

EPLAW

European Patent Lawyers Association

YEARBOOK

2007 – 2008

(Editor : F. de Visscher, Past Secretary to the Association)

Association européenne d'avocats spécialisés dans le contentieux des brevets d'invention
Europäische Vereinigung der Patentrechtsanwälte

Siège : Avenue Louise, 149 (boîte 20) 1050 BRUXELLES - BELGIQUE
Association sans but lucratif (Loi du 27 juin 1921)

Dear Friends,

Our Association is steadily growing and certainly finding recognition with the Patent Judiciary, the Commission and the EPO. Together with the EPO we have successfully organized the fourth Venice Forum. The initiative to give access to 10 members who were the lucky winner of the draw in the beginning of the year proved a success - all enjoyed the participation. The Forum, for which we organized the program, was again of high quality and ended with a further important Resolution adopted by the Judges. The EPO and EPLAW intend to have a fifth Forum next year.

This year we organized for the first time a Young EPLAW Congress. Although I had to urge you to send your youngsters (and was somewhat nervous whether or not we would attract enough participants) many of you supported us in the end and the Congress (and the social event the evening before) was a great success. We will organize again a Young EPLAW Congress in 2009 and I trust you again will support it. We will keep the price as low as possible and, as last year, make sure that the program is of high educative value.

We remain closely involved in the work of the Commission towards a European Patent Jurisdiction. Our intent is to ensure that the system will be equitable and efficient, but also that the primary role of the specialist patent litigator, who is not only a specialist in patent law but also fully versed in procedural and other related areas of law, remains recognised and maintained.

We live in interesting times where patent law is the subject of heated public debate. I refer for instance to the Report of the Commission in the Pharmaceutical Sector Inquiry. I am very proud that the first debate with respect to this Report, attended by representatives of the Commission and industry, will take place during our 2008 Annual Congress.

Being President of your Association is a great honour but combined with the daily practice you all know too well, a sometimes tough task. I am very grateful that we have a Board whose members are of great help to me. This year, two members will leave the Board: Kevin Mooney, my predecessor who has supported me magnificently in my first year as President, and Peter Heinrich our Treasurer who has done a wonderful job with Swiss precision and who leaves the Association in a healthy financial state.

Of course without your continued support the Association would not have been where we are today. Please continue that support, keep visiting our website, keep coming to our meetings and keep sending your youngsters to Young EPLAW.

I wish you all an excellent Annual Congress and a prosperous 2009.

Your President,
Willem A. Hoyng

**EPLAW Congress
2007**

President's Report

16 November 2007

Kevin Mooney

Simmons & Simmons

President's Report

- **Guests:**
- **EPLAW'S MAIN OBJECT**
 - “The consistent and cost-effective enforcement of patent rights throughout Europe in one court offering local access to patentees and a simple language regime”

Simmons & Simmons

President's Report

- 2006 was a good year for EPLA
 - July 2006: Brussels meeting reports that users overwhelmingly support EPLA
 - C McCreedy stated on 28 September 2006: “there is a strong call for the improvement of the existing European Patent system... by the successful conclusion of a... EPLA”... BUT... “the Community needs to get involved in EPLA”
 - September 2006 Thessaloniki declaration – now 73 judges support EPLA
 - October 2006 – further AIPPI resolution in Gothenburg in favour of EPLA

President's Report

- October 2006 – European Parliament urges Commission to co-operate with EPLA BUT – mixed competence?
- November 2006 – Venice II Resolution re Rules of Procedure for EPLA courts

President's Report

■ HOWEVER

- October 2006 – The Guillaume Paper reflected opposition to EPLA from France – followed in early 2007 by Spain, Italy, Portugal, Cyprus and Luxembourg: "Communitise the EPLA"
- January 2007 – Legal Services of European Parliament say EPLA is "mixed competence". Now Parliament Commission and Counsel are unanimous
- Commission stalled until 03 April 2007 when it finally published its Communication to the European Parliament and the Council – recommends "Compromise C"
- June 2007 Germany: Presidency organises Munich Symposium: The arrival of Dr. Fröhlinger
- Content of Munich Symposium is confused – "bifurcation" over lunch

President's Report

■ PORTUGUESE PRESIDENCY:

- 12 July 2007 – Agenda for 4 meetings with national experts
- 10 October – First "Non-Paper": bifurcation on table – UK v Germany
- 30 October – Third Paper (Working Document No 14492/07) – now has UK and broad support for:
 - Central chamber and national/regional chambers
 - Pure validity actions and declarations of non-infringement go to central chamber
 - Counterclaims for invalidity heard locally with full court (German support?)
 - Standard procedures for all courts (based on Venice Resolution)

President's Report

- One level of appeal on substantive patent issues
- Limited review by ECJ
- Flexible language regime

■ VENICE 2007

- Dr. Fröhlinger wins cautious support of Judges for Portuguese proposals: "EPLA IS DEAD"

President's Report

■ FUTURE

- Portuguese report to Competitiveness Council dated 9th November:
- Broad agreement on "most" of key features of 14992/07
- Outstanding is issue of bifurcation at first instance and the language of judicial proceedings
- Work must now begin on COMPAT urgently
- Slovenian Presidency: 4 further meetings of experts planned
- French Presidency July 2008

■ PROGRESS?

