Paper No. 17

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte HENNING BÖTTCHER, KARL J BUHRING,
HARTMUT GREINER, GERD BARTOSZYK,
and CHRISTOPH SEYFRIED,

_____

Appeal No. 1998-1487
Application No. 08/628,250

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ON BRIEF

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Before WINTERS, WILLIAM F. SMITH and MILLS, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 13-29, which are all of the claims pending in this application.

We reverse.

Claims 13 and 16 are illustrative of the claims on appeal and read as follows:

13. The compound 3-[4-(4-(4-cyanophenyl)-1-piperazinyl)butyl]-5-cyanoindole hydrochloride.

16. A method comprising administering to a patient an anxiolytic, antidepressant, antipsychotic, neuroleptic or antihypertensive active effective amount of the compound of claim 13 for the treatment or control of an illness associated with such activity.

The prior art references relied upon by the examiner are:

Böttcher et al. (Böttcher 1)	5,418,237	May 23, 1995
German Patent Application Böttcher et al. (Böttcher 2)	41 01 686 A1	Jul. 23, 1992

Grounds of Rejection

Claims 16, 20, 25 and 29 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter not described in the specification in such a way as to enable one of skill in the art to make and use the invention.

Claims 16, 20, 25 and 29 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellants regard as the invention.

Claims 13-29 stand rejected under 35 U.S.C. § 103 as unpatentable for obviousness over Böttcher 1 or 2.

DISCUSSION

In reaching our decision in this appeal, we have given consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the noted rejections, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellants' Brief for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

35 U.S.C. § 112, first and second paragraphs

Claims 16, 20, 25 and 29 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter not described in the specification in such a way as to enable one of skill in the art to make and use the invention. Claims 16, 20, 25 and 29 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellants regard as the invention.

The second paragraph of 35 U.S.C. § 112 requires claims to set out and circumscribe a particular area with a reasonable degree of precision and particularity. In

re Johnson, 558 F.2d 1008, 1015, 194 USPQ 187, 193 (CCPA 1977). In making this determination, the definiteness of the language employed in the claims must be analyzed, not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. Id.

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. § 112, second paragraph, is whether the claims meet the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. As stated above, if the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. See Ex parte Porter, 25 USPQ2d 1144, 1146 (Bd. Pat. App. & Int. 1992). With this as background, we analyze the specific rejections under 35 U.S.C. § 112, second paragraph, made by the examiner of the claims on appeal.

With respect to both rejections under 35 U.S.C. § 112, the examiner is troubled by the language “for the treatment or control of an illness associated with such activity” in claim 16 and related claims. The examiner suggests that this phrase “implies more than anxiety, depression, etc.” Answer, page 4. In our view, the examiner has not applied the appropriate legal standard to the rejections for indefiniteness and lack of enablement. With regard to the rejection for claim indefiniteness, we find that claim 16, for example,

clearly describes the desired activity of the claimed compound, i.e., anxiolytic, antidepressant, antipsychotic, neuroleptic or antihypertensive activities. Thus the phrase "treatment or control of an illness associated with such activity", in claim 16 is limited by the specific activities previously recited in the claim. We find no ambiguity or indefiniteness here. The examiner appears to have confused the definiteness requirement of 35 U.S.C. § 112, second paragraph, with the enablement requirement of 35 U.S.C. § 112, first paragraph. As set forth in In re Skoll, 523 F.2d 1392, 1395, 187 USPQ 481, 482-83 (CCPA 1975), the use of a broad term in a claim does not make that claim indefinite.

With respect to the 35 U.S.C. § 112, first paragraph rejection, we find the rejection not entirely clear as to whether it is predicated on the written description or enablement requirement of 35 U.S.C. § 112, first paragraph. To the extent that the rejection is predicated upon the written description requirement, we summarily reverse as we find the examiner has failed to specifically indicate what language in the claims is inadequately supported by the original specification.

