

Pricing approach to data compensation under the BPR

- Legal Seminar on Data Sharing, 13th International Fresenius Conference -

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Agenda

- 1. BPR provisions on mandatory/voluntary data sharing**
 - 2. Game theory: Does fairness matter?**
 - 3. The win-win-situation**
 - 4. Study value and data compensation**
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Mandatory Data Sharing

- Data involving tests on vertebrates
Recital 57: **Animal welfare**
(Art. 62 & 95)
- Non vertebrate tox/ecotox data
Recital 58: **Level playing field/SMEs**
(Art. 95)
- Revision of BPR ⇒
Extension to e-fate data ?
Recital 58: **Level playing field/SMEs**
(Art. 95)

Voluntary Data Sharing

- Data not involving tests on vertebrates
(Art. 62)

To consider ...

- **Data owner and prospective applicant**

Ideal scenario: The companies reach an agreement without involving a third party

- **Arbitration bodies**

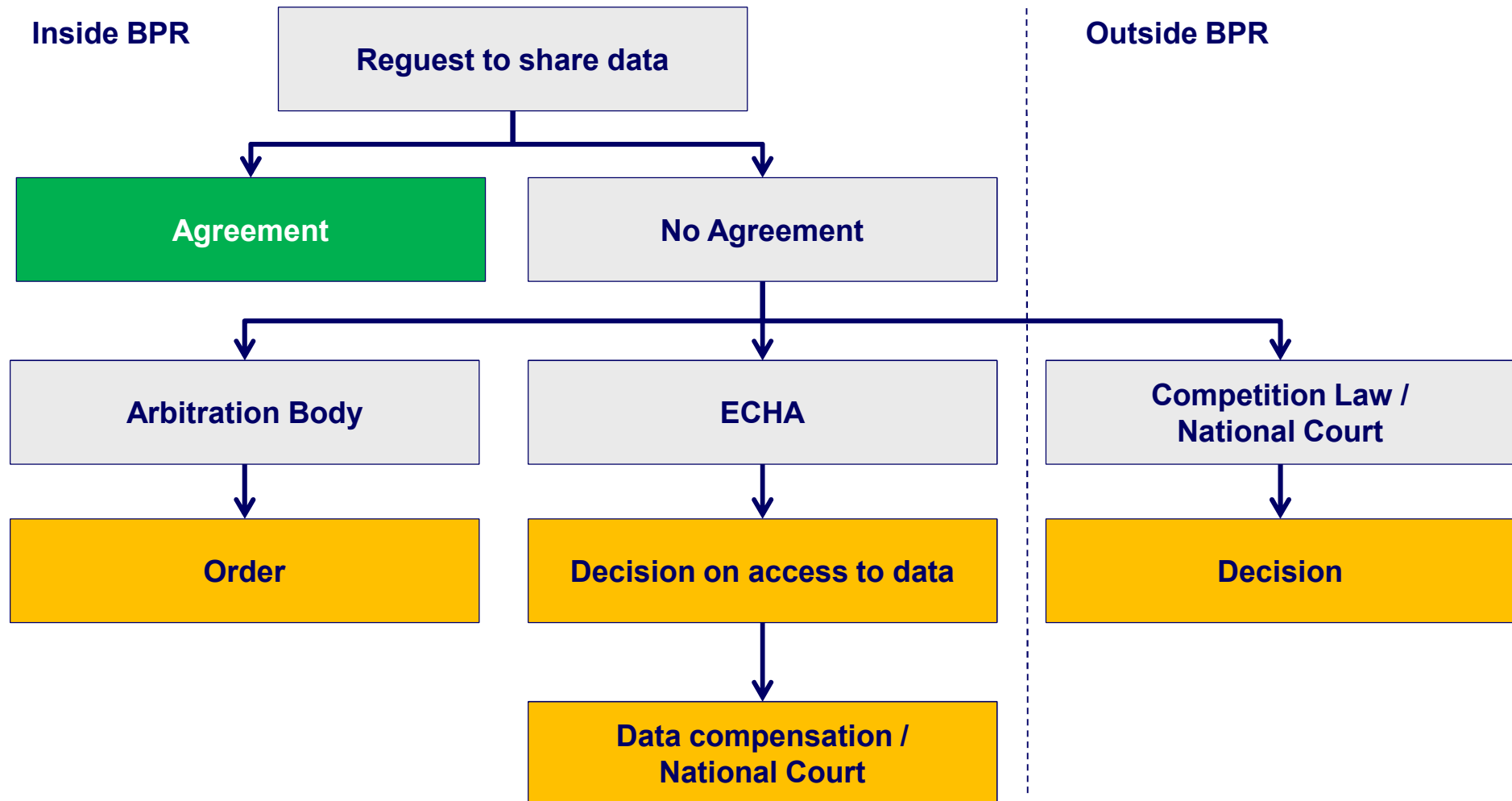
Data owner and prospective applicant commit to accept arbitration order
Art. 63(1)

