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Writing a 35 USC 112(a)- Enablement Rejection

Methods of Treatment with Organic Compounds- TC 1600

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Objectives

- Review of Wands Factors
- Example of a less than ideal rejection on how to apply the Wands Factors
- Examples of better rejections on how to apply the Wands Factors

Wands Factors MPEP §2164.04

<u>Undue Experimentation Factors (Wands Factors)</u>

(a) The breadth of the claims;

(b) The nature of the invention;

(c) The state of the prior art;

(d) The level or ordinary skill in the art;

(e) The level of predictability in the art;

(f) The amount of direction provided by the inventor

(g) The existence of working examples; and

(h) The quantity of experimentation needed to make use of the invention based on the content of the disclosure

Example

- Claim 1: A method of treating a neurological disease selected from a group consisting of vascular dementia, spinal cord trauma, Huntington's chorea, Alzheimer's disease, Parkinson's disease, and age-related disorders comprising administering to a subject in need thereof an effective amount of compound X.

- The specification discloses that compound X inhibits acetylcholinesterase.

A Less Than Ideal Rejection

Claim 1 is rejected under 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, because the specification, while possibly enabling for some diseases, does not reasonably provide enablement for the full scope of the claim. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claim.

Rejection continues on next slide

A Less Than Ideal Rejection (*cont.*)

Wands analysis of the Claim in the rejection (**The breadth of the Claim**):

The claim is broad, encompassing many different neurological diseases. Spinal cord trauma is not a disease at all.

The nature of the invention is a method of treating neurological disease comprising administering compound X.

A Less Than Ideal Rejection (*cont.*)

Wands analysis of the Claim in the rejection (**The state of the prior art**):

The prior art teaches that treatment of neurological diseases is difficult. Neurological diseases have different causes and progress differently; no single agent can treat them all. Further, such treatment as is available does not treat the disease itself, only the symptoms.

A Less Than Ideal Rejection (*cont.*)

Wands analysis of the Claim in the rejection (**The level of ordinary skill and the level of predictability in the art**):

One of ordinary skill in the art would have an M.D.

The art generally teaches that treatment of neurological disease is unpredictable.

A Less Than Ideal Rejection (*cont.*)

Wands analysis of the Claim in the rejection (**The working examples discussion**):

No working examples are provided. The specification shows only *in vitro* results.

Thus, since there are many different causes of neurological diseases and no single agent can be expected to treat them all, and only *in vitro* results are shown, it would require undue experimentation to practice the invention commensurate in scope with the claims.

What's Wrong with All of This?

- The rejection is generic. The specific teachings of the specification and the art are not addressed.
- It doesn't address the limitations of the claim.
- It doesn't specify what is enabled, (i.e., the rejection states that the specification is "possibly enabling" for some of its scope and does not specifically state what portion of the claims are enabled.)

Here’s a Better Approach:

- The specification is in fact enabling for treatment of Alzheimer’s disease. Acetylcholinesterase inhibitors do that. A quick search also shows that they’ve been used to treat Parkinson’s disease. They’ve been tried for vascular dementia but didn’t work. Nothing else shows up in our search.
- So, here’s our fact-specific rejection and Wands analysis:

Better Rejection

Claim 1 is rejected under 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, because the specification, while enabling for the treatment of Alzheimer's and Parkinson's diseases, does not reasonably provide enablement for the full scope of the claim. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claim.

Better Rejection (*cont.*)

Wands Analysis of the Claim in the rejection (**The breadth of the Claim**)

The claim is broad, encompassing many different neurological diseases. Vascular dementia, Huntington's chorea, Alzheimer's disease, and Parkinson's disease all have different causes, affect different physiological processes, and are treated with different agents. "Age-related disorders" encompasses many conditions, including those not affecting the nervous system. Spinal cord trauma is not a disease at all.

The **nature of the invention** is a process of treatment of all of these different diseases and conditions with a novel agent that inhibits acetylcholinesterase.

Better Rejection (*cont.*)

Wands analysis of the Claim in the rejection (**The state of the prior art**):

The prior art teaches that acetylcholinesterase inhibitors are useful for treatment of Alzheimer's disease (Wilkinson et al., Drugs Aging 2004) and Parkinson's disease (Werber et al., J. Neural Transm 2001). Treatment of vascular dementia has proven unsuccessful (Kavirajan et al., Lancet Neurol 2007). Limited studies in animal models have indicated potential use in moderation of damage resulting from spinal cord injury, but such studies are preliminary in nature (Antar et al., J. Neurosurg Sci 2015). Clinical trials have failed to show any efficacy in Huntington's disease (Vattakatuchery et al., WJP, 2013). The prior art does not appear to provide any evidence as to treatment of the other conditions recited in the instant claim.

Better Rejection (*cont.*)

Wands analysis of the Claim in the rejection (**The level of ordinary skill in the art**):

An ordinary artisan in the area of drug development would have experience in screening chemical compounds for particular activities. Screening of new drug candidates, while complex, is routine in the art. The process of finding new drugs that have *in vitro* activity against a particular biological target, (i.e., receptor, enzyme, etc.) is well known. Additionally, while high throughput screening assays can often be employed, developing a therapeutic method, as claimed, is generally not well-known or routine, given the complexity of certain biological systems such as the brain.

