

Hot Topics in IP Licensing



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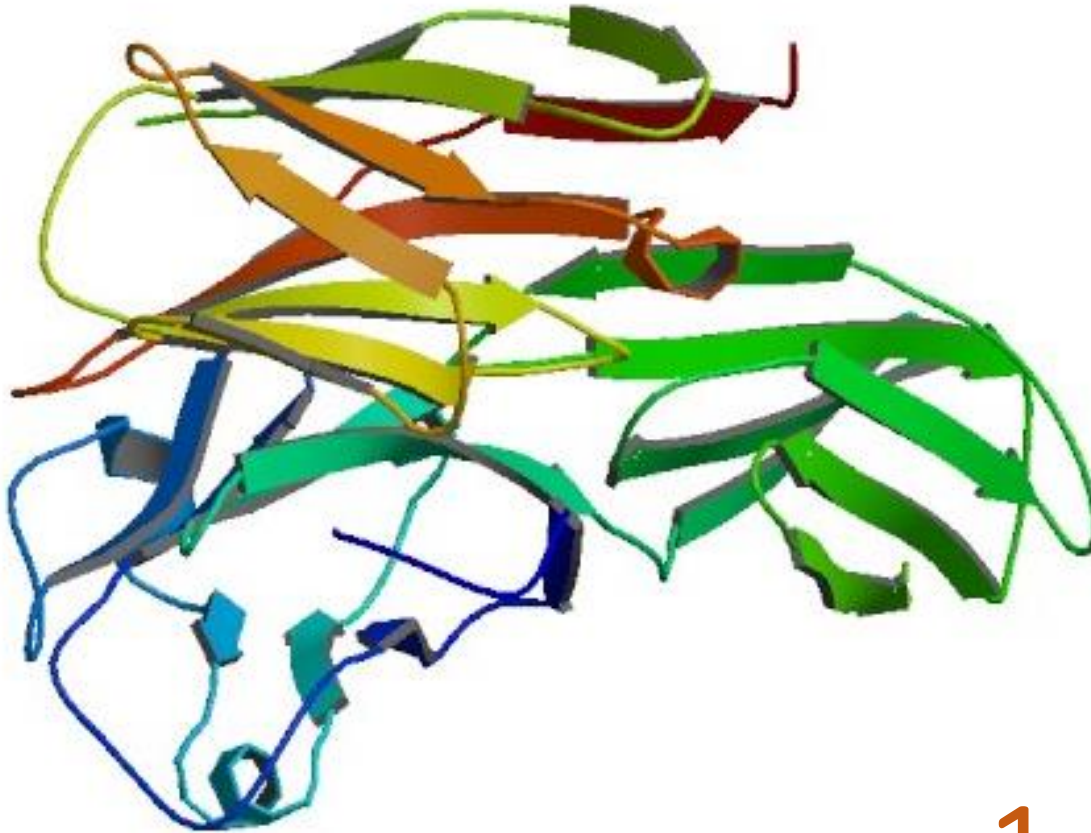
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1. Licensing Hypothetical
2. Royalty Term
3. Governmental Entities as Licensors
4. Prior Art Traps for the Unwary



1. Licensing Hypothetical

The Players:

