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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/807,209	05/25/2007	Edward S. Boyden	SE1-0228-US	4405

80118 7590 09/02/2015

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ART UNIT	PAPER NUMBER
1676	

MAIL DATE	DELIVERY MODE
09/02/2015	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Ex parte EDWARD S. BOYDEN, RODERICK A. HYDE, MURIEL Y. ISHIKAWA, EDWARD K.Y. JUNG, NATHAN P. MYHRVOLD, THOMAS A. WEAVER, and LOWELL L. WOOD JR.

_____

Appeal 2012-000833
Application 11/807,209
Technology Center 1600

_____

Before ERIC B. GRIMES, ULRIKE W. JENKS, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

PER CURIAM.

DECISION ON APPEAL

This is a decision on appeal[1] under 35 U.S.C. § 134 from the Examiner's rejection of claims 1, 3, 6–8, 20, 21, 23, 25, 28, 32, 35, 38, 39, 43, 44, 49, 52, 53, 57, 109, and 111–115. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

[1] The Real Party in Interest is Searate, LLC (App. Br. 8).

STATEMENT OF THE CASE

The claims are directed to methods, computer programs, and systems for determining disease treatment characteristics based on polypeptide sequences. Claims 1, 53, 57, 109, and 111 are the only independent claims on appeal. Claim 1 is illustrative and read as follows:

> 1. A method comprising:
>
> determining at least one amino acid sequence alteration of an amino acid sequence of a disease associated polypeptide, relative to an amino acid sequence of a corresponding non-disease associated polypeptide;
>
> identifying a sub-sequence in the amino acid sequence of the disease associated polypeptide in which the amino acid sequence alteration occurs;
>
> relating the sub-sequence in the amino acid sequence of the disease associated polypeptide to a corresponding sub-sequence of the amino acid sequence of the corresponding non-disease associated polypeptide; and
>
> determining a treatment characteristic, based on the relating.

The claims stand rejected as follows:

I. Claim 57 under 35 U.S.C. § 112, second paragraph, as being indefinite (Ans. 6–7);

II. Claim 57 under 35 U.S.C. § 112, first paragraph, as lacking adequate written description in the Specification (Ans. 7–9);

III. Claims 1, 3, 6–8, 20, 21, 23, 25, 28, 32, 35, 38, 39, 43, 44, 49, 52, 53, 57, and 111–115 under 35 U.S.C. § 101 as being directed to non-statutory subject matter (Ans. 5–6);

IV. Claims 1, 3, 6–8, 20, 21, 23, 25, 28, 32, 35, 38, 39, 43, 44, 49, 52, 53, 57, 109, and 111–115 under 35 U.S.C. § 103(a) over the combination of Roy[2] and Fikes[3] (Ans. 11–13), and

V. Claims 1, 3, 6–8, 20, 21, 23, 25, 28, 32, 39, 44, and 112–115 under 35 U.S.C. § 102(b) in view of Roy (Ans. 9–10).

I.

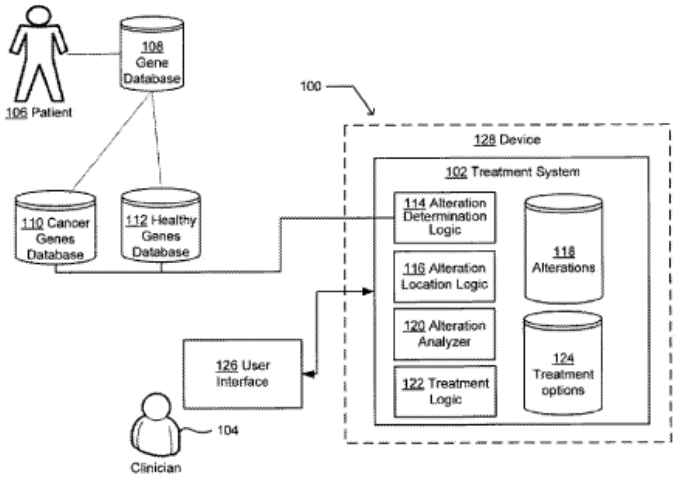
Issue

The Examiner has rejected claim 57 under 35 U.S.C. § 112, second paragraph, as being indefinite (Ans. 6–7).

