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Latest Developments in European Patent Law:
How to Apply Them in Both the United States and Europe

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Agenda

- UK Supreme Court Decision on Infringement
  - “Equivalents”
  - Use of the prosecution history
- Doctrine of Equivalents in the United States
- Plausibility before the EPO and UK courts
  - Inventive step of product claims
  - Sufficiency of medical use claims
- Utility in the United States

UK Supreme Court Decision on Infringement

Lilly v Actavis [2017] UKSC 48

- 12 July decision from UK Supreme Court
- Change in approach to assessing whether immaterial variants can be considered to fall within the scope of a patent claim (direct infringement)
- Change in approach to use of prosecution file history during later proceedings

Background

- Eli Lilly patent relates to the use of *pemetrexed disodium* in the manufacture of a medicament for use in combination with vitamin B12 (and, optionally, folic acid) for the treatment of cancer

- Actavis produced a treatment including either pemetrexed diacid or a different pemetrexed salt

- First instance - no direct or indirect infringement
- Court of appeal - indirect infringement, but agreed no direct infringement
- Appeals filed by both sides

Protocol on interpretation of Article 69 EPC

Article 1:

"Article 69 should **not** be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the **strict, literal meaning of the wording** used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. **Nor** should it be taken to mean that the claims **serve only as a guideline** and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining **a position between these extremes** which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties."

Protocol on interpretation of Article 69 EPC

Article 2 - Equivalents

"For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is **equivalent** to an element specified in the claims."

- Claim must be properly interpreted:

1. The description and claims can be taken into account
2. The scope of the claim may extend beyond the literal meaning of the claims
3. An equivalent or immaterial variant may be covered where this falls outside the scope of the claim (as properly interpreted)

Previous infringement test

- *Catnic, Kirin Amgen* and *Improver* rejected

- *Catnic (1982)* – it was obvious that "extending vertically" *could not have been intended to exclude lintels in which the back plate … was close enough to 90º to make no material difference to the way the lintel worked*.

Previous infringement test

- *Improver Questions (1990):*

1. Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no –

2. Would this (i.e. that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes –

3. Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim

Previous infringement test

- *Improver* – claim to “helical metal spring” infringed by slotted rubber rod
- *Kirin Amgen (2005)* - “purposive construction” – *what would skilled person have understood patentee to be using the language of the claim to mean?*
- No infringement of claim to production of EPO by recombinant DNA technology
- Did not rule out/supersede *Improver Questions*

Updated infringement test

1. Does the item infringe any of the claims as a matter of normal interpretation?

   If yes – direct infringement

   If no – go to qu.2

2. Although the item may be characterised as a variant, does it nonetheless infringe because it varies from the invention in a way which is immaterial?

   If yes – direct infringement

   If no – no direct infringement

Comments on the updated test

- Separate tests:
  - Qu 1 – matter of interpretation
  - Qu 2 – not only matter of interpretation, but also determination of extent of the scope of protection

- Qu 2 concerning assessment of immaterial variants - reformulated *Improver questions* for chemical-type cases

- Guidelines (not strict rules) for assessing immaterial variants

Reformulated *Improver Questions*

- Original question 1:
  - Does the variant have a material effect upon the way the invention works?
- Reformulated question 1:
  - Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent?

If yes, go to Qu 2
If no – no direct infringement

Question 1 changes

- No great change intended
- Focus on inventive concept
- Reworded to apply more clearly to non-mechanical cases

Reformulated Question 2

- Original question 2:
  - Would this (i.e. that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art?
- Reformulated question:
  - Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?

