Appendix 1

Table 1 Reexamination decisions on pharmaceutical cases made by the Patent Reexamination Board (PRB) from early 2015 to the end of 2017

No.	Judgment No.	Applicant	Application No. / Publication No.	Whether the effect proved by supplementary experimental data is mentioned in the original description	Whether the effect proved by supplementary experimental data is deducible from the original description	Whether relevant data are disclosed in the original description	Whether supplementary data are considered	Result of ruling
1	FS129376	German Cancer Research Cente (DKFZ), Ruprechts-Karls -Universität Heidelberg	CN201180064964(A) CN103328463(A)	Yes	-	Yes	Yes	Decision of rejection revoked
2	FS123930	Nihon Medi-Physics Co., Ltd.	CN201280027545(A) CN103596950(A)	Yes	-	Yes	Yes	Decision of rejection revoked
3	FS110886	Akaal Pharma Pty Ltd.	CN200980141188(A) CN102186845(B)	Yes	-	Yes	Yes	Decision of rejection revoked after amendment

4	FS95454	Sunesis Pharmaceuticals, Inc., Millennium Pharmaceuticals, Inc.	CN200880022788(A) CN101784545(A)	Yes	-	Effect ①: No Effect ②: Yes	Effect ①: No Effect ②: Notarized experiment record considered	Decision of rejection revoked after amendment
5	FS89092	Celgene Corporation	CN200780036550(A) CN101583359(A)	Yes	-	Yes	Supplementary experimental data not mentioned in the description, given sufficiency of disclosure in the description	Decision of rejection revoked
6	FS95698	The Council of Scientific & Industrial Research	CN200980152325(A) CN102264716(A)	Effect ①: No Effect ②: Yes	Effect ①: No Effect ②: -	Effect ①: No Effect ②: Yes	Effect ①: No Effect ②: Yes	Decision of rejection revoked after amendment
7	FS103917	Samyang Biopharmaceuticals Corporation	CN201080029072(A) CN102458373(A)	Yes	-	Yes	Effect not recognised for not being parallel experiments	Decision of rejection upheld

8	FS103243	AbbVie Inc., Abbvie Deutschland GmbH & Co. KG	CN201080064024(A) CN102753541(A)	Yes	-	Yes	Effect and authenticity not recognised	Decision of rejection upheld
9	FS99656	The Hong Kong Polytechnic University	CN201110208539(A) CN102895258(A)	Yes	-	Yes	Effect not recognised	Decision of rejection upheld
10	FS87391	F. Hoffmann-La Roche AG	CN200880022591(A) CN101687930(A)	Yes	-	Yes	Effect not recognised	Decision of rejection upheld
11	FS86137	Nicox S.A.	CN200880004081(A) CN101652380(A)	Yes	-	Yes	Effect not recognised	Decision of rejection upheld
12	FS77207	Reviva Pharmaceuticals, Inc.	CN201080019233(A) CN102413830(A)	Effect ①: No Effect ②: Yes	-	Effect ①: No Effect ②: Yes	Effect ①: No Effect ②: Not recognised	Decision of rejection upheld
13	FS130009	Boehringer Ingelheim Pharma GmbH & Co.KG	CN201410065809(A) CN104055778(A)	Yes	-	No	No	Decision of rejection upheld

14	FS126576	Artificial Cell Technologies, Inc.	CN201310173837(A) CN103357007(A)	Yes	-	No	No	Decision of rejection upheld
15	FS123914	Euro Euro Celtique SA	CN201310269906(A) CN103394090(A)	Yes	-	No	No	Decision of rejection upheld
16	FS123955	International Institute of Cancer Immunology, Inc.	CN201310009095(A) CN103103246(A)	Yes	-	No	No	Decision of rejection revoked after removal of the solution
17	FS123972	Merck & Co., Inc.; Istituto Di Ricerche Di Biologia Molecolare P. Angeletti Spa	CN200780048666(A) CN101611039(A)	Yes	-	No	No	Decision of rejection upheld
18	FS121933	Life Technologies Corporation	CN201180018980(A) CN103097547(A)	Yes	-	No	No	Decision of rejection revoked after removal of the solution

19	FS116396	Novartis A.G.	CN201210290408(A) CN102861332(A)	Yes	-	No	No	Decision of rejection upheld
20	FS73780	Celgene Corporation	CN200780042615(A) CN101535291(A)	Yes	-	No	No	Decision of rejection upheld
21	FS114965	AbbVie Biotechnology Ltd	CN201210239238(A) CN102755646(A)	Yes	-	No	No	Decision of rejection upheld
22	FS114794	Mitsubishi Tanabe Pharma Corporation	CN201210006859(A) CN102584799(A)	Yes	-	No	No	Decision of rejection upheld
23	FS113787	Novo Nordisk A/S	CN201180023303(A) CN102883743(A)	Yes	-	No	No	Decision of rejection upheld
24	FS112943	Morphochem Aktiengesellschaft für kombinatorische Chemie	CN200480038072(A) CN1898238(A)	Effect ①: Yes Effect ②: Yes	-	Effect ①: No Effect ②: No	Effect ①: No Effect ②: Technical effect not recognised	Decision of rejection upheld

25	FS112101	Teva Pharmaceutical Industries Ltd	CN201180040545(A) CN103038227(A)	Yes	-	No	No	Decision of rejection upheld
26	FS106209	Wyeth LLC	CN200980129758(A) CN102202667(A)	Yes	-	No	No	Decision of rejection upheld
27	FS106047	Biolab Sanus Farmaceutica Ltda.	CN201080038108(A) CN102625800(A)	Yes	-	No	No	Decision of rejection upheld
28	FS96928	L'Universite Montpelier II; Idenix Pharmaceuticals, Inc.; University of Cagliari; The Centre National de la Recherche Scientifique	CN201110253393(A) CN102424698(A)	Yes	-	No	No	Decision of rejection upheld
29	FS96776	Laboratoire M2	CN200980121508(A) CN102083307(A)	Yes	-	No	No	Decision of rejection upheld

30	FS89967	Health Research, Inc.	CN200880012072(A) CN101675066(A)	Yes	-	No	No	Decision of rejection upheld
31	FS87913	Cytochroma Inc.	CN200980112429(A) CN101998949(A)	Yes	-	No	Effect not recognised	Decision of rejection revoked after amendment
32	FS52756	Eisai R & D Management Co., Ltd.	CN200580023071(A) CN1984890(A)	Effect ①: No Effect ②: Yes	Effect ①: No Effect ②: -	Effect ①: No Effect ②: No	No	Decision of rejection upheld
33	FS85966	Novartis A.G.	CN200510072738(A) CN1733307(A)	Yes	-	No	Considered on the basis of Guidelines of 1993.[1]	Decision of rejection upheld
34	FS125512	FibroGen, Inc.	CN201310337398(A) CN103497184(A)	No	Yes	No	No	Decision of rejection upheld

[1] In respect of the case a reexamination decision was made earlier in which the Collegiate Panel did not accept the supplementary experimental data submitted by the applicant, who subsequently filed an administrative appeal with the Beijing Higher People's Court (BHPC). BHPC overturned said reexamination decision, and accordingly the Patent Reexamination Board (PRB) reissued a reexamination decision accepting the post-filing data in accordance with the final judgement made by BHPC.