The issue presented is: Does the preponderance of the evidence of record support the Examiner's finding that the *means-plus-function* language of claim 57 renders the claim indefinite?

Findings of Fact

FF1. Figure 1 of the Specification is reproduced below:



[2] Meenakshi Roy et al., *Evidence that public database records for many cancer-associated genes reflect a splice form found in tumors and lack normal splice forms*, 33 NUCLEIC ACIDS RESEARCH 5026–5033 (2005).
[3] John Fikes et al., US 2007/0020327 A1, Jan. 25, 2007.

Figure 1 shows a clinical system 100 which "may be implemented, perhaps in a device, to perform gene analysis for determination of a treatment characteristic" (Spec. 4–5 ¶ 26). "[C]linical system 100 includes a treatment system 102 . . . to determine a treatment characteristic that may be used in the treatment of one or more cancers or cancer-related illnesses" (*id.* at 5 ¶ 26). "[G]ene database 108 represents systems and/or devices for storage of genetic/genomic information for the patient 106" (*id.* at 6 ¶ 30). "The treatment system 102 may be configured to perform a comparative analysis between such sequence information stored in the cancer genes database 110 and the healthy genes database 112 . . . [to] determine, for example, treatment-relevant information for . . . a cancer of the patient 106" (*id.* at 7 ¶ 32).

FF2. Figure 16 of the Specification is reproduced below:

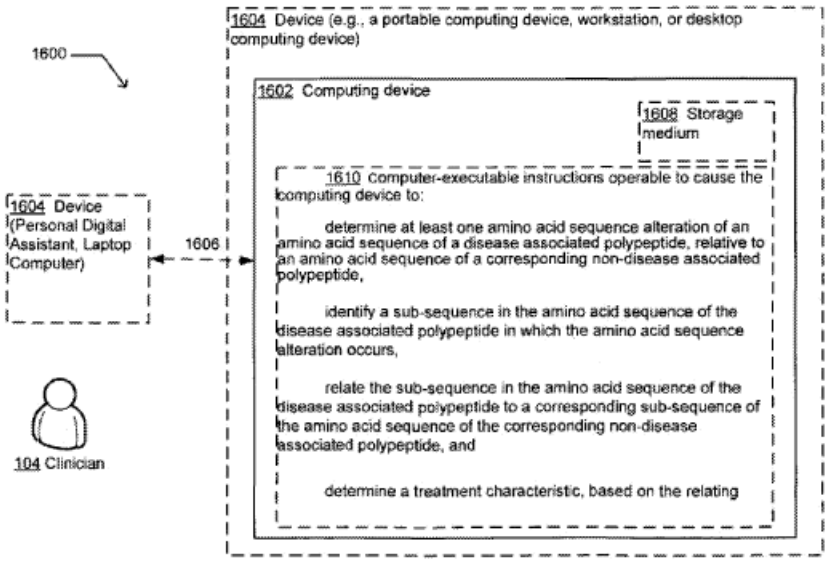


Figure 16 "illustrates an example system 1600 in which embodiments may be implemented. The system 1600 includes a computing system environment" (*id.* at 32 ¶ 125) and

> at least one computing device (e.g., 1602 and/or 1604). The computer-executable instructions 1610 may be executed on one or more of the at least one computing device. For example, the computing device 1602 may implement the computer-executable instructions 1610 and output a result to (and/or receive data from) the computing (clinician) device 1604

(*id.* at 33 ¶ 127).

Analysis

Appellants argue that the Examiner has not produced "evidence as to why one of ordinary skill in the art would not have been able to ascertain with a reasonable degree of particularity the area circumscribed by [claim 57] when read in light of the specification" (App. Br. 31). Appellants point to the Specification, Figures 1 and 16, which are set forth above (FFs 1 and 2), and argue that "one of ordinary skill in the art would be able to understand the scope of these recitations with a reasonable degree of particularity when read in light of" this disclosure in the Specification (*id.* at 34).

The Examiner responds that "it is not clear from the specification that figures 1 and 16 correspond to the recited means" (Ans. 16). The Examiner further responds that, because the Specification "fails to disclose the structure materials and acts for performing the recited function, the claim fails to satisfy the requirements of 35 USC 112 second paragraph" (*id.* at 17).