To the extent that the rejection is based on the enablement requirement of 35 U.S.C. § 112, first paragraph, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir.1997) (quoting In re Wright, 999 F.2d 1557, 1561, 27

USPQ2d 1510, 1513 (Fed. Cir. 1993)). Conversely, the first paragraph of Section 112 requires that the scope of protection sought in a claim bear a reasonable correlation to the scope of enablement provided by the specification.

In addition, analysis of whether the claims under appeal are supported by an enabling disclosure requires a determination of whether that disclosure contains sufficient information regarding the subject matter of the appealed claims as to enable one skilled in the pertinent art to make and use the claimed invention. In order to establish a prima facie case of lack of enablement, the examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); In re Morehouse, 545 F.2d 162, 165, 192 USPQ 29 32 (CCPA 1976). The threshold step in resolving this issue is to determine whether the examiner has met his burden of proof by advancing acceptable reasoning inconsistent with enablement.

The examiner suggests (Answer, page 5) that

> To the extent any illness associated with anxiety, depression ... hypertension is embraced by the claim language (e.g., A person diagnosed with cancer or AIDS may be depressed) there is no enabling disclosure for all such diseases of varying etiology. Also [the] scope of antipsychotic disorders (even if such only intended by the claim language “associated with”) embraces a variety of dysfunctions such as Tourette's Syndrome, Huntington's Disease) not shown to be ... associated with simply being [a] serotonin antagonist or having dopamine activity as described in the specification, p. 2.

In our view, the specification discloses the scope of the invention in a manner discernable by one of ordinary skill in the art. We find the examiner's concerns that any illness associated with anxiety, depression, and hypertension is embraced by the claim language, and that there is no disclosure for treatment of all of such diseases of varying etiology, including AIDS, to be misplaced. For example, the specification discloses that the claimed compounds show "actions on the central nervous system, especially 5-HT_{1A}-antagonist and 5-HT-reuptake-inhibiting actions. They inhibit the binding of tritiated serotonin ligands to hippocampal receptors." Specification, page 2. The specification also discloses that the compounds have anxiolytic, antidepressant, antipsychotic, neuroleptic or antihypertensive activities. Id.

The examiner has not provided evidence or argument establishing that one of ordinary skill in the art with a disclosure in the specification of the above symptomology and with knowledge of the manner in which the claimed compounds are disclosed to act upon the central nervous system, would not have a sufficient teaching to treat associated anxiolytic, antidepressant, antipsychotic, neuroleptic or antihypertensive conditions.

A legal standard which governs determination of enablement under this section of the statute that does not appear to have been taken into account by the examiner is that the specification need not disclose what is well known in the art. See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986).

It is well established that enablement issues must be decided on the basis of the information imparted by appellants in the specification of the patent application under review in conjunction with the relevant prior art. Viewing a given patent specification in a vacuum apart from the prior art to determine whether the claims of such a patent application are enabled is incorrect. See, e.g., Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), ("A specification need not disclose what is well known in the art.")

From a review of Böttcher 1, it would appear that those of ordinary skill in the art are aware of how similar compounds act on the central nervous system and are aware that similar compounds possess anxiolytic, antidepressant, antipsychotic, neuroleptic or antihypertensive activities. Böttcher 1, columns 1-2.

The examiner also appears to have misapprehened what the claims actually require. The examiner (Answer, page 5) appears to set up a straw man argument suggesting that, to the extent that any illness associated with anxiety, depression or hypertension is embraced by the claim language, such as depression associated with cancer or AIDs, there is no enabling disclosure for treatment of such illnesses. However, the claims are not so broad, as they are limited to a method comprising administering to a patient an anxiolytic, antidepressant, antipsychotic, neuroleptic or antihypertensive active effective amount of the compound of claim 13 for the treatment or control of an illness

associated with the specific activities recited in the claim. For these reasons, the rejection of the claims under 35 U.S.C. § 112, first and second paragraphs are reversed.

35 U.S.C. § 103

Claims 13-29 stand rejected under 35 U.S.C. § 103 as unpatentable for obviousness over Böttcher 1 or 2.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). With this as background, we analyze the prior art applied by the examiner in the rejection of the claims on appeal.

