

University College London  
IBIL Innovation Seminar 2018

**Pregabalin:  
Where stand plausibility, Swiss-form  
claims, late amendment and more?**

Dr. Matthias Zigann  
Presiding Judge  
Regional Court Munich I

# Infringement of Second Medical Use Claims

Swiss Type Claims and EPC 2000 Claims before:

Pemetrexed

- **"use of a substance X for the preparation of a medicament for the treatment of the disease Y"**  
(Swiss Type Claim)
- **"use of substance X for the treatment of disease Y"**  
(EPC 2000 Claim)

**→ both are treated as use claims**

# Infringement of Second Medical Use Claims

direct infringement of a swiss type claim before:

Pemetrexed

- **Directly infringing acts:**

- use of the product in respect to the patented indication

- purposefully preparing for the patented use  
(e.g. formulation, dosage, packaging, labelling, package leaflet and/or SmPC of the medicament which specifically direct towards the patented use)

- offering, putting on the market, importing and possessing of products that had been purposefully prepared

- **Not directly infringing acts:**

- making the drug as such and/or for a non patented indication

- acts not sufficiently attributable to the product (see next slide)

# Infringement of Second Medical Use Claims

direct infringement of a swiss type claim before:

Pemetrexed

## Not directly infringing acts:

- acts not sufficiently attributable to the product

*Higher Regional Court Düsseldorf, 31 January 2013 - “Cistus Incanus”*

*Regional Court Düsseldorf, 14 March 2013 - “Chronische Hepatitis C”*

- general announcements in marketing materials

- flyers and advertisements

- indications given by sales people

*Regional Court Düsseldorf, 24 February 2004 - “Ribavirin”*

- no infringement even if the generic product can be used in more than 50 % of the patients in the patented indication where the purpose to treat the specific patient group is not mentioned in the label instructions

# Infringement of Second Medical Use Claims

indirect infringement of a swiss type claim before:

Pemetrexed

**offering or supplying** within Germany  
a drug suitable for the patented indication

**for purposefully preparing within Germany for the patented indication**

by e.g. label instructions, confectioning, ready-to-use preparation or dosage

**not: for using the not purposefully prepared drug within Germany for the patented indication (*under dispute*)**

**if** the person offering or supplying the drug **knows** or it is obvious from the circumstances

- that the drug is suitable for getting purposefully prepared for the patented indication  
and

- **that the customer intends to purposefully prepare the drug for the patented indication**

- **not: that the customer intends to use the not purposefully prepared drug for the patented indication (*under dispute*)**

# Infringement of Second Medical Use Claims

## Regional Court Hamburg – 2 April 2015 – Pregabalin

327 O 143/15, BeckRS 2015, 08691

- Claim 1:  
Use of Pregabalin or a pharmaceutically acceptable salt thereof for the preparation of a pharmaceutical composition for treating pain.

Claim 3:

Use according to Claim 1 wherein the pain is neuropathic pain.

- Attacked embodiment:



- **Epilepsy**
- **Generalized anxiety disorder**
- **(Skinny Labeling)**

# Infringement of Second Medical Use Claims

## Regional Court Hamburg – 2 April 2015 – Pregabalin

327 O 143/15, BeckRS 2015, 08691

### → indirect infringement

- *Obiter* if concept of manifest arrangement is applicable in the context of indirect infringement at all
- Here manifest arrangement already by the manufacture of PregabaHEXAL® as it can (although skinny labeled) readily be used to treat neuropathic pain (*under dispute*)
- Signing the rebate agreement without clarifying that the offered product cannot be sold/prescribed for the patented second medical indication constitutes an indirect patent infringement
  - as the purpose is added by the pharmacist due to the automatic substitution rule
  - and it is obvious that the products offered and supplied under the rebate agreement will be used in the patented indication given the regulatory / social law environment

# Infringement of Second Medical Use Claims

## Regional Court Hamburg – 2 April 2015 – Pregabalin

327 O 143/15, BeckRS 2015, 08691

- Carving out / skinny labelling does not exclude indirect patent infringement if the rebate agreement is not limited to the non-patented indication(s)
- Obligation under social law to dispense a substitute does not justify an infringement of the patent
- Patent law requirements must be respected at all times



# Infringement of Second Medical Use Claims Regional Court Hamburg – 2 April 2015 – Pregabalin

327 O 143/15, BeckRS 2015, 08691

- **Operational part of the judgment:**

*“Hexal must not enter into a rebate agreement on Pregabalin or supply Pregabalin in course of such a rebate agreement if the use of Pregabalin for treating pain is not excluded in that rebate agreement without explicitly pointing out to the other party that the offered or supplied Pregabalin is not offered for treating pain and if supplied must not be used for treating pain, especially not for treating neuropathic pain.”*

# Infringement of Second Medical Use Claims

## Federal Court of Justice – 14 June 2016 – Pemetrexed

X ZR 29/15, GRUR 2016, 921

- (Pharmaceutical) use patents and manufacturing use claims relate to the suitability of an already known substance for a specific therapeutic use and, therefore, ultimately to a property which is inherent to the substance itself.
- Therefore these claims both grant a "purpose-limited substance protection".

# Infringement of Second Medical Use Claims

direct and indirect infringement of a swiss type claim after:  
Pemetrexed

- Accordingly, in infringement cases, Swiss Type Claims are to be treated like "ordinary" purpose limited substance claims.  
  
→ The “use for the preparation” in the claim language is of no more importance!

