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Life Sciences Patent Prosecution Pitfalls

By Robert E. Hanson, Ph.D., Esq.

Today's Talk Will Cover …

- **The unique application of basic patentability requirements to biotechnology and life science inventions**
- **What it means to you**

Non-Obviousness

- ***KSR v. Teleflex* likely heightened bar for patentability. 550 U.S. 398 (2007).**
  - A motivation or suggestion to combine elements to arrive at the invention need not be explicit in prior art.
  - U.S. Sup. Ct.: "The combination of familiar elements according to known methods is likely to be obvious when it does *no more than yield predicable results*."
- **Take Away – obtain unexpected results for combination inventions, *i.e.*, "more than predictable results"**
  - Having inventors run relevant experiments is critical.

Patentable Subject Matter Post-*Bilski*

- *Bilski* applied "machine-transformation" test to find business method claims invalid. (Fed. Cir. 2008)
- Test finds patentable subject matter only if: (1) tied to a particular machine or apparatus, or (2) transforms a particular article into a different state or thing.

1. A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:

(a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;

(b) identifying market participants for said commodity having a counter-risk position to said consumers; and

(c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.

Relevance of *Bilski* to the Life Sciences?

- *Mayo v. Prometheus* (Fed. Cir. 2009): CAFC applies *Bilski* test to find claims patentable - "administering a drug" and "determining the level" steps are considered transformative
- Conclusion: include transformative step or apparatus element in claims
- But: U.S. Sup. Ct. expected to decide *Bilski* in 2010

We claim:

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

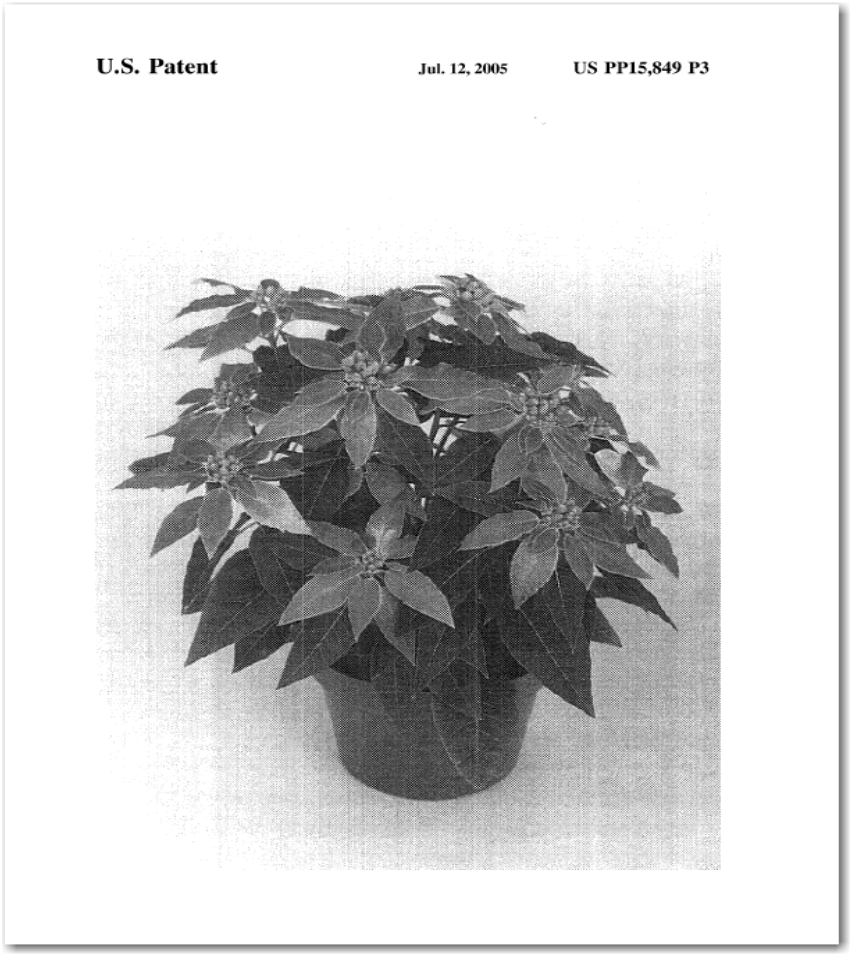
Common Legal Issues – Biological Deposits

- Required if words or drawings alone are insufficient to describe and "enable" production of biological material
  - Examples: plant seeds; embryos; microorganisms; cell lines and hybridomas; viruses; plasmids and vectors
- Deposit must be made pre-filing for foreign patent rights.
- Deposit can be delayed in the U.S., but only if material adequately described
- Budapest Treaty approved depository required
  - The ATCC or NRRL in the U.S.

Case Example – US 6,515,200

Seed deposit required?

1. An interspecific hybrid Euphorbia plant produced from a cross between *Euphorbia pulcherrima* as a female parent and *Euphorbia cornastra* as a male parent.



Case Example – US 6,515,200

Not in this case: a deposit is not required if a biological material is "known and readily available." See MPEP 2404.01

The parent plants from which the interspecific hybrid plant of the invention was obtained, *Euphorbia pulcherrima* and *Euphorbia cornastra*, are both known and available to the public. The parent plant *Euphorbia pulcherrima*, commonly known as the Poinsettia or Christmas Poinsettia is widely cultivated and is publicly available by way of numerous cultivated varieties. These varieties may be clonally propagated by cuttings, as is well known to those of skill in the art (Ecke et al., 1990, the disclosure of which is specifically incorporated herein by reference in it's entirety).

The second parent plant, *Euphorbia cornastra*, is commonly known as the Dogwood Poinsettia and is a fairly recently discovered Euphorbia from Guerrero, Mexico (lat. 17°35'N, long. 99°54'W) (Le Duc and Albrecht, 1996). The species was collected in 1973 and described as a new species by Dressier (1975). The native habitat of the species is tropical deciduous forests at high elevations (1930m), where it can be found growing in rich humus soil at the foot of large limestone outcrops.

Novelty of Genetic Materials

- An *enabling* disclosure is required to destroy novelty.
- *In re LeGrice*, 301 F.2d 929 (CCPA 1962) Printed publication >1 yr prior to filing showed color pictures of claimed rose plant. Held: not a bar to patentability – did not enable reproduction of the plant.
- But: watch out for on sale and public use bar.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