(Federal Domestic Assistance Catalog 11.419 Coast Zone Management Program Administration)

Dated: February 6, 1997.

David L. Evans,

Acting Deputy Assistant, Administrator for Ocean Services and Coastal Zone Management, National Oceanic and Atmospheric Administration.

Robert H. Wayland, III,

Director, Office of Wetlands, Oceans and Watersheds, Environmental Protection Agency.

[FR Doc. 97–3397 Filed 2–10–97; 8:45 am]

BILLING CODE 3510–12–M

[I.D. 020497B]

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will convene a public meeting of the Standing and Special Reef Fish Scientific and Statistical Committee (SSC).

DATES: The meeting will be held on March 3, 1997, from 9:00 a.m. to 4:00 p.m.

ADDRESSES: The meeting will be held at the Holiday Inn Crown Plaza, 333 Poydras Street, New Orleans, LA; telephone 504–525–9444.

Council address: Gulf of Mexico Fishery Management Council, 3018 U.S. Highway 301 North, Suite 1000, Tampa, FL 33619.

FOR FURTHER INFORMATION CONTACT: Wayne E. Swingle, Executive Director, Gulf of Mexico Fishery Management Council; telephone: 813–228–2815.

SUPPLEMENTARY INFORMATION: The Reef Fish SSC will review additional analyses of shrimp trawl bycatch of red snapper prepared by NMFS. These analyses may include revisions to the data base and to the methodology based on recommendations developed at the Reef Fish Stock Assessment Panel (RFSAP) meeting held February 12–14, 1997.

The SSC will also consider recommendations, if any, of the RFSAP for phasing in over a 3-year period levels of total allowable catch, bag limits, and quotas for vermilion snapper in the Gulf of Mexico. The SSC will develop their recommendations to the Council on these issues.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Anne Alford at the Council (see **ADDRESSES**) by February 24, 1997.

Dated: February 5, 1997.

Bruce Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 97–3259 Filed 2–10–97; 8:45 am]

BILLING CODE 3510–22–F

Patent and Trademark Office

[Docket No. 970129014–7014–01]

RIN 0651–XX09

Interim Guidelines for the Examination of Claims Directed to Species of Chemical Compositions Based Upon a Single Prior Art Reference

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: The Patent and Trademark Office (PTO) requests comments from any interested member of the public on interim guidelines to be used by office personnel in their review of patent applications which contain claims directed to a species or subgenus of chemical compositions for compliance with 35 U.S.C. 103 based upon a single prior art reference which discloses a genus embracing the claimed species or subgenus but does not expressly describe the particular claimed species or subgenus.

DATES: The interim guidelines are effective February 11, 1997.

Written comments on the interim guidelines will be accepted by the PTO until April 14, 1997.

ADDRESSES: Written comments should be addressed to the attention of Linda Moncys Isacson, Office of the Solicitor, P.O. Box 15667, Arlington, Virginia 22215 or to Linda S. Therkorn, Box Comments, Assistant Commissioner for Patents, Washington, DC. 20231, or by facsimile transmission to (703) 305–9373 or by electronic mail to baird-comments@uspto.gov.

Written comments will be made available for public inspection at the Patent Search Room, Crystal Plaza 3, 2021 South Clark Place, Arlington, VA. In addition, comments provided in machine-readable format will be available through the PTO's Website at http://www.uspto.gov.

FOR FURTHER INFORMATION CONTACT: Linda Moncys Isacson, Office of the Solicitor, P.O. Box 15667, Arlington, Virginia 22215 or Linda S. Therkorn, Box Comments, Assistant Commissioner for Patents, Washington, DC. 20231, or by facsimile transmission to (703) 305–9373 or by electronic mail to baird-comments@uspto.gov.

SUPPLEMENTARY INFORMATION: The Commissioner of Patents and Trademarks issued a Notice in the Official Gazette (O.G.) on April 17, 1995 (1174 O.G. 68), withdrawing the Office's March 22, 1994 O.G. Notice (1161 O.G. 314). Both notices were entitled ''In re Baird.'' Pursuant to the April 17, 1995 O.G. Notice, the following interim examination guidelines are being published for public comment. The purpose of these guidelines is to assist PTO personnel in the examination of applications which contain claims directed to a species or subgenus of chemical compositions for compliance with 35 U.S.C. 103 based upon a single prior art reference which discloses a genus embracing the claimed species or subgenus but does not expressly describe the particular claimed species or subgenus. Thereof, these interim guidelines will be referred to as ''Genus-Species Guidelines.''

It has been determined that these interim guidelines are not a significant rule for purposes of Executive Order 12866. Because these guidelines govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

Members of the public may present written comments on these guidelines. Written comments should include the following information:

—Name and affiliation of the individual responding;

—An indication of whether the comments offered represent views of the respondent's organization or are the respondent's personal views; and

—If applicable, information on the respondent's organization, including the type of organization (e.g., business, trade group, university, nonprofit organization).

The PTO is particularly interested in comments relating to the accuracy of the emphasized prior art teachings, and comments identifying any additional teachings that should be emphasized in determining whether a prima facie case of obviousness exists in the types of cases covered by these interim guidelines. The PTO is also interested in comments relating to the effect these guidelines may have on future application submissions.

Dated: February 5, 1997.

