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Young EPLAW Congress

Bolar provision: a European tour

Brussels, 27 April 2015
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Strengthening links between patent lawyers in Europe

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Bolar provision: a European tour

Introduction

Part 1 – UK

- A) Recent Developments – Changes in the law
- B) Bolar v. research exemption – Differences
- C) What is covered?


Part 2 – Germany

- A) Recent Developments – New jurisprudence
- B) Bolar v. research exemption – Research exemption influence
- C) What is covered?

Part 3 – France

- A) Recent Developments
- B) Bolar v. research exemption – Bolar instead of research exemption
- C) What is covered?

Part 4 – UPC



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INTRODUCTION - ISSUES

- PATENTS MAY HINDER OR PREVENT MANUFACTURERS OF GENERIC DRUGS FROM ENTERING THE MARKET EVEN AFTER THEIR EXPIRATION

- **EVEN FAST-TRACK MARKETING AUTHORIZATION (“MA”) CAN TAKE UP TO 3 YEARS FOR GENERIC DRUGS**

- Prevents access to cheaper drugs for the patients
- Costs €billions to Healthcare Agencies

- TO OVERCOME THIS PROBLEM, COUNTRIES HAVE RESORTED TO LEGAL EXEMPTIONS FROM INFRINGEMENT

- **RESEARCH EXEMPTIONS**

- Coherent with ART 30 TRIPS: balance of interests → does unauthorized use unreasonably conflict with the normal exploitation of the patent?



INTRODUCTION – BOLAR V. ROCHE

- **ROCHE PRODUCTS, INC. V. BOLAR PHARMACEUTICAL CO., INC., 733 F.2D 858 (1984)**

- While seeking FDA approval, Bolar used Roche's patented chemical to determine whether Bolar's drug was bioequivalent to Roche's

- **THE COURT RULED**

- Bolar intended to market its generic product and would therefore be a competitor to Roche → **business oriented criterion**
- Research exemption did not apply
- Argument that denying BOLAR its right to use the patent for the purposes of its MA application extended ROCHE's monopoly beyond the life span of the patent
→ **rejected**

- **CONGRESS ENACTED A LAW TO OVERTURN THIS PRECEDENT → “BOLAR EXEMPTION”**

- Interestingly, French Courts introduced the Bolar exemption in France by following an opposite reasoning



INTRODUCTION – EUROPEAN FRAMEWORK

- **DIRECTIVE EC/2001/83 ART. 10(6) PROVIDES FOR THE BOLAR EXEMPTION IN EUROPE (AMENDED BY DIRECTIVE EC/2004/27)**

- **USEFUL FOR HARMONIZATION OF THE GENERIC DRUG PRODUCTION AND IMPORTATION IN THE EU**

- *The scope, language and interpretation of Bolar exemptions vary across Europe*

- **TWO TYPES OF TRANSPOSITIONS TO NATIONAL LAWS:**

- *Limited exemption → acts relating to the obtaining of MAs for generic drugs*
- *Broader exemption → any acts required for MA of new and/or innovative medicines*

- **NO DIFFERENCE MADE BETWEEN BIOSIMILAR AND BIOEQUIVALENT DRUGS**

- *Biosimilar generic drugs must undergo full MA examination (~7 years)*

- **ONLY REQUIREMENT: A GENERIC MAY NOT ENTER THE MARKET UNLESS 10 YEARS HAVE PASSED SINCE THE PRINCEPS WAS FIRST OFFERED FOR SALE**



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Recent developments – UK

- 1977 – Patents Act exempts acts done for “*experimental purposes relating to the subject-matter of the invention*” – narrowly interpreted by UK courts
- 2005 – UK adopts “narrow” Bolar exemption covering only studies carried out with a view to obtaining an EU generic marketing authorisation
- 2008 – 2014 – Intellectual Property Office consultation on scope of experimental use and Bolar exemptions