President's Report

■ VENICE 2007 – 02-04 NOVEMBER

- 34 Judges from 15 countries
- 15 Lawyers from 8 countries
- President of EPO
- President of epi

■ PROGRAMME

- Mock Trial: Enantiomers and rules for novelty/obviousness/insufficiency
- The clash between EPO post-grant procedures and national litigation
- Debate on Portuguese Proposals

President's Report

■ WEBSITE

- Demonstration at 2.30pm
- Expenditure

■ MEMBERSHIP AND FEES

- No change

■ BOARD OF DIRECTORS

- President: Willem Hoyng
- Vice President: Mario Franzosi
- Directors to be confirmed:
 - Peter Ulrik-Plesner
 - Gonzalo de Ulloa

President's Report

- Approval of Minutes of General Assembly of 20 November 2006
- Financial Statement of EPLAW as of 31 December 2006
- Budget for 2008
- Quietus to Board for 2006

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EPLAW Congress
2007

President's Report

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Damages in German Patent Litigation

presented at the
EPLAW Congress
Brussels
16 November 2007

by

Dr. Klaus Grabinski
Presiding Judge at the District Court,
Düsseldorf, Germany

• I Court System in Patent litigation:

- 1) Infringement Courts**
 - District Court (limited number)
 - Court of Appeal
 - Federal Supreme Court

- 2) Invalidation Courts**
 - Federal Patent Court
 - Federal Supreme Court

• **II Two-Step Patent Infringement Proceedings:**

– **Remedies available in first proceeding:**

- cease and desist (injunction)
- supply of information (about origin and routes and amount of delivery)
- rendering account (of the extent of the infringing actions and the profit achieved)
- declaration that the infringer is liable for damages
- destruction of the infringing product

Damages in German Patent Litigation

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– **Remedy available in second proceeding:**

- order to pay damages

Damages in German Patent Litigation

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- **III Entitlement**

- Patent holder
- Exclusive licensee
- Not: Simple licensee
 - Patent holder (or exclusive licensee) can transfer the claim for damages to a simple (sub)licensee.

- **IV Three methods of computing damages:**

- return of profit made by the infringer
- reimbursement of lost profits incurred by the infringed party
- payment of a reasonable royalty (licence analogy)

- **V Lost profits:**

- 1) **General:**

- Compensation for damage means **restoring the previous situation**, sec. 249 Civil Code.
 - E.g. recall of infringing products, but generally a restitution is impossible, insufficient or inappropriate for the patent holder.
 - The infringed patent holder can claim to be reimbursed for **the loss of profit** he suffered as a result of marketing the infringing product, sec. 251 (1) Civil Code.
 - **Facilitation of burden of proof:** Such profits are deemed to be lost that can **probably be expected** in the normal course of affairs or under special circumstances, and in particular in accordance with the arrangements and provisions made, sec. 251 (2) Civil Code.

Damages in German Patent Litigation

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- 2) **Causation:**

- **According to the normal course of matters it has to be expected with probability that the lost profits claimed were caused by the patent infringement.**
 - **How to prove? An example:**
 - The infringed patent concerned the construction of a power plant. Patent holder, patent infringer and a third company were in competition for constructing the plant. The patent infringer won and realized the construction by infringing the patent. Would the patent holder have been ordered to carry out the construction if the infringer had abstained from the infringement? How to prove this allegation? By hearing the sales people from the patent holder or the infringer? By hearing a court appointed expert? By hearing the purchase people from the power plant?

Damages in German Patent Litigation

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3) Calculation of lost profits:

- **Lost profits can result from:**
 - **lost sales** (sales the patent holder would have made, if the infringer had abstained from infringing actions)
 - **price reductions** (price reductions the patent holder was compelled to concede in order to match the infringer's prices), **loss of prestige** (because of bad quality of the infringing product)
- The prejudiced patent holder has to **reveal details of his proceeds** in order to allow a sufficiently precise assessment of the lost profits.
- In case the defendant disputes the alleged profits the court may order that a **court appointed expert** (normally a certified accountant) examines the cost structure of the patent holder's company.