Bruce A. Lehman,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

I. Interim Guidelines for the Examination of Claims Directed to Species of Chemical Compositions Based Upon a Single Prior Art Reference

These ''Genus-Species Guidelines'' are to assist Office personnel in the examination of applications which contain claims to species or a subgenus of chemical compositions for compliance with 35 U.S.C. 103 based upon a single prior art reference which discloses a genus encompassing the claimed species or subgenus but does not expressly disclose the particular claimed species or subgenus. Office personnel should attempt to find additional prior art to show that the differences between the prior art primary reference and the claimed invention as a whole would have been obvious. Where such additional prior art is not found, Office personnel should follow these guidelines to determine whether a single reference 35 U.S.C. 103 rejection would be appropriate. The guidelines are based on the Office's current understanding of the law and are believed to be fully consistent with binding precedent of the Supreme Court, the Federal Circuit, and the Federal Circuit's predecessor courts.

The analysis of the guidelines begins at the point during examination after a single prior art reference is found disclosing a genus encompassing the claimed species or subgenus. Before reaching this point, Office personnel should follow normal examination procedures. Accordingly, Office personnel should first analyze the claims as a whole in light of and consistent with the written description, considering all claim limitations.[1] Next, Office personnel should conduct a thorough search of the prior art and identify all relevant references.[2] If the most relevant prior art consists of a single prior art reference disclosing a genus encompassing the claimed species or subgenus, Office personnel should follow the guidelines set forth herein.

These guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rather, they are to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Thus, rejections must be based upon the substantive law, and it is these rejections which are appealable, not any failure by Office personnel to follow these guidelines.

Office personnel are to rely on these guidelines in the event of any inconsistent treatment of issues between these guidelines and any earlier provided guidance from the Office.

II. Determine Whether the Claimed Species or Subgenus Would Have Been Obvious to One of Ordinary Skill in the Pertinent Art at the Time the Invention Was Made

The patentability of a claim to a specific compound or subgenus embraced by a prior art genus should be analyzed no differently than any other claim for purposes of 35 U.S.C. 103.[3] A determination of patentability under 35 U.S.C. 103 should be made upon the facts of the particular case in view of the totality of the circumstances.[4] Use of per se rules by Office personnel is improper for determining whether claimed subject matter would have been obvious under 35 U.S.C. 103.[5] The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness.[6]

A proper obviousness analysis involves a three-step process. First, Office personnel should establish a prima facie case of unpatentability considering the factors set out by the Supreme Court in Graham v. John Deere.[7] If a prima facie case is established, the burden shifts to applicant to come forward with rebuttal evidence or argument to overcome the prima facie case.[8]

Finally, Office personnel should evaluate the totality of the facts and all of the evidence to determine whether they still support a conclusion that the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made.[9]

A. Establishing a Prima Facie Case of Obviousness

To establish a prima facie case of obviousness in a genus-species chemical composition situation, as in any other 35 U.S.C. 103 case, it is essential that Office personnel find some motivation or suggestion to make the claimed invention in light of the prior art teachings.[10] In order to find such motivation or suggestion there should be a reasonable likelihood that the claimed invention would have the properties disclosed by the prior art teachings.[11] These disclosed findings should be made with a complete understanding of the first three ''Graham factors.'' [12] Thus, Office personnel should (1) determine the ''scope and content of the prior art''; (2) ascertain the ''differences between the prior art and the claims at issue''; and (3) determine ''the level of ordinary skill in the pertinent art.'' [13]

1. Determine the Scope and Content of the Prior Art

As an initial matter, Office personnel should determine the scope and content of the relevant prior art. Each reference must qualify as prior art under 35 U.S.C. 102,[14] and should be in the field of applicant's endeavor, or be reasonably pertinent to the particular problem with which the inventor was concerned.[15]

In the case of a prior art reference disclosing a genus, Office personnel should make findings as to (1) the structure of the disclosed prior art genus and that of any expressly described species or subgenus within the genus; (2) any physical or chemical properties and utilities disclosed for the genus, as well as any suggested limitations on the usefulness of the genus, and any problems alleged to be addressed by the genus; (3) the predictability of the technology; and (4) the number of species encompassed by the genus taking into consideration all of the variables possible.

2. Ascertain the Differences Between the Prior Art Genus and the Claimed Species or Subgenus

Once a relevant prior art genus is identified, Office personnel should compare it to the claimed species or subgenus to determine the differences. Through this comparison, the closest disclosed species or subgenus in the prior art reference should be identified and compared to that claimed. Office personnel should make explicit findings on the similarities and differences between the closest prior art reference and the claimed species or subgenus including findings relating to similarity of structure, chemical properties and utilities.[16]

3. Determine the Level of Skill in the Art

Office personnel should evaluate the prior art from the standpoint of the hypothetical person having ordinary skill in the art at the time the claimed invention was made.[17] In most cases, the only facts of record pertaining to the level of skill in the art will be found within the prior art reference. However, any additional evidence presented by applicant should be evaluated.