Recent developments – UK – policy

- “*The UK is in direct competition with other countries, both within the EU and internationally, as a location for clinical trials... everything else being equal, it is likely that trials would be located in a jurisdiction with more generous Bolar or research exceptions*”
- Key problems with “narrow” exemption identified by IPO:
 - Comparator product might be patented
 - Comparator may not be available on the open market
 - One or more drugs in a proposed combination product may be patented

Recent developments – UK – new exemption

From 1 October 2014:

(6D) For the purposes of subsection (5)(b) [the existing exemption for experimental use], **anything done in or for the purposes** of a **medicinal product assessment** which would otherwise constitute an infringement of a patent for an invention is to be **regarded as done for experimental purposes relating to the subject-matter of the invention**.

Recent developments – UK – new exemption

(6E) In subsection (6D), “*medicinal product assessment*” means any testing, course of testing or other activity undertaken with a view to providing data for any of the following purposes—

- (a) **obtaining or varying an authorisation** to sell or supply, or offer to sell or supply, a medicinal product (**whether in the United Kingdom or elsewhere**);
- (b) complying with any **regulatory requirement** imposed (**whether in the United Kingdom or elsewhere**) in relation to such an authorisation;
- (c) enabling a government or public authority (**whether in the United Kingdom or elsewhere**), or a person (**whether in the United Kingdom or elsewhere**) with functions of—
 - (i) providing health care on behalf of such a government or public authority, or
 - (ii) providing advice to, or on behalf of, such a government or public authority about the provision of health care,

to carry out an **assessment of suitability** of a medicinal product for human use for the purpose of determining whether to use it, or recommend its use, in the provision of health care.

Bolar v. experimental use – UK

- Experimental use
 - Narrowly interpreted by Court of Appeal in 1985 decision (*Monsanto v Stauffer* [1985] R.P.C. 515)
 - Must “*test a hypothesis*”, not merely “*amass information to satisfy a third party*”
 - Test must “*relate to the subject matter of the invention*”
 - Relatively little recent case law – is no one doing it, or no one suing?

Bolar v. experimental use – UK

- New Bolar
 - NB – not a separate exemption, falls within experimental use
 - Aim = encourage specific types of clinical trial in the UK
 - Principal acts covered are clear, although always room for debate, e.g. is regulatory approval “*in view*” from the outset?
 - Uncertainty at the edges – e.g. third party suppliers

What is covered – UK

Act	Permitted under UK law?
Study to generate data for <u>generic</u> MA or health technology assessment	YES
Study to generate data for <u>innovator</u> MA or health technology assessment	YES
Study comparing new drug to patented comparator	YES, if carried out with a view to submitting data to a regulatory body Possibly also experimental use, depending on circumstances
Incidental use of a “research tool”	UNCLEAR
Third party manufacturer supplying product for use in trials	UNCLEAR

What is covered – UK – suppliers

“anything done in or for the purposes of a medicinal product assessment”?

ORIGINAL GUIDANCE (September 2014)

- *Can I supply a patented drug to a person for use in a medicinal product assessment without a licence from the patent owner?*
- Sections 60(2) and (6) of the Patents Act 1977 have not been amended. The consent of the patent owner would be needed to supply a patented drug to a person for use in a medicinal product assessment.

REVISED GUIDANCE (October 2014)

- *Does the amendment cover commercial use of a patented drug in a product?*
- The new provisions **do not** extend to commercial activities, such as sale, commercial supply, or manufacture in preparation for sale or supply. A licence, or other agreement, will be required from the patent holder before a product can be sold or supplied commercially.

