AMERICAN ANTI-VIVISECTION SOCIETY

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ALTERNATIVES RESEARCH & DEVELOPMENT FOUNDATION

Assistant Commissioner for Patents

Mail Stop Inter-Partes Reexamination

PO Box 1450

Alexandria VA 22313-1450

March 23 , 2007

In Re U.S. Patent No. US-6,924,413-B2

Dear Sir or Madam:

Inter-Partes Reexamination under 35 U.S.C. §§ 311-318 and 37 CFR §§ 1.902-1.997 is respectfully requested of U.S. Patent No. 6,924,413 (issued on 02 August 2005) to Iwao Katsuyama. It is believed that this patent is still within its period of enforceability. Requesters hereby certify that a copy of the request has been served in its entirety on the Patent Owner at the address provided for in § 1.33(c). The name and address of the party served is:

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I. Requesters and Real Parties in Interest

The Requesters and the real parties in interest are: (1) American Anti-Vivisection Society (AAVS), a nonprofit organization of Pennsylvania, with offices at 801 Old York Rd., #204, Jenkintown, PA 19046; *and* (2) International Center for Technology Assessment (ICTA), a 501(c)(3) organization of Washington DC, with offices at 660 Pennsylvania Avenue SE, Suite 302, Washington DC 20003; *and* (3) Alternatives Research & Development Foundation (ARDF), a 501(c)(3) organization of Pennsylvania, with offices at 801 Old York Rd., #316, Jenkintown, PA 19046.

The mission of the AAVS is to unequivocally oppose and work to end experimentation on animals and to oppose all other forms of cruelty to animals. ICTA is committed to providing the public with full assessments and analyses of technological impacts on society. The mission of the ARDF is to fund and promote the development, validation and adoption of non-animal methods in biomedical research, product testing and education. The Requesters, opposed to the use of animals in research, testing, and education, assert that the instant patent, and others like it, do not fulfill the requirement of patent law, because neither rabbits, nor any other such animals, fit into any of the patentable categories; and, in any event, the claims of the instant patent fail to be novel and/or nonobvious within the field of biomedical research.

II. Certification Regarding Estoppel Provisions of 37 C.F.R. § 1.907

The Requesters and all real parties in interest hereby certify that the estoppel provisions of 37 C.F.R. § 1.907 do not prohibit *inter partes* reexamination.

III. Claims for which reexamination is requested.

Reexamination is requested of claims 1-28 ("instant claims") of the Katsuyama patent, US 6,924,413 B2 ("instant patent"). This request is accompanied by payment of the

government filing fee of $8,800.

IV. Nomenclature for References

A copy of every reference relied upon to support the below-described Substantial New Questions of Patentability is herein enclosed and listed on Form PTO/SB/42.

A. I. Katsuyama, U.S. Patent 6,924,413 B2, Aug. 2, 2005.

B. K.Green et al., "Reduction of Corneal Thickness with Hypertonic Solutions." *Amer. J. of Ophthalmology* **1973**, 75, (3), 507-510.

C. J.P.McCulley, "Ocular Hydrofluoric Acid Burns: Animal Model, Mechanism of Injury and Therapy." *Trans. Amer. Ophth. Soc.* **1990**, 88, 649-684.

D. M.N.Luxenberg, et al., "Reduction of Corneal Edema with Topical Hypertonic Agents." *American Journal of Ophthalmology* **71**, (4), 847-853, **1971**.

E. J.Obenberger, "Paper Strips and Rings as Simple Tools for Standardization of Experimental Eye Injuries." *Ophthalmic Research* **1975**, 7, 363-367.

F. D.W.Lamberts, "Topical Hyperosmotic Agents and Secretory Stimulants." *International Ophthalmology Clinics* **1980**, 20, (3), 163-169.

G. In Toxicology of the Eye, Ear, and Other Special Senses; A.W.Hayes, Eds. Raven Press: 1985; pages 106 and 130-132 and 139.

H. K.C.Swan, "A Dehydrating Jelly to Clear Corneal Bedewing." *A.M.A. Archives of Ophthalmology* **1953**, 50, (1), 75-77.

I. R.D.Harley, "An Experimental Study on the Evaluation of Hydrosulphosol in the Treatment of Ocular Injuries Due to Chemical Burns." *Trans. Amer. Ophthalmol. Soc.* **1951**, 49, 557-594.

J. J.P.Gilbard et al., "Tear Film Osmolarity and Ocular Surface Disease in Two Rabbit Models for Keratoconjunctivitis Sicca." *Investigative Ophthalmology & Visual Science* **1988**, 29, (3), 374-378.

K. P.M.Hazel et al., US Patent 4,051,842, Oct.4, 1977.

L. M.F.Saettone et al., US Patent 6,056,950, May 2, 2000.

M. H.W.Holtmann et al., "Uber die Wirkungen des Actihaemyls auf die Epithel-regeneration." *Klin. Monatbl. Augenheilk.* **1975**, 167, 437-441.

N. R.A.Levinson et al., "Ascorbic acid prevents corneal ulceration and perforation following experimental alkali burns." *Investigative Ophthalmology* **1976**, 15, (12), 986-993.

O. M.S.Insler et al., "Topical hyperosmolar solutions in the reduction of corneal edema." *The CLAO journal* **1987**, 13, (3), 149-151.

P. J.P. Gilbard et al., "Morphologic Effect of Hyperosmolarity on Rabbit Corneal Epithelium." *Ophthalmology* **1984**, 91, (10), 1205-1212.

Q. J.V.Jester et al., "Area and Depth of Surfactant-induced Corneal Injury Correlates with Cell Death." *Investigative Ophthalmology & Visual Science* **1998**, 39, (6), 922-936.

R. L.D.Ormerod et al., "Standard Models of Corneal Injury using Alkali-immersed Filter Discs." *Investigative Ophthalmology & Visual Science* **1989**, 30, (10), 2148-2153.

S. G.Wilson et al., "Does Topical Hydrogen Peroxide Penetrate the Cornea? *Investigative Ophthalmology & Visual Science* **1993**, 34, (9), 2752-2760.

T. B.O. Hedbys et al., "The Thickness-Hydration Relationship of the Cornea." *Experimental Eye Research* **1966**, 5, 221-228.

U. J.A.Stanley et al., "In Vivo Determination of Endothelial Permeability to Water." *Investigative Ophthalmology* **1966**, 5, (4), 371-377.

V. I.Katsuyama et al., "A convenient rabbit model of ocular epithelium damage induced by osmotic dehydration." *Journal of Ocular Pharmacology and Therapeutics* **2003**, 19, (3), 281-289.

W. J.L.Haslam et al., US Patent 4,474,751, Oct.2, 1984.

X. D.A.Fremstad, US Patent 5,472,436, Dec.5, 1995.

Y. S. Mishima et al., "The permeability of the corneal epithelium and endothelium to water." *Experimental Eye Research* **1967**, 6, 10-32.

Z. F.Theeuwes et al., US Patent 4,014,334, Mar. 29, 1977.

AA. R. A. Moses et al., "A Standard Large Wound of the Corneal Epithelium in the Rabbit." *Investigative Ophthalmology & Visual Science* **1979**, 18, (1), 103-106.

BB. M. Leesti, Decisions of the Commissioner of Patents (Canadian Intellectual Property Office), Decision #1203, Application #484723, 04 August 1995.

CC. J. Nadon. Harv. Coll. v. Canada (Comm'r of Patents), [1998] 3 F.C. 510. (Can.), Fed. Court of Can. Trial Div., Nadon, Judge. Date made public: April 21, 1998.

DD. F. J. Holly. U.S Patent 4,271,144, June 2, 1981.

