THE PRACTICAL IP FOR NATURAL SCIENCES WEBINAR SERIES

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US VS. INTERNATIONAL:
CLAIM SCOPE AND APPLICATION SUPPORT

THE PRACTICAL IP FOR NATURAL SCIENCES WEBINAR SERIES

MEET THE PRESENTER

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- **Registered patent attorney w/ technical emphasis on small- molecule pharma, formulations, polymers, OLED materials, and materials science**
- **Previously worked as a principal scientist at GlaxoSmithKline**

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What's Needed to Support Claims in non-US Jurisdictions?

- Applications often drafted with the US in mind, but frequently find themselves in foreign jurisdictions
- Although generally similar requirements as in US, there are differences that can have significant impact on claim scope
- Support means: can you point to something in the application that adequately describes the claim feature you wish to include or argument you wish to make

Routine US Application Practices

- Reference to another document (incorporation by reference) for technical details
- Submitting additional data after filing the application (post-filing data) to show unexpected results or the like
- Routine practice in the US may not be possible or can lead to difficulties in foreign jurisdictions
- We will look at some examples from Europe, Japan, and China

A Brief Interlude – Obviousness vs. Inventive Step

- US: focused on closest prior art and whether differences between what is claimed and the prior art would be obvious to a hypothetical person of ordinary skill in the art

- EP/JP/CN (generally)
  - problem-solution approach
  - identification of the effects associated with the different features and expressing the step in going from the closest prior art to the claimed subject matter in terms of the solution to an objective technical problem
  - EPO believes this is an objective approach, so less weight given to, for example, inventor declarations

Europe – General Disclosure Considerations

- "Under Art. 123(2), it is impermissible to add to a European application subject-matter which is not directly and unambiguously derivable from the disclosure of the invention as filed, also taking into account any features implicit to a person skilled in the art in what is expressly mentioned in the document."

- The term "implicit disclosure" means no more than the clear and unambiguous consequence of what is explicitly mentioned in the application as filed.

- Thus, the common general knowledge must be taken into account in deciding what is clearly and unambiguously implied by the explicit disclosure of a document.

Europe – Example where optional claim feature held not supported.

- Claim recites: “1. A water-based thermosetting transparent colorant coating composition comprising… (iii) an ultraviolet light absorber in an amount ranging from between 0 and 5.0 percent by weight… .”
  - This claim encompasses having no UV absorber
  - Would person of skill in the art clearly and unambiguously derive from the specification that the compositions include UV absorbers as optional components (i.e., 0 % UV absorber)?

- EPO said no implicit support for this feature – why?

Europe – Example where optional claim feature held not supported.

- Applicant argued:
  - invention only “encompassed” compositions with UV absorber, but it was not the invention, was only a preferred embodiment
  - Sentence that stated that the composition can protect from exposure to “visible light and/or ultraviolet light” would lead a person of ordinary skill in the art to conclude a UV absorber not needed
- EPO stated
  - Preferred embodiment had UV absorber
  - Specification stated that UV absorber “typically” present in amount of 0.5% to 5%
  - Requiring UV absorber consistent with the specification

Europe – Post-filing Data

- You can submit additional data after you file your application in Europe, but:
  - May not serve as the sole basis for establishing that the application solves the alleged problem.
- Example:
  - Claim directed to "[a] polynucleotide encoding a polypeptide having GDF-9 activity selected from the group consisting of: (a) a polynucleotide having the nucleic acid sequence of SEQ ID NO:3… ." (GDF-9 required for proper functioning of ovaries and human egg development)
  - Application only stated GDF-9 expressed in ovarian tissues; no functional data provided
- Post-filing data NOT accepted:
  - Function of GDF-9 speculated based on other proteins with significantly different sequences/structures (no data presented)
  - Post-filing data was first showing beyond speculation of the function of GDF-9

Europe – Incorporation by reference

- Often, a US-originating patent application will incorporate by reference subject matter found in another application (e.g. “application no. 61/555,555 is herein incorporated by reference in its entirety”)

- What if this subject matter is essential to invention, can you include it? Maybe, but with conditions!
  - EPO will require you to add subject matter to application
  - Subject matter must contribute to solving technical problem, at least implicitly belong to description as filed, and precisely defined and clearly identifiable in reference