We conclude that the Examiner has the better position. "Section 112, paragraph 6 provides that a patentee [or applicant] may define the structure for performing a particular function generically through the use of a means expression, provided that it discloses specific structure(s) corresponding to

that means in the patent specification." *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 1360 (Fed. Cir. 2000). The "structure corresponding to the claimed function must be disclosed in the specification with clear linkage between the structure and the claimed function." *Medical Instrumentation and Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1220 (Fed. Cir. 2003). "A computer-implemented means-plus-function term is limited to the corresponding structure disclosed in the specification and equivalents thereof, and the corresponding structure is the algorithm." *Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241, 1253 (Fed. Cir. 2005).

Appellants point to the Specification, Figures 1 and 6, as providing a disclosure of what is meant by the means-plus-function language of claim 57. However, at most, Figures 1 and 16 show general computing devices that run software, and Appellants have not pointed to anything in the Specification as disclosing algorithms that correspond to any of the means-plus-function limitations of claim 57. Thus, we affirm the rejection of claim 57 under 35 U.S.C. § 112, second paragraph.

II.

The Examiner has rejected claim 57 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 7–9). The Examiner finds that the Specification

> fails to set forth an adequate disclosure of what is meant by "*means for* determining at least one amino acid sequence alteration of an amino acid sequence of a disease associated polypeptide, relative to an amino acid sequence of a corresponding non-disease associated polypeptide", "*means for* identifying a sub-sequence in the amino acid sequence of the disease associated polypeptide in which the amino acid sequence alteration occurs", "*means for* relating the sub-

> sequence in the amino acid sequence of the disease associated polypeptide to a corresponding sub-sequence of the amino acid sequence of the corresponding non-disease associated polypeptide", and "*means for* determining a treatment characteristic, based on the relating" as recited in claim 57[.]

(*Id.* at 8 (emphasis added).)

Appellants argue that the Examiner has not met the burden to establish a prima facie case of unpatentability of claim 57 under 35 U.S.C. § 112, first paragraph, because "the rejections are based upon standards that are not required by the written description requirement" (App. Br. 37). Appellants argue that "the written description requirement is satisfied when the specification describes the claimed invention in sufficient detail [so] that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention . . . [and] it is not required that the exact words used in the claims be present in the specification" (*id.*).

The Examiner responds that, "[w]ith respect to the rejection of claim 57 as indefinite under 35 USC 112, [f]irst paragraph . . . [t]he disclosure as originally filed fails to describe or correlate the recited means of claim 57 with a corresponding structure or act" (Ans. 17).

We agree with Appellants that the Examiner has not adequately explained why the Specification lacks an adequate written description of system of claim 57. "[T]he test for sufficiency [of written description] is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). The Examiner has not discussed or applied this standard to the system of claim 57, but only discusses a lack of

correlation between the means-plus-function language and particular structure. For this reason, we are constrained to reverse the rejection of claim 57 under 35 U.S.C. § 112, first paragraph.

III.

Issue

The Examiner has rejected claims 1, 3, 6–8, 20, 21, 23, 25, 28, 32, 35, 38, 39, 43, 44, 49, 52, 53, 57, and 111–115 under 35 U.S.C. § 101 as being directed to non-statutory subject matter (Ans. 5–6).

The issues presented are: Did the Examiner err in concluding that independent claims 1, 53, 57, and 111 are directed to non-statutory subject matter because they are directed to a mental process or abstract idea?

Analysis

In rejecting the claims as directed to ineligible subject matter under 35 U.S.C. § 101, the Examiner finds that "the claims are directed to the abstract idea of comparing sets of data to identify similarities and differences between the data. The processes do not recite a physical transformation of matter from one state to another" (Ans. 5). "[T]he mechanism by which the steps are implemented is subjective or imperceptible" (*id.* at 6).