V. Statement pointing out each substantial new question of patentability based on the cited printed publications, and a detailed explanation for every claim for which reexamination is requested.

Lack of Novelty

Grounds I

Claims 1-2, 15, 26, and 28 lack novelty under 35 U.S.C. 102(b) as being anticipated by Green, et al. (REFERENCE B); with Hazel (REFERENCE K) cited only to state an inherent fact.

Green contacts an ocular cornea of a rabbit with a water-absorbing material comprising a polyol (namely, glycerin), said water-absorbing material being used in the form of what is termed a "cream." This material was termed "BP-E Ocular." The *stated* result is that the thickness of the rabbit cornea was reduced. See page 507, column 1, line 17 through page 507, column 2, last line.

Note that the material also contained 5% NaCl in addition to the glycerin, and was characterized as being "hypertonic." See page 509, column 2, lines 6-8. The BP-E substance had the "same formula as EKG-Sol, an electrocardiography electrode cream, by Burton, Parsons and Company, Inc., Washington DC." See page 507, column 2, lines 7-13.

Green does not literally state that the material containing glycerin was in the physical state of a gel or a jelly.

Hazel is relied upon solely to teach the inherent fact that EKG-Sol is inherently a "gel." Specifically, Hazel teaches that EKG-Sol is a conventional, commercially available conductive "gel" (see column 4, lines 60-69 of Hazel). Hazel is not relied upon to teach anything other than inherency in this proposed rejection.

Green teaches that the glycerin-containing gel produces a reduction in thickness of a normal rabbit cornea when applied thereto (see page 507, column 2, last paragraph). Green also refers to the agents tested as hypertonic, i.e., hyperosmotic (page 507, column 1, line 1). The glycerin taught by the Green reference inherently teaches the limitation of "polyol", as evidenced by the instant patent specification at column 8, lines 6-10. The instant specification is solely relied upon to provide a dictionary or lexicography for determining claim scope. Patent Owner's specification is not at all relied upon as a grounds of rejection, but merely as a "dictionary" for the breadth of the terms of the claims.[1]

Since Green teaches all the same positive process steps as are necessary to make the "experimental animal" of instant claim 1, then it must inherently produce a rabbit having "corneal epithelial damage in a part of the ocular cornea" to the same extent as in the present claims. Furthermore, and in the *alternative*, the "thinning" of the cornea which is explicitly taught in Green can be taken to meet the claim limitation of "damage", given the broadest reasonable interpretation of the latter, because a rabbit with a thinned cornea is clearly one in which corneal dystrophy or Keratoconus has been induced.

Grounds II.

Claims 5-8, 10, 16, and 24 lack novelty under 35 U.S.C. 102(b) as being anticipated by McCulley (REFERENCE C).

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1 Markman v. Westview Instruments, 52 F.3d 967, 979,(Fed. Cir. 1995), 34 U.S.P.Q. 2d 1321, 1329-30 (rev'd en banc), aff'd, 517 U.S. 370 (1996) (stating: "For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims.")

McCulley teaches a method of producing an experimental rabbit having corneal epithelial damage, which method comprises an initial step of covering the ocular cornea of the rabbit with Handi-Wrap plastic film having a small slit in the center of it. The eyeball of the rabbit is then contacted, through the slit in the plastic film, with a hyperosmotic solution of saturated potassium chloride (KCl, an alkali metal salt), resulting in a difference in osmotic pressure and causing corneal injury "due primarily to osmotic assault to the cornea."

See page 652, lines 1-15, and Figure 1 on page 652, and page 653, lines 25-33.

The "hole" in the instant claims is sufficiently broad to embrace the "small slit" in the film shown in the reference, given the ordinary & normal meaning of "hole" as an opening or a perforation, and given that there is no shape or size limitation to the hole of the instant claims. The placement of the "hole" in the instant claims is broadly given as anywhere "around the pupil area" of the rabbit; thus it appears reasonable to take this placement as broad enough to embrace the slit of the reference, which allows delivery of the osmotic agent to the area of the rabbit's ocular cornea.

Thus, McCulley meets all the positive process limitations of claim 24, and inherently produces an animal having the same characteristics as that of claims 5-8, 10 and 16.

Obviousness

Grounds III.

Claim 25 is unpatentable under 35 U.S.C. §103(a) as being obvious to the person of ordinary skill in the art, in view of Gilbard 1984 (REFERENCE P) and Harley (REFERENCE I).

Gilbard contacts the corneas of rabbits with hypertonic solutions of alkali salts having osmolarity of up to 407 mOsm/L. See pages 1207, column 1, line 1 to column 2, line 14. Microscopic examination of the corneas bathed in hypertonic solutions showed "increased cell desquamation" and other signs of corneal epithelial damage. See page 1209, column 1, line 5 to page 1211, column 2, line 11. Gilbard reports that the corneal epithelial changes seen in the

rabbits treated with the hyperosmotic solution are those also reported in the disease keratoconjunctivitis sicca, i.e., dry eye. See page 1211, column 1, lines 12-17.

Gilbard appears to differ from instant claim 25 in that its hypertonic solutions are not contacted with the rabbit cornea through a water-permeable membrane or film.

Harley teaches methods for forming standard chemical lesions of the rabbit cornea for experimental purposes, comprising covering the cornea with a 6 mm diameter piece of filter paper, then delivering drops of a lesion-causing chemical to the filter paper. Then, the filter paper is removed and the eye washed with normal saline. Using a small disc of filter paper causes the most nearly standard and uniform lesions. See page 564, lines 7-12 and page 565, lines 14-22. After the lesion was formed, a medicament was applied to the cornea, and the eyes re-examined.

It would have been obvious to the person having ordinary skill in the art to have contacted Gilbard's hypertonic solution to a rabbit cornea via delivery of that solution to a disc of filter paper upon the rabbit cornea, because Harley teaches forming standard chemical lesions of the rabbit cornea for experimental purposes, comprising covering the cornea with filter paper, then delivering drops of a lesion-causing chemical to the filter paper. The motivation for doing so, is that this procedure would result in the most nearly standard and uniform lesions.

The filter paper of Harley is taken to meet the limitation of water-permeable membrane or film, since it is water permeable. See also instant column 9, line 69 of the instant patent, which indicates that one example of a water-permeable membrane can be a "cellulose" substance (paper is made of cellulose). The instant specification is not cited as a grounds of rejection but only to define & indicate the breadth of the claim limitation to "water-permeable membrane".

Grounds IV.

Claims 1-2, 15, 26 and 28 are unpatentable under 35 U.S.C. §103(a) as being obvious to the person of ordinary skill in the art, in view of Green, Luxenberg, Swan, and Haslam (i.e., REFERENCE B, REFERENCE D, REFERENCE H, AND REFERENCE W, respectively).

Green contacts an ocular cornea of a rabbit with a water-absorbing material comprising a polyol (namely, glycerin), said water-absorbing material being used in the form of

what is termed a "cream". This material was termed "BP-E Ocular". The result is that the thickness of the rabbit cornea was reduced. See page 507, column 1, line 17 through page 507, column 2, last line.

Note that the cream also contained 5% NaCl in addition to the glycerin, and was characterized as being "hypertonic". See page 509, column 2, lines 6-8. The BP-E substance had the "same formula as EKG-Sol, an electrocardiography electrode cream, by Burton, Parsons and Company, Inc., Washington DC". See page 507, column 2, lines 7-13.

Green teaches that the glycerin-containing material produces a reduction in thickness of a normal rabbit cornea when applied thereto (see page 507, column 2, last paragraph). Green also refers to the agents tested as hypertonic, i.e., hyperosmotic (page 507, column 1, line 1).

