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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* TULSEE SATISH DOSHI

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Appeal 2011-013499  
Application 12/075,695  
Technology Center 1600

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Before DEMETRA J. MILLS, LORA M. GREEN, and  
ERICA A. FRANKLIN, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a method for detecting exposure to a first ionizing radiation and a method for inferring a likelihood of exposure to ionizing radiation. The Patent Examiner rejected the claims as failing to comply with the enablement requirement. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

## STATEMENT OF THE CASE

Claims 1-11 are on appeal. Claims 1 and 9 are representative and read as follows:

1. A method for detecting exposure to first ionizing radiation, comprising:

performing a first HbA1c test on blood extracted from an animal at a first time, to establish a baseline glycosylated hemoglobin score;

performing a second HbA1c test on blood extracted from said animal at a second time subsequent to said first time, to establish a test glycosylated hemoglobin score;

comparing said test score to said baseline score and to determine a difference therebetween; and

inferring whether the animal has or has not been exposed to the first ionizing radiation between said first and second times based at least in part on the amount of said difference.

9. A method for inferring a likelihood of exposure to ionizing radiation, comprising:

determining a baseline glycosylated hemoglobin score by performing a first HbA1c test on blood extracted from an animal at a first time;

determining a test glycosylated hemoglobin score by performing a second HbA1c test on blood extracted from said animal at a second time subsequent to said first time;

determining a difference between said test score and said baseline score by comparing said test score to said baseline score;

quantifying the amount of ionizing radiation received by said animal by comparing said difference between said test score and said baseline score to a radiation exposure function relating radiation dosage to HbA1c score,

wherein said radiation exposure function relates radiation dosage to changes in HbA1c score and increases in HbA1c score positively correlate with increases in radiation dosage; and

inferring a likelihood of exposure to ionizing radiation between said first and second times based at least in part on said quantified amount of ionizing radiation.

The Examiner rejected claims 1-11 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

#### ENABLEMENT

The Examiner's position is the Specification would not have enabled a person of ordinary skill in the art to practice the claimed invention without undue experimentation. (Ans. 6.) Specifically, the Examiner found that the *quantity of experimentation* to perform the claimed methods would be undue because the person of ordinary skill in the art would first have to correlate in vivo levels of HbA1c in all possible test subjects with a change caused by exposure to every type of ionizing radiation to the exclusion of all other factors of HbA1c fluctuation. (*Id.*) According to the Examiner, this experimentation would require determining normal HbA1c levels for every type of animal, including humans, determining the response of every said animal to every form of ionizing radiation; determining all sources of variability of glycosylated hemoglobin levels in these animals; and determining how to predict the effects thereof and/or control for these outside factors. (*Id.* at 7.)

The Examiner also found that the Specification did not provide sufficient *direction or guidance* to a skilled artisan as to how to differentiate a change in HbA1c scores caused by exposure to ionizing radiation to the

exclusion of changes caused by other factors. (*Id.*) For example, the Examiner found that HbA1c levels can vary seasonally, with age, between human smokers and non-smokers, and in response to a menopausal condition. (*Id.*)(citing Simon at 864, 866). Additionally, the Examiner found that it was well known in the art that HbA1c levels are used to diagnose diabetes, which can manifest as an increase in glycosylated hemoglobin over normal values. (*Id.*)(citing Spec. [0013]). Further, the Examiner found that exposure to gamma rays, x-rays, and radium causes hemolysis of human blood erythrocytes and blood, which leads to a decrease in glycosylated hemoglobin. (*Id.*)(citing Kollmann 551, ll. 24-25). According to the Examiner, a skilled artisan would expect that the levels of glycosylated hemoglobin in a subject could be affected by these factors apart from, or in addition to, exposure to ionizing radiation. (*Id.*)

The Examiner also found that the Specification does not provide any evidence of a correlation between actual exposure to ionizing radiation in an animal with a concurrent change in its HbA1c levels. (*Id.*) In particular, the Examiner found that the *examples* in the Specification are not drawn to in vivo assays of subjects exposed to ionizing radiation. (*Id.* at 8.) Rather, the Specification examples are drawn to in vitro isolated blood samples placed in proximity to an x-ray machine. (*Id.*) According to the Examiner, these examples do not support an inference of whether an animal has been exposed to ionizing radiation because a skilled artisan would have recognized that the in vitro assay could not necessarily be correlated to an in vivo assay involving a more complex whole organism- especially in view of known variables potentially affecting glycosylated hemoglobin. (*Id.*)

The Examiner found that the *nature of the invention* involves performing HbA1c tests on blood extracted from an animal twice, comparing the results of two tests, and inferring whether or not the animal has or has not been exposed to ionizing radiation between the first and second tests. The Examiner found that significant *unpredictability* exists with respect to the use of HbA1c levels to infer whether an animal has or has not been exposed to ionizing radiation due to the many art-recognized sources known to cause variability in glycosylated hemoglobin levels. (*Id.* at 10.)

The Examiner found that in addition to encompassing all animals, the *breadth of the claims* is also unlimited with respect to the time period between the performance of the first and second HbA1c tests, which is significant because the Specification discloses that all red blood cells die by about 120 days. (*Id.* at 11.) Additionally, the Examiner found that claims were broader than the sole example in the Specification which involved a time period of only one hour between the performance of the first and second HbA1c tests. (*Id.* at 12.)

