TINTED LENSES AND METHODS OF MANUFACTURE

The present application claims benefit of priority to United States provisional patent application serial number 60/162,695 to Doshi, filed November 1, 1999, and United States provisional patent application serial number 60/218,710 to Doshi, filed July 17, 2000, each of which is incorporated herein by reference.

TECHNICAL FIELD

The present invention generally relates generally to the fields of tinted lenses and methods of manufacture.

BACKGROUND

Tinted contact lenses have steadily gained in popularity since their introduction into the marketplace. In particular, colored contact lenses that include images that mimic the iris of an eye are particularly popular. However, colored contact lenses made by traditional technologies suffer from poor image quality and other difficulties, including leaching of pigments present on the surface of lenses, unnatural appearances, fading of colors and limited number of colors to choose from. The present invention addresses these problems, and provides additional and related benefits as well.

A variety of colored contact lenses and methods of making them have been described. For example, United States Patent No. 5,018,849 to Su et al., issued May 28, 1991, describes colored contact lenses that form a laminated structure whereby a pigment is provided on the top layer of the contact lens and opaque material is sandwiched between two layers of the contact lens material, such as polymers. The opaque material blocks the natural color of the wearer's iris, and the pigment gives the wearer's eye the appearance of a desired color. These contact lenses have the undesirable quality of looking unnatural due to the limited number of colors that are available. In addition, during manufacture the opaque material and pigment are applied to the contact lens material in a plurality of steps, using one color per step.

In United States Patent No. 5,034,166 to Rawlings et al., issued July 23, 1991, non-laminated colored contact lenses are described. The pigment in this type of colored contact lens is casted into the structure of the lens material. The pigment is dispensed one color at a time during lens manufacturing which limits the number of colors that can be used to make colored contact lenses. The resulting colored contact lens is undesirable because the wearer's eyes appear unnatural. Furthermore, the pattern and pigments used in this method is limited which results in an unnatural looking contact lens. Also, existing methods provide customers with limited choices of colors and patters and the lenses produced by these methods can provide pigments on

the a surface of a lens, which can make the lenscs uncomfortable for the wearer and prone to fading of the pigment.

The colored contact lenses described in United States Patent No. 5,106,182 to Briggs et al., issued April 21, 1992, described a laminated colored contact lens. In this contact lens, pigmentation is provided on one portion of a contact lens using a pad transfer method using a rubber stamp having raised radial segments. The pad transfer method applies pigment to the portion of the contact lens to form a crude pattern. The pad is then pressed to the portion of the contact lens to smear the pigment and the pad disengaged from the portion of a contact lens. The lens is rotated, and the process is repeated as desired. The resulting colored contact lens is undesirable because of the limited number of colors that can be used and the resulting pigmentation pattern has an unpredictable and unnatural appearance.

United States Patent No. 5,160,463 to Evans et al., issued November 3, 1992, describes a colored contact lens made by applying a first pigment in a first pattern to a molding device. Additional pigments in additional patterns can be applied to the molding device in independent applications. The resulting image on the molding device can be transferred to a contact lens. The use of multiple printing steps is undesirable due to the increased number of applications that are needed to create an image. In addition, this method results in an image of unnatural appearance due to the limited number of colors that can be used to create the image.

Colored contact lenses reported in United States Patent No. 5,414,477 to Jahnke, issued May 9, 1995, relate to images that are made using pad transfer methods to form a plurality of dots of unnatural appearance. A plurality of printing processed can be used to create an image comprising more than one color that reportedly results in an image with a more natural appearance. These dots are of relatively definite in shape and relatively large in size and thus have an unnatural appearance. The colored contact lenses made using these methods also have a limited number of colors and patterns that can be used, which results in an unnatural looking product.

The present invention addresses the problems associated with described tinted contact lenses by providing an image on or within a contact lens that is of superior quality. The increased quality of the image results in a tinted contact lens that has a natural appearance.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 depicts a schematic diagram of a method of printing digitally encoded images. A1 denotes black ink; A2 denotes magenta ink; A3 denotes yellow ink; A4 denotes cyan ink; A6 denotes color ink coat / layer of A1 + A2 + A3 +A4. The digitally encoded image is printed on a surface such as a lens.

FIG. 2 depicts diagram of laminate digitally encoded images encased within a structure. A6 denotes color ink coat / layer of black, magenta, yellow and cyan; A7 denotes partially polymerized monomer mix for clear lens; A8 denotes partially polymerized A6; A9 denotes fully polymerized clear lens.

FIG. 3A depicts a method of encasing a layer of ink between a primary surface and a polymer layer. A5 denotes a monomer mix for clear lens; A6 denotes color ink coat / layer of black, magenta, yellow and cyan; A7 denotes partially polymerized A5; A8 denotes partially polymerized A6; A9 denotes fully polymerized clear lens; A10 denotes fully polymerized A6. **FIG. 3B** depicts a method of applying ink to a surface.

FIG. 4 depicts a diagram of pad transfer printing method of the present invention. A7 denotes partially polymerized monomer mix for clear lens; A8 denotes partially polymerized color ink coat / layer of black, magenta, yellow and cyan; A9 denotes fully polymerized clear lens. A10 denotes a fully polymerized A8.

FIG. 5 depicts a method of a lathe/fabrication process that can be used to produce lens of the present invention.

FIG. 6 depicts cast molded method that can be used to produce lens of the present invention.

FIG. 7A and **FIG. 7B** depict spin cast methods that can be used to produce lens of the present invention.

FIG. 8A depicts examples of indentation structures that can be formed on the convex portion of the present invention and are depicted as filled with an ink of the present invention.

FIG. 8B depicts examples of indentation structures that can be formed on the concave portion of the present invention and are depicted as filled with an ink of the present invention. The indentation structures are not necessarily shown to scale and preferably are relatively small such that they have a volume of less than about 10 microliters, less than about 5 microliters, less than about 1 microliter, less than about 0.1 microliter, less than about 1 nanoliter, less than about 0.1 nanoliter or less than about 0.01 nanoliters.

FIG. 9 depicts deposition of ink into a variety of indentation structures of the present invention. Different angles represent rotation of surface. The indentation structures are represented as being partially filled with an ink of the present invention. The remaining void volume in the indentation structures can be filled with, for example, a monomer or a polymer such as to trap the ink of the present invention. Droplets of one or more colors of ink can be deposited into such indentations to allow for a variety of colors to be present in such indentations.

FIG. 10 depicts a fixture for centering and masking for lenses, preferably but not limited to hydrated or partially hydrated lenses.

FIG. 11 depicts schematic diagram of a variety of methods for printing digitally encoded images in conjunction with the present invention.

FIG. 12 depicts schematic diagrams of a variety of methods of making polymers having printed digitally encoded images. A5 denotes a monomer mix for clear lens.

FIG. 13 depicts diagram of laminate digitally encoded images within a structure of the present invention. A5 denotes a monomer mix for clear lens; A6 denotes color ink coat / layer of black, magenta, yellow and cyan; A7 denotes partially polymerized A5; A8 denotes partially polymerized A6; A9 denotes fully polymerized clear lens; A10 denotes fully polymerized A6.

FIG. 14 depicts printing methods within a well on a surface of the present invention. A5 denotes a monomer mix for clear lens; A6 denotes color ink coat / layer of black, magenta, yellow and cyan; A7 denotes partially polymerized A5; A8 denotes partially polymerized A6; A9 denotes fully polymerized clear lens.

SUMMARY

The present invention recognizes that lenses, such as contact lenses, can be tinted using ink that include polymers or polymerizable monomers, preferably the same monomers used to make the lens. The ink can be used to make images on or within the lens. Images made using these inks are preferably in a modified or unmodified digital format and can be used in a variety of printing methods, including ink-jet printing. Modified digital formats can be made by altering the digital image before or after printing such as by vibration applied to the printed surface.

A first aspect of the present invention is an article of manufacture, including: a polymer and a digitally encoded image made with ink, wherein the polymer forms a lens.

A second aspect of the present invention is a method of making an article of manufacture that includes a digitally encoded image and a polymer, including the steps of: printing a digitally encoded image on a composition that includes a polymer, wherein the polymer forms a lens.

A third aspect of the present invention is a method of making an article of manufacture that includes a digitally encoded image and a polymer, including the steps of: printing a digitally encoded image on a composition comprising a polymer, and forming a lens from said polymer.

A fourth aspect of the present invention is a method of making an article of manufacture that includes a digitally encoded image and a polymer, including the steps of: printing a digitally encoded image on a composition comprising at least one monomer, polymerizing said at least one monomer to form at least one polymer, and forming a lens from said at least one polymer.

A fifth aspect of the present invention is a method of making an article of manufacture that includes a digitally encoded image and a polymer, including the steps of: printing an image on at least one first surface, transferring said image to at least one second surface comprising a monomer or a polymer, and forming a lens from said second surface.

A sixth aspect of the present invention is an article of manufacture, including: at least one information storage medium, and at least one digital image, wherein the at least one digital image comprises at least a portion of an image or other image.

A seventh aspect of the present invention is a system, including: an article of manufacture of the present invention and a printing device.

An eighth aspect of the present invention is a composition of matter, including an ink, dye, vat dye, particle, pigment, reactive dye or diazo dye. The composition of matter also includes a binder, monomer, polymer, homopolymer, heteropolymer, copolymer, and initiator, UV initiator, thermal initiator, solvent, dispersant, anti-bacterial agent, anti-microbial agent, anti-fungal agent, disinfectant, thickener or humectant.

A ninth aspect of the present invention is a method of doing business, including the steps of: obtaining a digital image from a person, database or image and printing said digital image on a lens.

DETAILED DESCRIPTION OF THE INVENTION

DEFINITIONS

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Generally, the nomenclature used herein and the laboratory procedures well known and commonly employed in the art. Conventional methods are used for these procedures, such as those provided in the art and various general references such as U.S. Patent No. 5,160,463; 5,271,874; 5,018,849; 5,034,166; 5,414,477; Day et al., Current Optometric Information and Terminology, Third Edition, American Optometric Association (1980); Howley's Condensed Chemical Dictionary (1981); and Federation of Societies for Coatings Technology, Glossary of Color Terms, Federation of Societies for Coatings Technology (1981). Where a term is provided in the singular, the inventors also contemplate the plural of that term. The nomenclature used herein and the laboratory procedures described below are those well known and commonly employed in the art. As employed throughout the disclosure, the following terms, unless otherwise indicated, shall be understood to have the following meanings:

"Directly" refers to direct causation of a process that does not require intermediate steps.