35	FS119880	Boehringer Ingelheim International Gmbh	CN201310093566(A) CN103204903(A)	No	Yes	No	No	Decision of rejection upheld
36	FS96530	International Institute of Cancer Immunology, Inc.; Chugai Seiyaku Kabushiki Kaisha; Dainippon Sumitomo Pharma Co., Ltd.	CN200680051914(A) CN101336249(A)	No	Yes	No	No	Decision of rejection upheld
37	FS129717	Cadila Healthcare Limited	CN201280006760(A) CN103354757(A)	No	No	No	No	Decision of rejection upheld
38	FS127243	Endorecherche Inc.	CN201180039155(A) CN103037862(A)	No	No	No	No	Decision of rejection upheld
39	FS126730	Merck & Co., Inc.	CN201410039746(A) CN10372433	No	No	No	No	Decision of rejection upheld

			5(A)					
40	FS125319	Novartis A.G.	CN201210101874(A) CN102627658(A)	No	No	No	No	Decision of rejection upheld
41	FS124697	Tactical Therapeutics, Inc	CN201310005468(A) CN103251601(A)	No	No	No	No	Decision of rejection upheld
42	FS124264	Pfizer Inc.; Provectus Pharmaceuticals, Inc.	CN201280018290(A) CN103476943(A)	No	No	No	No	Decision of rejection upheld
43	FS123804	Abraxis BioScience, Inc.	CN201310233709(A) CN103285395(A)	No	No	No	No	Decision of rejection upheld
44	FS122196	L'Universite Montpelier II; Idenix Pharmaceuticals, Inc.; University of Cagliari; The Centre National de la	CN201310036638(A) CN103319554(A)	No	No	No	No	Decision of rejection upheld

		Recherche Scientifique						
45	FS115563	Exelixis, Inc.	CN201080012656(A) CN102388024(A)	No	No	No	No	Decision of rejection revoked after amendment
46	FS113303	The Board of Trustees of the Leland Stanford Junior University	CN201080030632(A) CN102459273(A)	No	No	No	No	Decision of rejection upheld
47	FS110935	Xigen Inflammation Ltd	CN200980130207(A) CN102112149(A)	No	No	No	No	Decision of rejection upheld
48	FS102364	Cornell University	CN200980112730(A) CN101998987(A)	No	No	No	No	Decision of rejection upheld

Appendix 2

Table 3 Rulings related to supplementary experimental data made by Beijing Intellectual Property Court (BIPC), Beijing Higher People's Court (BHPC), and Supreme People's Court of China (SPC) during the period between 2014 and 2017

No.	Judgment No.	Responsible court	Patentee	Whether the effect proved by supplementary experimental data is mentioned in the original description	Whether the effect proved by supplementary experimental data is deducible from the original description	Whether relevant data are disclosed in the original description	Whether supplementary experimental data are considered by court	Reasoning behind ruling
1	Gaoxingzhongzi 1127/2014	BHPC	Bristol-Myers Squibb Company; Zymogenetics, Inc.	Yes	-	No	No	Publication date of supplementary evidence subsequent to patent filing date
2	Gaoxingzhongzi 2364/2013	BHPC	Mitsubishi Tanabe Pharma Corporation	Yes	-	No	No	Supplementary evidence submitted after patent filing date and not

								disclosed in the original application
3	Xingtizi 8/2014	SPC	Warner-Lambert Company LLC	Yes	-	No	No	Not easily conceivable by a person skilled in the art
4	Gaoxingzhongzi 1244/2013	BHPC	Novartis A.G.	Yes	-	No	Yes[2]	Misapplication of law; Judgment to be reissued on the basis of the Guidelines of 1993
5	Jingzhixingchuzi 2069/2015	BIPC	Celgene Corporation	Yes	-	No	No	Technical effect unlikely to be reasonably expected
6	Gaoxingzhongzi 1184/2014	BHPC	Boehringer Ingelheim	Yes	-	No	No	Technical effect not

[2] This case is an appeal based on Reexamination Decision No. 48 of Table 1 in which the Beijing Higher People's Court (BHPC) reversed the first reexamination decision and subsequently the Patent Reexamination Board (PRB) reissued a reexamination decision on the basis of said final judgement made by BHPC.

			Pharma GmbH & Co.KG					disclosed in the description
7	Jingzhixingchuzi 3431/2015	BIPC	Boehringer Ingelheim Pharma GmbH & Co.KG	Yes	-	No	No	Technical effect unlikely to be reasonably expected
8	Jing73xingchuzi 2599/2016	BIPC	Boehringer Ingelheim Pharma GmbH & Co.KG	Yes	-	No	No	Technical effect unlikely to be reasonably expected
9	Jingxingzhong 3668/2017	BHPC	Boehringer Ingelheim Pharma GmbH & Co.KG	Yes	-	No	No	Technical effect unlikely to be reasonably expected
10	Gaoxingzhongzi 382/2014	BHPC	Otsuka Pharmaceutical Co., Ltd.	Yes	-	No	No	Technical effect unlikely to be reasonably expected
11	Jingzhixingchuzi 1599/2015	BIPC	Zhou Xingyuan et al.	Yes	-	No	No	Technical effect unlikely to be

								reasonably expected
12	Gaoxing(zhi)zhongzi 2305/2014	BHPC	Eisai R & D Management Co., Ltd.	Effect ①: No Effect ②: Yes	Effect ①: No Effect ②: -	Effect ①: No Effect ②: No	No	Technical effect unlikely to be reasonably expected
13	Jingzhixingchuzi 5395/2015	BIPC	Shandong Xinshidai Medicine Industry Co., Ltd.	No	No	No	No	Technical effect not disclosed in the description
14	Jingxingzhong 3046/2017	BHPC	Shandong Xinshidai Medicine Industry Co., Ltd.	No	No	No	No	Technical effect not disclosed in the description
15	Gaoxingzhongzi 309/2015	BHPC	Celgene Limited	No	No	No	No	Technical effect not disclosed in the description

MPEP

716 Affidavits or Declarations Traversing Rejections, 37 CFR 1.132 [R-11.2013]

716.01(a) Objective Evidence of Nonobviousness

OBJECTIVE EVIDENCE MUST BE CONSIDERED WHEN TIMELY PRESENT

Affidavits or declarations, when timely presented, containing evidence of criticality or unexpected results, commercial success, long-felt but unsolved needs, failure of others, skepticism of experts, etc., must be considered by the examiner in determining the issue of obviousness of claims for patentability under **35 U.S.C. 103**. The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983) that "evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." Such evidence might give light to circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or unobviousness, such evidence may have relevancy. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *In re Palmer*, 451 F.2d 1100, 172 USPQ 126 (CCPA 1971); *In re Fielder*, 471 F.2d 640, 176 USPQ 300 (CCPA 1973). The *Graham v. John Deere* pronouncements on the relevance of commercial success, etc. to a determination of obviousness were not negated in *Sakraida v. Ag Pro*, 425 U.S. 273, 189 USPQ 449 (1979) or *Anderson's-Black Rock Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969), where reliance was placed upon *A&P Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 87 USPQ 303 (1950). See *Dann v. Johnston*,425 U.S. 219, 226 n.4, 189 USPQ 257, 261 n. 4 (1976).