4. Determine Whether One of Ordinary Skill in the Art Would Have Been Motivated To Select the Claimed Species or Subgenus

In light of the findings made relating to the three Graham factors, Office personnel should determine whether one of ordinary skill in the relevant art would have been motivated to make the claimed invention as a hole, i.e., to select the claimed species or subgenus from the disclosed prior art genus.[18] To address this key issue, Office personnel should consider all relevant prior art teachings, focusing on the following, where present.

a. Consider the Size of the Genus. Consider the size of the prior art genus, bearing in mind that size alone cannot support an obviousness rejection.[19] There is no absolute correlation between the size of the prior art genus and a conclusion of obviousness.[20] Thus, the mere fact that a prior art genus contains a small number of members does not create a per se rule of obviousness. Some motivation to select the claimed species or subgenus must be taught by the prior art.[21] However, a genus may be so small that it would anticipate the claimed species or subgenus. For example, it has been held that a prior art genus containing only 20 compounds inherently anticipated a claimed species within the genus because ''one skilled in (the) art would * * * envisage each member'' of the genus.[22]

b. Consider the Express Teachings. If the prior art reference expressly teaches a particular reason to select the claimed species or subgenus, Office personnel should point out the express disclosure which would have motivated one of ordinary skill in the art to select the claimed invention.[23]

c. Consider the Teachings of Structural Similarity. Consider any teachings of a ''typical,'' ''preferred,'' or ''optimum'' species or subgenus within the disclosed genus. If such a species or subgenus is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species or subgenus from the genus,[24] based on the reasonable expectation that structurally similar species usually have similar properties.[25] The utility of such properties will normally provide some motivation to make the claimed species or subgenus.[26]

In making an obviousness determination, Office personnel should consider the number of variables which must be selected or modified, and the nature and significance of the differences between the prior art and the claimed invention.[27] The closer the physical and chemical similarities between the claimed species or subgenus and any exemplary species or subgenus disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner to the genus.[28]

Similarly, consider any teaching or suggestion in the reference of a preferred species or subgenus that is significantly different in structure from the claimed species or subgenus. Such a teaching may weigh against selecting the claimed species or subgenus and thus against a determination of obviousness.[29] For example, teachings of preferred species of a complex nature within a disclosed genus may motivate an artisan of ordinary skill to make similar complex species and thus teach away from making simple species within the genus.[30] Concepts used to analyze the structural similarity of chemical compounds in other types of chemical cases are equally useful in analyzing genus-species cases.[31] Generally, some teaching of a structural similarity will be necessary to suggest selection of the claimed species or subgenus[32]

d. Consider the Teachings of Similar Properties or Uses. Consider the properties and utilities of the structurally similar prior art species or subgenus. It is the properties and utilities that provide real world motivation for a person of ordinary skill to make species structurally similar to those in the prior art.[33] Conversely, lack of any known useful properties weighs against a finding of motivation to make or select a species or subgenus.[34] However, the prior art need not disclose a newly discovered property in order for there to be a prima facie case of obviousness.[35] If the claimed invention and the structurally similar prior art species share a useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species.[36] For example, based on a finding that a tri-orthoester and a tetra-orthoester behave similarly in certain chemical reactions, it has been held that one of ordinary skill in the relevant art would have been motivated to select either structure.[37] In fact, similar properties may normally be presumed when compounds are very close in structure.[38] Thus, evidence of similar properties weighs in favor of a conclusion that the claimed invention would have been obvious.[39]

e. Consider the Predictability of the Technology. Consider the predictability of the technology.[40] If the technology is unpredictable, it is less likely that structurally similar species will render a claimed species obvious because it may not be reasonable to infer that they would share similar properties.[41] However, obviousness does not require absolute predictability, only a reasonable expectation of success, i.e., a reasonable expectation of obtaining similar properties.[42]

f. Consider Any Other Teaching to Support the Selection of the Species or Subgenus. The categories of relevant teachings enumerated above are those most frequently encountered in a genus-species case, but they are not exclusive. Office personnel should consider the totality of the evidence in each case. In unusual cases, there may be other relevant teachings sufficient to support the selection of the species or subgenus and, therefore, a conclusion of obviousness.

5. Make Express Fact-Findings and Determine Whether They Support A Prima Facie Case of Obviousness

Based on the evidence as a whole,[43] Office personnel should make express fact-findings relating to the Graham factors, focusing primarily on the prior art teachings discussed above. The fact-findings should specifically articulate what teachings or suggestions in the prior art would have motivated one of ordinary skill in the art to select the claimed species or subgenus.[4] Thereafter, it should be determined whether these findings, considered as a whole, support a prima facie case that the claimed invention would have been obvious to one of ordinary skill in the relevant art at the time the invention was made.

B. Determining Whether Rebuttal Evidence Is Sufficient To Overcome the Prima Facie Case of Obviousness

If a prima facie case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the prima facie case.[45] Rebuttal evidence and arguments can be presented in the specification,[46] by counsel,[47] or by way of an affidavit or declaration under 37 CFR 1.132.[48] However, arguments of counsel cannot take the place of factually supported objective evidence.[49]

Office personnel should consider all rebuttal arguments and evidence presented by applicants.[50] Rebuttal evidence may include evidence of ''secondary consideration,'' such as ''commercial success, long felt but unsolved needs, (and) failure of others,''[51] evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art,[52] or evidence that the claimed invention was copied

by others.[53] It may also include evidence of the state of the art, the level of skill in the art, and the beliefs of those skilled in the art.[54]

Consideration of rebuttal evidence and arguments requires Office personnel to weigh the proffered evidence and arguments. Office personnel should avoid giving evidence no weight, except in rare circumstances.[55] However, to be entitled to substantial weight the applicant should establish a nexus between the rebuttal evidence and the claimed invention,[56] i.e., objective evidence of nonobviousness must be attributable to the claimed invention.[57] Additionally, the evidence must be reasonably commensurate in scope with the claimed invention.[58] However, an exemplary showing may be sufficient to establish a reasonable correlation between the showing and the entire scope of the claim, when viewed by a skilled artisan.[59] On the other hand, evidence of an unexpected property may not be sufficient regardless of the scope of the showing.[60] Accordingly, each case should be evaluated individually based on the totality of the circumstances.

