

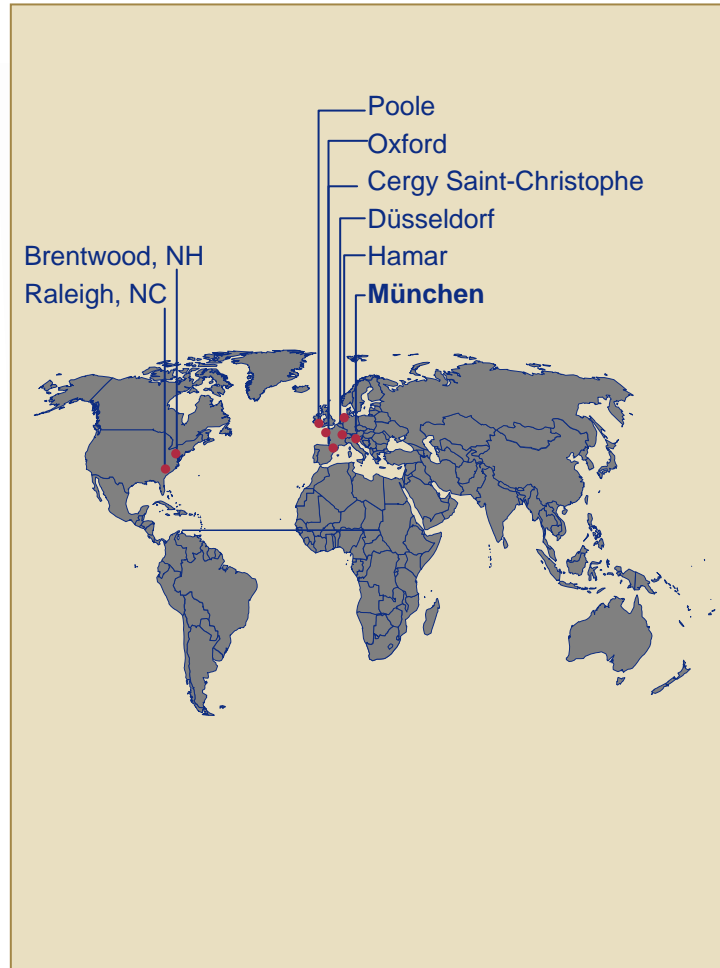
US and European Patent Law: Anticipated Changes & the Impact on the Life Sciences Industry



BIO Europe, November 12, 2007, HAMBURG

Stephen S. Yoder
Head of Licensing & Intellectual Property
MorphoSys AG, Munich

The MorphoSys Group Today



■ Company Facts

- | | |
|-----------------------------|--|
| ■ Listed | ■ Frankfurt, TecDAX |
| ■ Headquarters | ■ Munich |
| ■ Subsidiaries | ■ AbD Serotec |
| ■ No. of Employees | ■ ~300 |
| ■ Revenues | ■ €53 million (2006)
■ Growth 22% (58%) (2006) |
| ■ Profitable | ■ Since 2004 |
| ■ Focus | ■ Antibodies, using proprietary technologies built around HuCAL® |
| ■ HuCAL® is used for | <ul style="list-style-type: none"> ■ Therapeutics ■ Research reagents ■ Diagnostics |

MorphoSys' Partnering Record



✓	Pfizer	1999		
	GlaxoSmithKline			
	Sanofi-Aventis			
✓	Johnson & Johnson	2000		
✓	Merck & Co.			
	AstraZeneca	2001		
✓	Novartis			
✓	BMS	2003		
	Wyeth			
	Abbott Labs			
✓	Eli Lilly	2004		
✓	Roche			
	Amgen	2005		
✓	Boehringer Ingelheim			
	Takeda	2006		
✓	Schering-Plough			
✓	Astellas			
✓	Schering	2007		
✓	Bayer			
✓	Daiichi-Sankyo			

Sources: PharmaExec50 / MOR Research, Pro forma
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- 1: Are we in the Lurch? (a Tribute to GSK!)**
- 2: Assuming the Worst: from Gamesmanship to Marksmanship
(with some nasty traps along the way)**
- 3: More to Life Than the Continuation Rules: the Upstream and
Downstream Conundrums, With no Rights in Between**

