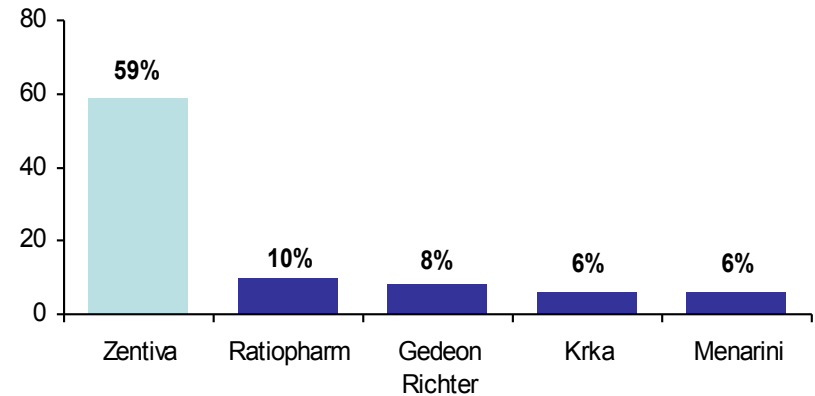


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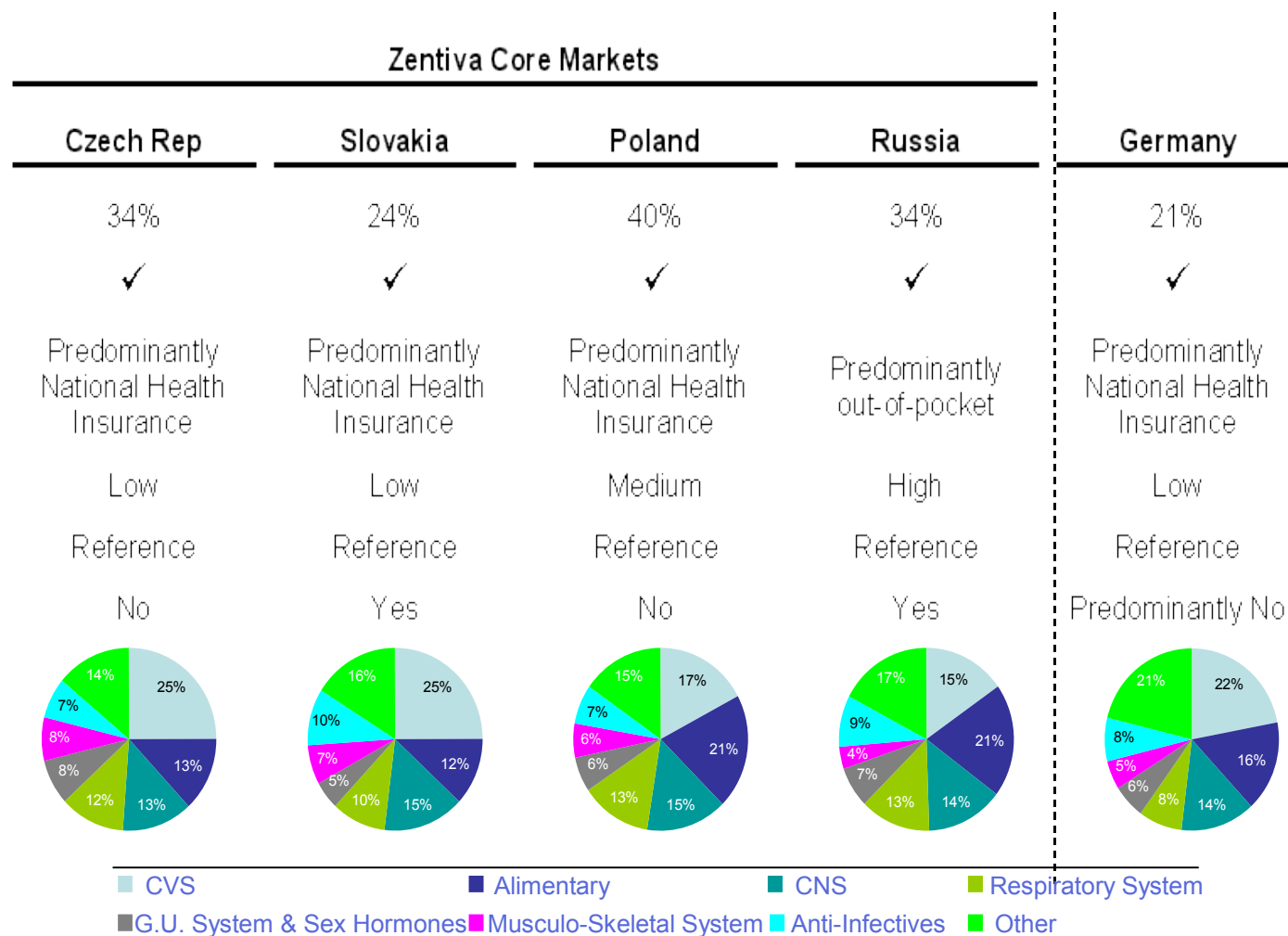
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... and Slovakia

