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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 GRÉGORY STRUBEL, MAUD ARSAC, DENIS DESSEREE, PIERRE-JEAN COTTE-PATTAT and PIERRE MAHÉ[1]

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Appeal 2018-007935
Application 14/361,885
Technology Center 1600

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Before ERIC B. GRIMES, JEFFREY N. FREDMAN, and ULRIKE W. JENKS, *Administrative Patent Judges*.

Opinion for the Board filed by *Administrative Patent Judge* GRIMES.

Opinion Dissenting filed by *Administrative Patent Judge* FREDMAN.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims relating to a method of identifying a microorganism in a sample, which have been rejected as being directed to patent-ineligible subject matter. We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE.

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[1] Appellant identifies the Real Party in Interest as BIOMERIEUX, Inc. Appeal Br. 4.

STATEMENT OF THE CASE

"It is known to use mass spectrometry to identify microorganisms." Spec. ¶ 2. The peaks in a mass spectrum are "'analyzed' and 'compared', by means of classification tools, with data of a knowledge base built from lists of peaks, each associated with an identified microorganism." *Id*.

"SVM ('*Support Vector Machine*') classifications of 'one versus all' type are known." *Id*. ¶ 3. In this classification, "[t]he identification of an unknown object . . . comprises querying each of the classifiers by calculating the algebraic distance between the unknown object and the boundary" that separates one class of objects from other classes. *Id*.

However, "[i]n real cases, it is difficult or even impossible to directly deduce relevant information regarding the calculated distances to the boundaries." *Id*. ¶ 8. "[T]he calculated distances are only partially relevant." *Id*. ¶ 10. "It is thus necessary to analyze these distances to deduce the type of unknown microorganism therefrom, as well as the degree of reliance to be had on this identification. This additional analysis step is conventional[ly] carried out by . . . a biologist or a doctor." *Id*.

"The present invention aims at solving the above-mentioned problem by providing an algorithm for identifying a microorganism based on mass spectrum measurements and classification tools, which enable to more reliably identify a microorganism." *Id*. ¶ 13. The Specification states that

> a classification generates distances, which are objective quantities measuring distances to reference elements. According to the invention, these distances are transformed into probabilities normalized between 0 and 1 according to a "sigmoid"-type law. As a result, these probabilities are themselves objective quantities comparable with one another,

> and thus real measurements of the "similarity" of an unknown microorganism with a previously-identified microorganism.

Id. ¶ 18.

Claims 1, 3–16, and 18–22 are on appeal. Claim 1 is illustrative and reads as follows:

> 1. A method of identifying by mass spectrometry a microorganism from among a predetermined set of reference microorganisms, each reference microorganism being represented by a set of reference data from mass spectrometry measurements of each said reference microorganism, the method being implemented in a data processing system comprising a mass spectrometer and a data processing unit connected to the mass spectrometer and to a knowledge base data storage unit, wherein the method comprises:
>
> determining, using the data processing unit, a set of data representative of the microorganism to be identified from a mass spectrometry measurement of said microorganism acquired from the mass spectrometer connected to said data processing unit; then
>
> for each reference microorganism, calculating, using the data processing unit, the set of reference data of each reference microorganism stored in the knowledge base data storage unit, and classification tools also stored in the knowledge base data storage unit, a distance *m* between said determined set of data representative of the microorganism to be identified and the set of reference data of the reference microorganism, said distance *m* being representative of the microorganism to be identified; then
>
> for each reference microorganism, calculating, using the data processing unit, a probability for the microorganism to be identified to be the reference microorganism, according to relation:

$$f(m) = \frac{pN(m|\mu,\sigma)}{pN(m|\mu,\sigma) + (1-p)N(m|\overline{\mu},\overline{\sigma})}$$

where:

> *m* is the distance calculated between the determined set of data for the microorganism to be identified to the set of reference data of the reference microorganism;
>
> *f*(*m*) is the probability calculated for said distance *m*;

