

# 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

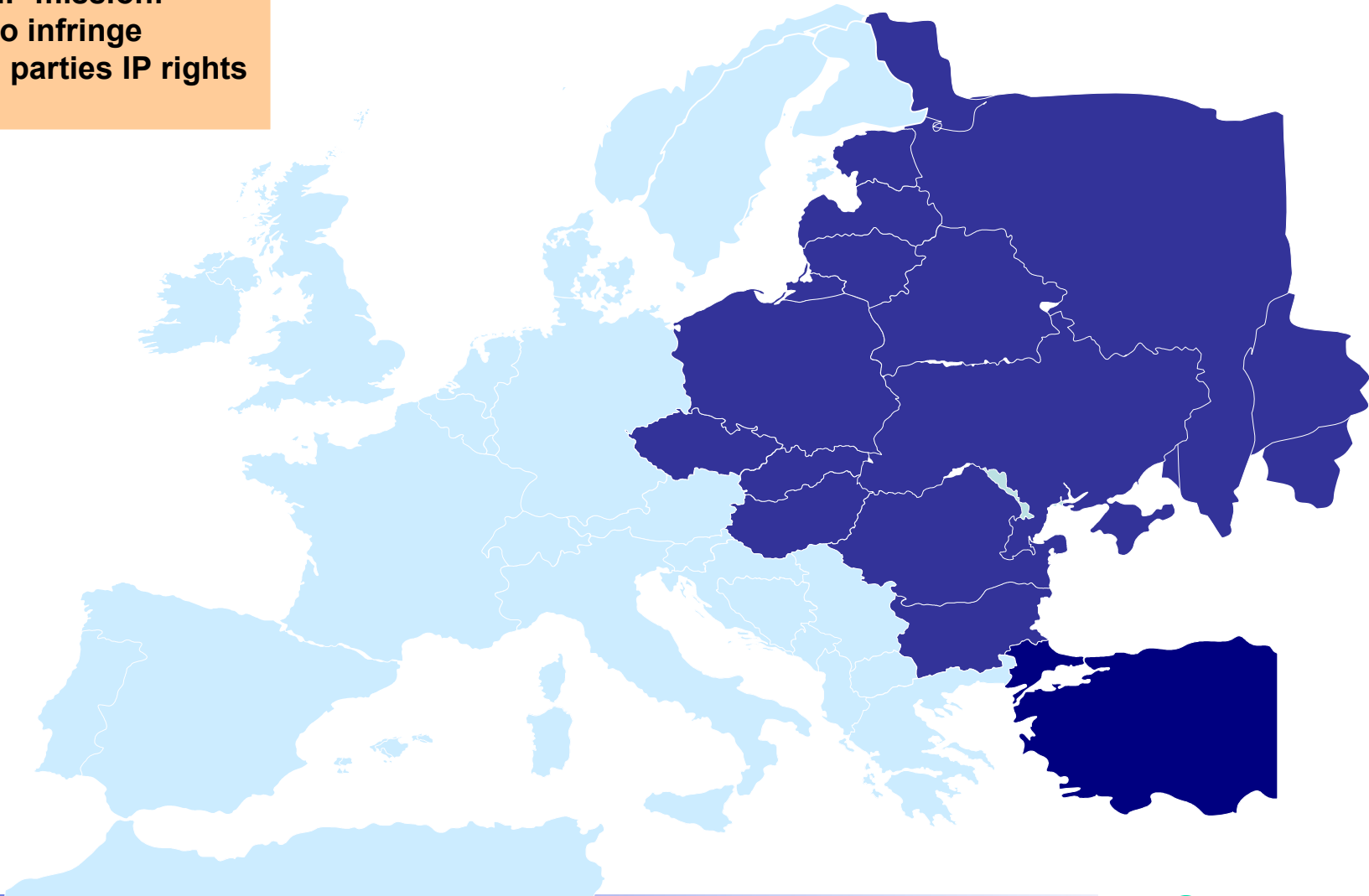
# CEE specifics

- „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**

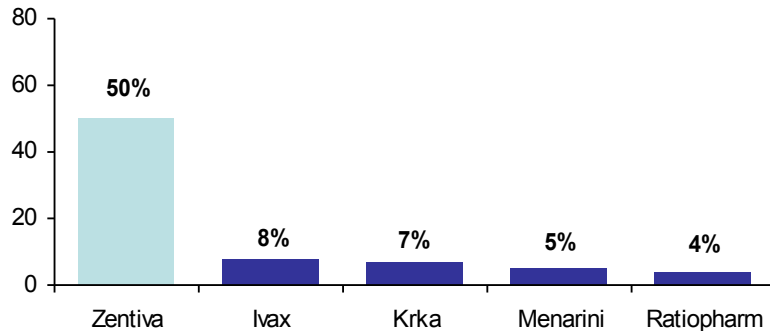
**Our IP mission:  
not to infringe  
third parties IP rights**



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

