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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/145,759	10/05/2011	Gregor Stobrawa	3081.322WOUS	7782

24113 7590 06/28/2018

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ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
06/28/2018	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GREGOR STOBRAWA, MARK BISCHOFF
and MICHAEL BERGT

Appeal 2016-004596
Application 13/145,759
Technology Center 3700

Before STEVEN D.A. McCARTHY, MICHELLE R. OSINSKI and PAUL J. KORNICZKY, *Administrative Patent Judges*.

McCARTHY, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

The Appellants[1] appeal under 35 U.S.C. § 134(a) from the Examiner's decision finally rejecting claims 20–50. A hearing was held in this appeal on April 17, 2018. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] The Appellants identify the real party in interest as Carl Zeiss Meditec AG. (*See* "Appeal Brief under 37 C.F.R. § 41.37," dated Sept. 3, 2015, at 2).

We sustain the rejection of claims 25–50 under 35 U.S.C. § 101 as ineligible for patent protection.[2]

We do not sustain the rejection of claims 20–24 under 35 U.S.C. § 101 as ineligible for patent protection; or the rejection of those claims under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Rathjen (US 2007/0173793 A1, publ. July 26, 2007); Cox (US 2004/0054358 A1, publ. Mar. 18, 2004); and Rajan (US 5,891,131, issued Apr. 6, 1999).

THE CLAIMED SUBJECT MATTER

The appealed claims are directed to the field of refractive surgery, the aim of which is "to selectively alter the cornea so as to influence" the refraction (that is, bending), of light entering the eye, thereby improving focus. (Substitute Specification, dated July 21, 2011 ("Specification" or "Spec."), at 2, l. 23 – 3, l. 1). According to the Specification:

> In order now to carry out a correction of defective vision, material is removed from a region within the cornea 5 by means of . . . pulsed laser radiation by cutting tissue layers[,] thus isolating the material[,] and then mak[ing] it possible for the material to be removed. The removal of material effects a change

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[2] The Examiner also provisionally rejected claims 25–50 in the Final Office Action under 35 U.S.C. § 101 as claiming the same invention as that of claims 24–38 and 49–60 of co-pending Application 13/145,761. (Final Office Action, mailed January 8, 2015, at 6). Application 13/145,761 has since issued as Stobrawa (US 9,050,172 B2, issued June 9, 2015). The claims of Stobrawa, as issued, are not identical to the claims of Application 13/145,761, as those claims existed as of the date of the Final Office Action. In the Answer, the Examiner "note[d] the statutory double patenting rejection [was] no longer valid; however, there remains potential for an obviousness-type double patenting rejection." (Examiner's Answer, mailed January 28, 2016, at 6). We deem the double patenting rejection under § 101 withdrawn. We will not address the rejection further in this opinion.

> in the volume of the cornea which results in a change in the optical imaging effect of the cornea 5, which change is calculated exactly such that the previously determined defective vision thus is/becomes corrected as much as possible. To isolate the volume to be removed, the focus of the laser radiation 2 is directed towards target points in the cornea 5, generally in an area which is located beneath the epithelium and the Bowman's membrane and above the De[s]cemets's membrane and the endothelium. For this purpose the treatment apparatus 1 has a mechanism for shifting the position of the focus of the laser radiation 2 in the cornea 5.

(Spec. 24, l. 22 – 25, l. 9 & Fig. 1). Because this technique requires a high degree of accuracy, the cornea typically is pressed against a curved contact glass to immobilize the cornea during surgery. (*See* Spec. 6, ll. 6–9; *see also id.* 36, ll. 12–19).

A control apparatus *12*, depicted schematically in Figure 4 of the underlying application, controls, among other functions, the position and movement of the focal point of the laser radiation within and across the cornea. (Spec. 26, ll. 15–17). "The control apparatus 12 operates according to predetermined control data which predetermine the target points for shifting the focus" of the laser radiation. (Spec. 27, ll. 1 & 2). The control data, in turn, derives from the geometry or, equivalently, the refractive power, of the cornea before surgery; and from the desired geometry or refractive power of the cornea after surgery. (*See generally* Spec. 27, l. 10 – 33, l. 5 & Fig. 10). The Specification also teaches that the control data must be corrected or adjusted to account for the distortion of the cornea when pressed against the contact surface during the surgical procedure. (*See* Spec. 36, l. 12 – 37, l. 8, citing Muhlhoff (US 2007/0293851 A1, publ. Dec. 20, 2007)).