- **ECHA**

- i. Prospective applicant can raise a dispute; ECHA can give permission to refer to data; Art. 63(3)1
- ii. Appeals may be brought against ECHA decisions; Art. 63(3)5

- **National courts**

- i. Decision on data compensation; Art. 63(3)3
- ii. Disputes involving competition law



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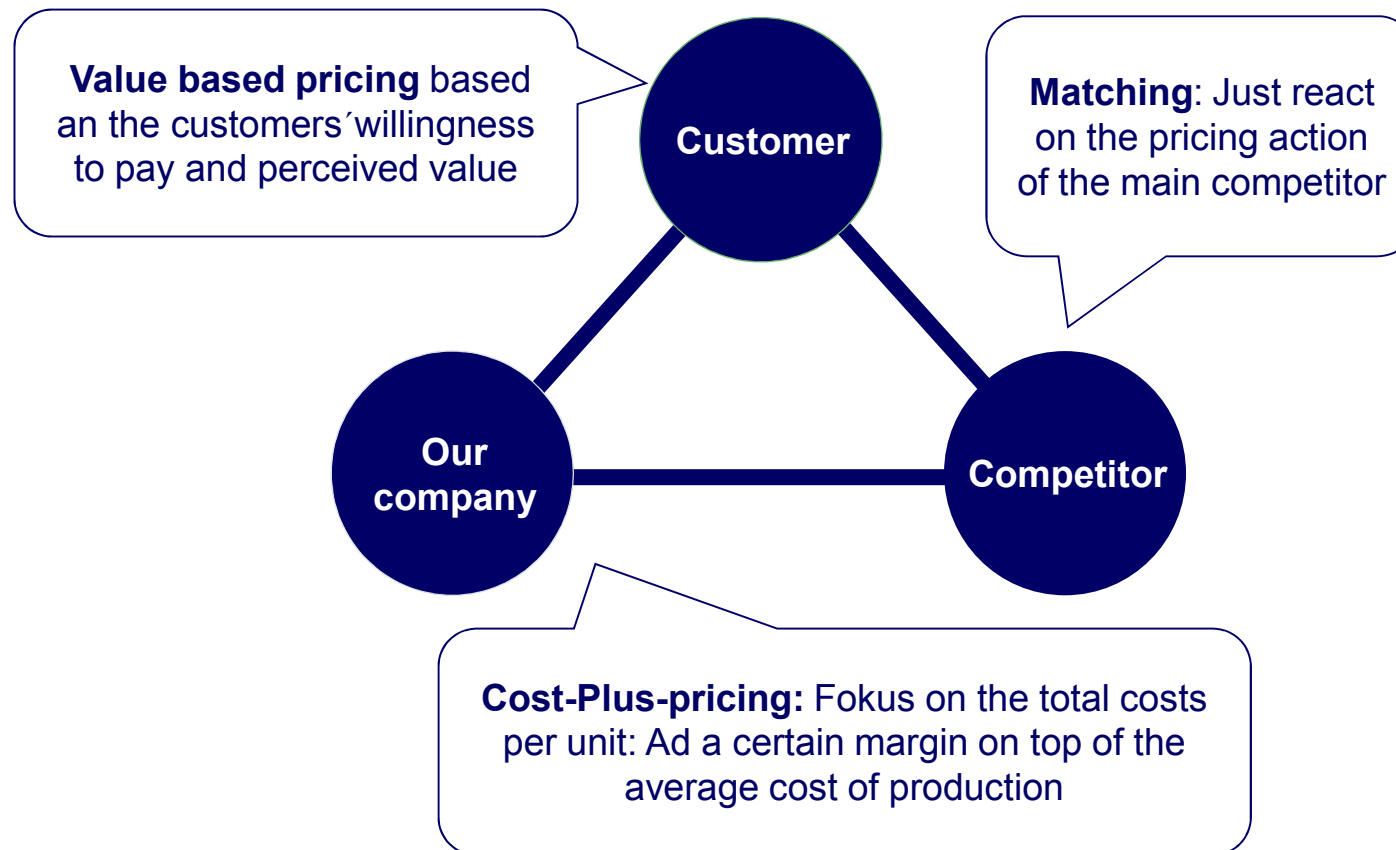
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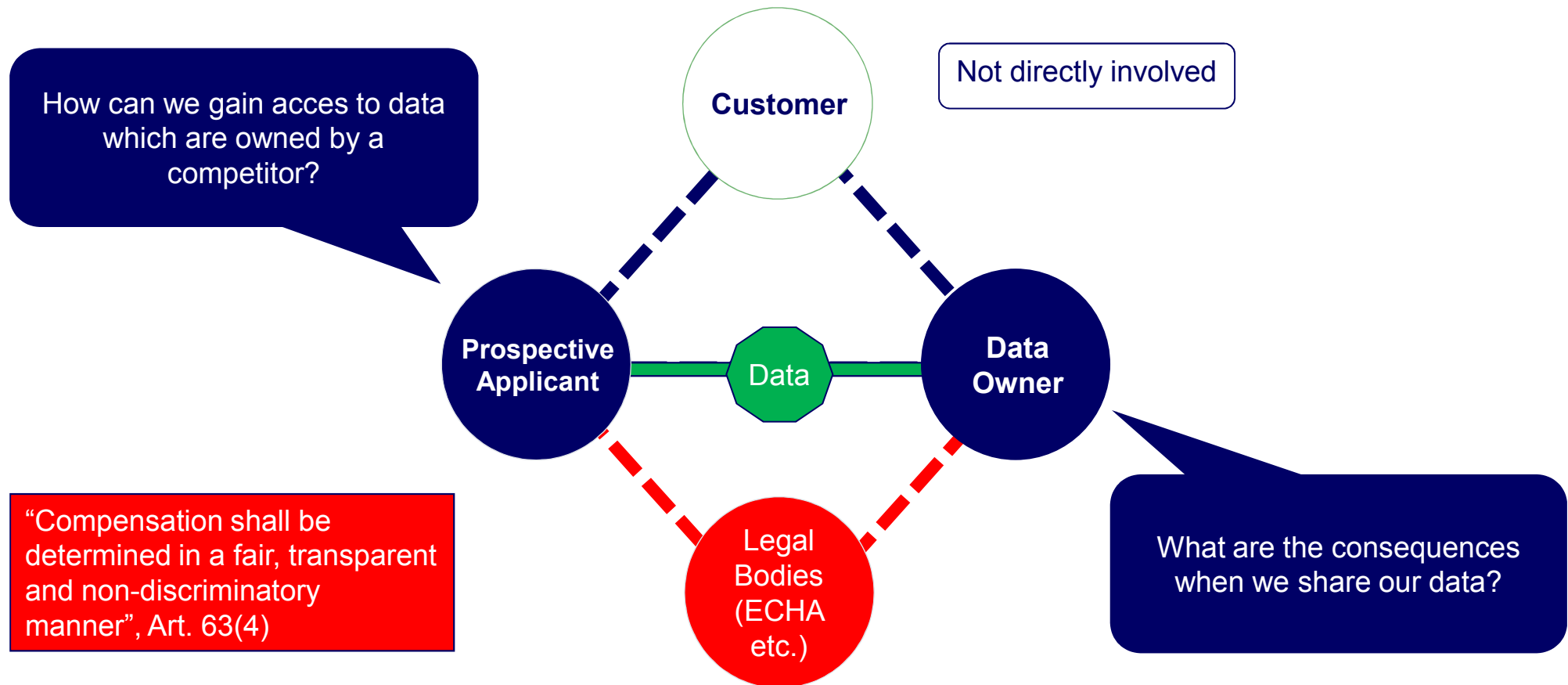
Classic approach to pricing: The strategic triangle and options to determine the price

The strategic triangle: The classical pricing approach



Specific case: Relation between data owner and prospective applicant

The specific situation



Framework

In a classic experiment known as the Ultimatum Game, **person A** is given **10 coins** to split between himself and person B. If person B accepts the distribution, they both keep the coins; if not, no one gets paid.

