

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte RALPH L. BASS

Appeal No. 2005-1164
Application No. 09/721,131

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 22-42, which are all the claims pending in the application.

Claims 22, 27 and 28 are illustrative of the subject matter on appeal and are reproduced below:

22. A method for providing sodium chloride to a human having HIV infection by administering to the upper gastro-intestinal tract of the human a selected amount of a formulation of sodium chloride, said method comprising:
 - (a) administering the sodium chloride formulation to the human's upper gastrointestinal tract so as to introduce the sodium chloride formulation to the metabolism of the human, wherein the amount of the sodium chloride in the sodium chloride formulation administered is (i) sufficient to provide more sodium chloride than the human's average daily intake for sodium chloride, as determined after monitoring the human for about 1

Claim 35 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification that fails to provide an enabling description of the claimed invention.

We affirm the rejection of claims 22-42 under 35 U.S.C. § 101 and § 112, first paragraph. Having disposed of all claims on appeal, we do not reach the separate rejection of claim 35 under 35 U.S.C. § 112, first paragraph.

CLAIM CONSTRUCTION

Claim 22:

The method of claim 22, comprises two steps.

Step 1: administer a sodium chloride formulation to a human's upper gastrointestinal tract in an amount¹ that is (i) sufficient to provide more sodium chloride than the human's average daily intake for sodium chloride², but (ii) less than a toxic amount measured by TClO and LD50.³

Step 2: periodically repeat the first step.

As we understand it, part (c) of claim 22 sets forth the result obtained by performing two method steps – alleviate HIV infection. As the examiner points out (Answer, page 2), the phrase “alleviation of the HIV infection”, as it appears

¹ According to appellant's specification (page 12), “whatever administrative method is chosen should result in circulating levels of the NaCl within a range of about 0.05 μ M to about 1.0 μ M.”

² According to appellant's specification (bridging paragraph, pages 10-11), [a]dministration of the NaCl formulation should be sufficient to provide more than the minimum daily requirement of NaCl according to the National Academy of Sciences, which is a minimum recommendation for Americans of 500 mg/day of sodium (1250 mg/day of NaCl). More preferably, administration of the NaCl formulation should be sufficient to provide more than what the average American chooses to consume (which is 4960 to 6230 mg/day of NaCl according to the U.S. Food and Drug Administration) and should be sufficient to provide more than what the average human of the world's population chooses to consume where salt is readily available (which is 6000 to 11000 mg/day of NaCl....

³ Claim 22 defines “TClO” as the dosage for oral consumption that is the lowest dosage of sodium chloride that has produced toxic side effects in humans, and “LD50” as the dosage of sodium chloride that is lethal for 50% of the human population.

in part (c) of claim 22 “means reduction of HIV infection with the end or desired result being testing negative for the presence of HIV infection (Specification, pg. 11, lines 18-23).” Accordingly, for the purposes of our discussion we have construed part (c) of claim 22 to mean that the end result of performing method steps 1 and 2 is that a human having HIV infection prior to treatment will test negative for the presence of HIV infection after treatment of the method steps.

Claim 28:

Claim 28 depends from claim 27, which in turn depends from claim 22. Accordingly, claim 28, through its dependency on claim 27, provides two additional limitations to the method of claim 22. First, claim 28 requires that the sodium chloride formulation of the method set forth in claim 22 “is a mixture with a form of potassium in a weight ratio amount of Na:K up to about 1:1.” See claim 27. The second limitation added by claim 28 is that “the mixture contains up to about 20% by weight of another ingredient selected from the group consisting of S, P, Zn, Mn, Fe, Cu, Cr, I, Mg, Co, Se, and combinations thereof.” See claim 28, emphasis added. However, as the examiner points out (Answer, page 10), the phrase “up to about 20%” includes zero as the lower limit. In re Mochel, 470 F.2d 638, 640, 176 USPQ 194, 195 (CCPA 1972). Accordingly, we interpret the phrase “up to about 20%” as it appears in claim 28 to include 0%.

Accordingly, as we understand it, claim 28 further limits claim 22 by requiring that the sodium chloride formulation is a mixture with a form of potassium in a weight ratio amount of Na:K up to about 1:1.

