

# DO LESS GAIN MORE

Pharmaceutical and Biotech Litigation Strategies

Anke Heezius, partner at  London, 25/05/2010

Life Sciences **Legal**



# Agenda

1. Filing, drafting and litigating secondary patents
2. Logical order of proceedings
3. Review of marketing authorizations

Advice 1

# SECONDARY PATENTS

# Types of Claims in Secondary Patents

| Category of product claim | % of all product claims |
|---------------------------|-------------------------|
| Formulations              | 57%                     |
| Devices                   | 7%                      |
| Combinations              | 7%                      |
| Polymorphic forms         | 5%                      |
| Salts                     | 4%                      |
| Intermediates             | 4%                      |
| Substances                | 4%                      |
| Product by-process        | 4%                      |
| Unspecified               | 3%                      |
| Hydrates                  | 2%                      |
| Particles                 | 1%                      |
| Solvates                  | 1%                      |
| Others                    | 1%                      |

TABLE 18:  
Break-down of product claims <sup>213</sup>  
in secondary applications

Source:  
Pharmaceutical  
Sector Inquiry

# Types of Patents most Litigated

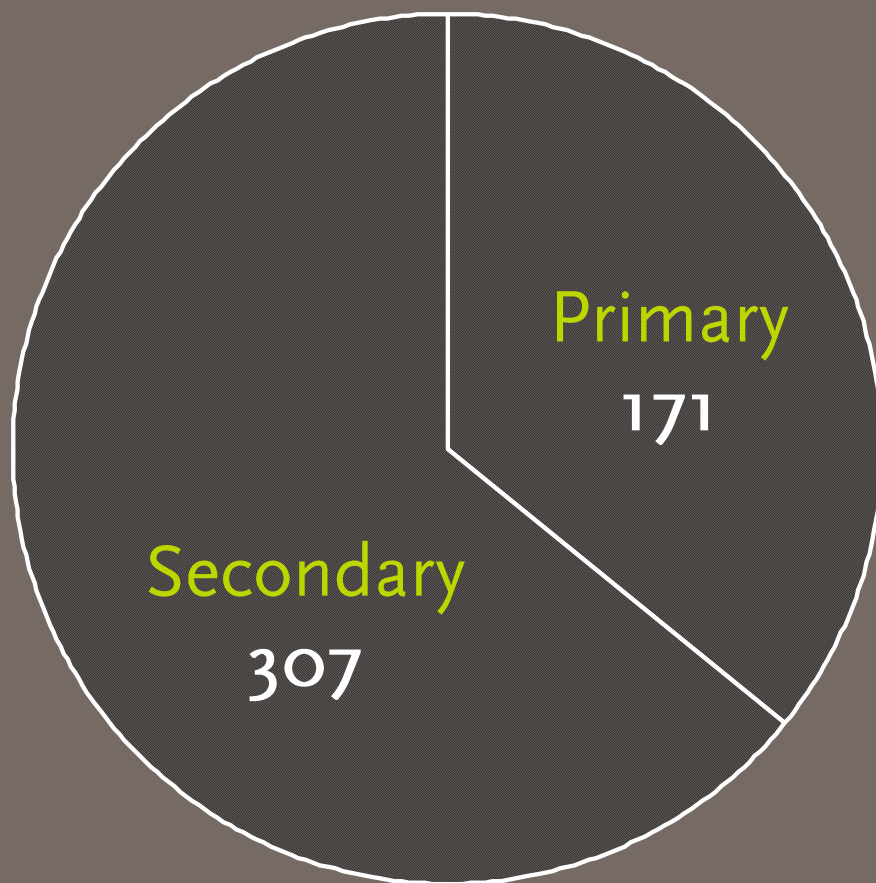


TABLE 7:  
Types of patents which are  
most often litigated in the EU  
(2000-2007)

Source:  
Pharmaceutical  
Sector Inquiry

# Chances of Success

- (507) As shown in Figure 73, originator companies won 57% of all cases concerning primary patents in which a final judgement was given, versus 43% for generic companies.<sup>261</sup>
- (508) The picture is different for secondary patents. Generic companies won nearly three quarters (74%) of all cases concerning secondary patents in which a final judgement was given.<sup>262</sup> In contrast, originator companies were successful in over one quarter of litigations over secondary patents (26%). It should be recalled that secondary patents