Bolar provision: a European tour Part 2 - Germany

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IPMT / Düsseldorf



Recent developments - Germany

- No provision in the 1968 German Patent Act (GPA)
- 1989 BGH (*Bundesgerichtshof*) "*Ethofumesat*" decision based on 1968 GPA – exemption for experiments directed at the patented substance
- Section 11.2 of the 1981 GPA – research exemption for "*acts done for experimental purposes relating to the subject-matter of the patented invention*" – not interpreted by the BGH until end of the 90'

Recent developments - Germany

- 1995 BGH "Clinical Trials I" ("*Klinische Studien I*") – research exemption for experiments having the purpose of finding a new indication for the patented substance
- 1997 BGH "Clinical Trials II" ("*Klinische Studien II*") – purpose is rather to gather new scientific information through the experiments
- Section 11.2b) GPA: "broad" Bolar exemption since 2005

Recent developments - Germany

- Section 11.2b): "*studies and trials and the resulting practical requirements necessary for obtaining a marketing authorization to place a medicinal product on the market in the European Union or a marketing approval for a medicinal product in the Member States of the European Union or in third countries*"
- "Broad" Bolar provision
 - ✓ Activity: broader than clinical trials
 - ✓ Product: beyond simple generic product
 - ✓ Relevant market: any market even outside the EU

Recent developments - Germany

Extension of the exemption to the third party supplier?

Astellas Pharma v. Polypharma case ("Marktzulassungsprivileg")

- July 2012, Landgericht Düsseldorf
 - ✓ "Co-organiser" criterion
 - ✓ The supplier has a clear interest in the studies and trials
 - ✓ Manufacturing and supplying becomes a "practical requirement" with the intention of carrying out trials or studies
- December 2013, Oberlandesgericht Düsseldorf – referral order: question to the CJEU
 - ✓ *"Must Article 10(6) of Directive 2001/83 be interpreted as meaning that those acts of delivery are also excluded from patent protection by which a third party offers or delivers a patented active substance to a manufacturer of generic products for purely commercial reasons, which the manufacturer of generics intends to use for studies or trials in order to obtain a marketing authorisation or approval within the meaning of Article 10(6) of Directive 2001/83?"*

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Recent developments - Germany

Extension of the exemption to the third party supplier?

Astellas Pharma v. Polypharma case

- December 2013, Oberlandesgericht Düsseldorf
 - ✓ Supplier can rightly assume that the product will be used for studies and trials necessary to marketing authorisation:
 - ✓ the profile of the supplied company → generic manufacturing,
 - ✓ the small amount of product delivered → trials for regulatory purposes,
 - ✓ the imminent expiration of the patent or SPC → market entry possible,
 - ✓ the reliability of the supplied company.
 - ✓ It has also taken precautionary measures to avoid any non-privileged use such as:
 - ✓ supplying small quantities, and
 - ✓ setting contractual penalties in case the supplied company uses the products not only in view of obtaining a marketing authorisation.

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Bolar v. research exemption - Germany

- **Type of Product or Process**
 - medicinal product v. any patented product or process

Influence of research exemption → Bolar wider than EU-directive

- **Type of Registration**
 - any marketing authorization (MA) in any country v. no specific registration has to be involved
 - May 2001 German Constitutional Court re Clinical Trials II: no unjustified factual extension of the patent owner's rights when the development of technical state of the art and/or public interest are at stake

Influence of research exemption's purpose → registration logic not geographically restricted to the markets in the EU

Bolar v. research exemption - Germany

- **Type of Activity**
 - trials and studies nec. to obtain a MA v. experiments to gather scientific information on the patented subject-matter which overcomes an existing uncertainty
 - practical requirements resulting from the above mentioned trials and studies v. experiments as such

The extension of the research exemption to other acts than mere experiments is established in the jurisprudence (e.g. manufacturing, use, possession and importing) → broad wording of the Bolar provision

The extension of both exemptions to a third party supplier is still questionable because there is no established jurisprudence.

