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Background

• 35 U.S.C. § 271(e)(1):
  - It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary products.

• “research tool” = device or thing which serves to facilitate the discovery or development of a drug or other therapeutic agent
§ 271(e)(1) – Legislative History

• § 271(e)(1) reflects the Hatch-Waxman Act’s attempt to balance competing interests

• In particular, is part of scheme to address two perceived distortions in the patent system vis-à-vis FDA-approved drugs:
  – First: Reduction in patentees’ effective patent term due to lengthy FDA review process
  – Second: *De facto* extension of patent term because competitors couldn’t begin development process until patent expired
§ 271(e)(1) – Legislative History

• Congress addressed distortions with two complementary provisions:
  – 35 U.S.C. § 271(e)(1): immunized activities related to development of data and information for submission to FDA

• Over time, case law had progressively extended the reach of the 271(e)(1) safe harbor

• *Proveris*, however, may signal the high-water mark of § 271(e)(1)’s reach
§ 271(e)(1) – Prior Case Law

• *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990):
  
  – Extended safe harbor beyond drugs, to encompass medical devices subject to FDA approval

  – Stated that “patented invention” includes “all inventions, not drug-related inventions alone.” (*Id.* at 665)

  – Interpreted phrase: “a Federal law which regulates the manufacture, use, or sale of drugs or veterinary products”

  – Looking at overall statutory scheme, held that phrase encompassed the FDCA as a whole, not just the provisions therein that applied to drug products
§ 271(e)(1) – Prior Case Law

- *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997):
  
  - Extended *Eli Lilly* to tests in seeking approval for a “Class II” medical device, which is subject to less rigorous review by FDA, and not eligible for § 156 patent term extension
  
  - “Must follow the Supreme Court’s broader holding, which remains in force despite a potential conflict with its own narrower reasoning. . . . In other words, the Supreme Court commands that statutory symmetry is preferable but not required.” (*Id.* at 1029)
§ 271(e)(1) – Prior Case Law

• *Merck KgA v. Integra*, 545 U.S. 193 (2005):
  
  – Interpreted meaning of “reasonably related” to the development and submission of information under FDCA
  
  – Extended safe harbor to early stage, pre-clinical testing, even where the data ultimately is not included in any FDA submission
  
  – “Use of patented compounds in preclinical studies is protected under § 271(e)(1) as long as there is a reasonable basis for believing that the experiments will ‘produce the types of information that are relevant to an IND or NDA.’” (*Id.* at 208).
  
  – Expressly reserved opinion as to whether § 271(e)(1) immunizes use of ‘research tools’ in the development of information for FDA
§ 271(e)(1) – Prior Case Law

• Thus, by the time of *Proveris*, decisions in the *Eli Lilly*, *Abtox*, and *Merck* cases had broadened the reach of § 271(e)(1) to encompass:

  – devices as well as drugs, and

  – a wide range of early stage activities that may not generate any data that is itself ever submitted to the FDA
Proveris – Background

- *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008):
  - Involved apparatus used to characterize aerosol sprays in certain drug delivery devices, such as inhalers and nasal spray pumps
  - Accused infringer, Innovasystems, manufactured and sold such an apparatus, known as the “Optical Spray Analyzer”
  - Device was not itself a device subject to premarket approval by the FDA, but Innova’s customers used it for the sole purpose of developing information to be submitted to the FDA
**Proveris – Lower Court**

- *Proveris v. Innovasystems:*
  
  - Innova sought protection of safe harbor, arguing that it fell squarely within language of the statute because sole use of accused device was “reasonably related” to the development of information for FDA submission.

  - District Court was not persuaded, and before trial, ruled that § 271(e)(1)’s immunity did not apply.
Proveris – Federal Circuit Decision

• Proveris v. Innovasystems:
  – Affirmed: relied heavily on Eli Lilly’s discussion of policies underlying the safe harbor, found that the case did not implicate either of the two distortions of the patent system that § 156 and § 271(e)(1) were intended to remedy:

  • The first distortion (reduction of effective patent life caused by the FDA premarket approval process) was not implicated because the patented device was not itself subject to FDA approval

  • Similarly, because the accused device was not subject to premarket FDA approval, Innova would not have been adversely affected by the second distortion (de facto extension of patent term) – upon the expiration of any applicable patent, Innova would be able to enter the market without delay
Proveris – Holding

- *Proveris v. Innovasystems:*
  - Because it was not within the category of entities for whom the safe harbor provision was designed to provide relief, the Court found that Innova was not entitled to the benefit of the 271(e)(1) safe harbor.
  - But, the Court needed a statutory “hook” on which to base its determination that safe harbor did not apply—the “hook” it found was the term “patented invention”
  - Despite *Abtox*, held that because the accused device was not a “patented invention” for purposes of § 271(e)(1) because it was not subject to FDA premarket approval.
**Proveris – Ramifications**

- Are all “research tools” exempt from protection of § 271(e)(1) safe harbor?
  
  - Question raises a whole host of interesting policy considerations given somewhat unique status of patented research tools as inventions designed to facilitate development of other inventions
  
  - Answer: not necessarily – possibility of research tool that is itself subject to FDA regulation
  
  - Answer: not necessarily – *Proveris* is in tension with both Supreme Court (*Eli Lilly*) and Federal Circuit (*Abtox*) precedent, may be overruled or limited to its particular facts
**Proveris – Ramifications**

- **Bottom Line:**
  - Questions remain as to the applicability of the Hatch-Waxman Act safe harbor provisions to patented research tools and the long-term viability of the *Proveris* holding
  
  - Users of patented research tools will need to act carefully and with caution as they try to navigate these still murky waters.
THE END – Thank You