Claims 20, 22, 24–26, 31, 32, 38 and 39 are independent. Claims 20, 25 and 26 recite:

> 20. A method for generating control data that control a laser for surgical correction of defective vision of an eye of a patient, wherein prior to application of the laser to a cornea is brought from an undeformed state to a deformed state by pressing a front surface of the cornea against a contact surface; the method comprising:
>
> a) predetermining a correction surface by application of a control unit, which correction surface relates to the cornea in the undeformed state and is to be produced for correction of defective vision as a cut surface of the cornea;
>
> b) selecting several points lying in the correction surface or in an approximation surface derived therefrom by application of the control unit, the several points being a subset of points lying in the correction surface or the approximation surface derived therefrom;
>
> c) generating transformed points by transforming by application of the control unit, coordinates of the selected points into coordinates of the same points for the cornea in the deformed state to compensate for the deformed state of the cornea during operation of the laser;
>
> d) generating an interpolation surface by interpolating between the transformed points by application of the control unit; and
>
> e) selecting target points lying on the interpolation surface by application of the control unit; and
>
> f) using the target points for generating the control data.
>
> 25. A device, the device including a control unit that generates control data, the control data controlling a laser for surgical correction of defective vision of an eye of a patient, wherein:

- the control data are adapted to control the laser which cuts cornea tissue by irradiating laser radiation into the cornea of the eye and wherein the control unit is operably coupled to the laser,

- the control unit generates the control data such that the laser, during operation according to the control data, emits the laser radiation such that a volume in the cornea is isolated, the removal of which volume from the cornea effects a desired correction of the defective vision, and

- to determine the control data, the control unit calculates a radius of curvature R_{CV}* of the cornea reduced by the volume further wherein

- the radius of curvature R_{CV}* is locally varying and satisfies the following equation:

$$R_{CV}^*(r,\varphi) = 1 / ((1/ R_{CV}(r,\varphi)) + B_{COR}(r,\varphi)/ (n_c-1)) + F,$$

wherein $R_{CV}(r,\varphi)$ is the local radius of curvature of the cornea before the volume is removed, n_c is a refractive index of the material of the cornea, F is a coefficient, and $B_{COR}(r,\varphi)$ is the local change in optical refraction power in a plane lying in the vertex of the cornea and required for the desired correction of the defective vision,

- wherein there are at least two radii, r1 and r2, for which $B_{COR}(r=r1,\varphi) \neq B_{COR}(r=r2,\varphi)$ holds true.

26. A device, the device including a control unit for generating control data that controls a laser for surgical correction of the defective vision of an eye of a patient, wherein:

- the control data are adapted to control a laser which cuts cornea tissue by irradiating laser radiation into the cornea of the eye,

- the control unit generates the control data such that the laser, during operation according to the control data, emits the laser radiation such that a volume in the cornea is isolated, the removal of which volume from the cornea effects a desired correction of the defective vision, and

- to determine the control data, the control unit calculates an optical refraction power B^*_{CV} the cornea has without the volume, further wherein

- the optical refraction power B_{CV}^* is locally varying and satisfies the following equation:

$$B^*_{CV}(r, \varphi) = \frac{1}{\frac{1}{B_{CV}(r,\varphi)+B_{COR}(r,\varphi)}+\frac{F}{(n_c-1)}}$$

wherein $B_{CV}(r,\varphi)$ is the local optical refraction power of the cornea before the volume is removed, n_c is a refractive index of the material of the cornea, F is a coefficient, and $B_{COR}(r,\varphi)$ is the local change in optical refraction power in a plane lying in the vertex of the cornea and required for the desired correction of the defective vision,

- wherein there are at least two radii, r1 and r2, for which $B_{COR}(r=r1,\varphi) \neq B_{COR}(r=r2,\varphi)$ holds true.

NON-OBVIOUSNESS

Rathjen describes a device for limiting damage to eye tissues outside an operating area during laser surgery by generating control data that limits the time during which the eye is exposed to laser radiation. (*See* Rathjen, para. 13). As depicted schematically in Figure 1, such a device *1* includes a processing module *14* connected to a data acquisition module *11* for generating the control data from information stored in the data acquisition module. (*See* Rathjen, paras. 28 & 33). The information stored in the data acquisition module *11* for use in generating the control data includes "information about size and relative position of eye structures," including the cornea, "in the undeformed and/or deformed state (e.g. various deformed states of the eye structures depending on different contact bodies)." (Rathjen, para. 31; *see also id.*, para. 34).

Cox describes a system *100* "for providing a predictive outcome instruction for a proposed therapeutic ophthalmic correction." (Cox, para. 43 & Fig. 1). The system *100* includes a computing station *110*. Before a procedure, the computing station *110* receives "new" information including refraction and optical aberration data obtained from a patient's eye, as well as other information. (*See* Cox, paras. 43–45). The computing station *110* then compares the "new" information to stored theoretical and actual historical, therapeutic-outcome data to generate the predictive outcome instructions. (*See* Cox, para. 45). Cox describes a number of mathematical techniques for use in generating the predictive outcome instructions. For example, Cox teaches the use of a finite element analysis to model mechanical properties of the cornea and to predict the mechanical reaction of the corneal tissues to the proposed correction. (*See generally* Cox, paras. 61–119 & Figs. 14–24).