DISCUSSION

Utility:

According to appellant (Brief, page 4), “[c]laim 28 does not stand or fall together with the remaining claims 22-27 and 29-42.” Accordingly, we limit our discussion to representative claims 22 and 28. Claims 23-27 and 29-42 will stand or fall together with claim 22. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

The examiner rejected all of the claims as lacking patentable utility.⁴

Claim 22

We recognize that “it is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works.” Newman v. Quigg, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989). However, as a starting point we will discuss appellant’s two theories as to how his invention works (Brief, page 6). We take each in turn.

Appellant’s first theory,

the administration of sodium chloride beyond the average daily intake, but less than the toxic amount, should not disrupt the larger human cells, but should be enough to disrupt the smaller HIV virus cells. In other words, this particular amount of sodium chloride should result in a change in osmotic pressure that dehydrates the smaller HIV cells. They should thus be ruptured. Since the particular amount of sodium chloride is still less than the toxic amount, the particular amount should not be enough for rupturing the larger human body cells by a change in osmotic pressure resulting in dehydration.

⁴ The examiner rejected the claims under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. However the rejection for nonenablement was presented simply as a corollary of the finding of lack of utility. See Paper mailed April 19, 2004, page 3, and Answer, page 5. Therefore, although we discuss only the § 101 rejection, our conclusion also applies to the § 112 rejection.

Brief, page 6. The examiner finds (Paper mailed April 19, 2004, page 3), however, that Hrinda disclose (col. 8, line 51 – col. 9, line 12), “NaCl concentrations as high as 1.4 M for prolonged periods, such as greater than 18 hours, only resulted in partial disassembling of HIV particles with dilution to 0.25 M being sufficient to prevent the same.” As the examiner points out (*id.*), “it appears that the effective amount of NaCl needed to disrupt the HIV virus far exceeds what is disclosed and claimed as being the effective therapeutic range....”⁵

In response, appellant asserts (Brief, page 7), the NaCl concentrations set forth in Hrinda “are concentrations for HIV particles floating in phosphate buffered aqueous sodium chloride. In contrast, appellant’s desirable circulating levels of sodium chloride ... are concentrations in human blood in a human body for HIV particles attached to human CD4 T-cells, not for HIV particles floating in phosphate buffered aqueous sodium chloride.” According to appellant (*id.*), “an HIV cell attached to a CD4 T-cell in the human body would act differently from free HIV cells in phosphate buffered saline.” Therefore, appellant asserts (Brief, page 8), a “person of ordinary skill in the art would expect that HIV cells attached to CD4 T-cells in the human body should act differently from free HIV cells floating in phosphate buffered saline.” Appellant, however, provides no evidence to support this conclusion. As the examiner points out (Answer, page 7),

⁵ According to the examiner (Paper mailed April 19, 2004, page 3, emphasis added), “[a]pplicant indicates that the administration should result in circulating levels of NaCl within the range of about 0.05 μ M to about 1.0 μ M and that the extra amount of NaCl will disrupt the HIV virus.” See e.g., appellant’s specification, page 12, emphasis added, “whatever administrative method is chosen should result in circulating levels of the NaCl within a range of about 0.05 μ M to about 1.0 μ M.” We understand this to mean that the “circulating levels” of NaCl includes the amount of NaCl administered plus the amount of NaCl that is already present in the human to be treated.

“arguments of counsel alone cannot take the place of evidence in the record....”

In re Pearson, 494 F.2d 1399, 1405, 181 USPQ 641, 646 (CCPA 1974)

(“Attorney’s argument in a brief cannot take the place of evidence.”).

Accordingly, we are not persuaded by appellant’s unsupported assertions.

Appellant’s second theory, is that “the disruption/rupturing of the smaller HIV cells should cause them to be removed from the larger human cells, thereby alleviating the HIV infection.” Brief, page 6. According to appellant (Brief, page 8), since Hrinda demonstrates that salt can be used to remove HIV particles from a chromatography resin “and appellant does theorize that the particular amount of sodium chloride formulation will remove the HIV cells from the human CD4 T-cells. ... [O]ne could also argue in the alternative that Hrinda ... is supportive of appellant’s theory of how and why his invention works.”