Damages in German Patent Litigation

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• VI Return of infringer's profits:

1) General:

- Reclaiming the profit made by the infringer is an **alternative way to compensate the prejudiced patent holder.**
- This method has been **accepted for long but became popular only a few years ago after a landmark decision of the Federal Supreme Court** (145 BGHZ 366, 2001 GRUR 329, IIC 900 (2002) – Share of Overheads).
- The "Share of overheads"-decision did concern the infringement of an industrial design but according to the case law of the Düsseldorf Court of Appeal and District Court its legal principles are also **applicable in patent infringement cases** (Düsseldorf Court of Appeal, 2.6.2005, I-2 U 39/03, 5 InstGE 251 – Lifter)

Damages in German Patent Litigation

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- **In favour of the patent holder it is presumed that he could have made the same profit achieved by the infringer.**
- **The infringer is treated as if he had pursued the production and sale of the infringing object as the prejudiced patent holder's managing director on the basis of a management without mandate (Federal Supreme Court – Share of Overheads).**

2) Computing loss of profits:

– General formula:

- **profit = sales – costs**

– Sales:

- **protected product**
- **non-protected product which is sold due to the sell of the protected product (not due to other reasons like e.g. exploitation of business relationship between infringer and customers or a reduced price for the purchase of the protected and the non-protected product)**

– **Costs:**

- As a rule, **only variable costs of the manufacture and the marketing** of the infringing product can be deducted from the proceeds achieved.
- **No global deduction of pro-rata overheads.**
- **Overheads** may only be deducted if and to the extent that they can in exceptional cases be directly ascribed to the infringing object. The infringer bears the burden of submission and proof.
- The infringer shall **not** retain a **contribution margin to his fixed costs.**

(Federal Supreme Court, Share of Overheads).

– **What do these principles mean in practice?**

- **Deductible** are costs for the manufacture or the distribution of the infringing product that also the patent holder would have had incurred if he had run the business.
- **Non-deductible** are costs that had to be incurred „in any event“, meaning independently from the manufacture and the distribution of the infringing product
- **Non-deductible** are costs that would not have been incurred by the patent holder even though they would not have been incurred „in any event“.

– **Examples of deductible costs:**

- **Material and energy costs** for the production and the assembling of the infringing product
- **Costs for deficient products** unless the costs are start-up costs that would not have been incurred by the patent holder because he already maintained a respective production
- **Costs for the purchase of a machine** which is exclusively used for producing the infringing product
- **Expenses for personal** that was employed or used only for manufacturing the infringing product
- **Rent for production halls** that were exclusively used for the manufacturing of the infringing product
- **Freight charges with regard to sales**
- **Cash-discounts on sales**
- **Sale-dependent costs for insurances**
- **Sale-dependent agent's commissions**

Damages in German Patent Litigation

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– **Examples of non-deductible costs:**

- **Expenses for personal** that is also concerned with the manufacturing of other products (this may be different when the infringer can prove that he would have licensed some of his workers if he had not produced the infringing product)
- **Costs for the general management of the company including CEO's salary**
- **Costs for machines or rent for production halls** that are also used for the manufacturing of other products
- **General marketing costs**
- **Development and start-up costs** for the marketing of the infringing product
- **Damages paid to customers** with regard to the infringing product

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- **Attorney's or court fees for the defence in patent infringement proceedings**
- **Costs for infringing products that cannot be sold due to a court injunction issued in the infringement proceedings**
- **Costs for the recall, removal and destruction of the infringing product**

3) Causation

- **The profit from the infringement is only to be surrendered to the extent that it is based on the infringement (Federal Supreme Court – Share of Overheads).**
- **It has to be assessed by the trial judge which factors did influence the purchase decisions of the customers and what is the share of the sales that is due to the use of the infringed patent (Federal Supreme Court, 2007 GRUR 431 – Steckverbindergehäuse, Düsseldorf Court of Appeal – Lifter).**

– **Assessing the share of the proceeds** due to the infringement of the patent-in-suit may get difficult in the following kind of situation:

- The patent infringement concerns only a part of the entire product sold on the market,
- The product sold on the market makes use of several IP rights (technical or design),
- The product is sold under a famous brand or company name.

– **Particular sales activities of the infringer**

- In its decision “Share of Overheads“ the Federal Supreme Court pointed out that particular sales activities of the infringer (e.g. the exploitation of business relationships, the use of distribution knowledge, and sales promotion) should not be taken into account as a relevant cause.
- The case concerned a clamping ring which was protected by an industrial design. The commercial success was only due to the design of the ring.

- With regard to technical IP rights like patents and utility models a comparable situation can be found when the use of technical IP right **made it possible to sell the product on the market**. Under these circumstances all of the profit is due to the infringement of the patent or utility model and, consequently, sales activities cannot be taken into account.
- The case is different when the infringed patent **concerns only a detail of the product** which is not very important for the commercial success of the product.

– **Interests**

- Interests have to be payed **in analogy to sect. 668 Civil Code** which provides that the agent who is using money for himself which he is obliged to return to his principal has to pay interests from the time he uses the money (cf. Düsseldorf Court of Appeal, 2.6.2005, I-2 U 39/03, 5 InstGE 251 – Lifter).
- Interests have also to be payed when the infringer comes into **default**.

• VII Reasonable royalty:

- A reasonable royalty is a **safe and comfortable way** to get compensation for the incurred damages
- A reasonable royalty can be claimed by a patent holder who is not exploiting the patent himself and, therefore, cannot claim lost profits.
- **The patent infringer has to pay the royalty that would have been agreed for a licence by reasonable contractual partners if they had known the situation at the end of the infringement period.**
- A penalty surcharge is not permissible.