Left in the Lurch? Suspension, possibly retraction, of the Rules

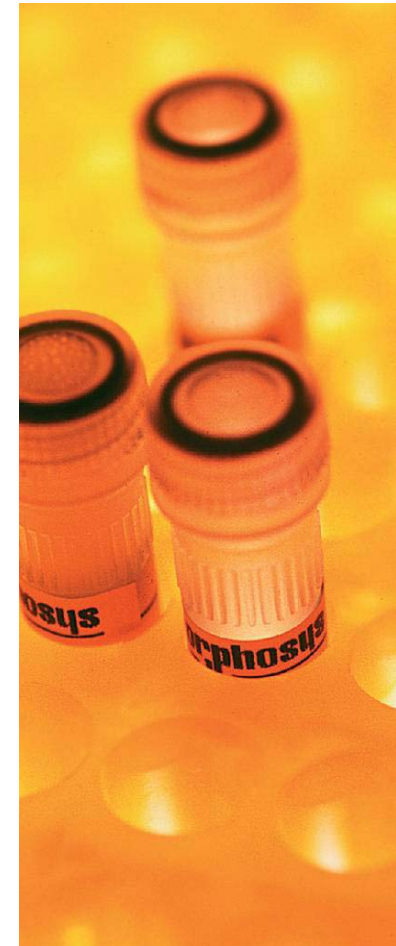
- **Pronunciation:** \ˈlɜrch\
 - **Intransitive verb; dialect chiefly England:** to loiter about a place furtively
 - **Idiom:** to *leave someone in the lurch*: to abandon them in a difficult situation, especially when they might have expected help.

Can it get any worse? Hopefully, prior due diligence suffices

- **2** (continuations) + **1** (RCE)
 - If you've had two bites at the apple, finish it quickly or throw it away
- **5** (*pending* indep. claims) / **25** (total *pending* claims)
 - If you've been gorging on claims, think about going on a diet

Sources: www.m-w.com; www.allwords.com

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The way it's (alleged to have) been

- **Gamesmanship:** Prosecution on the merits falls prey to feel-good horse-trading with the patent examiner, under the current USPTO Examiner quota system:
 - RCE Freedom
 - Continuation Application Practice
 - The proverbial RCE after final rejection, coupled with a continuation → at least 3 “counts” for the examiner!
- **Restriction-of-Invention Practice**
 - *e.g.*, (i) polypeptide, (ii) DNA molecule, (iii) vector encoding the DNA molecule and (iv) methods of treatment, *with respect to the **same** drug*, are nonetheless **different** inventions
 - We **hate** this (but other than having to pay the USPTO more money, there is no real drawback).



The way (we fear) it's Gonna Be



■ Marksmanship:

- Get all of your arguments on the record before Final Rejection
- From your first Reply, act as though you're going to the BPAI
- **No more** proverbial RCEs after final rejection, coupled with a continuation → at least 3 “**strikes**” against you!

■ Restriction-of-Invention Practice

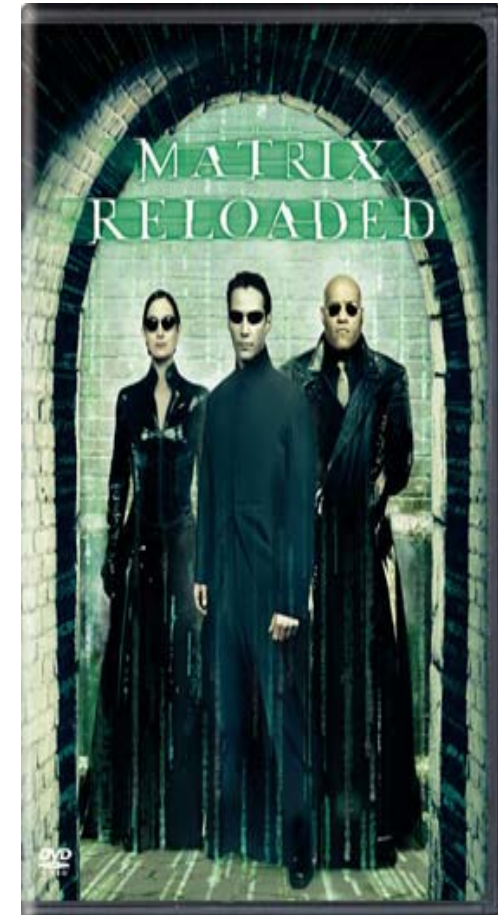
- *e.g.*, (i) polypeptide, (ii) DNA molecule, (iii) vector encoding the DNA molecule and (iv) methods of treatment, *with respect to the same drug*, are nonetheless **different** inventions
- We **love** this! And give me **more**!



Navigating the Maze to Maximize Value: A Different Kind of Matrix

The Suggested Restriction Requirement(!)