Green does not literally state that the cream containing glycerin was in the physical state of a gel or a jelly.

Luxenberg teaches that application of a hypertonic agent to the ocular cornea was effective to reduce the thickness of the human cornea. One of the most effective agents was "BP-E ocular", an agent comprising glycerin in an emulsive vehicle. See page 847, column 2, line 12 through to page 848, column 1, last line; and Table 1 on page 847. These hypertonic agents are taught as being capable of "dehydration of the epithelium". See page 853, column 1, lines 8-12. Luxenberg teaches that the most advantageous hypertonic agents are the highly viscous ones (compared to less viscous mixtures), due to their "prolonged retention on the cornea". See page 853, column 1, last 15 lines.

Swan teaches a method of removing excess hydration ("bedewing") of the corneal epithelium, comprising contacting the corneal epithelium with a composition comprising hydroscopic glycerin. See page 75, lines 1-7 and 27-29 and page 76, line 1. However, Swan also teaches that glycerin has a short duration of action due to lacrimation (page 76, lines 3-7). Therefore, Swan adds carboxymethylcellulose to the glycerin, in order to increase its viscosity and to confine it to the cornea or a section of a cornea. See page 76, lines 8-17. The final composition of glycerin and carboxymethylcellulose is referred to as a "dehydrating jelly". See page 76, lines 25-28.

It would have been obvious to one of ordinary skill in the art to have contacted a

rabbit cornea with Green's glycerin-containing hyperosmotic agent formulated as a "jelly", because Luxenberg teaches that the most effective hypertonic agents are the highly viscous ones due to their prolonged retention on the cornea, and because Swan teaches increasing the viscosity of hyperosmotic glycerin to form a jelly, in order to confine it to the cornea or a section of a cornea.

Haslam teaches that when drugs are administered to the eye, a major loss of these drugs is via the lacrimal drainage system, so that only a small fraction of the dose remains in the eye. One approach used to slow down the rapid loss of drugs is through use of viscous gels. See column 1, lines 1-12. In particular, Haslam provides a new viscous gel which provides drug delivery to the eye. See column 1, lines 60-69. Among possible drugs delivered from the gel are hyperosmotic agents such as glycerin or mannitol. See column 5, lines 27-34. The advantage of using a drug in this gel form is its prolonged residence time in the eye. See column 4, lines 30-40.

It would have been obvious to one of ordinary skill in the art to have contacted a rabbit cornea with Green's glycerin-containing hyperosmotic agent formulated as a "gel" (to the extent it is not inherently already a gel), because Luxenberg teaches that the most effective hypertonic agents are the highly viscous ones due to their prolonged retention on the cornea, and because Haslam teaches that providing a hyperosmotic agent such as glycerin in the form of a gel slows down its rapid loss dues to lacrimation and provides prolonged residence time in the eye.

Grounds V.

Claims 15, 18 and 21 are unpatentable under 35 U.S.C. §103(a) as being obvious to the person of ordinary skill in the art, in view of Green, Luxenberg, Swan, and Haslam as already applied to claims 1-2, 15, 26 and 28 above, and further in view of Gilbard 1984 (REFERENCE P) and Hayes (REFERENCE G)

With respect to instant claims 18 and 21, these are method claims requiring the following:

administering a medicine to a cornea of the animal claimed in instant claim 1; and

evaluating a therapeutic effect thereof on the corneal epithelium by staining an area of

the corneal epithelium, either after administration of the medicine or both before and after administration of the medicine; and

determining change in the stained area of the corneal epithelium.

Note, however, that Hayes teaches that it is desired to know the effect of ophthalmic drugs on ocular healing. See page 130, lines 21-28. Hayes also teaches a method for studying the healing of the corneal epithelium by first making a chemical wound of uniform size, and then the rate of healing is determined by periodic measurements of the fluorescein-stained area of the cornea. The stained wound can be photographed to determine its area in order to quantify the degree of healing. See page 131, line 23 through page 132, line 11.

Gilbard 1984 contacts the corneas of rabbits with hypertonic solutions of alkali salts having osmolarity of up to 407 mOsm/L. See pages 1207, column 1, line. 1 to column 2, line 14. Microscopic examination of the corneas bathed in hypertonic solutions showed "increased cell desquamation" and other signs of corneal epithelial damage. See page 1209, column 1, line 5 to page 1211, column 2, line 11. Gilbard reports that the corneal epithelial changes seen in the rabbits treated with the hyperosmotic solution are those also reported in the disease KCS, keratoconjunctivitis sicca, i.e., dry eye. See page 1211, column 1, lines 12-17. This appears to teach the person of ordinary skill in the art to expect that rabbit corneas damaged by treatment with highly hyperosmotic solutions can be considered as alleged "models" for dry eye.

It would have been obvious to have performed the steps claimed in instant claims 18 and 21 upon the animal suggested by the combined *teachings* of Green, Luxenberg, Swan, and Haslam, because Gilbard teaches one to expect that a rabbit cornea treated with hyperosmotic agents can be considered a "model" of dry eye, and because Hayes teaches the steps of the instant claims in order to know the effect of ophthalmic drugs on ocular healing.

Grounds VI.

Claims 3-4 and 27 are unpatentable under 35 U.S.C. §103(a) as being obvious to the person of ordinary skill in the art, in view of Green, Luxenberg, Swan, and Haslam as already applied to claims 1-2, 15, 26 and 28 above, and further in view of Holly (REFERENCE DD).

With respect to claims 3-4 and 27, which require the water-absorbing material to be a saccharide such as sucrose or glucose, in the physical form of a gel or jelly, please note the further teachings of Holly.

Holly teaches using a hyperosmotic 40% glucose "ointment" to dehydrate the intact corneal epithelium. This glucose ointment is said to have a dehydrating effect higher than that of 5% sodium chloride solution. For all these features see column 2, lines 32-60. The ointment of Holly is taken to fairly teach and/or suggest the claimed element of a "jelly" containing glucose, since an ointment ordinarily has the consistency of a jelly.

It would have been obvious to have substituted the hyperosmotic jelly suggested by the combined *teachings* of Green, Luxenberg, Swan, and Haslam (which would contain 5% sodium chloride in combination with glycerin), with the hyperosmotic 40% glucose ointment taught by Holly, because Holly teaches that it has a higher dehydrating effect than a 5% sodium chloride solution.

Grounds VII.

Claims 11-12 and 17 are unpatentable under 35 U.S.C. §103(a) as being obvious to the person of ordinary skill in the art, in view of Green, Luxenberg, Swan, and Haslam as already applied to claims 1-2, 15, 26 and 28 above, and further in view of Harley (REFERENCE I) and Theeuwes (REFERENCE Z).

The method and animal suggested by the combined *teachings* of Green, Luxenberg, Swan, and Haslam would suggest an experimental animal having corneal damage caused by contact with hyperosmotic glycerin in the form of a gel or jelly; however, these references lack a teaching of performing this contact "through a water-permeable or semi-permeable membrane or film and thereby generating a difference in osmotic pressure between the inside and outside of the ocular corneal epithelium cells."

Harley teaches methods for forming standard chemical lesions of the rabbit cornea for

experimental purposes, comprising covering the cornea with a 6 mm diameter piece of filter paper, then delivering drops of a lesion-causing chemical to the filter paper. Then, the filter paper was removed and the eye washed with normal saline. Using a small disc of filter paper causes the most nearly standard and uniform lesions. See page 564, lines 6-12 and page 565, lines 14-22. After the lesion was formed, a medicament was applied to the cornea, and the eyes re-examined.