Office personnel should not evaluate rebuttal evidence for its ''knockdown'' value against the prima facie cases [61] or summarily dismiss it as not compelling or insufficient. If the evidence is deemed insufficient to rebut the prima facie case of obviousness, Office personnel should specifically set forth the facts and reasoning that justify this conclusion.

III. Reconsider All Evidence and Clearly Communicate Findings and Conclusions

A determination under 35 U.S.C. 103 should rest on *all* the evidence and should not be influenced by any earlier conclusion.[62] Thus, once the applicant has presented rebuttal evidence, Office personnel should reconsider any initial obviousness determination in view of the entire record.[63] All the proposed rejections and their bases should be reviewed to confirm their correctness. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the Office's findings and conclusions, articulating how the conclusions are supported by the findings.

Where applicable, the findings should clearly articulate which portions of the reference support any rejection. Explicit findings on motivation or suggestion to select the claimed invention should also be articulated in order to support a 35 U.S.C. 103 ground of rejection.[64] Conclusory statements of similarity or motivation, without any articulated rationale or evidentiary support, do not constitute sufficient factual findings.

VI. Footnotes

1. When evaluating the scope of a claim, every limitation in the claim must be considered. E.g., In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). However, the claimed invention may not be dissected into discrete elements to be analyzed in isolation, but must be considered as a whole. E.g., *W.L. Gore & Assoc., Inc.* v. *Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984); *Jones* v. *Hardy*, 727 F.2d 1524, 1530, 220 USPQ 1021, 1026 (Fed. Cir. 1983) (''treating the advantage as the invention disregards the statutory requirement that the invention be viewed 'as a whole' '').

2. Both claimed and unclaimed aspects of the invention should be searched if there is a reasonable expectation that the unclaimed aspects may be later claimed.

3. ''The section 103 requirement of unobviousness is no different in chemical cases than with respect to other categories of patentable inventions.'' In re Papesch, 315 F.2d 381, 385, 137 USPQ 43, 47 (CCPA 1963).

4. E.g., In re Dillon, 919 F.2d 688, 692–93, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (in banc), cert. denied, 500 U.S. 904 (1991).

5. E.g., In re Brouwer, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996); In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995); In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

6. In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) (''The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.''); In re Jones, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (Federal Circuit has ''decline[d] to extract from Merck (& Co. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989)) the rule that * * * regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it.''). See also In re Deuel, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995).

7. E.g., In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) (''The PTO bears the burden of establishing a case of prima facie obviousness.''); In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993); In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966), requires that to make out a case of obviousness, one must: (1) Determine the scope and contents of the prior art; (2) ascertain the differences between the prior art and the claims in issue; (3) determine the level of skill in the pertinent art; and (4) evaluate any evidence of secondary considerations.

8. E.g., Bell, 991 F.2d at 783–84, 26 USPQ2d at 1531; Rijckaert, 9 F.3d at 1532, 28 USPQ2d at 1956; Oetiker, 977 F.2d at 1445, 24 USPQ2d at 1444.

9. Id.

10. E.g., In re Brouwer, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996) (''[T]he mere possibility that one of the esters or the active methylene group-containing compounds * * * could be modified or replaced such that its use would lead to the specific sulfoalkylated resin recited in claim 8 does not make the process recited in claim 8 obvious 'unless the prior art suggested the desirability of [such a] modification' or replacement.'') (quoting In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984); In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991) (''[A] proper analysis under section 103 requires, inter alia, consideration of * * * whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process.'').

11. The prior art disclosure may be express, implicit, or inherent. Regardless of the type of disclosure, the prior art must provide some motivation to one of ordinary skill in the art to make the claimed invention in order to support a conclusion of obviousness. E.g., Vaeck, 947 F.2d at 493, 20 USPQ2d at 1442 (A proper obviousness analysis requires consideration of ''whether the prior art would also have revealed that in so making or carrying out (the claimed invention), those of ordinary skill would have a reasonable expectation of success.''); In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) (''The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art.''); Hodosh v. Block Drug Co., 786 F.2d 1136, 1143 n. 5, 229 USPQ 182, 187 n. 5 (Fed. Cir.), cert. denied, 479 U.S. 827 (1986).

12. When evidence of secondary considerations such as unexpected results is initially before the Office, for example, in the specification, that evidence should be considered in deciding whether there is a prima facie case of obviousness. The determination as to whether a prima facie exists should be made on the full record before the Office at the time of the determination.

13. Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Accord, e.g., In re Paulsen, 30 F.3d 1475, 1482, 31 USPQ2d 1671, 1676 (Fed. Cir. 1994).

14. E.g., Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir.) (''Before answering Graham's 'content' inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. § 102.''), cert. denied, 481 U.S. 1052 (1987).

15. In re Oetiker, 977 F.2d 1443, 1447, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). Accord, e.g., In re Clay, 966 F.2d 656, 658–59, 23 USPQ2d 1058, 1060 (Fed. Cir. 1992).

16. In Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1537, 218 USPQ 871, 877 (Fed. Cir. 1983), the Court noted that ''the question under 35 U.S.C. 103 is not whether the differences [between the claimed invention and the prior art] would have been obvious'' but ''whether the claimed invention

as a whole would have been obvious.'' (emphasis in original).