$N(m|\mu,\sigma)$ is a value, for the distance m, of a first random variable modeling the distance between the set of data associated with the microorganism to be identified and the set of reference data of the reference microorganism, when the microorganism to be identified is the reference microorganism;

$N(m|\bar{\mu},\bar{\sigma})$ is a value, for the distance m, of a second random variable modeling the distance between the set of data associated with the microorganism to be identified and the set of reference data of the reference microorganism, when the microorganism to be identified is not the reference microorganism;

wherein the random variables $N(m|\mu,\sigma)$ and $N(m|\bar{\mu},\bar{\sigma})$ are Gaussian random variables, having averages respectively equal to μ and $\bar{\mu}$, and standard deviations respectively equal to σ and $\bar{\sigma}$; and

p is a predetermined scalar in the range from 0 to 1,

wherein the calculated probabilities for the microorganism to be each of the reference microorganisms are stored in the knowledge base data storage unit; then

comparing, using the data processing unit, the calculated probabilities for the microorganism to be each of the reference microorganisms, and

providing an identification decision for the microorganism based on the comparing of the calculated probabilities.

Claim 16 is the other independent claim and is directed to a device comprising a mass spectrometer, and a data processing unit that carries out the method of claim 1.

DISCUSSION

The Examiner has rejected claims 1, 3–16, and 18–22 under 35 U.S.C. § 101 on the basis that they "recite the judicial exceptions that are the abstract ideas of a mathematical relationship and comparison of data. Thus, claims 1, 3–16, and 18–22 are directed to at least one judicial exception." Final Action 4. The Examiner finds that the "claims . . . recite additional

elements that equate to adding insignificant extrasolution activity to the judicial exception, appending well-understood, routine and conventional activities previously known in the art and adding mere instructions to implement abstract ideas on a computer with generic computer components." *Id*. at 4–5.

Specifically, "determining sets of data from mass spectrometric data of microorganisms . . . equate[s] to mere data gathering," "obtain[ing] mass spectrometric data . . . was a well-understood, routine and conventional activity," and "additional limitations . . . equate[] to mere instructions to implement the abstract idea on a computer." *Id*. at 5. The Examiner concludes that "the claims do not amount to significantly more than the judicial exception itself." *Id*.

Appellant argues that the claimed invention "uses algorithms and rules to provide a technological solution to a technological problem . . . the automated identification decision about the unknown microorganism." Appeal Br. 13. Appellant also argues that the claimed process "results in a technological product – the identification decision – whose quality has been significantly improved." *Id*. at 16. "Correspondingly, the microorganism identification device has been technically improved, and not just used as a tool to implement a conversion or comparison, as a substitute or alternative to performing a conversion of [sic] comparison automatically instead of a subjective evaluation or correction." *Id*. Appellants argue that "[t]he concrete benefits of the specific technological solution are clearly

demonstrated by the improvement in the accuracy and reliability of the identification decision." *Id*. at 43 (citing the Mahé Declaration[2] ¶¶ 20–23).

An invention is patent-eligible if it claims a "new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. However, the Supreme Court has concluded that "[l]aws of nature, natural phenomena, and abstract ideas" are not patentable under 35 U.S.C. § 101. *See, e.g.*, *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014).

To determine if a claim falls into an excluded category, we apply a two-step framework, described in *Mayo* and *Alice*. *Id.* at 217–18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). We first determine what the claim is "directed to." *See Alice*, 573 U.S. at 219 ("On their face, the claims before us are drawn to the concept of intermediated settlement, *i.e.*, the use of a third party to mitigate settlement risk."); *see also Bilski v. Kappos*, 561 U.S. 593, 611 (2010) ("Claims 1 and 4 in petitioners' application explain the basic concept of hedging.").