"Indirectly" refers to indirect causation that requires intermediate steps.

"Digitally Encoded Image" or "Digital Image" refers to an image that has been created or stored in a digital format. A digitally encoded image can be made using methods known in the art, such as artistic renditions or scanning or otherwise translating an image, including a naturally occurring image such as the iris of an eye, such as a human eye. A digitally encoded image can

be stored on appropriate storage medium, such as magnetic medium or polymers such as cyclolifin copolymers. A plurality of digitally encoded images can be stored together or separately to form a database of digitally encoded images that are accessible individually or in combination. Such digitally encoded images can be altered using established methods, such as artistic renditions or image modulating software. A plurality of images can also be merged to form a new digitally encoded image. A digital image is where a given image is presented as made from multiple dots of different colors. For example, an image produced by using a scanner or digital camera. Modified digital images may be defined as a digital image that is changed with a secondary process like polymerization or mixing of colored dots.

"Ink" as used herein refers to any colored compound, chemical or structure, such as a dye, vat dye, particle, pigment, reactive dye, diazo dye and the like. Ink also includes structures that while not colored give the appearance of color by, for example, diffraction or deflection (for example) of light by a particle. An ink can be water based, monomer based or solvent based.

"Dye" in the context of inks refers to a variety of dyes as they are known in the art, such as diazo dyes, such as Diazo 15 (4-diazo-(4'-toluyl)-mercapto-2,5-diethoxy benzyene zinc chloride) (U.S. Patent No. 5,662,706).

"Vat Dye" in the context of inks refers to a variety of vat dyes as they are known in the art, such as Vat Blue 6 (7,16-dichloro-6,15-dihydro-9,14,18-anthrazinetertrone) and Vat Green 1 (16,17-dimethyoxydinaphtho (1,2,3, ed: 31, 2'-1'-1-m)perylene-5) (U.S. Patent No. 5,302,978).

"Particle" in the context of inks refers to a variety of particles as they are known in the art, such as India Ink.

"Pigment" in the context of inks refers to a variety of pigments as they are known in the art, such as titanium dioxide, red iron oxide, yellow iron oxide U.S. Patent No. 5,160,463, Pigment Blue 15 (phthalocynine blue (CI # 74160)), Pigment Green 7 (pthalocynine green (CI # 74260)), Pigment Blue 36 (cobalt blue (CI # 77343)) or chromium sesquioxide (U.S. Patent No. 5,272,010).

"Reactive Dye" in the context of inks refers to a variety of reactive dyes as they are known in the art, such as Reactive Blue No. 4 (2-anthra-cene-sulfonic acid, 1-amino-4,3 ((4,6-dichloro-s-triazine-2-yl) amino)-4-sulfoaniline)-9-10-dihydro-9-10-dixo, disodium salt; CAS Reg. 4499-01-8); Reactive Yellow No. 86 (1,3-ben-zendisulfonic acid 4-((5 amino carbonyl-1-ethyl-1,6-dihydro-2-hydroxy-4-methyl-6-oxo-3-pridinyl)azo)-6-(4,6-dichloro-1,2,5-triazine-zyl)amino)-disodium salt) (U.S. Patent No. 5,106,182).

"Solvent" in the context of inks refers to an aqueous, organic or inorganic solvent, such as water, isopropanol, tetrahydrofuran or acetone (U.S. Patent No. 5,271,874).

"Surfactant" refers to a surfactant as that term is known in the art, such as, for example, acetylene glycol or polyoxyethylene alkyl ether (U.S. Patent No. 5,746,818 and U.S. Patent No. 5,658,376, respectively).

"Dispersant" in the context of inks refers to dispersants as they are known in the art, such as, for example, the Tergitol series from Union Carbide, polyoxylated alkyl ethers, alkyl diamino quarternary salts or "Pecegal "O"" from GAF (U.S. Patent No. 5,560,766). Dispersants are preferably used at between about 0.1% and about 10%, more preferably between about 0.5% and about 5%.

"Lens" as used herein refers to a composition of matter that can transmit light. A lens preferably can act as an optical lens, such as a contact lens. In certain aspects of the present invention, a lens need not act as an optical lens, such as a contact lens that is used for vanity purposes as opposed to purposes relating to the correction, improvement or alteration of a user's eyesight.

"Contact Lens" refers to a structure that can be placed on or within a wearer's eye. A contact lens can correct, improve, or alter a user's eyesight, but that need not be the case. A contact lens can be of any appropriate material known in the art or later developed, and can be a soft lens, a hard lens or a hybrid lens. A contact lens can be in a dry state or a wet state.

"Soft Lens" refers to a variety of soft lenses as they are known in the art that are characterized as having, for example, at least one of the following characteristics: oxygen permeable, hydrophilic or pliable.

"Hard Lens" refers to a variety of hard lenses as they are known in the art that are characterized as having, for example, at least one of the following characteristics: hydrophobic, gas permeable or rigid.

"Hybrid Lens" refers to a variety of hybrid lenses as they are known in the art, such as, for example, a lens having a soft skirt and a hard center.

"Dry State" refers to a soft lens in a state prior to hydration or the state of a hard lens under storage or use conditions.

"Wet State" refers to a soft lens in a hydrated state.

"Single color" refers to a discrete color made of one or more ink.

"Multi-colored image" refers to an image that includes more than one single color. A multi-colored image can be made using a plurality of single colors. For example, a multi-colored image can be made using two or more single colors, three or more single colors, or four or more single colors, preferably primary colors. The colors can be mixed before or during the formation of a multi-colored image, such as during a printing process, such as printing processes using dispensation, such as ink jet printing.

"Transparent" refers to a substantial portion of visible light transmitted through a structure, such as greater than or equal to 90% of incident light.

"Opaque" refers to a substantial portion of visible light reflected or absorbed by a structure, such as greater than or equal to 90% of incident light.

"Partially opaque" refers to a combination of transparent and opaque.

"Hydrogel" refers to a polymer that swells in an aqueous solution due to the absorbance of water. A hydrogel includes water or an aqueous solution as part of its structure.

"Polymer" refers to a linkage of monomers. Preferably, a polymer is a polymer appropriate for use in lenses, such as contact lenses. A polymer can be, for example, a homopolymer, a heteropolymer, a copolymer, a hydrophobic polymer, a hydrophilic polymer or any combination thereof.

"Hydrophobic Polymer" refers to a polymer that does not absorb an appreciable amount of water or an aqueous solution (see, U.S. Patent No. 5,034,166). "Hydrophilic Polymer" refers to a polymer that absorbs an appreciable amount of water or an aqueous solution (see, U.S. Patent No. 5,034,166). Lens forming materials that are suitable in the fabrication of contact lenses are illustrated by one or more of the following U.S. Patent Numbers: 2,976,576; 3,220,960; 3,937,680; 3,948,871; 3,949,021; 3,983,083; 3,988,274; 4,018,853; 3,875,211; 3,503,942; 3,532,679; 3,621,079; 3,639,524; 3,700,761; 3,721,657; 3,758,448; 3,772,235; 3,786,034; 3,803,093; 3,816,571; 3,940,207; 3,431,046; 3,542,461; 4,055,378; 4,064,086; 4,062,624; and 5,034,166.

"Hydrophilic Monomer" refers to monomers used to make soft lenses, such as hydroxyethylmetheylacrylate, methaerylic acid or n-vinylpyrrolidone (U.S. Patent No. 5,271,874; U.S. Patent No. 5,272,010). "Hydrophilic Monomer" refers to monomers used to make hard lenses, such as methylmethacrylate, ethoxyethyl methacrylate, styrene or silicone (U.S. Patent No. 5,271,874; U.S. Patent No. 5,272,010).

"Homopolymer" refers to a polymer comprising a single type of monomer such as hydroxyethylmethyl acrylate.

"Heteropolymer" refers to a polymer comprising more than one type of monomer such as hydroxyethylmethylacrylat and mehtylacrylic acid.

"Copolymer" refers to the use of two different polymers to make a polymer chain.

"Acrylic Polymer" or "Acrylics" refers to a variety of polymer of that genus and species as they are known in the art, such as, for example, hydroxylethylmethyle acrylate.

"Silicone Polymer" or "Silicones" refers to a variety of polymers of that genus and species as they are known in the art, such as, for example Tris (such as Tris (pentamethyldisiloxyanyl)-3-methacrylate-propylsilane or 3-methacryloxypropy tris(trimethylsiloxy)silane).

"Polycarbonate Polymer" or "Polycarbonate" refers to a variety of polymers of that genus and species as they are known in the art, such as, for example Lexan.

"Initiator" in the context of polymerization refers to an initiator as that term is known in the art, such as, for example, a chemical that starts a polymerization reaction.

"UV Initiator" in the context of polymerization refers to a UV initiator as that term is known in the art, such as, for example, a chemical that becomes reactive or active with the adsorption of energy, such as UV energy, such as, for example benzoin methyl ether.

"Binder" or "bonding agent" refers to compounds used perform the function of increasing the interaction between moieties, such as between a dye and a polymer or monomer or between monomers and polymers such as those terms are known in the art. Examples of binders or binding agents are hexamethylene diisocyanate or other isocyanate compounds.

"Thickener" refers to compounds that is used to increase the viscosity of a liquid or partially liquid mixture or solution such as that term is known in the art. An example of a thickener are polyvinyl alcohols.

"Anti-kogating agent" or "non-kogating agent" refers to compounds that facilitate printing processes that utilize nozzles, such as such terms are known in the art.

"Dispersant" refers to a surface active agent added to a suspending medium to promote the distribution and separation of fine or extremely fine solid particles.

"Thermal Initiator" in the context of polymerization refers to a thermal initiator as that term is known in the art, such as, for example, a chemical that becomes active or reactive with the absorption of heat energy, such as, for example, Vazo-64 or azobisilobutyronitrile.

"Anti-Bacterial Agent" refers to a compound or composition that can act as a bactericidal or bacteriostatic or can reduce the growth rate of a bacteria such as tetrabutylamonium chloride.

"Anti-Fungal Agent" refers to a compound or composition that can act as a fungicidal or fungalstatic or can reduce the growth rate of a fungi such as benzakonium chloride salicylic acid.

"Disinfectant" refers to a compound or composition that can reduce the type, number or diversity of microorganisms.

"Humectant" refers to compounds that reduce evaporation, such as ethylene glycol.