Examiners must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. *In re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986). The lack of objective evidence of nonobviousness does not weigh in favor of obviousness. *Miles Labs. Inc. v. Shandon Inc.*, 997 F.2d 870, 878, 27 USPQ2d 1123, 1129 (Fed. Cir. 1993), *cert. denied*,127 L. Ed. 232 (1994). However, where a *prima facie* case of obviousness is established, the failure to provide rebuttal evidence is dispositive.

716.01(b) Nexus Requirement and Evidence of Nonobviousness

TO BE OF PROBATIVE VALUE, ANY SECONDARY EVIDENCE MUST BE RELATED TO THE CLAIMED INVENTION (NEXUS REQUIRED)

The weight attached to evidence of secondary considerations by the examiner will depend upon its relevance to the issue of obviousness and the amount and nature of the evidence. Note the great reliance apparently placed on this type of evidence by the Supreme Court in upholding the patent in *United States v. Adams*, 383 U.S. 39,148 USPQ 479 (1966).

To be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 305 n.42, 227 USPQ 657, 673-674 n. 42 (Fed. Cir. 1985), *cert. denied*,475 U.S. 1017 (1986). The term "nexus" designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), *cert. denied*, 488 U.S. 956 (1988).

716.02 Allegations of Unexpected Results [R-08.2012]

Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (differences in sedative and anticholinergic effects between prior art and claimed antidepressants were not unexpected). In *In re Waymouth,* 499 F.2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974), the court held that unexpected results for a claimed range as compared with the range disclosed in the prior art had been shown by a demonstration of "a marked improvement, over the results achieved under other ratios, as to be classified as a difference in kind, rather than one of degree." Compare *In re Wagner,* 371 F.2d 877, 884, 152 USPQ 552, 560 (CCPA 1967) (differences in properties cannot be disregarded on the ground they are differences in degree rather than in kind); *Ex parte Gelles,* 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992) ("we generally consider a discussion of results in terms of 'differences in degree' as compared to 'differences in kind' . . . to have very little meaning in a relevant legal sense").

716.02(a) Evidence Must Show Unexpected Results

I. GREATER THAN EXPECTED RESULTS ARE EVIDENCE OF NONOBVIOUSNESS

"A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness ... of the claims at issue." *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985). In *Corkhill*, the claimed combination showed an additive result when a diminished result would have been expected. This result was persuasive of nonobviousness even though the result was equal to that of one component alone. Evidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (i.e., demonstrating "synergism"). *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). However, a greater than additive effect is not necessarily sufficient

to overcome a *prima facie* case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte The NutraSweet Co.*, 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991) (Evidence showing greater than additive sweetness resulting from the claimed mixture of saccharin and L-aspartyl-L-phenylalanine was not sufficient to outweigh the evidence of obviousness because the teachings of the prior art lead to a general expectation of greater than additive sweetening effects when using mixtures of synthetic sweeteners.).

II. SUPERIORITY OF A PROPERTY SHARED WITH THE PRIOR ART IS EVIDENCE OF NONOBVIOUSNESS

Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness. "Evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a *prima facie* case of obviousness." No set number of examples of superiority is required. *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987) (Evidence showing that the claimed herbicidal compound was more effective than the closest prior art compound in controlling quackgrass and yellow nutsedge weeds in corn and soybean crops was sufficient to overcome the rejection under **35 U.S.C. 103**, even though the specification indicated the claimed compound was an average performer on crops other than corn and soybean.). See also *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (unexpected superior therapeutic activity of claimed compound against anaerobic bacteria was sufficient to rebut *prima facie* obviousness even though there was no evidence that the compound was effective against all bacteria).

III. PRESENCE OF AN UNEXPECTED PROPERTY IS EVIDENCE OF NONOBVIOUSNESS

Presence of a property not possessed by the prior art is evidence of nonobviousness. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (rejection of claims to compound structurally similar to the prior art compound was reversed because claimed compound unexpectedly possessed anti-inflammatory properties not possessed by the prior art compound); *Ex parte Thumm*, 132 USPQ 66 (Bd. App. 1961) (Appellant showed that the claimed range of ethylene diamine was effective for the purpose of producing "'regenerated cellulose consisting substantially entirely of skin'" whereas the prior art warned "this compound has 'practically no effect.' "). The submission of evidence that a new product possesses unexpected properties does not necessarily require a conclusion that the claimed invention is nonobvious. *In re Payne*, 606 F.2d 303, 203 USPQ 245 (CCPA 1979). See the discussion of latent properties and additional advantages in **MPEP § 2145**.

IV. ABSENCE OF AN EXPECTED PROPERTY IS EVIDENCE OF NONOBVIOUSNESS

Absence of property which a claimed invention would have been expected to possess based on the teachings of the prior art is evidence of unobviousness. *Ex parte Mead Johnson & Co.*, 227 USPQ 78 (Bd. Pat. App. & Inter. 1985) (Based on prior art disclosures, claimed compounds would have been expected to possess beta-andrenergic blocking activity; the fact that claimed compounds did not possess such activity was an unexpected result sufficient to establish unobviousness within the meaning of **35 U.S.C. 103**.).

I. BURDEN ON APPLICANT TO ESTABLISH RESULTS ARE UNEXPECTED AND SIGNIFICANT

The evidence relied upon should establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992) (Mere conclusions in appellants' brief that the claimed polymer had an unexpectedly increased impact strength "are not entitled to the weight of conclusions accompanying the evidence, either in the specification or in a declaration."); *Ex parte C*, 27 USPQ2d 1492 (Bd. Pat. App. & Inter. 1992) (Applicant alleged

unexpected results with regard to the claimed soybean plant, however there was no basis for judging the practical significance of data with regard to maturity date, flowering date, flower color, or height of the plant.). See also *In re Nolan*, 553 F.2d 1261, 1267, 193 USPQ 641, 645 (CCPA 1977) and *In re Eli Lilly*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) as discussed in **MPEP § 716.02(c)**.

II. APPLICANTS HAVE BURDEN OF EXPLAINING PROFFERED DATA

"[A]ppellants have the burden of explaining the data in any declaration they proffer as evidence of non-obviousness." *Ex parte Ishizaka*, 24 USPQ2d 1621, 1624 (Bd. Pat. App. & Inter. 1992).

III. DIRECT AND INDIRECT COMPARATIVE TESTS ARE PROBATIVE OF NONOBVIOUSNESS

Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) and **MPEP § 716.02(d)** - **§ 716.02(e)**. See *In re Blondel*, 499 F.2d 1311, 1317, 182 USPQ 294, 298 (CCPA 1974) and *In re Fouche*, 439 F.2d 1237, 1241-42, 169 USPQ 429, 433 (CCPA 1971) for examples of cases where indirect comparative testing was found sufficient to rebut a *prima facie* case of obviousness.