# Winning Rate Statistics (general)

1. Difference between litigated and not litigated patents
2. In ideal case: 50 % plaintiff and defendant
3. Deviation of 50 % outcome >> selection of cases

# Secondary Patents

1. New technological area's (polymorphs)
2. Oversimplification and lack of inventive step
3. Timing (opposition, credibility of invention)

# Raising the Bar

Amended  
guidelines  
per 1 /04/ 2010

Extension  
of knowledge  
skilled person

Could-would:  
implicit pointer  
to solution

11.3  
neighboring field,  
own field, general,  
remote if prompted

11.5  
implicit prompting or  
implicitly recognizable  
incentive

# Secondary Patents: Drafting

Specify technical  
problem

Include evidence

**Specify Skilled Person**

# Filing Secondary Patents

1. Opposition proceedings slow
2. Interference with litigations
3. Filing to obtain grant more than two years before expiry primary patent

# Example 1: Polymorph Patent

We have discovered that X can exist in at least two distinct crystalline forms, [...] "Form A" and "Form B".

**Drugs currently on the market are formulated from the thermodynamically more stable Form B.**

Therefore, preparation of the current commercial entity requires converting the Form A crystals to Form B. Typically this is done by heating the Form A crystals under vacuum at a temperature of greater than 50 °C.

# Example 2: EPO Formulation patent

Erfindungsgemäss wird diesen Schwierigkeiten dadurch begegnet, dass Konservierungsmittel eingesetzt werden, welche wenig mit Humanproteinen reagieren und wenig sensibilisierend wirken.

## **Beispiel 4: EPO spritzfertige Injektionslösung**

Es hat sich gezeigt, dass es besonders vorteilhaft ist, Kombinationen der einzelnen Konservierungsmittel einzusetzen. Dadurch wird ein besserer Konservierungseffekt erreicht und die nachteiligen Wechselwirkungen mit den Humanproteinen minimiert.

## Advice 2

# LOGICAL ORDER OF PROCEEDINGS

# Costs of patent litigation

Source:  
Pharmaceutical  
Sector Inquiry  
& AIPLA Economic survey 2007;  
Internet

| Country             | x 1.000 EURO         |    |        |             |
|---------------------|----------------------|----|--------|-------------|
| United Kingdom      | 993                  |    |        |             |
| Netherlands         | 476                  |    |        |             |
| France              | 449                  |    |        |             |
| Italy               | 115                  |    |        |             |
| Belgium             | 115                  |    |        |             |
| Spain               | 115                  |    |        |             |
| Germany             | 76                   |    |        |             |
| Austria             | 46                   |    |        |             |
| <b>TOTAL EUROPE</b> | <b>4.000</b>         | >> | Market | 450 million |
| <b>TOTAL USA</b>    | <b>2.000 - 8.000</b> | >> | Market | 300 million |

# No Data for Decision Making

1. 'Effectiveness of proceedings'
2. Speed
3. Specialized patent courts
4. Respected and experienced judges

source: GIPI, 2009, 18.000 interviews

Resulting in a *ranking* of countries,  
not a strategy: UK, DE, US, AU, NL

# Logic in European Patent Litigation

1. Strong negotiation position, as soon as possible
2. Installing consequential proceedings
3. Evidence and arguments are re-used