"Printing" refers to the application of at least one ink to a surface or structure to form an image. Printing can use any appropriate device or method known in the art of later developed for a particular purpose.

"Printing Device" refers to any appropriate device for printing an image on a surface or structure known in the art or later developed for a particular purpose. Preferably, a printing device includes the dispensation of microdroplets of liquid that includes an ink that form an image. The size or volume of the microdroplets can vary, but generally the smaller the microdroplet, the higher the quality of the image produced. Preferred microdroplets are between

about 1 nanoliter and about 100 microliters, preferably between about 10 nanoliters and about 10 microliters or between about 100 nanoliters and about 1 microliter.

"Ink Jet Printing" refers to printing using a printing device that comprises at least one ink jet. Ink jet printing can use a single color or can use a plurality of colors. For example, ink jet printing can use a printing device that contains a plurality of different colored inks that can be provided separately. In this aspect of the invention, the inks are preferably at least two, at least three or at least four primary colors and black that can be mixed to form a very large number of different colors. Such printing devices are commercially available such as through, for example, Hewlett Packard Corporation (such as DeskJet 560C printer cartridges) and Encad Corporation. Ink can be applied to a surface more than once to obtain the desired intensity, hue or other color characteristic.

"Piezo Printing" refers to printing using a printing device that comprises at least one piezo printing structure. Such piezo printing structures are known in the art, such as, for example, those available through Packard Instruments and Hewlett Packard Corporation or Canon Inc.

"Thermal Printing" refers to printing using a printing device that comprises at least one thermal printing structure. Such thermal printing structures are known in the art, such as, for example, those available through Hewlett Packard Corporation.

"Laser Printing" refers to printing using a printing device that uses at least one laser printing structure. Such printing structures are known in the art, such as, for example, those available through Cannon or Hewlett Packard Corporation.

"Pad Transfer Printing" refers to printing using a pad transfer printing device. Such pad transfer printing devices are known in the art, particularly for printing in the field of contact lenses. Briefly, an image is placed or printed on a pad transfer device and the image on the pad transfer device is transferred to another surface, such as a polymer or lens (United States Patent No. 3,536,386 to Spivack, issued October 27, 1970; United States Patent No. 4,582,402 to Knapp, issued April 15, 1986; United States Patent No. 4,704,017 to Knapp, issued November 3, 1987; United States Patent No. 5,034,166 to Rawlings et al., July 23, 1991; United States Patent No. 5,106,182 to Briggs et al., issued April 21, 1992; United States Patent No. 5,352,245 to Su et al., issued October 4, 1994; United States Patent No. 5,452,658 to Shell, issued September 26, 1995 and United States Patent No. 5,637,265 to Misciagno et al., issued June 10, 1997).

"Impregnation" refers to an ink being contacted with a surface, such as a polymer, and the ink diffuses into the polymer where it is reacted to precipitate to a size larger than the average pore size of the polymer (EP 0357062 to Pfortner, published March 7, 1990).

"Photolithography" refers to a process as it is known in the art, such as wherein at least one photosensitive ink is used to provide a desired image using a mask that blocks light.

"Chemical Bond" refers to a covalent bond or non-covalent bond.

Under certain circumstances, inks can form chemical bonds with polymers or monomers if the reactive groups on each are appropriate (EP 0393532 to Quinn, published October 24, 1990 (referring to United States Patent No. 4,668,240 to Loshaek and United States Patent No. 4,857,072); United States Patent No. 5,272,010 to Quinn, issued December 21, 1993;

"Polymer-Polymer Bond" refers to two polymers forming covalent or non-covalent bonds, such as by cross linking polymers formed between two polymers, such as hydroxyethyl methylacrylate and ehtyleneglycoldimethacrylate.

"Pattern" refers to a predetermined image (United States Patent No. 5,160,463 to Evans et al., issued November 3, 1992; United States Patent No. 5,414,477 to Jahnke, issued May 9, 1995;).

"At least two separate colors or a mixture thereof," "at least three separate colors or a mixture thereof," or "at least four separate colors or a mixture thereof" refers to the use of inks of different colors being provided in separate containers or separate portions within a container. The colors are preferably primary colors or fundamental colors and black, more preferably black, cyanine, magenta and yellow. The inks can be mixed in different proportions (including zero) to obtain a very large spectrum of colors. The mixing can occur within a printing structure, for example, before the ink is dispensed in a printing process. Alternatively, the mixing can occur outside of a printing structure, for example, after the ink is dispensed in a printing process. Furthermore, a combination of the foregoing can also occur.

"Dry State" refers to a polymer that is not fully hydrated.

"Wet State" refers to a polymer that is fully hydrated.

"Forming a Lens" or "Fabricating a Lens" refers to any method or structure known in the art or later developed used to form a lens. Such forming can take place, for example, using cast-molding, spin-casting, cutting, grinding, laser cutting, stamping, trimming, engraving, etching or the like (United States Patent No. 4,558,931 to Fuhrman, issued December 17, 1985).

"Cast-Molding" in the context of forming a lens refers to the formation of at least a portion lens using a mold (United States Patent No. 3,536,386 to Spivak, issued October 27, 1970; United States Patent No. 3,712,718 to LeGrand et al., issued January 23, 1973; United States Patent No. 4,582,402 to Knapp, issued April 15, 1986; United States Patent No. 4,704,017 to Knapp, issued November 3, 1987; United States Patent No. 5,106,182 to Briggs et al., issued April 21, 1992; United States Patent No. 5,160,463 to Evans et al., issued November 3, 1992; United States Patent No. 5,271,874 to Osipo et al., issued December 21, 1993 and EP 0357062 to Pfortner, published March 7, 1990)

"Spin-Casting" in the context of forming a lens refers to the formation of a lens using centrifugal force (United States Patent No. 3,557,261 to Wichterle, issued January 19, 1971 and United States Patent No. 5,034,166 to Rawlings et al., issued July 23, 1991).

"Information Storage Medium" refers to any medium of expression that can store information in any appropriate format either permanently or transiently. Preferred information storage medium includes paper, electronic medium, magnetic medium or polymers, such as cyclolifin copolymers.

"Electronic Medium" refers to information storage medium that can store information in electronic form. For example, electronic medium includes magnetic storage medium, such as diskettes.

"Machine Readable Format" refers to information stored on or within an information storage medium in a form, language or arrangement such that a machine, such as a central processing unit (CPU) can access and use the information.

"Database" refers to a collection of information, such as digital images. The information is preferably provided on or within an information storage medium and can be separate from or integral with a central processing unit.

Other technical terms used herein have their ordinary meaning in the art that they are used, as exemplified by a variety of technical dictionaries.

INTRODUCTION

The present invention recognizes that lenses, such as contact lenses, can be tinted using ink that include polymers or polymerizable monomers, preferably the same monomers used to make the lens. The ink can be used to make images on or within the lens. Images made using these inks are preferably digital and can be used in a variety of printing methods, including ink-jet printing.

As a non-limiting introduction to the breath of the present invention, the present invention includes several general and useful aspects, including:

1) an article of manufacture, including: a polymer and a digitally encoded image made with ink, wherein the polymer forms a lens;

2) a method of making an article of manufacture that includes a digitally encoded image and a polymer, including the steps of: printing a digitally encoded image on a composition that includes a polymer, wherein the polymer forms a lens, wherein such lenses can optionally include indentation structures to facilitate localizing inks used to make the digitally encoded image;

3) a method of making an article of manufacture that includes a digitally encoded image and a polymer, including the steps of: printing a digitally encoded image on a composition comprising a polymer, and forming a lens from said polymer;

4) a method of making an article of manufacture that includes a digitally encoded image and a polymer, including the steps of: printing a digitally encoded image on a composition comprising at least one monomer, polymerizing said at least one monomer to form at least one polymer, and forming a lens from said at least one polymer;

5) a method of making an article of manufacture that includes a digitally encoded image and a polymer, including the steps of: printing an image on at least one first surface, transferring said image to at least one second surface comprising a monomer or a polymer, and forming a lens from said second surface;

6) an article of manufacture, including: at least one information storage medium, and at least one digital image, wherein the at least one digital image comprises at least a portion of an image or other image;

7) a system, including: an article of manufacture of the present invention and a printing device;

8) a composition of matter, including an ink, dye, vat dye, particle, pigment, reactive dye or diazo dye. The composition of matter also includes a binder, bonding agent, monomer, polymer, homopolymer, heteropolymer, copolymer, and initiator, UV initiator, thermal initiator, solvent, dispersant, surfactant, anti-bacterial agent, anti-microbial agent, anti-fungal agent, disinfectant, thickener or humectant; and

9) a method of doing business, including the steps of: obtaining a digital image from a person, database or image and printing said digital image on a lens.

These aspects of the invention, as well as others described herein, can be achieved by using the methods, articles of manufacture and compositions of matter described herein. To gain a full appreciation of the scope of the present invention, it will be further recognized that various aspects of the present invention can be combined to make desirable embodiments of the invention.

I LENS WITH DIGITALLY ENCODED IMAGE

The present invention includes an article of manufacture, including: a polymer and a digitally encoded image comprising at least one ink, wherein the polymer forms a lens. *Digitally Encoded Image*

The digitally encoded image can include a single color image or a multi-colored image. The single color image preferably comprises one ink, but that need not be the case because many inks have similar colors and different colored inks can be combined to produce an ink with a color different from the individual inks used to make the combination. The multi-colored image is preferably made using a plurality of inks either alone or in combination.

The digitally encoded image can be transparent, opaque or partially opaque. For transparent digitally encoded images, the ink within the image does not substantially interfere with the transmission of light through the polymer. For opaque digitally encoded images, the ink within the digitally encoded image substantially interferes with the transmission of light through the polymer. When the lens is a contact lens, opaque digitally encoded images can substantially block the natural color of the contact lens wearer's iris. Ink used to create an opaque digitally encoded image can include materials such as particles, for example as mica or ground oyster shells or particulates, in a type and amount sufficient to make the digitally encoded image opaque. Another alternative is a pigment, vat dye, diazo dye or reactive dye. For partially opaque digitally encoded images, the ink within the digitally encoded image can include materials such as particles and particulates, such as mica, ground oyster shells or particulates, in a type and amount sufficient to partially block the transmission of light through the digitally encoded image. Partially blocking the transmission of light, in this instance, refers to the ability of the digitally encoded image to allow a portion of incident light to transmit through a digitally encoded image.

