

Avoiding Loss of Patent Rights From Your Grant Applications

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Presented by

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What's the problem?

- ▶ 2005 worldwide pharma market = \$602 billion
 - North America = 47% (\$265 B)
 - Europe = 28% (\$170 B)
 - Japan = 10% (\$60 B)
- ▶ Big Pharma will probably only partner or acquire invention if worldwide rights are available
- ▶ So, IP rights in Europe and Japan may be the difference as to whether your invention ever makes it to commercial use . . . or to a patient
- ▶ But, losing rights can happen in an instant!
- ▶ So, today
 - The context
 - U.S. versus The World
 - 50 Ways to lose your rights
 - Grants
 - Provisionals as a means for saving rights

Context

- ▶ (1) New
- ▶ (2) Useful
- ▶ (3) Non-obvious

What's "New" (in the U.S.)

- ▶ 35 U.S.C. §102:
A person shall be entitled to a patent unless-
- ▶ (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this or a foreign country, more than **one year prior to the date of the application for patent** in the United States . .

What's "New" (Outside the U.S.)

- ▶ Novelty is lost immediately in important jurisdictions upon an enabling disclosure (with certain exceptions)
- ▶ What constitutes a disclosure varies by jurisdiction

Examples:

- EP: any enabling disclosure, written or oral = immediate loss
- JP: - an oral disclosure in the U.S. = no effect
- a publication = immediate loss
(unless you publish in the right journals!)

What's an “enabling disclosure”?

- ▶ If you've taught a person of “ordinary skill in the art” how to make and use the invention, you've enabled it.
- ▶ Fact and case specific
 - PCR
 - Gene sequence

What's "New"

- ▶ Figuring out when a disclosure is made may or may not be easy
- ▶ And, for the U.S., what's a "printed publication"?
 - Your thesis?
 - The poster presentation you just presented at that conference?
 - The abstract you submitted to next spring's national meeting?
 - The manuscript you just submitted to PNAS?
 - *Your grant application?*

Grants and what's "new"

- ▶ Grant applications aren't public
- ▶ But, awarded NIH grants are indexed and searchable on-line on "CRISP".
- ▶ What and when of CRISP
 - An abstract, not the application
 - But maybe not quite the abstract you submitted
 - On-line within 10 days of the grant award
- ▶ The Notice of Grant Award is public
 - Notice of Grant Award = Need to Get Application filed!

▶ **Abstract**

- ▶ **Grant Number:** 1R43NS051878-01A2**PI Name:** WILSON, MARK THOMAS**PI Email:** mwilson@ecmbio.com **PI Title:** Project Title: *Peptidomimetics for Manipulation of Growth Cone Motility and Axon Regeneration***Abstract:** DESCRIPTION (provided by applicant): Thousands of people every year experience long-term or lifelong disabilities in motor, sensory, and cognitive function as result of central nervous system (CNS) injuries. There has been little hope for recovery from these dysfunctions because axons from injured neurons in the brain and spinal cord do not regenerate. A major impediment to regeneration is the formation of a glial scar that expresses axon growth inhibiting molecules like chondroitin sulfate proteoglycans (CSPGs). Novel technologies that can overcome the inhibitory effects of CSPGs could lead to major advancements in therapies that promote functional recovery after CNS injury. In this SBIR project, an innovative panel of cell permeant peptidomimetics will be developed that manipulate the activity of cytoskeletal proteins implicated in the axon growth cone responses to CSPGs. In Phase I, the efficacy of this approach will be tested by developing technologies that manipulate the activity of cofilin, an important cytoskeletal protein in CSPG-activated signaling pathways. Fluorescence microscopy assays will be used to select an optimal peptide transport system for neurons. In vitro biochemical assays will be used to screen cofilin-related peptides (CRPs) designed to manipulate cofilin protein activities. Growth cone motility assays will be used to assess the efficacy of the selected peptide transport system and CRP peptides for altering cofilin activity in a manner that promotes axon growth across CSPG containing borders. In Phase II, the methods and technologies developed in Phase I will be used to create a panel of cell-permeant peptidomimetics that can regulate the activity of a variety of cytoskeletal proteins implicated in the growth cone responses to CSPGs. These peptidomimetics will be commercialized by ECM Biosciences in two ways, as novel protein-manipulating research tools and as new therapeutic strategies for promoting functional recovery from CNS injuries. **Project Relevance** Currently, there are limited therapeutic strategies for promoting recovery from central nervous system (CNS) injuries. A major factor limiting the development of therapies that promote recovery from CNS injuries is the difficulty promoting axon regeneration in the injured region. Advancements in the molecular tools used to study axon growth and regeneration is critical for new discoveries of the mechanisms involved with repair of the injured CNS. This SBIR proposal will facilitate the development of novel peptidomimetic technologies that can be used to manipulate protein function in neurons in vivo. These technologies will target proteins critical for axon outgrowth in an attempt to produce unique tools for studying axon regeneration. More importantly these research tools may lead to the development of agents that can promote axon regeneration in the injured CNS. Thus, successful development of peptidomimetic technologies in this SBIR proposal will significantly advance axon regeneration research and could lead to the discovery of novel therapeutic strategies for promoting recovery from CNS injuries.
- ▶ **Institution:** ECM BIOSCIENCESVERSAILLES, KY 40383**Fiscal Year:** 2006**Department:** Project Start: 15-SEP-2006**Project End:** 31-AUG-2007 **ICD:** NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE**IRG:** ZRG1

Grants and what's new (II)

- ▶ Besides CRISP, the grant applications are “FOIAble”!!
- ▶ When is a grant publicly available?
 - When it's awarded?
 - When it's FOIA'ed?
 - When the agency makes its determination?
- ▶ If you get a notice re a FOIA request and you haven't filed a patent application, this is a good time!!
- ▶ Stamp your grant applications “confidential”!

Protecting rights

- ▶ Provisional applications
 - Can be as carefully drafted as regular utility applications (preferred)
 - Can be quick, easy, cheap (better than nothing - usually),
 - You get your filing date only for what's in the provisional

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