

Routine Optimization

Jean Witz, tQAS, TC1600
571-272-0927

Basis of a Rejection Under 35 U.S.C. 103

The standard of patentability under 35 USC 103 was described by the Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966):

- Determining the scope and contents of the prior art
- Ascertaining the differences between the prior art and the claims in issue
- Resolving the level of ordinary skill in the pertinent art
- Evaluating evidence of secondary considerations

In re Aller, 220 F.2d 454, 105 USPQ 233 (CCPA 1955)

- Invention: process for production of phenols using sulfuric acid with acetone as a by-product
- Claimed process was identical to prior art **except** for lower temperatures and higher sulfuric acid concentrations
- Claims: 25 - 70% H₂SO₄ at 40 - 80° C
- Prior Art: 10% H₂SO₄ at 100 ° C

***In re Aller*, 220 F.2d 454, 105 USPQ 233 (CCPA 1955)**

- Prior art phenol yield was 75% while Appellants showed phenol yields from 83.7 – 100%
- Prior art acetone yield was about 60% while Appellants' acetone yield was 71 - 88%
- Examiner asserted that the claimed conditions resulted from routine experimentation to determine the optimum reaction condition
- Appellants asserted that the claimed conditions produced unexpected results

***In re Aller*, 220 F.2d 454, 105 USPQ 233 (CCPA 1955)**

- Appellants contended that the claimed conditions would not have been discovered by one skilled in the art
- The court held that it would have been expected that the reaction rate would have been slowed at a known rate when the temperature was reduced, and that the reaction rate would have been accelerated at a known rate by an increase in acid concentration

***In re Aller*, 220 F.2d 454, 105 USPQ 233 (CCPA 1955)**

- No evidence of a critical temperature range or acid concentration
- “Any chemist reading the [prior art] could logically assume that higher yields might be obtainable, and by experimentally varying the conditions of temperature and acidity could find the most productive conditions”

Highlights and Guidance

- MPEP 2144.05 - Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical
- If the prior art recognizes the known effect attributed to a claimed parameter, then it is logical to conclude that changes to that parameter produce expected results

Highlights and Guidance, cont'd

- “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *Aller* at 456.
- *Aller* stands for the proposition that it would have been obvious to one of ordinary skill in the art at the time the invention was made to engage in routine experimentation to determine optimal or workable ranges that produce expected results.
- This proposition may be rebutted by objective evidence of unexpected results.

***In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969)**

- Invention: Polyurethane elastomers exhibiting strength and resilience and while remaining soft for protracted periods at low temperatures
- Claims: Elastomers containing specific proportions and specific molecular weights of specific glycols: PTME and PPE
- Prior art: mixtures of two or more of glycols such as PPE or PTME are used to produce elastomers which have excellent resistance to heat and cold, a low brittle point and are particularly useful for fabricating articles to be used at low temperatures, such as -20° C

***In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969)**

- The prior art identified the products to be made from these elastomers (tires, inner tubes and belts)
- The Examiner asserted that optimization of the amounts and molecular weights of each glycol was routine
- Appellant asserted an unexpected improvement in long-term freeze resistance

***In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969)**

- The court found that the results of claimed combination were not unexpected
- The prior art recognized a lack of brittleness of the elastomers at freezing temperatures
- There was no evidence of criticality of the claimed molar proportions or ranges of molecular weights

Highlights and Guidance

- *Hoeschele* is consistent with the holding in *Aller*
- When claimed properties are expected, routine optimization permits a finding of obviousness in the absence of objective evidence of unexpected or critical properties

***In re Orfeo*, 440 F.2d 439, 169 USPQ 487 (CCPA 1971)**

- Invention: Refrigeration process utilizing a mixture of trifluoromethane (CHF_3) and monochlorotrifluoromethane (CClF_3)
- Claims: process of producing refrigeration comprising condensing a mixture consisting of CHF_3 and CClF_3 having CHF_3 in the range of about 20-75 mole %

***In re Orfeo*, 440 F.2d 439, 169 USPQ 487 (CCPA 1971)**

- Prior Art: CHF_3 and CClF_3 each had been used individually as refrigerants
- Prior Art: method of preparing fluorochlorohydrocarbons resulting in a mixture of CClF_3 and CHF_3 having desirable temperature ranges and suitable for use as refrigerants
- The examiner asserted routine optimization to find claimed amounts of refrigerants

***In re Orfeo*, 440 F.2d 439, 169 USPQ 487 (CCPA 1971)**

- Rule 132 affidavit - showed that the use of the CHF₃/ CCIF₃ mixture as a refrigerant produces a new and unexpected reduction in power requirements lower than the individual power requirements of CHF₃ or CCIF₃

***In re Orfeo*, 440 F.2d 439, 169 USPQ 487 (CCPA 1971)**

- The Board stated that improved refrigeration was expected in view of known lower boiling point of the combination
- The court found “no indication that the lower boiling point is directly responsible for the lower power requirement, and, to the contrary, it appears that there are numerous factors (some of them not fully comprehended) which lead to the unexpectedly low power requirement of the [mixture].”

Highlights and Guidance

- Results that are unexpected in view of the disclosure of the prior art may overcome an examiner's finding of obviousness

Federal Circuit Cases Addressing Routine Optimization

- *Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989)
- *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990)
- *In re Huang*, 100 F.3d 135, 40 USPQ2d 1685 (Fed. Cir. 1996)

***Pfizer, Inc. v. Apotex, Inc.* 480 F.3d 1348,
82 USPQ2d 1321 (Fed. Cir. 2007)**

- Pfizer held patents to amlodipine and to amlodipine besylate salt
- Apotex filed ANDA with the FDA for generic amlodipine besylate tablets prior to expiration of Pfizer's patent
- Pfizer filed suit alleging infringement
- Apotex countersued alleging invalidity

***Pfizer, Inc. v. Apotex, Inc.* 480 F.3d 1348, 82 USPQ2d 1321 (Fed. Cir. 2007)**

- Apotex argued that prior patent to Pfizer for amlopidine salts combined with prior art to the conventional use of besylate salts in pharmaceutical formulations rendered the claims to amlopidine besylate in the second Pfizer patent obvious
- District Court found for Pfizer
- Apotex appealed to the Fed. Cir.

***Pfizer, Inc. v. Apotex, Inc.* 480 F.3d 1348,
82 USPQ2d 1321 (Fed. Cir. 2007)**

- Pfizer asserted and provided evidence that the besylate salt produced improvements in formulation and stability over the maleate salt

***Pfizer, Inc. v. Apotex, Inc.* 480 F.3d 1348, 82 USPQ2d 1321 (Fed. Cir. 2007)**

- The court points to the specific facts in the case to conclude that the amount of experimentation was routine because
 - it was conventional to produce a variety of acid addition salts for any given pharmaceutical formulation
 - the prior art showed that it was routine to verify the expected physiochemical characteristics of each salt

Highlights and Guidance

- When all claimed elements are present in the prior art but differ in specific values, an obviousness rejection may be made
- Evidence that an element is result-effective may be important
- Evidence of unexpected results should always be considered by the examiner
- Verify that the scope of the claims are commensurate with evidence of unexpected results

Questions?

- Jean Witz, QAS, TC1600
- jean.witz@uspto.gov
- 571-272-0927