Europe – Incorporation by reference

- But wait, there's more…
  - Reference document must be available to EPO on or before application filing date AND reference document available to public no later than date of publication of application
- Example: applicant relied on 3 documents incorporated by reference

Application	Ref. 1	Ref. 2	Ref. 3
Priority Jan 16, 2000	Not referred to in priority application	Incorporated by reference	Incorporated by reference
Filing date Jan 12, 2001			
Published Jul 19, 2001	Published Aug 10, 2000	Published Nov. 7, 2002	Published Nov. 7, 2002

- Ref. 2 and 3 published AFTER Jul 19, 2001 → not allowed
- Ref. 1 was ok, but since not in priority document, effective filing date of application w.r.t Ref. 1 was Jan 12, 2001 → Ref. 1 is prior art

Japan – General Considerations

- It is necessary to demonstrate that the purpose of a claimed invention can indeed be realized by (any embodiment of) the claimed invention, based on the specification

- For the above demonstration, in general, experimental data showing the effects of a claimed invention are necessary. This applies mainly to chemical inventions.

Japan - How much support do you need?

Claim 1: A process for preparing a polarizing film, comprising uniaxially stretching a polyvinylalcohol-based original film wherein the original film has a thickness of 30 to 100 µm, and satisfies the following equations:

(1) Y>-0.0667X+6.73

(2) X=>65

wherein

X denotes a temperature at which the original film (2 cm x 2 cm) completely dissolves in hot water; and

Y denotes an equilibrium swelling index calculated by …

The specification describes that satisfying the above equations (1) and (2) results in the stable production of a polarizing film with excellent polarizing properties and durability.

Japan - How much support do you need?

- The original specification includes only two examples and two comparative examples as the basis of the two equations (1) and (2) in Claim 1.

- The IP High Court concluded that Claim 1 is not supported by the specification, because it is not possible to understand that any embodiment satisfying the two equations (1) and (2) in Claim 1 could realize target effects.

- The IP High Court did not accept additional experimental data submitted by the patentee during the court proceeding, implying that the original specification should have included such experimental data.

Japan – Very Strict

- Post-filing data not allowed
- Incorporation by reference not allowed
- For pharmaceutical/biological applications, failure to include pertinent data in the application can seriously reduce odds of patentability

China – Sufficiency of Support

- In US, written description must be sufficient to inform person of skill in the art that applicant was in possession of invention at time of filing
- China has a different view: claimed solution should be directly reached or properly generalized from the specific embodiments in description – what does this mean in practice?
- You should have lots of specific embodiments, preferably, at least 3
  - The number of embodiments is actually important in avoiding a rejection for lacking written description

China – Incorporation by Reference

- Allowed but more limited than in US
- Cited reference must be
  - published before filing date of application at issue or
  - be a Chinese application published before publication of the application at issue
- This means you cannot incorporate subject matter from priority application
- Any technical information required to satisfy written description in China must be in the application
  - Very difficult to convince Chinese examiner to allow amendment to the description
- China also more cautious regarding what is known in the art (e.g. known techniques), so can be safer to include specific details even if “common sense” or prior art

China – Post-filing Data Example

- Chinese Examiners typically will not consider any supplemental data submitted after filing
  - May be allowed in some circumstances to confirm the statements made in specification with respect to function of invention (usually chemical cases)
- Boehringer Ingelheim filed patent application directed to compounds for inhibiting Hepatitis C
- Boehringer submitted amended claims to just four specific compounds and post-filing comparative experimental data showing unexpectedly superior oral bioavailability
- Post-filing data <u>not accepted</u>
  - No experimental data to support superior oral bioavailability in original application
  - Experimental protocols in post-filing data not described in original application

Tips for Ensuring Application Has Support – Be explicit!

1. Be aware of what is optional and what isn't. If something is optional, important to explicitly say so.
2. Consider what properties of individual features are important (not necessarily essential) to the intended functioning of the invention, and mention these properties explicitly.
3. Do not rely on incorporation by reference. If some process used in application is same as in reference application, better to expressly include it in body of application.
4. Put in experimental data in the application, to the extent practicable given other considerations (e.g. competitors). Even some preliminary data better than nothing.
5. Have at least three working examples.

