

The fine line between Intellectual Property & Competition

IGBA Annual Conference - Orlando

Sergio Napolitano

16 February 2023



ANATOMY OF A FAILURE TO LAUNCH:

Barriers to generic market entry and
the use of competition law as a remedy

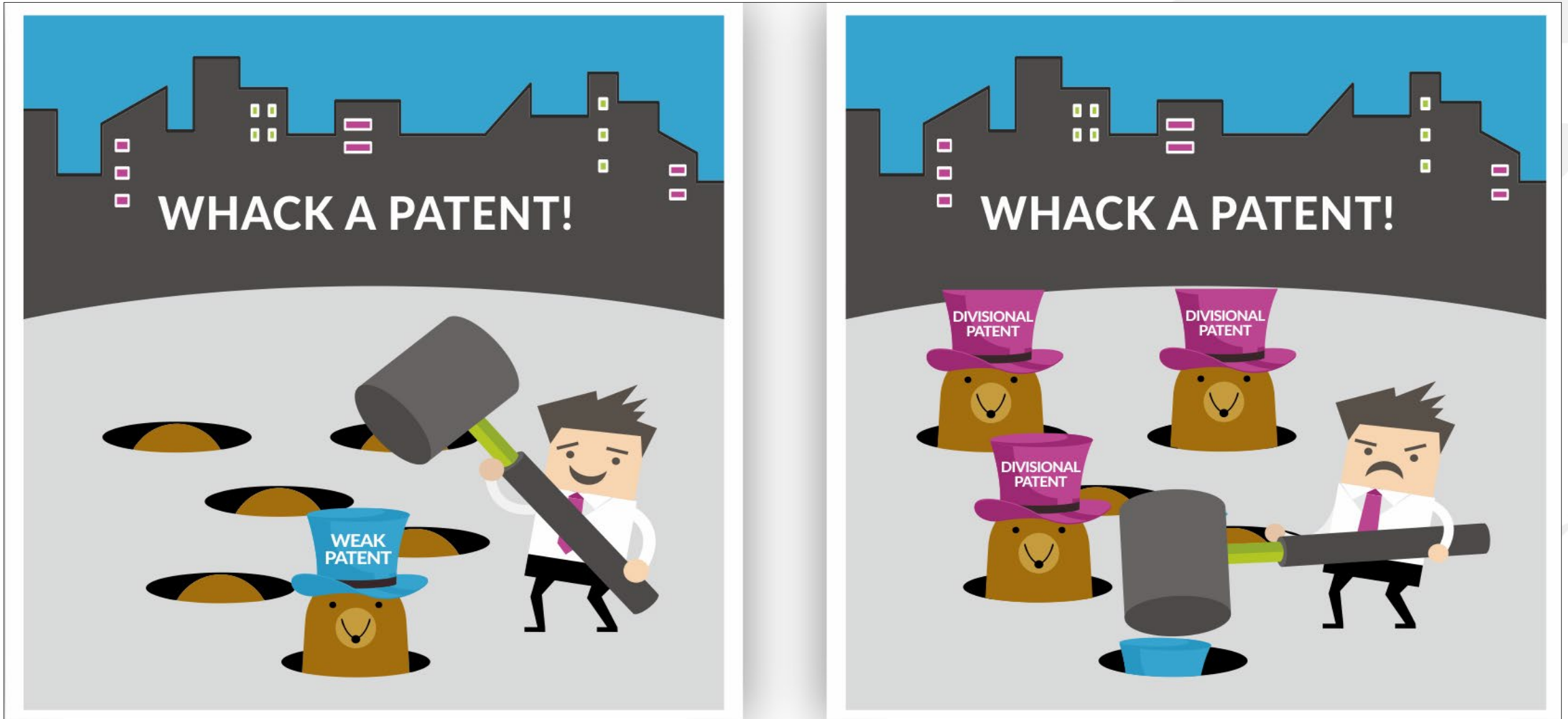
Identified barriers to Generic/Biosimilar market entry

- Patent Thickets
- Divisional patents
- Patent Linkage (MA/P&R/Tenders blocked b/c of patents)
- Product Hopping
- Predatory Pricing / Anti-competitive rebates
- Disparagement

Abuses/Misuses of Divisional Patent Procedures at EPO

- **The issue:**
 - No limit to divisional tactics → Abused/misused to delay generic/biosimilar market entry
 - 2009 European Commission Preliminary [Pharmaceutical Sector Inquiry Report](#) declared it anti-competitive → EPO introduced limitations → in 2014, EPO removed limitations
- **The “*divisional patent game*” at EPO:**
 1. cascades of divisional patent applications related to same weak parent patent;
 2. defended in EPO oppositions;
 3. enforced in national courts, incl. via preliminary injunctions;
 4. used to block P&R procedures for generics/biosimilars (“*unlawful*” patent linkage);
 5. eventually withdrawn, just before EPO decision, to avoid invalidity;
 6. even if invalidated in Court, other divisionals cover the same product
- **This extends the enforceable life of patents!**

“Divisional patent games” defeat checks & balances of the system



The rationale of the system

- **Designed for (1) rewarding innovation with market exclusivities AND (2) ensuring immediate generic/biosimilar market competition after IP expiry**
 - Bolar exemption (for reg. approvals of Gx/Bios to be ready on day-1)
 - SPC manufacturing waiver (for actual production to launch on day-1)

What solutions?

Regionally:

- Equip patent system with guardrails (eg. stricter requirements, justifications, etc.)
- Adapt regulation to prevent/ limit damages (eg. ban EU patent linkage, etc.)
- Set up/improve cooperation b/w competent authorities

Internationally:

- Awareness raising where IP systems are (still) less sophisticated
- Set up/improve cooperation b/w regional competent authorities

● **17th LEGAL AFFAIRS
CONFERENCE**
HILTON HOTEL
MALTA | 12-13 JUNE 2023

L A C 2 3

● **28th ANNUAL
CONFERENCE**
HILTON HOTEL
MALTA | 14-16 JUNE 2023

A C C E S S F O R A L L



◀ **JOIN US**



 **medicines
for europe**
better access. better health.