Market Share (Value of Generics market)
%



Focused on Attractive Branded Generics Markets



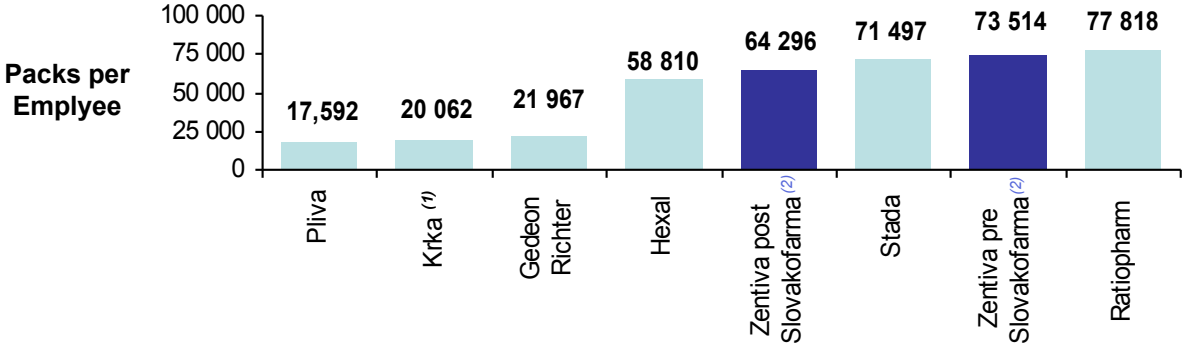
Integrated, Scalable and Low Cost Business Processes

Best in Class Cost and Efficiency

Leading Efficiency Levels

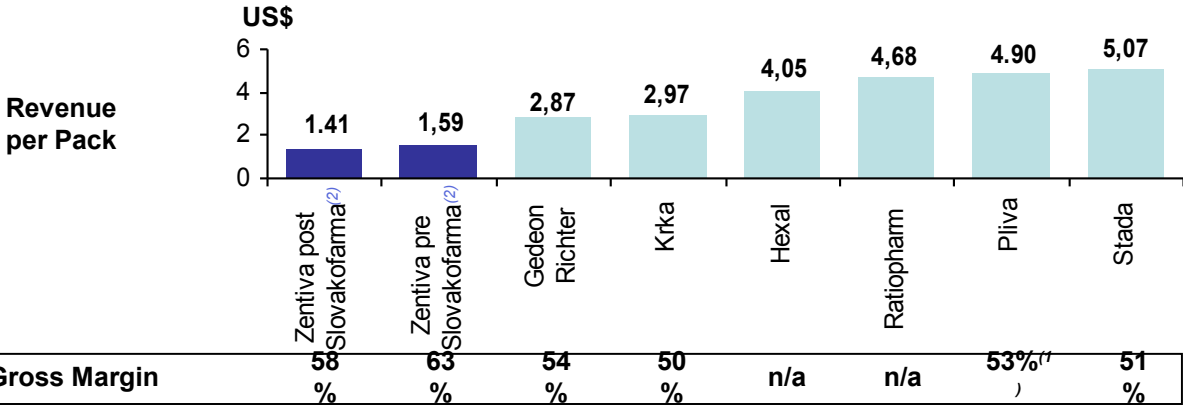
Efficiency through

- Rigorous process management
- Leading IT infrastructure



Competitive Pricing at Attractive Gross Margins

Efficiency with low cost environment allows for most competitive pricing while retaining leading margins