17. See, Ryko Manufacturing Co. v. Nu-Star Inc., 950 F.2d 714, 718, 21 USPQ2d 1053, 1057 (Fed. Cir. 1991) (''The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry.''); Uniroyal Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1050, 5 USPQ2D 1434, 1438 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988) (evidence must be viewed from position of ordinary skill, not of an expert).

18. E.g., Ochiai, 71 F.3d at 1569–70, 37 USPQ2d at 1131; Deuel, 51 F.3d at 1557, 34 USPQ2d at 1214 (''[A] prima facie case of unpatentability requires that the teachings of the prior art suggest the claimed compounds to a person of ordinary skill in the art.'' (emphasis in original)); Jones, 958 F.2d at 351, 21 USPQ2d at 1943–44 (Fed. Cir. 1992); Dillon, 919 F.2d at 692, 16 USPQ2d at 1901; In re Lalu, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984) (''The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound.''). See also In re Kemps, 97 F.3d 1427, 1430, 40 USPQ2d 1309, 1311 (Fed. Cir. 1996) (discussing motivation to combine).

19. See, e.g., Baird, 16 F.3d at 383, 29 USPQ2d at 1552 (observing that ''it is not the mere number of compounds in this limited class which is significant here but, rather, the total circumstances involved'').

20. Id.

21. See, e.g., Deuel, 51 F.3d at 1558–59, 34 USPQ2d at 1215 (''No particular one of these DNAs can be obvious unless there is something in the prior art to lead to the particular DNA and indicate that it should be prepared.''); Baird, 16 F.3d at 382–83, 29 USPQ2d at 1552; Bell, 991 F.2d at 784, 26 USPQ2d at 1531 (''Absent anything in the cited prior art suggesting which of the 10^{36} possible sequences suggested by Rinderknecht corresponds to the IGF gene, the PTO has not met its burden of establishing that the prior art would have suggested the claimed sequences.'').

22. In re Petering, 301 F.2d 676, 681, 133 USPQ 275, 280 (CCPA 1962) (emphasis in original). Accord In re Schaumann, 572 F.2d 312, 316, 197 USPQ 5, 9 (CCPA 1978) (prior art genus encompassing claimed species which disclosed preference for lower alkyl secondary amines and properties possessed by the claimed compound constituted description of claimed compound for purposes of 35 U.S.C. 102(b)). C.f., In re Ruschig, 343 F.2d 965, 974, 145 USPQ 274, 282 (CCPA 1965) (Rejection of claimed compound in light of prior art genus based on Petering is not appropriate where the prior art does not disclose a small recognizable class of compounds with common properties.).

23. An express teaching may be based on a statement in the prior art reference such as an art recognized equivalence. For example, see Merck & Co. v. Biocraft Labs., 874 F.2d 804, 807, 10 USPQ2d 1843, 1846 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989) (holding claims directed to diuretic compositions comprising a specific mixture of amiloride and hydrochlorothiazide were obvious over a prior art reference expressly teaching that amiloride was a pyrazinoylguanidine which could be co-administered with potassium excreting diuretic agents, including hydrochlorothiazide which was a named example, to produce a diuretic with desirable sodium and potassium eliminating properties). See also, In re Kemps, 97 F.3d 1427, 1430, 40 USPQ2d 1309, 1312 (Fed. Cir. 1996) (holding there is sufficient motivation to combine teachings of prior art to achieve claimed invention where one reference specifically refers to the other).

24. E.g., Dillon, 919 F.2d at 696, 16 USPQ2d at 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214 (''Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.'').

25. E.g., Dillion, 919 F.2d at 693, 16 USPQ2d at 1901.

26. See id.

27. E.g., In re Jones, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (reversing obviousness rejection of novel dicamba salt with acyclic structure over broad prior art genus encompassing claimed salt, where disclosed examples of genus were dissimilar in structure, lacking an ether linkage or being cyclic); In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971) (the difference from the particularly preferred subgenus of the prior art was a hydroxyl group, a difference conceded by applicant ''to be of little importance.'').

In the area of biotechnology, an exemplified species may differ from a claimed species by a conservative substitution (''the replacement in a protein of one amino acid by another, chemically similar, amino acid * * * (which) is generally expected to lead to either no change or only a small change in the properties of the protein.'' *Dictionary of Biochemistry and Molecular Biology* 97 (John Wiley & Sons, 2d ed. 1989)). The effect of a conservative substitution on protein function depends on the nature of the substitution and its location in the chain. Although at some locations a conservative substitution may be benign, in some proteins only one amino acid is allowed at a given position. For example, the gain or loss of even one methyl group can destabilize the structure if close packing is required in the interior of domains. James Darnell et al., *Molecular Cell Biology* 51 (2d ed. 1990).

28. E.g., Dillion, 919 F.2d at 696, 16 USPQ2d at 1904 (and cases cited therein). C.f. Baird, 16 F.3d at 382–83, 29 USPQ2d at 1552 (disclosure of dissimilar species can provide teaching away).

29. Baird, 16 F.3d at 382–83, 29 USPQ2d at 1552 (reversing obviousness rejection of species in view of large size of genus and disclosed ''optimum'' species which differed greatly from and were more complex than the claimed species); Jones, 958 F.2d at 350, 21 USPQ2d at 1943 (reversing obviousness rejection of novel dicamba salt with acyclic structure over broad prior art genus encompassing claimed salt, where disclosed examples of genus were dissimilar in structure, lacking an ether linkage or being cyclic).

