Practical Considerations Regarding TK

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Medical History of the Periwinkle

- Vinca species are widespread, widely referenced, and their uses have been publicized for centuries:
  - AD 77-79: Pliny the Elder, in *Naturalis Historiae*
  - 14th Century: Chaucer, references to "p*arwynke*"
  - 1480: Apuleius's *Herbarium*, as a treatment for "devil sickness and demoniacal possessions"
  - 1552: Macer's *Herbal*, to counter "wykked spirytis"
  - 1657: William Coles' *Adam in Eden* describes its use for wounds and other inflammatory conditions

Vinca Extracts for Treatment of Cancer: Key Facts

- Two research groups working simultaneously in the late 1950's
  - U. Western Ontario (Canada) scientists investigating anti-diabetic properties
  - Lilly scientists screening more widely for endocrine, oncology, neuroscience, antimicrobial, antiviral, or insecticidal properties
    - All extracts subject to the same screens, "regardless of medical claims found in the literature."
- Vinca plants are widespread and plentiful throughout the world
  - Evidence suggests Western Ontario team received first sample from Jamaica.
  - Lilly received first sample from commercial biological supplier, and plant material for commercialized product was sourced worldwide from any available supplier.
  - To ensure constant supply, plants were eventually sourced from commercial growers in Texas, United States.

Evidence Demonstrates GR Use Is Often Not Accompanied by Use of TK

- Development of vinca drugs for cancer was unrelated to any traditional uses or prior scientific studies, which focused on diabetes.
- INBio (Costa Rica) Agreements with multiple commercial and academic institutions
  - No specific reference to collection or use of TK in any of 22 collaborations
  - In the Lilly-INBio Agreement (1999-2000), scientists deliberately did not collect TK, to avoid undue bias
- Griffith University-AstraZeneca Collaboration (1993-2007)
  - “Traditional knowledge was not collected….”

Would Vinca Drugs Have Been Developed Today?

- Would samples have been available for biological tests?
  - Many countries have no national laws governing ABS, and previous attempts to secure ABS agreements have failed for this very reason
- This should create an incentive to implement national laws that facilitate new discoveries
  - If Jamaica has no ABS regulations, or South Africa has burdensome regulations, why not enter into ABS agreement with Australia, where vinca is plentiful, and ABS laws are well-developed?
- Would uncertainty over potential "after-the-fact" claims of misappropriation, combined with possible patent revocation, dissuade researchers from such research?

Conclusions

- National laws governing access to TK and mutually-agreed terms between user and provider are the best means for ensuring appropriate ABS.
- Natural product R&D is already highly risky and complex
  - The path of uncertainty and controversy will be avoided
- Lack of legal clarity creates risk that any product could be subject to claims of misappropriation
  - Who bears the burden of proof?
  - What evidence can an accused entity use to “prove a negative?”
- Industry wants to comply with ABS obligations, but we must have legal certainty

THANK YOU

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