In response the examiner finds (Answer, page 7), Hrinda discloses that a NaCl concentration of 0.6-2 M is required to elute HIV particles from the chromatography resin. Hrinda, column 8, lines 57-61. In this regard, the examiner points out (Answer, bridging sentence, pages 7-8), “[a]ccording to [a]ppellant’s [s]pecification, the administration of sodium chloride as claimed should result in circulating levels of NaCl within the range of about 0.05 to about 1.0 μ M ... which is far below the levels disclosed in Hringa [sic] et al. to be useful for washing HIV without removing the same from the [chromatography] resin.” Therefore, in contrast to appellant’s assertion, the examiner finds (Answer, page 8), Hrinda, “even under this alternative theory, supports the conclusion that [a]ppellant’s claimed invention lacks credible utility.” We agree. There is no

evidence on this record to demonstrate that the concentration of NaCl required to dissociate an HIV particle from the chromatography resin as taught by Hrinda would be different than the concentration of NaCl required to dissociate an HIV particle from a T-cell.

“The PTO may establish a reason to doubt an invention's asserted utility when the written description ‘suggest[s] an inherently unbelievable undertaking or involve[s] implausible scientific principles.’” In re Cortright, 165 F.3d 1353, 1357, 49 USPQ2d 1464, 1466 (Fed. Cir. 1999 (quoting In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995)), alteration original. Stated differently, we find that the examiner has presented the evidence necessary to establish a reason for one skilled in the art to question the objective truth of the statement of utility. In re Langer, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974). Specifically, we agree with the examiner, that the evidence of record establishes that the amount of salt necessary to “alleviate” an HIV infection⁶ as set forth in appellant’s claimed invention, is expressly excluded by appellant’s claims. See e.g., claim 22, part (a)(ii) and (iii). Stated differently, the evidence of record demonstrates that the amount of NaCl required to dissociate an HIV particle from a T-cell, or disrupt an HIV particle exceeds the circulating level (0.05 μ M to about 1.0 μ M) of NaCl appellant proposes to maintain in the human being treated. Accordingly, in our opinion, the examiner has met his burden of challenging applicant’s presumptively correct assertion of utility. Brana, 51 F.3d at 1566, 34 USPQ2d at 1441. If the PTO provides evidence

⁶ By “disrupting” the HIV particle, disassociating the HIV particle from a T cell, or by some other means.

showing that one of ordinary skill in the art would reasonably doubt the asserted utility, the burden shifts to the applicant to submit evidence sufficient to convince such a person of the invention's asserted utility. Id.

We now consider the evidence of record that is in favor of appellant's claimed invention. The prophetic examples set forth in appellant's specification (pages 13-17) are insufficient to rebut the evidence relied upon by the examiner to demonstrate that the amount of NaCl required to dissociate an HIV particle from a T-cell⁷, or disrupt an HIV particle, exceeds the circulating level (0.05 μM to about 1.0 μM) of NaCl appellant proposes to maintain in the human being treated. Accordingly, we do not find appellant's prophetic examples persuasive.

We recognize appellant's reliance (see e.g., Brief, bridging paragraph, pages 10-11) on a number of "research studies" which the examiner attaches to the Answer as Exhibit B. However, as appellant admits (Brief, page 11), "[t]he research studies do not address the nutrients, sodium chloride and potassium...." Accordingly, we do not find this evidence persuasive.

We are also not persuaded by appellant's reliance (Brief, page 6) on the Merck brochure⁸ entitled "Livin' It"⁹, which the examiner finds (Answer, page 6, footnote omitted), "does not provide evidence that administration of sodium chloride as claimed would be effective in alleviating HIV infection or otherwise show that sodium chloride would act to disrupt the smaller HIV [particle]."

⁷ Note, there is no evidence on this record to demonstrate that the concentration of NaCl required to dissociate an HIV particle from the chromatography resin as taught by Hrinda would be different than the concentration of NaCl required to dissociate an HIV particle from a T-cell.

⁸ Attached to the Answer as Exhibit A.

Accordingly, there is no evidence on this record supporting appellant's asserted utility.

