Upstream Inventions

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Key Takeaways

- Patent law has difficulties with inventions that are upstream in the research process
- Cases have developed an unwritten requirement of “completeness” to police patents on some upstream inventions
- Understanding this requirement could lead to a more rational framework of patent rights and remedies for upstream inventions

What Are Upstream Inventions?

- Research tools and research intermediates
- Wish, plan, or hypothesis (“research project”)
- Inventions that center on laws of nature, natural phenomena, and scientific truths

Pros and Cons of Upstream Patents

- Pro: They incentivize foundational inventions and promote disclosure
  - Existence of a patent right also aids in coordination and commercialization
- Con: They inhibit future innovation and lead to anticommons problems
  - Functional concern is undue preemption of downstream applications, particularly further research

The Current Law

- The “completeness” requirement
  - An unwritten validity requirement focused on the developmental stage of the invention
  - Derived from three separate statutory sources

Three Lines of Completeness Cases

- Utility (*Brenner v. Manson*, *In re Fisher*)
  - "A patent is not a hunting license"
- Written Description (*Rochester*, *Ariad v. Lilly*)
  - "Attempt to preempt the future before it has arrived"
- Patentable subject matter (*Mayo*, *Myriad*)
  - Certain patents "tie up too much future use of laws of nature"

Problems with the Requirement

- Subjective, inconsistent, ad hoc – likely underinclusive and overinclusive
- In tension with doctrines promoting early patenting
- Complete invalidation is too harsh a remedy for undue preemption

Other Proposals to Deal with Upstream Patents that Survive Completeness

- Infringement exemptions and remedies
  - Invigorated experimental use defense, patent misuse, reverse DOE
  - Lower damages, no injunctions
  - Problem: costly, unpredictable litigation (status known only ex post)
- Sui generis solutions
  - Problem: limited coverage

Roadmap for Proposed Improvements

- Make the requirement less ad hoc and more in line with concerns about undue preemption
- Balance pros and cons of upstream patents by providing some type of a limited patent right
- Ex ante solution to reduce litigation costs

Proposed Statutory Ex Ante Solution

- 1. Create new statutory home for completeness as a standalone patentability requirement
- 2. Abrogate controversial completeness cases
- 3. Patents that meet extant requirements but fail completeness would qualify for a Research Patent (RP) – limited bundle of rights

1. Statutory Test of Completeness

- Whether, according to a person of ordinary skill in the art, the claims would cover many significant downstream applications, many of which are yet to be discovered, at the time of patent filing
- Whether a person of ordinary skill in the art would recognize that the claimed invention has features of a hypothesis or a conjecture

Possible Examples of Research Patents

Currently unpatentable	Currently patentable
Expressed Sequence Tags	Polymerase Chain Reaction
gDNA	cDNA
chemical methods and products with only research utility	Other broadly applicable tools: electron microscopes, scintillation counters, etc.
Treatment claims based on a newly identified biological target (but no drug)	Functionally drafted software claims

2. Abrogation

- Research utility satisfies Section 101
- No *Rochester-Ariad* written description
- No *Mayo* "conventional activity" test
  - Complete ineligibility reserved for nonstatutory categories and "manifest" claims to natural phenomena and ideas, *cf. CLS v. Alice* panel opinion
  - Enablement would still police claims that are scientifically invalid or require undue experimentation to practice; also 102/103

3. Enforcement of Research Patents

- No district court litigation
- Scheduled/capped damages – pre-set variation based on entity size and/or extent of patent use
- Defenses limited to prior art invalidity; no DOE, willfulness claims
  - If PTO erroneously grants a full patent that should have been an RP, that can be an invalidity defense or basis for inter partes review

Thank You

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