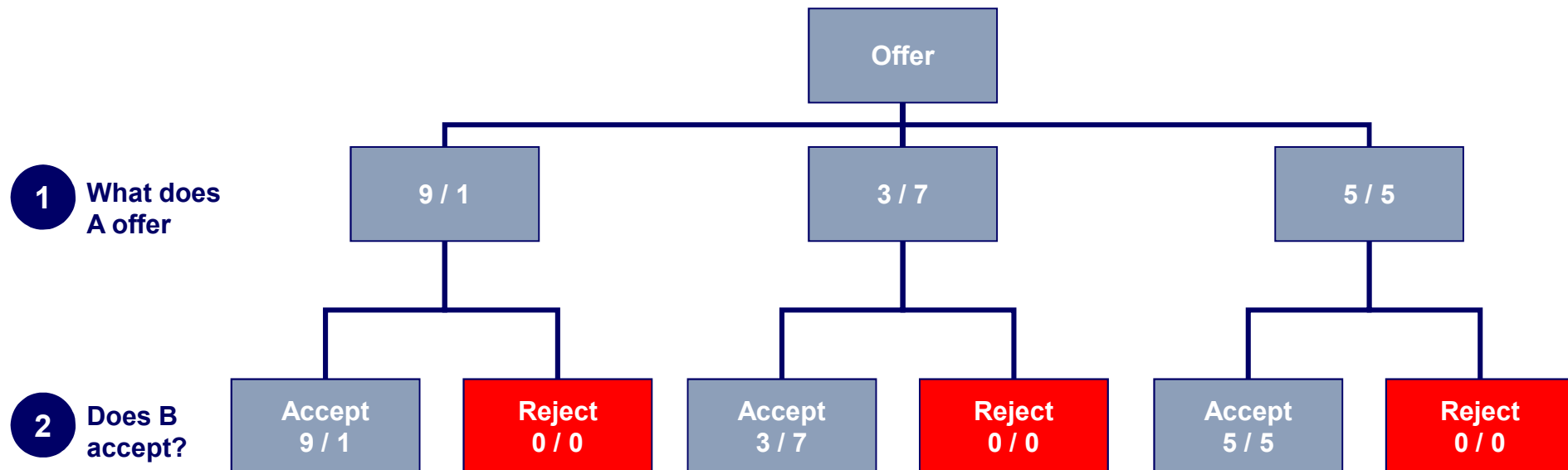


A
(Adalbert)
can offer...



B (Boris)
can accept
or reject
the offer

Decision making: Different Options



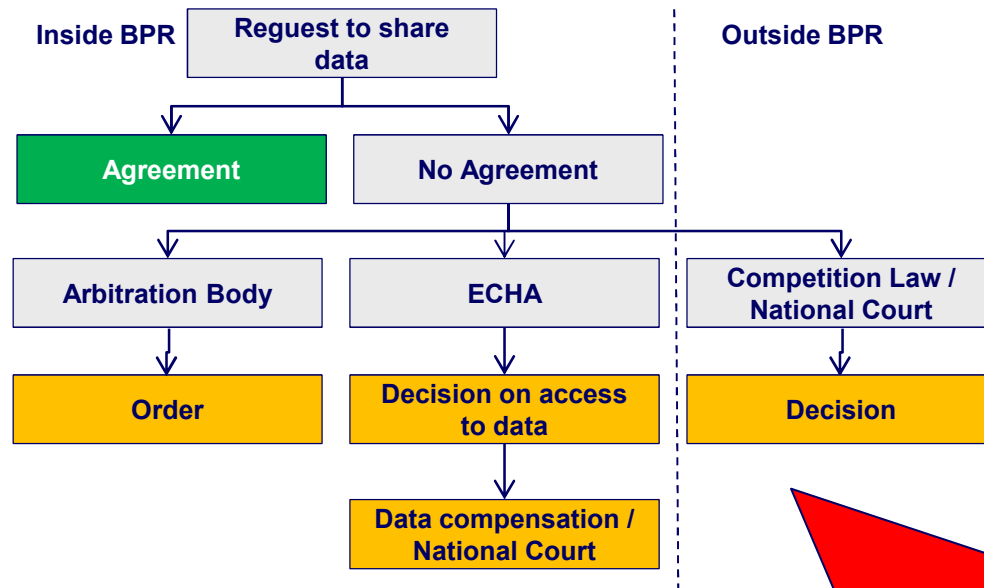
According to Game Theory, the optimal solution is for person A to give himself nine coins and person B one coin - both will end the game richer than when they started. However, played in the wild, the most common distribution is 6-to-4, a ratio seen as fair by both parties.

