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Adapting US Practice to Patenting Pharmaceuticals in China

US Practices for Using Supplemental Data to Support Patentability

Scott McMurry, PhD
Mayer Brown
New York, NY
smcmurry@mayerbrown.com
212-506-2216

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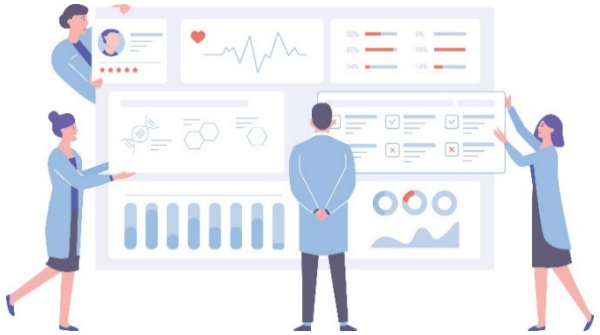
Data Submission to the USPTO

- Data generated after the filing of a patent application has long been accepted for supporting patentability in the US
  - *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)
- Such data historically was not accepted in China

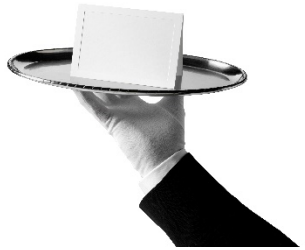
Data Submission to the USPTO

- Experimental data can overcome USPTO rejections
  - Provide evidence of objective indicia of non-obviousness to overcome 103 rejections
    - Typically surprising results, commercial success
  - Provide evidence to overcome some 112 or 101 rejections
  - Prove lack of enablement of 102 art
- Using supplemental data can
  - Defer costs for tests
  - Defer choice of preferred embodiment



USPTO Data Submission Mechanisms

- Several mechanisms exist to present data to USPTO Examiners
  - Specification
  - Declarations under 37 CFR 1.132
  - Attorney Remarks
- Applicant's duty to present
- Examiners required to consider data submitted when timely
- MPEP § 716 overviews the USPTO's supplemental data submission requirements



USPTO Treatment of Data Submissions

- If USPTO Examiner doubts data submitted, must provide proof
  - Legitimate reason and/or evidence (e.g. scientific literature)
- Examiners must accept some data submissions as accurate (absent a legitimate reason to doubt)
  - Specification – Inventor's Oath
  - 1.132 Declaration – Sworn to truth of statements under penalty of perjury
- However, data submitted only in Attorney Remarks can be disregarded as attorney argument
  - Often, data submitted in ROAs are favorably considered even without a sworn declaration
  - Best to draw such data from peer-reviewed scientific literature

Quality of Data Submitted

- Accurate, not misleading, and complete
  - Failure can violate duty of good faith & candor under 37 CFR § 1.56, if material
  - Risks rendering entire patent unenforceable for inequitable conduct
  - Withholding inconsistent results will likely be inequitable conduct
    - This often comes out during discovery in US litigation
  - Can infect continuing applications

Data Submitted – 35 USC §§ 112 & 101

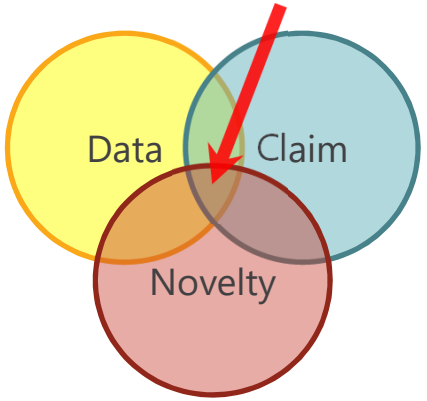
- Can overcome Examiner's reasoned doubts as to the disclosed effects of claimed pharmaceuticals
- Certain doubts typically will not be overcome without substantial amounts of evidence, e.g. historically incredible assertions
  - Cold fusion
  - Perpetual motion
  - Preventing/curing cancer, HIV
    - Clinical data was submitted for allowance of HIV prevention claims (PreP), though clinical data is typically not required for patentability

USPTO Data Submission - Limits

- Data generated post-filing should only confirm assertions in the specification as filed
  - Typically non-obviousness, utility and enablement
  - Generally cannot cure a lack of written description (may be considered new matter)
  - China may be more lenient now
- Experimental results need to be "significant" to overcome a "strong showing of prima facie obviousness" *Tokai Corp. v. Easton Enters.*, 632 F.3d 1358, 1370 (Fed. Cir. 2011)

USPTO Data Submission - Limits

- Data submitted must have a nexus to the claimed invention and its novel points
  - "There is no nexus unless the evidence presented is 'reasonably commensurate with the scope of the claims'" *In Re: Affinity Labs of Tex.*, 856 F.3d 883 (Fed. Cir. 2017)
  - "[A] nexus must exist between the evidence and the merits of the claimed invention" *Novartis v. Torrent*, 853 F.3d 1316 (Fed. Cir. 2017)
  - "Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention" *Id.*
  - "If commercial success is due to an element in the prior art, no nexus exists" *Id.*
    - *See also PPC Broadband, Inc.* v. *Iancu*, 739 Fed. Appx. 615 (Fed. Cir. 2018); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340 (Fed. Cir. 2012); *Lectrosonics, Inc. v. Zaxcom, Inc.*, No. IPR2018-01129, Paper 33 (P.T.A.B. 2020)
- Safest to claim the effect the supplemental data shows – though will likely narrow the claim
- Clinical studies are rich in useful data
- USPTO and US courts are increasingly scrutinizing nexus



US Data Submission Concerns

- Locks you into a position for later patent litigation
- Flags potential enablement issues
- Focus of attacks in later patent litigation
- Material inaccuracies or omissions risk inequitable conduct – even if not appreciated during prosecution
- Declarant may later refuse to cooperate
  - Assignor estoppel in question - *Minerva Surgical v. Hologic*
- Mitigate by
  - Avoid using supplemental data - overcome rejection by argument, amendment, or data in original specification
  - Ensure supplemental data 100% accurate, complete and not misleadingly presented
  - Stick to the facts! – Don't interpret the data or don't have the declarant do so

Supplemental Data and Patentability in China

- Lessons learned for submitting data in the US should aid practitioners in taking advantage of the new Chinese rules – though there is not a one-to-one correlation
  - E.g. Chinese law imposes a "specificity" requirement that partly spans the US's written description and enablement requirements
- As in the US, supplemental data in China can now:
  - Prove surprising results to show inventiveness
  - Prove a statement of effect
- But there are limits to the new Chinese practice
  - Supplemental testing data currently can only support effects described in the original specification
  - Supplemental testing data cannot add a new therapeutic effect not mentioned in the original specification

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