It would have been obvious to the person having ordinary skill in the art to have provided the hyperosmotic glycerin gel/jelly suggested by the combined *teachings* of Green, Luxenberg, Swan, and Haslam to a rabbit ocular cornea via action through a semipermeable small disc of filter paper, because Harley teaches such delivery of lesion-causing chemicals to a rabbit cornea as a method for forming standard chemical lesions for experimental purposes.

In order to teach to the person of ordinary skill in the art what would be the *expected* result of such action, the Theeuwes reference is relied upon.

Theeuwes teaches an ocular osmotic system comprising a semipermeable lamina surrounding a compartment. The compartment can contain a mixture of an osmotically effective compound that exhibits an osmotic pressure gradient across the laminate, and an other agent. The other agent is released from the system when fluid is imbibed through the semipermeable lamina, thereby producing a solution containing the agent. See column 2, lines 39-60. The system can be placed on the eyeball. See Figure 4 and column 5, line 65 - column 6, line 38. The shape of the system can be circular. The agent can be any physiologically active substance that produces a localized effect in mammals. See column 13, lines 50-65, col. 14, lines 1-11 and col. 15, lines 3-6 of Theeuwes (REFERENCE Z).

The osmotically effective compound can be any organic compound that exhibits an osmotic pressure gradient against an external fluid. See column 12, lines 47-51. The osmotically effective compound can be present in any physical form. See column 13, lines 7-11 of Theeuwes (REFERENCE Z). Finally, the semipermeable membrane lamina can be made of a wide variety of polymeric cellulose derivatives, such as cellulose acetate. See, e.g., column 6, line 55 to column 7, line 45.

In summary, Theeuwes teaches an expected result: if you place an osmotically effective compound on one side of a cellulosic semipermeable membrane, and place the other side

on the eye, fluid will be imbibed from the eye, then pass across the membrane, and into the osmotically effective compound. This is precisely the result which is explicitly claimed in instant claims 11-12 and 17, and is an *expected* result. Expected results are indicative of obviousness. The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc*., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Grounds VIII.

Claims 13-14 are unpatentable under 35 U.S.C. §103(a) as being obvious to the person of ordinary skill in the art, in view of Green, Luxenberg, Swan, and Haslam and further in view of Harley (REFERENCE I) and Theeuwes (REFERENCE Z) as already applied to Claims 11-12 and 17 above, and yet further in view of Holly (REFERENCE DD).

With respect to claims 13-14, which require the water-absorbing material to be a saccharide such as sucrose or glucose, in the physical form of a gel or jelly, please note the further teachings of Holly.

Holly teaches using a hyperosmotic 40% glucose ointment to dehydrate an intact corneal epithelium. This glucose ointment is said to have a dehydrating effect higher than that of 5% sodium chloride solution. For all these features see column 2, lines 32-60. The ointment of Holly is taken to fairly teach and/or suggest the claimed element of a "jelly" containing glucose, since an ointment ordinarily has the consistency of a jelly.

It would have been obvious to have substituted the hyperosmotic gel/jelly suggested by the combined *teachings* of Green, Luxenberg, Swan, Haslam, Harley and Theeuwes, with the hyperosmotic 40% glucose ointment taught by Holly, because Holly teaches that it has a higher dehydrating effect than a 5% sodium chloride solution.

Grounds IX.

Claims 20 and 23 are unpatentable under 35 U.S.C. §103(a) as being obvious to the person of ordinary skill in the art, in view of Green, Luxenberg, Swan, and Haslam and further in

view of Harley (REFERENCE I) and Theeuwes (REFERENCE Z) as already applied to Claims 11-12 and 17 above, and yet further in view of Hayes (REFERENCE G).

With respect to instant claims 20 and 23, these are method claims requiring the following:

administering a medicine to a cornea of the animal claimed in instant claim 11; and

evaluating a therapeutic effect thereof on the corneal epithelium by staining an area of the corneal epithelium, either after administration of the medicine or before and after administration of the medicine; and

determining change in the stained area of the corneal epithelium.

Note, however, that Hayes teaches that it is desired to know the effect of ophthalmic drugs on ocular healing. See page 130, lines 21-28. Hayes also teaches a method for studying the healing of the corneal epithelium by first making a chemical wound of uniform size, and then the rate of healing is determined by periodic measurements of the fluorescein-stained area of the cornea. The stained wound can be photographed to determine its area in order to quantify the degree of healing. See page 131, line 23 through page 132, line 11.

It would have been obvious to have performed the steps claimed in instant claims 20 and 23 upon the animal suggested by the combined *teachings* of Green, Luxenberg, Swan, and Haslam and further in view of Harley and Theeuwes, because Hayes teaches these steps in order to know the effect of ophthalmic drugs on ocular healing.

Grounds X.

Claims 5-8, 10, 16, 19, 22 and 24 are unpatentable under 35 U.S.C. §103(a) as being obvious to the person of ordinary skill in the art, in view of McCulley (REFERENCE C), Gilbard 1984 (REFERENCE P), Hayes (REFERENCE G) and Moses (REFERENCE AA).

McCulley teaches a method of producing an experimental rabbit having corneal epithelial damage which method comprises an initial step of covering the ocular cornea of the rabbit with Handi-Wrap plastic film having a small slit in the center of it. The eyeball of the rabbit is then contacted, through the slit in the plastic film, with a hyperosmotic solution of

saturated potassium chloride (KCl, an alkali metal salt), resulting in a difference in osmotic pressure and causing cornea injury "due primarily to osmotic assault to the cornea".

See page 652, lines 1-15, and Figure 1 on page 652, and page 653, lines 25-33.

The "hole" in the instant claims is sufficiently broad to embrace the "small slit" in the film shown in the reference, given the ordinary & normal meaning of "hole" as an opening or a perforation, and given that there is no shape or size limitation to the hole of the instant claims. The placement of the "hole" in the instant claims is broadly given as anywhere "around the pupil area" of the rabbit; thus it appears reasonable to take this placement as broad enough to embrace the slit of the reference, which allows delivery of the osmotic agent to the whole area of the rabbit's ocular cornea.

However, to the the extent that the McCulley reference is construed as not inherently teaching the application of a hyperosmotic agent to a rabbit cornea via steps comprising "covering the ocular cornea . . . with a water-impermeable membrane or film having a hole or holes in it, said membrane or film being placed on the ocular cornea so that the hole or holes in the membrane or film comes on around the pupil area thereof" (not admitted to here), the Gilbard, Hayes, & Moses references are relied upon.

Gilbard contacts the corneas of rabbits with hypertonic solutions of alkali salts having osmolarity of up to 407 mOsm/L. See pages 1207, column 1, line. 1 to column 2, line 14. Microscopic examination of the corneas bathed in hypertonic solutions showed "increased cell desquamation" and other signs of corneal epithelial damage. See page 1209, column 1, line 5 to page 1211, column 2, line 11. Gilbard reports that the corneal epithelial changes seen in the rabbits treated with the hyperosmotic solution are those also reported in the disease KCS, keratoconjunctivitis sicca, i.e., dry eye. See page 1211, column 1, lines 12-17. This appears to teach the person of ordinary skill in the art to expect that rabbit corneas damaged by treatment with highly hyperosmotic solutions can be considered as alleged "models" for dry eye.

Hayes teaches the method for studying the healing of the corneal epithelium. First, a wound of uniform size is made by some chemical treatment, and then the rate of healing is determined by periodic measurements of a fluorescein-stained area of the cornea. The stained

wound can be photographed to determine its area in order to quantify the degree of healing. See page 131, line 23 though page 132, line 11.