Ink

Inks used in the present invention can include any single colored compound or composition or any combination of colored compounds or compositions. Inks can be provided in water, monomer or solvents, preferably at a concentration between about 0% and greater than about 99.5% or between about 0.01 % and about 99.5%, preferably between about 0.1% and about 90% or between about 1% and about 80%, and more preferably between about 10% and about 60% or between about 20% and about 40%. Inks can also include particles or particulates, preferably at a concentration of between about 0% and about 5% or between about 0.01% and about 5%, preferably between about 0.1% and about 4% or between about 1% and about 3% to render a digitally encoded image opaque or partially opaque. Examples of inks include dyes, vat dyes, particles, pigments, reactive dyes or diazo dyes. As discussed herein, the characteristics

and compositions including inks and other components include inks that are part of an article of manufacture of the present invention, such as a lens, such as a contact lens, and also include compositions that include at least one ink that can be used to make an article of manufacture of the present invention.

Inks can include water, monomer, polymer or an appropriate solvent in order for the ink to be suitable in the making of a digitally encoded image. An appropriate solvent is a solvent that is compatible with the creation of a digitally encoded image on or within a surface, such as on or within a polymer. For example, solvents appropriate for polymers used to make lenses, such as contact lenses, include, but are not limited to isopropanol, water, acetone or methanol, either alone or in combination and can include a monomer. Appropriate concentrations of solvents are between about 0% and greater than about 99.5% or between about 0.1% and about 99.5%, preferably between about 1% and about 90% or between about 10% and about 80%, and more preferably between about 20% and about 70% or between about 30% and about 60%. Different polymers, monomer and inks have different tolerances and reactivities to different solvents. Thus, appropriate matches between solvent and polymer, monomer and ink should be considered. For hydrogel polymers, adjustment in swelling ratios may be achieved with a variety of concentrations of solvents.

An ink can also include a monomer, polymer, homopolymer, heteropolymer or copolymer. In a preferred aspect of this embodiment of the present invention, an ink includes a monomer that can be polymerized to form a polymer using polymerization methods appropriate for a given monomer, mixtures thereof, or polymers, or mixtures thereof. Monomers can also be used to decrease the viscosity of the ink. Alternatively, the ink can include a polymer such that the viscosity of the ink is increased. Alternatively, the ink can include polymer and monomer. Appropriate concentrations of monomers are between about 5% and greater than 99%, preferably between about 25% and about 75%, and more preferably between about 35% and about 60%. Appropriate concentrations of polymers are between about 0% and about 50%, preferably between about 5% and about 25%, and more preferably between about 10% and about 20%. When monomers and polymers are mixed, the total concentration of monomer and polymer are between about 10% and greater than 99%, preferably between about 25% and about 75% and more preferably between about 35% and about 65%.

The viscosity of a solution including an ink can be as high as between about 500 centipoise and about 5,000 centipoise and is preferably between about 1 to about 200 centipoise or between about 10 and about 80 centipoise, preferably between about 20 and about 70 centipoise or between about 30 and about 60 centipoise or between about 1 and about 10

centipoise. Solutions having low viscosity tend to be "runny" when dispensed, and can allow different colors to merge and blend, resulting in an image with a more natural appearance. Such blending can be enhanced using a variety of methods, including sonication or vibration at appropriate duration and frequency to promote appropriate blending. Solutions having too low a viscosity can result in images that are too "runny" and thus have potentially undesirable characteristics, such as pooling of ink in a digitally encoded image or spreading of ink to an unintended location. Solutions having too high a viscosity may not be easily dispensed using a variety of printing structures, such as ink jets and thus may not be appropriate for the present invention. Furthermore, solutions having high viscosity can tend to "bead" on a surface and not blend with the surrounding environment, including surrounding droplets or beads of ink. Under these circumstances, the ink may form unnatural appearing images (see, for example, U.S. Patent No. 5,160,463 and U.S. Patent No. 5,414,477). Agents such as thickeners or diluents (including appropriate solvents) can be used to adjust the viscosity of the ink.

An ink that includes at least one monomer can also include a polymerization initiator, so that once an ink that includes at least one type of monomer is dispensed, the polymerization of the monomer in the ink is initiated. The number, type and amount of initiator is a matter of choice depending on the type of monomer or monomers in the ink. Appropriate initiators include, but are not limited to, UV initiators that initiate polymerization by UV irradiation, thermal initiators that initiate polymerization by thermal energy.

An ink can also include a dispersant to allow uniform composition of ink in a container. Dispersants are preferably provided at an appropriate concentration, such as between about 1% and about 10%.

An ink can also include at least one anti-microbial agent or antiseptic agent to kill or reduce the number or multiplication microbial agents, reduce the number of microbial agents, or keep microbial agents from multiplying. Preferred anti-microbial agents include anti-bacterial agents, anti-fungal agents and disinfectants. Preferably, such anti-microbial agents, anti-bacterial agents, anti-fungal agents and disinfectants are provided at an appropriate concentration such as between about 0% and about 1%.

An ink can also include at least one humectant such as 1,3-diozane-5,5-dimethanol (U.S. Patent No. 5,389,132) at an appropriate concentration. Preferably, the range of concentration of a humectant is between about 0% and about 2%.

An ink can also include at least one antioxidant agent or a low corrosion agent, such as alkylated hydroquinone, at an appropriate concentration, such as between about 0.1% and about 1% (U.S. Patent No. 4,793,264). An ink can also include a non-kogating agent or non-kogating agent, such as 2-methyl-1,3-propanediol at an appropriate concentration, such as between about 0% and about 1%. An ink can also include an evaporation retarding agent, such as, for example,

diethylene glycerol or ethylene glycol at between about 0% and about 2% (U.S. Patent No. 5,389,132).

A preferred ink can have the following composition:

Component	Percentage
Monomer	0% to 99%
Pigment and/or colorant and/or reactive dye	0.1% to 15%
Initiator	0.01% to 2%
Solvent	0% to 80%
Binder or Bonding Agent	0% to 10%
Thickener	0% to 1%
Anti-kogating Agent	0% to 1%
Humectant	0% to 1%
Surfactant	0% to 10%
Cross-linker	0% to 1%
Dispersant	0% to 10%

Printing

The digitally-encoded image is preferably applied to a structure, such as a lens, using a printing method or printing structure. The digitally encoded image can be stored digitally in at least one information storage medium, such as an electronic medium. The stored digitally encoded image can be printed using printing structures and printing methods that can convert the stored digitally encoded image into a printed image using an appropriate interface. For example, a central processing unit can include a stored digitally encoded image. Software can interface the stored digitally encoded image with a printing structure such that the printing structure prints the digitally encoded image. Such interfaces are known in the art, such as those used in digital printing processes that use ink-jets (Hewlett Packard; Encad) (see, for example, **FIG. 1**.

Preferred printing methods and printing structures include, but are not limited to, ink-jet printing, piezo printing, thermal printing, bubble jet printing, pad-transfer printing, impregnation, photolithography and laser printing. Ink-jet printing can use appropriate ink-jet printing structures and ink-jet printing methods as they are known in the art or later developed. For example, appropriate ink-jet printing structures include, but are not limited to HP Desk Jet 612 or Cannon color bubble jet BJC1000 color printer hardware. Furthermore, appropriate ink-jet

printing methods, include, but are not limited to thermal ink jet printing, piezo printing or bubble jet printing.

Ink-jet printing can include piezo printing structures and piezo printing methods as they are known in the art or later developed. For example, appropriate piezo printing structures include, but are not limited to Cannon color bubble jet printer BJC1000.

Ink-jet printing can include thermal printing structures and thermal printing methods as they are known in the art or later developed. For example, appropriate thermal printing structures include, but are not limited to HP Deskjet 612 color printer.

Ink-jet printing can include bubble jet printing structures and bubble jet printing methods as they are known in the art or later developed. For example, appropriate thermal bubble jet structures include, but are not limited to Cannon BJC1000 color printer.

Pad-transfer printing can include pad-transfer printing structures and pad-transfer printing methods as they are known in the art or later developed. For example, appropriate pad-transfer printing structures include, but are not limited to Tampo-type printing structures (Tampo vario 90/130), rubber stamps, thimbles, doctor's blade, direct printing or transfer printing as they are known in the art.

Impregnation printing can include impregnation printing structures and impregnation printing methods as they are known in the art or later developed. For example, appropriate impregnation printing structures include, but are not limited to applying solubilized vat dyes, masking device, developer and the like.

Photolithography printing can include photolithographic printing structures and photolithography printing methods as they are known in the art or later developed. For example, appropriate photolithography printing structures include, but are not limited to applying diazo dyes, masking devices, developers and the like.

Laser printing can include laser printing structures and laser printing methods as they are known in the art or later developed. For example, appropriate laser printing structures include, but are not limited to HP Laser Jet printer hardware, particularly the 4L, 4M series.

More than one printing structure or more than one printing method can be used to make a digitally encoded image of the present invention. For example, ink-jet printing and pad transfer printing can be used in combination.

Digitally encoded images can be printed on the surface of a structure, such as on the surface of a lens, such as on the surface of a contact lens. In this aspect of the present invention, the printing structures and printing methods deposit ink onto a surface. The ink can then dry to produce a non-transient image, or monomers or polymers within the ink can be polymerized to produce a non-transient image. In the latter instance, the monomers or polymers are preferably the same or result in the same polymer that comprises the surface. Digitally encoded images can

be printed on at least one surface of a structure. For example, if the structure is a lens, such as a contact lens, a digitally encoded image can be printed on either or both sides of the contact lens. Printing methods preferred for this type of printing include, but are not limited to thermal inkjet or bubble jet printing.

As depicted in **FIG. 2**, digitally encoded images can also be trapped within a structure, such as a lens, such as a contact lens. In this aspect of the present invention, the image can be trapped within a structure using laminate printing, including sandwich laminate printing. For example, an image is printed on a surface, such as a first portion of a lens, then a second portion of a structure, such as a second portion of a lens, is attached to the first portion of a lens such that the image is trapped between the first portion of a structure and the second portion of a structure.

Preferably, the first portion of a structure includes a polymer and the digital image includes a monomer. The monomer can be polymerized such that the digitally encoded image becomes non-transient and substantially immobile. Then the second portion of a lens is attached to the first portion of a structure such that the digitally encoded image becomes trapped between the first portion of the structure and the second portion of a structure. In this aspect of the present invention, the digitally encoded image preferably includes a monomer that can be polymerized to form a polymer, preferably a polymer that is included in the first portion of a structure or the second portion of a structure, preferably both.

