

# Access to Scientific Data: Some Legal Considerations

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# PI generates raw crystallography data....

- Do the data constitute a form of “intellectual property”?
- Who owns rights in the data, and what rights do they own?
- Who gets to decide whether and how it is shared with others?
- What affect might sharing the data have on intellectual property rights regarding the data or things created by the owner, or the subsequent users, through the use of the data?
- How does one go about sharing data in a way that is lawful and takes all these issues into account?
- Are there any other legal issues to be aware of?

# Are scientific data themselves “intellectual property”?

- Intellectual Property =
  - Patent
  - Copyright
  - Trade Secret



# Patent

- Inventions that are novel, useful, non-obvious, and original to applicant, AND patentable subject matter
- NOT theories, abstract ideas, pure algorithms, scientific principles, laws of nature
- 20 years from filing -- exclusive right to make, use, sell, offer for sale (and to license others)
- US – “first to invent” system dated from conception of invention; not “first to file” (but maybe not for long!)
- Where do “data” end and “invention” begin?

# Examples of Patentable Subject Matter

- 1) New chemical entities, including new intermediates and in appropriate cases new salts, enantiomers and polymorphs.
- 2) Methods of making new compounds.
- 3) Methods of treatment, diagnosis etc using new compounds.
- 4) New methods of making both old and new compounds.
- 5) New compositions, possibly containing known compounds but in different dosage amounts or forms.
- 5) New methods of treatment, diagnosis etc. using old or new compounds.
- 6) New methods of modulating biochemical processes which are carried out in a human, animal or plant.
- 7) New kits for example containing a new combination of materials or of materials and equipment used for diagnosis or treatment.
- 8) Newly identified DNA as long as it is claimed in a form which differs from that in which it occurs naturally (that is to say it is claimed in purified or isolated form). Newly created DNA is treated as a new chemical compound.
- 9) New organisms and parts of organisms such as seeds, for example those containing modified DNA.
- 10) New vaccines.
- 11) New vectors, such as plasmids, new hybridomas and new antibodies.
- 12) New research techniques and in some cases at least the products obtained from using these techniques.

Source: Ladas & Parry, LLC, at <http://www.ladas.com/Patents/Biotechnology/USPharmPatentLaw/USPhar03.html>

# Copyright

- Original expression that is fixed in a tangible medium from which it may be perceived
- Does NOT protect facts or ideas
- Generally, life of author plus 70 years – exclusive right to copy, adapt, and distribute, perform, and display work publicly
- Compilation copyright gives some protection for original selection and organization of data—but NOT the underlying data
  - Must be some originality/creativity
- Attempts at establishing separate database protection under the law have failed
- Data in databases protected by contract if at all
- European Database Directive – “sweat of the brow” protection for 15 years, for EU country databases

# Trade Secrets

- Information that derives independent economic value from not being publicly known or readily ascertainable
- Unlike patent and copyright, primarily state rather than federal law
- Trade secret protection vanishes when the secrecy vanishes
- Assertion of trade secret protection runs headlong into norms of data sharing and validation in academic research

# Who owns rights in the data, and what rights do they own?

- Depends on the policies and agreements in place between those involved in data creation
  - Researchers
  - Institutions
  - Sponsors (private/govt)
  - Collaborators or those who provide materials and tools for research
- University data policies tend to say that university owns the data created under its auspices or with its resources, with rights reserved to researchers
- Private sponsors often seek ownership/control over data; same with providers of materials and tools
- Govt sponsors retain rights to data (copies, audit rights) and IP (licenses) created in whole or in part with federal funds

# Who gets to decide whether and how data is shared?

- Again, it depends on the policies and agreements in place
  - University policies – Researchers, tech transfer office, administrative officials
  - Govt generally reserves rights to use, reproduce, etc. data first produced under grant, and license others to do same for federal purposes
  - Govt policies on sharing of research data and unique research resources – contract and grant term

# Government Sponsors

- NSF Grant Proposal Guide:
  - *“[NSF] expects PIs to share with other researchers, at no more than incremental cost and within a reasonable time, the data, samples, physical collections and other supporting materials created or gathered in the course of the work.”*

# Government Sponsors

- NIH Grants Policy Statement:
  - *“We believe that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. The NIH endorses the sharing of final research data to serve these and other important scientific goals. The NIH expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers.”*
- Timely release and sharing: no later than acceptance for publication of main findings from data set
- Proposals for \$500K+ in direct costs: must include data sharing plan

# Government Sponsors

- NIH Grants Policy Statement also addresses “Unique Research Resources”
  - Includes “synthetic compounds” and “crystallographic coordinates”
- *“NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources developed with NIH funds and the associated research findings have been published or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community.”*

# Does sharing data affect IP rights?

- Possibly...should consult with tech transfer folks
- Could muddy waters about inventorship, “first to invent”; originality for any copyright claim
- Sharing too early might defeat patent claim if data makes later-filed invention “obvious” to one skilled in the art
- Timing is often the issue, not whether data are ultimately shared

# IP and Openness/Sharing

- US Const. Art. 1, Section 8: “To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries;”
- Patent and copyright regimes are limited monopolies granted in exchange for dissemination of inventions and creative works
  - Must file enabling disclosure and “best mode” of practicing invention
  - Publication doesn’t undermine or weaken copyright

# How may data be shared?

- Contracts!!!!
- Rights can be sliced, diced, distributed and shared in essentially any way the participants agree
- Exception: “Moral rights” cannot be contracted away, though one may agree not to enforce them
  - Attribution/anonymity/integrity
  - End with death of author

# Other legal considerations

- “Shelby amendment,” effective 4/00:
  - Arose out of Harvard study/EPA air pollution standards controversy
  - Amended OMB Circular A-110 to require that raw data produced in project funded wholly or in part with federal funds, and cited by federal agency in connection with action having the force of law, be made available through FOIA
  - “research data” defined to NOT include trade secrets, IP, personal identifiers, data that must be held prior to publication, etc.

# Other legal considerations

- Limits on data sharing/access:
    - National security
    - Export control
    - Biosafety/select agent rules
    - Privacy of personal data
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# Questions?