Moses is relied upon to teach that it is known to produce a "standard" lesion upon the epithelium of a rabbit cornea by a chemical treatment, wherein a "plastic mask" is used so as to "denude a standard area" of cornea. See page 106, column 2, lines 9-19.

It would have been obvious to the person having ordinary skill in the art to have recognized the rabbit of McCulley as being an alleged "model" for dry eye syndrome, because: McCulley teaches causing corneal injury in a rabbit by osmotically assaulting it with saturated potassium chloride solution through the slit in a plastic film over the rabbit's eye; and because Gilbard reports that the corneal epithelial changes seen in the rabbits treated with the hyperosmotic solution are those also reported in the disease KCS, keratoconjunctivitis sicca, i.e., dry eye.

It would have been obvious to the person having ordinary skill in the art to have modified McCulley (viewed together with Gilbard) so as to have made a standard-sized injury upon McCulley's rabbit cornea, because Hayes teaches that in order to study the healing of the corneal epithelium, a wound of uniform size is made by some chemical treatment, and then the rate of healing is determined by periodic measurements of a fluorescein-stained area of the cornea.

One of ordinary skill in the art would have been motivated to modify McCulley's Handi-Wrap film having a slit into the form of a plastic mask of standard size, because Moses teaches that it is known to produce a standard lesion upon the epithelium of a rabbit cornea by a chemical treatment with alcohol, wherein a plastic mask is used to denude a standard area of cornea.

With respect to instant claim 16, please note again that Gilbard reports that the corneal epithelial changes seen in the rabbits treated with the hyperosmotic solution are those also reported in the disease KCS, keratoconjunctivitis sicca, i.e., dry eye. This appears to teach the person of ordinary skill in the art to expect that rabbit corneas damaged by treatment with highly hyperosmotic solutions can be considered as alleged "models" for dry eye.

With respect to instant claims 19 and 22, these are method claims requiring the following:

administering a medicine to a damaged cornea of the animal claimed in instant claim 5; and

evaluating a therapeutic effect thereof on the corneal epithelial damage by staining a damaged area of the corneal epithelium, either after administration of the medicine or before and after administration of the medicine; and

determining change in the stained area of the corneal epithelium.

Note, however, that Hayes teaches that it is desired to know the effect of ophthalmic drugs on ocular healing. Furthermore, as already noted, Hayes teaches a method for studying the healing of the corneal epithelium by first making a chemical wound of uniform size, and then the rate of healing is determined by periodic measurements of the fluorescein-stained area of the cornea. The stained wound can be photographed to determine its area in order to quantify the degree of healing. It would have been obvious to have performed the steps claimed in instant claims 19 and 22 upon the animal of McCulley modified in view of Gilbard, Hayes, Moses (as combined above), because Hayes teaches these steps in order to know the effect of ophthalmic drugs on ocular healing.

Grounds XI.

Claim 9 is unpatentable under 35 U.S.C. §103(a) as being obvious to the person of ordinary skill in the art, in view of McCulley (REFERENCE C), Gilbard 1984 (REFERENCE J), Hayes (REFERENCE G) and Moses (REFERENCE AA) as already applied to claims 5-8, 10, 16, 19, 22 and 24 above, and further in view of Theeuwes (REFERENCE Z).

The teachings of the heretofore combined references do not appear to show contact of a rabbit cornea with a hyperosmotic saccharide such as sucrose or fructose, as in instant claim 9.

Theeuwes teaches a series of osmotically effective agents including potassium chloride (KCl), fructose, and sucrose-fructose mixtures. See Table 1 at column 13. The fructose and sucrose-fructose mixture had a significantly higher osmotic pressure than the KCl. The

osmotically effective agent is active in an ocular environment for administering drugs at an osmotically metered rate. See column 5, line 65 - column 6, line 10.

It would have been obvious to have utilized fructose and/or sucrose for the osmotic "assault" in the process suggested by the combined *teachings* of McCulley, Gilbard, Hayes, and Moses, because Theeuwes teaches that these agents have a higher osmotic effect than the KCl taught by McCulley.

Number of References Used

It is noted that a fair number of references have been used to prove obviousness against certain of the claims. It would be error to focus on the number of references. Reliance on a large number of references in a rejection does not of itself weigh against the combination thereof: see In re Gorman[2] (in Gorman, the Court affirmed a rejection of a detailed claim based on thirteen prior art references). In fact, the number of references that may be combined is theoretically infinite: see Ex parte Fine[3].

Lack of Statutory Subject Matter

Grounds XII.

Claims 1-17 lack statutory subject matter under 35 U.S.C. §101 in view of evidence that the person of ordinary skill in the art would reasonably doubt that the claimed “non-human mammal or a fowl”, as a whole, is a "machine," "manufacture," or "composition of matter." The evidence is in the form of the following prior art printed publications: Leesti (Reference BB), and Nadon (Reference CC).

The Leesti reference[4] pertains to the question of whether or not non-human mammals

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2 In re Gorman, 933 F.2d 982, 986 (Fed. Cir. 1991), 18 U.S.P.Q.2d 1885, 1888 (1991).

3 Ex parte Fine, 1927 Dec. Comm'r Pats. 84, 86 (1927).

4 The Leesti reference is a decision of the Commissioner of Patents of Canada, available at http://patents1.ic.gc.ca/details_comdec?comdec_number=1203&-n=0&-p=0&-t=0&-

are directed to patentable subject matter. The Leesti reference grapples with the question of the meaning of "patentable subject matter", which in this context is defined as: "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter." The Examiner will readily appreciate that this language is almost precisely the same as the language found in 35 U.S.C. 101. See page 4, line 24 (not counting spaces) through to page 5, line 3 of Leesti. The Leesti reference is reasonably pertinent to the subject matter which Patentee claims, which is also directed to a type of nonhuman mammal, and was published in 1995; thus Leesti is *pertinent* ***prior art***.

The relevant teaching of Leesti is as follows: "However I cannot extend the meaning of 'manufacture' or 'composition of matter' to include a non-human mammal. On the plain and ordinary meaning of the words ...I do not find that a non-human mammal ...falls within the definition of" patentable subject matter as defined above. See page 9, lines 22-27.

The author of the Leesti reference wrote the above in his capacity as the Commissioner of Patents of Canada in 1995.

The person having ordinary skill in the art, in view of the Leesti reference, would have reasonable doubt that the subject matter of instant claims 1-17, *as a whole*, constitutes statutory subject matter under 35 U.S.C. §101, because Leesti teaches that a non-human mammal does not fall within the definition of machine, manufacture, or composition of matter based upon the plain and ordinary meaning of the words, and because instant claims 1-17 embrace nonhuman mammals.

Similarly, the Nadon reference[5] also pertains to the question of whether or not non-human mammals are directed to patentable subject matter. In this context, patentable subject matter is defined as: "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful

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l=E or http://tinyurl.com/2fuch , both last accessed 21 June 2006. Date made public: 04 August 1995.

5 Harv. Coll. v. Canada (Comm'r of Patents), [1998] 3 F.C. 510. (Can.), Fed. Court of Can. Trial Div., Nadon, Judge. Date made public: April 21, 1998.

improvement in any art, process, machine, manufacture or composition of matter." That is the language used in the Canadian Patent Act[6], and is almost completely identical to the words of 35 U.S.C. §101.

The following are quotes from the majority decision reported in the Nadon publication:

"A complex life form does not fit within the current parameters of the Patent Act without stretching the meaning of the words to the breaking point . . ."

"On even the broadest interpretation I cannot find that a mouse is 'raw material' which was given new qualities from the inventor."

" ... [S]uch a mouse 'cannot really be said, other than on the most metaphorical level, to have been produced from raw materials or to be a combination of two or more substances united by chemical or mechanical means' ". See page 14, lines 33-36 and page 16, lines 22-24.