The patentability of an intermediate may be established by unexpected properties of an end product "when one of ordinary skill in the art would reasonably ascribe to a claimed intermediate the 'contributing cause' for such an unexpectedly superior activity or property." *In re Magerlein*, 602 F.2d 366, 373, 202 USPQ 473, 479 (CCPA 1979). "In order to establish that the claimed intermediate is a 'contributing cause' of the unexpectedly superior activity or property of an end product, an applicant must identify the cause of the unexpectedly superior activity or property (compared to the prior art) in the end product and establish a nexus for that cause between the intermediate and the end product." *Id.* at 479.

716.02(d) Unexpected Results Commensurate in Scope With Claimed Invention

Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens,* 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Claims were directed to a process for removing corrosion at "elevated temperatures" using a certain ion exchange resin (with the exception of claim 8 which recited a temperature in excess of 100^{C}). Appellant demonstrated unexpected results via comparative tests with the prior art ion exchange resin at 110C and 130C. The court affirmed the rejection of claims 1-7 and 9-10 because the term "elevated temperatures" encompassed temperatures as low as 60C where the prior art ion exchange resin was known to perform well. The rejection of claim 8, directed to a temperature in excess of 100C, was reversed.). See also *In re Peterson,*315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not evidence unexpected results for the entire claimed range of about 1-3% rhenium); *In re Grasselli,* 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalysts containing sodium with the prior art. The court held this evidence insufficient to rebut the *prima facie* case because experiments limited to sodium were not commensurate in scope with the claims.).

I. NONOBVIOUSNESS OF A GENUS OR CLAIMED RANGE MAY BE SUPPORTED BY DATA SHOWING UNEXPECTED RESULTS OF A SPECIES OR NARROWER RANGE UNDER CERTAIN CIRCUMSTANCES

The nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof. *In re Kollman*, 595 F.2d 48, 201 USPQ 193 (CCPA 1979) (Claims directed to mixtures of an herbicide known as "FENAC" with a diphenyl ether herbicide in certain relative proportions were rejected as *prima facie* obvious. Applicant presented evidence alleging unexpected results testing three species of diphenyl ether herbicides over limited relative proportion ranges. The court held that the limited number of species exemplified did not provide an adequate basis for concluding that similar results would be obtained for the other diphenyl ether herbicides within the scope of the generic claims. Claims 6-8 recited a FENAC:diphenyl ether ratio of 1:1 to 4:1 for the three specific ethers tested. For two of the claimed ethers, unexpected results were demonstrated over a ratio of 16:1 to 2:1, and the effectiveness increased as the ratio approached the untested region of the claimed range. The court held these tests were commensurate in scope with the claims and supported the nonobviousness thereof. However, for a third ether, data was only provided over the range of 1:1 to 2:1 where the effectiveness decreased to the "expected level" as it approached the untested region. This evidence was not sufficient to overcome the obviousness rejection.); *In re Lindner*,457 F.2d 506, 509, 173 USPQ 356, 359 (CCPA 1972) (Evidence of nonobviousness consisted of comparing a single composition within the broad scope of the claims with the prior art. The court did not find the evidence sufficient to rebut the *prima facie* case of obviousness because there was "no adequate basis for reasonably concluding that the great number and variety of compositions included in the claims would behave in the same manner as the tested composition.").

II. DEMONSTRATING CRITICALITY OF A CLAIMED RANGE

To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960).

716.02(f) Advantages Disclosed or Inherent

The totality of the record must be considered when determining whether a claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore, evidence and arguments directed to advantages not disclosed in the specification cannot be disregarded. *In re Chu,* 66 F.3d 292, 298-99, 36 USPQ2d 1089, 1094-95 (Fed. Cir. 1995) (Although the purported advantage of placement of a selective catalytic reduction catalyst in the bag retainer of an apparatus for controlling emissions was not disclosed in the specification, evidence and arguments rebutting the conclusion that such placement was a matter of "design choice" should have been considered as part of the totality of the record. "We have found no cases supporting the position that a patent applicant's evidence or arguments traversing a § 103 rejection must be contained within the specification. There is no logical support for such a proposition as well, given that obviousness is determined by the totality of the record including, in some instances most significantly, the evidence and arguments proffered during the give-and-take of *ex parte* patent prosecution." 66 F.3d at 299, 36 USPQ2d at 1095.). See also *In re Zenitz,* 333 F.2d 924, 928, 142 USPQ 158, 161 (CCPA 1964) (evidence that claimed compound

minimized side effects of hypotensive activity must be considered because this undisclosed property would inherently flow from disclosed use as tranquilizer); *Ex parte Sasajima,* 212 USPQ 103, 104 - 05 (Bd. App. 1981) (evidence relating to initially undisclosed relative toxicity of claimed pharmaceutical compound must be considered).

The specification need not disclose proportions or values as critical for applicants to present evidence showing the proportions or values to be critical. *In re Saunders,* 444 F.2d 599, 607, 170 USPQ 213, 220 (CCPA 1971).

716.09 Sufficiency of Disclosure [R-11.2013]

Affidavits or declarations presented to show that the disclosure of an application is sufficient to one skilled in the art are not acceptable to establish facts which the specification itself should recite. *In re Buchner,* 929 F.2d 660, 18 USPQ2d 1331 (Fed. Cir. 1991) (Expert described how he would construct elements necessary to the claimed invention whose construction was not described in the application or the prior art; this was not sufficient to demonstrate that such construction was well-known to those of ordinary skill in the art.); *In re Smyth,* 189 F.2d 982, 90 USPQ 106 (CCPA 1951).

Affidavits or declarations purporting to explain the disclosure or to interpret the disclosure of a pending application are usually not considered. *In re Oppenauer,* 143 F.2d 974, 62 USPQ 297 (CCPA 1944). But see *Glaser v. Strickland,* 220 USPQ 446 (Bd. Pat. Int. 1983) which reexamines the rationale on which *In re Oppenauer* was based in light of the Federal Rules of Evidence. The Board stated as a general proposition "Opinion testimony which merely purports to state that a claim or count, is 'disclosed' in an application involved in an interference . . . should not be given any weight. Opinion testimony which purports to state that a particular feature or limitation of a claim or count is disclosed in an application involved in an interference and which explains the underlying factual basis for the opinion may be helpful and can be admitted. The weight to which the latter testimony may be entitled must be evaluated strictly on a case-by-case basis."

United States Court of Customs and Patent Appeals.
Application of Bernard L. ZENITZ.

Patent Appeal No. 7142.
July 9, 1964.

Proceeding on application for patents relating to chemical compounds said to be useful as hypotensive agents, antinauseants, antipyretics and sedatives. The Board of Patent Appeals, Serial No. 746,615, rejected claims 3, 5, 9 through 12 and 21 and appeal was taken. The Court of Customs and Patent Appeals, Worley Chief Judge, held that claims 3, 9, 10 and 11 were not obvious but that claims 5, 12 and 21 were properly rejected.

Modified.

West Headnotes

[1] Patents 291 51(1)

291 Patents
291II Patentability
291II(D) Anticipation
291k50 Prior Knowledge or Use
291k51 Nature and Extent in General
291k51(1) k. In general. Most Cited Cases

Patents 291 66(3)

291 Patents
291II Patentability
291II(D) Anticipation
291k63 Prior Patents
291k66 Operation and Effect
291k66(3) k. Date of patent as affecting anticipation. Most Cited Cases

United States patent speaks for all it discloses as of its filing date, even when used in combination with other references. 35 U.S.C.A. § 103.