We recognize appellant's assertion (Brief, page 10), "that treating HIV infection was once considered an inherently unbelievable undertaking, but since then, treatments for HIV infection have gained acceptance, and both AZT (zidovudine) and 3TC (lamivudine) are recognized as effective for treating HIV infection." Both AZT and 3TC function by blocking reverse transcription. See Goldman, bridging paragraph, pages 1934-1935. There is no evidence on this record that NaCl in the amount set forth in appellant's claim would block reverse transcription of HIV RNA. Further, as explained in the Merck brochure entitled "Livin' It" the drug CRIVAN[®] is a protease inhibitor which functions to "stop the protease enzyme from cutting protein chains into the smaller pieces that are needed for new virions." There is no evidence on this record that NaCl in the amount set forth in appellant's claim would act as a protease inhibitor.

⁹ According to appellant this brochure illustrates (1) the "size difference" between an HIV particle and a T-cell (Brief, page 6), and (2) "how HIV infects a person" (Brief, page 8).

Accordingly, we are not persuaded by appellant's intimation that because AZT and 3TC, or for that matter CRIXIVAN[®], are recognized as effective for treating HIV infection, that objective evidence demonstrating the operability of the use of salt for treating HIV infection is not required to rebut the examiner's prima facie case. By analogy, we note that a number of methods for producing energy are well known to a person of ordinary skill in the art. Producing energy by "cold fusion," however, is not. See e.g., In re Swartz, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) ("the PTO provided several references showing that results in the area of cold fusion were irreproducible"). In Swartz, the court found "the PTO provided substantial evidence that those skilled in the art would 'reasonably doubt' the asserted utility and operability of cold fusion." Id. Accordingly, the evidentiary burden was shifted to Swartz to submit "evidence of operability that would be sufficient to overcome reasonable doubt." Id. Failing to satisfy his evidentiary burden the court found that "the utility of Mr. Swartz's claimed process had not been established and that his application did not satisfy the enablement requirement." Id.

As in Swartz, on this record, the examiner provided evidence that those skilled in the art would "reasonably doubt" the asserted utility and operability of appellant's claimed invention. Accordingly, in our opinion, the evidentiary burden was properly shifted to appellant. For the reasons set forth above, we find that appellant failed to carry his burden. Accordingly, we affirm the rejection

of claim 22 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph¹⁰. As discussed supra claims 23-27 and 29-42 fall together with claim 22.

Claim 28

As discussed above, we interpret the phrase “up to about 20%” as it appears in claim 28 to include 0%. Therefore, as we understand it, claim 28 further limits claim 22 by requiring that the sodium chloride formulation is a mixture with a form of potassium in a weight ratio amount of Na:K up to about 1:1.

Appellant relies on a number of “research studies”¹¹, which according to appellant “report a correlation between a decrease in the ability to inhibit HIV and the presence in HIV infected persons of nutrient deficiency for many of the nutrients ... that appellant has recited in his dependent claim 28.” However, appellant admits (Brief, page 11), “[t]he research studies do not address the nutrients, sodium chloride and potassium....” Accordingly, the “research studies” relied upon by appellant do not address the requirements of claim 28, which, as we understand it, further limits claim 22 by requiring that the sodium chloride formulation is a mixture with a form of potassium in a weight ratio amount of Na:K up to about 1:1. Therefore, in our opinion the “research studies” fail to support appellant’s claimed invention.

¹⁰ In re Brana, 51 F.3d 1560, 1564, 34 USPQ2d 1436, 1439 (Fed. Cir. 1995) (“Obviously, if a claimed invention does not have utility, the specification cannot enable one to use it.”).

¹¹ The examiner attached as Exhibit B of the Answer, “[a] copy of the research studies submitted by [a]ppellant, with references 1-6, [and] 10-19 redacted.” Answer, page 10. According to the examiner (Answer, page 9), “[a]ppellant has withdrawn references 1-6 [and] 10-19 as being published after the November 22, 2000 filing date of the application....”

As a result, we are left with no evidence on this record to rebut the examiner's finding that NaCl, with or without potassium, will function as required by the claimed method. Accordingly, we affirm the rejection of claim 28 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph.

Claim 35:

Having disposed of all claims on appeal, we do not reach the merits of the separate rejection of claim 35 under 35 U.S.C. § 112, first paragraph.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith)	
Administrative Patent Judge)	
)	
)	BOARD OF PATENT
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Appeal No. 2005-1164
Application No. 09/721,131

Page 14

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