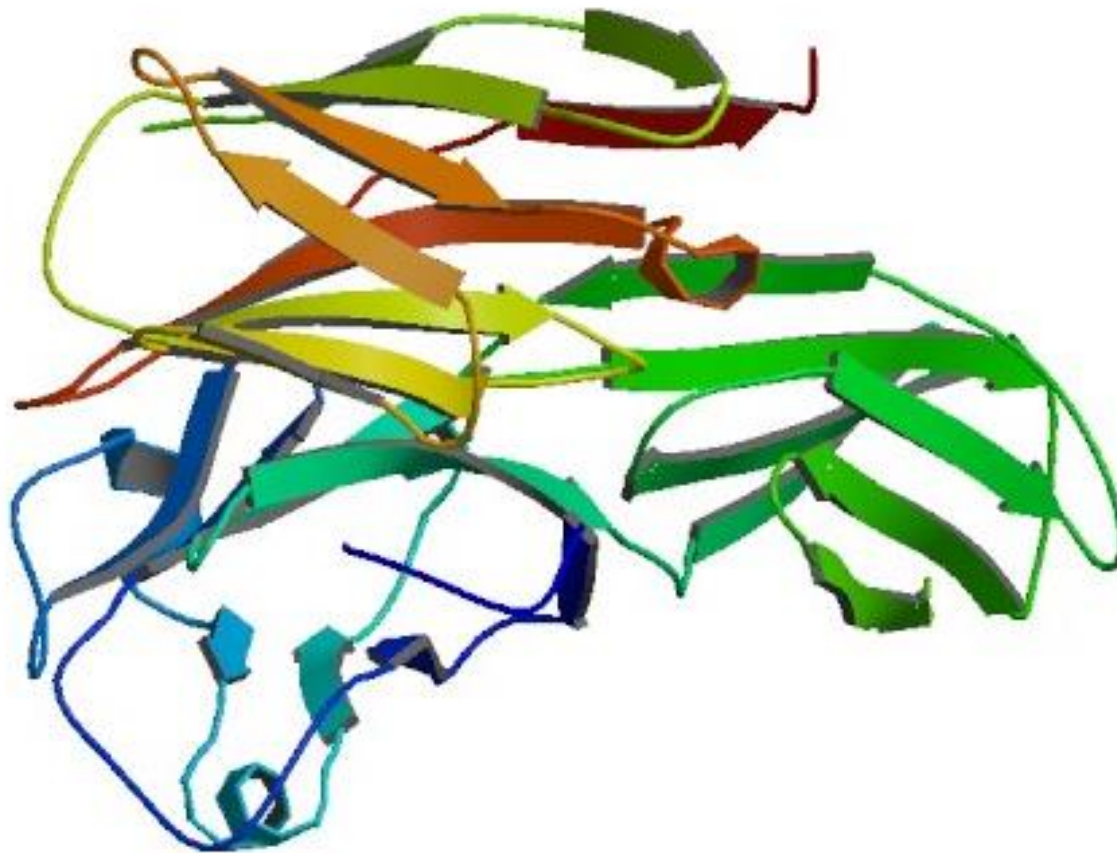
- The Cancer Immunotherapy Center at the University of Texas (TCIC)
- GIANT, a Really Big Pharma company, the product of megamerger activity in 2017
- SuperMouse LLC, a contract manufacturer that uses proprietary transgenic mouse technology to generate high-affinity, fully human monoclonal antibodies

The Technology:

Novel T cell receptor NBK (Natural Born Killer) and its ligand NBK-L, and the use of antibodies against NBK or NBK-L for treatment of cancer.

The parties are discussing a Term Sheet.

Licensed Technology	<p>Worldwide, exclusive license to TCIC’s patents and know-how now in existence or created during the term of this agreement relating to prevention or treatment of cancer using NBK or NBK-L antibodies (the “Field”).</p> <p>A detailed description of the Technology and the experimental data generated to date will be attached to the definitive agreement.</p>
Licensed Product	Any antibody or fusion protein that practices any Licensed Technology in the Field
Term	Until terminated for cause
Royalty	3% of net sales of Licensed Product, until the expiration of the later of: ((i) the last to expire of any licensed patents, or (ii) 25 years after the first commercial sale of a Licensed Product, whichever is later
Sublicenses	GIANT may grant use-limited sublicenses. TCIC to receive 15% of all sublicensing revenue.
Patent Rights	TCIC will grant GIANT exclusive, worldwide licenses in the Field to all patents and patent applications, if any, within the Technology
Patent Prosecution	GIANT will, at its own expense, control the filing, prosecution, maintenance, and enforcement of the Patent Rights
Know-How	TCIC will promptly disclose to GIANT any information, data, process, method, or know-how within the Field that is developed by TCIC before the date of this agreement or during the Term of the Agreement
Contract Manufacture	TCIC agrees that GIANT may engage SuperMouse as a contract manufacturer to develop and produce samples of Licensed Product for clinical development



2. Royalty Term

Background: The *Brulotte* Rule

“ [A] patentee’s use of a royalty agreement that projects beyond the expiration date of the patent is unlawful *per se*...”

