

Master of European Intellectual Property Law – Module 2A
Sufficiency and support issues
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Outline of the seminar

- Introduction of a European patent attorney
- The disclosure requirements in Europe
 - Legal basis and application within the EPC framework
 - *Case law from European courts*
- Please interrupt – please ask questions!

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Introduction of a European patent attorney

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General points

- Experience-based, practical viewpoints
- No manual or set of instructions
- IP consultancy work is very case-by-case dependent

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Real life

- Different types of clients:
 - Large pharmaceutical companies
 - Established research companies
 - Start-up companies
 - Individual entrepreneurs
- *NB: BUSINESS is the basis for applying for patents; not law, not technology!*

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TASK 1: Create patents

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Strategy parameters

- Subject-matter – *for what* is exclusivity needed?
- Geography – *where* are patents needed?
- Competitors – against *whom* is IPR to be asserted?
- Money – *how much* can be invested in IPR?
- Timing – *when* is the invention mature enough?

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Finding the invention

- Inventions are *not* served on a silver platter
 - In fact, an invention (in the patent sense) is not created until the claims are drafted
- Study all aspects of ongoing research
- Isolation of "candidate inventive concept"
 - Be mindful of exclusions from patentability
- Interviews, business focus *and* technology focus
 - Make sure you know the purpose of the patenting effort (and make sure the applicant knows it, too...)

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Evaluating the invention

- Perform search for prior art
 - NB: no search is ever 100 % complete
- Is the concept novel and inventive?
- What is the experimental support and "proof-of-concept"?
- What are the benefits and which problems are solved?

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Drafting claims

- Include as many categories of claims as possible
 - Products ("things")
 - Methods of production
 - Methods of application
 - Uses
- Mind the legal framework
 - Exclusions, novelty, inventive step, clarity, enablement, unity etc.
- Mind the business framework
 - Scope of protection, possible infringers, claims for different jurisdictions should all be present

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Drafting claims (cont.)

- Use dependent claims as fall-back positions
 - Additional specifications, which provide additional distinction over prior art
- Use established terms to define the features of the invention
 - May also define terms in description of application

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Patent description

- Summary of the invention
 - Aid to define and discuss scope of protection
 - Cite claims and discuss general aspects (*independent claims*)
 - Advantages, differences, possibilities
- Detailed description and examples
 - Aid to provide enablement; reproducible teaching
 - Details and specifics (does not limit scope)
 - Drawings, tables, diagrams, sequence listings, deposition of microorganisms
- Background
 - Use search result or text from inventors
 - Do not overemphasize importance (patent, not article)

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TASK 2: Watch the world around you

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Freedom to operate

- Most important IP question for many life science companies
- Does owning a patent mean that you don't infringe...?
- Methodology
 - Search
 - Evaluation of results
 - Status check
 - Infringement and/or validity analysis
 - License negotiation
- Ongoing effort!

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Using patent information

- Source of technical information to guide research
- Identification of business opportunities
- Knowledge of the competitive landscape

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The disclosure requirements in Europe

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Purpose of a patent system – discussion

- What's the purpose of a patent system?
 - From society's viewpoint
 - From the inventor's viewpoint
- How is this purpose served?
 - *Quid pro quo* – who gets what?
- Alternative scenarios?

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"The fourth patentability criterion"

- A patent is a limited monopoly granted in return for a reproducible description of the invention
- The criteria novelty, inventive step and industrial applicability are well-known and discussed, and apply to the invention
- Important to also keep in mind that the application must provide enough technical information for the whole scope of the invention to be practised

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Legal framework (EPC)

- Patentability
 - Art 54 & 56: Invention must be new and involve inventive step
 - Art 53(a): Exception for certain inventions on moral grounds
 - Art 53(c): Exception for "medical methods" (therapy, surgery, diagnostics performed *on the body*)
 - Rule 27: Isolated biological material OK
- Experimental support and scope
 - Art 83: Application must enable whole scope of invention
 - Art 84: Claims must be clear
- Amendments
 - Art 123(2): Application cannot be amended to include subject-matter not present upon filing

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Legal framework (EPC)