The author of the Nadon reference wrote the above words in his capacity as Judge of the Federal Court of Canada, Trial Division.

The person having ordinary skill in the art, in view of the Nadon reference, would have reasonable doubt that the subject matter of instant claim 1-17, *as a whole*, constitutes statutory subject matter under 35 U.S.C. §101, because Nadon teaches that a complex life form does not fall within the definition of machine, manufacture, or composition of matter based upon the plain and ordinary meaning of the words, and because the claimed animals, be they monkey, dog, cat, rabbit, guinea pig, rat, mouse, cow, sheep, pig, goat, chicken, domestic duck, or quail, are all complex life forms.

Patent Examination Guidelines

According to recently published USPTO examining guidelines, the examiner should review the totality of the evidence (including the *relevant prior art*) before reaching a conclusion

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6 R.S.C. 1985, §2 (2003)(Can.) {Statutes of Canada}

with regard to whether the claimed invention sets forth patent eligible subject matter. The examiner must weigh the determinations made above to reach a conclusion as to whether it is more likely than not that the claimed invention as a whole falls either inside or outside of one of the enumerated statutory classes. See *United States Patent and Trademark Office Official Gazette Notices*, 22 November 2005, "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility."

Since the examiner is charged with evaluating whether the claims, as a whole, constitute patentable subject matter, he/she should look to the record, which now includes the Nadon and Leesti Prior Art, to make this evaluation. Claims 1-17 embrace animals (e.g., monkey, dog, cat, etc.) inherently having the mental condition of sentient, self-aware beings; no article of manufacture (e.g., a toaster) or mere inventor's composition of matter (e.g., a vitamin pill) can be characterized as such.

Remarks Pertaining to Scope of Reexamination

It is noted that the following is found in MPEP 2617, relating to the "scope of reexamination":

"Substantial new questions of patentability must be based on prior art patents or printed publications. Other matters, such as public use or sale, inventorship, 35 U.S.C. 101, 35 U.S.C. 112, fraud, etc., will not be considered when making the determination on the request and should not be presented in the request."

No authorities are cited for this limitation as to the "scope of reexamination."

However, it is to be noted that the decisions cited in MPEP §§ 2258 and 2258.01 for determining the presence or absence of "a substantial new question of patentability" in *ex parte* reexamination proceedings apply equally in *inter partes* reexamination proceedings, since the statutory language relied upon in those decisions, which is taken from the *ex parte* reexamination statute, is also found in the *inter partes* reexamination statute.

Therefore, it is noted that the following discussion of relevant decisions is found in MPEP 2258:

"Rejections will not be based on matters other than patents or printed publications, such as public use or sale, inventorship, 35 U.S.C. 101, fraud, etc. In this regard, see In re Lanham, 1 USPQ2d 1877 (Comm'r Pat. 1986), and Stewart Systems v. Comm'r of Patents and Trademarks, 1 USPQ2d 1879 (E.D. Va. 1986). A rejection on prior public use or sale, insufficiency of disclosure, etc., cannot be made even if it relies on a prior patent or printed publication. Prior patents or printed publications must be applied under an appropriate portion of 35 U.S.C. 102 and/or 103 when making a rejection."

However, the decisions said to underlie this MPEP section can easily be distinguished from the case at hand. In the case of Stewart Systems, the matter upon which a reexamination could not proceed, was the matter of "fraud". This matter could not be dealt with in a reexamination proceeding since it is not based upon prior art printed publications; moreover the USPTO is not suited to consider issues of fraud during reexamination. The Patent and Trademark Office does not conduct evidentiary hearings in connection with the proceedings, and would not be able to observe the demeanor of witnesses or hear testimony in determining whether fraud had occurred. None of these considerations are present in the case at hand. The Director is not being asked to review a charge of "fraud", but, rather, to review a Substantial New Question of Patentability based solely upon evidence presented in the form of prior art printed publications, and nothing else. No hearing or testimony is required to determine what the prior art printed publications of record mean. Similarly the case of Lanham (noted in MPEP 2258 *supra*) can be easily distinguished, since that case, too, concerned an issue of "fraud" being raised in a reexamination proceeding. Since the "fraud" issue which was raised in Lanham, was not based upon "prior art consisting of patent or printed publication", it was clearly outside of the proper scope. No issues of fraud or inequitable conduct are raised (or are going to be raised) in this present *inter partes* reexamination request.

Furthermore, Stewart Systems, goes beyond merely excluding "fraud" issues from the scope of reexamination; it positively *includes* issues of "double patenting". Although sometimes confused with §§ 102 and 103 of the Patent Act, double patenting is firmly rooted in *§101* of the

Patent Act. According to In re Lonardo,[7] " 'Same invention' double patenting is based upon 35 U.S.C. § 101 (1994), which states that an inventor may obtain 'a patent' for an invention.".

The reason given (in Stewart) as to why an issue under Section 101 (namely, double patenting) *can* be entertained in a Reexamination, was the following: "Double patenting is necessarily based on a U.S. patent". Thus, it is the *type* of evidence presented, and not how that evidence is used, which is what controls what issues may be within the scope of a reexamination. Stated simply, MPEP section 2258 is not fully supported by the case law said to underlie it.

In any event the position of the MPEP (that Section 101 issues are allegedly outside the "scope of reexamination") is not reflected in the statute itself, nor even in any duly promulgated rule. While 37 C.F.R. §1.906(a) recites that "[c]laims in an inter partes reexamination proceeding will be examined on the basis of patents or printed publications", this does not preclude treatment of an issue under 35 U.S.C. §101, **as long as it is based upon printed publications**. The Examiner may safely admit this grounds of rejection into Reexamination proceedings without fear of contravening *any* rule or *any* law.

It is understood that Section 101 has several distinct prongs, including utility, statutory subject matter, and the prohibition against double patenting; Requester has not confused these prongs. However, it is only logical to conclude that if reexamination can proceed to decide one prong or another of §101 (as in Lonardo and Stewart, supra), then that would appear to indicate that there is no statutory reason why reexamination cannot decide any prong of §101, as long as the evidence proffered during the reexamination proceeding is limited to prior art consisting of patents and printed publications.

Compliance with §101 May Depend Upon Underlying Facts

The Federal Circuit has indicated that sufficiency of a claim under Section 101 *depends upon which printed publications are on the record*. It noted in 1992 that "Whether a claim is directed to statutory subject matter is a question of law." However, they also recognized

7 119 F.3d 960 (Fed. Cir. 1997), 43 U.S.P.Q.2d (B.N.A.) 1262 (1997).

the fact that it may also be an evidentiary question, remarking that "[D]etermination of this question may require findings of underlying facts specific to the particular subject matter and its mode of claiming ...". See Arrhythmia Research Technology v Corazonix Corp.[8].

Requesters are simply calling into question whether some of the Patent claims are of patentable “subject matter”, again based upon evidence presented in the form of prior art printed publications.

Legislative Intent of Reexamination Statute Circumscribes Scope Only in Terms of Type of Evidence Proffered

The legislative intent behind Reexamination Statutes also supports Requesters. The following is an excerpt from the Lonardo decision, which discusses the legislative history of the original Reexamination Statute:

“The legislative history indicates that considerations such as cost and availability of evidence were among the criteria Congress considered in determining the scope of reexamination. ... [T]he purpose in restricting reexamination to printed documents 'was to provide a cheaper and less time-consuming alternative way to challenge patent validity on certain issues'. A patent is clearly the type of evidence that Congress intended the PTO to consider during reexamination, and the cost of examination is not significantly increased by having the PTO consider the ground of double patenting, as it involves issues of claim identity and obviousness, well within the PTO's everyday expertise." See In re Lonardo, *vide supra*.