• However, **additional boni** are possible, e.g.:

- According to German law, past licence fees do not have to be paid back if the licensed patent is invalidated. The licensee is simply exempted from paying any further licence fee in the future. The infringer, however, is not required to make any payments for past use either. Consequently, the licence fee in the imaginary „licence agreement“ is increased. **The infringer is compared to a licensee whose licence agreement provides that all licence fees are to be repaid if the licensed patent should be invalidated at any time (Düsseldorf District Court, 2000 GRUR 690 – Reactance Loop [Reaktanzschleife]).**
- Many licence agreements grant **additional advantages to the licensor like the right to carry out quality controls, audits, etc.** In order to compensate the prejudiced patent holder who can only require the infringer to render account of the infringing actions an additional bonus might be justified.

- **Indications for determining the rate of a reasonable royalty may come from**
 - existing licence agreements
 - reports dealing with licence fee regularly payed in the respective branch of industry
 - the case law of the courts and the arbitration board at the German Patent Office dealing with employee inventor compensation
 - the opinion of a court-appointed expert
- **The entire market value can become the basis for determining the the reasonable royalty provided reasonable parties would have made such an agreement.**
- **If the entire market value is taken as a referential basis for determining the royalties the rate will normally be lower as if only the value of the protected item is taken.**

Damages in German Patent Litigation

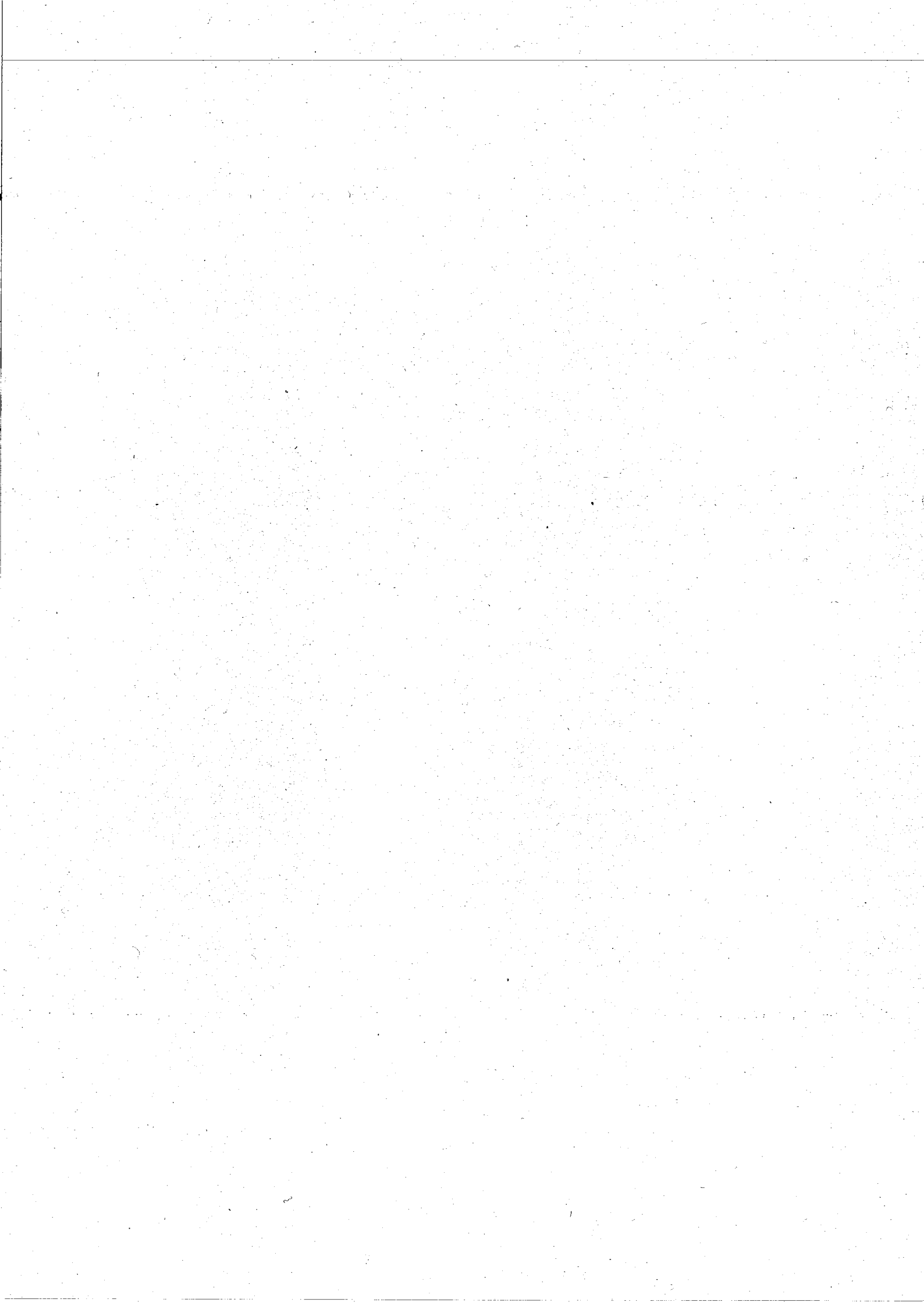
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- **Interests**