Rajan teaches an improved method for predicting the outcomes of refractive surgery by simulating deformations of the cornea resulting from corneal incisions. (*See* Rajan, col. 3, ll. 25–31). According to Rajan:

> [The method] involves constructing a model of a human eye using a suitable three-dimensional finite element analysis (FEA) model which includes a mesh that generally corresponds to the shape of the human eye. The shape of the human eye is described by the finite element mesh obtained using data measured from a corneal mapping device and translated into the nodal points of the FEA model. The nodal points in a small region are connected to each other by means of sharing common nodes. The thickness value at any particular region are obtained using ultrasonic measuring devices, and are applied to the elements. The "loading" of the finite element mesh structure is represented by the intraocular pressure, and the resistance of the structure to such applied "loading" is measured by the stiffness of the

> structure, which is computed on the basis of its geometry, boundary conditions, and its material properties, namely Poisson's ratio ν, and Young's modulus E.

(Rajan, col. 4, ll. 30–47). Once a finite element model of the eye is constructed from clinical measurements, the effect of various patterns of incisions, excisions or ablations is predicted from the model. (*See* Rajan, col. 3, ll. 40–59).

> Independent claim 20 of the present application recites a method including the steps of:
>
> a) predetermining a correction surface by application of a control unit, which correction surface relates to the cornea in the undeformed state and is to be produced for correction of defective vision as a cut surface of the cornea;
>
> b) selecting points lying in the correction surface or in an approximation surface derived therefrom by application of the control unit, the several points being a subset of points lying in the correction surface or the approximation surface derived therefrom;
>
> c) generating transformed points by transforming by application of the control unit, coordinates of the selected points into coordinates of the same points for the cornea in the deformed state to compensate for the deformed state of the cornea during operation of the laser.

Independent claim 22 recites a system including structure for performing analogous steps. Independent claim 24 recites a non-transitory computer readable medium including instructions for performing analogous steps.

Rathjen teaches generating control data for refractive surgery from information about the size and relative position of eye structures such as the cornea, in either a deformed or undeformed state. Cox and Rajan teach generating finite element models, that is, models based on graphs derived from measured properties in regions defined by discrete nodes or points, for

the geometric and mechanical properties of the cornea. None of the three references, alone or in combination, teaches modeling a cornea deformed by contact with a contact body by performing a mathematical transformation on coordinates describing points on the correction surface of the cornea. (*See generally* "Appeal Brief under 37 C.F.R. § 41.37," dated Sept. 3, 2015 ("App. Br."), at 35–38). Therefore, we do no sustain the rejection of claims 20–24 under § 103(a) as being unpatentable over Rathjen, Cox and Rajan.

INELIGIBLE SUBJECT MATTER

Under 35 U.S.C. § 101, "[w]hoever 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." Nevertheless, the courts have recognized three exceptions to this general rule, excluding from patentability laws of nature, physical phenomena and abstract ideas. *See Bilski v. Kappos*, 561 U.S. 593, 601 (2010). The Supreme Court has established a two-step analysis for determining whether the subject matter of a claim is eligible for patent protection. First, one must determine whether the claim is "directed to one of [the] patent-ineligible concepts," such as an abstract idea. *Alice Corp. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2355 (2014). Second, if so, one must determine if the remainder of the claim recites an "inventive concept," such that the claim as a whole recites a specific application of the patent-ineligible concept. *Id.* at 2357 & 2358.

Claims 20–24

Turning to the first step of the analysis, neither the Supreme Court, nor our reviewing court, has rigorously defined the term "abstract." *See, e.g., Alice* at 2357; *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 868 (Fed. Cir. 2010). The contours of what constitutes an "abstract idea" have developed on a case-by-case basis.

The Examiner concludes that claims 20, 22 and 24 are directed to "either [1] a general concept for accounting for deformation of a cornea when generating control data or [2] a mathematical relationship/formula with respect to a radius of curvature and an optical refraction power of the eye (*see* R_{CV}* *and* B_{CV}* *equations recited in the independent claims*)." (*See* Final Office Action, mailed January 8, 2015, at 4). Neither rationale is persuasive. As to the first formulation, the Examiner has not cited to any decision of the Supreme Court or of our reviewing court; to any precedential decision of the Board; or to any instruction issued by, or on behalf of, the Director, identifying either "a general concept for accounting for deformation of a cornea when generating control data," or an analogous formulation, as being an abstract idea within the exception enunciated by the Supreme Court. Absent such a citation, the Examiner's bald statement that "a general concept for accounting for deformation of a cornea when generating control data" is an abstract idea is not persuasive.

