

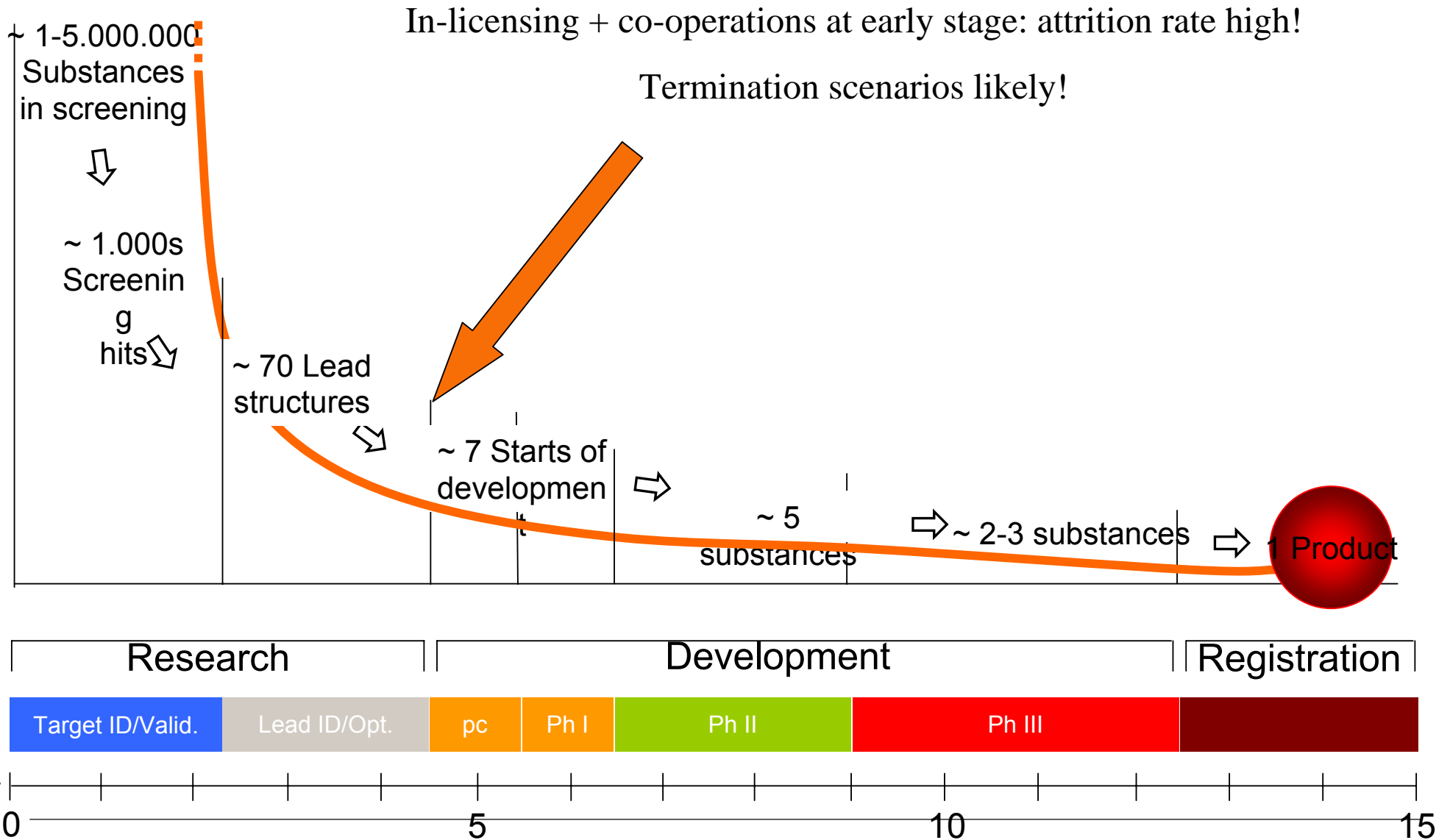
Mannheimer Swartling Russia

Worldwide R&D co-operations in the pharmaceutical industry

Dr. Christoph C. Dengler

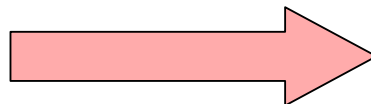


Research & Development Process of pharmaceutical drug



What means this attrition rate?

Объединение
„together!“



Развод
That's it!



In early stage RX (not OTC):
high probability of failure!

Scenario: In-licensing for Alzheimer

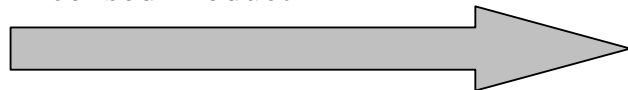
Biotech A

has developed certain compounds at pre-clinical stage which might be suitable to cure Alzheimer, generated know-how and filed patent applications in this field (Biotech A IP), and has „Other Background IP“

Biotech A IP

Other Background IP

Grant of **exclusive** license under the Biotech A IP to develop, manufacture, market and distribute Licensed Product



Licensed Product might violate Other Background IP of A

Big Pharma B

has knowledge and expertise in the field of developing pharmaceutical products, in particular in the field of Alzheimer (Big Pharma IP“)

