Patent litigation in the pharmaceutical sector in Germany

Bird & Bird

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What are we going to discuss?

- Infringement of pharmaceutical patent claims/scope of protection
- Infringement of use claims
- Privileged use acts – Bolar exemption
- Evidence gathering
- Enforcement
- Preliminary injunction proceedings

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Some background information …

What kind of products are at issue?

- Final medicinal product: tablet, solution, injection etc. for treatment of a certain indication
- Intermediates obtained in manufacturing process
- Diagnostics
- Research tools used for developing products
- Laboratory products
- Standards, quality control etc.

- One central battlefield: originator vs. generic (or biosimilar) manufacturer

Lifecycle of pharmaceutical products

- Research & development
- Formulation of pharmaceutical product
- Testing (animal tests, clinical trials)
- Marketing authorization (MA)
- Further indications
- Protection:
  - Patents, supplementary protection certificates (SPC)
  - Data protection, market exclusivity
- Maintenance & commercial use of monopoly as long as possible

Generic competition

- Generally not to be expected before expiration of data protection period
  - Genercis usually refer to MA dossier of originator
  - Product will be almost identical
  - Differences possible, e.g. in choice of additives
- Causes price erosion and substantial market loss for originator (rapid substitution)

What kind of patents are relevant?

- Compound patents: active ingredient, intermediate
- Product patent: final medicinal product
- Process patent: manufacturing process
- Medical use patent: indication
- Formulation patent: administration
- Dosage regime
- Patient populations

- Extension by SPCs/further pediatric extensions
- Patient thickets?

When to expect litigation?

- Basic compound patents
  - Data protection may still exist
  - Often respected by competitors if strong patent
- Process patents
  - Depending on details of method steps in patent claims
  - Information available about manufacturing method?
  - Depending on jurisdiction, i.e. procedural disclosure means

When to expect litigation?

- Medical use patents
  - If validity is questionable
  - Carve-out options in summary of product characteristics (SmPC) & possibility to obtain duplicate MA
- Dosage regimens and administration means
  - Validity potentially challengeable
- Patient populations
  - Validity potentially challengeable

Infringement of a pharmaceutical patent …

What patent claims are to be considered?

- Product claim
  - *Substance x*
- Method claim
  - *Manufacture of pharmaceutical product containing substance x, dissolving substance x in water, adding excipients y and z, stirring solution and drying*
- Use claim
  - *Use of substance x in the manufacture of a medicament for the treatment of cancer*
  - *Use of substance x for the treatment of cancer in patients not responding to substance y*

How to construe a patent claim?

- Art. 69 para. 1 EPC/§ 14 German Patent Act:
  - Claims are decisive
  - Patent specification (& drawings) can be considered for claim construction
- Definitions in patent specification binding, even if different common understanding of terms (specification as dictionary), Federal Court of Justice (BGH) IIC 1999, 932 – *Tension Screw*
- Examples are not limiting if claim language is broader, BGH GRUR 2004, 1023 – *Bodenseitige Vereinzelungseinrichtung*

Equivalent infringement

- Equivalent infringement, BGH IIC 2002, 873 – *Cutting Blade I*:
  - Equal effect of exchanged means
  - Obviousness of exchange for person skilled in the art
  - Equal quality based on the essential meaning of the claim
- Contradictions between claims and description:
  - Elements of description not reflected in claims generally not included in scope of protection,
  - Alternatives described in specification, but not claimed, regularly do not constitute equivalent infringement, BGH IIC 2011, 851 - *Occlusion Means*

Equivalent infringement

- BGH GRUR 2012, 45 - *Diglycid Compounds*: Extension of *Occlusion Means* case-law also to exchange means which are not disclosed in the patent specification, but similar to alternatives disclosed in description, but not claimed
  - Unless non-disclosed alternative is closer to patent claim than disclosed (but not claimed) alternative

- Recent case-law of Regional Court (LG) Düsseldorf in preliminary injunction (PI) proceedings (4a O 192/12):
  - BGH decisions do not suggest that when embodiments are not mentioned in the patent specification as exchangeable means, they regularly establish equivalent infringement.

Equivalent infringement

- If certain reagent is specifically identified in patent claim, person skilled in the art will not consider replacement
- Principle of legal certainty: rather limited claim scope for precise manufacturing process, cannot not be broadened by doctrine of equivalence in inadequate manner
- Reluctance of person skilled in the art to consider exchange means in chemical/pharmaceutical manufacturing processes (although equivalent infringement not generally excluded in this area)

Use of the claimed technical teaching?

