Non-obviousness in the United States

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INTELLECTUAL PROPERTY LAW

U.S. Non-obviousness vs. Japanese and EPO Inventive Steps

35 U.S.C. § 103

A patent may not issue:

"if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious"

(1) at time invention filed

(2) to a [skilled artisan]

A question of law, based on underlying facts, the later of which are:

(1) Scope and content of the prior art

(2) Differences between prior art and claims

(3) Level of ordinary skill at the time of filing (or if pre-AIA, time of invention)

(4) Objective indicia

KSR v Teleflex

- Each and every element in references
  - Explicitly, or inherently (limited to what was known to "naturally flow from" or be "predictable" at time of filing)
- Motivation to combine multiple embodiments/references
  - Explicit (teaching, suggestion, motivation)
  - Implicit (skilled artisan's knowledge, common sense, other recognized benefit)
- Reasonable expectation of success
  - Known options with finite number of identified solutions
- PREDICTABLE (mentioned ~10 times)
- Flexible → *ad hoc* and factually intensive

- Determine Prior Art
  - Analogous art
    - GENERALLY same field or
    - solving GENERALLY same sub-problem
  - Hard to show non-analogous, but can be done with properly drafted background section

All Limitations

- Assert primary (one or several closest references) & secondary references
  - Can have more than 2 references
  - Inherent limitations (naturally flow from), unless:
    - Specific claim limitation not known at filing date
    - Foundation for reason to combine
    - Foundation for reasonable expectation of success

Motivation to Combine

- Motivation to combine
  - Any motivation, actual one used by inventor irrelevant
  - Need not achieve advantage stated only in the specification
  - Skilled artisan can draw knowledge of all art from many sources, anywhere in entire patent (not only background and textbooks)

Reasonable Expectation of Success

- Reasonable expectation of success
  - Skilled artisan would reasonably expect results
    - Why pick lead compound?
    - Why pick modification?
    - Degree of results predicable?

Objective Indicia

- (1) Commercial Success, (2) Unexpected Results, (3) Long felt but unresolved needs, (4) Failure of others, (5) Skepticism in the art, (6) Praise by others, (7) Teaching away by others, (8) Recognition of a problem, (9) Copying of the invention by competitors, (10) Licensing, (11) Market trend of similar work (cuts against patent)
- Evidence must be linked to/caused by claimed invention, and now even non-obvious limitations, not marketing or distribution efforts, etc.

Typical Prosecution Counterarguments

- Teaching away – reference would lead inventor along a divergent path from claimed invention
- Non-operability / Unsuitable for intended purpose
- Routine Optimization - result-dependent variable must have been recognized as such
- Unexpected results – through specific claim limitation functionality or comparative test data
  - Lead compound or modification one of many possible equally promising choices (obvious to try not enough)
  - Degree of actual results much higher than **a skilled artisan would predict**

U.S. vs. Japanese vs. EPO Inventive Step in the Chemical Arts

Par Pharma v TWI Pharma (1)

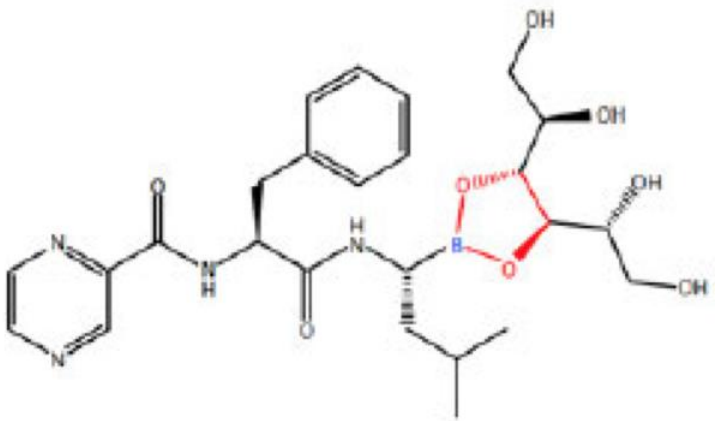
Ex. 6 U.S. Pat. No.: 7,101,576 JP4838514(1); EPO1494649(1)	MEGACEOS	Other Refs.
1. A method of increasing [body mass comprising] administering a megestrol formulation,	YES	NO
(a) the megestrol acetate formulation is a dose of about 40 mg to about 800 mg[…];	YES	NO
(b) the megestrol acetate formulation comprises [nano-sized] megestrol particles, and [assoc.] surface stabilizer;	YES	Nano-sized particles increase bioavailability
(c) the administration is once daily;	YES	NO
wherein after a single administration in a human subject**… there is no substantial difference in the C.sub.max of megestrol when the formulation is administered to the subject in a fed versus a fasted state**,	NO, but expect decrease in fed-state effect bc Other Refs.	NO, nanoparticle drugs provide greater bioavailablity, reduce fed-state absorption
[fasted state = no food within > 10 hrs., fed state = high-calorie within 1/2 hr., of dose.]	NO	NO