With respect to claim 53, the Examiner finds that it "is drawn to a computer program on computer readable media" (*id.*). And because "[a] review of the specification does not show a definition of computer readable media . . . that excludes an embodiment that is information in a signal," claim 53 reads on non-statutory subject matter (*id.* (citing *In re Nuijten*, 500 F.3d 1346 (Fed. Cir. 2007))). The Examiner further interprets the "system comprising means" of claim 57 as "a program per se," whereas the "system

comprising logic" of Claim 111 "is broadly interpreted to encompass a program per se" (Ans. 6 (noting that "MPEP, at 2106.01, guides that computer programs *per se* are non-statutory")).

Appellants argue that a prima facie case for unpatentability under 35 U.S.C. § 101 has not been made because the rejections were made "without consideration of the U.S. Supreme Court *Bilski* decision or its progeny and . . . [the Examiner] appear[s] to base the rejections solely on the since overruled machine-or-transformation test" (App. Br. 25 (citing *Bilski v. Kappos*, 561 U.S. 593 (2010) and *Research Corp. Techs. v. Microsoft Corp.*, 627 F.3d 859 (Fed. Cir. 2010))). Appellants also argue that the Examiner erred in stating that the claims were directed to comparing sets of data to identify similarities and differences because independent claims 1, 53, 57, and 111 "do not include the recitation 'comparing sets of data to identify similarities and differences between the data.'" (*Id.*) Appellants also argue that claims 1, 53, 57, and 111

> include language directed toward determining an amino acid sequence alteration of . . . a disease associated polypeptide . . . [and the Examiner] has not explained how such [a] determining operation can be performed merely b[y] mental steps (e.g. how it is that a human being can determine the amino acid sequence of a polypeptide relying entirely on his or her own mind)

(*id.* at 26).

While we affirm the Examiner's rejection of independent claims 1, 53, 57, and 111 under 35 U.S.C. § 101, as set forth below, we designate the affirmance as a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) because the case law has developed substantially since the briefs in this case were filed. We also set forth a new ground of rejection pursuant to

37 C.F.R. § 41.50(b) for independent claim 109 under 35 U.S.C. § 101 for essentially the same reasons that we affirm the rejection of the other independent claims.

Overview

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. Supreme Court precedents, however, provide three specific exceptions to the broad categories of § 101: laws of nature, natural phenomena, and abstract ideas. *Bilski v. Kappos*, 561 U.S. at 625. "The 'abstract ideas' category embodies the longstanding rule that '[a]n idea of itself is not patentable.'" *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014) (citing *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

In *Alice*, the Supreme Court referred to the two-step analysis set forth in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012), as providing "a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice*, 134 S. Ct. at 2355 (citing *Mayo*, 132 S. Ct. at 1289). Under *Mayo*, "[w]e must first determine whether the claims at issue are directed to a patent-ineligible concept." *Id.* Next, "we consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (citing *Mayo*, 132 S. Ct. at 1297–98).

Under *Mayo*, to be patentable, a claim must do more than simply state the law of nature or abstract idea and add the words "'apply it.'" *Mayo*, 132 S. Ct. at 1294; *Benson*, 409 U.S. at 67. For example, "the mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention." *Alice*, 134 S. Ct. at 2358. "Thus, if a patent's recitation of a computer amounts to a mere instruction to 'implemen[t]' an abstract idea 'on . . . a computer,' that addition cannot impart patent eligibility." *Id*. (internal citation omitted).

A challenged patent claim, properly construed, must incorporate enough meaningful limitations to ensure that it claims more than just an abstract idea and not just a mere "drafting effort designed to monopolize the [abstract idea]." *Alice*, 134 S. Ct. at 2357 (quoting *Mayo*, 132 S. Ct. at 1297). "Simply appending conventional steps, specified at a high level of generality," is not "*enough*" for patent eligibility. *Id.* (quoting *Mayo*, 132 S. Ct. at 1300). Thus, we analyze the instantly pending claims to determine whether the claims embody a patent-eligible application of an abstract idea or merely the abstract idea itself.