Brulotte v. Thys Co., 379 U.S. 29 (1964)



Kimble v. Marvel Enterprises

- Kimble pitches web blaster toy idea and patent license to Marvel
- Marvel says “no thanks” but orally agrees to pay if idea is used
- Marvel uses idea, doesn’t pay. Kimble sues.
- Kimball loses patent infringement claim but wins on oral contract
- Parties settle during appeal
 - Marvel obtains assignment of patent
 - Kimble releases contract claim
 - Marvel agrees to pay 3% royalty on past, present and future sales
 - Neither party aware of *Brulotte*
- *Royalty continues indefinitely, does not distinguish between patent and non-patent rights*
- Marvel later discovers *Brulotte*, sues for DJ that royalty unenforceable after expiration of patent



Kimball goes to the Supreme Court

- District court agrees with Marvel, royalty unenforceable
- 9th Circuit affirms, reluctantly
 - “The *Brulotte* rule is counterintuitive and its rationale is arguably unconvincing.”
 - Academic commentators and economists unanimously agree that *Brulotte* should go. Post-expiration royalty can be pro-competitive
 - Kimball counsel pitches cert petition to Justice Breyer
- Supreme Court grants cert over SG’s objection
 - Question Presented: “Whether this Court should overrule *Brulotte v. Thys Co.*, 379 U.S. 29 (1964).”
- Oral argument: mostly about *stare decisis*; Justice Breyer concerned about extending patent term and reducing competition

Supreme Court Decision:

- “Finding many reasons for staying the *stare decisis* course and no ‘special justification’ for departing from it, we decline Kimble’s invitation to overrule *Brulotte*.”
- Congress made a judgment “that the day after a patent lapses, the formerly protected invention must be available to all for free. And further: that post-expiration restraints on even a single licensee’s access to the invention clash with that principle.”


Kimble, 135 S.Ct. at 2413.

Brulotte's Essence Distilled


- Court: *Brulotte* is “simplicity itself to apply.”
- “A court need only ask whether a licensing agreement ***provides royalties for post-expiration use of a patent.***”

If not?	If so?
“No problem”	“No dice”

Know Your *Brulotte* Quiz

	NO PROBLEM	NO DICE	JURY STILL OUT
The later of patent expiration or 25 years after first commercial sale			


Know Your *Brulotte* Quiz

	NO PROBLEM	NO DICE	JURY STILL OUT
A royalty requiring payment for many patents, extending until the <i>last</i> patent expires			

Kimball v. Marvel Entertainment

Kimball at 2408 (under *Brulotte*, royalties may run until the last-running patent covered in the parties' agreement expires")

Know Your *Brulotte*


	NO PROBLEM	NO DICE	JURY STILL OUT
A step-down in the royalty rate after patent expiration			

Kimball v. Marvel Entertainment


Kimball at 2408 (“for example, a license involving both a patent and a trade secret can set a 5% royalty during the patent period (as compensation for the two combined) and a 4% royalty afterward (as compensation for the trade secret alone”).

- NB: courts do not appear to scrutinize the amount of the step down or assess the relative value of patent and non-patent rights covered by the license

Know Your *Brulotte*

	NO PROBLEM	NO DICE	JURY STILL OUT
A step-up in royalties upon the issuance of patents, followed by a step-down upon patent expiration			


Know Your *Brulotte*

	NO PROBLEM	NO DICE	JURY STILL OUT
A higher royalty percentage accruing based on sales during the patent term, but for which payments are amortized over a longer period			

Kimball v. Marvel Entertainment

- *Kimball* at 2408 (for example, licensee could agree to pay licensor “a sum equal to 10% of sales during the 20-year patent term, but to amortize that amount over 40 years”)

Know Your *Brulotte*

	NO PROBLEM	NO DICE	JURY STILL OUT
Post-expiration payments tied to other pre-expiration use of a patent			


Bayer AG v. Housey Pharmaceuticals

Reach-through royalties:

E.g., payments for post-expiration sales of an unpatented pharmaceutical discovered using patented screening technology during the patent term

Bayer AG v. Housey Pharms., Inc., 228 F. Supp.2d 467 (D. Del. 2002)