- It is presumed that reasonable contractual partners would have agreed that royalty fees are payable within a certain term and interests have to be payed if no payment has been made in time even if the licensee did not come into default. **Accordingly, the infringer has to pay interests on the reasonable royalty after every accounting period (normally one year).** The interest rate can be fixed in analogy to the statutory interest rate of 8 % above the basis interest rate (fixed by the Deutsche Bundesbank), sect. 288 (2) Civil Code.
- Higher interest rates are possible, when the infringer comes in default (e.g. interest rate of a credit which the patent holder had to take).

Damages in German Patent Litigation

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EPLAW Principles on Art. 13 EnfDir in it's application to Patents

I. General Principles

1. Whereas the title "Damages" and the words "damages appropriate to the actual prejudice suffered by him/her" (the rightholder) would suggest that Art. 13 is dealing only with the negative economic effects of a patent-infringement on the side of the rightholder, the aspects listed in para. 1 (a) and (b) clarify that Art. 13 is providing for a compensation of the rightholder including "unfair profits" of the infringer and including a "lump sum" which may be higher than a lost licence fee (see the words "on the basis", "of elements", "such as", "at least" in para. 1 (b)), thus taking into account also elements on the side of the infringer.
2. Therefore, it is not justified
 - a) to restrict "unfair profits" to those profits which the rightholder would have been able to achieve
 - b) to restrict the lump sum/licence fee to cases where the rightholder would have been willing to grant a licence.
3. The two aspects of "negative economic consequences" and of "unfair profits" as well as the alternative of a "lump sum / licence fee" should be regarded as options between which the rightholder (and not the court on its own) may make a choice. The rightholder should be able to make this choice on the basis of accounts of the infringer at the latest date for presenting facts and defining claims in the court-procedure on damages.
4. The three options (Nr. 3), principally, should not be mixed regarding one and the same infringing act. Regarding different infringing acts the rightholder may decide to apply different options.

II. Principles on negative economic consequences

5. The wide formulation allows to include all negative economic consequences (NEC) on the side of the rightholder, not only lost profits, which is mentioned by Art. 13 only as an example.
6. The rightholder may ask for recovery only of his own NEC (including a loss of licence fees), not of the NEC of his licensees. At least the exclusive licensees should be regarded as independent rightholders.
7. The NEC include the effects of a market disturbance and of a negative price spiral.
8. It should be further examined whether the NEC may include the negative effect that the rightholder was not able to sell his original products and, thereby, lost the possibility not only to make profit with the unsold products but also lost the possibility of covering a part of overhead costs normally attributed to (and carried by) the said products.
9. Where full proof is impossible, the courts should establish certain NEC (e. g. Nr. 7) by reasoned estimates. Where the infringer is closer to the underlying facts a change of the burden of proof should be considered.
10. Interest should be granted on the amount established on the basis of NEC. The interest-period should start at the beginning of default.

III. Principles on "unfair profits"

11. It is acknowledged practice in many states that the obligation of the infringer to render "unfair profits" is a kind of compensation different from the right to seek redress of "damages" in the narrower legal sense (France, Germany, UK, USA). See Nr. 1, 2 a), above.
12. Other causes of the profit (other than the infringement) should be taken into account, diminishing the amount of the profit to be rendered to the rightholder. However, the court should differentiate:
 - a) Other causes with clearly deductible effects are
 - (1) the production costs
 - (2) the sales costs as far as they are attributable to the infringing products
 - (3) use of other rights (e. g. patents), at least as far as they are claimed or expected to be claimed
 - b) Questionable appears the deduction of the impact of known trademarks and of market prestige. These influences, in most cases, will not lend themselves to calculation.
 - c) No deduction should be allowed for: general costs, not attributable to the infringing goods (especially: overhead costs), taxes, capital investment and general entrepreneurial skills.
13. The causal nexus (link) between the infringing use of the patent and the profit (part of the profit) must be established, at least in the way of a reasoned estimate to what degree the infringement has been increasing the value of the good. One, but not the only, test could be to what degree it may be assumed that the customer bought the infringing good because the patent has been used.
14. The rightholder should have the right to ask the unfair profits from all stages of the distribution chain (producer, grossist, retailer)
15. The word "unfair" (in "unfair profits") should be understood as meaning "illegitimate" or "illegal". Since all profits caused by the infringement (see Nr. 12, 13) are "illegal", the word "unfair" should have no additional consequence.