What did we learn?



Fairness matters !!!

Documentary evidence of data sharing negotiations is key!



Documentary evidence:
Fair? ...Transparent? ...
... Non-discriminatory?

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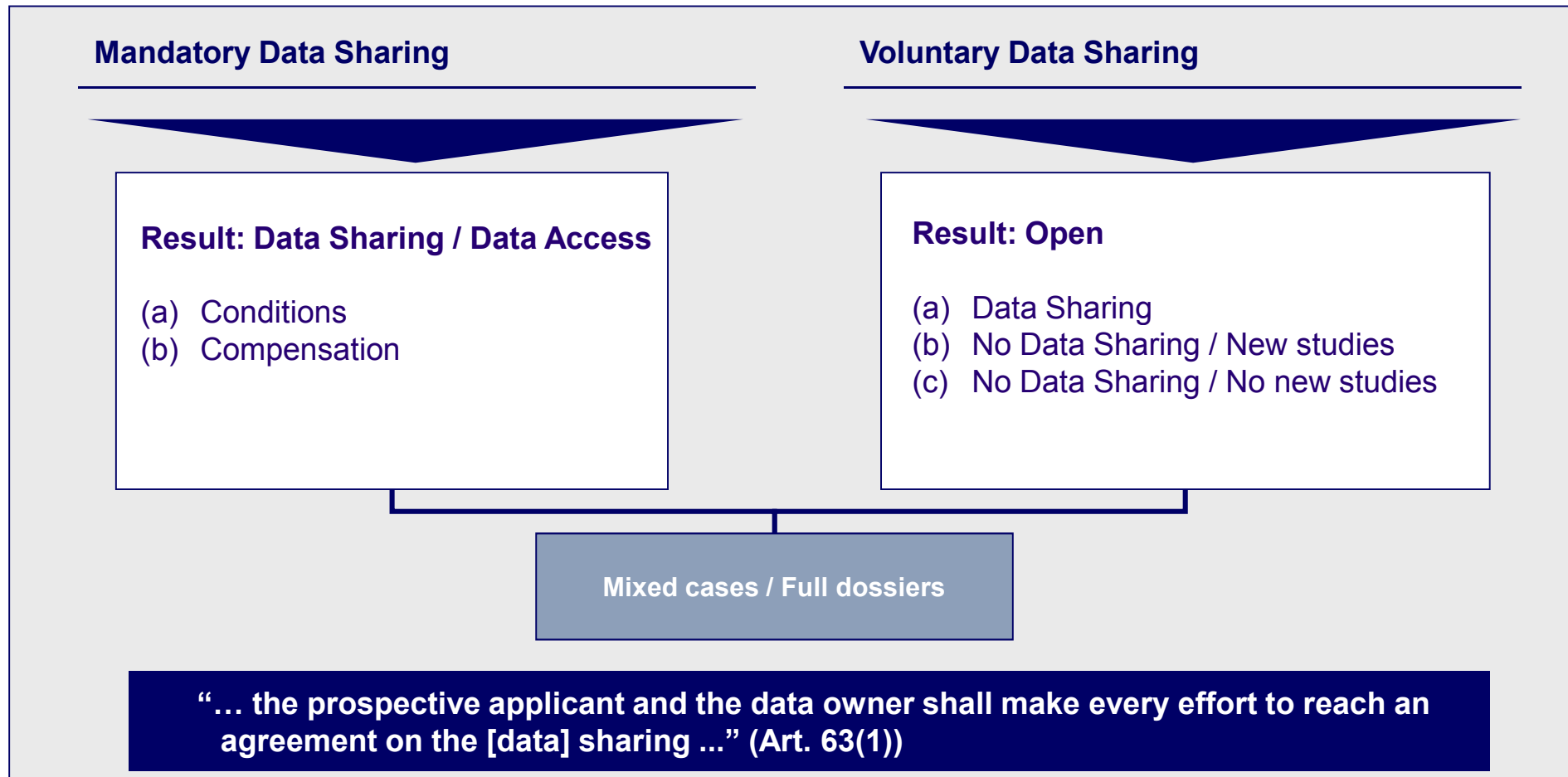
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We have to differentiate between 2 different scenarios ...