In a preferred aspect of the present invention, the first portion of a structure is a non-polymerized monomer or semi-polymerized polymer that includes monomer onto which the digitally encoded image, which preferably comprises the same monomer as the first portion of a structure, is printed. This composite structure can be partially or fully polymerized and a second portion of a structure attached thereto to entrap the digitally encoded image therein. In the alternative, the second portion of a structure, which preferably includes monomer and optionally polymer, preferably the same as the first portion of a lens and the digitally encoded image, is contacted with this first portion of a structure and digitally encoded composite such that the digitally encoded image is trapped between the first portion of a structure and the second portion of a structure. The resulting laminate composite structure includes a digitally encoded image trapped within the structure. In one aspect of the present invention a partially polymerized layer of ink is contacted with a monomer, or alternatively a monomer is partially polymerized and contacted with a layer of ink. Each combination can be partially polymerized and transferred to a primary surface and fully polymerized such that the polymerized layer of ink is sandwiched in between a polymer layer and the primary polymerized surface (see, for example, **FIG. 3**).

The laminate composite structure can be fashioned into a lens using methods described herein and as they are known in the art or later developed, such as, for example, laser cutting, stamping, grinding, polishing or the like. In the alternative, the laminate composite structure made using the foregoing methods results in a lens. For example, the laminate composite can be made in a mold that has the shape of a lens. Such molds are known in the art and have been described herein. In the alternative, the method used to make the laminate can form a lens, such as spin-casting methods.

Lenses made using spin casting are preferable in the present method. In the alternative, other appropriate methods, such as those described herein, known in the art, or later developed, that can form at least a portion of a lens can also be used. In this aspect of the present invention, a first portion of a structure is printed with a digitally encoded image and the second portion of a structure is added thereon to form a laminate structure. Spin-casting or other lens forming methods and polymerizing can optionally take place any time during this process and the first portion the structure, the second portion of a structure and the digitally encoded image can be in various states of polymerization, such as non-polymerized, partially polymerized or polymerized. Optionally, the digitally encoded image need not include monomer or polymer.

For example, a first portion of a structure can be non-polymerized, polymerized or partially polymerized and can be spin-cast (or other lens forming method) or not spin-cast (or other lens forming method). A digitally encoded image including or not including a monomer and/or a polymer can be printed on the first portion of a lens to form a composite. This composite can be polymerized, not polymerized or partially polymerized and can optionally be spin-cast (or other lens forming method) or at least a portion of a lens formed by another appropriate method (the optional polymerization and optional spin-casting (or other lens-forming method) can take place in either order). This composite is then contacted with a second portion of a structure that can be polymerized, partially polymerized or non-polymerized and then can be optionally spin-cast (or other lens forming method) to form a portion of a lens to form a composite laminate. The composite laminate, or at least a portion thereof, is or are optionally polymerized. Preferably, the first portion of a structure, the digitally encoded image and the second portion of a structure all share at least one common monomer or polymer, but that need not be the case.

One example of this method includes a first portion of a structure dispensed into a receiving structure such as a mold, wherein the first portion of a structure is non-polymerized, partially polymerized or polymerized and is not spin-cast (or other method of forming at least a portion of a lens). The digitally encoded image is printed on the first portion of a structure, wherein the digitally encoded image optionally includes a monomer and/or a polymer to form a composite structure. A second portion of a structure is contacted with the composite structure,

wherein the second portion of a structure is non-polymerized, partially polymerized or polymerized to form a laminate composite. The laminate composite is then spin-cast (or other method of forming at least a portion of a lens).

Another example of this method includes a first portion of a structure dispensed into a receiving structure, such as a mold, wherein the first portion of a structure is non-polymerized or partially polymerized and is optionally spin-cast (or other method of forming at least a portion of a lens) and is optionally polymerized. The digitally encoded image is printed on the first portion of a structure, wherein the digitally encoded image optionally includes a monomer and/or a polymer to form a composite structure and is optionally spin-cast (or other method of forming at least a portion of a lens) and optionally polymerized. A second portion of a structure is contacted with the composite structure, wherein the second portion of a structure is non-polymerized, partially polymerized or polymerized to form a laminate composite. The laminate composite is optionally spin-cast (or other method of forming at least a portion of a lens). Preferably, the first portion of a structure and second portion of a structure include the same or similar monomer and polymer and are partially polymerized such that a polymerization (such as a final polymerization of a laminate structure) results in a relatively or substantially "seamless" laminate structure (fused or connected). Preferably, the digitally encoded also includes the same or similar monomer and polymer (non-polymerized or partially polymerized) so that a polymerization (such as a final polymerization of a laminate structure) results in a relatively or substantially "seamless" laminate structure.

During this course of this method, the digitally encoded image can form a chemical bond with either or both of the first portion of a structure and the second portion of a structure. In this instance, the digitally encoded image comprises an ink that can form such a chemical bond.

Also, the digitally encode image can form a polymer-polymer bond with either one or both the first portion of a structure and second portion of a structure. In this instance, the digitally encoded image includes a monomer or polymer that formed a polymeric bond with at least one of the first portion of a structure and second portion of a structure.

In this aspect of the invention, the digitally encoded image preferably includes at least one pattern. The pattern can be any pattern, including naturally and non-naturally occurring patterns. For example, a naturally occurring pattern can include a fractile-like pattern. Non-naturally occurring patterns can include geometric patterns or non-geometric patterns, such as are used in vanity contact lenses. A digitally encoded image can include at least one color, but preferably includes a plurality of colors. A digitally encoded image preferably includes at least a portion of an image of an eye, such as the iris of an eye, such as the iris of a human eye.

The image can include at least one color, but preferably includes two or more colors. The colors used in the image can be derived from a mixture of separate colors, such as two or more separate colors, three or more separate colors or four or more separate colors. For the purposes of this aspect of the invention, black is considered a separate color. The separate colors are preferably primary colors that can be mixed in different proportions to form a wide array of colors on an image.

Polymers and Lenses

Structures, such as lenses, of the present invention preferably include at least one polymer. When the structure of the present invention is a lens, such as a contact lens, the at least one polymer is preferably a polymer that is compatible with the eye. Preferable polymers for use in making contact lenses include, but are not limited to acrylics, silicones, polycarbonates and others known in the art or later developed. Polymers useful in the present invention can be hydrophobic or hydrophilic. In the case of hydrophilic polymers, the polymer preferably forms a hydrogel. Generally, polymers used to make contact lenses result in "hard lenses," "soft lenses" or "hybrid lenses" as those terms are known in the art.

II METHOD OF MAKING A LENS WITH A DIGITALLY ENCODED IMAGE - I

The present invention also includes a method of making an article of manufacture that includes a digitally encoded image and a polymer, including the steps of printing a digitally encoded image on a composition that includes a polymer, wherein the polymer forms a lens. The polymer can be any polymer, but is preferably a polymer in a wet state or a dry state, such as polymers used in the manufacture of lenses, such as contact lenses.

The article of manufacture is made by providing a composition that includes a polymer that the digitally encoded image is to printed upon. The polymer is preferably a polymer used to make lenses, such as contact lenses, and include, but are not limited to, hydrophobic polymers, hydrophilic polymers, homopolymers, heteropolymers, copolymers, acrylic polymers, silicone polymers or polycarbonate polymers either alone or in combination. One preferred lens includes the following: HEMA (hydroxyekyl methaenylate), EOEMA (ethoxyethylmethacrylate, MAA (methacrylic acid), EGDMA (ethylene glycoldimethacrylate), Vazo-64 (azobisilobutyronitrile), BME (benzoin methylether), IPA (isopropyl alcohol), THF (terahydrofuran), Mercap-2 (mercaptoethanol), c-pentanone (cyclopentanone) and MEHQ (methylethyl hydroquinone) (see U.S. Patent No. 5,271,874).

In this aspect of the present invention, the polymer at least in part forms a lens, such as a contact lens, such as a soft contact lens, a hard contact lens or a hybrid contact lens. It is the structure that forms at least in part a lens that a digitally encoded image is printed. Preferably, the digitally encoded image is printed on the lens and can be printed on either or both sides of the

lens. The digitally encoded image can be printed on the entire lens or a portion thereof. For example, the digitally encoded image can depict the iris of an eye such that the area corresponding the pupil of the eye is not printed.

The digitally encoded image is preferably encoded electronically, such as in a database. The digitally encoded image can be prepared by any appropriate method, such as by scanning an image into a processing unit using appropriate scanning and storage hardware and software. The digitally encoded image can be selected and can be conveyed to a printing device as an electronic signal using appropriate hardware and software.

The digitally encoded image is preferably printed using a printing device that is capable of producing a digital image, such as an ink jet printing device, a piezo printing device, a thermal printing device or a laser printing device. The printing devices preferably include at least one ink, wherein if more than one ink is present in such printing device, the different inks are provided in separate containers or separate portions of the same containers, such as provided in Hewlett Packard Color DeskJet printer cartridges (HP51649A).

An ink preferably contains at least one monomer, such as a hydrophobic monomer or hydrophilic monomer that preferably corresponds to a polymer that is included in the lens. The ink can also include a variety of other components, such as an appropriate initiator, such as a UV initiator or a thermal initiator to initiate polymerization of the monomer after being dispensed by a printing device on a polymer. An ink can optionally also include at least one of a binder, an ant-bacterial agent, an anti-fungal agent, a disinfectant or a humectant at an appropriate concentration for the intended function. Preferably inks include, but are no t limited to, pigment black 7 (carbon black), pigment black 11 (iron oxide), pigment brown 6 (iron oxide), pigment red 101 (iron oxide), pigment yellow 42 (iron oxide), pigment while 6 (titanium dioxide), pigment green 17 (chromium oxide), pigment blue 36 (chromium aluminium cobaltous oxide), pigment blue 15 (copper phthaloxyanine), pigment violet 23 (3,amino-9-ethyl carbazole-chloronil) (U.S. Patent No. 5,302,479), Millikan ink yellow 869, Millikan ink blue 92, Millikan ink red 357, Millikan ink black 8915-67 (see U.S. Patent No. 5,621,022).