30. Baird, 16 F.3d at 382, 29 USPQ2d at 1552. See also Jones, 958 F.2d at 350, 21 USPQ2d at 1943 (disclosed salts of genus held not sufficiently similar in structure to render claimed species prima facie obvious).

31. For example, a claimed tetra-orthoester fuel composition was held to be obvious in light of a prior art tri-orthoester fuel composition based on their structural and chemical similarity and similar use as fuel additives. Dillion, 919 F.2d at 692–93, 16 USPQ2d at 1900–02.

Likewise, claims to amitriptyline used as an antidepressant were held obvious in light of the structural similarity to imipramine, a known antidepressant prior art compound, where both compounds were tricyclic dibenzo compounds and differed structurally only in the replacement of the unsaturated carbon atom in the center ring of amitriptyline with a nitrogen atom in imipramine. In re Merck & Co., 800 F.2d 1091, 1096–97, 231 USPQ 375, 378–79 (Fed. Cir. 1986).

Similarly, a claimed protein compound having an amino acid sequence including Met-Phe-Pro-Leu-$(Asp)_4$-Lys-Y was held to be obvious in light of structural similarities to the prior art. One reference provided motivation to create fusion proteins in the forms X-$(Asp)_4$-Lys-Y. Other references taught positioning Met at the start of the amino acid sequence and that the sequences Phe-Pro-Ile or Leu-Pro-Leu could serve as X in the basic formula. The known structural similarity of Ile and Leu meant that appellants merely substituted one element known in the art for a known equivalent. Thus, the substitution was held to be obvious. In re Mayne, No. 95–1522, slip op. at 6–8 (Fed. Cir. Jan. 17, 1997).

Other structural similarities have been found to support a prima facie case of obviousness. E.g., In re May, 574 F.2d 1082, 1093–95, 197 USPQ 601, 610–11 (CCPA 1978) (stereoisomers); In re Wilder, 563 F.2d 457, 460, 195 USPQ 426, 429 (CCPA 1977) (adjacent homologs and structural isomers); In re Hoch, 428 F.2d 1341, 1344, 166 USPQ 406, 409 (CCPA 1970) (acid and ethyl ester); In re Druey, 319 F.2d 237, 240, 138 USPQ 39, 41 (CCPA 1963) (omission of methyl group from pyrazole ring).

32. Id.

33. Dillion, 919 F.2d at 697, 16 USPQ2d at 1905; In re Stemniski, 444 F.2d 581, 586, 170 USPQ 343, 348 (CCPA 1971).

34. In re Albrecht, 514 F.2d 1389, 1392, 1395–96, 185 USPQ 585, 587, 590 (CCPA 1975) (The prior art compound so irritated the skin that it could not be regarded as useful for the disclosed anesthetic purpose, and therefore a person skilled in the art would not have been motivated to make related compounds.); Stemniski, 444 F.2d at 586, 170 USPQ at 348 (close structural similarity alone is not sufficient to create a prima facie case of obviousness when the reference compounds lack utility, and thus there is no motivation to make related compounds.).

35. Dillion, 919 F.2d at 697, 16 USPQ2d at 1904–05 (and cases cited therein).

36. E.g., id.

37. Id. at 692, 16 USPQ2d at 1900–01.

38. Dillion, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also In re Grabiak, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) (''When chemical compounds have 'very close' structural similarities and similar utilities, without more a prima facie case may be made.'').

39. Dillion, 919 F.2d at 697–98, 16 USPQ2d at 1905; In re Wilder, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); In re Linter, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

40. See, e.g., Dillion, 919 F.2d at 692–97, 16 USPQ2d at 1901–05; In re Grabiak, 769 F.2d 729, 732–33, 226 USPQ 870, 872 (Fed. Cir. 1985).

41. See e.g., In re May, 574 F.2d 1082, 1094, 197 USPQ 601, 611 (CCPA 1978) (prima facie obviousness of claimed analgesic compound based on structurally similar prior art isomer was rebutted with evidence demonstrating that analgesia and addiction properties could not be reliably predicted on the basis of chemical structure); In re Schechter, 205 F.2d 185, 191, 98 USPQ 144, 150 (CCPA 1953) (unpredictability in the insecticide field, with homologs, isomers and analogs of known effective insecticides having proven ineffective as insecticides, was considered as a factor weighing against a conclusion of obviousness of the claimed compounds).

42. See, e.g., In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

43. In re Bell, 991 F.2d 781, 784, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993); In re Kulling, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1057 (Fed. Cir. 1990).

44. Kulling, 897 F.2d at 1149, 14 USPQ2d at 1058; Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1579 n.42, 1 USQP2d 1593, 1606 n.42 (Fed. Cir.), cert. denied, 481 U.S. 1052 (1987).

45. E.g., Dillon, 919 F.2d at 692, 16 USPQ2d at 1901.

46. In re Soni, 54 F. 3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995).

47. In re Chu, 66 F.3d 292, 299, 36 USPQ2d 1089, 1094–95 (Fed. Cir. 1995).

48. E.g., Soni, 54 F.3d at 750, 34 USPQ2d 1687; In re Piasecki, 745 F.2d 1468, 1474, 223, USPQ 785, 789–90 (Fed. Cir. 1984).