If yes, go to Qu 3
If no – no direct infringement

Question 2 changes

- Biggest change
- For chemical cases, the previous version did not work well
- The result of substituting one chemical for another is often not at all obvious to the skilled person
- Would need to try it in order to find out what the result is
- Reworded to assume variant does achieve the same result in the same way - new starting point for assessment
- Also applies to variants not known at priority date

Question 2 changes

- Effect of this is likely to increase the scope of what can be caught as a variant
- Variants which do work in the same way, but where it would not have been obvious that they work in the same way at priority/publication date, might not have been caught before, but are more likely to be caught now
- Expressed as a reformulation for chemical cases, but it could have application for mechanical cases

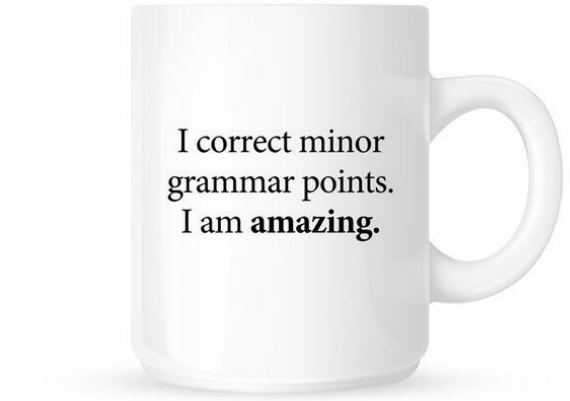
New Question 3

- Original question 3:
  - Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention?
- Reformulated question:
  - Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant scope of the relevant claim(s) of the patent was an essential requirement of the invention?

If no – direct infringement

Question 3 changes

- No real change to question 3



- Except to clarify that too much weight should not be placed on words of claims
- Scope of protection rather than claim interpretation important

Summary

- In summary:
  - Two stages of assessment, i.e. interpretation and considering immaterial variants, need to be kept separate
  - No change to the approach on interpretation
  - Some reformulation of the *Improver* questions, particularly question 2

- Some commentators heralding a revolution
- “Now we have equivalents!”
- In practice, likely to be much less dramatic than that

Application to this case

- Falls into “is this an immaterial variant?” category
  - Qu 1 – yes – inventive concept – manufacturing method enabling pemetrexed anion to be administered with vitamin B12
  - Qu 2 – yes – obvious at priority date that these do so in substantially the same way as the invention
    - Old Qu 2- perhaps not – preparation of other salt forms not a predictable exercise
  - Qu 3 – no – v.unlikely skilled person would have concluded that patentee was intending to specifically exclude certain equivalents (used in the Actavis products) from the scope of protection by the wording of the claim. Spec did not teach essentiality of disodium salt
- RESULT = Actavis products directly infringe Eli Lilly's patent in the UK (France, Italy and Spain)
- Obiter – CofA was correct about indirect infringement

Practice points – drafting and clarity

- “The point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point”
- Try and make your claims clear!
- When framing a description, avoid passages which seem to state that a narrow example or embodiment is essential, or wildly preferred over others, or the only thing that really works
  - But balance with sufficiency and inventive step
- Biotech/chem inventions – seemingly cannot now rely on lack of predictability in arguing variant not obvious (see Qu 2)

Additional practice points

- Patentees could claw back some claim scope after strict EPO added matter approach
  - No basis for broader claim, but scope extends to cover
- Key to distinguish between disclosure of patent specification and scope of protection provided by the claims
- Previous FTOs where it was determined that it would not have been obvious that an potentially infringing variant works in the same way at priority/publication date (but it does in fact work in the same way) should be re-visited
- Future FTOs will need to take this into account

Use of prosecution history

Previous approach:

- Prosecution history not generally referred to or relied upon
- Re-inforced in *Kirin-Amgen* judgement, which stated:
    - Meaning of patent should not change according to whether skilled person has access to the file

- The judgement departs from previous practice:
    - May be occasions when justice may fairly be said to require reference to contents of the file history to determine scope of protection, but must be limited

New approach - prosecution file *can* be considered

- Prosecution file can be considered where:

    1. The point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point; or
    2. It would be contrary to the public interest for the contents of the file to be ignored
        - E.g. where applicant had made it clear to the EPO that he was not seeking to contend that the patent would, if granted, cover this variant

- Sceptical but not absolutist approach

Practice points

- On the facts of this case, judge held these 2 requirements were not met
- EPO practitioners already acutely aware of US prosecution history estoppel – now more important to ensure we do not (unless it is unavoidable) make any kind of statement that even vaguely implies that we do not intend the claims/resulting patent to cover something
- Other than this, practice shouldn't change greatly
- Should not be afraid of making the usual kind of arguments about patentability that we routinely make at the moment