# Anchors Efficient Litigation Strategy

Costs

Settlement  
and timing

Timelines of  
proceedings

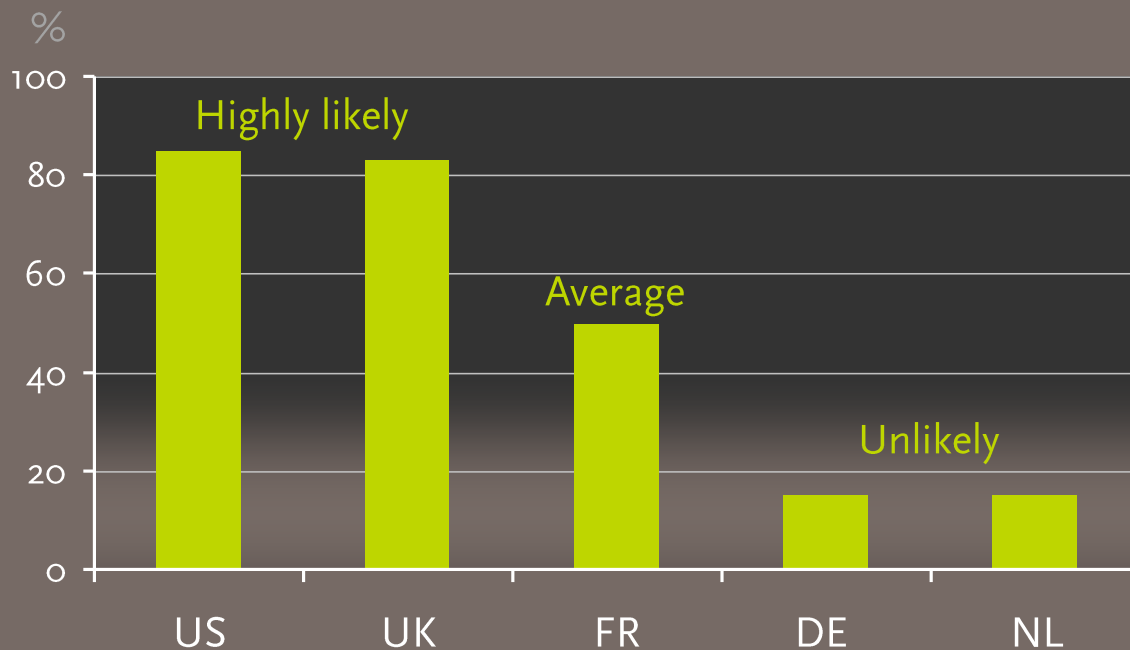
Re use of  
evidence

# Settlements before 1st Judgment

Source:

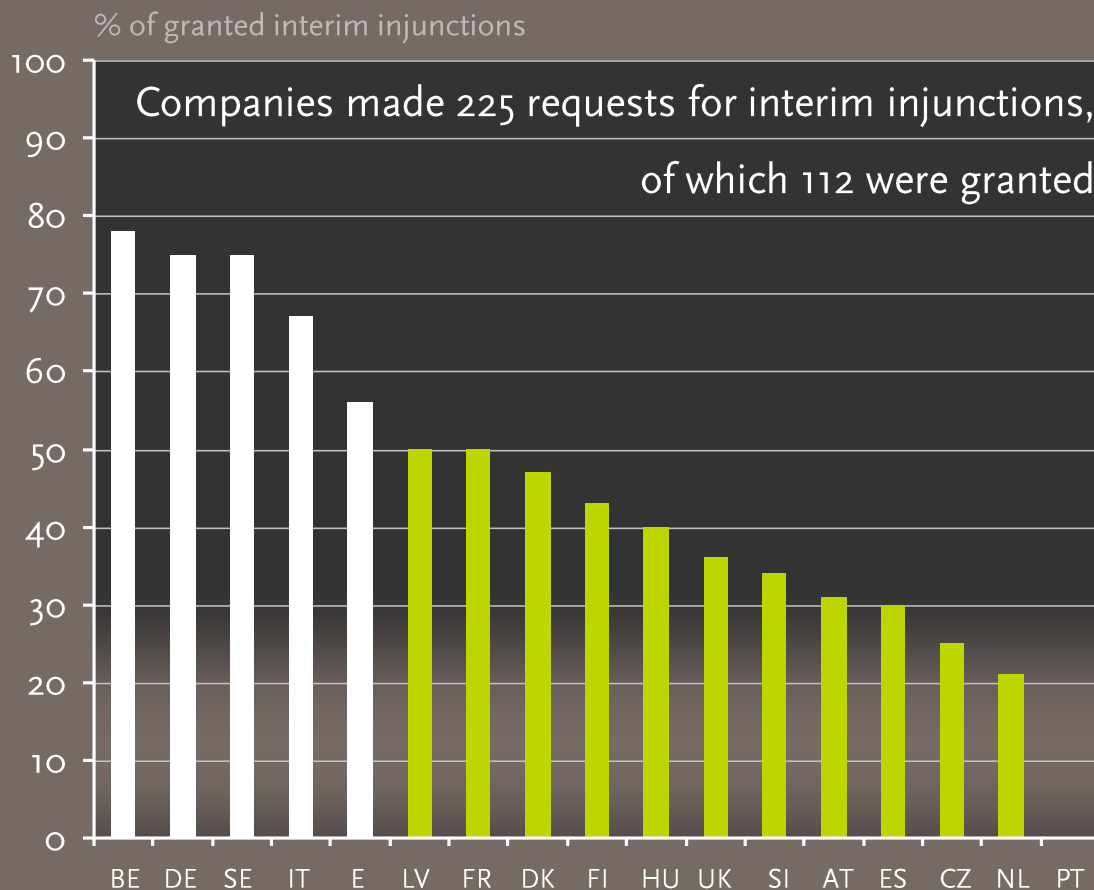
CJA Consultants (2006)