## Clear Generics Leader in Czech Republic...

Market Share (Value of Generics market)  
%

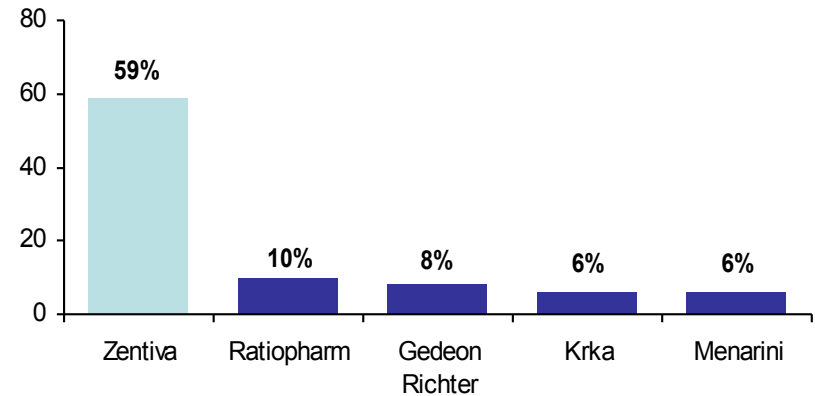


(1)

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## ... and Slovakia

Market Share (Value of Generics market)  
%



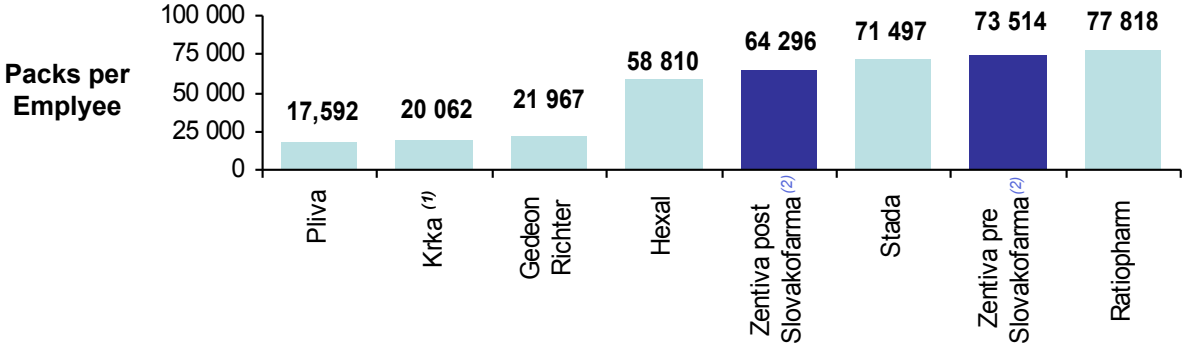
## Focused on Attractive Branded Generics Markets