49. E.G., In re Huang, 100 F.3d 135, 139–40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

50. E.G., In re Soni, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995) (error not to consider evidence presented in the specification). C.F., In re Alton, 76 F.3d 1168, 37 UPSPQ2d 1578 (Fed. Cir. 1996) (error not to consider factual evidence submitted to counter a section 112 rejection); In re Beattie, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042–43 (Fed. Cir. 1992) (Office personnel should consider declarations from those skilled in the art praising the claimed invention and opining that the art teaches away from the intention.); Piasecki, 745 F.2d at 1472, 223 USPQ at 788 (''(Rebuttal evidence) may relate to any of the Graham factors including the so-called secondary considerations.'').

51. Graham v. John Deere Co., 383 U.S. at 17, 148 USPQ at 467. See also, e.g., In re Piasecki, 745 F.2d at 1468, 1473, 223 USPQ 785, 788 (Fed. Cir. 1984) (commercial success).

52. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties. Dillon, 919 F.2d at 692–93, 16 USPQ2d at 1901. A showing of unexpected results must be based on evidence, not argument or speculation. In re Mayne, No. 95–1522, slip op. at 9–10 (Fed. Cir. Jan. 17, 1997) (conclusory statements that claimed compound posses unusually low immune response or unexpected biological activity that is unsupported by comparative data held insufficient to overcome prima facie case of obviousness).

53. E.G., In re GPAC, 57 F.3d 1573, 1580, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995); Hybritech Inc. v. Monoclonal Antibodies, 802 F.2d 1367, 1380, 231 USPQ 81, 90 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987).

54. E.G., In re Oelrich, 579 F.2d 86, 91–92, 198 USPQ 210, 214 (CCPA 1978) (Expert opinions regarding the level of skill in the art were probative of the nonobviousness of the claimed invention.); Piasecki, 745 F.2d at 1471, 1473–74, 223 USPQ at 790 (Evidence of non-technological nature is pertinent to the conclusion of obviousness. The declarations of those skilled in the art regarding the need for the invention and its reception by the art were improperly discounted by the Board); Beattie, 974 F.2d at 1313, 24 USPQ2d at 1042–43 (Seven declarations provided by music teachers opining that the art teaches away from the claimed invention must be considered, but were not probative because they did not contain facts and did not deal with the specific prior art that was the subject of the rejection.).

55. Id. See also In re Alton, 76 F.3d 1168, 1174–75, 37 USPQ2d 1578, 1582–83 (Fed. Cir. 1996).

56. The Federal Circuit has acknowledged that applicant bears the burden of establishing nexus, stating:

In the *ex parte* process of examining a patent application, however, the PTO lacks the means or resources to gather evidence which supports or refutes the applicant's assertion that the sales constitute commercial success. *C.f. Ex parte Remark*, 15 USPQ2d 1498, 1503 ([BPAI] 1990) (evidentiary routine of shifting burdens in civil proceedings inappropriate in *ex parte* prosecution proceedings because examiner has no available means for adducing evidence). Consequently, the PTO must rely upon the applicant to provide hard evidence of commercial success.

In re Huang, 100 F.3d 135, 139–40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996). See also GPAC, 57 F.3d at 1580, 35 USPQ2d at 1121; In re Paulsen, 30 F.3d 1475, 1482, 31 USPQ2d 1671, 1676 (Fed. Cir. 1994).

57. E.G., Paulsen, 30 F.3d at 1482, 31 USPQ2d at 1676. (Evidence of commercial success of articles not covered by the claims subject to the 35 U.S.C. 103 rejection was not probative of nonobviousness).

58. E.g., In re Kulling, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 777 (Fed. Cir. 1983). In re Soni, 54 F.3d 746, 34 USPQ2d 1684 (Fed. Cir. 1995) does not change this analysis. In Soni, the Court declined to consider the Office's argument that the evidence of non-obviousness was not commensurate in scope with the claim because it had not been raised by the Examiner. 54 F.3d at 751, 34 USPQ2d at 1688.

When considering whether proffered evidence is commensurate in scope with the claimed invention, Office personnel should not require the applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition. E.g., In re Chupp, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a prima facie case of obviousness. Id.

For example, a showing of unexpected results for a single member of a claimed subgenus, or a narrow portion of a claimed range would be sufficient to rebut a prima facie case of obviousness if a skilled artisan ''could ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof.'' In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Evidence of the unobviousness of a broad range can be proven by a narrower range when one skilled in the art could ascertain a trend that would allow him to reasonably extend the probative value thereof.). But see, Grasselli, 713 F.2d at 743, 218 USPQ at 778 (evidence of superior properties for sodium containing composition insufficient to establish the non-obviousness of broad claims for a catalyst with ''an alkali metal'' where it was well known in the catalyst art that different alkali metals were not interchangeable and applicant had shown unexpected results only for sodium-containing materials); In re Greenfield, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) (evidence of superior properties in one species insufficient to establish the nonobviousness of a subgenus containing hundreds of compounds); In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972) (one test not sufficient where there was no adequate basis for concluding the other claimed compounds would behave the same way).

59. E.g., Chupp, 816 F.2d at 646, 2 USPQ2d at 1439; Clemens, 622 F.2d at 1036, 206 USPQ at 296.

60. Where the claims are not limited to a particular use, and where the prior art provides other motivation to select a particular species or subgenus, a showing of a new use may not be sufficient to confer patentability. See Dillon, 919 F.2d at 692, 16 USPQ2d at 1900–01.

