Compulsory license actions in Germany: The *Shionogi/Merck*-case

Mike Gruber, LL.M. IP (GWU)
Attorney at Law
Compulsory license actions in Germany: The Shionogi/Merck-case

Introduction

Requirements

Procedure

The Shionogi/Merck-case

Future developments
“After the grant of a compulsory license in the Shionogi/Merck-case the interest in this patent infringement defense strategy has increased substantially.”
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Main requirements:

1. (failed) attempt to obtain a license to use the invention under appropriate terms during an appropriate length of time and

2. grant of a compulsory license is in the public interest
Requirements

**attempt to obtain a license**

appropriate terms = what a reasonable third party would be willing to agree to in that situation

appropriate length of time = start and end of negotiations before request is filed
Requirements

attempt to obtain a license

• willingness to take a reasonable license sufficient; license proposal not required

• (future) licensee's perspective relevant

• royalty deductions due to uncertainties of the patent’s validity may be allowed

• fake licensing attempts are insufficient, e.g. delaying/stalling tactics
public interest

• *e.g.* needed to provide general health care, particularly in the treatment of deadly or infectious diseases

• no “more or less” equally effective alternatives available
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Procedural aspects

• request for compulsory license filed at the Federal Patent Court
• appeals to the Federal Court of Justice

• (additional) preliminary proceedings if grant of compulsory license is “urgent”, i.e. compulsory licenses needed until the decision in main proceedings; no urgency for filing of the request needed
Procedural aspects

- **royalty setting** can be deferred to main proceedings
- **security** is set for patentee’s potential damages until the decision in main proceedings plus legal costs
- no limitation of compulsory license to certain patient groups if they cannot be defined
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The Shionogi/Merck-case

SHIONOGI

• patent owner of EP 1 422 218 (EP’218) covering the use of raltegravir in a drug for preventing/treating a viral disease, granted in 2012
• opposition proceedings against EP’218 pending on appeal (hearing Oct. 2017)
• does not sell its own raltegravir drug
• manufacturer of the antiretroviral drug Isentress® (API: raltegravir) marketed since 2007
The Shionogi/Merck-case

History

• 6/2014: Shionogi notifies the Japanese Merck subsidiary of patent infringement of the Japanese counterpart of EP‘218

• Shionogi makes two offers: one time payment for past sales, running royalty

• Merck makes a counter-offer with lump sum of $10M for a world-wide license

• 8/2015: Shionogi files infringement actions in Germany and the UK
Expert opinion

- two alternative integrase inhibitor APIs *dolutegravir* and *elvitegravir* available
- *Isentress®* is more effective for certain patient groups, *i.e.* pregnant women, infants, children, and patients treated for HIV already for several years
- increased infection risk for the general population if *Isentress®* is unavailable
Decision

• preliminary compulsory license granted to use EP’218 for offering, selling, etc. current versions of Isentress® until the decision in main proceedings
• no compulsory license for versions that are still under development
• security of €6.5M by Merck required
• no royalty setting (→main proceedings)
Future developments

• there will be more cases!
• limitations/non-assertion of injunction claim in certain infringement situations
• implications for negotiation strategy in certain patent infringement cases
• devaluation of patents in certain fields?
• open issue: license fee calculation?
Thank you for your attention

Mike Gruber, LL.M. IP (GWU)
Attorney at Law
mgruber@hoffmanneitle.com