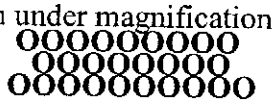
Preferably, four separate ink colors, which can include one or more individual inks, are used in a printing device **FIG. 1**. The four inks correspond to black, magenta, yellow and cyan. The printing device can mix these inks to provide a wide diversity of colors for use in the printing process. A typical ink formulation includes: monomer (HEMA), initiator (BME), crosslinker (EGDMA), pigment #1 (pthalocynine blue), diluent (glycerine), solvent (isopropanol), pigment #2 (titanium dioxide), dispersant (polyvinyl alcohol), humectant (ethylene glycol), co-monomer (methacrylic acid), inhibitor (MEHQ), anti-kogating agent

(methylpropanediol) and anti-oxidant (alkylated hydroquinone). The monomer can also be a mixture of two or more monomers. A preferred mix of monomers that results in a clear polymer, such as for a clear contact lens, include monomer HEMA (hydroxyethyl methacrylate), monomer EOEMA (ethoxyethylmethacrylate), monomer MAA (methacrylic acid). Optionally included are at least one of the following: crosslinker EGDMA (ethylene glycoldimethacrylate), initiator Vazo 64 (azobisiloburyronitrile), solvent isopropyl alcohol, inhibitor MEHQ (methyletherhydroquinone) and diluent glycerine. All components are at appropriate concentrations for their intended purpose.

Optionally, a printing device can include a mixture as described above without an ink that can be dispensed along with at least one ink in a separate container such that the ink and monomer and other optional components are mixed and dispensed onto a polymer. In either instance, the monomer in the dispensed fluid can be polymerized, thus immobilising the ink therein at a defined locus.

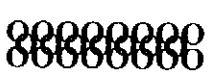
Preferably, during printing, a printing device, such as an ink jet printer, will dispense four different main colors (Black, Magenta, Cyan and Yellow) as discrete dots that correspond to one or more dispensation volumes of the printing device that do not mix. The dots are deposited as any combination of the main colors to form a collage of discrete dots of different main colors that, to the unaided human eye generally appear to be a color or pattern rather than a collage of discrete dots. Thus, what is formed is a matrix of individual color dots next to each other with a boundary between them.

Such a pattern under magnification may appear as:



Depending on the number of dots, their density and distribution the unaided human eye would perceive different colors, intensity, hue and brightness.

The ink used in available technology, such as pad transfer printing and pad transfer devices, is highly viscous, such as up to 40,000 cps and is partially polymerized. Such inks do not run and forms a large discrete dot on dispensation. Such printing results in a very unnatural appearance due to the large, unmixed dots. In the present technology, the viscosity of the ink can be low, such as less than about 100 cps, and can be between about 1 cps and about 10cps. This low viscosity allows the dots to blend, either on their own, or upon the exertion of external forces, such as vibrational energy. In this instance, the dots do not remain discrete, but rather blend together, such as:



The result being an image that is a color and pattern that is a "non-dot" color matrix that has a highly realistic appearance to the unaided human eye.

The printing device dispenses ink or mixtures of inks onto a polymer, such as a lens, that corresponds to the digitally encoded image. More than one digitally encoded image can be dispensed onto a polymer. Monomer in at least one ink can be appropriately polymerized such that the ink is immobilized on or within the polymer. This process can be repeated with the same or different digitally encoded image in the same or different orientation.

In the alternative, the digitally encoded image can be printed on a pad transfer printing device where it is optionally polymerized. The printed image can then be transferred to a polymer, such as a contact lens, using appropriate pad transfer printing devices such as they are known in the art **FIG. 4**.

III METHOD OF MAKING A LENS WITH A DIGITALLY ENCODED IMAGE - II

The present invention includes a method of making an article of manufacture that includes a digitally encoded image and a polymer, including the steps of printing a digitally encoded image on a composition comprising a polymer, and forming a lens from said polymer.

In this aspect of the present invention, the digitally encoded image is printed on a polymer that does not form a lens using a printing device. The polymer with the digitally encoded image is then formed into a lens using an appropriate method, such as, for example, fabrication, cast-molding, spin-casting or a combination thereof.

When the lens is made using fabrication, the polymer with the digitally encoded image is formed into a lens using appropriate fabrication methods, including, for example, stamping, grinding or trimming (see the **FIG. 5**). The lens can also be made using cast-molding and spin casting (see, for example, **FIG. 6, FIG. 7A** and **FIG. 7B**).

FIG. 7B depicts one preferred aspect of the present invention. A lens structure is made using, for example, spin casting. Etching, burning or cutting processes, such as methods using chemical, mechanical or laser methods, are used to create well(s) or indentations. These wells or indentations preferably are aligned at a locus that corresponds to the iris of an eye. A digitally encoded image is printed on the lens, preferably at the location of the wells or indentations. The ink can optionally be polymerized or partially polymerized when monomers are present in the ink. A layer of polymer is then created on top of this structure to form a lens structure. Any appropriate polymerization of the structure thus formed or portions thereof can be accomplished using appropriate methods.

In one instance, a digitally encoded image can be printed onto the surface of a spin

casting device, where the printed digitally encoded image can be optionally polymerized or partially polymerized. A solution including at least one monomer that can be polymerized to form a lens, such as a contact lens, can be dispensed on the printed digitally encoded image and spin cast to form a lens. Preferably, the ink(s) used to print the digitally encoded image include the same monomer(s) used to make the lens, but that need not be the case. Preferably, the printed digitally encoded image is non-polymerized or partially polymerized and contacted with the solution including at least one monomer (preferably the same monomer used in the ink(s)). The lens is formed by spin-casting, and the polymerization process completed. In that way, a self-adhesion bond or a polymer-polymer bond between the printed digitally encoded image and the lens is made.

In another instance, a first solution including at least one monomer can be polymerized or partially polymerized to form a lens, such as a contact lens, in a spin cast device. A digitally encoded image can be printed on the exposed surface of the lens using a printing device and the printed digitally encoded image optionally polymerized. A second solution including at least one monomer that can be polymerized to form a lens, such as a contact lens, is placed on top of the printed digitally encoded image and is spin cast to form a lens. The second solution preferably is the same solution as the first solution. Preferably, the first solution is partially polymerized prior to the printing of the digitally encoded image, wherein the printed digitally encoded image includes the monomer of the first solution. This structure is optionally polymerized or partially polymerized. The second solution preferably includes the monomer of the first solution and the ink(s) used to make the digitally encoded image. Preferably, the first solution, the printed digitally encoded image and the second solution form a partially polymerized structure, and the polymerization is then completed. In that way a polymer-polymer bond form between the polymerized first solution and the polymerized printed digitally encoded image or between the polymerized printed digitally encoded image and the polymerized second solution. Preferably, such polymer-polymer bond forms between the polymerized first solution, the polymerized printed digitally encoded image and the polymerized second solution.

In another instance, the present invention includes a polymeric surface that includes indentation structures, such as but not limited to grooves or wells that can be formed in the polymeric surface by a variety of methods, including casting and etching, cutting, drilling or burning, such as by laser etching, physical etching or chemical etching (see, for example, **FIG. 8A** and **FIG. 8B**). Preferably, the indentation structures are made using appropriate laser etching technologies, such as those made by Lumonics Inc.

The indentation structures can be provided at any locus at any appropriate density of indentation structures on a surface, but are preferably located in areas where pigmentation or printing is targeted, such as where a desired cosmetic effect is desired for contact lenses.

Locations where printing is not desired or desirable can be provided substantially without such indentation structures such that printing can be particularly directed or not directed to chosen locations.

The indentation structures can be of different sizes and shapes, but are preferably relatively small such that one, a few or many droplets of ink can be deposited into such indentation structures using appropriate printing methods or devices (see, for example, **FIG. 9**). Preferably, one or a few of the same color or different colors can be deposited in the indentation structures. In one aspect of the present invention, the indentation structures are partially filled or fully filled with ink during printing processes. If the indentation structures are over-filled, then steps can be taken to remove excess ink, such as, for example, blotting, scraping or machining, such as polishing, buffing or grinding.

In a particularly preferred aspect of the present invention, the ink includes at least one polymerizable monomer that can be polymerized after dispensation. If the indentation structures are not filled with such ink, then additional material, such as monomer with or without ink can be dispensed onto the polymer. As in other aspects of the present invention, the skilled artisan has the choice of when and how the ink or monomer can be polymerized. For example, in one preferred aspect of the present invention, the ink is dispensed into indentation structures such that the indentation structures are not filled. The ink is then optionally polymerized, and additional monomer is dispensed on the polymer to fill or overfill the indentation structures. The monomer is then polymerized, and the polymer is ready for final processing, if any.

Preferably, the indentation structures facilitate holding the dispensed ink in a location such that a digitally encoded image is localized and held in place. This aspect of the present invention is most appropriate for inks that are of relatively low viscosity such that the ink does not run due to the curvatures of printed surfaces, such as are present in lenses.

In one preferred aspect of the present invention, droplets of ink that include a monomer are deposited on a surface, such as a polymer, that includes indentation structures. One or more droplets of the same or different color are deposited in such indentation structures such that different combinations of colors, chroma, intensity and hues can be localized in one or more indentation structures.

In another aspect of the present invention, a lens such as a non-hydrated lens or hydrated lens, such as a partially hydrated or fully hydrated lens, can be mounted, preferably centered, and masked on a fixture (see, for example **FIG. 10**). When hydrated, water on or in the lens can optionally be removed, such as by blotting. A hydrated lens can optionally then be dehydrated, such as to partial or substantial dehydration, by appropriate methods such as by air, heat or

centrifugation. The lens can be printed or tinted using appropriate methods such as those described herein. Preferably but optionally, the lens includes indentation structures such as those described herein. This process and device allow for the automation of printing processes and manufacture processes described herein.

The present invention also includes a method of making an article of manufacture that includes a digitally encoded image and a polymer, including the steps of printing a digitally encoded image on a composition comprising at least one monomer, polymerizing said at least one monomer to form at least one polymer, and forming a lens from said at least one polymer.

The present invention includes a method of making an article of manufacture that includes a digitally encoded image and a polymer, including the steps of printing an image on at least one first surface, transferring said image to at least one second surface comprising a monomer or a polymer, and forming a lens from said second surface.

IV DIGITAL IMAGES

The present invention includes an article of manufacture, including: at least one information storage medium, and at least one digital image, wherein the at least one digital image comprises at least a portion of an image, such as, but not limited to, the iris of an eye. The information storage medium can be any appropriate electronic storage medium and is preferably in a machine-readable format and preferably associated with a central processing unit. A plurality of digital images can be stored in a database. The invention is drawn not only to digitally encoded images, but also to the digitally encoded images when provided in a format, such as data, such as data in a patentable format. Thus, for example, the present invention encompasses a format such as a machine-readable format comprising data such as one or more digitally encoded images of interest as determined or isolated according to the present invention.