Patent-ineligible abstract ideas include certain methods of organizing human activity, such as fundamental economic practices (*Alice*, 573 U.S. at 219–20; *Bilski*, 561 U.S. at 611), mathematical formulas (*Parker v. Flook*, 437 U.S. 584, 594–95 (1978)), and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 69 (1972)). In contrast, patent-eligible inventions include physical and chemical processes, such as "molding rubber products" (*Diamond v. Diehr*, 450 U.S. 175, 192 (1981)); "tanning, dyeing, making water-proof cloth, vulcanizing India rubber, smelting ores" (*id.* at 182 n.7

[2] Declaration under 37 C.F.R. § 1.132 of Pierre Mahé, filed July 31, 2017.

(quoting *Corning v. Burden*, 56 U.S. 252, 267–68 (1854))); and manufacturing flour (*Benson*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876))).

In *Diehr*, the claimed method employed a mathematical formula, but the Supreme Court held that "[a] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula." *Diehr*, 450 U.S. at 176; *see also id.* at 192 ("We view respondents' claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula."). The Supreme Court noted, however, that a claim "seeking patent protection for that formula in the abstract . . . is not accorded the protection of our patent laws, . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment." *Id.* (citing *Benson* and *Flook*); *see, e.g.*, *id*. at 187 ("It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.").

If the claim is "directed to" an abstract idea, we turn to the second step of the *Alice* and *Mayo* framework, and "examine the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application." *Alice*, 573 U.S. at 221 (quotation marks omitted). "A claim that recites an abstract idea must include 'additional features' to ensure 'that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].'" *Id.* (quoting *Mayo*, 566 U.S. at 77 (alterations in original)). "[M]erely

requir[ing] generic computer implementation[] fail[s] to transform that abstract idea into a patent-eligible invention." *Id.*

The PTO recently published revised guidance on the application of § 101. *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50 (January 7, 2019) ("Revised Guidance"). Under that guidance, we first determine whether the claim recites:

> (1) any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts; certain methods of organizing human activity such as a fundamental economic practice; or mental processes); and
>
> (2) additional elements that integrate the judicial exception into a practical application (*see* MPEP § 2106.05(a)–(c), (e)–(h)).

See 84 Fed. Reg. at 54–55. Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then determine whether the claim:

> (3) adds a specific limitation beyond the judicial exception that is not a "well-understood, routine, conventional activity" in the field (*see* MPEP § 2106.05(d)); or
>
> (4) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception.

See 84 Fed. Reg. at 56.

Revised Guidance Step 2(A), Prong 1

Following the Revised Guidance, we first consider whether the claims recite a judicial exception. Claim 1 recites, among other elements, the

relation:

$$f(m) = \frac{pN(m|\mu,\sigma)}{pN(m|\mu,\sigma) + (1-p)N(m|\bar{\mu},\bar{\sigma})}$$

where:

m is the distance calculated between the determined set of data for the microorganism to be identified to the set of reference data of the reference microorganism;

f(*m*) is the probability calculated for said distance *m*;

$N(m|\mu,\sigma)$ is a value, for the distance *m*, of a first random variable modeling the distance between the set of data associated with the microorganism to be identified and the set of reference data of the reference microorganism, when the microorganism to be identified is the reference microorganism;

$N(m|\bar{\mu},\bar{\sigma})$ is a value, for the distance *m*, of a second random variable modeling the distance between the set of data associated with the microorganism to be identified and the set of reference data of the reference microorganism, when the microorganism to be identified is not the reference microorganism;

wherein the random variables $N(m|\mu,\sigma)$ and $N(m|\bar{\mu},\bar{\sigma})$ are Gaussian random variables, having averages respectively equal to μ and $\bar{\mu}$, and standard deviations respectively equal to σ and $\bar{\sigma}$; and

p is a predetermined scalar in the range from 0 to 1.

Claim 1.

The recited relation is a "mathematical relationship[], mathematical formula[] or equation[]." 84 Fed. Reg. at 52. Thus, we agree with the Examiner that claim 1 recites the "abstract idea[] of a mathematical relationship." Final Action 4.

Revised Guidance Step 2(A), Prong 2

Although claim 1 recites an abstract idea, it is still patent-eligible if "the claim as a whole integrates the recited judicial exception into a practical application of the exception"; i.e., whether the claim "appl[ies], rel[ies] on, or use[s] the judicial exception in a manner that imposes a meaningful limit on the judicial exception." 84 Fed. Reg. at 54. This analysis includes "[i]dentifying whether there are any additional elements recited in the claim beyond the judicial exception(s)" and "evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application." *Id.* at 54–55.

Among the "exemplary considerations [that] are indicative that an additional element (or combination of elements) may have integrated the exception into a practical application" is when "[a]n additional element reflects . . . an improvement to other technology or technical field." *Id*. at 55 (footnotes omitted).

Here, we agree with Appellant that claim 1 "provide[s] a technological solution to a technological problem," Appeal Br. 13, and therefore integrates the recited abstract idea into a practical application. In addition to the judicial exception, claim 1 recites "determining . . . a set of data . . . from a mass spectrometry measurement of said microorganism acquired from the mass spectrometer connected to said data processing unit," "comparing . . . the calculated probabilities for the microorganism to be each of the reference microorganisms," and "providing an identification decision for the microorganism based on the comparing of the calculated probabilities." Claim 1.

The Specification states that mass spectrometry data has been used to identify microorganisms, based on detecting peaks, analyzing the list of peaks, and comparing with data in a knowledge base of known microorganisms. Spec. ¶ 2. The Specification also states that classification tools, such as "SVM ('*Support Vector Machine*') classifications of 'one versus all' type are known," in which "for each class of objects . . . , an oriented boundary which separates this class from the other classes" is determined, and an unknown object is identified "by calculating the algebraic distance between the unknown object and the boundary associated with [each] classifier." *Id*. ¶ 3.

The Specification states, however, that identifying microorganisms based on mass spectrometry data using known classification tools presents problems, because "[i]n real cases, it is difficult or even impossible to directly deduce relevant information regarding the calculated distances to the boundaries." *Id*. ¶ 8. Because "the calculated distances are only partially relevant," it is "necessary to analyze these distances to deduce the type of unknown microorganism therefrom, as well as the degree of reliance to be had on this identification." *Id*. ¶ 10. This additional analysis "is conventional[ly] carried out by an operator, be it a biologist or a doctor, who determines by means of his/her know-how what conclusion can be drawn from the distances calculated by the classification tool." *Id*.

The Specification discloses a solution to these problems:

> [T]hese distances are transformed into probabilities normalized between 0 and 1 according to a "sigmoid"-type law. As a result, these probabilities are themselves objective quantities comparable with one another, and thus real measurements of

> the "similarity" of an unknown microorganism with a previously-identified microorganism.

Id. ¶ 18.

As a result, the claimed method provides more accurate comparison of an unknown microorganism to microorganisms in a knowledge base, without human intervention. *See id*. ¶¶ 81–82.

> Advantageously, the method according to the invention also enables to judge whether or not the unknown microorganism is one of the reference microorganisms of the knowledge base. Indeed, values $f_j(m)$ represent measurements of the similarity of this microorganism with the reference microorganisms. Thus, if values $f_j(m)$ are low, it can be judged that the unknown microorganism is similar to none of the reference microorganisms, and is thus not referenced in the knowledge base.

Id. ¶ 83.

Thus, the mathematical relations that are recited in claim 1 increase the accuracy of identifying microorganisms based on mass spectrometry data, and reduce the need for human involvement in the process. The claimed method and device therefore improve the technology or technical field of identifying microorganisms using mass spectrometry, by addressing the problems with known classification methods. *See* Spec. ¶¶ 10, 18. *See also* the Mahé Declaration ¶ 23:

> [T]he computer that implements the method of the invention . . . , while being fed exactly the same data, . . . will process and structure that data in a very different way than the traditional identification machine. . . . In particular, the modification of the computer to re-evaluate the distance m into the probability *f(m)*, taking into account reference microorganisms of the other classes than the class with respect to which the distance m has

> been calculated, . . . improv[es] its operation by giving a significantly better prediction.

In summary, the Specification states that the claimed method is an improvement in the process of identifying microorganisms based on mass spectrometry data. Spec. ¶¶ 5, 7, 30, 35. The Mahé Declaration confirms that the claimed method gives a significantly better prediction, compared to conventional methods, of the identity of an unknown microorganism based on mass spectrometry data. We therefore conclude that the claims integrate the recited mathematical relations into a practical application, and are not directed to patent-ineligible subject matter under 35 U.S.C. § 101.

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
1, 3–16, 18–22	§ 101		1, 3–16, 18–22

REVERSED

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Ex parte GRÉGORY STRUBEL, MAUD ARSAC, DENIS DESSEREE, PIERRE-JEAN COTTE-PATTAT and PIERRE MAHÉ

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Appeal 2018-007935
Application 14/361,885
Technology Center 1600

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Before ERIC B. GRIMES, JEFFREY N. FREDMAN, and ULRIKE W. JENKS, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*, Dissenting

I concur with the Majority's findings that under Guidance Step 2A, Prong 1 the claims recite a nonstatutory judicial exception to Section 101, i.e., an abstract idea that is a mathematical relationship. However, I part ways with the Majority's reasoning under Guidance Step 2A, Prong 2.[1]

Specifically, I dissent from the finding that because the abstract idea recited in the claims is an "improvement in the process of identifying microorganisms based on mass spectrometry data", the "claims integrate the recited mathematical relations into a practical application."

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[1] I note that I concur in the related Appeal, 2018-007932, because I agree with the Majority that the claims in that Appeal function to improve computer capabilities and are therefore not abstract.

In my opinion, the claims do no more than recite an abstract idea, i.e., a judicial exception to Section 101, and merely directs the user to apply that judicial exception by appending a conventional steps of calculating whether data identifies microorganisms at a high level of generality using known mass spectrometers, already existing mass spectrometry data, and standard data processors. As such, I am not persuaded that the claims in question integrate the judicial exception into a practical application.

These claims are very similar to those in *SAP America, Inc. v. InvestPic*, LLC, 898 F.3d 1161 (Fed. Cir. 2018). Just as the instant claims are drawn to an improved method of "calculating a probability for the microorganism to be identified to be the reference microorganism" (Spec. ¶ 15) using mathematical analysis, *SAP* is drawn to "systems and methods for performing certain statistical analyses of investment information." *SAP*, 898 F.3d at 1163. *SAP* found the claims ineligible because the claim "subject is nothing but a series of mathematical calculations based on selected information and the presentation of the results of those calculations (in the plot of a probability distribution function)." *Id.* The same analysis applies here because the sole inventive concept is found in the mathematical algorithm.

SAP explains that "even if a process of collecting and analyzing information is 'limited to particular content' or a particular 'source,' that limitation does not make the collection and analysis other than abstract." *SAP*, 898 F.3d at 1168. The entire position of the Majority rests on the argument that the claims are limited to a particular data and particular issue, but *SAP* does not find that argument persuasive. SAP found that the use of

particular statistical methods including "bootstrap, jackknife, and cross-validation methods . . . add nothing outside the abstract realm." *Id*. at 1169. Therefore, consistent with *Alice* and *SAP*, even the inventive use of a new mathematical algorithm in a standard mass spectrometry method for detection of microorganisms is insufficient to transform the claim into patentable subject matter.

Appellant cites a number of cases and assert that these cases either differ from the current situation or support their conclusion that the abstract idea is integrated (*see* App. Br. 13–20). That Appellant uses a more complicated mathematical expression than some prior art cases is not, in my view, sufficient to demonstrate integration. I am not persuaded that these cases support Appellant's position.