[2] Patents 291 51(1)

291 Patents
291II Patentability
291II(D) Anticipation
291k50 Prior Knowledge or Use
291k51 Nature and Extent in General
291k51(1) k. In general. Most Cited Cases

Knowledge inconsistent with allowance of claim of patent application need not be limited to disclosure of identical invention. 35 U.S.C.A. § 103.

[3] Patents 291 16(3)

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16 Invention and Obviousness in General
291k16(3) k. View of person skilled in art. Most Cited Cases
(Formerly 291k18)

Question of patentability was not what prior art inventor was aware of at time he made his invention, but whether his invention would be obvious in view of state of art at time it was made. 35 U.S.C.A. § 103.

[4] Patents 291 113(6)

291 Patents
291IV Applications and Proceedings Thereon
291k113 Appeals from Decisions of Commissioner of Patents
291k113(6) k. Review on appeal in general. Most Cited Cases

That tranquilizer was a better one than that previously disclosed in that it minimized side effects of hypotensive activity must be considered in determining patentability of claimed compound. 35 U.S.C.A. § 103.

[5] Patents 291 16.25

291 Patents
291II Patentability
291II(A) Invention; Obviousness

291k16.25 k. Chemical compounds. Most Cited Cases
(Formerly 291k18)
Claims 3, 9, 10 and 11 of patent application dealing with chemical compounds said to be useful as hypotensive agents, antinauseants, antipyretics and sedatives were unobvious as to hydroxypropyl derivatives and corresponding hydroxy-ethyl and hydroxy-lower-alkyl derivatives and were patentable. 35 U.S.C.A. § 103.

[6] Patents 291 ⚿16.25

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.25 k. Chemical compounds. Most Cited Cases
(Formerly 291k18)
Claims 5, 12 and 21 of compounds said to be useful as hypotensive agents, antinauseants, antipyretics and sedatives were unpatentable as obvious. 35 U.S.C.A. § 103.

Patents 291 ⚿328(2)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(2) k. Original utility. Most Cited Cases
2,921,069, 2,928,767, 2,926,164. Cited.

****925 *746** Laurence & Laurence, Washington, D.C. (Dean Laurence, Herbert I. Sherman, Washington, D.C., of counsel), for appellant.

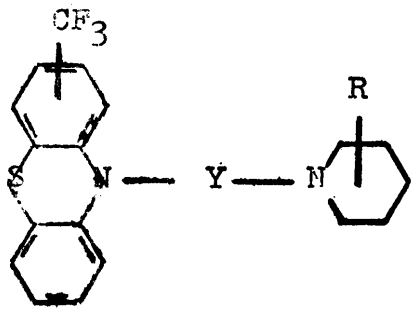
Clarence W. Moore, Washington, D.C. (George C. Roeming, Washington, D.C., of counsel), for the Commissioner of Patents.

Before WORLEY, Chief Judge, and RICH, MARTIN, SMITH, and ALMOND, judges.

WORLEY, Chief Judge.
Zenitz appeals from the affirmance by the Board of Appeals of the rejection of claims 3, 5, 9 through 12 and 21 of his patent application.[FN1]

The appellant deals with chemical compounds described as 10-piperidinoalkylene derivatives of trifluoromethyl phenothiazines which are said to be useful as 'hypotensive agents, antinauseants, antipyretics and sedatives.' Claim 3 reads:

'3. A pharmacologically acceptable acid-addition salt of a compound having the formula



***747** wherein Y represents lower-alkylene containing at least two carbon atoms separating the nitrogen atoms and R represents hydroxy-lower-alkyl.'

The references are:

Ullyot	2,921,069	January 12, 1960	(filed April 9, 1956)
Cusic et al.	2,926,164	February 23, 1960	(filed August 1, 1956)
Gulesich et al.	2,928,767	March 15, 1960	(filed July 17, 1957)
Belgian Patent	551,400	March 29, 1957	
Craig et al.	J.Org.Chem., Vol. 22, pages 709-11 (June 1957)		

Cusic, the primary reference, discloses compounds identical to those claimed except for a chloro (Cl) substituent in place of the trifluoromethyl (CF(3)) substituent in the claimed compounds. The secondary references establish that prior to the filing date of Zenitz's application the art was fully aware of the substitution of Cl and CF(3) potentiating groups in phenothiazines analogous to those now claimed by Zenitz.

The examiner held, and the board agreed, that the substitution of CF(3) for Cl in the phenothiazines disclosed by Cusic, would be obvious to one of ordinary skill in the art.

Zenitz contends that the Cusic, Gulesich and Ullyot patents are not available as ****926** references for an obviousness rejection under Section 103 because they issued on applications which, although filed earlier than his, were copending therewith. Zenitz maintains that he could not have been aware of the Cusic or Gulesich disclosures at the time he filed his application.

[1] This court has held in a number of decisions that a United States patent speaks for all it discloses as of its filing date, even when used in combination with other references. In re Kander, 312 F.2d 834, 50 CCPA 928; In re Gregg, 244 F.2d 316, 44 CCPA 904; In re Seid, 161 F.2d 229, 34 CCPA 1039.

[2][3] In re Harry, 333 F.2d 920, 51 CCPA, , decided concurrently herewith, holds that 35 U.S.C. § 103 is in parimateria materia with 35 U.S.C. § 102(e) and points out that the latter section was intended to enact the rule of Alexander Milburn Co. v. Davis-Bournonville Co., 270 U.S. 390, 46 S.Ct. 324, 70 L.Ed. 651, wherein the court said:

'* * * The delays of the patent office ought not to cut down the effect of what has been done. The description shows that Whitford was not the first inventor. Clifford had done all that he could do to make his description public. He had ***748** taken steps that would make it public as soon as the Patent Office did its work, although, of course, amendments might be required of him before the end could be reached. We see no reason in the words or policy of the law for allowing Whitford to profit by the delay and make himself out to be the first inventor when he was not so in fact, when Clifford had shown knowledge inconsistent with the allowance of Whitford's claim. * * *'

Although in Milburn, Clifford disclosed the same invention claimed by Whitford, the criterion was that Clifford had shown knowledge inconsistent with the allowance of Whitford's claim. That such knowledge need not be limited to a disclosure of the identical invention is shown by a later decision of the Supreme Court, Detrola Radio & Television Corp. v. Hazeltine Corp., 313 U.S. 259, 269, 61 S.Ct. 948, 952, 85 L.Ed. 1319 (1941) wherein the Court states:

'We conclude that Wheeler accomplished an old result by a combination of means which, singly or in similar combination, were disclosed by the prior art and that, notwithstanding the fact he was ignorant of the pending applications which antedated his claimed date of invention and eventuated into patents, he was not in fact the first inventor, since his advance over the prior art, if any, required only the exercise of the skill of the art.'

The question is not what prior art Zenitz was aware of at the time he made his invention, but whether his invention would be obvious in view of the state of the art at the time it was made.

