

INFRINGEMENT OF SWISS-TYPE SECOND MEDICAL USE  
PATENT CLAIMS IN GERMANY  
– RECENT DEVELOPMENTS IN CASE LAW

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ABSTRACT

*Following recent regional court decisions on the infringement of second medical use patent claims, the German concept of manifest arrangement—previously believed to provide a safe harbor for generic pharmaceutical companies as long as they skinny-labeled their products—may be subject to a new interpretation. The German decisions are part of a Europe wide series of decisions on the same or similar subject matter and prove to be patent owner friendly.<sup>1</sup>*

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<sup>1</sup> Denmark; <http://kluwerpatentblog.com/2015/08/06/pregabalin-second-medical-use-claims-construction-in-denmark/>; England & Wales: Generics (UK) Ltd (t/a Mylan) v Warner-Lambert Company LLC [2015] EWHC 2548 (Pat); France: <http://ipkitten.blogspot.de/2015/11/vive-la-difference-no-need-for.html> Spain: <http://www.internationallawoffice.com/Newsletters/Intellectual-Property/Spain/Grau-Angulo/Court-dismisses-preliminary-injunction-application-in-pregabalin-patent-case#decision>; The Netherlands: Novartis AG v Sun Pharmaceutical Industries (Europe) BV C/09/460540 / KG ZA; Warner-Lambert Company LLC v. the State of The Netherlands (Dutch Medicines Evaluation Board), District Court of The Hague, The Netherlands, 15 January 2016, Case file number: C/09/498943 / KG ZA 15-1656.

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## INTRODUCTION

In 2000, Swiss-type second medical use patent claims (e.g. “use of x for the manufacture of a medicament to cure illness y”)<sup>2</sup> were invented to overcome or circumvent the exclusion from patentability of methods to cure the human body as laid down in the original Art. 52 (4) EPC.<sup>3</sup> Since then, discussion has arisen about the new scope of protection for such claims. Particular attention has gone to distinguishing competitive legal behavior—which could be aimed at the production, distribution, and application of a medicament intended to cure the first now-unpatented indication—from illegal behavior aimed at the production, distribution, and application of the same medicament to cure a second patented indication.<sup>4</sup>

Recently confirmed<sup>5</sup> decisions<sup>6</sup> by the Federal Court of Justice found that the manifest arrangement of a medicament for the second medical use already constitutes a second medical use. In answer, the lower infringement courts granted injunctions against competitors for direct patent infringement, pursuant to Sec. 9

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<sup>2</sup> According to legal advice given by the Swiss Patent Office in May 1984, these are called Swiss Type Claims.

<sup>3</sup> Revision entered into force on 13 December 2007.

<sup>4</sup> *Königer/Kompter/Ludwig/Lunze/Prinz zu Waldeck und Pymont/Schüssler/Wiegeleben* GRUR Int. 2014, 906.

<sup>5</sup> Federal Court of Justice IBRR3 2016, 1909 – Pemetrexed [#83-88]. The Federal Court of Justice has indicated in that decision that a Swiss-type claim may provide the same purpose limited substance protection as a purpose limited substance claim does. The finding is however not final as the case has been sent back to the lower court for further consideration.

<sup>6</sup> Federal Court of Justice GRUR 1983, 729, 730/731–Hydropyridin; GRUR 2001, 730, 730/731 – Trigonellin.

German Patent Act,<sup>7</sup> if they manifestly arranged their product for the second medical use.<sup>8</sup> Processes such as making into a confection ready-to-use preparation, dosage, label instructions (as closely linked to the manufacturing process) or otherwise arranging the product were found to be manifest arrangements, especially if designed for a second medical use. The question as to whether the manifestly arranged product was later in fact used for the second indication was of no importance.<sup>9</sup> However, other activities—like general announcements in marketing materials, flyers, and advertisements or indications given by sales people—were held insufficient to constitute a manifest arrangement, as they were found to be not related closely enough to the product or package.<sup>10</sup> The so-called “skinny labeling” proved to be a way for the competitor to avoid allegations of direct patent infringement, even when the product was later used for its second indication<sup>11</sup>. As a result, patent owners raised fewer allegations of indirect patent infringement

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<sup>7</sup> A patent shall have the effect that the patentee alone shall be authorized to use the patented invention. A person not having the consent of the patentee shall be prohibited 1. from making, offering, putting on the market or using a product which is the subject matter of the patent or importing or stocking the product for such purposes; 2. from using a process which is the subject matter of the patent or, when he knows or it is obvious from the circumstances that the use of the process is prohibited without the consent of the patentee, from offering the process for use within the territory to which this Law applies; 3. from offering, putting on the market, using or importing or stocking for such purposes the product obtained directly by a process which is the subject matter of the patent.