Business concept

Primary care & prevention



Business strategy

- **Company goals**

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

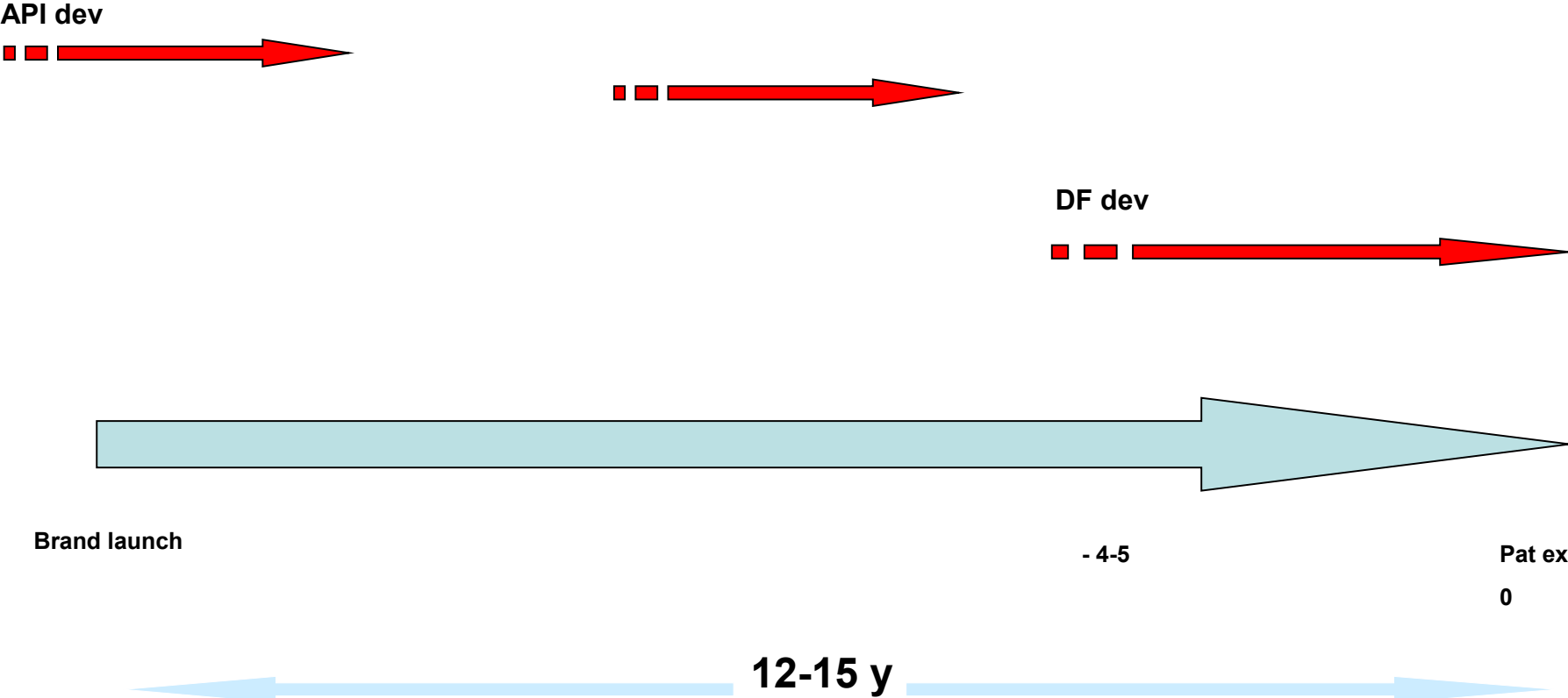
- **R&D and M&S goals**

- Full product availability
- Price competitiveness
- High share of new products
- First to market
- To be a market leader in all chosen molecules

