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Intellectual Property, Contracts and Disputes in Life Sciences


WIPO Conference on IP Dispute Resolution in
Life Sciences, Basel, 22 May 2015

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Intellectual Property, Contracts and Disputes in Life Sciences


- I. Overview of Life Sciences Areas
- II. Overview of IP Rights in Life Sciences
- III. Legal Developments (which may lead to an increased number of disputes)

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I. Overview of Life Sciences Area


Medicine




Pharma



Crops



Organisms as tools or objects of treatment
in science and technology

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Life Sciences Law

Innovation Innovation Incentives IP Law	Diffusion Technology Transfer Contract Law Competition Law	Application Safety Security Ethics Regulatory Law	Consequences Risk Allocation Liability Law
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II. Overview of IP Rights in Life Sciences

- I. Patents and SPCs
- II. Trademarks
- III. Regulatory Law

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III. Legal Developments (which may lead to an increased number of disputes)

- Pharma: Second Generation Patents, Increasing Influence of Regulatory Law
- Crops: Smart Breeding, Patent Pools


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“Second Generation” Patents (especially second medical use)

Life cycle management: Expiry of major drug substance patents leads to improved “second generation” patents

- Dosing patents
- Treatment regimes
- Suitable patient: patient sub-groups
- Dosage forms (tablets, capsules, injections etc.)
- Manufacturing processes
- Different salt forms
- Metabolites and combination products
- Racemic mixture v. enantiomer




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Data exclusivity, Concept of Global Marketing Authorisation and “Line Extensions”?

- Concept of Global Marketing Authorisation: Art. 6 Directive 2001/83/EC
 - **no evergreening of protection!**
 - no protection for line extension (exceptions: PUMA, Orphan drugs with known active substances)
 - specific regulations for new indications with known active substances (Art. 10 (1)(4), Art. 10 (5) Directive 2001/83/EC)
- Pending case on CJEU T-472/12 → new question arises:
 - identical NAS, but:
 - new indication
 - new independent MA
 - new trade name

} Different opinion?
CJEU – EU
Commission and EMA

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“Line Extensions” need more protection!

- Value of a pharmaceutical product often arises within the further development of the product
- Research with known active substances has the advantage that risk and potential are reasonably foreseeable
- Investments in line extension has to be protected for the purpose of public health and patient benefit


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**Patents for plant products:
Tomatoes II (G2/12) / Broccoli II (G2/13)**




- EPO EBA has declared that plants or seeds obtained through conventional breeding methods are patentable
- EBA stated that: "The mere fact that an applicant or patent proprietor chooses a product claim or product-by-process claim instead of a method claim directed to an essentially biological process for the production of a plant is not a matter of some sort of 'skilful claim drafting' or circumvention of legal hurdles but a legitimate choice to obtain patent protection for the claimed subject-matter, on condition that the requirements for allowability of such a claim are met."
- "The exclusion of essentially biological processes for the production of plants in article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as plant parts."

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And there is more....


- "Cross Label Use"
- SPC (CJEU C-210/13, C-484/12, C-443/12, etc.)
- Personalised Medicine, patenting diagnostic kits/methods
- Biologicals/Biosimilars (INN, Extrapolation)

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Thank you for your attention!



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