



BOEHMERT & BOEHMERT
ANWALTSSOZIOIETÄT

IP Litigation in Life Sciences – Germany 2016



Dr. Jan B. Krauss, Patent Attorney, Munich

2016 WIPO Conference Life Sciences Dispute Resolution



Agenda

- The current landscape of life sciences enforcement in Germany
- Changes and challenges for life sciences
- The German IP Court system and specific features thereof
- Costs and timing of court proceedings
- Featured: Preliminary injunctions
- Case examples
- Messages for the practitioner

Life sciences enforcement in Germany



- Germany is the biggest pharma market in the EU
- Market even more important after Brexit
- Litigation also even more important after Brexit
- Germany litigation is regarded as “patentee-friendly”, also for life sciences
- Germany the biggest litigation venue in Europe
- Main venues (forum shopping quite easy):
 - Düsseldorf
 - Mannheim
 - Munich



Life sciences enforcement in Germany

- Pharma litigation in the pharma and biotech sector is/has been widely dominated by disputes between originators and generics companies
- So far, strong focus on legal battle, e.g.
 - preparatory steps for market entry
 - offer for delivery after patent expiry infringes the patent
 - API suppliers and Bolar exemption
 - intelligence, fact finding and securing evidence

Changes and challenges



- The low hanging fruit has been harvested.
- The patent cliff has been left behind.
- Fewer blockbuster drugs will be approved.
- Shift towards more “technical” litigation based on claims could lead to legal uncertainties associated with the construal of claims by a court
- Is this a problem under the German system?
- Anything to do? Different behavior in litigation required?

The German IP Court system and specific features thereof



- Separate proceedings for infringement and validity (“bifurcation”)
- Mix of judges on the case, technical and non-technical
- Litigation is fast and relatively cheap
- No disclosure, no pre-trial discovery
- Injunctive relief will be granted as a general rule
- Injunction is immediately enforceable

- Preliminary injunctions (PIs) in patent cases available (ex parte)

Overview



- Bifurcation: Separation of infringement and invalidity proceedings
- District courts handling patent infringement have no jurisdiction over the validity of the patent - bound to enforce the patent as it is
 - Separate attack on validity before EPO (opposition) or Federal Patent Court (nullity action)
 - Infringement court may then suspend its proceedings to allow the corresponding opposition/nullity action to resolve validity first, if
 - validity attack is pending and
 - there is a high likelihood that the validity attack will be successful