IV. Lump sum / licence fee

16. As the "unfair profits" also the alternative "lump sum / licence fee" is a kind of compensation different from "damages" in the narrower legal sense (see Nr. 1, 2 b, 12, above). Therefore, the amount to be attributed under this alternative may differ (may be higher) than the licence fee in a normal licence contract between the rightholder and a loyal licensee. This is shown by the words "on the basis", "of elements", "such as" and "at least" in Art. 13 para 1 (b).
17. In fixing the amount of the lump sum / licence fee, the following aspects should be taken into account which put the infringer in a better position than a contractual licensee:

- a) He may hope not to get detected and has the possibility of surprising marketing strategies
 - b) He does not render constant information on turnover and on other facts to the rightholder
 - c) He does not follow the rightholder's prescription on quality, get-up, distribution, marketing and other obligations in licence-contracts.
 - d) He does not respect the territory of (real) licensees.
 - e) He does not hold price conformity.
 - f) He sees no problem in attacking the patent and will attack it.
18. The hypothetical contractors of the hypothetical licence contract (the rightholder and the infringer) should be understood as
- a) knowing the advantages of the infringer (Nr. 17) and
 - b) knowing the actual development of the infringers sales (which may be positive or negative for the interest of the rightholder), because all compensation is of a retrospective nature.
19. The lump sum / licence fee should be calculated from the infringing part of the product. If calculated from the turnover of the whole product, the licence fee should be divided (diminished) to correspond to the value of the part.
20. In order to arrive at an "appropriate" remedy even in cases of price-destruction ("cannibalism") the lump sum should include
- a) an entrance fee and
 - b) a fixed amount calculated on the basis of the prices at the beginning of the period of infringement.

The new EU Bolar-Type provision – Where do we stand?

**Marie Isabel Manley
Bristows**

EPLAW – 16 November 2007

Overview

- **Patent Law Experimental Use Exemption**
- **Overview of the New EU “Bolar” Provision**
- **What is Permissible under EU “Bolar”**
- **Implementation Status in various MS**
- **Conclusion**

BRISTOWS

Position prior to the EU "Bolar" Provision

- Position before Bolar-Type provision: most Member States (MS) had/have in their legislation the "experimental use exemption" which arises from the European Patent Convention.
- "experimental use exemption" interpreted differently among MS
 - UK (narrow approach): trials to discover something unknown or test hypothesis – exempt; trials to demonstrate to third party that product works or to amass information – not exempt (Monsanto)
 - Germany (more permissive approach): all testing relating to 'research purposes' are exempt even if serve a commercial purpose (except large scale testing) – includes clinical trials
- "Bolar exemption": US concept which consists of exempting from patent infringement, tests and studies conducted for regulatory approval

BRISTOWS

Overview of the EU Bolar-Type provision

- Article 10(6) of Directive 2001/83/EC (introduced by Directive 2004/27/EC) states that:

"Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 [abridged & hybrid abridged & biosimilar applications] and the consequential practical requirements shall not be regarded as contrary to patent rights or SPCs for medicinal products"

BRISTOWS

What is authorised under Article 10.6 ? (1)

- Article 10.6 for the relevant part states:
"Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2 3 and 4 and the consequential practical requirements ..."
- Therefore the exemption is only available for:
 - Applications submitted under the EU abridged/hybrid abridged procedure and biosimilar procedure
 - "necessary studies and trials" & "consequential practical requirements" (this will include filing of the application itself, conduct of bioequivalence studies, production of samples, comparability studies,...
 - The purpose of conducting the tests and studies is important as only activities conducted with the aim to submit an application for an MA under the specific procedure will be exempted
- However, cannot enter the market until RDP, patent and SPC have expired (or been revoked)

BRISTOWS

Implementation in the UK

- Implemented on time (30 October 2005) by modifying the Patent Act (ss. 60(5) & 60(7))
- **Narrow** implementation
- The new wording provides that
"an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs [...] 1 to 4 of the [Directive]; or any other act which is required for the purpose of the application of those paragraphs."
will not constitute an infringement of patent rights
- Guidelines issued by MHRA and UK Patent Office

BRISTOWS

What is permissible in the UK?

- **MHRA and Patent office Guidelines:**
 - Manufacture/Import of actives, validation of manufacturing process
 - Manufacture/Import of finished product, validation of manufacturing process
 - Development/testing/use of analytical techniques for manufacture of active & finished product
 - Conduct of pre-clinical tests, clinical and bio-availability trials, stability studies
 - Compilation and submission of MA plus samples to regulatory authorities
- Is only Guidance... but MHRA and Patent Office do not wish to legislate
- A dispute as to scope of UK Bolar-Type provision would be considered by UK Patent Court – it could make a reference to ECJ if ruled provisions unclear

BRISTOWS

The MHRA guidance

- **The Bolar-Type provision would cover, mainly:**
 - i.) the carrying out of chemical and biological synthetic processes suitable for the making, disposal or keeping of the active substance(s) including the manufacture or the import of batches in quantities sufficient to provide material for preparing investigative batches of the medicinal product and to validate the processes to the satisfaction of the competent authorities.
 - ii.) the development, testing and use of the associated analytical techniques for the above.
 - iii.) the development of the final pharmaceutical composition and manufacturing processes for the medicinal product to be marketed including the making, disposal or keeping or import of product batches in quantities sufficient to conduct the necessary pre-clinical tests, clinical and bioavailability trials and stability studies of the medicinal product and to validate the processes to the satisfaction of the competent authorities.
 - iv.) the development, testing and use of the associated analytical techniques for the above.