Based on the legislative intent, a printed publication, like a patent, is clearly the type of evidence that Congress intended the PTO to consider during reexamination (as long as it is prior art relative to the claim in question), by the plain language of the statute. Furthermore, it is well within the "PTO's everyday expertise" to determine whether a claim is statutory subject matter. It is respectfully submitted that any Primary Examiner, when presented with a claim has

8 Arrhythmia Research Technology v. Corazonix Corp., 958 F.2d 1053 (Fed. Cir. 1992), 22 U.S.P.Q.2d (B.N.A.) 1033 (1992).

the authority and expertise to decide whether such claim is (or is not) statutory subject matter. A plethora of decisions of the BPAI exist which have grappled with questions of whether claims satisfy Section 101 of the Patent Act. On the contrary, the MPEP explicitly forbids examiners from ever entertaining questions of fraud, *c.f.* M.P.E.P. 2010, so understandably issues of fraud are always outside of "PTO's everyday expertise".

There is no prior art evidence of record indicating that a "rabbit" (or any of the other claimed nonhuman mammals or fowl) positively is a "manufacture" or "composition of matter". Neither the Leesti reference nor the Nadon reference were made "of record" by the Examiner when the instant Patent was issued, and there is no reason to believe that the Examiner had considered either reference. This Request gives the Examiner, for the first time, a chance to benefit from the evidence set forth in those references. The Examiner may then proffer evidence of his/her own.

Printed Court Decisions Are Evidence

It is the respectful view of Requesters that printed publications comprising Court decisions constitute "prior art". Requesters' agent has performed a cursory search of the USPTO patent database, and has verified at least 64 issued US patents[9] which have, in their listing of prior art on the face of the patent, one or more legal decisions such as BPAI decisions, CCPA decisions, and European Patent Office decisions. Thus, Patent Examiners often are faced with Court decisions and Board decisions as evidence "on the record". Patent Examiners also know how to use evidence when making patentability determinations under Sections 101, 102, 103 and 112. The instant Request is no different. The evidence is presented in a properly limited fashion (i.e., in the form of a prior printed publication), and that is all which is required by 35 U.S.C. §§311-313.

Precedents Distinguishable

9 One may independently verify this by searching the USPTO internet patent database with search terms such as "OREF/parte or OREF/uspq".

Requesters note two apparently precedential decisions, Diamond v. Chakrabarty[10] (Sup. Ct.) and Ex parte Allen[11] (B.P.A.I.).

In Chakrabarty the Supreme Court concluded (from the Committee Reports accompanying the Patent Act of 1952[12]) that Congress intended statutory subject matter to "include anything under the sun that is made by man." However, that decision is distinguishable since there are new material facts now which were not present in that case. Firstly, Chakrabarty revolved around whether a bacterium (in which oil-degrading plasmids were rearranged) was statutory subject matter; it did not concern a rabbit or a dog or any other higher life form. The patentability of an animal was never raised in argument nor discussed in the opinion of the Chakrabarty Court. Questions which merely lurk in the record, neither brought to the attention of the court nor ruled upon, should not be considered as having been "decided". Any holding that is only implicit or assumed in the decision, but not announced, is not the same as deciding whether a companion animal or any other higher life form is a mere article of manufacture or chemical composition.

Secondly, the quote from the Committee Report (supra) refers to "anything"; the word "anything" is a contraction of "any thing". A rabbit or dog or cat is never just a "thing", and so this quote is inapplicable to the facts. Thirdly, it is also noted that the 1952 Senate Committee Report is entirely silent on the term "composition of matter". (Inspection would reveal this to be the case.) In the face of silence in the legislative history as to the breadth of "composition of matter", one ought to be reluctant to interpret it broadly. See Dewsnup v. Timm[13].

The phrase "anything under the sun" is not found in any law or any regulation. Please see what Judge Plager wrote for the majority in the decision of In re Warmerdam, 33 F.3d 1354; 31 USPQ2d 1754 (Fed. Cir. 1994) (emphasis added):

"Despite the oft-quoted statement in the legislative history of the 1952 Patent Act that Congress intended that statutory subject matter 'include anything under the sun that is

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10 Diamond, Commissioner of Patents and Trademarks v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (Sup. Ct., 1980).
11 2 U.S.P.Q.2d 1425 (P.T.O. B.P.A.I. 1987).
12 S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952).
13 Dewsnup v. Timm, 502 U.S. 410 (1992).

made by man,' S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952), reprinted in 1952 U.S.C.C.A.N. 2394, 2399; H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952), **Congress did not so mandate**. Congress included in patentable subject matter only those things that qualify as 'any ... process, machine, manufacture, or composition of matter, or any ... improvement thereof ....' 35 U.S.C. § 101 (1988). . . . To include some things is to exclude others."

Even more pertinent to the question of whether Congress intended statutory subject matter to "include anything under the sun that is made by man", are the words of Judge Giles S. Rich, to whom many attribute authorship of the Patent Act of 1952. In his dissent given in In re Kirk and Petrow[14], Rich plainly explained that there are no legislative materials on 35 USC 101 when it was first enacted.

As Rich stated in the year 1967 (emphases added):

"The Supreme Court in Manson found 'no specific assistance in the legislative materials underlying 101,' which was a 1952 enactment. That is because **the legislature was then taking no action with respect to that provision except to reenact it without change**, wherefore the true 'legislative materials' necessarily consist only of its long history of construction and repeated reenactment without change, rather than some revisor's note or testimony at a hearing. It is history one must consider, rather than one's inner consciousness and preconceptions. [...]

"It is true there are no legislative materials on 101 for the simple reason there was no discussion of this firmly fixed statute in the course of codifying it in 1952. **There is no legislative history**, therefore, to support a change from the historical construction."

Unless one were to believe that higher animals such as rabbits and cats and dogs (e.g.) were considered by Congress to be patent-eligible subject matter in 1836 or indeed 1790 (when the four categories were first established), then they are not patent-eligible subject matter in

[14] In re Kirk and Petrow, CCPA 1967, 376 F.2d 936 (1967).

2007.

It is more likely than not that a rabbit with a damaged eye is not a manufacture and is not an inventor's composition of matter.

In Ex parte Allen,[15] an oyster in which chromosomal polyploidy was induced, was held to constitute statutory subject matter. However, the facts here are distinguishable for at least the following reasons: Allen concerned an oyster, while the present case concerns, *inter alia*, a rabbit or dog or monkey, animals with large brains, feelings, sentience, self-awareness and intelligence. It is respectfully submitted that these are material differences that cannot be ignored. Also, Allen's oyster was manipulated in a systemic, genome-wide, permanent way while the claimed rabbit/dog/monkey is merely treated to damage him in some way; such damage can even be temporary. The Rule of Allen is presumably that "subject matter made by man" is statutory under 35 U.S.C. §101. However, Patentee did not "make" a rabbit: they **procured** him. Later, they treated him. The rabbit, when newborn, presumably was "made" in the natural fashion, by nonhuman forces.

If any precedential decision covers the facts at hand more closely, it is American Fruit Growers, Inc. v. Brogdex Co. [16] There, the Supreme Court, in deciding whether an orange with a rind coated with preservative was statutory subject matter, essentially held that *not everything touched by man rises to the level of manufacture.* "Addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property. The added substance only protects the natural article against deterioration by inhibiting development of extraneous spores upon the rind. There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange, fit only for the same beneficial uses as theretofore." See Brogdex at 12.

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15 Ex Parte Allen, 2 U.S.P.Q.2d 1425 (PTO B.P.A.I. 1987)
16 Diamond v. Chakrabarty, 283 U.S. 1, 8 U.S.P.Q. 131 (1931).

In like manner, a rabbit or cat or dog with reversible cornea damage is not statutory subject matter, since he remains a product of nature; the corneal damage does not change any of his essential characteristics. He was a rabbit to start with; and remains a rabbit with no new essential characteristics. Unlike the Allen oyster where the "new" oyster had an essential characteristic that the "old" oyster did not (inherent sterility), the claimed rabbit remains such: a nonmanufacture; a non-composition of matter.

Brogdex is not an isolated decision. The Court of Customs and Patent Appeals (decisions of which are precedential to the Federal Circuit) repeatedly held that not everything touched by man is a manufacture. In re McKee[17] concerned an animal carcass treated in a creative way. Still, they held that a "carcass is not a 'manufacture' as the term is employed in Sec. 4886 R. S. and as defined in the Century Dictionary. The addition of branding marks beneath the fell does not produce from the raw material (carcass) an article for use which possesses a new or distinctive form, quality or property." Similarly In re Ewald[18] held that a pear, cored in a particularly inventive way, was not statutory subject matter: "A cored half pear is merely a half pear with the inedible portion thereof removed. It, obviously, is not a new and different article, having a new name, character, or use."

A damaged rabbit is still a rabbit.

Although it may appear to some that Requesters are going over the ground well-trod in Chakrabarty, please note that Requesters are not proposing that a rabbit or other animal within the scope of the instant claims is not patentable solely because he is alive; rather, Requesters respectfully submit that he is a complex life form, a companion to many, and never fit to be categorized as mere manufacture or inventor's composition of matter. This is a new issue never decided in Chakrabarty.

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17 In re McKee, 75 F.2d 991(C.C.P.A. 1935).
18 In re Ewald, 129 F.2d 340 (C.C.P.A. 1942).

Lack of Utility/Moral Utility

Grounds XIII

Claims 1-17 lack utility/moral utility under 35 U.S.C. §101.

Statement of Position

The U.S. Patent and Trademark Office should not issue a patent for injuring a complex, sentient, higher life form, such as the rabbit claimed in this patent. Several years ago, the issue of whether the U.S. Patent and Trademark Office has authority to reject patents on moral grounds was clarified. Bruce Lehman, a Commissioner of the United States Patent & Trademark Office (USPTO) has explained that the PTO's legal authority allows the agency to deny patents "injurious to the well-being, good policy or good morals of society." [19]

Animal patents provide an incentive to harm animals for economic gain and this directly conflicts with good policy or good morals of society. For example, under the Animal Welfare Act, Congress explained that alternatives that replace the use of animals in experiments, such as product testing, should be actively encouraged and developed.[20] Allowing patents for animals, however, provides financial incentives that encourages the development of animal models and this inhibits the growth of nonanimal alternatives. Allowing patents on higher life forms means "providing private entities, via granted patents, to develop and exploit morally controversial inventions without engaging in any analysis of the policy implications of such decisions ." [21]

In addition, public opinion provides evidence of whether animal patents are contrary to good policy or good morals of society. If a public abhorrence test were applied, it would be obvious that the public is overwhelmingly opposed to the granting of patents on animal life. As measured in a 2004 poll, 68 percent of Americans believe it is unethical for governments to issue

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[19] United States Patent & Trademark Office MEDIA ADVISORY, April 1, 1998, FACTS ON PATENTING LIFE FORMS HAVING A RELATIONSHIP TO HUMANS, found on http://www.uspto.gov/web/offices/com/speeches/98-06.htm, viaited 21 March 2007.

[20] 7 U.S.C. § 2131.

[21] Bagley, M.A. Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law, *William and Mary Law Review, 45*, 469

patents on animals as if they were human inventions. [22]

Legal Authority

The 1817 case Lowell v. Lewis[23] handed down the first judicial interpretation of the statutory requirement that an invention must be "useful" in order to be eligible for patent protection. In that case, the Court identified certain standards of morality that must be met for an invention to be considered "useful," stating that, "[a]ll that the law requires is that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word 'useful,' therefore, is incorporated into the act in contradistinction to mischievous or immoral." The "moral utility" doctrine was thus formulated in the context of the utility requirement of patent law.

The 1952 revision of the Patent Act neither specifically mandated nor prohibited the application of the moral utility doctrine in determining patent eligibility, but rather left the matter to the courts. Thus, moral utility is not necessarily inconsistent with statutory mandate.

Juicy Whip v. Orange Bang[24] pertains to subject matter that is deceptive, and thus does not apply to claims 1-17. In Juicy Whip, the Court of Appeals for the Federal Circuit ruled that the moral utility principle "has not been applied broadly in recent years … Of course, Congress is free to declare particular types of inventions unpatentable for a variety of reasons, including deceptiveness … Until such time as Congress does so, however, we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public [emphasis added]." However, the Court did not refuse to ever uphold the moral utility requirement, but rather declined to do so as it pertains to subject matter that is deceptive in nature. The moral utility doctrine may be applied in other circumstances, and as the subject matter of claims 1-17 does not involve deception, it is thus not necessarily precluded from the moral utility requirement.

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[22] AAVS survey, conducted by Opinion Research Corp. in Feb. 2004 of 1,008 U.S. adults.

[23] Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817)

[24] Juicy Whip v. Orange Bang, 185 F.3d 1364 (Fed. Cir. 1999)

Persistent Questions, Answered

It has often been stated that: (1) patent examiners should not be arbiters of ethics; and (2) opposition to ethically challenged patents is a poor proxy for opposition to the activity which may underly such patents, and such activity is what ought to be proscribed by law.

As for item (1): Requesters are not asking for any patent examiner to be an arbiter of ethics. Although the motivation of Requesters is an ethical one, and although patent law (*vide supra*) permits "ethics" (in the form of the moral/beneficial utility requirement) to be considered, we are simply asking USPTO to reject animal patents as a categorical matter of definition. One bright line test could be based upon the existing classification system, based on the fact that examiners know how to classify a claim into Class 800, Subclasses 8 to 20 inclusive. If a claim properly belongs in such classification, then it may be an "animal patent claim" and would raise the issue of compliance with 35 USC 101. Other tests could be devised that accomplish the same result (e.g., "if the broadest reasonable interpretation of a claim embraces a complex multicellular animal organism ..."). By following an appropriate bright line test, any examiner can know when a claim is directed to an complex animal organism, and thus be categorically outside of the scope of 35 USC 101. Ethical decisions need never be made by examiners.

As for item (2), it fails to comprehend that the patent system has become a significant economic incentive for the production and proliferation of animals used in medical and other forms of research, and that it discourages the use of alternatives. Merely because something is currently permitted (*viz.*, animal research) does not mean that it must be offered every economic incentive under the sun. Patents add the fuel of lucre to the pyre of expended animals. By removing the economic incentive to do animal experimentation that causes suffering, the recission of this and other animal patents will mitigate investment in such experimentation. However, if animal patents are permitted to continue, they will offer a financial incentive that will directly or indirectly increase activities that are cruel to animals.

Modern societies consider certain rights for animals, and a growing number of people believe that animals deserve to live a life with dignity, free from exploitation. Meanwhile, the U.S. patent system continues to operate in ways that treat animals as nothing more than products somehow ‘created’ by humans, or as inanimate objects. Requesters ask that the patent

system the system be restored, so as to properly accomodate the special case of creatures who, like us, move, breed, feel, and breathe.

For all of the foregoing reasons, Reexamination of all the claims of the above-captioned Patent is respectfully requested.

Very respectfully submitted,

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