QUESTIONS & DISCUSSION

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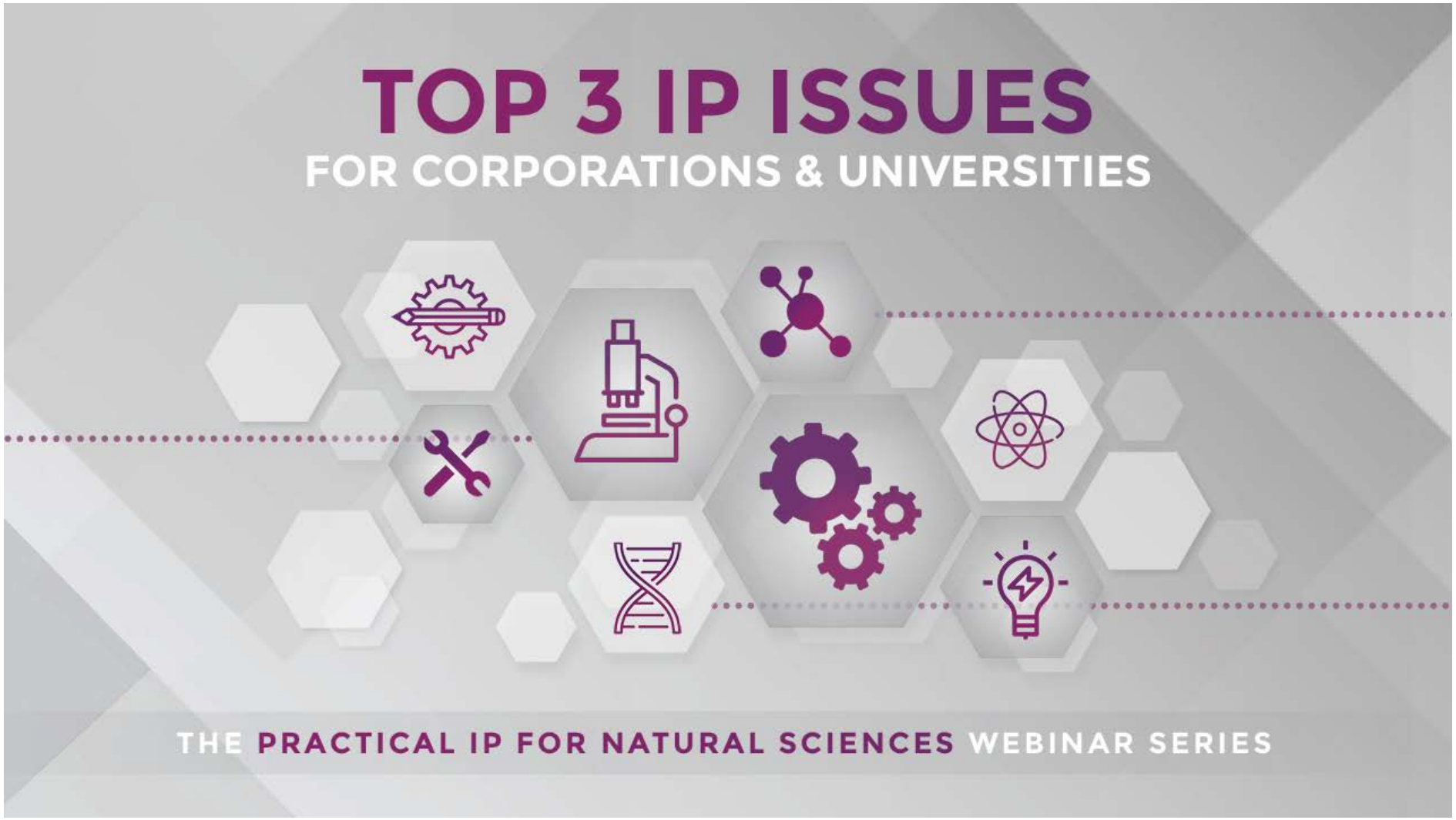

Please join us for the next presentation

Thursday, January 25

1:00 PM (CT)