	Zentiva Core Markets				Germany			
	Czech Rep	Slovakia	Poland	Russia				
Generic Value Penetration <sup>(1)</sup>	34%	24%	40%	34%	21%			
Branded Prescribing <sup>(2)</sup>	✓	✓	✓	✓	✓			
Payment <sup>(2)</sup>	Predominantly National Health Insurance	Predominantly National Health Insurance	Predominantly National Health Insurance	Predominantly out-of-pocket	Predominantly National Health Insurance			
Co-payment Practice <sup>(2)</sup>	Low	Low	Medium	High	Low			
Pricing <sup>(2)</sup>	Reference	Reference	Reference	Reference	Reference			
Pharmacist Substitution <sup>(2)</sup>	No	Yes	No	Yes	Predominantly No			
Therapeutic Categories <sup>(3)</sup>								
	<span style="color: #A9C94A;">■</span> CVS	<span style="color: #0056B3;">■</span> Alimentary	<span style="color: #008080;">■</span> CNS	<span style="color: #808000;">■</span> Respiratory System	<span style="color: #808080;">■</span> G.U. System & Sex Hormones	<span style="color: #FF00FF;">■</span> Musculo-Skeletal System	<span style="color: #00FFFF;">■</span> Anti-Infectives	<span style="color: #00FF00;">■</span> Other