What is covered - Germany

Act	Permitted under German law?
Study to generate data for <u>generic</u> MA or health technology assessment	YES
Study to generate data for <u>innovator</u> MA or health technology assessment	YES
Study comparing new drug to patented comparator	YES, if carried out with a view to submitting data to a regulatory body Possibly also experimental use, depending on circumstances
Incidental use of a “research tool”	Not if the info gathered does not relate to the tool
Third party manufacturer supplying product for use in trials	Possibly yes if the German courts follow OLG Düsseldorf

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BOLAR EXEMPTION IN FRANCE – PART 3

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RECENT DEVELOPMENTS - FRANCE

• UP TO THE TRANSPOSITION OF THE DIRECTIVE IN 2007

➤ L.613-5 B), FRENCH INTELLECTUAL PROPERTY CODE (“IPC”)

→ *research and experiment exemption*

➤ L.5121-10 AL. 10, FRENCH CODE FOR PUBLIC HEALTH (“CPH”)

→ *A MA may be delivered for a generic drug prior to the lapse of the active ingredient patent*

• SINCE THE TRANSPOSITION OF THE DIRECTIVE IN 2007 AND THE ENACTMENT OF LAW NO. 2007-2048

➤ L.613-5 d) IPC

→ *Specific Bolar exemption*

→ *Broad scope: applies to all drugs (not restricted to generic drugs)*

→ *Extend to all studies and assays for the obtaining of a MA, including all other acts necessary for their carrying out*



RECENT DEVELOPMENTS - FRANCE

• PRIOR TO 2007

• TGI PARIS, NOVEMBER 1 2001, *WELLCOME V. PAREXEL*

➤ *Clinical trials and studies performed for the purpose of the obtaining of a marketing authorization amounts to experimental use*

• TGI PARIS, 3RD CH., 2ND SECT., JANUARY 25 2002, *SCIENCE UNION V. BIOPHELIA*

➤ *All “necessary” acts performed for the purpose of obtaining a MA are exempted from patent infringement → similar to L.613-5 IPC*

• CA PARIS, PÔLE 1, 2ND CH., MARCH 21 2012, *NOVARTIS V. MYLAN*

➤ *Generic drug manufacturers are entitled to proceed with all necessary formalities towards the marketing of their products prior to the lapse of the patent*

- *E.g., registration on the List of Drugs for which Reimbursement is Available in France and/or on the List of Generic Drugs*



RECENT DEVELOPMENTS - FRANCE

- **AFTER 2007 → ONLY ONE BOLAR EXEMPTION CASE**

- **TGI PARIS, 3RD CH., 1ST SECT, LILLY FRANCE V. SANOFI**

- *Lilly France is developing a Biosimilar drug to Aventis's in France. Aventis has succeeded in performing two saisie-contrefaçons at Lilly's France head office and production unit*

- **Only preliminary judgements have been issued on the matter → no final decision**

- *As of now: judge has decided that there was no evidence of infringement/imminent infringement sufficient to justify the award of a preliminary injunction*

- ➔ **Consistent with a broad construction of the Bolar exemption**

- *Acknowledgement of the right for a party to perform a saisie-contrefaçon at a competitor's place of business when he is aware that such competitor is developing a biosimilar generic drug even before the award of the MA → **extremely broad and intrusive***



BOLAR V. RESEARCH EXEMPTION - FRANCE

- **BOLAR EFFECTIVELY REPLACED THE RESEARCH EXEMPTION**

- **SAFE TO ASSUME THAT CASE LAW PRINCIPLES WILL BROADLY REMAIN THE SAME**

- **MAJOR DIFFERENCE → ART. L613-5 IPC APPLIES TO BOTH GENERIC AND NEW DRUGS**

- **TYPES OF PRODUCTS OR PROCESSES:**

- **UNCLEAR WHETHER BOLAR EXEMPTION IS ALSO APPLICABLE TO ANY PATENTABLE MEDICAL PRODUCTS AND PROCESSES → PROBABLY NOT**

- **EXTENSION TO A THIRD PARTY SUPPLIER → NO APPLICABLE CASE LAW FOR BOLAR EXEMPTION**



BOLAR V. RESEARCH EXEMPTION - FRANCE

- **INFRINGEMENT ACTS:**

- **UNDER THE RESEARCH EXEMPTION → ACTS WITH NO COMMERCIAL PURPOSE**

- *CA Paris, July 3rd 2002, 4th sect., RG no. 2000/14939: acts performed for the purpose of researching the technical interests or improvement possibilities of that invention*