Lanjouw and Schankerman, 2001)



EC Report: likely (decision in 20% of cases)

# Interim Injunctions



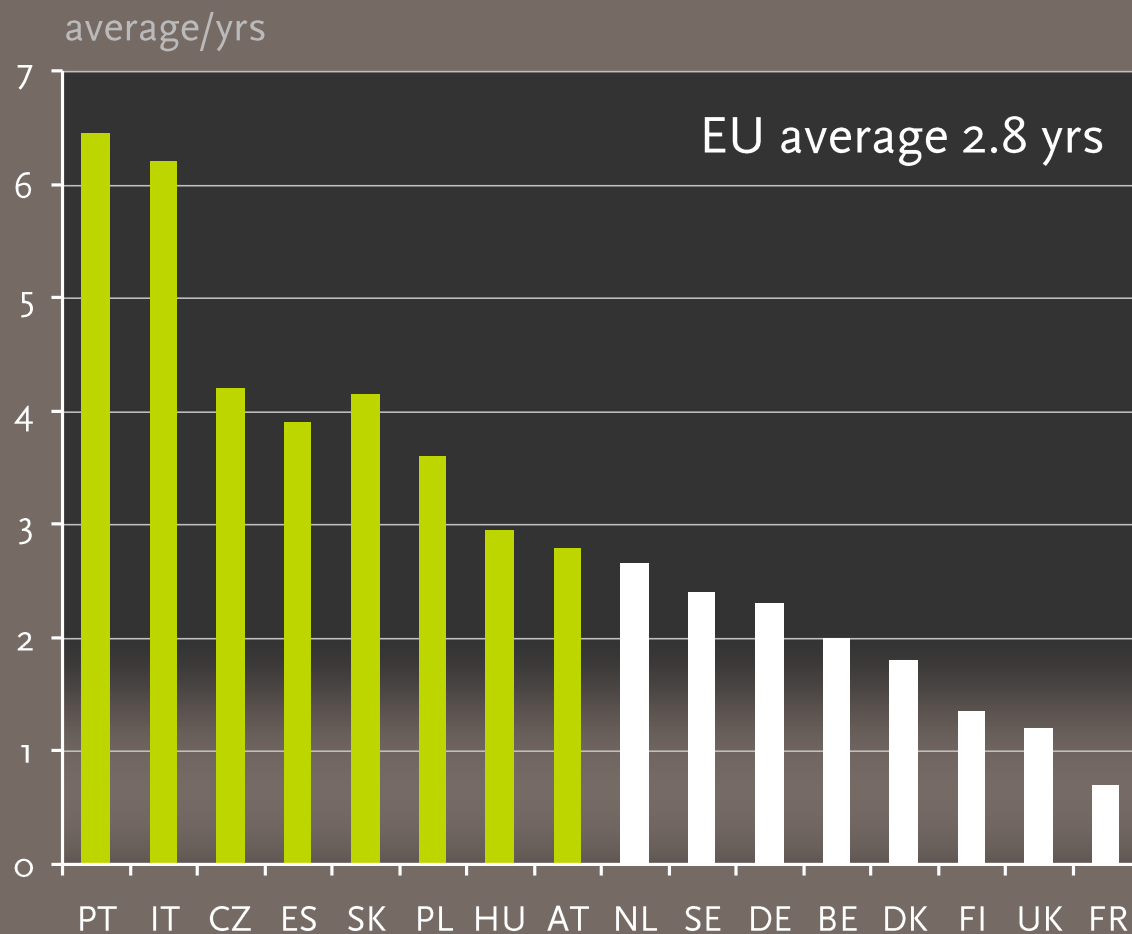
Percentage of granted interim injunctions per EU Member State (2000-2007)