- Product claim on substance x
  - If substance x is used in any kind of way (absolute substance protection)
- Method claim
  - If method is used or offered for use
  - Use of process product directly obtained from method, § 9 clause 2 no. 3 German Patent Act
    - In order to cover products manufactured abroad
    - Decisive whether characteristic features of patented product still present
    - Equivalent infringement rather limited, however, depends on formulation of patent claim and description

Infringement of a use claim

- Infringement of use claim only if the patented use is envisaged
  - Use for treatment of cancer
  - Purposeful preparation of product for treatment of cancer
  - Manufacture, preparation, formulation, dosage, packaging, labelling, package insert, summary of product characteristics (SmPC) for treatment of cancer
  - Offering or marketing respectively designed product
  - Importing or possessing of respectively designed product for offering, marketing or using

Infringement of a use claim

- Offering of substance as such is not covered
  - No infringement, if purpose neither intended nor purposefully achieved (BGH GRUR 1987, 794 – *Antivirusmittel*)
  - Even if patented purpose is obvious or immanently realized (LG Düsseldorf GRUR-RR 2004, 193 – *Ribavirin*)
  - Mentioning of symptoms is sufficient, disease does not have to be mentioned expressly (Higher Regional Court Munich NJW-RR 1999, 269 – *Buspiron*)
  - Generally, no contributory infringement either (LG Düsseldorf GRUR-RR 2004, 193 – Ribavirin)

Infringement of a use claim

- General principle: Art. 3 para. 3b) Regulation 726/2004/EC: generic SmPC to be consistent with original product
- Carve-out options regarding patented indications in SmPC:
  - EMA Procedural Advice allows carve-out:
    - Sections 4.1 therapeutic applications
    - 4.2 posology and method of administration
    - 5.1 pharmacodynamic properties
  - No carve-out for safety-related information:
    - Sections 4.3 to 4.8
    - Consultation with EMA to extend carve-out?

Infringement of a use claim

- General principle, Art. 6 para. 1 Regulation 726/2004/EC:
  - Only 1 name allowed to identify approved product
- EU Commission can provide exception if product can be marketed under central MA in certain countries, while still patent protected in others (Art. 82 para. 1 Regulation 726/2004/EC, Guideline for Handling of Duplicate MA)
  - References required to patented indication potentially required in safety sections of SmPC (consulation with EMA)
- Infringement if references to patented indication in safety-related information of SmPC?
- Effect on substitution?

When can patentee get started?

First infringing act

- Research?
  - Experimental use exemption, § 11 No. 2 Patent Act
  - BGH in "*Clinical Trials I*" decision (IIC 1997, 103) excluded tests from experimental use exemption that use the invention only as a "means" to carry out tests that relate to a different subject matter:

    "the subject matter of the invention must be the object of the test activity for the purpose of gaining knowledge".
- Experiments must be directed to gaining knowledge about the invention, not with the invention
  - Patented research tools rather not covered

First infringing act

- Clinical testing?
  - Is privileged under Bolar-exemption, § 11 No. 2 b Patent Act
- Art. 10 para. 6 Directive 2004/27/EC:

  "*Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4* [relating to authorisation of generics and biosimilars in EU] *and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.*"
- Implemented differently in EU Member States:
  - Broadly in Germany not limited to generic/biosimilar MAs or to MAs in EU

First infringing act

- However, recent decision of LG Düsseldorf (4a O 282/10, 26.07.2012 - *Solifenacin*) stipulates that importer of active pharmaceutical ingredient is not privileged (!)
  - Appeal hearing in December 2013 before Higher Regional Court (OLG) Düsseldorf
- Practical requirements usually covered as long as in order to obtain MA
- Legal uncertainty: scope of application of exemption under new Unified Patent Court system?

First infringing act

- Applying for or obtaining an MA in most European jurisdictions no act of infringement (in dispute e.g. in Italy)
- Recent case-law from OLG Düsseldorf (I-2 U 44/12 – *Virostatikum*, 20.09.2012) clarifies that MA grant and lacking response to warning letter does not create an imminent threat of infringement (confirmed also in the Netherlands)
  - Concrete facts that suggest a launch to be imminent must be submitted by patentee
  - Fact that MA is obtained long time before patent expiration does not create imminent threat as such (not only in 3-year period of "Sunset Clause") – UK decided differently!