Par Pharma v TWI Pharma (2)

- "naturally flows from" vs. "predictability" standards – "inherency" not found in Japan or the EPO, thus U.S. claims narrower in this respect
- Generally cannot use obviously inherent limitation when limitation is unknown (unappreciated) at time of filing
  - Foundation for motivation to combine
  - Foundation for reasonable expectation of success
- Art suggested improved bioavailability and thus reduced fed-state effect, but not to the extent claimed because that claim limitation was unknown – (EPO649 claims narrower due to Art 123(2); JPO 2011-251989(82) like US thus far)
- USPTO can however use *prima facie* unknown limitation:
  - In re *Dillon* – use of substantially similar composition differing only by interchangable equivalents, if alternate motivation/expectation exist (can overcome e.g., by testing PA equivalent as against claimed composition).
  - In re *Kubin* – if limitation claimed functionally, and knowing limitation not required to provide motivation or expectation of success.

Millennium Pharm v Sandoz (1)

- Velcade® - oncology product for multiple myeloma and mantle cell lymphoma
- Freeze-dryed bortezomib with mannitol to produce:

Ex. 7 U.S. Pat. No.: 6,713,446 JP4162491(17);EP1355910(12)	Bortezomib	Other Refs.
20. The lyophilized **compound** [D-mannitol ester of bortezomib 	Proteasome inhibiter with anticancer properties; highly unstable, insoluble in water (humans), rapidly degrades, thus no form ever FDA approved despite 20 different formulations	Lyophilization (a/k/a feeze-drying) a known technique for bulking (“not intended to change structure of pharmaceutical agent”); mannitol known bulking agent

MILLENNIUM®

Millennium Pharm v Sandoz (2)

- District Court held “the inherent result of an obvious process” – common to bulk this way when liquid formulation provided limited success.
- No teaching in art of new compound formation – CAFC used “lead compound” analysis
- Motivation to combine mannitol and drug via lyophilization was too general
- Compound-specific results/properties not predicted
  - “It was discovered that the reason for the dramatic improvement in dissolution and stability for this formulation was the formation of a new chemical compound during lyophilization”
- JPO granted very similar claims in ‘491(17)(among several)
- EPO granted very similar claims in 910(12)
- JP or DE court of first instance likely not invalidate because of no inherency issues.

Honeywell v Mexichem Amanco (1)

Ex. 8 U.S. Pat. No.: 7,534,366 JP4699758(8); EP2546221(1)	Inagaki JP Pat. H04-110388	Magid, A & Admiss, Bivens
1. A heat transfer composition for use in air conditioning system comprising:	YES	NO
(a) > 50% by weight of [HFO-1234yf] with no substantial acute toxicity; and	YES, eco-friendly function	NO, only w older cheaper HFC lubricants
(b) at least one [PAG] lubricant in the form of[….] Objective evidence of : (1) HFO disfavored: reactive unstable (2) PAG disfavored: unstable (would degrade HFO) (3) HFO+PAG unexpect stable/soluble (4) Long-felt unmet need for ecofriend (5) Skepticism of eco+ low toxic/solubl	NO, teaches with old HFC eco-unfriendly lubricants **“(3) Inherent to HFO”?** NOT allowed because not predictable	YES, but not mentioned with HFO-type; HFC used because soluble, stable, less reactive Omure: “another HFO relatively stable w/ PAG”

Honeywell v Mexichem Amanco (2)

- PTAB combines based on trade off of using eco-friendly yet reactive HFO, plus possible PAG lubricant; "compatible"
- PTAB said Omure shows unpredictability and thus routine testing overcomes objective stability/solubility/etc. evidence
  - "[I]nherent properties of refrigerants include their [toxicity and solubility], whether or not these properties are predictable"
- CAFC Adopts In re *Henderson*'s "predictable" standard
  - "What is important regarding properties that may be inherent, but unknown, is whether they are unexpected. All properties of a composition are inherent in that composition, but unexpected properties may cause what may appear to be an obvious composition to be nonobvious."
  - "Thus, the Board here, in dismissing properties of the claimed invention as merely inherent, without further consideration as to unpredictability and unexpectedness, erred as a matter of law."
- Result is wider US claims so far than JP758(1-8) EP221(1)
  - EP has about 100 cases (many methods); JPO has many as well
- Perhaps JPO/EPO will not accept claim amendments/data

Thanks for your attention. Questions?

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