<sup>8</sup> Regional Court Düsseldorf GRUR-RR 2004, 193 – Ribavirin.

<sup>9</sup> Regional Court Düsseldorf GRUR-RR 2004, 193 – Ribavirin.

<sup>10</sup> Regional Court Düsseldorf –Ribavirin“, 24 February 2004 – 4a O 12/03, BeckRS 2004, 05148; Higher Regional Court Düsseldorf - “Cistus Incanus”, 31 January 2013 – I-2 U 53/11, BeckRS 2013, 03824; Higher Regional Court Düsseldorf - “Cistus Incanus”, 31 January 2013 – I-2 U 54/11; BeckRS 2013, 11782; Regional Court Düsseldorf - “Chronische Hepatitis C”, 14 March 2013 – 4a O 145/12, Düsseldorf Entscheidungen No. 2011.

<sup>11</sup> Higher Regional Court Düsseldorf BeckRS 2013, 11782 – Cistus Incanus; Regional Court Düsseldorf, Case No. 4 a O 145/12, decision of 14 March 2013 – Chronische Hepatitis C.

pursuant to Sec. 10 of the German Patent Act.<sup>12</sup> Notably, this was because patent owners could not prove that the competitor knew that the customer was inclined to use the product for the second indication and not the first.

### I. THE HAMBURG REGIONAL COURT'S DECISION

However, recent decisions by the Hamburg Regional Court<sup>13</sup> in five parallel preliminary proceedings may have taken away the “safe harbor” of skinny labeling, particularly in the context of rebate agreements.

#### A. *Factual Circumstances*

The second medical use patent in suit covered the use of Pregabalin for the preparation of a pharmaceutical composition for treating pain. The defendants, pharmaceutical companies, produced a medicament for the (patent-free) first medical uses of Pregabalin—namely, to treat epilepsy and generalized anxiety disorder.<sup>14</sup> The labels did not mention pain as an indication and there was no advertisement or marketing activity in that direction. After tender procedures for providing Pregabalin in large quantities to public health insurers, the defendants entered into rebate agreements with these health insurers. The rebate agreements were silent on the intended medical uses; in particular, they did not carve

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<sup>12</sup> A patent shall have the further effect that a person not having the consent of the patentee shall be prohibited from supplying or offering to supply within the territory to which this Law applies a person, other than a person entitled to exploit the patented invention, with means relating to an essential element of such invention for exploiting the invention, where such person knows or it is obvious from the circumstances that such means are suitable and intended for exploiting the invention.

<sup>13</sup> 2 April 2015 – 327 O 67/15; BeckRS 2015, 08240; GRUR-RR 2015, 330; 4 out auf 5 parallel preliminary injunctions have become final. One appeal is still pending, an oral hearing (case no. 3 U 91/15) scheduled for July 28, 2016 has been postponed to February 2017 to await the outcome of pending nullity proceedings.

<sup>14</sup> 2 April 2015 – 327 O 67/15; BeckRS 2015, 08240; GRUR-RR 2015, 330; appeal is pending, an oral hearing is scheduled for July 28, 2016.

out the use of Pregabalin to be provided to treat pain.<sup>15</sup>

Sec. 130a (8) of the German Social Law Book V provides for the possibility of health insurers entering into such rebate agreements with pharmaceutical companies. Sec. 129 (1) of that law provides that pharmacists, in order to not endanger their reimbursement by the health insurer, must take account of these rebate agreements. The section puts pharmacists under the obligation to dispense the cheapest drug to an insured patient unless the doctor's prescription explicitly orders to provide a specific brand by striking out the "aut idem" field. This is referred to as the "automatic substitution rule." By budget control, doctors on the other hand are motivated to leave the "aut idem" field on their prescriptions and, consequently, allow substitution.<sup>16</sup>

### *B. Decision and Reasoning*

The Regional Court of Hamburg found that the defendants indirectly infringed the second medical use claim by signing the rebate agreement without explicitly carving out the use to treat pain and by providing Pregabalin to pharmacies in the course of the agreement.<sup>17</sup> With respect to the regulatory environment, it was found to be manifestly clear that the defendants provided the Pregabalin for a later use to treat pain.