- *CA Paris, 4th ch., Sect. B, October 7, 2005, RG no. 2002/03956: improvements of the product for the benefit of the consumer, not mere adjustments, do not fall within the scope of the research exemption*

- **BOLAR EXEMPTION → ACTS GOING BEYOND WHAT IS NECESSARY FOR OBTAINING A MA**

- *Much broader...*

- Courts already construed art. L.613-5 b) IPC in a similar way



WHAT IS COVERED ? - FRANCE

- **ACTS PERFORMED FOR THE PURPOSE OF OBTAINING MAS IN FRANCE, IN EUROPE AND IN ANY OTHER COUNTRIES.**

- *Art. L.613-5 d) does not provide for a limitation to a French MA or to a MA having effect on the French territory.*

- *Lilly v. Sanofi: the judge expressly recognized that Lilly SAS was entitled to perform acts towards the obtaining of MAs all around the world*

- **USE/SALE OF PRODUCTS MANUFACTURED DURING THE COURSE OF THE OBTAINING OF THE MA**

- **INFRINGEMENT EVEN AFTER THE ACTIVE INGREDIENT PATENT HAS EXPIRED**

- *Lilly v. Sanofi: the parties agreed that stockpiling products amounted to infringement.*



WHAT IS COVERED ? - FRANCE

• THE FOLLOWING ACTS ARE NOT DEEMED INFRINGING UNDER THE BOLAR AND RESEARCH EXEMPTIONS

1. **GENERIC DRUG SAMPLE DEPOSIT WITH THE FRENCH NATIONAL AGENCY FOR DRUG SAFETY AND HEALTHCARE PRODUCTS**
→ for future pricing of the product
2. **A DECISION FOR THE PRICING OF A GENERIC DRUG BY THE AGENCY**
→ it does not either involve or provoke the marketing of the drug
3. **THE INSCRIPTION OF A GENERIC DRUG IN A SPECIALTY GROUP**
4. **THE INSCRIPTION OF A GENERIC DRUG ON THE LIST OF DRUGS FOR WHICH REIMBURSEMENT IS AVAILABLE**
5. **ACTS PERFORMED AFTER THE GRANT OF A MA**
→ when other MAs for the drug are still pending



WHAT IS COVERED ? - FRANCE

Act	Permitted under French law?
Study to generate data for <u>generic</u> MA or health technology assessment	YES
Study to generate data for <u>innovator</u> MA or health technology assessment	YES
Study comparing new drug to patented comparator	YES, if necessary for the award of a MA (broad) Also applicable for the research and experimental use exemption
Incidental use of a "research tool"	UNCLEAR
Third party manufacturer supplying product for use in trials	UNCLEAR, probably not



Part 4 - Impact of the UPC

Article 27 UPCA: Limitations of the effects of a Patent

- Research-exemption → paragraph (b), and
- Bolar-exemption → paragraph (d).

"The rights conferred by a patent shall not extend to any of the following:

[...]

(b) acts done for *experimental purposes relating to the subject matter of the patented invention*;

[...]



(d) the *acts* allowed pursuant to Article 13(6) of *Directive 2001/82/EC* or Article 10(6) of *Directive 2001/83/EC* in respect of any patent covering the product within the meaning of either of those Directives; [...]"


Impact of the UPC

- Type of Product or Process
 - ✓ *generic* medicinal product or improvement thereof
 - ✓ however "improvement" implies innovation so not only generics but products which derive from a "reference product"
 - Type of Registration
 - ✓ regulatory marketing approval *within the EU*
 - Type of Activity
- Guidance from the CJEU will be needed
- ✓ *Astellas Pharma v. Polypharma in Poland*: Supreme Court came to the opposite conclusion → some EU judges construe narrowly the Bolar rule of the Directive
 - ✓ German case was dropped before CJEU could give its own interpretation of the EU directives on the Bolar rule
 - ✓ Trend towards broadening of the exemption scope as in the UK (cf. changes July 2014)
 - ✓ Influence of the national provisions on the research exemption of the UPCA

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Any questions?

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