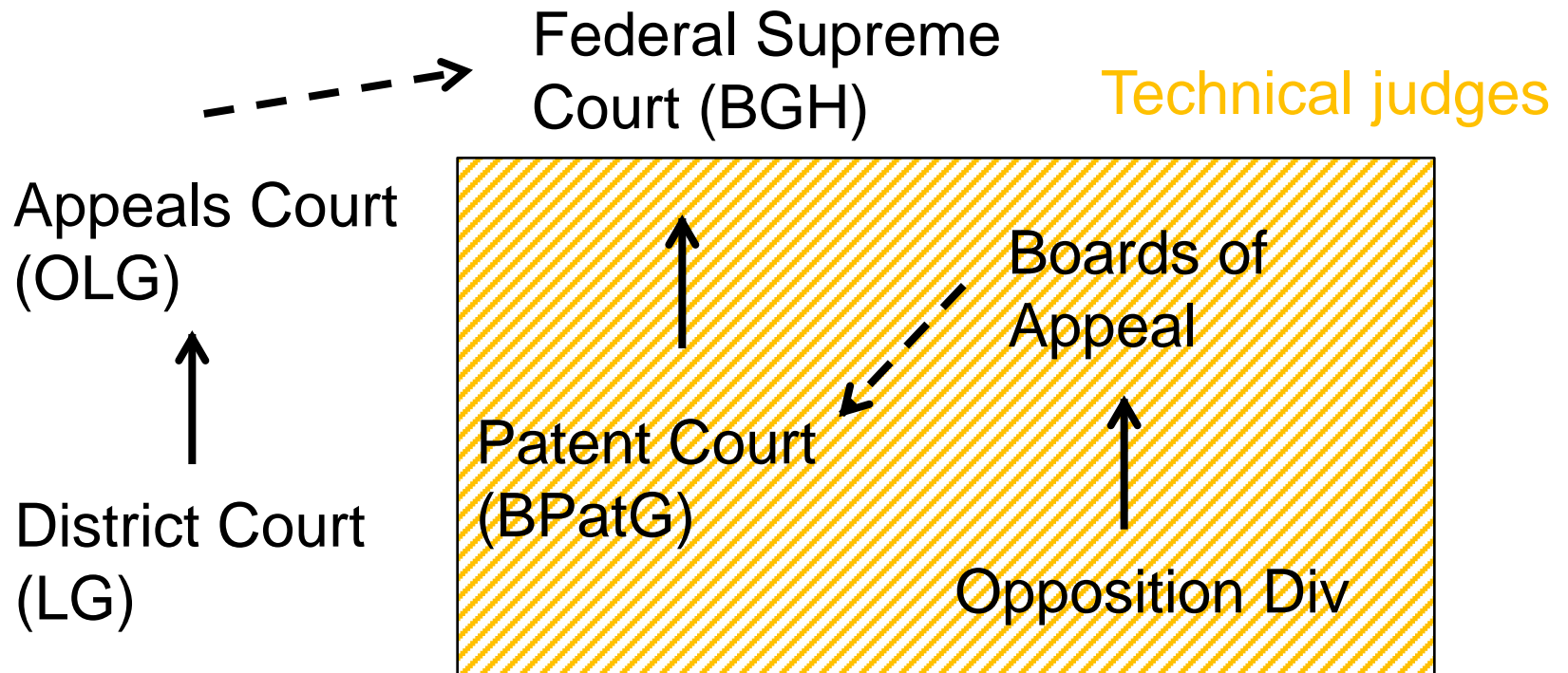
Overview



Litigation

Nullity

Opposition



Timing



- EPO (opposition)
 - 1. Instance – 1-2 years
 - 2. Instance - **3-4 years**
- Federal Patent Court (nullity action)
 - 1. Instance – **2-3 years**
 - 2. Instance – 2-3 years
- Infringement court
 - Düsseldorf : 10-12 months (1. instance)
 - Munich, Mannheim and Hamburg: 6-8 months
- Appeals Court – 18-24 months
- Experts may delay the proceedings
- Federal Supreme Court – 2-3 years

Costs



- EPO (opposition) – costs marginal, each party bears own costs
- Federal Patent Court (nullity action), Infringement courts, Appeals Court and Federal Supreme Court – statutory table of costs
- The losing party must reimburse costs by winning party, but no compensation of costs actually incurred

Approximate cost risk of litigation in first instance:

Value in dispute	1 Million	5 Million	15 Million
Court fees	20,000	60,000	170,000
2 Lawyers, 2 Patent Attorneys	60,000	210,000	570,000

Preliminary Injunctions



- German law permits a patent holder (or licensee) to seek an injunction, also in the form of a preliminary injunction (PI).
- Threat of infringement is a sufficient basis to apply for such a PI.
- PIs can be obtained ex parte – even within a day - and enforced later (“Schubladenverfügung”, but usually only 1 month)
- PIs require clear cut infringement cases and that patent is "sufficiently valid" (i.e. no presumption of validity).
- Another requirement is "urgency". Application must be made shortly (approximately one month) after awareness of the infringement.

Preliminary Injunctions



- Defense against PI:
 - Protective letter with the infringement court
 - May allow defendant to present arguments in advance in a hearing
 - Requires some kind of knowledge
 - Only “provokes” hearing
 - Judge has full discretion
- Objection/Appeal against PI possible
 - Leads to oral proceedings (objection)
 - Does not stop enforcement
- Bond/Surety for enforcement not always required

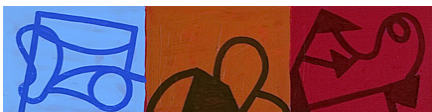
Preliminary Injunctions



- Defense against PI:
 - Protective letter with the infringement court
 - NEW(ish) – centralized register for protective letters

<https://www.zssr.justiz.de/>

Case law



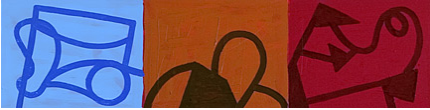
- OLG Karlsruhe (LG Mannheim) - 6 U 52/15 (October 2015)
 - Prerequisite for issuance of PI; no serious doubts about validity and balancing the interests of the parties involved.
 - **Validity only sufficient, if patent survived first instance of opposition or nullity.** If such decision available, in general sufficient validity has to be assumed.
 - Urgency requires no undue delay by requesting party, nevertheless, without the necessity to suffer from an increased risk. Waiting for parallel cases may be justified before filing a request.
 - Requirement of a bond depends on the circumstances of the case and prospective damages.

Case law II



- LG München I, decision of 20.05.2016 – 21 O 22243/15; LG München I, decision of 24.06.2016 – 21 O 5583/16 - Pemetrexed
- PI is not only limited to those cases, where the validity of the protective right is fully assured.
- The balancing of the interests in case of generics may include drop in pricing for originator vs „normal“ compensation for generics. This also holds true for an infringement under the doctrine of equivalence.
- Requesting party may wait for the actual infringement to happen.
- A bond is not required, if there is no indication that damages can not be borne by the losing party.

Case law III



- LG Düsseldorf
- 4a O 106/14 – Irbesartan, April 28, 2016
 - Damages because of PI based on invalid SPC (generics)
- 4b O 139/14 – Ezetimib, March 15, 2015
 - Infringement of an SPC, parallel import, exhaustion
- 4c O 61/15 – Fulvestrantformulierung, November 19, 2015
 - PI rejected because of lack of a decision confirming validity (opposition was withdrawn)

Notes



- Germany will continue to be an important venue for litigation, also in the area of life sciences
- Germany still is a more pro-patentee system
- A shift from proceedings based on regulatory and legal arguments towards “classical patent infringement” will present additional challenges, in particular with respect to claim drafting and validity – cases will get more technical
- Because of the involvement of technical judges, the German system may be better equipped for these challenges
- Because of the recent case law, in cases of PIs, forum shopping should be considered

Thank you!

Boehmert & Boehmert
Dr. Jan Krauss
Pettenkoferstrasse 20-22
80339 Munich
Germany

Krauss@Boehmert.de
+49-89-559680



BOEHMERT & BOEHMERT
ANWALTSOZIELTÄT