# Infringement of Second Medical Use Claims

direct infringement of a swiss type claim after:

Pemetrexed

- - use of the product in respect to the patented indication
- - purposefully preparing for the patented use  
(e.g. formulation, dosage, packaging, labelling, package leaflet and/or SmPC of the medicament which specifically direct towards the patented use)
- - offering, putting on the market, importing and possessing of products that had been purposefully prepared
- - **new:**  
no purposeful preparation but protected use is ensured "in some other way"

**Infringement of Second Medical Use Claims**  
**Higher Regional Court Duesseldorf - 5 May 2017 and 1 March 2018**  
**- Estrogen Blocker and Dexmedetomidin**  
I-2 W 6/7 and I-2 U 30/17, GRUR 2017, 1107 and GRUR-RS 2018, 2410

**New requirements for the direct infringement of a second-medical-use claim:**

- Suitability of the medicament for the patented purpose
- Taking advantages of circumstances by the supplier of the medicament, which – similar to an "active" purposeful preparation by the infringer himself – ensure that the medicament offered and distributed is used for the patented therapeutic purpose:
  - sufficient and not only occasional use of the medicament according to the patent
  - respective knowledge or at least bad faith of the supplier

**Infringement of Second Medical Use Claims**  
**Higher Regional Court Duesseldorf - 5 May 2017 and 1 March 2018**  
**- Estrogen Blocker and Dexmedetomidin**  
I-2 W 6/7 and I-2 U 30/17, GRUR 2017, 1107 and GRUR-RS 2018, 2410

**e.g. Skinny labeling but cross-label use:**

supplier of the medicament is liable, if:

- he knows or should have known the prescription and substitution practice, which is favorable for him
- takes advantage of this practice nevertheless by supplying wholesalers with skinny labeled drug

**→ in Pregabalin case: direct infringement!**

# Infringement of Second Medical Use Claims

Regional Court Munich I – 7. June 2018 – 7 O 12868/17 – Dexmedetomidin

not published

Patent: Swiss type dosage regime, including a loading dose

package information: do not apply a loading dose for medicinal reasons

No proof that knowledge or reason to know that users ignore the package information

**→ no direct infringement!**

(case stayed in respect to auxiliary request (patent as granted – without loading dose - but invalidated by Federal Patent Court)

# Infringement of Second Medical Use Claims

indirect infringement of a swiss type claim after:

Pemetrexed

## **offering or supplying within Germany**

- a (neutral) drug suitable for the patented indication for purposefully preparing within Germany for the patented indication
- a (neutral) component suitable for preparing a drug suitable for the patented indication for purposefully preparing a drug within Germany for the patented indication
- a (neutral) component suitable for preparing a drug suitable for the patented indication for preparing within Germany a (neutral) drug suitable for the patented indication if the patented use is to be expected



# Infringement of Second Medical Use Claims

## Conclusions

Defendant manufactures the known medicament in Germany and

- purposefully prepares it for the patented use in Germany

- skinny labels the product but protected use in Germany is ensured "in some other way" (e.g. rebate agreement)

→ direct infringement

# Infringement of Second Medical Use Claims

## Conclusions

Defendant manufactures the known medicament in Germany and/or

- purposefully prepares it for a non patented use

→ no direct infringement and no indirect infringement

# Infringement of Second Medical Use Claims

## Conclusions

Defendant manufactures the known medicament in Germany and  
- purposefully prepares it for the patented use abroad

→ no direct infringement and no indirect infringement?

*(Kühnen, Handbuch des Patentrechts, 10<sup>th</sup> ed., A.368 Fn. 461)*

# Example

**Regional Court Munich I – 12 July 2017 – 7 O 9110/17 – Esterase Inhibitor**  
not published

Manufacture and labeling (in English) in Germany for the patented use but export to the US and – undisputed - danger of first infringement within Germany

manufacture for US exports = infringement in Germany?

**→ Case stayed in respect to opposition proceedings; but doubts as to US exports**

# Plausibility

**-Federal Patent Court, decision of 24 Jan. 2017 - 3 Ni 3/15 (EP); BeckRS 2017, 113852**

German part of EP 0 934 061 is

- sufficiently disclosed (auxiliary request - obiter)
- new (main request 1)
- no inventive step (main request 2)

# Late Amendments

## Sec. 83 Patent Act:

(4) The Federal Patent Court may reject means of challenge or defence introduced by a party or a change to the action or a defence brought forward by the defendant by means of an **amended version of the patent** which are brought forward only after the expiry of a time limit set for this under subsection (2) and may decide without further examination if

1. giving consideration to the new submission **would require the postponement of the scheduled oral proceedings**, and
2. the party affected does not sufficiently excuse the delay, and
3. the party affected has been instructed about the consequences of failing to observe a time limit.

The ground of excuse shall be substantiated.

(**at FCJ:** Sec. 117 Patent Act; Sec. 529-531, 296 Code of Civil Procedure)

# Late Amendments

**Federal Court of Justice - 2 Dec. 2014 – X ZR 151/12 - Forced Action Mixer**  
IIC 2015, 974

2.If the patent court holds that the patent at issue is legally valid in the version of an auxiliary request that the defendant only submitted during the oral proceedings following an indication by the court, a new ground for objection that is alleged to derive from the technical information of a document only cited at second instance is to be admitted if it was not apparent to the plaintiff from the indication that the patent court regarded the subject matter of the auxiliary request as (possibly) patentable.