N° of cases in which interim relief was requested in given after country codes

|    |    |    |    |
|----|----|----|----|
| BE | 13 | HU | 5  |
| DE | 28 | UK | 17 |
| SE | 12 | SI | 3  |
| IT | 15 | AT | 32 |
| EL | 9  | ES | 37 |
| LV | 4  | CZ | 7  |
| FR | 4  | NL | 9  |
| DK | 24 | PT | 13 |
| FI | 14 |    |    |

Source:  
Pharmaceutical Sector Inquiry

# Speed of Proceedings



Duration of litigations ending with final judgement in the EU (200-2007)

Number of litigations

|    |    |    |    |
|----|----|----|----|
| PT | 10 | NL | 11 |
| IT | 13 | SE | 18 |
| CZ | 10 | DE | 29 |
| ES | 24 | BE | 5  |
| SK | 3  | DK | 5  |
| PL | 4  | FI | 10 |
| HU | 9  | UK | 46 |
| AT | 21 | FR | 4  |

Source:  
Pharmaceutical  
Sector Inquiry

# Consequent Litigation to Re-use Arguments

1. Courts willing to take foreign evidence and decisions into account
2. mere reference not sufficient
3. Prepare case with this in mind

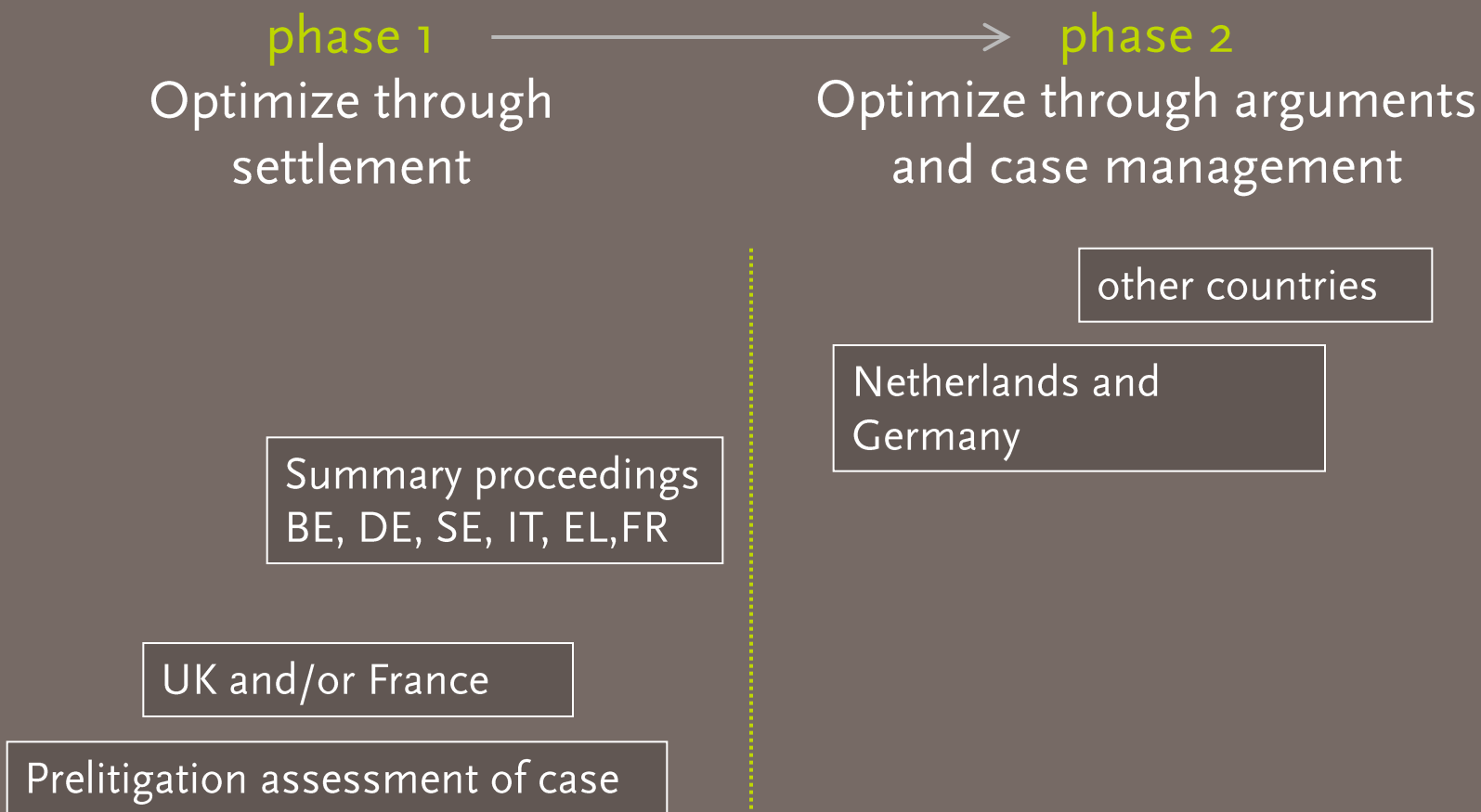
# JURISDICTION SELECTION & ORDER

# Status Quo Pharmaceutical Patent Litigation

|                         | UK | FR | NL | DE | SE | IT | DK | BE | FI |
|-------------------------|----|----|----|----|----|----|----|----|----|
| Prejudgement Settlement | x  | x  |    |    |    |    |    |    |    |
| Interim Injunctions     |    | x  |    | x  | x  | x  | x  | x  |    |
| Fast proceedings        | x  | x  | x  | x  | x  |    | x  | x  | x  |

1. Costs depend on number of proceedings
2. Conflicting decisions 'only' in 10 % of cases
3. Re use of mainly UK evidence common