# Integrated, Scalable and Low Cost Business Processes

Best in Class Cost and Efficiency

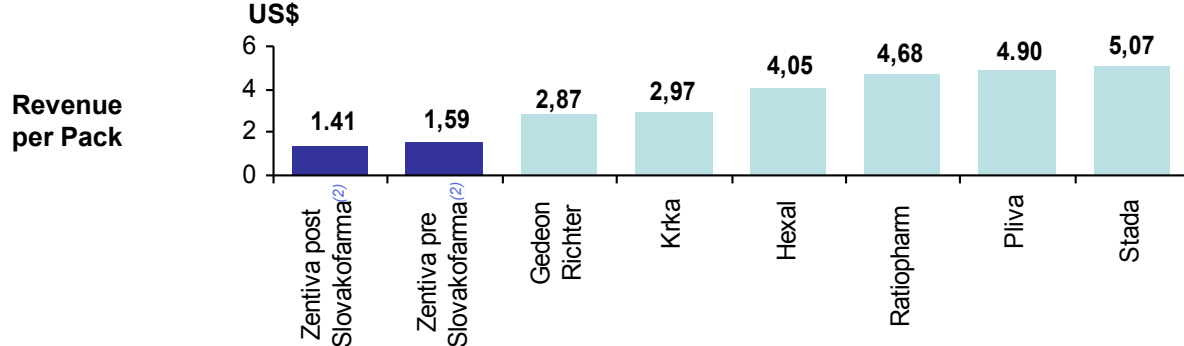
## Leading Efficiency Levels



Efficiency through

- Rigorous process management
- Leading IT infrastructure

## Competitive Pricing at Attractive Gross Margins



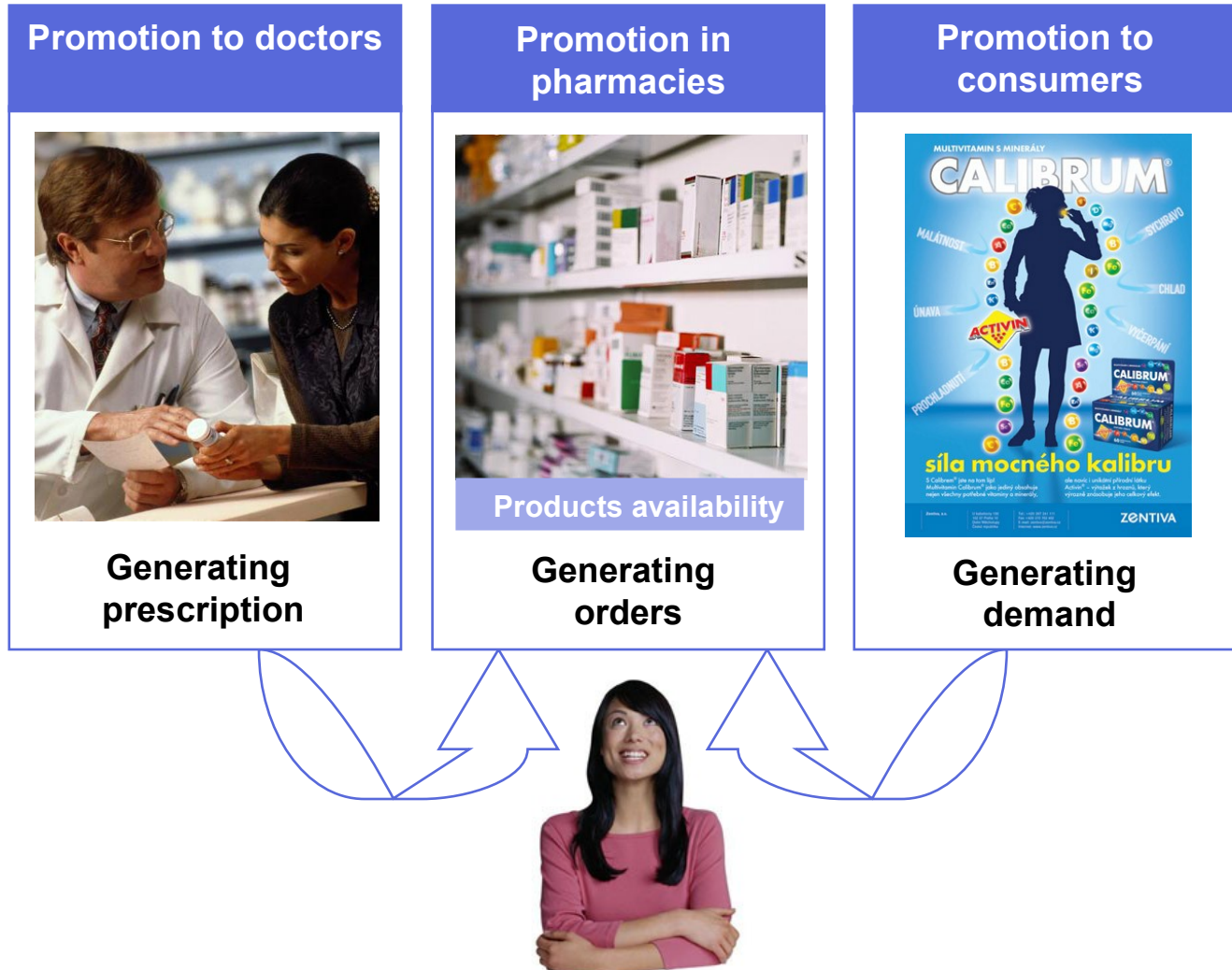
Efficiency with low cost environment allows for most competitive pricing while retaining leading margins

Gross Margin	Zentiva post Slovakofarma (2)	Zentiva pre Slovakofarma (2)	Gedeon Richter	Krka	Hexal	Ratiopharm	Pliva	Stada
	58%	63%	54%	50%	n/a	n/a	53% (1)	51%