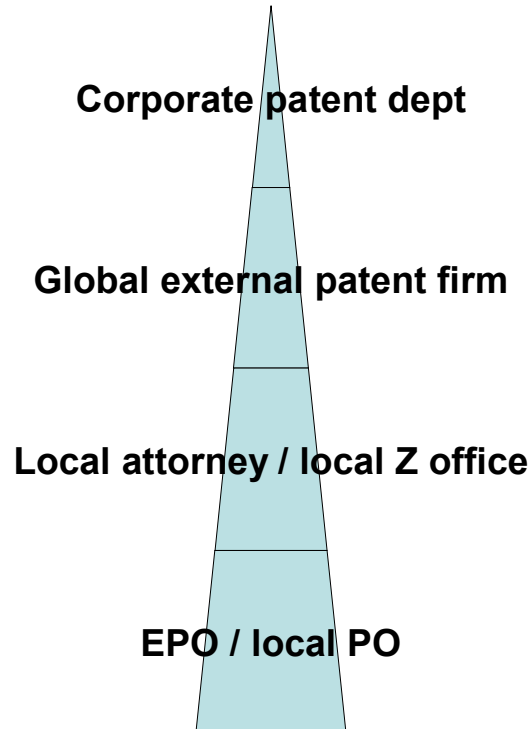
Research and development

- 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

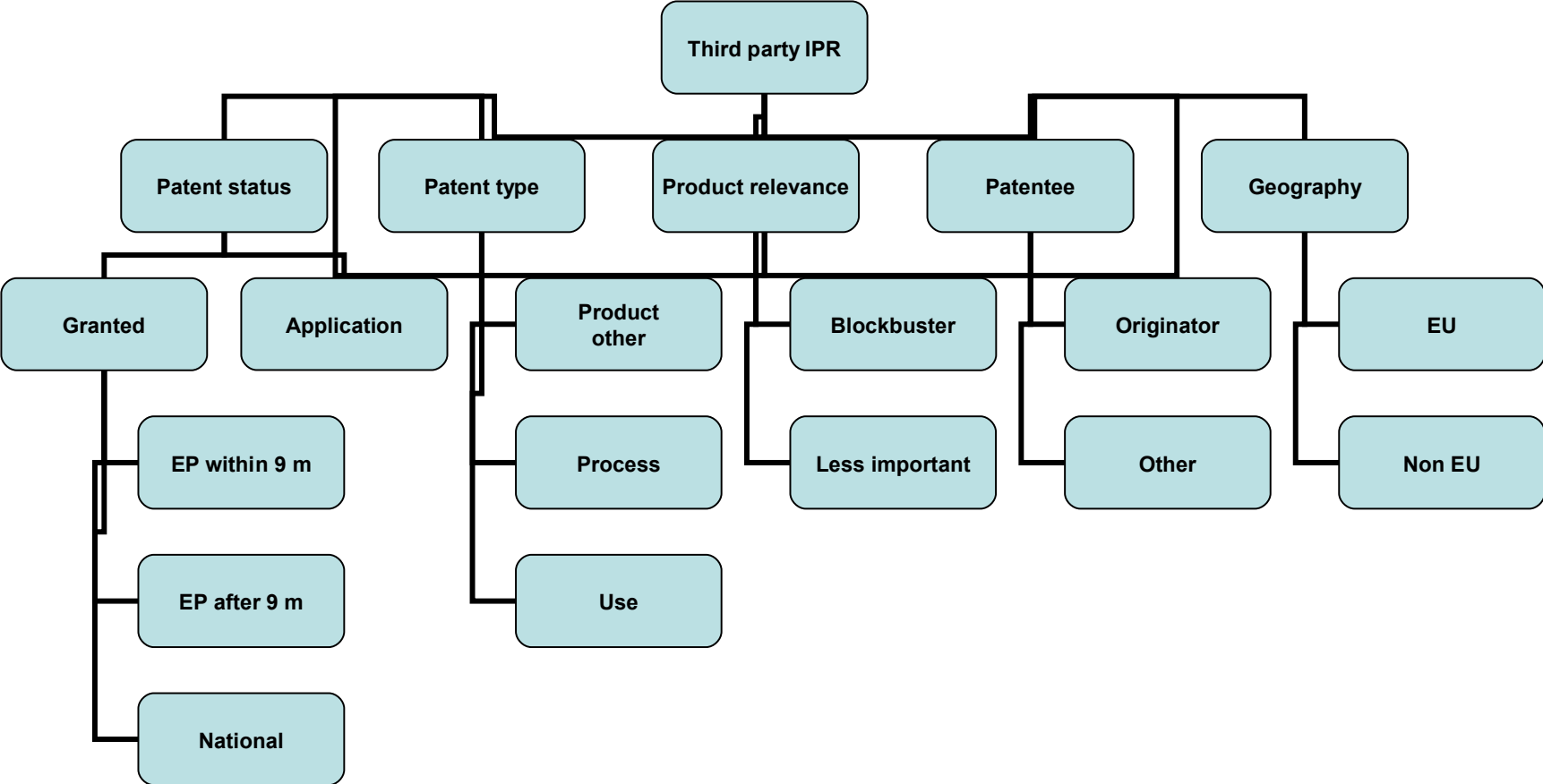


How do we work in IP field

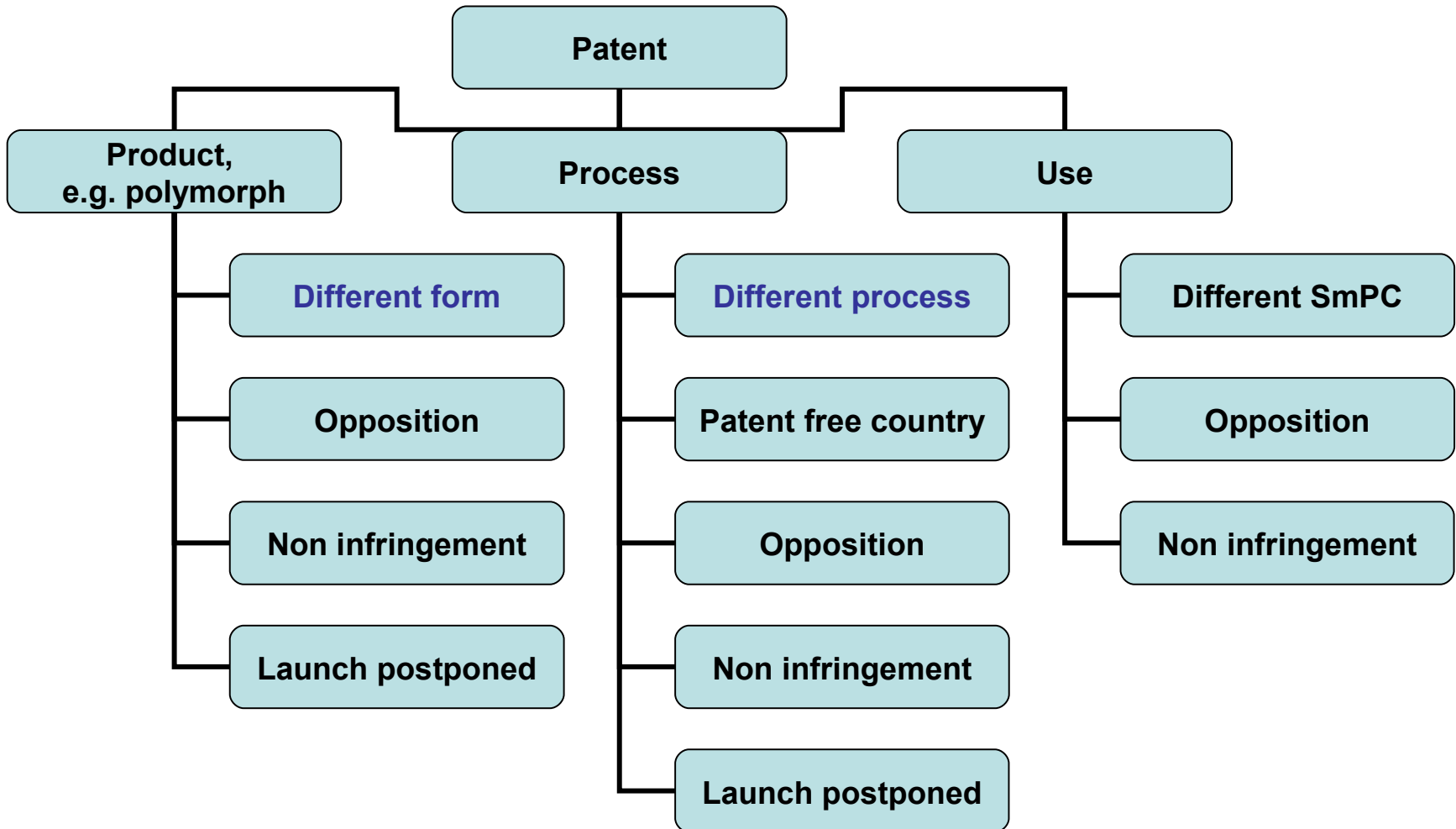


- **Corporate patent dept**
 - Detailed patent search
 - Decisions
 - Coordination
 - Own patent applications
- **Global external PF**
 - Complex cases (EP, more countries)
 - Legal advise & coordination
 - Case performance
- **Local attorney**
 - Country specific cases
- **Local Zentiva office**
 - Information
 - Liaison officer