Know Your *Brulotte*

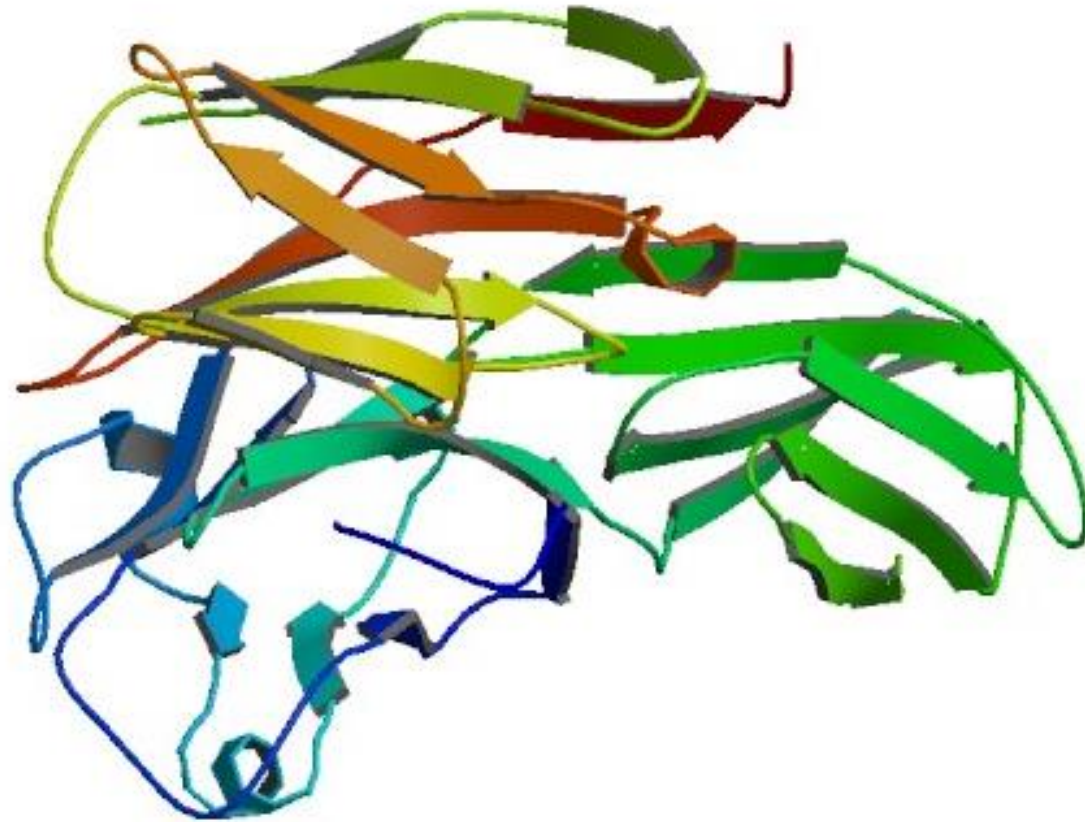
	NO PROBLEM	NO DICE	JURY STILL OUT
Fixed or milestone payments which do not vary according to use of patent rights, i.e, not based on sales of the patented product			

Know Your *Brulotte*

	NO PROBLEM	NO DICE	JURY STILL OUT
Business arrangements other than royalties, such as profit sharing in a joint venture			

Kimball v. Marvel Entertainment

- *Kimball* at 2408 (*Brulotte* poses no bar to business arrangements other than royalties—all kinds of joint ventures, for example—that enable parties to share the risks and rewards of commercializing an invention”)
- *See MedImmune LLC v. Bd. of Trs. of Univ. of Mass.*, 2015 Md. App. LEXIS 493 (June 3, 2015), *cert. denied*, 136 S. Ct. 898 (2016) (parties collaborated on developing antibody therapeutic against RSV; MedImmune agreed to pay UMass percentage of net sales of “Royalty-Bearing Products,” defined as any products in the Field, regardless of whose technology they used. Held: no violation of *Brulotte*, even though payments continued after expiration of UMass patents).



3. Governmental Entities as Licensors

Examination of Public Records

- Public records statutes capture records of state universities, including contracts
- Certain “exceptions” apply, but vary by state

- **Texas, Sec. 552.101. EXCEPTION: CONFIDENTIAL INFORMATION.** “[E]xcepted...if it is...confidential by law”.



- **Texas, Sec. 552.110. EXCEPTION: CONFIDENTIALITY OF TRADE SECRETS; CONFIDENTIALITY OF CERTAIN COMMERCIAL OR FINANCIAL INFORMATION.** (a) A trade secret obtained from a person and privileged or confidential by statute or judicial decision is excepted


Examination of Public Records

- **Iowa Code § 22.7 CONFIDENTIAL RECORDS.** (3) Trade secrets which are recognized and protected as such by law. (6) Reports to governmental agencies which, **if released, would give advantage to competitors and serve no public purpose.**
- **Mass. G. L. c. 4, § 7(26)(g). Public Records. Exemptions (g) trade secrets or commercial or financial information** voluntarily provided to an agency for use in developing governmental policy and upon a promise of confidentiality; but **this subclause shall not apply** to information submitted as required by law or as a condition of receiving a governmental contract or other benefit.
- **Cal. Gov't Code 6253(k):** Records, the disclosure of which is exempted or prohibited pursuant to federal or state law, including, but not limited to, provisions of the Evidence Code relating to privileged. "Privilege" under the California Evidence Code is not limited to legal privileges, and **the code has provisions protecting trade secrets and confidential information.**

Exceptions to Public Record Statutes

- Balancing public interest in disclosure
- Some exemptions provide agencies with the ability to withhold information provided to the agency
- Some states: if request not covered by an explicit exception, documents must be provided
- Trade secrets and confidential information are exceptions to the rule, but can be limited
- Questions for analysis:
 - Is licensing technology a core function of the university?
 - Is the subject agreement carrying out a core function in place of the university?