Determination of whether independent claims 1, 53, 57, 109, and 111 are unpatentable under 35 U.S.C. § 101 as being directed to an abstract idea

Our initial question with regard to the claim 1 process is whether a person would also be capable of performing the acts of the claimed method as mental steps, or with the aid of pen and paper. *See CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1375 (Fed. Cir. 2011) ("That purely mental processes can be unpatentable, even when performed by a computer, was precisely the holding of the Supreme Court in *Gottschalk v. Benson.*"). Our reviewing court further guides that "a method that can be performed by

human thought alone is merely an abstract idea and is not patent-eligible under § 101." *CyberSource*, 654 F.3d at 1373. "Sets of steps occurring only in the mind have not been made subject to patenting because mental processes are but disembodied thoughts, whereas inventions which Congress is constitutionally empowered to make patentable are tangible embodiments of ideas in the useful, or technological, arts." *In re Sarkar*, 588 F.2d 1330, 1333 (CCPA 1978).

Claim 1 is directed to a method that could be conducted in the mind of one of skill in the art while reading a scientific paper that identifies amino acid sequence alterations in a disease associated polypeptide as compared to the normal or non-disease associated polypeptide. As recognized by the Examiner (Ans. 14), claim 1 does not require the step of sequencing a protein, but rather requires determining at least one amino acid sequence alteration in an amino acid sequence relative to another amino acid sequence. Although the Specification discloses that the amino acid sequences to be compared may be contained in computer databases (FF 1), the Specification does not specifically define how the determining steps or the relating step of claim 1 are to be conducted, and thus claim 1 is broad enough to include performing the steps mentally, which falls within the judicial exception of an abstract idea.

Regarding the second prong of the test articulated by the Supreme Court in *Alice*, we further consider the elements of claim 1 "both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 132 S. Ct. at 1297–1298)). In this case, the recited elements, and the particular order of the

elements, i.e., determining amino acid sequences and then comparing them to identify altered sequences in disease associated polypeptides, are all conventional in the art, and Appellants' claim 1 contains no inventive concept. Thus, we agree with the Examiner that claim 1 is directed to an unpatentable abstract idea.

The other independent claims, claims 53, 57, 109, and 111, are directed to computer-environment implementations of the process of claim 1. That is, claims 57, 109, and 111 are directed to systems that apply the process of claim 1, and claim 53 is directed to computer program product comprising a signal-bearing medium that comprises instructions for implementing the process of claim 1.

The case law is clear, however, that the mere recitation of generic computer elements in Appellants' claims cannot transform a patent ineligible abstract idea into a patent-eligible invention. Likewise, limiting an abstract idea to a computer environment does not make an invention patent-eligible. *Alice*, 134 S. Ct. at 2359 (holding patent ineligible claims that "amount to nothing significantly more than an instruction to apply the abstract idea . . . using some unspecified, generic computer" and in which "each step does no more than require a generic computer to perform generic computer functions" (internal quotation marks, citation omitted)); *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 716 (Fed. Cir. 2014) ("Adding routine[,] additional steps . . . does not transform an otherwise abstract idea into patent-eligible subject matter."); *Bancorp Servs., LLC v. Sun Life Assurance Co. of Can.*, 687 F.3d 1266, 1278 (Fed. Cir. 2012) (appending generic computer components does not "salvage an otherwise patent-ineligible process"); *CyberSource*, 654 F.3d at 1375 ("[T]he incidental use of a

computer to perform the [claimed process] does not impose a sufficiently meaningful limit[ation] on the claim's scope") (holding that methods of offer-based price optimization in an e-commerce environment were drawn to an abstract idea); *see also SmartGene, Inc. v. Advanced Biological Labs., SA*, 555 F. App'x 950, 951, 954 (Fed. Cir. 2014) (determining that a computer-implemented method for "guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition" was directed to an abstract idea); *Planet Bingo, LLC v. VKGS LLC*, 576 F. App'x 1005, 1006 (Fed. Cir. 2014) (determining that claims to a computer-aided management system for bingo games was directed to an abstract idea).

Thus, because 57, 109, and 111, merely limit the process of claim 1 to a computer environment, we also find that these claims are unpatentable under 35 U.S.C. § 101. Additionally, because the mere recitation of generic computer elements in a claim cannot transform a patent ineligible abstract idea into a patent-eligible invention, we also affirm the rejection of claim 53 under 35 U.S.C. § 101. We also affirm the rejection of claim 53 under 35 U.S.C. § 101 for reasons set forth by the Examiner in view of *In re Nuijten*, 500 F.3d at 1356–57 (transitory embodiments are not directed to statutory subject matter); *see also Ex parte Mewherter*, 107 USPQ2d 1857, 1862 (PTAB 2013) (precedential) (finding a machine readable storage medium non-statutory under § 101).