# 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

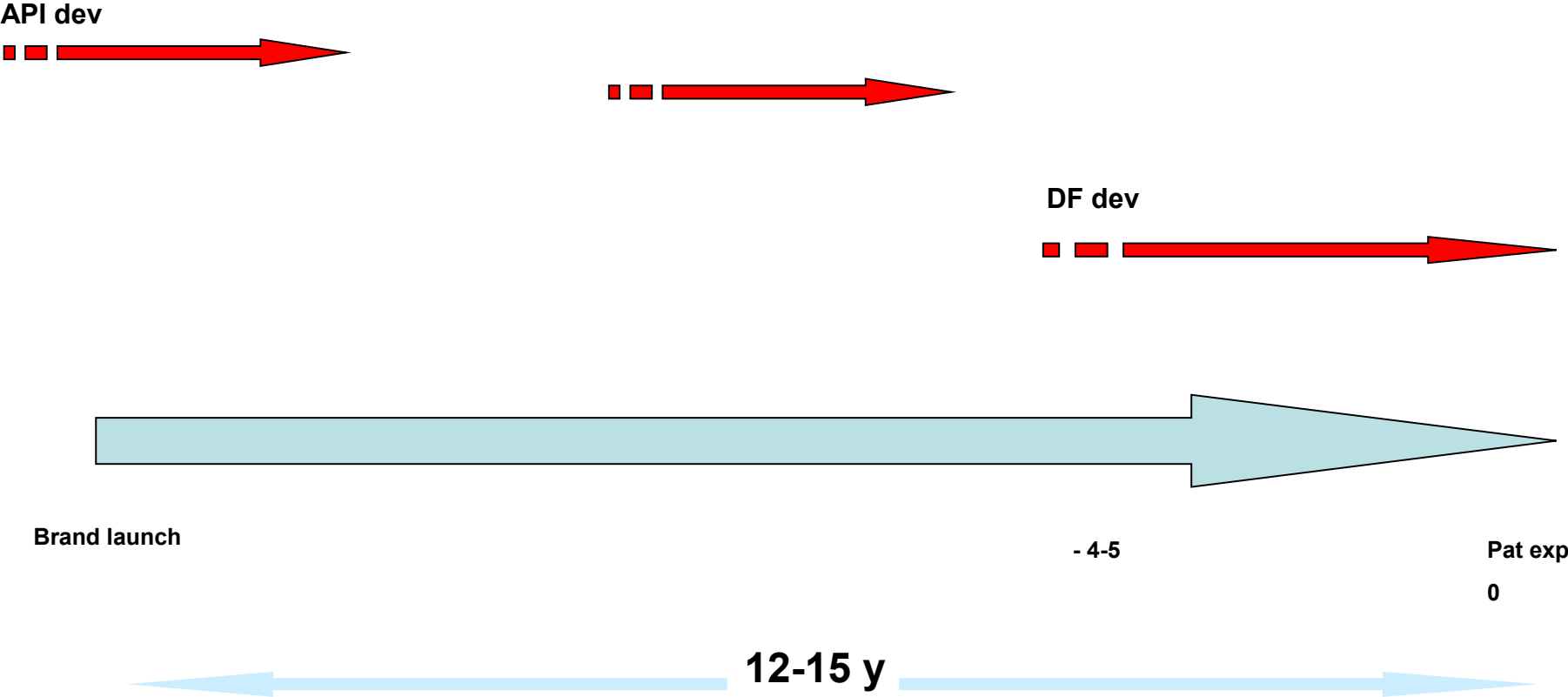
- **R&D and M&S goals**

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

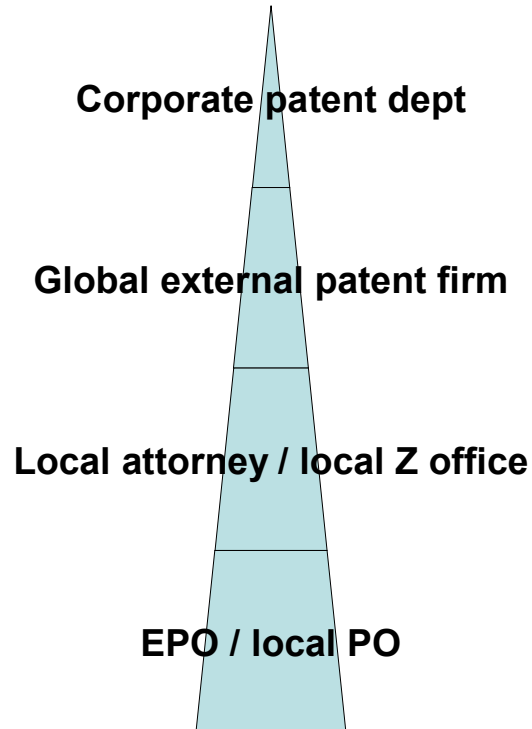
# Research and development

- 