We therefore proceed to the question whether the differences between Zenitz's invention and the state of the art at the time the invention was made, here as-

sumed to be Zenitz's filing date, are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art to which said subject matter pertains.

Zenitz submitted affidavits by Wylie and by Luduena to show that his compounds have unexpected properties. The affidavits compare the tranquilizing activity and hypotensive effect of hydroxy and hydroxypropyl piperidyl propyl trifluoromethyl phenothiazine derivatives of Zenitz with the corresponding chloro compounds of Cusic. The examiner allowed Zenitz's claims to the hydroxy but not to the hydroxy propyl derivatives. Claims 3, 9, 10 and 11 on appeal are drawn to those hydroxy propyl derivatives. Claims 5, 12 and 21, however, are drawn to compounds having an acyloxy-lower-alkyl substituent, e.g. an acetate. As to the latter compounds the examiner said:

'* * * Note also that appellant has not compared the instant compounds**927 against those of Cusic et al. shown to have particularly good tranquilizing activity, viz. the acetates * * *.'

As to those compounds which have been compared, the Luduena affidavit confirms the following conclusion of Wylie:

'Moreover, I have noted that not only are the trifluoromethyl compounds considerably more active as tranquilizers and sedatives than the corresponding ***749** chloro and unsubstituted compounds as shown above but also show considerably less undesirable side effects, such as a hypotensive effect, making them superior with respect to decreased side effects than either the corresponding chloro compounds or the unsubstituted compounds. a hypotensive effect alone is useful in compounds that are to be used specifically to lower the blood pressure, but when this property is also possessed by compounds used as tranquilizers or sedatives, it is regarded as a serious side-effect which can cause other side-effects such as dizziness or blurring of vision. Its minimization or complete elimination in compounds to be used as sedatives and tranquilizers is, therefore, to be desired.'

The examiner considered the affidavits and said:

'* * * Patentability has been consistently urged during prosecution upon this newly introduced 'surprising separation of hypotensive and tranquilizing properties' which was not disclosed in the specification as filed. The specification at page 21 merely indicates that results indicate their use as hypotensive agents, antinauseants, antipyretics and sedatives. * * *'

Since the separation of hypotensive from tranquilizing effect was not originally disclosed, the examiner, citing In re Stewart, 222 F.2d 747, 42 CCPA 937, held that Zenitz could not now rely on that effect as a ground for establishing unobviousness. The board agreed.

A case much in point is Westmoreland Specialty Co. v. Hogan, 167 F. 327, CCA 3 (1909). The patent there involved a celluloid top for a dredge for holding salt. The patentee discovered subsequent to the issuance of his patent that the celluloid top had the advantage that it did not conduct moisture from the atmosphere to the salt in the cellar. The court said:

'* * * It is true that at the time this patent was applied for the particular process of moisture supply from a metal cap and the insulating capacity of celluloid to stop it were not stated, or, indeed, known to the patentee. He knew metal caps would oxidize, and substituted celluloid to stop oxidation, and such use has shown that the stoppage of oxidation resulted in keeping the salt dry. But the mere failure of a patentee to realize all the benefits and possibilities of his invention is not fatal. The after-discovery of unsuspected usefulness in a disclosed apparatus, far from detracting from its value, may serve to enhance it. It is the benefits which test, use, and time unfold that really determine merit. * * *'

In the case before us Zenitz disclosed his compounds to be useful as tranquilizers as well as hypotensives, sedatives, etc. It is true he made no mention of the separation of hypotensive and tranquilizing activity, but as with the celluloid top in Westmoreland, the advantage of minimized hypotensive activity would inherently flow from the indicated use of the compounds as tranquilizers.

[4] The present facts are to be distinguished from those in the ***750** several cases cited by the solicitor[FN2] to support the contention that appellant is not in a favorable position to urge undisclosed ****928** properties as a ground for establishing unobviousness. One of those cases, In re Herr, 304 F.2d 906, 907, 50 CCPA 705, involved certain testosterone derivatives. The affidavit presented evidence of oral anabolic and androgenic activity. The specification was devoid, however, of any mention of such activity for the compounds and the sole utility disclosed in Herr's specification was that the compounds were useful intermediates in the making of other compounds which had anabolic and androgenic activity. It is readily seen that if the disclosure of Herr was followed the compounds would be used as intermediates and no benefit from their anabolic and androgenic activity would flow from such use. Here, Zenitz disclosed a tranquilizer and subsequently established that if it is used as a tranquilizer it is a better one for it minimizes the side effects of hypotensive activity. Therefore we think the latter property must be considered in determining the patentability of the claimed compound.

[5] We find the affidavits establish unobviousness as to the hydroxypropyl derivatives and the corresponding hydroxy-ethyl and hydroxy-lower-alkyl derivatives. Therefore, we are obliged to reverse as to claims 3, 9, 10 and 11.

[6] As to compounds having acyloxy-lower-alkyl, none of which have been compared, we are unable to find support in the record for concluding that proof of unobviousness of the compounds having hydroxy alkyl substituents establishes that the corresponding compounds wherein the hydroxy alkyl substituents are esterified, are also unobvious.[FN3] We therefore affirm the rejection of claims 5, 12 and 21 as being obvious from the corresponding compounds of Cusic in view of the secondary references showing that Cl and CF(3) are commonly employed potentiating groups on compounds of the type here claimed.

The rejection of claims 3, 9, 10 and 11 is reversed.

The rejection of claims 5, 12 and 21 is affirmed.

Modified.

FN1. Serial No. 746,615, filed July 7, 1958.

FN2. In re Milton E. Herr, 304 F.2d 906, 907, 50 CCPA 705; In re Lundberg, 253 F.2d 244, 45 CCPA 838; In re Crawford, 250 F.2d 370, 45 CCPA 750; In re Rossi, 241 F.2d 726, 44 CCPA 750; In re Stewart, 222 F.2d 747, 42 CCPA 937; In re Dalzell et al., 166 F.2d 834, 35 CCPA 1024; Abbott et al. v. Coe, 71 App.D.C. 195, 109 F.2d 449.

FN3. Unfortunately Zenitz's brief does not help any. The entire discussion of the actual facts before us is relegated to the following paragraph:

'THE SUBJECT MATTER INVOLVED

'The structure of the compounds on appeal can be seen from the claims on appeal * * *. Their relationship to the references is described in the Examiner's Answer * * *. No further chemical details are here offered because they are unnecessary to decide any issue in this case.'

Cust. & Pat.App.,1964.
Application of Zenitz
52 C.C.P.A. 746, 333 F.2d 924, 142 U.S.P.Q. 158

END OF DOCUMENT

Part G Patentability – Chapter VII Inventive Step

11. Arguments and evidence submitted by the applicant

The relevant arguments and evidence to be considered by the examiner for assessing inventive step may either be taken from the originally-filed patent application or submitted by the applicant during the subsequent proceedings (see G-VII, 5.2, and H-V, 2.2 and 2.4).

Care must be taken, however, whenever new effects in support of inventive step are referred to. Such new effects can only be taken into account if they are implied by or at least related to the technical problem initially suggested in the originally filed application (see also G-VII, 5.2, T 386/89 and T 184/82).