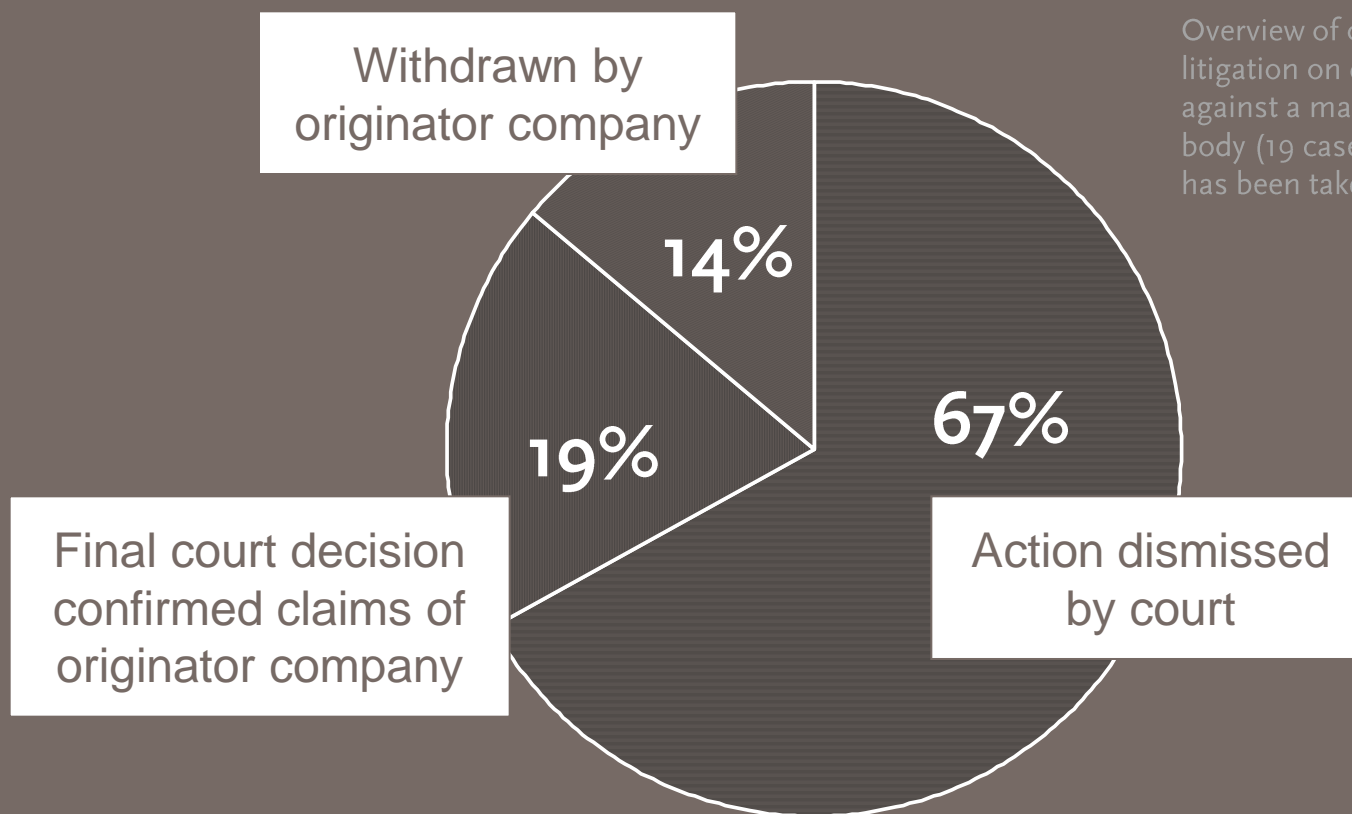
# Logic Process to Success - Advice 2



## Advice 3

KEEP AN EYE ON  
MARKETING  
AUTHORIZATIONS

# Marketing authorisations



Source:  
Pharmaceutical Sector Inquiry

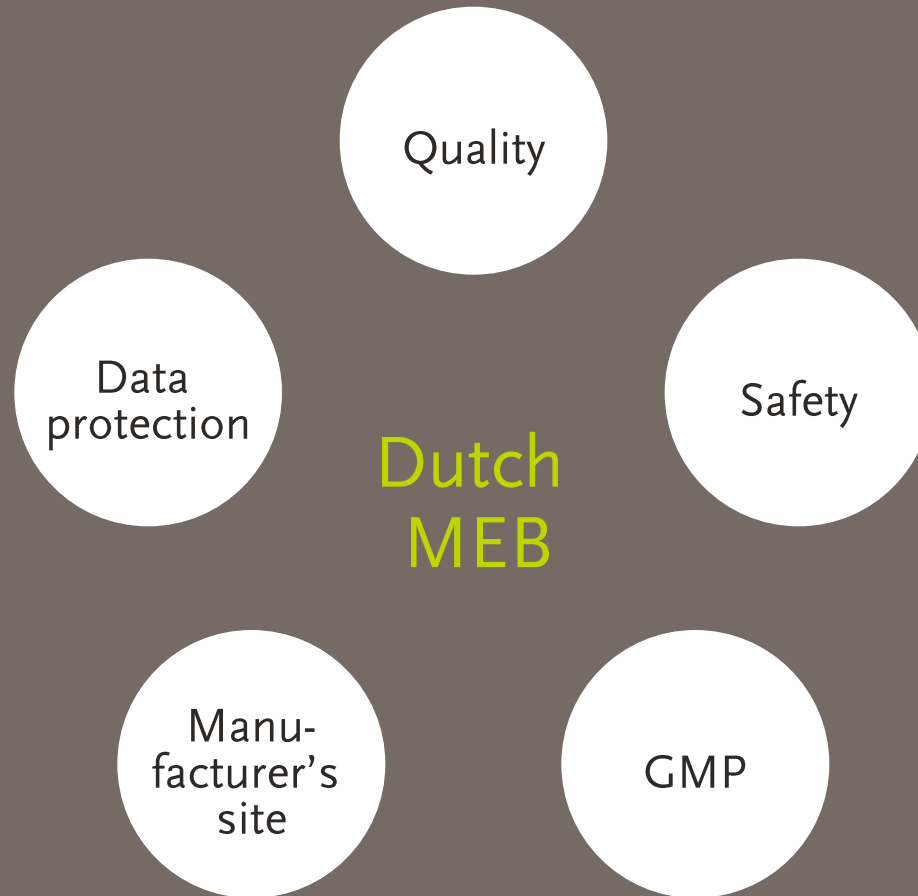
# Regulatory Action

1. Sector enquiry: critical on regulatory litigation
2. However: emphasis on (informal) interventions and patent linkage (Portugal)