Regarding claims 1-8, Appellant contends that “the specification and figure as originally filed fully complies with the enablement requirement because one of ordinary skill in the art would be able to practice the recitations of claim 1 based on the disclosure of the specification without undue or unreasonable experimentation.” (App. Br. 12-13.) Appellant asserts that Specification “Figure 1 plainly shows a change in HbA1c score as a function of radiation exposure.” (*Id.* at 13.) Therefore, according to Appellant, “a person of ordinary skill in the art would know how to perform the first and second HbA1c tests,” and further “be able to infer from a small

difference or no difference that the person was not exposed to ionizing radiation or would be able to infer, at least in part, from a large difference that the person was exposed to ionizing radiation.” (*Id.*) Appellant asserts that “[a]ny experimentation required to determine which differences may appropriately be considered ‘small’ or ‘large’ for a particular embodiment would be routine.” (*Id.*)

Regarding claims 9-11, Appellant contends that “the specification and figure as originally filed fully complies with the enablement requirement because one of ordinary skill in the art would be able to practice the recitations of claim 1 [sic] based on the disclosure of the specification without undue or unreasonable experimentation.” (*Id.* at 16.) Appellant asserts that with regard to the recitation in claim 9 of “quantifying an amount of ionizing radiation received by said animal,” the Specification states “where the photon energy of the ionizing radiation is known and a radiation function is constructed utilizing data corresponding to the same photon energy, direct comparison can be made to infer dosage.” (*Id.* at 17.) With regard to the step of “inferring a likelihood of exposure to ionizing radiation between said first and second times based at least in part on said quantified amount of ionizing radiation,” Appellant asserts that Figure 1 plainly shows a change in HbA1c score as a function of radiation exposure. (*Id.*)

#### *Analysis*

“[T]o 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.’” *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991). Factors to

consider include “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If the PTO meets this burden, the burden then shifts to the applicant to provide suitable proofs indicating that the specification is indeed enabling.

*Wright*, 999 F.2d at 1561-62.

We agree with the Examiner that the Specification would not have enabled a person of ordinary skill in the art to practice the claimed invention without undue experimentation. (Ans. 5-13.) The Examiner set forth in the Answer a reasonable factual basis for why the claims are not enabled, and Appellant has not presented persuasive arguments, supported by sufficient facts, indicating otherwise. (*See* App. Br. 12-20; Reply Br. 5-26.)

In particular, the Examiner found that the quantity of experimentation that a skilled artisan would need to undertake to perform the “inferring” step of the claims would be undue, as the artisan would need to first correlate in vivo levels of HbA1c in all possible test subjects with a change caused by exposure to every type of ionizing radiation, to the exclusion of all other factors potentially causing HbA1c fluctuations. (Ans. 6.) The artisan

would also need to determine all sources potential variations in glycosylated hemoglobin levels in animals and further determine how to predict the effects of these sources and/or control for these outside factors. (*Id.*) Additionally, the Examiner found that the Specification did not provide direction or guidance to one of ordinary skill in the art as to how to differentiate a change in HbA1c scores caused by exposure to ionizing radiation to the exclusion of other factors. (*Id.*) The Examiner provided evidence that HbA1c levels can vary seasonally, with age, according to smoking status, based upon menopausal status, and the existence of a diabetic condition. (*Id.*) Such variability also indicates the unpredictability of relying on a change in the HbA1c level as a basis for detecting exposure to ionizing radiation.

In response, Appellant does not challenge the Examiner's finding that factors such as smoking, menopausal status, diabetes, age, and seasonality may affect HbA1c levels. Rather, Appellant asserts that “[c]laims 1 and 9 recite that an inference is made regarding exposure to radiation *at least in part* on the amount of difference between the first and second blood tests.” (Reply Br. 5.) In other words, Appellant acknowledges that variables exist that may cause a change between the first and second blood tests. However, according to Appellant, if any of these factors is present in an animal, “the factor would presumably have the same influence on both the first and second blood tests.” (*Id.* at 5-6.) However, Appellant has not provided any evidence to support this presumption.

Further, Appellant asserts, “if the animal stops smoking, develops diabetes, reaches menopause, or ages by many years, then one of ordinary skill would understand that *the part* of difference between the first and

second blood tests may be increased or decreased from the case where none of the factors changes for the individual,” in which case “the test is less helpful.” (*Id.* at 6.) Appellant refers to paragraph [0023] of the Specification, which states in part, “it may be desired to supplement the HbA1c test with other standard blood tests, other tests on the animal, to confirm the cause of the change in score.” (*Id.*) However, this guidance is vague, as it does not disclose when such “standard blood tests” should be used in combination with the claimed method, or how their results should be factored into the claimed “inferring” step.

In response to the Examiner’s finding that the Specification does not provide sufficient guidance, Appellant asserts that “[t]he claims do not require ... differentiating changes in HbA1c levels caused by other factors from changes in HbA1c levels caused by exposure to ionizing radiation” nor do the claims “require prediction and correction for other factors that may cause a change in HbA1c level.” (Reply Br. 8.) However, we agree with the Examiner that the step of inferring whether the animal has or has not been exposed to ionizing radiation, and the step of inferring a likelihood of exposure to ionizing radiation, based at least in part on the amount of the difference in first and second HbA1c tests necessarily requires consideration and correction of other factors that could influence or cause such difference.

After considering all of the evidence and arguments, we conclude that the Examiner set forth a reasonable explanation as to why the scope of protection provided by the claimed methods is not adequately enabled by the description of the invention provided in the Specification. On rebuttal, Appellant has not provided sufficient evidence (*see, e.g.*, Reply Br. 18-26) to

Appeal 2011-013499  
Application 12/075,695

overcome the conclusion of non-enablement. *See Wright*, 999 F.2d at 1561-62.

#### SUMMARY

We affirm the rejection of claims 1-11 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

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

AFFIRMED

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