Additional practice points

- In practice, it seems that courts will not refer to the prosecution file often
- However, now we have a judgement saying that the file can be considered - we can expect this argument to be run
- Attacking others' patents:
  - Gives another line of attack - can try to use EPO/IPO prosecution history when considering infringement, or preparing observations on validity
  - For an effective argument, probably need a real lack of clarity in the granted claims, or a reckless statement that the claims are not intended to cover something

Conclusions

- Supreme court cases dealing with interpretation are usually few and far between
- We can expect this decision to set the standard for a while to come

- This case is not (in my opinion) a revolution, but it leads to changes in practice and approach that we need to bear in mind

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Doctrine of Equivalents in the United States

Doctrine of Equivalents in United States

- No statute - Solely case law
- Supreme Court first ruled that infringement may occur even though the literal language of the claims was avoided in *Winans v. Denmead*, 56 U.S. 330 (**1854**)
- *Graver Tank & Manufacturing Co. v. Linde Air Products Co.,* 339 U.S. 605 (**1950**) established two tests for equivalence
  - Triple Identity Test
    - performs substantially the same **function**
    - in substantially the same **way**
    - to yield substantially the same **result**.
  - Insubstantial differences

Doctrine of Equivalents in United States

- *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.,* 520 U.S. 17 (**1997**):
  - Reaffirmed existence of Doctrine of Equivalents
  - All elements rule
    - Equivalence is determined element-by-element
    - Not determined based on claim as a whole
    - Every element of claim must be present either literally or as an equivalent
  - Particular linguistic framework for equivalence is flexible
    - Triple identity test and insubstantial differences retained
    - Left to lower courts to refine specific tests for each case
- Subsequent Federal Circuit decisions clarified:
  - Triple identity test may be relevant in determining equivalence
  - Key is to determine whether one skilled in the art would expect to substitute one thing for the other

Limitations on Doctrine of Equivalents

- All-elements rule from *Warner-Jenkinson*
- Prosecution History Estoppel (*Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.* 535 U.S. 722 (2002))
    - Any narrowing claim amendment creates presumption that narrowed element not entitled to equivalents
        - Exceptions
            - » Equivalent was unforseeable
            - » Reason for amendment was only *tangentially related* to the equivalent
            - » "some other reason"
- Disclosure Dedication Rule
    - Alleged equivalent was disclosed but not claimed
    - If disclosed as an alternative to claimed limitation, presumed dedicated to public

Limitations on Doctrine of Equivalents

- Equivalents Cannot Cover Prior Art (*Wilson Sporting Goods Co. v. Davis Geoffrey & Assoc.*, 904 F.2d 677 (Fed. Cir. 1990))
  - Hypothetical claim that encompasses equivalent
  - Must be patentable over the prior art for Doctrine of Equivalents to apply

Plausibility before the EPO and UK courts

Plausibility – Dasatinib – T0488/16

- Dasatinib has the following structure:

- Developed by Bristol-Myers Squibb – marketed at Sprycel®

- Approved for treating chronic myelogenous leukaemia (CML) and Philadelphia chromosome-positive acute lymphoblastic leukaemia (Ph+ ALL) – being evaluated in other cancers

Plausibility – Dasatinib – T0488/16

- EP1169038 (Owned by Bristol-Myers Squibb Holdings Ireland) - granted 8 August 2012