3. Interventions still allowed when legal and supported by reasonable grounds

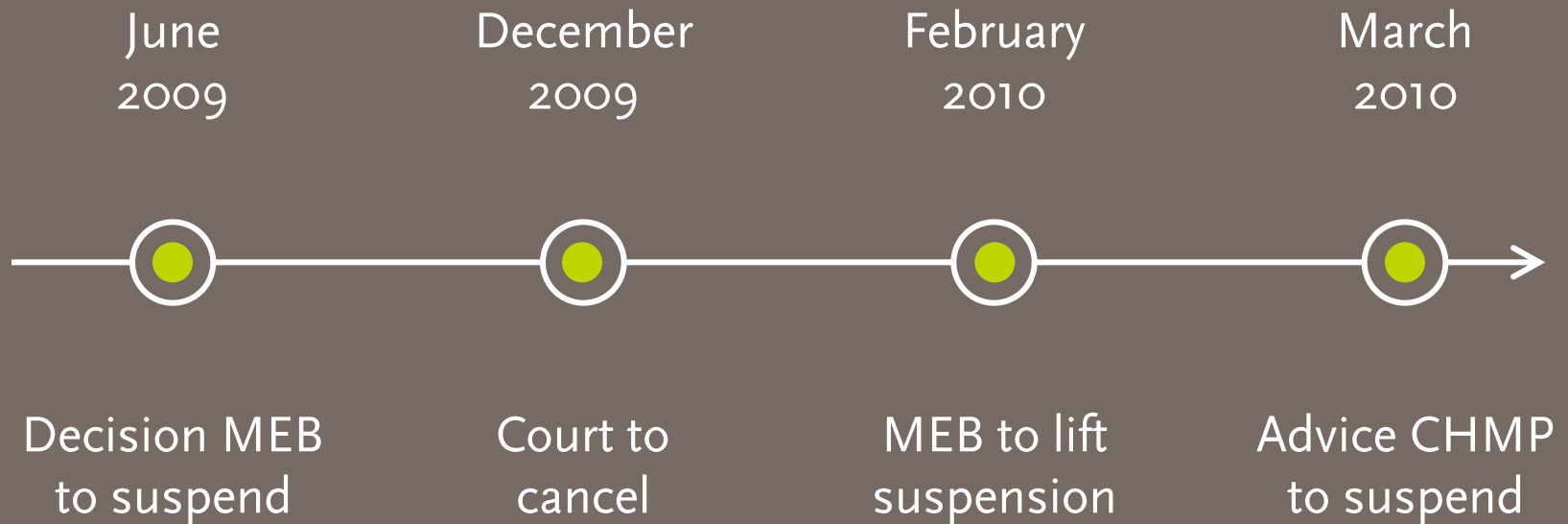
# Practical Consequences

1. 22 % of all generic registrations filed via NL
2. Parties have a formal right to ask for review of granted marketing authorisations
3. Via escalation procedure effect in Europe

# Grounds for Revocation or Suspension



# Recent Example Case MEB



# Summary

## Secondary patents

- Earlier filing
- Description.

## Logical order of proceedings

- **phase 1**  
Settlement
- **phase 2**  
Argument and casemanagement

## Marketing authorizations

- awareness in NL during litigation

# THANK YOU!

Please send your questions to [anke.heezius@lslegal.nl](mailto:anke.heezius@lslegal.nl)

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