For the reasons set forth above, we affirm the rejection of independent claims 1, 53, 57, and 111 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. We designate our affirmance as new grounds of rejection pursuant to 37 C.F.R. § 41.50(b) to give Appellants a fair opportunity to respond because our reasoning differs from that of the

Examiner. We leave it to the Examiner to apply our reasoning to the dependent claims. We also enter a new ground of rejection for independent claim 109 under 35 U.S.C. § 101 pursuant to § 41.50(b).

IV.

Issue

The Examiner has rejected claims 1, 3, 6–8, 20, 21, 23, 25, 28, 32, 35, 38, 39, 43, 44, 49, 52, 53, 57, 109, and 111–115 under 35 U.S.C. § 103(a) as obvious over the combination of Roy and Fikes (Ans. 11–13). We focus our initial analysis on independent claim 1.

The issue presented is whether the Examiner has provided evidence and reasoning sufficient to show prima facie obviousness for the rejected claims.

Findings of Fact

FF3. Roy discloses that "[a]lternative splicing is widespread in the human genome, and it appears that many genes display different splice forms in cancerous tissue than in normal human tissues" (Roy, Abstract). Noting that "cDNAs for many cancer-associated genes were originally cloned from tumor samples," Roy investigated "whether this repertoire of cDNAs provides a complete or representative picture of the transcript isoforms found in normal tissues" (*id.*). Roy thus "used bioinformatics and RT–PCR to identify novel splice forms, focusing on in-frame exonskips [sic], for a panel of 50 cancer-associated genes in normal tissue samples" (*id.*). The study focused on "in-frame exon skips (i.e. alternative splicing events that add or remove an exact multiple of 3 nt, leaving the protein reading frame unchanged), to avoid including

alternative splice forms that might cause nonsense-mediated decay" (*id.* at 5027, left col.).

FF4. The resulting data showed that "in nearly two-thirds of the genes, normal tissues expressed previously unknown splice forms, of which 40% were normally a dominant splice form" (*id.* at Abstract). These "tumor-associated splice forms were twice as likely to be represented in GenBank than their normal tissue-associated splice forms, most likely because 70% of the mRNAs in GenBank for these genes were cloned from tumor samples" (*id.*).

FF5. The Examiner finds that Roy discloses that "cancer associated proteins are distinct from the equivalent proteins from non-cancer sources . . . [wherein] sequence comparison [shows] that the protein forms associated with the cancer state have subsequences that distinguish the proteins from the . . . protein [form] associated with the non-cancer state" (Ans. 11 (citing Roy 5027, col. 2)). The reference further discloses "the identification of sub-sequences specific to proteins variants associated with cancer . . . [and discloses] a database of cancer associated proteins and non-cancer associated proteins" (*id.* (citing Roy at 5028, col. 2, and 5032, Table 2)).

FF6. With respect to claims 112–114, the Examiner finds that "Roy shows proteins that have been determined to have at least one point mutation, multiple mutations, inserts or deletions in the disease related polypeptide relative to the sequence of a corresponding non-disease associated polypeptide" (*id.* at 12 (citing Roy 5029,Table 1, and 5032, Table 2)). And, "[w]ith respect to claim 115, Roy et al. shows the sub-sequence is

adjusted to include the positions corresponding to the amino acid alteration" (*id.* (citing Roy 5029,Table 1, and 5032, Table 2)).

FF7. The Examiner finds that Roy "does not show the selection of antigenic subsequences of the disease associated protein" (Ans. 12).

FF8. Fikes discloses the development of "epitope-based vaccines directed towards TAAs [tumor-associated antigens] . . . and methods of use of the epitopes for the evaluation of immune responses and for the treatment and/or prevention of cancer" (Fikes ¶ 54).