Know Your Public Records Quiz

	NO PROBLEM	NO DICE	JURY STILL OUT
Ability to protect TCIC's technical details (trade secrets, know-how) as an appendix to the agreement			

Practical Considerations

- Details of trade secrets should not be included
- Know-how may not meet the statutory requirements of trade secret protection
- Agree to disclose technical details outside of the agreement


Know Your Public Records Quiz

	NO PROBLEM	NO DICE	JURY STILL OUT
Ability to protect TCIC's patent list and economic terms of license agreement between TCIC-GIANT			

Practical Considerations

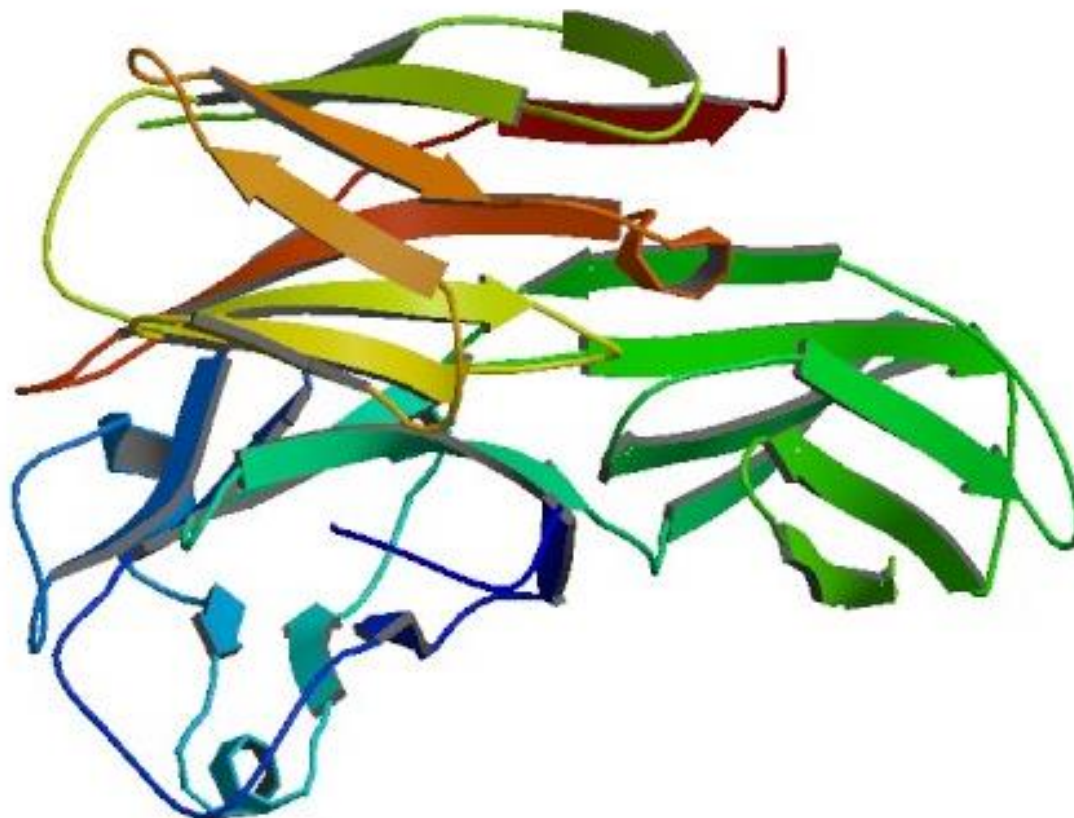
- Argue that these are confidential terms that do not serve a public interest and cause competitive harm
- Patent list and economics may be disclosed in other forums

Know Your Public Records Quiz

	NO PROBLEM	NO DICE	JURY STILL OUT
GIANT-SuperMouse contract to produce licensed product			

Practical Considerations

- Subcontracts don't belong to the university and are not public records



4. Prior Art Traps for the Unwary

On Sale Bar

“ [I]f “on sale” more than one year before filing an application for a patent..., any issued patent is invalid....”