PolyPep	DNA	Vector	Method	Vacuum Cleaner + PolyPep
P1	P1	P1	P1	P1
Con1	Con1	Con1	Con1	Con1
Con2	Con2	Con2	Con2	Con2
RCE	RCE	RCE	RCE	RCE



Mind the Traps: ESDs & Provisional Restrictions

- **Examination Support Documents (ESD) Trap**
 - Pre-requisite to exceeding the 5 / 25 Rule
 - Procedural nightmare: in pilot study, well over half bounced for non-compliance with procedures
 - Frought with inequitable conduct vulnerabilities



Mind the Traps: ESDs & Provisional Restrictions



Examination Support Documents (ESD) Trap

- Pre-requisite of exceeding the 5 / 25 Rule
- Procedural high score: in pilot study, well over half bounced for non-compliance with procedures
- Proceed with inequitable conduct vulnerabilities

eSpeed, Inc. v. Brokertec, 409 F.3d 1337 (Fed. Cir. 2007)
McKesson Info. Sol., Inc. v. Bridgepoint, 409 F.3d 1359 (Fed. Cir. 2007).
Cargill v. Canbra Foods, Ltd., 416 F.3d 1129 (Fed. Cir. 2007).
Dippin' Dots v. Mosey, 476 F.3d 897 (Fed. Cir. 2007).



Mind the Traps: ESDs & Provisional Restrictions

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■ Provisional Restriction Trap

- Genus-Species Restriction
- Be careful when at the **bottom** of the matrix



Mind the Traps: ESDs & Provisional Restrictions

PolyPep	DNA	Vector	Method	Vacuum Cleaner + PolyPep
P1	P1	P1	P1	P1
Con1	Con1	Con1	Con1	Con1
Con2	Con2	Con2	Con2	Con2
RCE	RCE	RCE	RCE	RCE



Mind the Traps: ESDs & Provisional Restrictions

PolyPep	DNA	Vector	Method	Vacuum Cleaner + PolyPep
P1	P1	P1	P1	P1
Con1	Con1	Con1	Con1	Con1
Con2	Con2	Con2	Con2	Con2
RCE	RCE	RCE	RCE	RCE



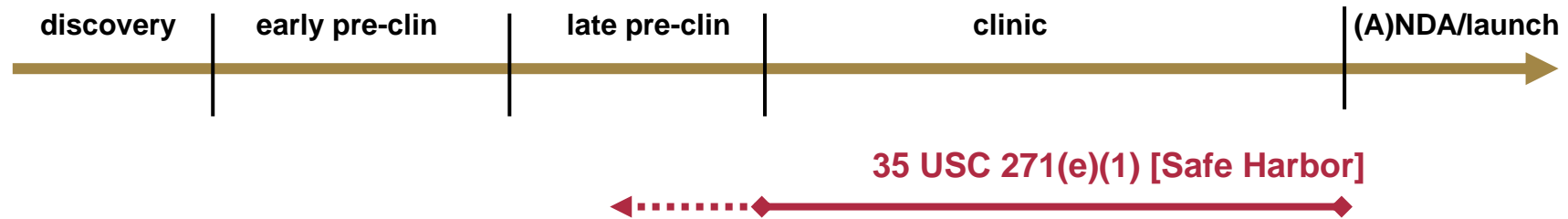
Mind the Traps: ESDs & Provisional Restrictions

PolyPep	DNA	Vector	Method	Vacuum Cleaner + PolyPep
P1	P1	P1	P1	P1
Con1	Con1	Con1	Con1	Con1
Con2	Con2	Con2	Con2	Con2
RCE	RCE	RCE	RCE	RCE