BRISTOWS

The MHRA guidance (cont.)

v.) the manufacture and supply to the competent authorities of samples of active substances, their precursors, intermediates or impurities and of finished product samples.

vi.) the compilation and submission of a MA or Variation application and application for a MA.

- However, the 'necessary studies and trials' and the 'consequential practical requirements' would not include:

vii) The manufacture, packaging and testing of the active substance or finished product not required for conducting the tests and trials necessary for gaining authorisation or for providing small quantities as samples.

- Therefore, manufacturing large quantities of products to storage in view of a launch of the generic product would not fall within the Bolar-type provision and would constitute patent infringement as the production of such a quantity of medicine would not be required in support of a marketing authorisation.

BRISTOWS

Implementation in Denmark

- Source: **Mikkel Vittrup** (Plesner Svane Grønberg)
- Implementation on 1 July 2007 (although unofficially implemented by 30 October 2005) by adding a new provision Section 3(3) (4) to the Patent Act
- **Broad** interpretation of Article 10(6) as the exemption applies to all types of application (i.e generics and "innovative" products) and extended the applications outside the EU
- The new wording provides that (loose translation):

"Acts, limited to the subject matter of the patented invention, which are necessary in order to obtain a marketing authorisation for a pharmaceutical for humans or animals in the EU, in an EU member state or in the other countries."

BRISTOWS

Danish provision

"4) Handlinger, der er afgrænset til genstanden for den patenterede opfindelse, som er nødvendige for at kunne opnå en markedsføringstilladelse for et lægemiddel til mennesker eller dyr i EU, i en EU-medlemsstat eller andre lande."

BRISTOWS

Implementation in Denmark (cont.)

- "Acts" necessary to obtain a marketing authorisation:
 - Studies, trials, investigations and other related procedures to a patented product
- Ambiguities:
 - It is thought that "necessary" must be interpreted broadly, but this is unclear
 - Does "limited to the subject of the patented invention" cover intermediary products and process. It does not cover patent protected "research tools"?

BRISTOWS

Implementation in Finland

- **Source:** Rainer Hilli (Roschier)
- Implementation on 1 May, 2006 by amending the Finnish Patent Act (HE/225/2005)
- **Broad** interpretation of Article 10(6)
- The new wording provides that (loose translation):

"The exclusive right shall not apply to:

[...]

examinations or experiments or measures arising from practical demands which are needed for an application to obtain a marketing authorisation for a medicinal product and which relate to the invention concerning that medicinal product (21.4.2006/295);

[...]"

BRISTOWS

Finnish provision

"Yksinoikeus ei käsitä:

[...]

lääkevalmisteen myyntilupahakemusta varten tarvittavia tutkimuksia, kokeita tai käytännön vaatimuksista aiheutuvia toimia, jotka koskevat kyseiseen lääkevalmisteseen kohdistuvaa keksintöä (21.4.2006/295);

[...]"

BRISTOWS

Implementation in France

- Source: **Pierre VÉRON** (Véron & Associés)
- Implemented by Article 10 of a French statute of February 26, 2007
- It supplements Article L. 613-5 of the French Intellectual Property Code which provides a list of patent infringement exemptions.
- **Broad** implementation as:
 - It is not limited to the studies and trials required for obtaining a French or EU marketing authorisation (it could be applied to obtaining a US NDA)
 - It is not limited to the patents covering the drug for which a generic is contemplated (it could be interpreted as creating a safe harbour against any patent, including laboratory equipment patent, and even research tools patents).

BRISTOWS

France (loose translation)

- It adds a new paragraph d) according to which the rights conferred by the patent do not extend to:
 - “the studies and trials required for obtaining a marketing authorization for a medicinal product, as well as to the acts necessary for carrying out these studies and trials and for obtaining the authorization”.

BRISTOWS

French provision

- « Les droits conférés par le brevet ne s'étendent pas :
[...]
d) aux études et essais requis en vue de l'obtention d'une autorisation de mise sur la marché pour un médicament, ainsi qu'aux actes nécessaires à leur réalisation et à l'obtention de l'autorisation. »

BRISTOWS

Implementation in Germany

- Source: **Max von Rospatt** (Rospatt Osten Pross)
- Implementation on 6 September 2005 in § 11 No. 2b PatG (patent law)
- **Broad** interpretation of Article 10(6)
- The new wording provides that (loose translation):
"The effect of the patent does not extend to the necessary studies and trials and the consequential practical requirements, which are necessary to obtain a marketing authorization for medicinal products in the European Union or an authorization for medicinal products in the Member States of the European Union or in other states."
- This implementation confirms the previous case law according to which such studies and trials do not constitute an infringing act (BGH NJW 1997, 3092 ff. – Klinische Versuche II.).