FF9. The Examiner finds that Fikes "shows the advantage of an epitope-based vaccine approach is the ability to combine selected epitopes (CTL and HTL) . . . [and] modify the composition of the epitopes" to achieve enhanced immunogenicity (Ans. 13 (citing Fikes ¶ 56)). The Examiner finds that Fikes discloses "the selection of antigenic subsequences of disease associated proteins . . . [and] the determination of a subsequence for administration" (*id.* at 12 (citing Fikes ¶¶ 46 and 189)). The Examiner further finds that Fikes discloses "a computer system comprising a signal bearing medium that is computer readable, recordable, or communication medium . . . [and] further describes the execution of computer algorithms for identifying subsequences . . . and selecting a treatment characteristic" (*id.* at 12–13 (citing Fikes ¶¶ 073, 179, and 183)).

Principles of Law

> [T]he PTO carries its procedural burden of establishing a prima facie case when its rejection satisfies 35 U.S.C. § 132, in "notify[ing] the applicant . . . [by] stating the reasons for [its] rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of [the] application."

In re Jung, 637 F.3d 1356, 1362 (Fed. Cir. 2011) (quoting 35 U.S.C. § 132, alterations by the *Jung* court).

"[A]ll that is required of the office to meet its prima facie burden of production is to set forth the statutory basis of the rejection and the reference or references relied upon in a sufficiently articulate and informative manner as to meet the notice requirement of § 132." *Id*. at 1363.

"If a person of ordinary skill can implement a predictable variation [of a known work], § 103 likely bars its patentability." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

"[T]he analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id*. at 418.

Analysis

In rejecting the claims as obvious over the combination of Roy and Fikes, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to modify Roy's "process for identifying the subsequence differences specific to disease associated variants of proteins of Roy et al. with the selection, generation and administration of vaccines developed from antigenic subsequences of disease associated proteins . . . because Fikes et al. shows the advantage of an epitope-based vaccine approach" (Ans. 13).

Appellants' main contention is that the Examiner has not made out a prima facie case of obviousness with respect to any of claim 1 (App. Br. 102–112), claim 53 (*id.* at 112–122), claim 109 (*id.* at 133–144), claim 111 (*id.* at 144–155), claim 112 (*id.* at 66–73), claim 113 (*id.* at 74–83), claim

114 (*id.* at 84–92), and claim 115 (*id.* at 92–101) because the cited references do not recite the text of the claim and the Examiner has not provided objectively verifiable evidence to show that the references teach or suggest the claimed limitations (*see, e.g.*, App. Br. 102).

Appellants' argument is unpersuasive. "[A]ll that is required of the office to meet its prima facie burden of production is to set forth the statutory basis of the rejection and the reference or references relied upon in a sufficiently articulate and informative manner as to meet the notice requirement of § 132." *In re Jung*, 637 F.3d at 1363. Section 132, in turn, requires notice to the applicant sufficient to inform him of the reasons for the rejection, "together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application." 35 U.S.C. § 132.

Here, the Examiner notified Appellants that the claims were being rejected as unpatentable under 35 U.S.C. § 103(a) and cited specific passages in Roy and Fikes, by page and column or paragraph, that were the basis for the conclusion of obviousness (FFs 5–6, 9; Ans. 11–13). The Examiner's rejection satisfies the notice requirement of § 132, and therefore meets the burden of establishing a prima facie case of unpatentability. *Cf. Jung*, 637 F.3d at 1363 ("[T]he examiner's discussion of the theory of invalidity . . . , the prior art basis for the rejection . . . , and the identification of where each limitation of the rejected claims is shown in the prior art reference by specific column and line number was more than sufficient to meet this burden.").

In summary, the Examiner has made a prima facie case that claims 1, 53, 109, and 111–115 would have been obvious to a person of ordinary skill

in the art, and a successful rebuttal of the Examiner's prima case would require evidence or reasoning to support a contrary position. *See In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

Because Appellants have not provided persuasive evidence or reasoning to support a contrary conclusion, we affirm the rejections of claims 1, 53, 109, and 111–115 as obvious based on Roy and Fikes.