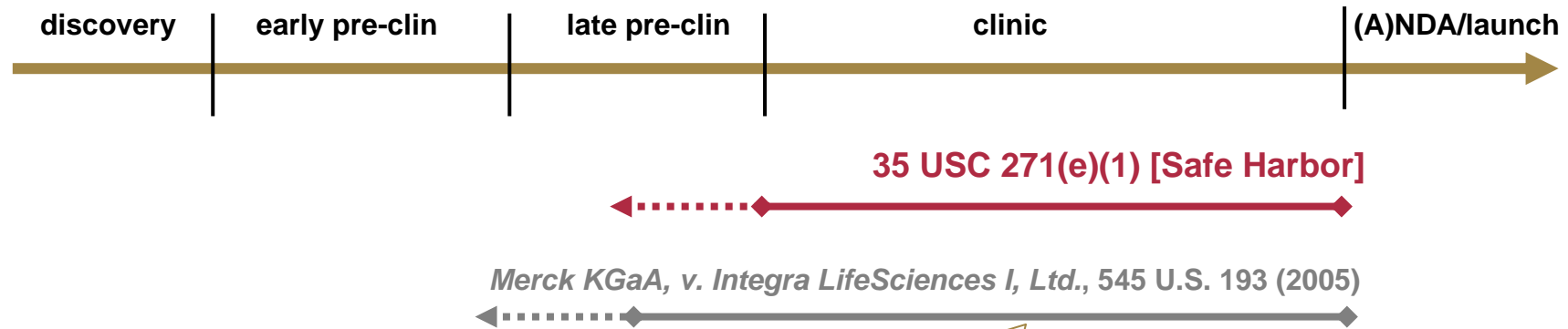


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...And Don't Forget about the Judiciary's New Rules: Legislating From The Bench



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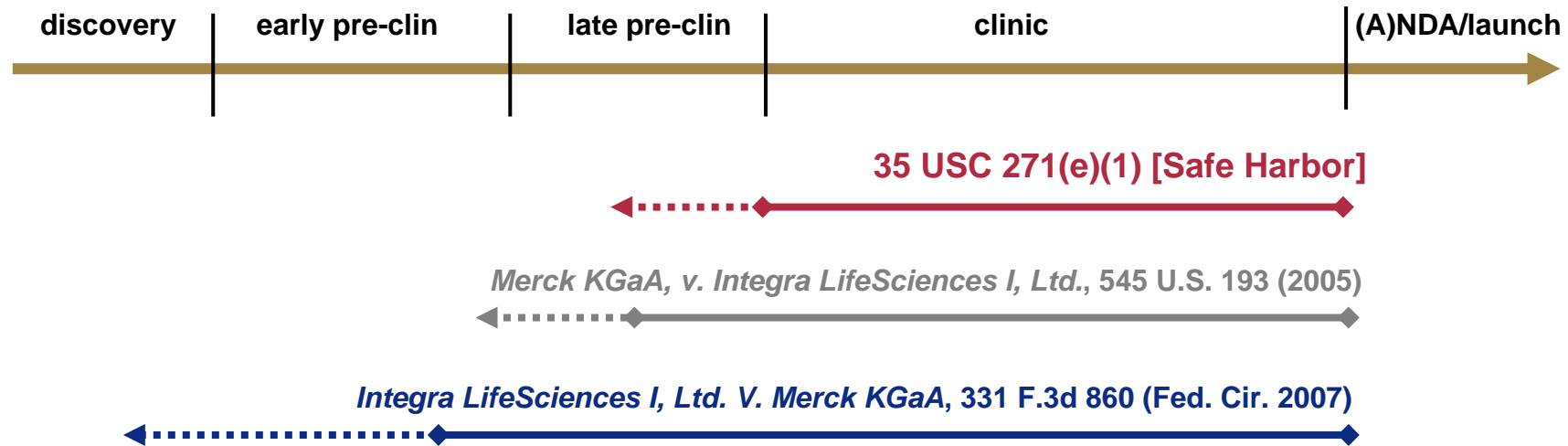


271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA...

This necessarily includes preclinical studies



...And Don't Forget about the Judiciary's New Rules: Legislating From The Bench



The safe harbor does not depend on a distinction between “discovery” and “routine,” but on whether the threshold biological property and physiological effect had already been recognized as to the candidate drug.

Experiments relating to efficacy, mechanism of action, pharmacology, pharmacokinetics and/or safety...

The [Supreme] Court recognized that experiments are run in order to learn information, whatever the stage of the research.

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35 USC 271(e)(1) [Safe Harbor]



Merck KGaA, v. Integra LifeSciences I, Ltd., 545 U.S. 193 (2005)



Integra LifeSciences I, Ltd. V. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2007)