As to the second formulation, the Examiner has not articulated the "mathematical relationship/formula with respect to a radius of curvature and an optical refractive power of the eye" to which claim 20, 22 or 24 might be directed. Although claims 25–50 recite particular mathematical formulae, claims 20–24 do not. As such, claims 20–24 do not preempt any

mathematical algorithm, either generally or in any particular field of endeavor; and thus, at least in the sense articulated by the Examiner, do not remove from the public domain any fundamental truth free for the use of all. Because the Examiner has not demonstrated that claims 20–24 are directed to an abstract idea (*see* App. Br. 26), we do not sustain the rejection of claims 20–24 under § 101 as ineligible for patent protection.

Claims 25–50

The Appellants' arguments do not distinguish between the respective language of independent claims 25, 26, 31, 32, 38 and 39. Neither do the Appellants appear to argue any dependent claim separately. Claims 25 and 26 will be taken as representative. *See* 37 C.F.R. § 41.37(c)(1)(iv). Even apart from this procedural consideration, it is noted that, although claims 25 and 26 recite "device[s];" claims 31 and 32 recite "method[s];" and claims 38 and 39 recite "non-transitory computer readable medi[a]," the bodies of these claims otherwise recite similar steps or limitations. In assessing a rejection for ineligible subject matter under § 101, we look not to the name or intended use assigned to the claimed subject matter in the preamble, but to the nature of the claimed subject matter as a whole, to determine whether the claim falls within the "abstract idea" exception. *See CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1374 (Fed. Cir. 2011) ("Regardless of what statutory category ('process, machine, manufacture, or composition of matter,' 35 U.S.C. § 101) a claim's language is crafted to literally invoke, we look to the underlying invention for patent-eligibility purposes"). Therefore, we may treat claims 25, 31 and 38 as interchangeable for

purposes of eligibility under § 101, just as we may treat claims 26, 32 and 39 as interchangeable.

Turning to the first step, the Examiner correctly concludes that claims 25 and 26 are directed to "a mathematical relationship/formula with respect to a radius of curvature and an optical refraction power of the eye (see R_{CV}* and/or B_{CV}* equations recited in the independent claims)." (*See* Examiner's Answer, mailed Jan. 28, 2016 ("Ans."), at 3). Claims 25 and 26 recite the use of mathematical formulae relating to the surface geometry of a cornea with the optical refractive power of the cornea in calculating control data for controlling a laser during optical surgery. These formulae, regardless how derived, are deemed abstract ideas. *See Diamond v. Diehr*, 450 U.S. 175, 186 (1981) (stating that a mathematical formula "is like a law of nature, which cannot be the subject of a patent."); *DDR Holdings, LLC, v. Hotels.com, L.P.*, 773 F.3d 1245, 1256 (Fed. Cir. 2014).

Turning to the second step, claim 25 recites:

> A device, the device including a control unit for generating control data that controls a laser for surgical correction of the defective vision of an eye of a patient, wherein:
>
> - the control data are adapted to control a laser which cuts cornea tissue by irradiating laser radiation into the cornea of the eye,
>
> - the control unit generates the control data such that the laser, during operation according to the control data, emits the laser radiation such that a volume in the cornea is isolated, the removal of which volume from the cornea effects a desired correction of defective vision.

Claim 26 includes a similar recitation. The "Background" section of the Specification teaches that a known surgical method uses a laser to isolate corneal tissue; and that this method requires the generation of control data to

operate the laser according to this method. (*See* Spec. 4, ll. 12–19). These teachings imply the limitations reproduced immediately above are well-known and conventional within the field of surgery employing a laser to isolate corneal tissue. This conclusion, in turn, implies that the unknown or unconventional features of claims 25 and 26 are the formulae recited in the last two indented limitations of each claim.

Therefore, claims 25 and 26 fail to recite "something more" that might transform claim 25 or claim 26 into a patent-eligible application of the formulae. We sustain the rejection of claims 25–50 under § 101 as being directed to ineligible subject matter.

DECISION

We sustain the rejection of claims 25–50 under 35 U.S.C. § 101 as ineligible for patent protection.

We do not sustain the rejection of claims 20–24 under 35 U.S.C. § 101 as ineligible for patent protection; or the rejection of those claims under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Rathjen, Cox and Rajan.

Therefore, we AFFIRM the Examiner's decision rejecting claims 25–50; and REVERSE the Examiner's decision rejecting claims 20–24.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART