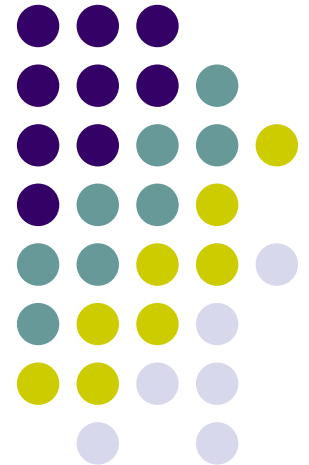


The Challenges of Patenting Biotech Inventions in the US

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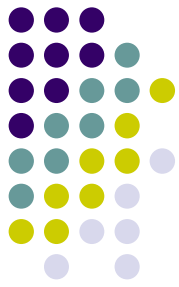




What is a Patent?

- A patent grants the right to exclude another party from making, using, selling, or offering for sale the claimed invention.
- A patent does NOT give the owner the right to practice his or her invention.
- Patents are national in scope – a US patent is enforceable only in the US.
- Patents are expensive to obtain and to enforce.

Applications Filed with the US PTO



2004 Utility, Plant, and Reissue Applications Filed

Technology Center	2004	2003 to 2004 Growth Rate
1600 – Biotechnology and Organic Chemistry	38,164	-1.2%
1700 – Chemical and Materials Engineering	49,334	-0.5%
2100 – Computer Architecture Software and Information Security	34,653	17.9%
2600 – Communications	48,210	16.1%
2800 – Semiconductor, Electrical, Optical Systems	81,144	7.6%
3600 – Transportation, Construction, Electronic Commerce	47,489	4.8%
3700 – Mechanical Engineering, Manufacturing and Products	56,533	5.5%
UPR Total	355,527	6.6%

Why the Drop in Biotech Patenting in the US?



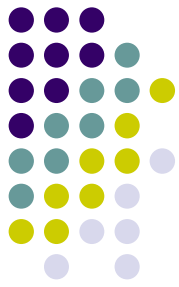
- General downturn in the biotech industry.
- Standards for patentability, particularly in the biotech area, have increased significantly.
- The US Patent Office and the courts are forcing applicants to define their claims more narrowly, particularly in the biotech area.

Why the Drop in Biotech Patenting in the US Cont'd.



- The amount of information required in a patent application is related to the degree of unpredictability – the less predictable the technology, the more disclosure required.
- Both the US Patent Office and the US Courts consider biotech to be an unpredictable art.
- In recent years it has become significantly harder to get biotech patents issued in the US.

Differences in the US Patent and NZ Patent Systems



- Methods of treatment are patentable in the US, not in NZ
- The US currently does not allow for post-grant opposition.
- The US currently has a first-to-invent, not first-to-file, system.

Differences in the US Patent and NZ Patent Systems Cont'd.



- The US has a one year grace period for public disclosures by the inventor, i.e. an inventor may delay filing a patent application up to 12 months after his/her first public disclosure of an invention.
- Possible to file continuation-in-part (CIP) applications in the US, including new disclosure and claiming priority to the parent application.
- The US Patent Office has strict restriction procedures for handling patent applications that claim more than one invention.

Patent Interferences



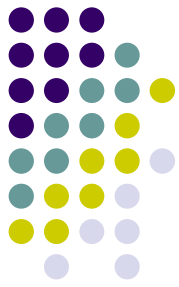
- When a patent application claims the same invention as another application or an issued patent, the US Patent Office resolves who is first to invent through a patent interference proceeding.
- The question of who first invented subject matter claimed in two issued patents can only be resolved in the courts.
- Only about 1% of patent applications become involved in an interference.
- Junior party rarely prevails.

Patent Interferences Cont'd.



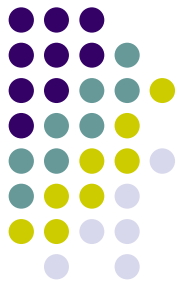
- Proof of inventorship requires a showing of earliest conception followed by diligent reduction to practice.
- Documentation of entire R&D process is essential; good Lab Notebook procedures are vital.
- Avoid if possible: focus on establishing earliest priority date for an invention by filing a patent application as soon as possible.

US Restriction Practice vs. Unity of Invention



- In both the US and NZ, only claims drawn to a single “invention” will be examined in a single application; the remaining claims may be pursued in a subsequent, divisional, patent application.
- Unity of Invention – in order to be examined together, claimed subject matter must be linked by a “special technical feature”.
- US Restriction Practice – in order to be examined together, inventions cannot be independent or distinct, i.e. inventions cannot be separately patentable.

Restriction Practice Cont'd. - Example



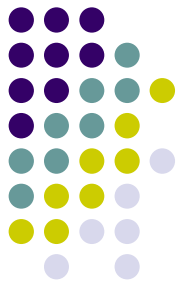
- Claim 1: An isolated polynucleotide comprising a sequence of SEQ ID NO: 1-10.
- Claim 2: A method for treating an immune disorder in a mammal, comprising administering a polynucleotide of claim 1.
- Claim 3: An isolated polypeptide encoded by a polynucleotide of claim 1.
- Claim 4: A method for treating an immune disorder in a mammal, comprising administering a polypeptide of claim 3.

Example Cont'd.



- Under Unity of Invention, each polynucleotide, its encoded polypeptide and methods for their use would constitute a single invention; therefore there are **10** inventions.
- Under US practice, each of these 4 claims is considered to be a separate invention PLUS each sequence is a separate invention, therefore there are **40** inventions.
- This creates a significant economic burden.
- US may change to a Unity of Invention standard.

Conditions for Patentability in the US

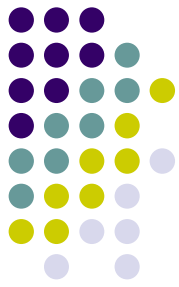


Claimed invention must:

- (a) be novel, i.e. no single prior art reference discloses the invention
 - generally not a problem for most biotech claims.

- (b) be non-obvious (comparable to inventive step in NZ), i.e. no combination of prior art references discloses the invention
 - threshold set by US Patent Office and Courts is surprisingly low.

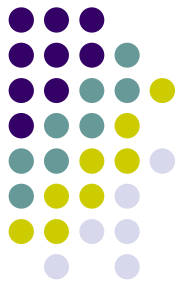
Conditions for Patentability Cont'd.



Claimed invention must:

- (c) have a substantial, specific and credible “real-world” utility
 - problematic for sequences that have not been well characterized,
 - can be problematic for research tools and for methods of treatment,
 - may be possible to overcome utility rejection by submitting additional data.

Conditions for Patentability Cont'd.



Patent application must:

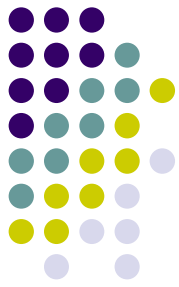
- (a) describe the “best mode” known to the inventors at the time of filing (rarely an issue during prosecution),
- (b) provide an adequate written description of the invention,
and
- (c) provide an enabling disclosure of the application.

Enablement



- Specification must teach one of skill in the art how to make and use the full scope of the claimed invention without undue experimentation.
- One of skill in the art is generally considered to be someone with a Ph.D. in the relevant subject (although advisable to include enough background that someone with little technical knowledge could understand the invention).
- Enablement standard for patentability is significantly higher than that for prior art – may lead to own published patent application outside the US invalidating US patent.

Enablement Cont'd.

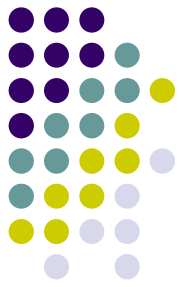


- Possible to overcome enablement rejections by submitting data during prosecution (but beware the need to provide both positive and negative data).
- Helpful to include “prophetic” examples in application, such as future planned experiments and assays for determining activity.
- US Patent Office requires a high level of support for inventions relating to biological subject matter, particularly for therapeutic methods and compositions - need to provide data demonstrating results in humans (even if only anecdotal) or in animal or *in vitro* models that are known to be predictive of humans.



Written Description

- Can one skilled in the art reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed?
- Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes does not necessarily describe the cDNA itself.
- Written description requirement should be separate and distinct from the enablement requirement, although in practice they often overlap.



Written Description Cont'd.

- Generally not an issue for claims to specific sequences, for example:

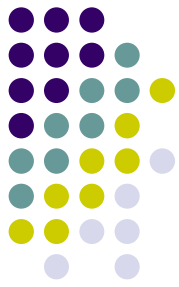
Claim 1. An isolated polypeptide comprising a sequence of SEQ ID NO: 1.

- Often problematic for claims to variant sequences, for example:

Claim 2. An isolated polypeptide comprising a sequence having at least 85% identity to SEQ ID NO: 1.

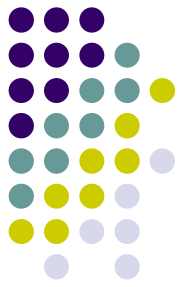
Particularly where the polypeptide does not belong to a well-characterized family of polypeptides.

Written Description Cont'd.



- Satisfy WD requirement by characterizing the molecule as much as possible, for example:
 - provide location of functional domains,
 - provide sequence comparison with known family members,
 - provide actual variant sequences.
- WD requirement can rarely be satisfied by submitting additional information during prosecution.

Duty of Disclosure



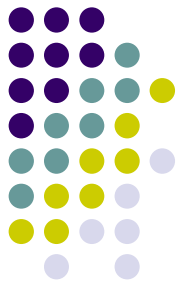
- Extends to inventors, assignee and attorney/agent.
- Required to disclose anything of which you are aware that may be relevant to patentability of the claims including, but not limited to, prior art.
- Applicant is not required to search for prior art.
- Not an issue during prosecution, but can be an issue during litigation.
- Patent can be invalidated due to failure to disclose information.

Challenging an Issued US Patent



- Issued patent enjoys a “presumption of validity”, i.e. a challenger must first provide some evidence that a patent must be invalid.
- Challenger can file Request for Reexamination by US Patent Office based on new prior art issues.
- Patent holder can sue for infringement. Accused infringer may assert that patent is invalid.

Infringement



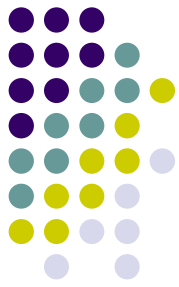
- Patent infringement lawsuits are expensive to undertake and frequently result in multi-million dollar damages.
- Literal infringement – every element of claimed invention is included in infringing device or composition. For example, a composition including components A, B and C would not infringe claims to a composition including components A, B and D.
- Doctrine of Equivalence – infringing device employs substantially the same means in substantially the same way to give substantially the same result. For example, **may** cover use of a variant sequence when patent claims sequence *per se*.
- **highly unpredictable.**

Infringement Cont'd.



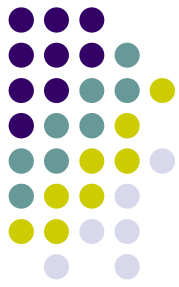
- Notify potential infringers of the existence of your patent and provide copies.
- Companies guard against infringement by:
 - a) performing freedom-to-operate searches (difficult to be sure that truly have freedom-to-operate),
 - b) licensing 3rd party IP, and/or
 - c) obtaining non-infringement/ invalidity opinions from counsel - can protect from finding of willful infringement, thereby avoiding treble damages.

Infringement and Experimental Use



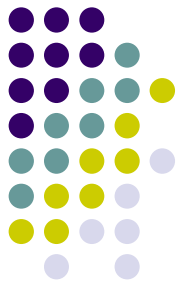
- Remember that patents are specific to particular countries and/or regions – few companies pursue patent protection in NZ.
- Under NZ law, must consider whether research enables party to make commercial advances in the market place or whether it simply adds to knowledge or skill
- In US, Hatch-Waxman Act permits experiments related to securing regulatory approval prior to patent expiration, for example, testing of generics (so-called “271(e) Safe Harbor”).
- 271(e)(1) Safe Harbor balances restoration of patent term lost due to delays in FDA approval.

Infringement and Experimental Use Cont'd. - Merck v. Integra



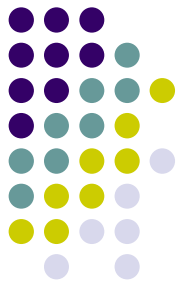
- Integra owns several patents on RGD peptides.
- From 1988 to 1998 Merck funded research at Scripps to identify potential drug candidates for inhibiting angiogenesis. Identified a cyclic RGD peptide as potential drug candidate, and performed efficacy and toxicity testing of this plus 2 other related peptides. An IND for one of the related peptides was filed in 1998.
- Integra sued Merck for patent infringement in 1996.
- Merck claimed its work fell under 271(e)(1) Safe Harbor.

Infringement and Experimental Use - Merck v. Integra Cont'd.



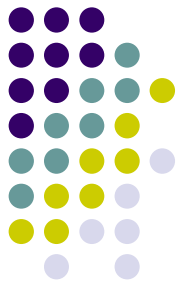
- In June 2003, US Federal Circuit ruled that research must be “solely for uses reasonably related” to information that is **subsequently submitted** to the FDA (Integra Life Sciences v. Merck, Fed. Cir. June 6, 2003).
 - i.e. basic research & drug discovery processes are not exempt from infringement, testing for safety and effectiveness is.
- **BUT** in June 2005, US Supreme Court overturned the Fed. Circuit decision, stating that the exemption extends to preclinical studies of patented compounds that are **appropriate for submission** to the FDA. i.e. does not exclude experimentation on drugs that are not ultimately submitted to the FDA.

Infringement and Experimental Use Cont'd.



- Invoke Safe Harbor by designating compound as a candidate for FDA approval?
- Merck v. Integra decision appears to reduce value of patents on research tools.

Conclusions

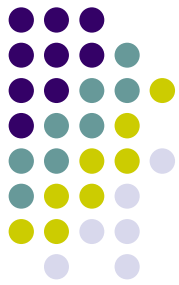


- **Downside**

Obtaining broad patent protection for biotech inventions in the US is difficult under the current climate and is unlikely to get easier in the short term.

- **Upside**

Many issued US biotech patents probably do not meet the current standards for patentability and therefore would be invalidated if challenged in the courts.



Questions?