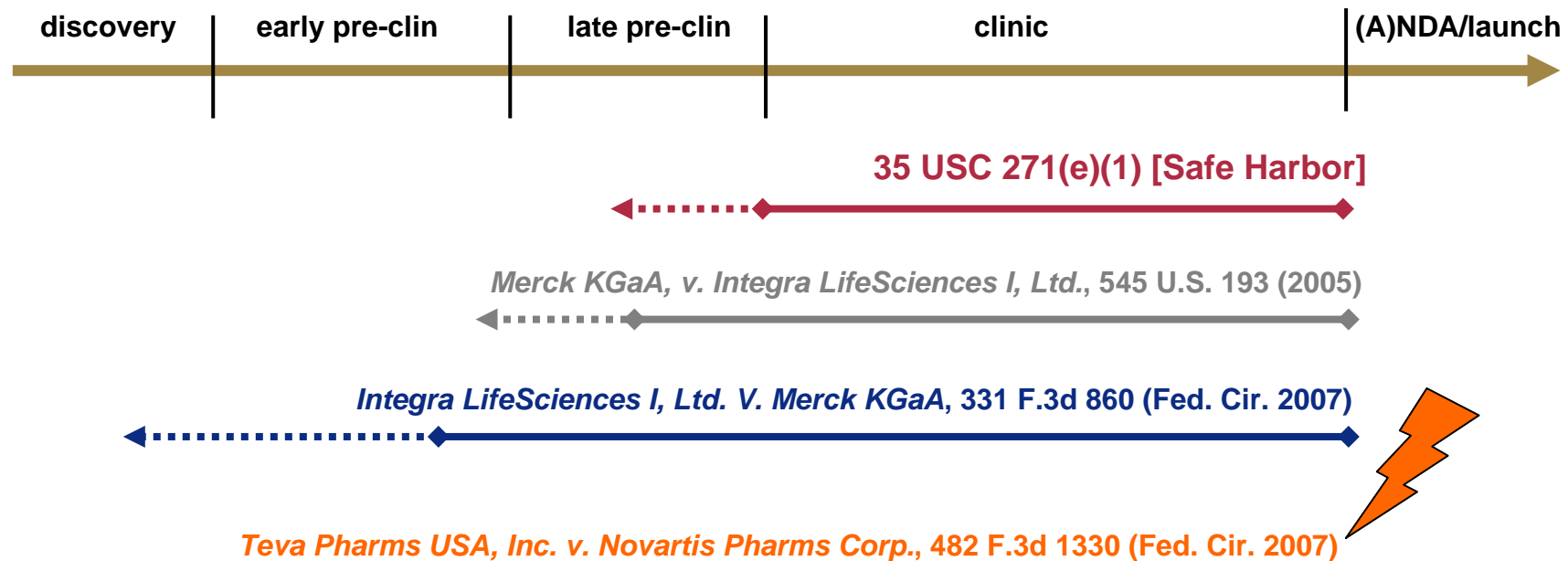
Teva Pharms USA, Inc. v. Novartis Pharms Corp., 482 F.3d 1330 (Fed. Cir. 2007)



A justiciable declaratory judgment controversy arises for an ANDA filer when **(i)** a patentee lists patents in the Orange Book, **(ii)** the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and **(iii)** the patentee brings an action against the submitted ANDA on one or more of the patents.

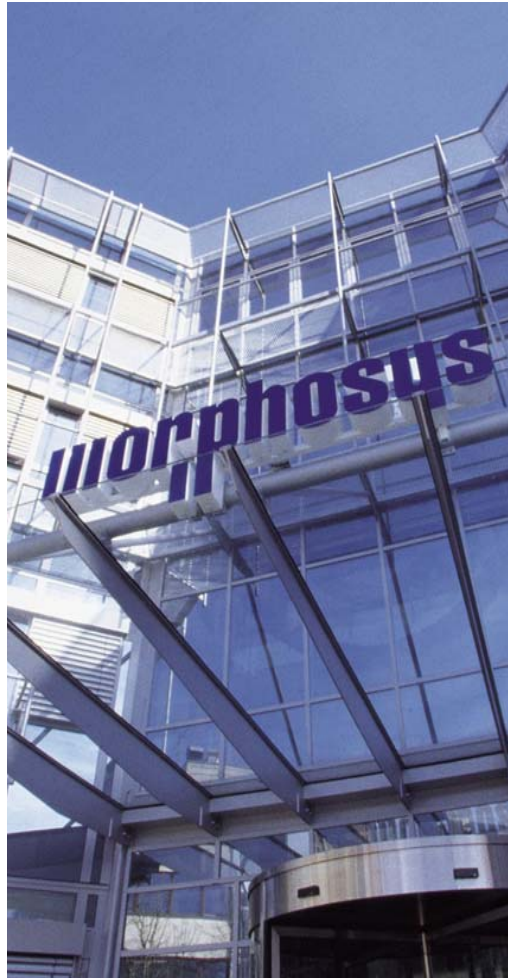


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- Is *Teva v. Pfizer* (a pre-*MedImmune* decision) still good law?
- It is uncertain whether a generic drug company has declaratory judgment jurisdiction where the pioneer company has **not** brought suit on any patent.

Thank You



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