Decision making: Different Options



Identifying a dominant strategy (1) - Mandatory Data Sharing

Mandatory Data Sharing - Decision Making: Different Options

Data owner	Co-operate	<p>No Data Sharing No Data Access</p> <p>Maintain monopoly</p>	<p>Data Sharing Fair compensation</p> <p>Lose monopoly</p>
	Don't Co-operate	<p>No Data Sharing Data Access ? Reduced compensation ?</p> <p>Lose monopoly ?</p>	<p>No Data Sharing Data Access Reduced compensation</p> <p>Lose monopoly</p>
		Don't co-operate	co-operate
Prospective Applicant			

Simplified Case
1 Data owner
1 Prospective
Applicant

Identifying a dominant strategy (2) - Voluntary Data Sharing

Voluntary Data Sharing - Decision Making: Different Options

Data owner	Co-operate	<p>No Data Sharing No new data</p> <p>Maintain Monopoly</p>	<p>Data Sharing Fair compensation Regulatory safety</p> <p>Lose Monopoly</p>
	Don't Co-operate	<p>No Data Sharing No new data</p> <p>Maintain Monopoly</p>	<p>No Data Sharing New data Regulatory risk</p> <p>Lose Monopoly</p>
		Don't co-operate	co-operate

Prospective Applicant

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1 Letter of Access (BPR /EU only) = 50 % of Equal Share

- This is the minimum a data owner must grant according to the BPR / ECHA
- But: A prospective applicant might need to pay again or generate new data to access other countries

2 Letter of Access (global) = 70 % of Equal Share

- Data owners might consider global access
- But: A prospective applicant might need to generate new data to access countries that don't accept the Letter of Access concept

3

Co-ownership = Equal Share

- Data owners are unlikely to give co-ownership to a prospective applicant
- Only this level of access is fully sufficient for a prospective applicant with global business

⇒ **The correction factors proposed by ECHA for the study value might not be appropriate for all biocide markets**

1 Historic costs

- Difficulties to provide proof of costs for data owner

2 Replacement costs

- Most practical approach is to obtain up to date quotations from laboratories

3 Any other?

- Value of the market? NPV of the business etc.
- *It is the responsibility of the members of the joint submission (Under the BPR: The companies) to agree on the cost model which is the most appropriate (historic costs, replacement costs or any other). This model must be fair, transparent and non-discriminatory. (ECHA Guidance on Data Sharing, Chapter 5.3.2)*

⇒ Strategic considerations can also determine the value of the data

1 Payment period

- The payment is made at once / upfront
- The payment is spread over several years

2 Start of payment

- Date of signature of the data sharing agreement
- A later date, e.g. for active substances that are not yet approved

3 Flexible payment

- Prospective applicant can pay instalments within payment time windows
- Anticipated payments could be rewarded with a discounts, etc.

⇒ The amount of compensation is important from an economic point of view, but payment terms are important from a financial point of view and can significantly influence the business case

1 Data owner

- A data owner is usually a manufacturer / supplier and supports itself the approval of the active substance

2

Prospective applicant

- A Prospective applicant is usually a manufacturer / supplier and wishes to support approval of the active substance

3

New players?

- Can a company act only as a trader and buy / resell data or data access at profit?
- Can a company act only as a sponsor for new data and sell it to prospective applicants at profit?
- Advantages: Laboratory discounts, synergies and reduced protocols, read across, etc.

⇒ Besides data owners and prospective applicants new players might show up on the playground



**Thank
you!**