- Priority
 - Art 87-89: If application claims priority from an earlier application, the date of the novelty assessment is *the priority date*, not the filing date
 - G2/98: Requires "clear and unambiguous" description in earlier application
- Opposition
 - Art 99: Any one can file an opposition to a granted European Patent within *nine months* from grant
 - No financial interest needed
 - Board of Appeal decision T798/93: OK to file out of curiosity or for training
 - Art 100: Three grounds of opposition
 - Not patentable, against Art 52-57
 - No enabling disclosure, against Art 83
 - Amendments beyond application as filed, against Art 123(2)

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Articles 83 & 84 EPC

Art 83: "The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art"

Art 84: "The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description"

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Decision T169/83

Writing with regard to Article 83 EPC:

"justification for patent protection is based on the fact that in making his invention generally available through publication an inventor enables the public at large to benefit from it in the sense that knowledge is increased and specialists in the field are stimulated to make further technical advances"

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Decision T26/81

Writing with regard to Article 84 EPC:

”Since most claims are generalisations of examples disclosed in the description, the purpose of this provision must be seen as safe-guarding that the claims do not cover any subject-matter which, after reading the description, still would not be at the disposal of a skilled person”

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Decision T409/91

Writing with regard to Articles 83 & 84 EPC:

”Although the requirements of sufficient disclosure of the invention (Art. 83 EPC) and support by the description (Art. 84 EPC) are related to different parts of the patent application, they give effect to the same legal principle that the patent monopoly should be justified by the technical contribution to the art. Therefore, the extent to which an invention is sufficiently disclosed is also highly relevant for the answer to the question of support “ [emphasis added]

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Undue experimentation

- The *quid pro quo* requires that the skilled person is able to use the patent application and carry out the invention "without undue burden" or "without undue experimentation"
- If too much work is needed e.g. to achieve all the claimed results, there is an undue burden

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Decision T409/91

Writing with regard to Article 83 and "undue experimentation":

"Even though a reasonable amount of trial and error is permissible when it comes to the sufficiency of disclosure, [...] there must then be available adequate instructions in the specification or on the basis of common general knowledge which would lead the skilled person necessarily and directly towards the success through the evaluation of initial failures or through an acceptable statistical expectation rate in case of random experiments"

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Guidelines for Examination, EPO

- C-III, 6.3: "a claim should be regarded as supported [...] unless there are [...] reasons to believe that the skilled man would be unable [...] to extend the [...] teaching of the description [...] by using routine methods of experimentation"
- C-III, 6.3: "Support must [...] be of a technical character; vague statements or assertions having no technical content provide no basis"

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Decision T435/91

"Thus, it is clear that the above definition [...] is not more than an invitation to perform a research programme..."

- Often cited against claims in which the generalisations are not considered supported by the disclosed embodiments/experiments

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EPO opposition proceedings

- Non-compliance with Article 83 is a ground for opposition (Article 100(c) EPC)
- Non-compliance with Article 84 is not a ground for opposition
- *Why, do you think?*

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General points

- The enabling disclosure must be present in the application, i.e. at the date of filing
- Evidence that the originally filed application was indeed enabling may be presented during prosecution of the application, or in post-grant proceedings
- Available state of the art is textbooks and printed materials, not necessarily patent publications

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Case law from national courts

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Biogen v. Medeva, UK House of Lords

- The invention: DNA sequences coding for a hepatitis B virus antigen
- The claims: any DNA encoding any HBV antigen
- The description: HBsAg and HBcAg (two specific examples)
- *Is the generalization justified?*

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Biogen v. Medeva, UK House of Lords

- The invention: DNA sequences coding for a hepatitis B virus antigen
- The claims: any DNA encoding any HBV antigen
- The description: HBsAg and HBcAg (two specific examples)
- *Is the generalization justified?*
- Answer: NO

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Biogen v. Medeva, UK House of Lords

From the Court of Appeals:

“[Biogen] had a choice how widely they would draw its claim. If it chose to draw it widely, it must accept the co-relative obligation to make a correspondingly wide disclosure. If it is unable to make that disclosure, that shows that it is seeking to claim an invention to which it is not entitled”

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Biogen v. Medeva, UK House of Lords

From the House of Lords:

“If the invention discloses a principle capable of general application, the claims may be in correspondingly general terms. [...] On the other hand, if the claims include a number of discrete methods or products, the patentee must enable the invention to be performed in respect of each of them”

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Questions and discussion

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Thank you for your attention!

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