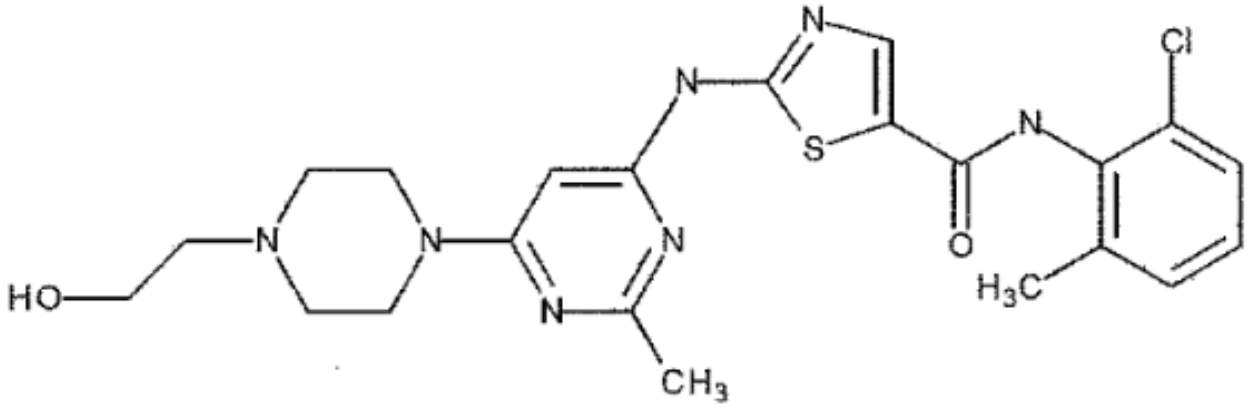
- Opposed by:
  - Anonymous (Isenbruck Bösl Hörschler LLP)
  - Apotex Inc.
  - Actavis Group PTC ehf
  - Generics [UK] Ltd

Plausibility – Dasatinib – T0488/16

- Patent revoked (in full) before OD on 20 January 2016
  - Medical use claims – T609/02 - lack of sufficiency
  - Product *per se* claims – T1329/04 - lack of inventive step
- Patentee appealed revocation
- BoA dismissed appeal in their decision of 1 February 2017- decision issued July 2017
- https://www.epo.org/law-practice/case-law-appeals/pdf/t160488eu1.pdf

Main request on appeal (2nd AR before OD)

1. The compound of formula:



or a salt thereof.

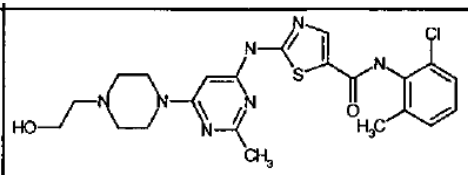
Single, specific compound

Data in the application as filed

Classic NCE case – 100s of characterised compounds

One was dasatinib, although not singled out in the many compounds disclosed (or stated to be particularly advantageous)

Example 455, page 157 of the PCT application:

455		'N-(2-Chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]amino]-5-thiazolecarboxamide	2.717

2717 refers to HPLC retention time

Data in the application as filed

- Application stated compounds of invention inhibit protein tyrosine kinases and are thus useful in treatment of PTK-associated disorders such as immunologic and oncologic disorders

- Included details of assays for protein tyrosine kinase (PTK) inhibition
- And statements that experiments had been done and that the activity of the compounds of the invention (i.e. including dasatinib) had been established

- But no actual experimental data or numerical data for PTK inhibition

1. OD - Sufficiency of medical use claims

- **T609/02**
- Application must show that claimed compound has direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the application *per se*

- Otherwise patent would be granted for technical teaching made after filing date

- Technical contribution at filing date

- Only then can post-published evidence be taken into account

1. Sufficiency of medical use claims - Applying T 609/02

- OD - “enormous number of compounds” falling within broad general formula – no pharmacophore identifiable
- OD - not plausible at filing date - because not credible all compounds in general formula inhibit PTK
- Post-published data could not be used [also data did not show that all family members inhibit the PTK family – casts doubt]
- Skilled person must carry out research program to find which compounds inhibit the PTK family

RESULT = Second medical use claims insufficient

2. BoA - Inventive step of compound *per se* claims

- Compound is **novel**
- Cited prior art did not disclose any compounds that were structurally similar to dasatinib
- No issue under **sufficiency** because Example 455 says how to make the compound
- Issue comes with **inventive step**…

Problem and Solution Approach: Overview

Step 1

- Identify the closest piece of prior art (PA)
  - ID differences between the closest PA and the claimed invention
  - ID the **technical effect** of these differences

Step 2

- Establish **objective technical problem** to be solved base on **technical effect**

Step 3

- Assess whether in the light of the objective technical problem, the prior art **would** (not merely could) prompt the skilled person in the direction of the invention… **with a reasonable expectation of success**

Problem and Solution Approach: A 4th Step

- There is a 4th step
- Comes once objective technical problem has been defined:
  - Is it **plausible** - from the application as filed only - that the objective technical problem has actually been solved by the claimed invention?
- If not:
  - Fall at first hurdle! (see **T1329/04**) – no data in application at all

T1329/04

"The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is **at least made plausible** by the disclosure in the application that its teaching solves indeed the problem it purports to solve.

Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve"

T1329/04: Headnote

Question to be answered

- **Main question** – does application as filed make a plausible and credible disclosure of the claimed invention (i.e. technical effect under-pinning non-obviousness)?

Patentee's arguments

- Statements in application - sufficient to meet the low plausibility threshold, which was satisfied in the absence of any substantiated doubts
- **T578/06** - absolute proof in the form of data not required in the application and EPC does not require data
- Since threshold met, post-published evidence merely confirmed the teachings that dasatinib has PTK-inhibitory activity
- Objection technical problem - provision of an **improved** PTK inhibitor
    - Prior art structurally v.different and no hint of technical effect

BoA's findings

- Even for product *per se* claim - needs to be more than alternative chemical compound – PTK-inhibiting activity has to be plausible
- Dasatinib not singled out in the application as being of particular interest, nor was there any relevant data provided for this compound
- Skilled person would not expect all disclosed compounds to be active against all kinases – absence of verifiable data concerning technical effect means not plausible, so post-published data dismissed
  - Did not help that some pp data did not work
- Broad teachings of compounds and targets give rise to a substantiated doubt that all would work for all targets disclosed
  - **Even** for claim limited to single, specific compound

BoA's findings - 2

- In the absence of verifiable technical evidence, statement in the application not sufficient to establish plausibility:

"*Compounds described in the following Examples have been tested in one or more of these assays, and have shown activity*".

- Broad, generic disclosure covering many compounds with a vague indication of "activity" against PTKs amounts to invitation to perform research project
    - PTK-inhibiting activity not plausible from application as filed

BoA's findings - 3

- 2 expert declarations & inventor declaration filed - useful pharmacophore could be identified from exemplified compounds
- Dismissed by BoA - no structure-activity relationships could be drawn due to complete absence of any data
- Inventor's declaration irrelevant as it concerned information only available to BMS. Although it referred to results obtained before the filing date, these results were not present in application and not provided to EPO during the examination

BoA's findings - 4

- Objective technical problem not plausibly solved because no evidence in application showing technical effect going beyond speculation – post-filed data can't cure this

- Objective technical problem should be formulated in a less ambitious way:

  provision of improved alternative low molecular weight compounds

- Narrow claim lacks IS - mere provision of NCE without showing any technical effect - arbitrary choice which does not require inventive ingenuity

Practice points

- Plausibility threshold slightly raised? “verifiable evidence” should be present in application as filed
- In pharma cases, safest to include some data - *in vitro* or *in vivo*. Data should make it plausible that the compounds have a therapeutic effect
- Data not always required - technical effect must be self-evident, predictable or based on a conclusive theoretical concept – e.g. CGK or explanation in application concerning structure-function relationships
- Consider parallel national applications for particularly important technologies where minimal data is available at filing date

Practice points - 2

- DRAFTING - Dasatinib case appears to have fallen because initial disclosure very broad in terms of compounds and targets

- 4.16.3 BoA referring to *Actavis v Eli Lilly [2015] EWHC 3294*:

- "Generally, it is likely to be easier, as a matter of fact, to show plausibility for a claim of narrow scope, for example a single drug for a single disease, than for a claim of wide scope, for example a class of drugs for multiple diseases". This statement has to be seen in the context of the case underlying the UK High Court decision, which was concerned with the use of tomoxetine in the treatment of attention-deficit/hyperactivity disorder, **i. e. a single use for a single disease**. In the present case, the application as filed was concerned with an extremely broadly defined group of compounds for a plethora of disorders based on the inhibition of different types of PTKs associated with the treatment of different diseases or disorders. This is a completely different situation, irrespective of the fact that the present main request is now limited to a single compound." [Emphasis added]