For example, the invention includes data in any format, preferably provided in a medium of expression such as printed medium, perforated medium, magnetic medium, holographs, plastics, polymers or copolymers such as cyclolifin polymers. Such data can be provided on or in the medium of expression as an independent article of manufacture, such as a disk, tape or memory chip, or be provided as part of a machine, such as a computer, that is either processing or not processing the data, such as part of memory or part of a program. The data can also be provided as at least a part of a database. Such database can be provided in any format, leaving the choice or selection of the particular format, language, code, selection of data, form of data or arrangement of data to the skilled artisan. Such data is useful, for example, for comparing sequences obtained by the present invention with known sequences to identify novel sequences.

One aspect of the invention is a data processing system for storing and selecting at least a portion of data provided by the present invention. The data processing system is useful for a

variety of purposes, for example, for storing, sorting or arranging such data in, for example, database format, and for selecting such data based on a variety of criteria, such as colors, patterns, sources and the like. Such a data processing system can include two or more of the following elements in any combination:

I. A computer processing system, such as a central processing unit (CPU). A storage medium or means for storing data, including at least a portion of the data of the present invention or at least a portion of compared data, such as a medium of expression, such as a magnetic medium or polymeric medium;

II. A processing program or means for sorting or arranging data, including at least a portion of the data of the present invention, preferably in a database format, such as a database program or an appropriate portion thereof such as they are known in the art (for example EXCEL or QUATROPRO);

III. A processing program or means for comparing data, including at least a portion of the data of the present invention, which can result in compared data, such as digital image comparing programs or an appropriate portion thereof;

IV. A processing program or means for analyzing at least a portion of the data of the present invention, compared data, or a portion thereof, particularly statistical analysis, such as programs for analyzing digitally encoded images using statistical analysis programs or image comparing programs
or an appropriate portion thereof as they are known in the art;

V. A formatting processing program or means that can format an output from the data processing system, such as data of the present invention or a portion thereof or compared data or a portion thereof, such as database management programs or word-processing programs, or appropriate portions thereof as they are known in the art; or

VI. An output program or means to output data, such as data of the present invention or a portion thereof or compared data or a portion thereof in a format useful to an end user, such as a human or another data processing system, such as database management programs or word-processing programs or appropriate portions thereof as they are known in the art. Such formats useful to an end user can be any appropriate format in any appropriate form, such as in an appropriate language or code in an appropriate medium of expression.

V SYSTEMS

The present invention also includes a system, including: an article of manufacture of the present invention and a printing device. The article of manufacture includes at least one digitally

encoded image, preferably in the form of a database within a central processing unit. The central processing unit preferably is linked to a printing device that includes appropriate software and hardware to direct the printing device to print a digitally encoded image, such as during the operation of a method of the present invention. The system can include additional components, such as devices for the manufacture of lens structures of the present invention. For example, the system of the present invention can include a lens manufacturing device, such as a spin casting device or a pad transfer device. Preferably, the central processing unit includes hardware and software that allows the central processing unit to direct the manufacture of a lens using at least one method of the present invention.

As a preferred embodiment of the present invention, a system of the present invention includes a first central processing unit that optionally includes an article of manufacture of the present invention, wherein the article of manufacture of the present invention can be located on at least one second central processing unit separate in distance from the first central processing unit and is linked to the remainder of the system. The system preferably includes a printing device as described herein or known in the art that is capable of printing at least one digital image of the present invention. The system preferably includes a lens manufacturing device, such as a spin-cast device or a pad transfer device. In that regard, the system of the present invention includes dispensation and other hardware, software and reagents used to practice a method of the present invention. Preferably, the system is automated such that a user can select a digital image and the first central processing unit directs and co-ordinates the manufacture of at least one lens by the remainder of the elements of the system, such as the printing device and a lens manufacture device.

VI COMPOSITIONS OF MATTER INCLUDING INK

The present invention also includes a composition of matter, including at least one ink, dye, vat dye, particle, pigment, reactive dye or diazo dye. The composition of matter also includes at least one of a binder, monomer, polymer, homopolymer, heteropolymer, copolymer, and initiator, UV initiator, thermal initiator, solvent, dispersant, anti-bacterial agent, anti-microbial agent, anti-fungal agent, disinfectant, thickener, humectant, non-kogating agent, anti-corrosion agent, antiseptic agent or non-oxidizing agent. The indicated agents can be provided in any combination and at concentrations or amounts appropriate for the indicated function.

The compositions of matter of the present invention do not include the inks set forth in United States Patent No. 4,303,9214 to Young, issued December 1, 1981. In particular, the composition of matter of the present invention are preferably water resistant after polymerization such that pigments in the ink substantially stay where they have been deposited by printing processes. In addition, the compositions of matter of the present invention are preferably

swellable after polymerization, particularly in solvents, preferably water. In addition, the inks of the present invention, are preferably capable of chemically bonding, cross-linking or otherwise binding with polymers or monomers on the surface being printed. For example, the ink of the present invention can include monomers that can be polymerized with a polymer or monomer on the surface being printed.

The composition of the present invention can be provided in a printing device, such as an ink jet printing device, a piezo printing device, a thermal printing device, a laser printing device or a pad transfer printing device.

VII METHOD OF DOING BUSINESS

The present invention also includes a method of doing business, including the steps of: obtaining a digital image from a person, database (such as a database of the present invention) or image and printing said digital image to make at least one lens or a pair of lenses that includes the printed digital image. Preferably, the lens or lenses are made using a method of the present invention. Furthermore, the lens or lenses are preferably made using a system of the present invention.

In this aspect of the present invention, a customer selects an image that s/he would like as part of a lens. The image can be any image, such as a fanciful image or any type, such as novelty images including swirls and the like, or an image that is a high quality image of an iris, such as from a human or animal. The image can be selected from a database, such as a database of digital images. Alternatively, the customer can identify and select an image from a variety of sources, such as a collection of photographs of people or animals. Such collections can be in an appropriate storage medium, such as an electronic database or a collection or compilation of photographs or pictures. Alternatively, the customer can provide a selected image for use in the present method. A selected non-digital image can be transformed into a digital image using appropriate scanning technologies as they are known in the art. Such scanned images can become part of a database of the present invention. The selection process can take place at virtually any location, such as at a vendor's or manufacture's physical location or via computer, such as via the Internet.

The digital image selected by the customer can then be conveyed to the vendor's or manufacture's physical location via an appropriate method, such as through personal communication, phone communication, communication through printed materials such as order forms through the mail, or through electronic media, such as through the Internet. A selected image can be analyzed using appropriate software, such as image analysis and comparing

software, for patterns, hue, chroma and intensity. The image can then be transformed into a signal for use by a printing device such that the image is reproduced as to colors and patterns by the printing device. The vendor notifies the manufacture of the order and provides the manufacture with the necessary information, such as the digital image. The vendor and manufacturer can be the same or different person, company or entity and can be at the same or different physical location. The manufacturer then manufacture's the lens or lenses and delivers the manufactured lens or lenses to the vendor or customer by an acceptable method such as check, cash, credit or credit card. The vendor or manufacturer receive payment as appropriate

The digital image can be printed by a printing device following a method of the present invention or other method known in the art or later developed that results in the production of a lens, particularly a contact lens, of the present invention. Preferably, a printing device that utilizes at least two colors, at least three colors or at least four colors is used. This aspect of the present invention preferably utilizes a system of the present invention.

EXAMPLES

EXAMPLE 1: PREPARATION OF INKS

This example provides ink compositions used to make lenses that include a digitally encoded image. Four ink preparations are preferred for use in printing devices, although more or less can be used.

The ink preparations include a base ink formulation that include the following: monomer (HEMA), initiator (BME), crosslinker (EGDMA), pigment #1, diluent (glycerine), solvent (isopropanol), optional pigment #2 (titanium oxide), dispersant (polyvinyl alcohol), humectant (ehtylene glycol), co-monomer (methacrylic acid), inhibitor (MEHQ), antikogating agent (methyl propanediol), and antioxident (alkylated hydroquinone). The concentration of these constituents are as appropriate for making a lens of desired characteristics and physical properties. Pigment #1 can be any ink or combination of inks to provide a desired color. The preferred colors for four ink formulations are **A1**: Black; **A2**: Magenta, **A3**: Yellow and **A4**: Cyan. Appropriate inks for A1, A2, A3, and A4 are described in U.S. Patent No. 5,176,745, U.S. Patent No. 4,889,520, U.S. Patent No. 5,658,376, U.S. Patent No. 4,793,264, U.S. Patent No. 5,389,132, U.S. Patent No. 5,271,765, U.S. Patent No. 5,062,892 and U.S. Patent No. 5,372,852.

A preferred monomer mixture for making clear lenses is designate **A5**, and has the following formulation: monomer (HEMA), monomer (EOEMA), monomer (MAA), crosslinker (EGDMA), initiator (Vazo-64), inhibitor (MEHQ) and diluent (glycerine). The concentration of these constituents are as appropriate for making a lens of desired characteristics and physical properties.

When inks are used in jet printing devices, the ink is preferably water based or monomer based (U.S. Patent No. 5,658,376). The ink is preferably soluble in water and an organic solvent and preferably includes a disperse dye or pigment. A water soluble polymer such as polyvinyl alcohol and a dispersant such as polyvinyl pyrolidone are preferred. A surfactant is preferably provided, such as polyoxyethylene alkyl ether or polyoxyethylene alkylpheyl ether having an aminic acid group. The ink preferably includes a surfactant, such as between about 0.3% and about 1% by weight. The ink preferably includes an antiseptic agent such as Proxel (Zeneca, U.K.). The ink preferably has a pH of between about 7 and about 10 and a viscosity at about 25C of between about 2 mPas and about 6 mPas. Antioxidants, such as low corrosion or antioxidant agents, such as alkylated hydroquinone can also be included, preferably between about 0.1% and about 0.5% by weight (U.S. Patent No. 5,389,132). An ink can also include a humectant such as 1,3-dioxane-5,5-dimethanol, 2-methyl-1,3-propane diol, ethylene glycol or diethylene glycol. When used in printing, the driving frequency is preferably between about 3 kHz and about 8 kHz (see generally, U.S. Patent No. 5,658,376). Preferred ink properties include a surface tension of between about 20 dynes/cm and about 70 dynes/cm and a viscosity between about 1.0 cp and about 2.0 cp (U.S. Patent No. 5,271,765).

