

New developments on enforcement of second medical use claims in Germany

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Introduction

- Former case law in Germany: Swiss type claims with an element of manufacturing in them;
- thus, only material directly associated with the product was considered;
- indirect infringement was never really tried until last year;
- it seems there are strong tendencies to consider
 - whether even in a Swiss type claim the „manufacturing element“ actually means that no other circumstances can be taken into account
 - whether at least in a use claim or purpose limited compound claim this should be different
- it also seems that the issue of effective enforcement of second medical use claims is not a patent issue alone, but a regulatory, social, medical issue as well

Regional Court Düsseldorf (docket no. 4aO 12/03) 24 February 2004

Active Substance: Ribavirin

- EP 0 903 148 B1 had Swiss-type claims relating to the use of ribavirin for the manufacturing of a medicament for the treatment of HCV infections in specific patient groups
- the package leaflet did not refer to the protected use
- the Court found non-infringement because there was no specific reference to the patient group defined in the claim in the package leaflet; the product was therefore not customized for the protected use
- even though court noted that “...it cannot be excluded that...patients belonging to the special subgroup described in the patent in suit are also treated with the contested embodiment” (off-label or cross-label use)

Regional Court Düsseldorf (docket no. 4a O 12/03) 14 March 2013

Active Substance: Ribavirin

- EP 0 956 861 B1 had Swiss-type claims relating to the use of ribavirin for the treatment of HCV infections in combination with interferon alpha in specific patient groups
- the defendant carved out all information regarding the patented patient group
- patentee argued that marketing material and sales people advertised it for all uses
- the court denied direct infringement because marketing material and advertising were not directly linked to the product
- patentee did not argue indirect infringement at the time
- even if: the result can only be a limited injunction to not offer and sell the product if at the same time it is advertised in a specific way

Regional Court Hamburg (docket no. 315 O 24/15 et al.) 2 April 2015

Active Substance: Pregabalin (Lyrica)

- generic pregabalin containing products authorized only for the off-patent indications epilepsy and anxiety disorder, **not** for patent protected indication neuropathic pain (EP 0 934 061 B3)
- generic manufacturers won tenders for rebate agreements (acc.to § 130a Section 8 SGB V) with several statutory health insurances
 - tenders only related to active ingredient, not restricted to patent free indications
- district court decided on indirect infringement: substance as such is offered or supplied without carving out the patent protected use even if it has not been customized
- defendants prohibited from entering rebate agreements without declaration that their pregabalin products cannot be used for treatment of neuropathic pain
- appeal pending (3 U 65/15)

Federal Cartel Office (docket no. VK 2-7/15) March 2015

Active Substance: Pregabalin (Lyrica)

- German Federal Cartel Office prohibited statutory health insurance to award active ingredient related tender regarding pregabalin for a rebate agreement (acc. to § 130a Section 8 SGB V)
- health insurance was ordered to restart tender procedure and to ensure this time that generic manufactures could only submit bids related to patent free indications
- Federal Cartel Office stated: "patent law must not stand behind social law"

Appeal: Higher Regional Court Düsseldorf (docket no. VII Verg. 20/15) 1 December 2015

- the appeal of the defendant was denied by the Higher Regional Court
- the court stated also: "social law does not rank above patent law" and emphasized the "constitutional protection" of intellectual property (Art. 14 sec. 1 GG)

Conclusions

- Second medical use claims are not a matter that can be solved by patent law only
- Tenders seem to have been addressed now by the courts, but what about
 - off-label/cross-label-use use: is this really an ethical subject, i.e. must doctors be allowed to decide whether an originator or generic product is given to the patient although there is still patent protection? This is not part of their freedom of therapy?
 - why can pharmacists not see what the prescription is for?
 - why can pharmacy software not provide information about patent protection for specific indications?

Thank you!

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