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

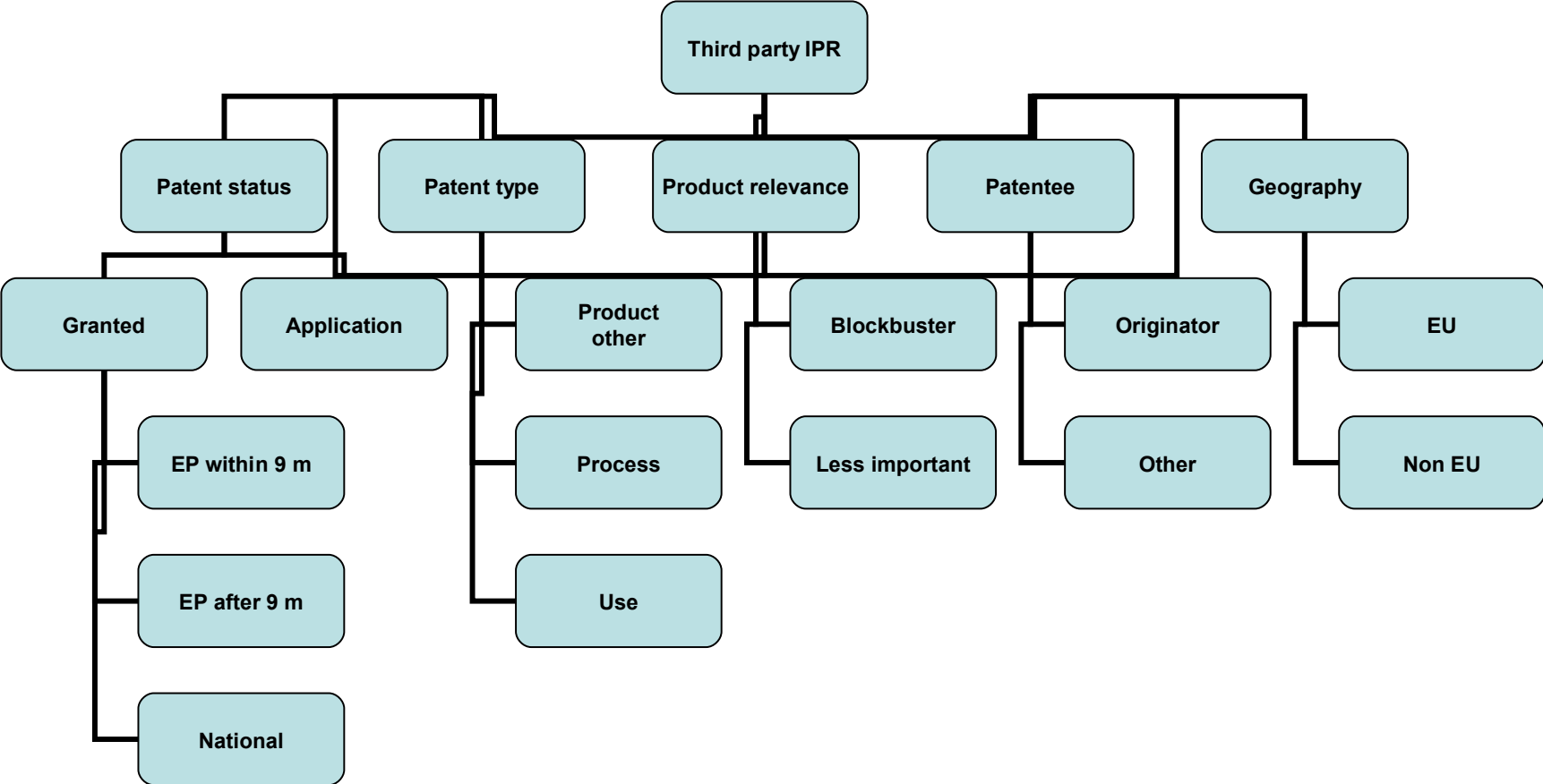


# How do we work in IP field

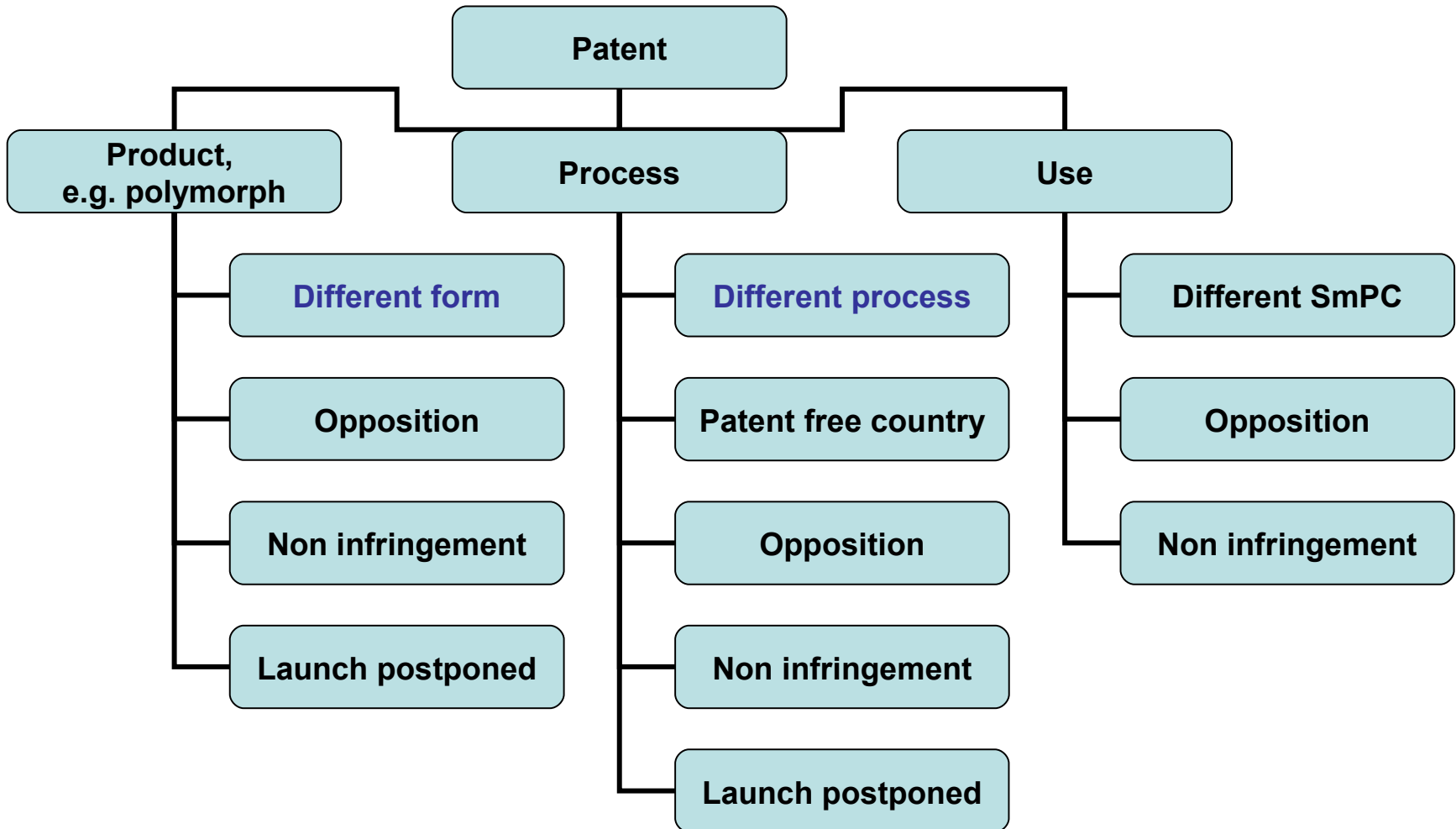


- **Corporate patent dept**
  - Detailed patent search
  - Decisions
  - Coordination
  - Own patent applications
- **Global external PF**
  - Complex cases (EP, more countries)
  - Legal advise & coordination
  - Case performance
- **Local attorney**
  - Country specific cases
- **Local Zentiva office**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