BRISTOWS

German provision (§11 No. 2b PatG)

II *Ausnahmen von der Wirkung des Patents. Die Wirkung des Patents erstreckt sich nicht auf*

1. Handlungen, die im privaten Bereich zu nichtgewerblichen Zwecken vorgenommen werden;
2. Handlungen zu Versuchszwecken, die sich auf den Gegenstand der patentierten Erfindung beziehen;
- 2 a. die Nutzung biologischen Materials zum Zweck der Züchtung, Entdeckung und Entwicklung einer neuen Pflanzensorte;
- 2 b. Studien und Versuche und die sich daraus ergebenden praktischen Anforderungen, die für die Erlangung einer arzneimittelrechtlichen Genehmigung für das Inverkehrbringen in der Europäischen Union oder einer arzneimittelrechtlichen Zulassung in den Mitgliedsstaaten der Europäischen Union oder in Drittstaaten erforderlich sind;
3. die unmittelbare Einzelherstellung von Arzneimitteln in Apotheken auf Grund ärztlicher Verordnung sowie auf Handlungen, welche die auf diese Weise zubereiteten Arzneimittel betreffen;
4. den an Bord von Schiffen eines anderen Mitgliedsstaates der Pariser Verbandsübereinkunft zum Schutz des gewerblichen Eigentums stattfindenden Gebrauch des Gegenstands der patentierten Erfindung im Schiffskörper, in den Maschinen, im Takelwerk, an den Geräten und sonstigen Zubehör, wenn die Schiffe vorübergehend oder zufällig in die Gewässer gelangen, auf die sich der Geltungsbereich dieses Gesetzes erstreckt, vorausgesetzt, daß dieser Gegenstand dort ausschließlich für die Bedürfnisse des Schiffes verwendet wird;
5. den Gebrauch des Gegenstands der patentierten Erfindung in der Bauausführung oder für den Betrieb der Luft- oder Landfahrzeuge eines anderen Mitgliedsstaates der Pariser Verbandsübereinkunft zum Schutz des gewerblichen Eigentums oder des Zubehörs solcher Fahrzeuge, wenn diese vorübergehend oder zufällig in den Geltungsbereich dieses Gesetzes gelangen;
6. die in Artikel 27 des Abkommens vom 7. Dezember 1944 über die internationale Zivilluftfahrt (BGBI. 1956 II S. 411) vorgesehenen Handlungen, wenn diese Handlungen ein Luftfahrzeug eines anderen Staates betreffen, auf den dieser Artikel anzuwenden ist.

BRISTOWS

Implementation in Italy

- **Source: Cristiano Cori** (Trevisan & Cuonzo Avvocati)
- Implementation on 19 March 2005 by a Decree
- Bolar-Type provision has been implemented in Article 68(1) of the Italian Intellectual Property Code
- **Broad** interpretation of Article 10(6)
- An issue currently questioned in Italy is what the notion of "practical requirements" actually includes

BRISTOWS

Implementation in Italy (cont.)

- Does this notion is limited to the preparation and use of the active ingredient contained in the reference product or does it also include the proper filing of the marketing authorisation application?
- In interlocutory proceedings in a recent decision from the IP Chamber of the District Court of Rome (23 October 2006) it was held that the mere filing of the application for marketing authorisation for a generic drug before the expiry of the relevant patent on the reference product may result in infringement.
- The situation is different if the reference product is protected through an SPC: in this case, generic drug companies may file the application for marketing authorisation up to one year before the expiry of the SPC.

BRISTOWS

Italy (loose translation)

"The exclusive rights granted by the patent owner do not extend, whatever the subject matter of the invention:

a) to the acts carried out in private without commercial purposes, as well as experimental acts, although aimed at obtaining, also abroad, an authorisation to the marketing of a medicinal product and to the carrying out of the consequent practical tasks including the preparation and use of the active ingredients strictly necessary thereto;

b) to the extemporaneous preparation in a pharmacy, for individual cases, of drugs in accordance with a medical prescription and the drugs so prepared, provided that no industrially obtained active ingredients are used."

BRISTOWS

Italian provision

- *"La facoltà esclusiva attribuita dal diritto di brevetto non si estende, quale che sia l'oggetto dell'invenzione:*
- *a) agli atti compiuti in ambito privato ed a fini non commerciali, ovvero in via sperimentale ancorché diretti all'ottenimento, anche in paesi esteri, di un'autorizzazione all'immissione in commercio di un farmaco ed ai conseguenti adempimenti pratici ivi compresi la preparazione e l'utilizzazione delle materie prime farmacologicamente attive a ciò strettamente necessarie".*

BRISTOWS

Implementation in the Netherlands

- Source: **Simon Dack** (De Brauw Blackstone Westbrook)
- Implemented on 1 February 2007 in Article 53, paragraph 4 of the Dutch Patents Act 1995 (*Rijksoctrooiwet 1995*)
- **Narrow** implementation
- According to this provision, studies, tests and related practical requirements for the purpose of applying Article 10, paragraph 1-4 of Directive 2001/83 do not constitute an infringement of a patent

BRISTOWS