As shown above other German courts have limited the use of a Swiss-type second medical use claim to a manifest arrangement that can be closely linked to the confectioning of the product or its packaging. Though the Regional Court raised the question whether the concept of manifest arrangement is to be applied to the test of indirect infringement at all. However, the court left this question open by finding that the products subject to the rebate agreements were already confectioned and ready to be used for the treatment of pain. The purpose, the court claimed, was added by the pharmacist

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<sup>15</sup> 2 April 2015 – 327 O 67/15; BeckRS 2015, 08240; GRUR-RR 2015, 330; appeal is pending, an oral hearing is scheduled for July 28, 2016.

<sup>16</sup> 2 April 2015 – 327 O 67/15; BeckRS 2015, 08240; GRUR-RR 2015, 330; appeal is pending, an oral hearing is scheduled for July 28, 2016.

<sup>17</sup> 2 April 2015 – 327 O 67/15; BeckRS 2015, 08240; GRUR-RR 2015, 330; appeal is pending, an oral hearing is scheduled for July 28, 2016.

due to the automatic substitution; and it is obvious that the products offered and supplied under the rebate agreements will also be used in the patented indication to treat pain given the regulatory/social law environment. Carving-out and skinny labelling do not exclude indirect patent infringement if the rebate agreement is not limited to non-patented indications. The obligation under social law to dispense a substitute does not justify an infringement of the patent, as patent law requirements must be respected at all times.

## II. OTHER DECISIONS

In the context of the legal disputes which led to the Hamburg decision, the Hannover Social Court<sup>18</sup> and the 2nd Federal Procurement Chamber of the Federal Cartel Office<sup>19</sup> each granted preliminary injunctions against a health insurer based on public procurement law only, requiring the insurer not to enter into such rebate agreements and not to close such tenders respectively, as they are not in line with patent law. The details of the Hamburg patent law discussion were left basically untouched. Parallel patent litigation in other European courts showed mixed results<sup>20</sup>.

## CONCLUSION

Until the Regional Court of Hamburg's decision, the belief existed that an indirect infringement of a Swiss-type second medical use claim encompassed actions such as providing a not-yet manifestly arranged drug to a customer in order to allow the customers to later manifestly arrange that drug for the second medical use. All intended activities by the customer aimed at the direct use of the drug rather than the manifest arrangement would not constitute indirect patent infringement by the manufacturer. If the Hamburg decisions are confirmed by the higher courts<sup>21</sup>,

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<sup>18</sup> 14 September 2015 – S 2 KR 374/15 ER.

<sup>19</sup> 16 March 2015 – VK2 – 7/15; VPRRS 2015, 0147.

<sup>20</sup> See footnote no. 1.

<sup>21</sup> Which is however kind of unlikely due to the procedural circumstances as 4 out of 5 parallel preliminary injunctions have by now become final as the defendants have accepted them. Only one appeal is still pending before the

however, this understanding of the concept of manifest arrangement would require modification. Currently, this understanding only provides a way to find direct patent infringement in a manifest arrangement, but no way to find indirect infringement in cases where the product itself or its packaging is neutral but other circumstances—as in the case decided in Hamburg—manifestly indicate the intention of the later use for the second indication. It has to be seen if the recent “Pemetrexed-decision”<sup>22</sup> shows a way out of this dilemma. The Federal Court of Justice has indicated in that decision that a Swiss-type claim may provide the same purpose limited substance protection as a purpose limited substance claim does. The finding is however not final as the case has been sent back to the lower court for further consideration.

#### PRACTICE POINTERS

- Skinny labeling and carving-out may no longer provide a safe harbor for competing pharmaceutical companies.
- Competing pharmaceutical companies are strongly advised to enter into rebate agreements only if any patented second medical uses are explicitly carved out.
- Health insurers are strongly advised to respect patent law in public tenders and rebate agreements, as social conventions no longer provide an excuse to disregard patent law.

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Hamburg Higher Regional Court (case no. 3 U 91/15). The oral hearing has been postponed from July 2016 to February 2017 to await the outcome of pending nullity proceedings.

<sup>22</sup> Federal Court of Justice IBRR3 2016, 1909 – Pemetrexed [#85-88].