Practice points - 3

- Safest to include sub-groups e.g. pharmacophores and have data/structure-function relationship in the application

- If referring to tests done but not disclosed:
    - be specific about which compounds and targets.
    - include detail on results and parameters used e.g. 10-fold increase over other named prior art compounds at specified concentration

- Make sure post-published data is consistent with teachings

Other cases in this area – threshold met

- **T1677/11, T1642/07 and T210/11** – no data but CGK and/or technical explanation in patent gave no substantiated doubts
- **T716/08** – screening examples in combo with CGK
- **T1336/04 & T604/04** - structural similarity to known members of a particular family
- **T433/05 & T108/09** – at least a plausible theoretical concept
  - T433/05 - improving *in vivo* stability of known peptides via coupling to a long living blood component
  - T108/09 - use of a known second-line agent in treatment of breast cancer as third-line agent for same disease – app contained protocol for clinical trial but not its results

Plausibility threshold – compounds *per se*

- No data or verifiable evidence & no structure-activity link (CGK or in app)
  - T1329/04, T0488/16

THRESHOLD LIMIT

- No data but CGK and/or convincing technical explanation in app
- *In vitro* data for invention claimed & technical explanation for broadening of claim (THRESHOLD here for medical use claims)
- *In vitro* data for all claimed embodiments

UK – *Warner Lambert v Generics & Actavis*

- Medical use – pregabalin for treating pain
  - Includes central neuropathic and peripheral neuropathic pain
  - Experimental models used could not measure effects CNS
  - Not plausible that pregabalin would be effective for all types of pain

RESULT = claims invalid for lack of sufficiency

- 2 types of insufficiency:
  - "Classical insufficiency" – failure to enable invention to be performed without undue burden
  - "*Biogen* insufficiency" – failure to enable invention to be performed over whole scope of claim

UK – *Warner Lambert v Generics & Actavis*

Principles:

- Mere assertion compound X suitable for treating disease Y not sufficient
- Eg of adequate support – experimental tests showing claimed compound has direct effect on a metabolic mechanism involved in the disease
- Post-published data not admissible if it alone renders invention plausible
- Sufficiency requires placing reader in possession of invention without imposing undue burden by way of further research

- FR, SE & SE decisions in favour of WL
- Heading for Supreme Court

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Utility in the United States

Utility

- 35 U.S.C. § 101: Whoever invents or discovers any new and **useful** process, machine, manufacture, or composition of matter . . .
  - At least some "utility" must either be disclosed in specification or be well-established in the art
    - Utility must be specific and substantial
    - Use of complex machinery as boat anchor would be insubstantial
  - Utility must be credible
    - If more than one utility present, only one needs to be credible
    - However, if multiple utilities claimed and not all are credible, claims may be invalid as overly broad for lack of enablement

Prima Facie Showing of Lack of Utility

- Establish that it is more likely than not that one of ordinary skill in the art would doubt the truth of Applicant's asserted utility
- Alternatively, establish that no utility would be apparent to a person of ordinary skill in the art

"Real World Value"

- "Immediate benefit to the public"
- Any reasonable use that provides a public benefit
- As long as specification provides one credible utility, requirement is satisfied
- Wholly inoperative inventions do not provide a public benefit
- Partially inoperative inventions may be rejected under § 112(a)

Requirements for Utility to be "Incredible"

- Violate a scientific principle
- Violate a law of nature
- Wholly inconsistent with contemporary knowledge in the art

Examples of "Incredible" Utility

- An invention to change the taste of food using a magnetic field
- A perpetual motion machine
- A method for increasing the energy output of fossil fuels through exposure to a magnetic field
- Uncharacterized compositions for curing cancer (*In re Citron*)
- A method of restoring hair growth

Therapeutic Utility

- Mere identification of pharmacological activity is sufficient
- Data from *in vitro* and animal testing is generally sufficient to support therapeutic utility
- Utility established if tests would be viewed by one of ordinary skill in the art to be reasonably predictive
- Safety and efficacy considerations are the domain of the FDA, not the Patent and Trademark Office

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