For example, *McRO* was a computer based process that improves operations on the computer animation process itself, while claim 1 uses naturally occurring data composed of mass spectrometer information in a mathematical operation to process and determine the data to identify the presence or absence of microorganisms. *See McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299 (Fed. Cir. 2016). Unlike *McRO*, the computer in claim 1 is simply used as a tool to perform the mathematical operation, and the claim does not improve the computer itself. Claim 1 does not integrate the process steps into a practical improvement because the final step simply provides data, generated by the mathematical algorithm based on naturally occurring information of the size of components found in microorganisms as determined by mass spectrometry, for further consideration. Therefore, contrary to *McRO*, where the ultimate product

produced was a synchronized computer animation that was itself the transformative use, the result of the presently claimed method is a drawn to a mathematical transformation of naturally occurring information without being directed to any particular use of the mathematically transformed data other than "providing an identification decision for the microorganism based on the comparing of the calculated probabilities" (Claim 1).

Enfish explains this integration step as asking at "whether the focus of the claims is on the specific asserted improvement in computer capabilities . . . or, instead, on a process that qualifies as an 'abstract idea' for which computers are invoked merely as a tool." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335–6 (Fed. Cir. 2016). As applied to the current claims, this method of identifying microorganisms does not teach a technical improvement in a computer processor, but rather uses the computer as a tool to improve data analysis (*see* Spec. ¶ 13 "The present invention aims at solving the above-mentioned problem by providing an algorithm for identifying a microorganism based on mass spectrum measurements and classification tools, which enable to more reliably identify a microorganism."). The Specification does not even purport, in this case, to improve the computer but rather expressly teaches "the invention applies to any type of classification" of measured data (Spec. ¶ 18). The Specification states "the invention is not limited to this type of algorithm and applies to any type of classification algorithm" (Spec. ¶ 91). This breadth of invention further supports the conclusion that the claims are drawn to abstract mathematical algorithms for data analysis.

I am also not persuaded by Appellant's reliance on *Rapid Litig. Mgmt. Ltd v. CellzDirect, Inc*., 827 F.3d 1042 (Fed. Cir. 2016) (App. Br. 19) because unlike *CellzDirect*, the instant claims do not result in a physical difference in a physical product such as preserved hepatocyte cells (*see id.* at 1048).

I find the instant claims similar to those in *SmartGene*, where the Federal Circuit held that claims directed to "comparing new and stored information and using rules to identify medical options" did not satisfy *Alice* step one. *See SmartGene, Inc. v. Advanced Biological Labs., SA*, 555 F. App'x 950, 951–52, 955–56 (Fed. Cir. 2014) (nonprecedential). As in *Smartgene*, the instantly claimed steps do not rely on an inventive device or technique for displaying information or new techniques for obtaining biological information, but rather constitute a recitation of steps for mathematically manipulating naturally occurring data. *See SmartGene*, 555 Fed. Appx. at 954 (holding claims were patent ineligible because they did "no more than call on a 'computing device,' with basic functionality for comparing stored and input data and rules, to do what doctors do routinely."). Indeed, the Specification teaches that this "analysis step is conventional[ly] carried out by an operator, be it a biologist or a doctor, who determines by means of his/her know-how what conclusion can be drawn from the distances calculated by the classification tool" (Spec. ¶ 10).

Finally, under Guidance Step 2B, there is no substantive dispute that all of the mass spectrometry and computer components used in the claimed method are generic and conventional (*see* Spec. ¶ 40 "MALDI-TOF mass spectrometry is well known per se" and Spec. ¶ 71 "a MALDI-TOF mass

spectrometer, as well as a data processing unit, connected to the spectrometer").

I would therefore affirm the Examiner's rejection that the claims are not directed to patent-eligible subject matter under 35 U.S.C. § 101.