Example of such a new effect:

The invention as filed relates to a pharmaceutical composition having a specific activity. At first sight, having regard to the relevant prior art, it would appear that there is a lack of inventive step. Subsequently, the applicant submits new evidence which shows that the claimed composition exhibits an unexpected advantage in terms of low toxicity. In this case, it is allowable to reformulate the technical problem by including the aspect of toxicity, since pharmaceutical activity and toxicity are related in the sense that the skilled person would always contemplate the two aspects together.

The reformulation of the technical problem may or may not give rise to amendment or insertion of the statement of the technical problem in the description. Any such amendment is only allowable if it satisfies the conditions listed in H-V, 2.4. In the above example of a pharmaceutical composition, neither the reformulated problem nor the information on toxicity could be introduced into the description without infringing Art. 123(2).

In **T 848/94** the solution of the existing technical problem required a combination of measures that was not suggested by the prior art in such a manner that it would have been adopted by the person skilled in the art. Therefore, the person skilled in the art was not in a "one-way-situation".

According to the boards' case law, an improvement is not a prerequisite for inventive step. In **T 154/87** it was pointed out that the achievement of a surprising effect was no precondition for the existence of inventive step. All that was necessary was to ascertain that the respective subject-matter could not be derived by the skilled person in an obvious manner from the available prior art (**T 426/92**, **T 164/94**, **T 960/95**, **T 524/97**, **T 888/08**).

In **T 551/89** the board stated that an effect which was to be expected as the result of an obvious measure could not contribute to recognition of the required inventive step, even if the scale of this effect was surprising to the skilled person. In this case an effect whose scale surpassed the skilled person's hopes merely represented a bonus effect following inevitably from the use of an obvious measure and obtained by the skilled person without any inventive effort on his part (**T 506/92**, **T 882/94**).

In **T 240/93** the application related to an apparatus for the surgical treatment of tissues by hyperthermia, equipped with heat protection means. The application was refused by the examining division, which considered the short treatment duration of one hour and further advantages resulting from the use of cooling means to be extra (bonus) effects. The board, however, stated that in the case in point the objective problem underlying the invention was to provide an apparatus for the effective therapeutic treatment of benign prostate hyperplasia in a short period of time. In view of the many considerable practical advantages of a single one-hour hyperthermia session for a patient, such a short treatment duration could not be dismissed as a mere "bonus" effect, but was crucial to the invention and the basis of the objective problem.

10.9. Comparative tests

According to the established jurisprudence, a surprising effect (advantageous effect or feature) demonstrated in a comparative test can be taken as an indication of inventive step. If comparative tests are chosen to demonstrate an inventive step on the basis of an improved effect, the nature of the comparison with the closest state of the art must be such that the alleged advantage or effect is convincingly shown to have its origin in the distinguishing feature of the invention compared with the closest state of the art (**T 197/86**, OJ 1989, 371; **T 234/03**; **T 378/03**) and alleged but unsupported advantages cannot be taken into consideration in respect of the determination of the problem underlying the invention (see also Chapter I.D.4.2 "Alleged advantages"; **T 20/81**, OJ 1982, 217; **T 561/94**).

In **T 197/86** (OJ 1989, 371) the board supplemented the principles laid down in earlier decision **T 181/82** (OJ 1984, 401), according to which, where comparative tests were submitted as evidence of an unexpected effect, there had to be the closest possible structural approximation in a comparable type of use to the subject-matter claimed. In

the case in point the respondent (proprietor of the patent) strengthened support for his claim by voluntarily providing comparisons with variants which, although not expressly belonging to the prior art, differed from the claimed subject-matter only by the distinguishing feature of the invention**.** The board summarised its position by stating, that in cases where comparative tests were chosen to demonstrate an inventive step with an improved effect over **a claimed area**, the nature of the comparison with the closest state of the art had to be such that the effect was convincingly shown to have its origin in the distinguishing feature of the invention. For this purpose it might be necessary to modify the elements of comparison so that they differed only by such a distinguishing feature (**T 292/92**, **T 412/94, T 819/96**, **T 133/01**, **T 369/02**, **T 668/02**, **T 984/03**, **T 2043/09**).

As early as **T 35/85** the board had stated that an applicant or patentee may discharge his onus of proof by voluntarily submitting comparative tests with newly prepared variants of the closest state of the art identifying the features common with the invention, in order to have a variant lying closer to the invention so that the advantageous effect attributable to the distinguishing feature is thereby more clearly demonstrated (**T 40/89**, **T 191/97**, **T 496/02**).

It is for the applicant (patentee) to furnish evidence of an improved effect of the subject-matter of a claim, which has been asserted, but was not mentioned in the application as filed, in the whole of the claimed area vis-à-vis the closest prior art (**T 355/97**, **T 1213/03**, **T 653/07**).

In **T 415/11** the board stated when the credibility that a technical effect is achieved by substantially all claimed compounds is at issue and in a situation where, it is prima facie unlikely that this is credible, it is not the opponent (here: the appellant), but the patentee (here: the respondent) who has the burden of proving that the effect is achieved (see for example **T 939/92**, OJ 1996, 309; **T 97/00**).

In **T 390/88** the board addressed the question of the circumstances under which the production of comparative examples was unnecessary. In the above-mentioned earlier cases the invention had been obvious prima facie because the products, although novel, were very close structurally to the prior art products. The case in point was different. Here, the board said that the production of comparative examples was not essential to establish inventiveness, as the invention had not been obvious from the outset (**T 656/91**).

In **T 702/99** the board stated that in cases concerning products such as cosmetics, in which applicants or patentees seek to establish that their inventions have an improved "feel" over the prior art, or opponents seek to deny such an improved "feel", it is common for one or more parties to file evidence of comparative tests conducted by a number of persons. It is essential for such tests to be made under conditions which ensure maximum objectivity on the part of those conducting the tests and who may be required at a later date to give evidence in proceedings. It is always desirable that such tests can be shown to be "blind" and that they have been conducted in the strictest conditions; that the testers have had no part in the making of the claimed invention or research leading

up to the invention or the patenting procedure (see also **T 479/06**, **T 275/11** and **T 1962/12**, which reiterates the conditions for plausibility of comparative tests).

In **T 234/03** the board stated that to be of relevance in demonstrating that a technical improvement is achieved in comparison with the closest state of the art, any comparative test presented must be reproducible on the basis of the information thus provided, thereby rendering the results of such tests directly verifiable (**T 494/99**). This requirement implies, in particular, that the procedure for performing the test relies on quantitative information enabling the person skilled in the art to reproduce it reliably and validly. Vague and imprecise operating instructions render the test inappropriate and thus irrelevant.

In **T 172/90** the comparative examples produced did not constitute suitable evidence of inventive step. The board said that the products adduced as a basis of comparison were commercially available and had evidently been selected at random. Technical progress shown in comparison with products of this kind could not be a substitute for the demonstration of inventive step with regard to the closest prior art (see also **T 164/83**, OJ 1987, 149; **T 730/96**)**.**

English Translation

Reference Purpose Only

Delivery Date of the Judgment:	July 15, 2010
Court:	Intellectual Property High Court, Third Division
Case Number:	2009 (Gyo-ke) 10238
Plaintiff:	The Procter & Gamble Company
Defendant:	Japan Patent Office (JPO)

Section 1. Demands <omitted>

Section 2. Facts not disputed between the parties <omitted >

Section 3. Allegations of the parties <omitted>

Section 4. Judgment of the Court

This court holds as follows.