Appellants also argue that the Examiner has not made out a prima facie case of obviousness with respect of claim 57 (App. Br. 122–133). We do not reach the merits of the obviousness rejection of claim 57 at this time. Before a proper review of the rejection under 35 U.S.C. § 103(a) can be performed, the subject matter encompassed by the claims on appeal must be reasonably understood without resort to speculation. Since claim 57 fails to satisfy the requirements of the second paragraph of 35 U.S.C. § 112, as discussed above, we reverse its rejection under 35 U.S.C. § 103(a) *pro forma*. *See In re Steele*, 305 F.2d 859, 862 (CCPA 1962) (A prior art rejection cannot be sustained if the hypothetical person of ordinary skill in the art would have to make speculative assumptions concerning the meaning of claim language.); *see also In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970).

Conclusion of Law

The Examiner has provided evidence and reasoning sufficient to show prima facie obviousness of claims 1, 53, 109, and 111–115. Claims 3, 6–8, 20, 21, 23, 25, 28, 32, 35, 38, 39, 43, 44, 49, and 52, were not argued separately from claim 1 and therefore fall with that claim. 37 C.F.R. § 41.37(c)(1)(vii).

We do not reach the merits of the rejection of claim 57 under 35 U.S.C. § 103(a) at this time, and we reverse the rejection *pro forma*.

V.

Issue

The Examiner has rejected claims 1, 3, 6–8, 20, 21, 23, 25, 28, 32, 39, 44, and 112–115 under 35 U.S.C. § 102(b) as anticipated by Roy. We focus our analysis on independent claim 1.

The issue presented is: Has the Examiner established by a preponderance of the evidence that Roy discloses a method comprising determining the amino acid sequence alteration of a disease associated polypeptide, identifying an amino acid sub-sequence in the polypeptide in which the amino acid sequence alteration occurs, and "relating the sub-sequence in the amino acid sequence of the disease associated polypeptide to a corresponding sub-sequence of the amino acid sequence of the corresponding non-disease associated polypeptide" to determine a treatment characteristic, as required by claim 1?

Analysis

Appellants argue generally that the Examiner has not met the burden of establishing a prima case of anticipation based on Roy because the

Examiner has not explained how Roy discloses the method steps of claim 1 (App. Br. 102–111). Upon review of the Roy reference, and the Examiner's statement of the anticipation rejection based on Roy, we conclude that the Examiner has not adequately explained how Roy discloses the claim 1 step of "determining a treatment characteristic, based on the relating," i.e., based on the step of "relating the sub-sequence in the amino acid sequence of the disease associated polypeptide to a corresponding sub-sequence of the amino acid sequence of the corresponding non-disease associated polypeptide." That is, even assuming that Roy discloses the relating step, the Examiner has not pointed to anything in Roy as specifically disclosing the determination of a treatment characteristic based on the relating.

Thus, we reverse the anticipation rejection of independent claim 1, and dependent claims 3, 6–8, 20, 21, 23, 25, 28, 32, 39, 44, and 112–115.

SUMMARY

We affirm the rejection of claim 57 under 35 U.S.C. § 112, second paragraph.

We reverse the rejection of claim 57 under 35 U.S.C. § 112, first paragraph.

We affirm the rejection of claims 1, 3, 6–8, 20, 21, 23, 25, 28, 32, 35, 38, 39, 43, 44, 49, 52, 53, 57, and 111–115 under 35 U.S.C. § 101 as being directed to non-statutory subject matter, but designate this affirmance as a new ground of rejection pursuant to 37 C.F.R. § 41.50(b).

We also enter a new ground of rejection of claim 109 under 35 U.S.C. § 101 pursuant to 37 C.F.R. § 41.50(b).

We affirm the rejection of claims 1, 3, 6–8, 20, 21, 23, 25, 28, 32, 35, 38, 39, 43, 44, 49, 52, 53, 109, and 111–115 under 35 U.S.C. § 103(a) over

the combination of Roy and Fikes. We reverse, however, the rejection of claim 57 under 35 U.S.C. § 103(a).

We reverse the rejection of claims 1, 3, 6–8, 20, 21, 23, 25, 28, 32, 39, 44, and 112–115 under 35 U.S.C. § 102(b).

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.

37 C.F.R. § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner . . .
>
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record . . .

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; 37 C.F.R. § 41.50(b)