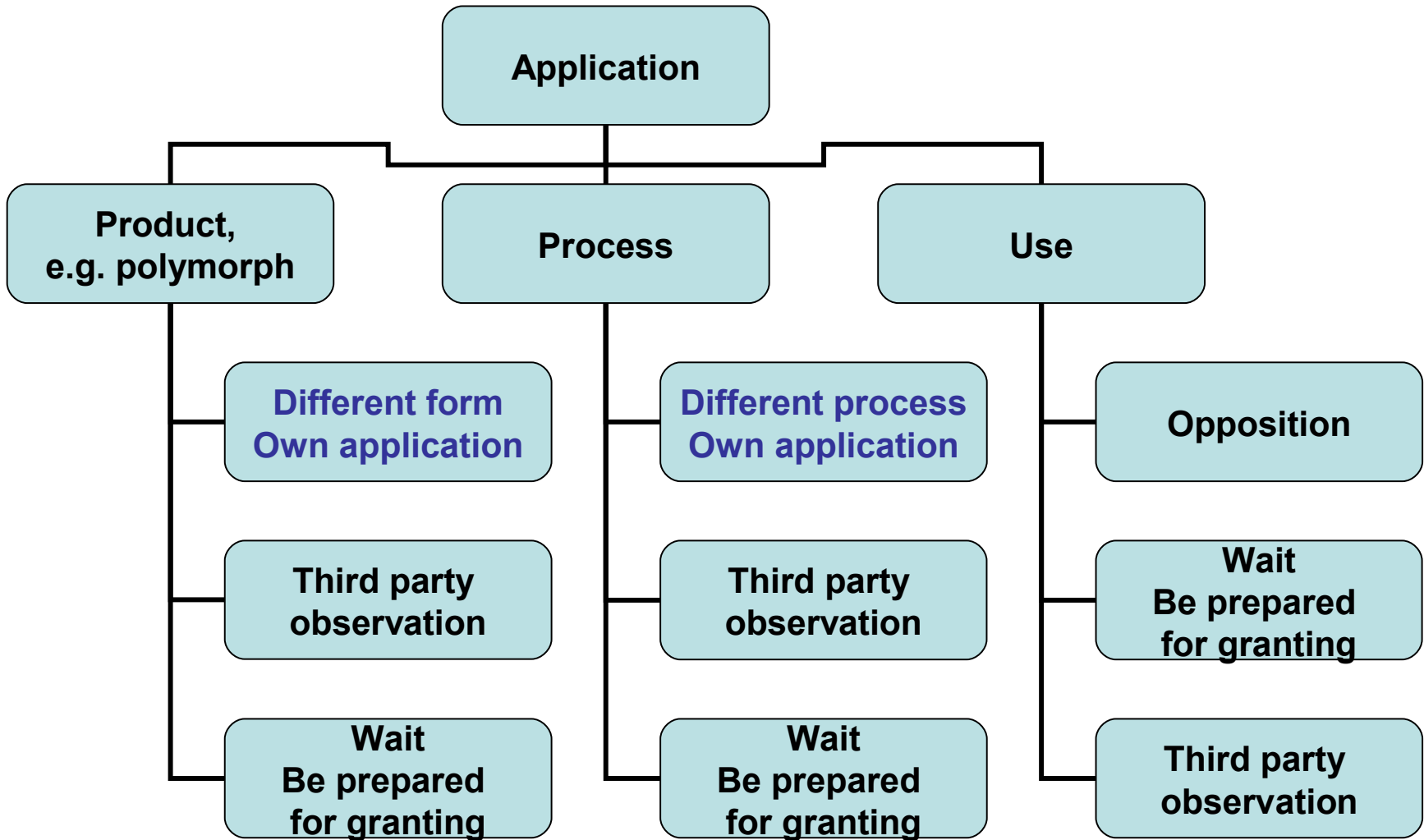
# Strategy differs



# Decision tree – granted patent



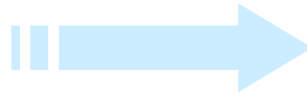
# Decision tree – patent application





# „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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