Better Rejection (*cont.*)

Wands analysis of the Claim in the rejection (**The level of ordinary skill in the art**) (*cont.*):

Determining how a particular chemical will impact the brain is not routine. There is no chemical targeting system at this time that can directly stimulate or block only a highly specific cluster of neurons while avoiding effects on other neurons of the same class where the same signal may have a different and unwanted effect. Further, the functioning of many neuronal systems and the pathology of many neurologic diseases involve complex systems involving more than one neurotransmitter (NeuroRX, Vol 1, No. 1, 2004). Thus, the level of ordinary skill in the art of treating neurodegenerative diseases is high, as an ordinary artisan in this art needs specialized knowledge of the complex nature of the brain.

Better Rejection (*cont.*)

Wands analysis of the Claim in the rejection (**The level of predictability in the art**):

While the use of acetylcholinesterase (AChE) inhibitors for treatment of Alzheimer's and Parkinson's disease is well known, the use of such agents to treat other diseases and conditions within the scope of the claim is not predictable. For instance, while AChE inhibitors are used to treat AD and Parkinson's disease (both neurodegenerative diseases) and are used to treat cognitive decline, a clinical study found that donepezil (an AChE inhibitor), was ineffective in improving either motor or cognitive dysfunction in HD (Pidgeon et al. Behavioural Neurology 26 2013). Thus, it is unpredictable whether an agent used for one type of neurodegenerative disease can be used to treat another neurodegenerative disease, even when the conditions share symptoms. The predictability of applying an AChE inhibitor to treatment of vascular dementia, spinal cord trauma and the various "age-related" disorders encompassed by the instant claim would be low given that there doesn't appear to a link between AChE inhibitors and treatment of these conditions.

Better Rejection (*cont.*)

Wands analysis of the Claim in the rejection (**The amount of guidance and working examples discussion**):

The specification shows that compound X inhibits acetylcholinesterase. Since such agents are well known to treat Parkinson's and Alzheimer's diseases, there is a nexus between *in vitro* results and the treatment of these diseases, but not to the full scope of the treatment claimed. The specification does not provide any additional examples or guidance on how to use the AChE inhibitor to treat the additional conditions recited in the claim.

Thus, the specification provides sufficient teachings only for the enablement of treatment of Parkinson's and Alzheimer's disease. The prior art provides no compensatory guidance, and since attempts to treat other neurodegenerative diseases, such as Huntington's disease, with AChE inhibitors have been unsuccessful, it would require undue experimentation to practice the invention as broadly claimed.

Better Rejection (*cont.*)

Wands analysis of the Claim in the rejection (working examples discussion):

The amount of experimentation would be undue because it would require determining which of the conditions listed in the instant claim would be reasonably treated with the AChE inhibitor of the claim. Since, as discussed above, it is not routine to determine how a chemical will act on the brain to treat different neurological conditions, knowing only that the compound of the instant claim inhibits AChE would mean that significant experimentation would be required to determine which other conditions the compound could treat. This is because one cannot extrapolate between the activity of the compound as an AChE inhibitor and the treatment of the other disorders claimed and since there is little guidance (in both the prior art and the specification) with respect to the use of such compounds for other disorders claimed.

Why is This Better?

- It's correct.
- It makes specific points for the attorney to respond to
- By specifying enabled embodiments, the examiner may be able to bring the case to allowance more quickly

Another Example

Claim 1. A method of treating an autoimmune condition selected from a group consisting of Crohn's disease, inflammatory bowel disease, organ transplant rejection, lupus, rheumatoid arthritis, psoriasis, and multiple sclerosis comprising administering to a patient in need thereof an effective amount of compound X.

The specification shows that compound X inhibits T-cell activation, like cyclosporine, which is a well-known immunosuppressive agent. Cyclosporine is known to treat Crohn's disease, inflammatory bowel disease, organ transplant rejection, lupus, rheumatoid arthritis, psoriasis and multiple sclerosis.

We Start the Wands Analysis and Find:

- **The Breadth of the Claims**: The claim encompasses several conditions, but they all have something in common. They are the result of the body's immune system attacking an organ.
- **The Nature of the Invention**: The invention is drawn to the use of an immunosuppressive agent to treat these conditions. While the claims recite several conditions, the conditions are related in that they are all autoimmune conditions. Further, they can all be treated with the same agent, cyclosporine. This agent inhibits t-cell activation, since compound X also has this activity, it is reasonable to expect that it would also be useful in treating these conditions.

We Start the Wands Analysis and Find (*cont.*):

- **State of the Prior Art** The background of the specification mentions this similarity to cyclosporine, and while there are no examples wherein compound X was administered to patients with claimed conditions, it is reasonable to presume that compound X, due to its similarity to cyclosporine, would be used in the same manner.
- **Predictability in the Art**: Due to the predictability in the art, it would not require undue experimentation to use the compound in the manner recited in the claims. Determining dosing, routes of administration regimens would be routine in the art. Thus, one could practice the claimed invention without undue experimentation.

Summary

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- Example of a less than ideal rejection on how to apply the Wands Factors
- Examples of better rejections on how to apply the Wands Factors

Questions ???

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