(1) In the context of the determination as to whether or not the plaintiff's claimed invention could have been easily conceived of, the specification originally attached to the plaintiff's application can be understood as explaining the effect of the claimed invention that can be achieved by designating "2-Phenylbenzimidazole-5-sulfonic acid" as "UV-B filter." Accordingly, **this case should be judged as a case where it is allowable to take into consideration the experimental results presented as Reference 1 in the supplementary statement of the reasons for the request for a trial, submitted by the plaintiff in the trial proceedings.** Therefore, there is an error in the JPO decision ruling, to the contrary, that said experimental results should not be taken into consideration.

(2) **By taking said experimental results into consideration, the claimed invention can be found to achieve a particularly unexpected, remarkable effect that a person ordinarily skilled in the art could not have expected as compared with the cited prior invention**, and it is deemed that the claimed invention could not have easily been conceived of by referring to the cited prior invention. Consequently, there is an error in the JPO decision ruling that the claimed invention could not achieve any unexpected, remarkable effect but could have been easily conceived by referring to the cited prior invention.

The reasons are as follows.

1. Error of the decision that the experimental results presented in the supplementary statement of the reasons for request for a trial should not be taken into consideration

(i) The JPO decision is based upon the grounds that the claimed invention does not meet the requirements prescribed in Article 29, Paragraph 2 of the Patent Act.

In the context of the determination as to whether the invention meets the requirements prescribed in Article 29, Paragraph 2, absent any special circumstances, in the event there is no description with regard to the "effect of invention" in the specification originally attached to the application, it should not be allowable to claim and/or prove [such effect] by submitting experimental results after filing of the application, since such act is against

the objectives of the patent system, which takes the first-to-file principle and grants the patent right (exclusivity) in compensation for the disclosure of the invention.

Furthermore, though the effect of the applied invention is not required to be described in the specification under the existing Patent Act, in a general practice, it is an important element to be taken into consideration in the context of determination as to whether the applied invention meets the inventive step in comparison with the conventional arts. Whether the applied invention meets the inventive step is determined by whether the applied invention includes the technology which could not have been easily conceived based upon the publicly known technologies from the perspectives of whether the problems to be solved and the means for solving the problems are disclosed. Accordingly, whether the problems to be solved and the means for solving the problems are disclosed is linked to what the "effect of invention" is. Considering these points, absent any special circumstances, in the context of determination of the inventive step, it should not be allowable to take into consideration experimental results, etc. that are supplemented after its application, in connection with the "effect of invention" which has not been disclosed in the specification originally attached to the application, because it causes the unfair results between the applicant and third parties.

On the other hand, because the reasons for not allowing consideration of experimental results, etc. that are supplemented after its application come from the objects of the patent system and the needs for fairness between the applicant and the third parties, etc., except in the case where there is no description of the "effect of invention" in the specification originally attached to the application, if there is some description enough for a person ordinarily skilled in the art to recognize or assume the "effect of invention" therein, it should be allowable to take into consideration experimental results, etc. that are supplemented after its application as long as they are considered only within the scope presented in said description. Whether it is allowable or not should be determined from the perspectives of fairness mentioned above.

(ii) This court considers this case from the above-mentioned perspectives.

In the specification originally attached to the plaintiff's application (Evidence A-3, paragraph [0011]), it is described that "[I]t has surprisingly now been found that the compositions of the present invention, which comprise a UVA-absorbing dibenzoylmethane sunscreen active, a defined stabilizing agent, a UVB sunscreen active, and a carrier, and which are substantially free of benzylidene camphor derivatives, provide excellent stability (especially photostability), efficiency, and UV protection efficacy (including both UVA and UVB protection), in a safe, economical and aesthetically appealing (particularly on-skin transparency and without undue skin irritation) manner."

Furthermore, in the specification originally attached to the plaintiff's application (Evidence A-3, paragraph [0025]), there is a description related to UVB sunscreen actives (UVB filter) that "[P]referred UVB sunscreen actives are selected from the group consisting of 2-phenylbenzimidazole-5-sulfonic acid, TEA salicylate, octyl dimethyl PABA, zinc oxide, titanium dioxide, and mixtures thereof. A preferable organic sunscreen active is 2-phenyl-benzimidazole-5-sulfonic acid."

In addition, "2-phenylbenzimidazole-5-sulfonic acid" is publically known as one of the paratactically listed "UV-B filters" (Evidence A2-1 to A2-9).

In light of the foregoing descriptions, a person ordinarily skilled in the art who reads the specification originally attached to the plaintiff's application naturally recognizes that

the effect of the claimed invention that selects "2-phenylbenzimidazole-5-sulfonic acid" as "UV-B filter" is to improve the broad spectrum UV efficacy and photostability.

On the other hand, according to the experimental results presented in [Reference 1], the effects of the invention of this application, which show the remarkable effects in each respect, are as follows.

① The SPF value of the claimed invention (Example 1) is "50+" and its PPD value is "8+", comparing with the conventional products (Comparative examples 1 to 4), it shows that its SPF value is about 3-10 times higher than that of the conventional products and its PPD value is about 1.1 or 2 times higher than that of the conventional products, which means its superiority in broad spectrum UV efficacy.

② The claimed invention is able to maintain high-level SPF and PPD values greater than those of the conventional products even after the exposure to ultraviolet radiation, which means its superiority in photostability.

In fact, the remarkable effects of the invention are not clearly described in the specification originally attached to the plaintiff's application such that SPF value presented in the experiment [Reference 1] is about 3-10 times higher than that of the conventional products and the PPD value presented in the experiment [Reference 1] is about 1.1 or 2 times higher than that of the conventional products. However, in the instant case, a person ordinarily skilled in the art who reads the specification originally attached to the plaintiff's application can recognize that the effect of the claimed invention is to improve broad spectrum UV efficacy and photostability. Therefore, it is allowable to take into consideration the experimental results that are supplemented after the application on the premise of determination of the inventive step, and even doing so does not cause unfairness between the applicant and the third parties.

(iii) Judgment on the defendant's assertions

(a) <omitted>

(b) Furthermore, the defendant (i.e., JPO) asserts that the paragraph [0011] merely provides general description of the effect of the claimed invention, and how high the SPF value or PPD value will be cannot be presumed from the description originally attached to the plaintiff's application.

However, we cannot take the defendant's assertion. If we follow the defendant's assertion, we cannot assume that the effect of the invention is described in case where the effect is described in a qualitative manner or its value is not clearly disclosed in the specification originally attached to the application, and the experimental results that are supplemented after the application cannot be taken into consideration. Considering that an applicant is not able to know which cited prior invention will be compared with the claimed invention in the future and the reasoning by the examination body etc. at the time of the application, such conclusion will cause excessive burden on the applicant, forcing it to lose its chance of objective verification based on the experimental results, and will violate the objective of fairness mentioned above. Therefore, such position cannot be taken.

<The rest is omitted.>