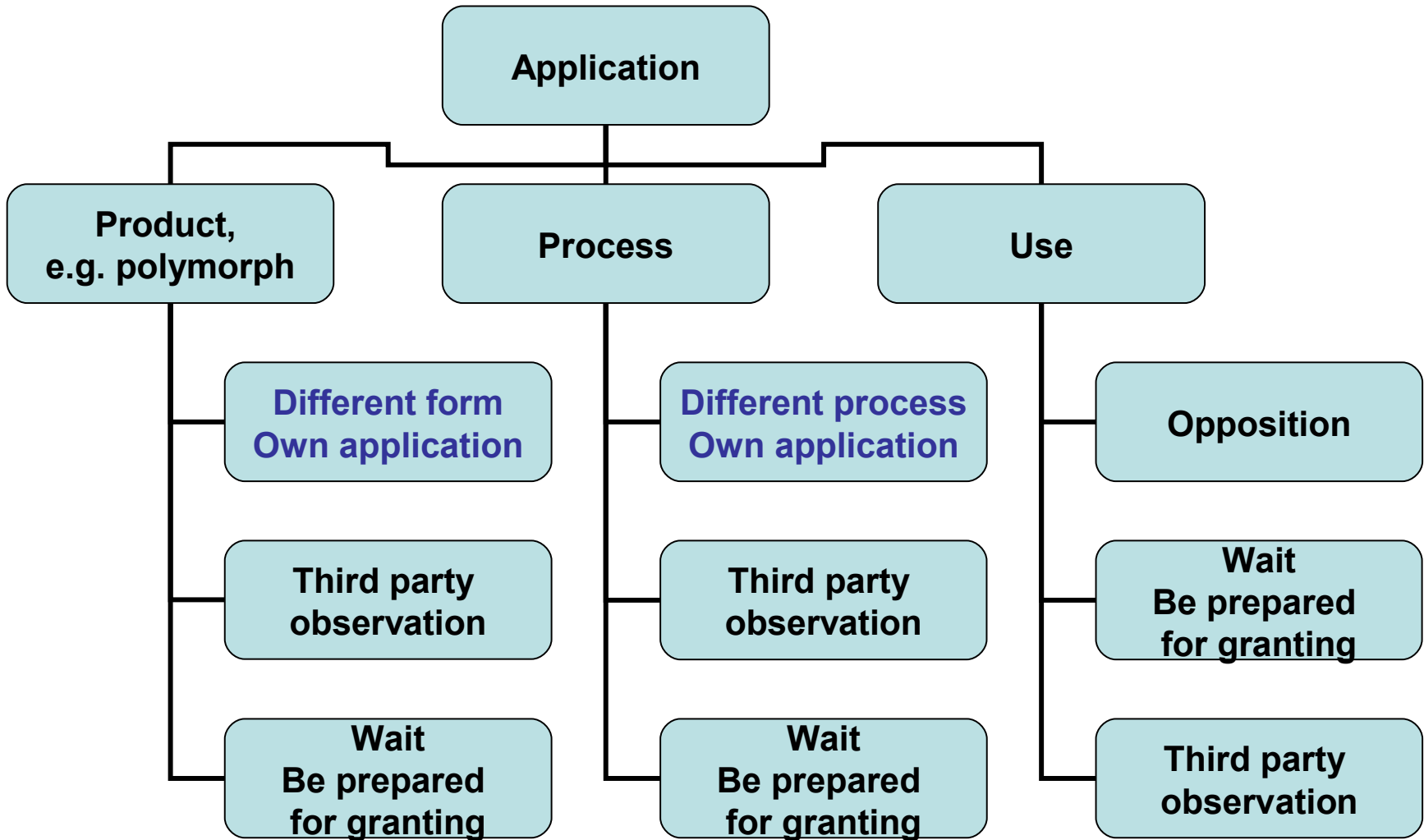
Strategy differs



Decision tree – granted patent

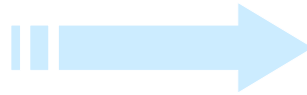


Decision tree – patent application



„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

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