First infringing act

- Entry in pharmaceutical databases ("Lauer-Taxe") for distribution is an act of infringement (offer for sale), also advertisement for distribution after patent expiry, BGH GRUR 2007, 221 - *Simvastatin*
- Application for listing in pharmaceutical database as patent infringing offer
  - LG Düsseldorf confirmed this when publication of entry occurs during patent's lifetime (4a O 16/06 - *Tamsulosin*, 31.01.2006)
  - OLG Düsseldorf, GRUR-RR 2011, 350 – *Pramipexol,* did not decide question

Where to obtain evidence?

Gathering evidence

- Typcial generic case:
  - Due to reference to MA dossier of original product, infringement often easy to demonstrate (provided that original product also makes use of patent)
  - Differences nevertheless possible, e.g. additives – analyses required
  - Publication of SmPC shortly after MA grant (database review)
  - Listing in Lauer-Taxe including basic information on composition of product

Gathering evidence

- Method claims: often difficult to prove
  - Analyses?
  - Freedom of Information Acts: Federal Institute for Drugs and Medicinal Devices does not provide information for confidentiality reasons
  - Inspection proceedings, § 140c German Patent Act
  - Information from foreign proceedings?
  - Foreign procedural tools (where efficient inspection measures available) if results can be used abroad
- Request for entitlement?

How to get a preliminary injunction…

Preparation of litigation

- Opposition or nullity action filed by any generic companies?
- Monitoring databases – as soon as MA is granted regular check in pharmaceutical database “Lauer-Taxe”
- Evidence gathering
- As soon as first act of infringement occurs, PI request can be filed with competent court (and has to be – urgency)
- Ex parte and inter partes PI available
  - Ex parte in case of high urgency, e.g. in case patent is very soon to expire, extraordinary high damages to be expected etc.

Requirements for obtaining PI

- Injunction claim
  - Substantiate infringement
  - Affidavits are sufficient as evidence
- Injunction grounds:
  - Urgency requirement
  - Timewise urgency (depends on court)
    - Analyses, preparations to be pursued without delay (LG Düsseldorf, 4b O 133/12, 6.11.2012 – *Flupirtin-Maleat;* OLG Düsseldorf, InstGE 10, 60 – *Olanzapin II)*
  - Threat of substantial damages (assumed for generics, OLG Düsseldorf, I-2 U 126/09, 29.04.2010 – *Harnkatheterset*)

Requirements for obtaining PI

- Patent's validity, particularly if validity attack is already pending
- Generally no PI in case of first instance revocation
  - Exceptional decision of Higher Regional Court Düsseldorf, GRUR 2008, 1077 - *Olanzapine*: Granted PI despite of first instance revocation stating that Federal Patent Court decision was obviously wrong
- Burden of patentee to substantiate that patent is valid (OLG Düsseldorf, I-2 U 126/09, 29.04.2010 – *Harnkatheterset)*
  - Validity generally only assumed in case patent has survived first instance opposition or nullity action or defendant has already participated in issuance procedure by filing third party observations

Requirements for obtaining PI

- Exceptions admissible in particular circumstances (e.g. patent respected by third parties)
- Examples:
  - Oral hearing in nullity action already scheduled – generic could be expected to await outcome (LG Düsseldorf, 4a O 50/12, 4.09.2012 – *Sustained Release Formulation*)
  - If nullity action is filed so late that it cannot be concluded before patent's expiry, PI request will only be dismissed in case of obvious invalidity (LG Düsseldorf, 4b O 123/12 – *Empfängnisverhütungspackung;* 4b O 135/12 - *Riluzol*)

Relief in PI proceedings

- General principle: no anticipation of main proceedings
- Injunction
- In case of obvious infringement information about provenience and distribution channels, § 140b para. 7 Patent Act
- Recall and removal from distribution channels (§ 140a para. 3 Patent Act)?
  - OLG Munich (6 U 1560/12, 28.06.12): in case of obvious infringement possible
  - Questionable as not expressly provided for in Patent Act
- No damages

Preparation of defense

- Bring invalidity actions well in advance
- Filing of protective letters?
- Foreign judgments, which are favourable?
- Favourable preliminary opinion in invalidity action available?
- Expert Reports?

Your views & Bird & Bird

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