The Medicines Company v. Hospira, Inc., D. Del. No. 1:09-cv-00750-RGA (2016)




On Sale Bar Test

Two-Step Test:

Was the claimed invention (1) the subject of a commercial offer for sale and (2) ready for Patenting?

Pfaff v. Wells Electronics, Inc., 525 U.S. 55 (1998)

Know Your On Sale Bar Quiz

	NO PROBLEM	NO DICE	JURY STILL OUT
TCIC agrees the GIANT may engage SuperMouse as a contract manufacturer to develop and produce samples for clinical development			

Know Your On Sale Bar Quiz

	NO PROBLEM	NO DICE	JURY STILL OUT
GIANT signs a contract with SuperMouse as a contract manufacturer to develop and produce samples for clinical trials			

The Medicines Company v. Hospira


- Title remains with GIANT
- SuperMouse is a contract manufacturer
- Product being produced for clinical trials

“The court agreed with Medco that the transactions between MedCo and Ben Venue were **sales of contract manufacturing services in which title ... always resided with MedCo**. It found that ‘this does not end the inquiry,’...”

“We...clarify that **the mere sale of manufacturing services** by a contract manufacturer to an inventor to create embodiments of a patented product for the inventor **does not constitute a ‘commercial sale’...**”

Medicines Co v. Hospira, (2016)

Know Your On Sale Bar Quiz

	NO PROBLEM	NO DICE	JURY STILL OUT
Immediately after signing the license with TCIC, GIANT engages another third party as the sole distributor to sell Licensed Product after launch			

The Medicines Company v. Hospira


- In *MedCo v. Hopsira*, MedCo entered into a distribution agreement with ICS prior to filing a patent application for the manufacturing process.
- Distribution agreement made ICS the exclusive distributor in the US

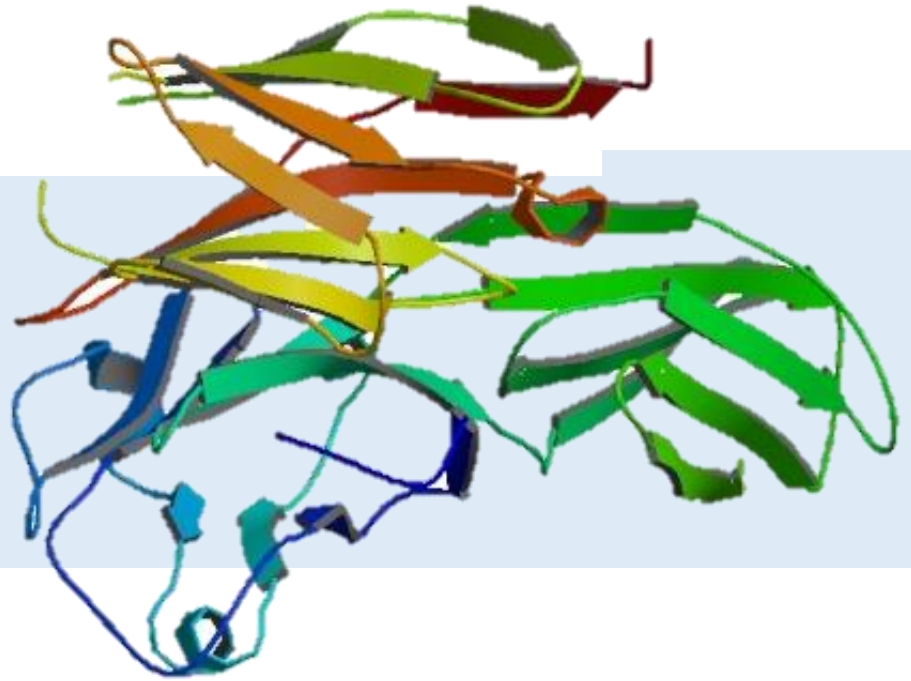
The court “held the [distribution] agreement was merely ‘an agreement for ICS to be the sole U.S. distributor’ The court concluded that the contract was merely **‘a contract to enter into a contract’ for future sales....**”

“[W]e find that the mere stockpiling of a patented invention by the purchaser of manufacturing services does not constitute a ‘commercial sale under § 102(b).”

Medicines Co v. Hospira, (2016)

Know Your On Sale Bar Quiz

	NO PROBLEM	NO DICE	JURY STILL OUT
GIANT agrees that SuperMouse shall have title to licensed product antibodies it manufactures for research use and shall have worldwide rights to market and sell such antibodies.			



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