



Transforming Discoveries into Products: *Maximizing NIH's Levers to Catalyze Technology Transfer*

**Partnering the Use of Therapeutic Antibodies as Novel Treatments for
Multiple Sclerosis (MS)**

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National Institutes of Health



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Turning Discovery Into Health

Technology – patent application filed

- Use of anti-Tac antibodies (Abs), either alone or in combination with Interferon beta (IFN- β), for treatment of multiple sclerosis (MS)
 - Research by scientists at the National Institute of Neurological Disorders and Stroke (NINDS) and the National Cancer Institute (NCI)
 - MS – Central nervous system (CNS) autoimmune disease attacking brain and spinal cord, resulting in muscle weakness, pain, problems with vision and coordination, and in some, cognitive impairment
- Anti-Tac Ab was a known Ab
 - Had been explored for other conditions, notably organ transplant rejection (FDA approval 1997)
 - Protein Design Labs (PDL) humanized a mouse version of anti-Tac Ab from NCI lab

Connections

- NIH reached out to companies known to be developing anti-Tac Abs
- NIH utilized other typical outreach efforts (e.g., abstract publication) to identify other potential partners



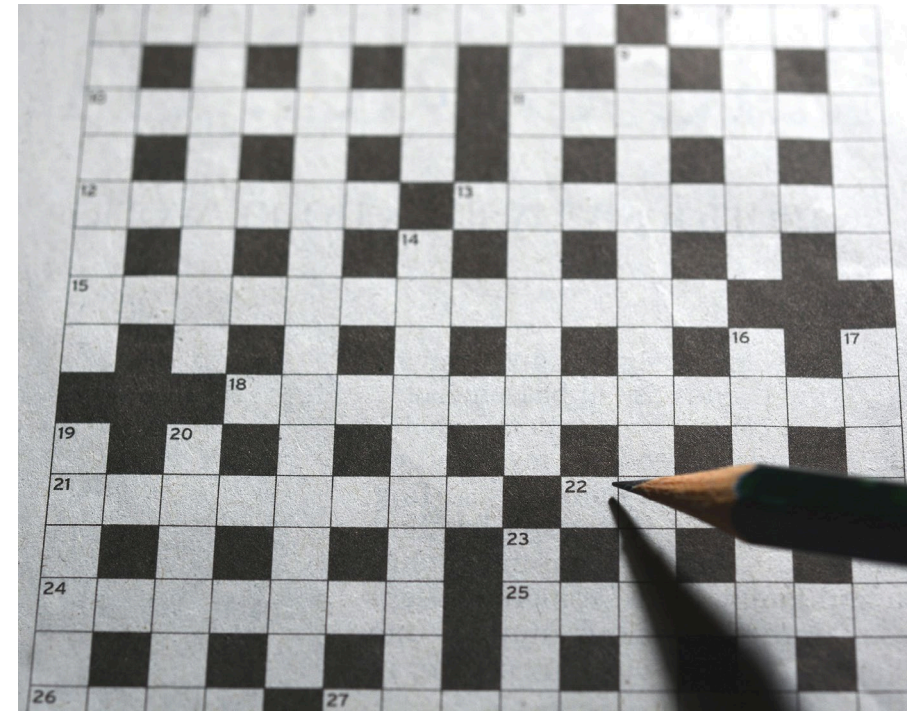
Evaluations



- PDL submitted a license application
 - Requested exclusive license
- All potential licensees are evaluated based on the same criteria
 - 35 USC 209
 - 37 CFR 404 (404.7 for exclusive licenses)
 - NIH licensing policies
- Serono S.A. submitted a license application through NIH's compliance with the laws and regulations
 - 35 USC 209(e) requires NIH to give public notice when intending to grant a license with any degree of exclusivity

Solutions

- NIH seeks to maximize number of partnership when there are multiple license applicants
- NIH entered into co-exclusive licenses with both PDL and Serono
 - Co-exclusive license - two parties are granted the same rights to the patents/patent applications to develop the invention
 - Only possible because all parties agreed to the approach
 - Required second public notice for Serono



Outcomes

- Serono terminated license
- PDL entered into several partnerships, created a separate company that developed the technology, and this company was eventually acquired
 - Product was modified in view of some clinical trial results
- Product received market approval and launched in US and EU
- Product withdrawn from market in view of risk:benefit profile





Thank you!