The cited German Patent (Böttcher 2) is the equivalent of the U.S. Patent (Böttcher 1). Böttcher 1 is relied on by the examiner, and indicated to establish "compounds within the instant scope for the same uses as claimed herein, anxiety, depression, as psychotic agents, hypertension among others." Answer, page 6. The claimed compounds are indicated to "differ from the closest Böttcher 1 compound (see col. 14, lines 17-19) in two respects - 1) having a 4-cyanophenyl vs 2-cyanophenyl and 2) being the HCl salt vs. the

free form." Id. Thus, the claimed compounds and the Böttcher 1 reference compounds would appear to be positional isomers.

Although the appellants would suggest that a prima facie case of obviousness has not been established by the examiner citing In re Jones, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) and In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994), we find it unnecessary to determine whether or not a prima facie case of obviousness has been established by the examiner, as we find the evidence provided by appellant would outweigh any prima facie case, if established.

Appellants have provided a Declaration under 37 CFR § 1.132 of Christoph A. Seyfried as evidence of the nonobviousness of the claimed invention. The Seyfried Declaration compares the claimed (claim 13) 4-cyanophenyl compound (Compound A of the Declaration) with the 2-cyanophenyl (Compound C3 of the Declaration) of Böttcher 1.

The evidence presented in the Declaration shows that compound A shows no σ_1 antagonistic action, in contrast to compound C3 which possesses σ_1 antagonistic action (Declaration pages 3 and 4 and Table II). In addition, in contrast to the prior art compound C3, compound A shows no antidopaminergic effect, which the Declarant finds to be unexpected. The antidopaminergic effect is also supported by in vivo test results. Declaration, page 4.

The Declarant summarizes (Declaration, page 4) that

> [l]ack of affinity to the α_1 receptor and lack of anti-dopaminergic effect are important features in the profile of compounds for treating depression. Due to the lack of affinity to the α_1 receptor cardiovascular, e.g.[,] hypotensive and/or negative inotropic side effects are not expected for A. Likewise, secondary effects such as extrapyrimidal motor effects should not occur.

In response to the Declaration evidence presented by appellants, the examiner finds that the properties relied on in showing evidence of nonobviousness, lack of α_1 antagonistic activity and the lack of anti-dopaminergic blocking, were never expressly described in the specification, citing In re Davies, 475 F.2d 667, 670, 177 USPQ 381, 381 (CCPA 1973) and In re Zenitz, 333 F.2d 924, 928, 142 USPQ 158, 161 (CCPA 1964) and thus cannot be relied upon to support patentability.

We agree with appellants that the properties described by appellants in the Seyfried Declaration would "inherently flow" from the subject matter disclosed and described in the original application. In re Khelghatian, 364 F.2d 870, 150 USPQ 661, 666 (CCPA 1966). Compare, In re Chu, 66 F.3d 292, 298, 36 USPQ2d 1089, 1095 (Fed. Cir. 1995) ["We have found no cases supporting the position that a patent applicant's evidence and/or arguments traversing a § 103 rejection must be contained within the specification".] The specification describes that the compounds can be used as pharmacologically active substances, in particular, as anxiolytics, antidepressants, antipsychotics, neuroleptics and/or antihypertensives. Specification, page 2. Thus, the

lack of affinity to the σ_1 receptor and lack of anti-dopaminergic effect are important features in the profile of compounds for treating depression and inherently flow from their described use in the specification as antidepressants.

After evidence or arguments are submitted by the appellants in response to rejection based on obviousness, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of the argument. On balance, we believe that the totality of the evidence presented by the examiner and appellants weighs in favor of finding the claimed invention nonobvious in view of the cited references. The rejection of the claims for obviousness of the claimed invention is reversed.

CONCLUSION

The rejections of claims 16, 20, 25 and 29 under 35 U.S.C. § 112, first and second paragraphs, and of claims 13-29 under 35 U.S.C. § 103 are reversed.

REVERSED

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SHERMAN D. WINTERS	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
WILLIAM F. SMITH	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
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DEMETRA J. MILLS	)	
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