61. Piasecki, 745 F.2d at 1473, 223 USPQ at 788.

62. E.g., Piasecki, 745 F.2d at 1472–73, 223 USPQ at 788; In re Eli Lilly & Co., 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990).

63. E.g., Piasecki, 745 F.2d at 1472, 223 USPQ at 788; Eli Lilly, 902 F.2d at 945, 14 USPQ2d at 1743.

64. Dillon, 919 F.2d at 693, 16 USPQ2d at 1901; In re Mills, 916 F.2d 680, 683, 16 USPQ2d 1430, 1433 (Fed. Cir. 1990).

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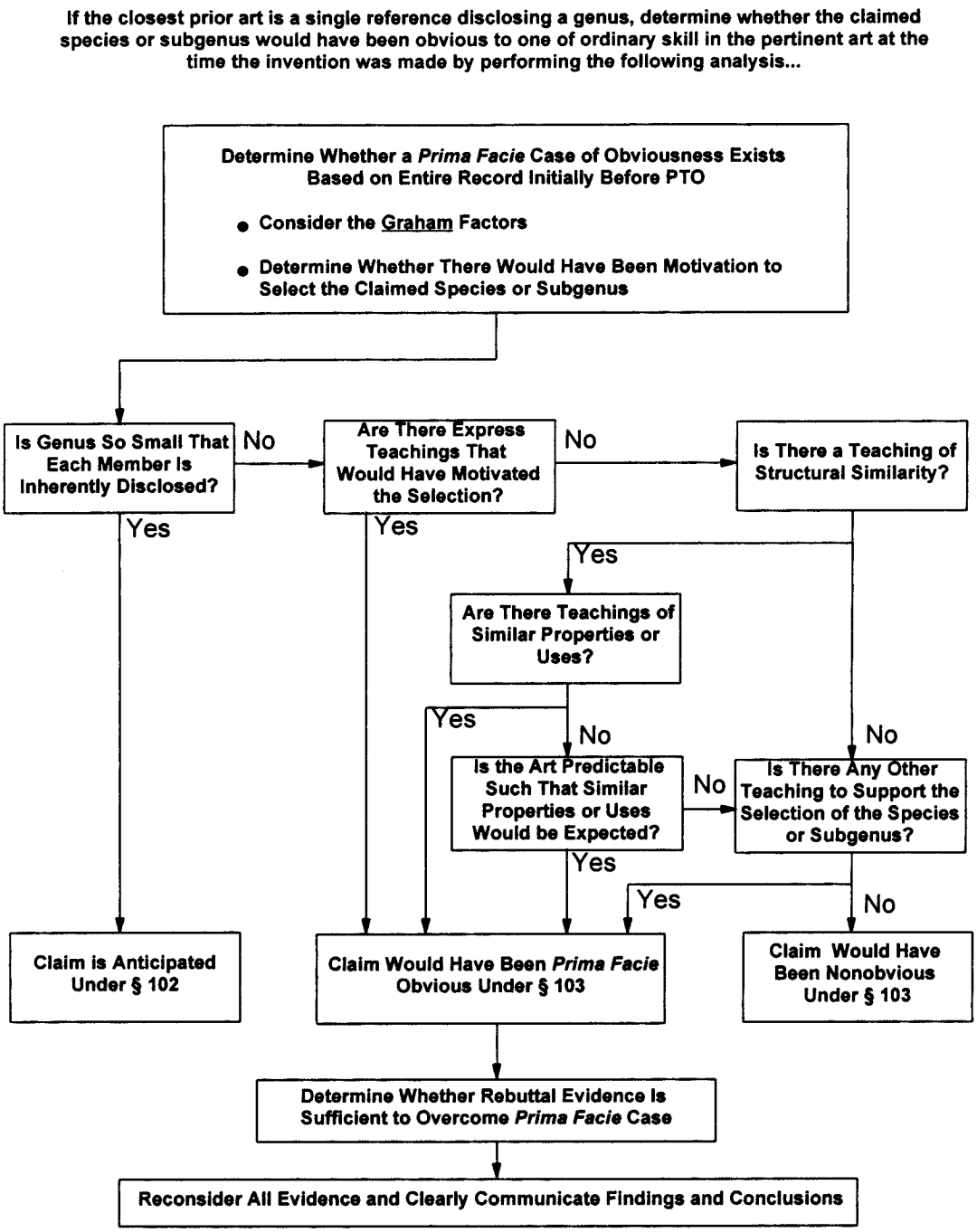

[FR Doc. 97–3362 Filed 2–10–97; 8:45 am]
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COMMODITY FUTURES TRADING COMMISSION

Applications of the Chicago Board of Trade as a Contract Market in Long Term Inflation-Indexed U.S. Treasury Note Futures and Options Contracts

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of availability of the terms and conditions of proposed commodity futures and option contracts.

SUMMARY: The Chicago Board of Trade (CBT or Exchange) has applied for designation as a contract market in long term inflation-indexed U.S. Treasury note futures and option contracts. The Director of the Division of Economic Analysis (Division) of the Commission, acting pursuant to the authority delegated by Commission Regulation 140.96, has determined that publication of the proposals for comment is in the public interest, will assist the Commission in considering the views of interested persons, and is consistent with the purposes of the Commodity Exchange Act.

DATES: Comments must be received on or before March 13, 1997.

ADDRESSES: Interested persons should submit their views and comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 21st Street NW, Washington, DC 20581. In addition, comments may be sent by facsimile