Research & development of Licensed Product



Entering into the cooperation agreement

СВИДЕТЕЛЬСТВО
О ЗАКЛЮЧЕНИИ БРАКА

Имя отчества
гражданство
подлинность (соответствует, если укажите и место акта о заключении брака)
№ _____ от _____ г.
Место рождения _____

Имя отчества
гражданство
подлинность (соответствует, если укажите и место акта о заключении брака)
№ _____ от _____ г.
Место рождения _____

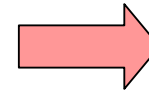
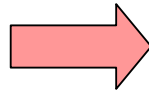
заключили брак
числа, дня, год (сентябрь и прочее)

о чем _____ года _____ месяца _____ числа
составлена запись акта о заключении брака № _____
После заключения брака присвоены фамилии:
мужу _____
жене _____
Место государственной регистрации _____
подлинность (соответствует, если укажите место государственной регистрации)

Дата выдачи « _____ » _____ г.
М.П. _____
Руководитель органа
записи актов гражданского состояния

ИСТ. 1996

Challenge: find a balance



Research and development obligations



- 1) Expectation Biotech A:** Big Pharma B shall develop Licensed Product in line with the Development Plan according to the schedule (contains timelines!)
- 2) Offer Big Pharma B:** intends to develop according to schedule
- 3) Fall back position of Biotech A:** B shall use best efforts to develop Licensed Product according to the schedule
- 4) Compromise:** B shall use reasonable efforts to develop Licensed Product according to the schedule

Governance



- 1) **Creation of various committees:**
„Joint Steering Committee“, „Joint Research Committee“, „Joint Development Committee“ etc.
- 2) **Purpose:** Exchange of information, know-how transfer...
- 3) **Members:** Also non-employees? Confidentiality!
- 4) **Power:** Scope of authority, escalation procedure of disagreement - who has decisionmaking authority,? Harmonization with development obligation of licensee!
- 5) **“Hidden purpose”:** Licensor to gain experience, smooth take over of Licensed Product in case of termination due to information or insolvency

Exchange of information



1) Purpose for Biotech A:

- Fulfils its obligations as licensor
- Monitoring of development objectives of B, therefore: regular updates, also regarding clinical trials
- „free of charge“ learning, in particular regarding commercialization
- Potential take over in case of termination and/or insolvency!

2) Interest of Big Pharma A: Restricting access

- no detailed reports
- No further expenses in terms of time
- No interest and resources in particular after termination, new focus!

Termination



1) **Typical:** This Agreement shall remain *valid until the last to expire Patent Right*.

Alternative: ...shall remain *valid for the time during which licensee remains obligated to pay royalties under section [xyz]...*

2) **Problem:** focus on patents, but know-how forgotten

3) **Important:** Termination at will by Big Pharma B at any time. Biotech A objects. Why important for B?

- a) be able to drop programs for prioritized other programs, potential contractual restrictions of alternative research
- b) overall strategy changes: focus on other therapeutic areas
- c) results not promising
- d) competitors faster, takes away future market share

Termination – what happens?



1) **Underestimated problem:** Termination for material breach.
But: If Biotech A commits material breach, and Big Pharma B terminates, it loses its licenses! Therefore:

2) **Solution:** differentiate who commits breach!

breach committed by:

Biotech A

Big Pharma B

Loses right to royalties
and payments (?)

Damage claims

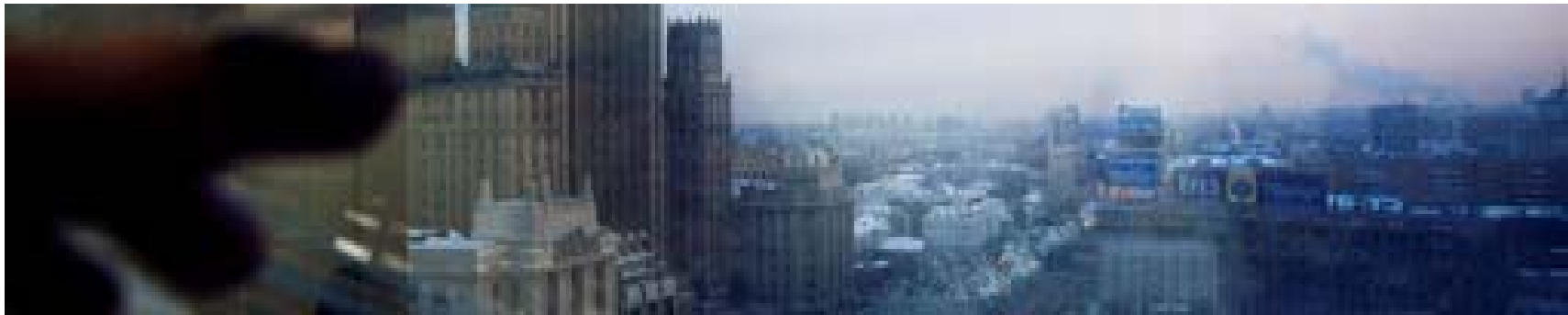
Grant license to use
Biotech A IP?

Loses right to use IP

Damage claims

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Thank you!



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