EXAMPLE 2: PRINTING METHODOLOGIES - SURFACES AND LAMINATES

This example, as depicted in **FIG. 1** and **FIG. 11**, provides a methodology for printing digitally encoded images. An image, such as of an iris, is scanned into a digital form using appropriate hardware and software to provide a digitally encoded image. The digitally encoded image is stored in an appropriate storage medium, such as an electronic medium, such as in a database. A selected image is sent via an electronic signal to a printing device, such as an inkjet printing device, a bubble jet printing device or a laser printing device, through a processing unit. The printing device preferably includes ink formulations **A1**, **A2**, **A3** and **A4** in separate compartments, such as in a printing cassette (Formulation **A6**), and optionally formulation **A5** in a separate compartment or in a separate cassette. The printing device, under the direction of a processing unit, prints the digitally encoded image by mixing and dispensing, or dispensing individually, the inks of formulation **A6** onto a surface, such as a polymerized polymer, a partially polymerized polymer or an unpolymerized polymer. After a printing step or other time during the manufacture process, the structure can be subjected to energy, such as vibrational energy, that can smear the printed digital image, particularly when in an unpolymerized or partially polymerized state, such that the resulting printed digital image has a natural appearance. This process can be repeated a plurality of times using the same or different digitally encoded

image. The surface can be maintained in the same orientation or rotated between printing steps. The printed digitally encoded image can be polymerized or partially polymerized after each printing step or after all printing steps are completed.

In the alternative, as depicted in **FIG. 12** a digitally encoded image can be printed on a structure designed to transfer a printed digitally encoded image to a surface. Such structures known in the art include pad transfer devices. The digitally encoded image can be printed onto the structure and polymerized or partially polymerized prior to the printed digitally encoded image being transferred to a surface.

The surface that the digitally encoded surface is printed upon, or transferred to, can be partially polymerized or fully polymerized, and can be rough or smooth. Roughened surfaces are obtained by methods known in the art, such as etching, laser cutting or burning, grinding or cutting. The surfaces can be made by appropriate methods, such as by cast molding, spin casting lathe fabrication or laser fabrication.

Laminate structures that include printed digitally encoded images can be made by forming a surface with printed digitally encoded image on such surface. Additional monomer, such as formulation **A5**, can be placed on the printed digitally encoded image and polymerized to form a laminate structure that includes a first polymer layer (preferably clear), a printed digitally encoded image, and a second polymer layer (preferably clear). In making these laminate structures, the first polymer layer can be partially or fully polymerized prior to printing of the digitally encoded image. This structure in turn can be partially or fully polymerized. The monomer for the second polymer layer is then dispensed, and this structure is then partially or fully polymerized (see, for example, **FIG. 2** and **FIG. 13**).

EXAMPLE 3: PRINTING METHODS - WITHIN A WELL OR INDENTATION ON A SURFACE

This example, as depicted in **FIG. 14** provides methods of making lenses that include a digitally encoded image, wherein the digitally encoded image is provided in a well structure(s) or an indentation(s). In this aspect of the present invention, a structure including a surface of fully polymerized or partially polymerized polymer is provided. A well or indentiation is created on the structure that corresponds at least in part to the size and shape of the digitally encoded image to be printed. The well can be larger in size or of a different shape than the digitally encoded image to be printed. The methods descried in **Example 2** are used to print the digitally encoded image on the surface of the well. A laminate structure within the well can also be made following the methods described in **Example 2**.

EXAMPLE 4: FINISHING OF LENSES

The structure resulting for these methods can be finished using secondary operations known in the art as they are needed, such as, for example, cutting, grinding, edging, polishing or the like to form a lens of desired optical, cosmetic or functional quality or characteristics. For soft contact lenses, the dry lenses may be hydrated using conventional methods to form a finished product. The finished lenses can be packaged in any appropriate packaging as they are known in the art, such as vials, tubes, blisters or other structures. The packaging can include appropriate solutions and instructions for use or description of the product and its care.

All publications, including patent documents and scientific articles, referred to in this application and the bibliography and attachments are incorporated by reference in their entirety for all purposes to the same extent as if each individual publication were individually incorporated by reference.

All headings are for the convenience of the reader and should not be used to limit the meaning of the text that follows the heading, unless so specified.

AMENDED CLAIMS

1. (Amended) An article of manufacture, comprising:
a) a polymer, and
b) a digitally encoded image made with ink, wherein said polymer forms a lens; further wherein at least a portion of said digitally encoded image is produced using ink jet printing; further wherein said digitally encoded image is provided directly to said polymer; further wherein said ink jet printing uses piezo printing.

2. The article of manufacture of claim 1, wherein said digitally encoded image comprises a single color or a multi-colored image.

3. The article of manufacture of claim 1, wherein said digitally encoded image is transparent, opaque or partially opaque.

4. The article of manufacture of claim 1, wherein said polymer comprises a hydrogel.

5. The article of manufacture of claim 1, wherein said lens is a soft lens, a hard lens or a hybrid lens.

6. The article of manufacture of claim 1, wherein said lens comprises between about 0% percent and about 80% percent water.

7. The article of manufacture of claim 1, wherein said lens is permeable to oxygen.

8. The article of manufacture of claim 1, wherein said polymer is hydrophobic or hydrophilic.

9. (Amended) The article of manufacture of claim 1, wherein said polymer comprises a polymer selected from the group consisting of acrylics, silicones and polycarbonates.

10. The article of manufacture of claim 1, wherein said lens is a contact lens.

11. (Amended) The article of manufacture of claim 1, further wherein said ink-jet printing uses thermal printing.

12. (Amended) The article of manufacture of claim 1, wherein a portion of said digitally encoded image is produced using pad-transfer printing.

13. (Amended) The article of manufacture of claim 1, wherein said digitally encoded image is on at least one surface of said polymer.

14. (Amended) The article of manufacture of claim 2, wherein said digitally encoded image comprises a single color image.

15. (Amended) The article of manufacture of claim 2, wherein said digitally encoded image comprises a multi-colored image.

16. (Amended) The article of manufacture of claim 3, wherein said digitally encoded image is transparent.

17. (Amended) The article of manufacture of claim 3, wherein said digitally encoded image is opaque.

18. (Amended) The article of manufacture of claim 3, wherein said digitally encoded image is partially opaque.

19. (Amended) The article of manufacture of claim 5, wherein said lens is a soft lens.

20. (Amended) The article of manufacture of claim 5, wherein said lens is a hard lens.

21. (Amended) The article of manufacture of claim 5, wherein said lens is a hybrid lens.

22. (Amended) The article of manufacture of claim 8, wherein said polymer is hydrophobic.

23. (Amended) The article of manufacture of claim 8, wherein said polymer is hydrophilic.

24. (Amended) The article of manufacture of claim 9, wherein said polymer comprises an acrylic.

25. (Amended) The article of manufacture of claim 9, wherein said polymer is an acrylic.

26. (Amended) The article of manufacture of claim 9, wherein said polymer comprises a silicone.

27. (Amended) The article of manufacture of claim 9, wherein said polymer is a silicone.

28. (Amended) The article of manufacture of claim 9, wherein said polymer comprises a polycarbonate.

29. (Amended) The article of manufacture of claim 9, wherein said polymer is a polycarbonate.

30. (Amended) The article of manufacture of claim 1, wherein said digitally encoded image is printed directly on said polymer.

31. (Amended) The article of manufacture of claim 1, wherein said digitally encoded image is printed directly on said lens.

32. (Amended) The article of manufacture of claim 1, wherein said digitally encoded image is printed directly on the surface of a mold.

33. (Amended) The article of manufacture of claim 32, wherein said mold is used to form at least one surface of said polymer.

34. (Amended) The article of manufacture of claim 32, wherein said mold is used to form at least one portion of said lens.

35. (Amended) The article of manufacture of claim 1, wherein said digitally encoded image is within said lens.

36. (Amended) The article of manufacture of claim 1, wherein said digitally encoded image is laminated within said lens.

37. (Amended) The article of manufacture of claim 1, wherein said digitally encoded image is provided directly to said lens.

38. (Amended) An article of manufacture, comprising:
a) a polymer, and
b) a digitally encoded image made with ink, wherein said polymer forms a lens; further wherein at least a portion of said digitally encoded image is produced using ink jet printing; further wherein said digitally encoded image is provided directly to said polymer; further wherein said ink jet printing uses thermal printing.

39. (Amended) The article of manufacture of claim 38, wherein said digitally encoded image comprises a single color or a multi-colored image.

40. (Amended) The article of manufacture of claim 38, wherein said digitally encoded image is transparent, opaque or partially opaque.

41. (Amended) The article of manufacture of claim 38, wherein said polymer comprises a hydrogel.

42. (Amended) The article of manufacture of claim 38, wherein said lens is a soft lens, a hard lens or a hybrid lens.

43. (Amended) The article of manufacture of claim 38, wherein said lens comprises between about 0% percent and about 80% percent water.

44. (Amended) The article of manufacture of claim 38, wherein said lens is permeable to oxygen.

45. (Amended) The article of manufacture of claim 38, wherein said polymer is hydrophobic or hydrophilic.

46. (Amended) The article of manufacture of claim 38, wherein said polymer comprises a polymer selected from the group consisting of acrylics, silicones and polycarbonates.

47. (Amended) The article of manufacture of claim 38, wherein said lens is a contact lens.

48. (Amended) The article of manufacture of claim 38, wherein said digitally encoded image is printed directly on said polymer.

49. (Amended) The article of manufacture of claim 38, wherein said digitally encoded image is printed directly on said lens.

50. (Amended) The article of manufacture of claim 38, wherein said digitally encoded image is printed directly on the surface of a mold.

51. (Amended) The article of manufacture of claim 50, wherein said mold is used to form at least one surface of said polymer.

52. (Amended) The article of manufacture of claim 50, wherein said mold is used to form at least one portion of said lens.

53. (Amended) The article of manufacture of claim 38, wherein said digitally encoded image is on at least one surface of said polymer.

54. (Amended) The article of manufacture of claim 39, wherein said digitally encoded image comprises a single color image.

55. (Amended) The article of manufacture of claim 39, wherein said digitally encoded image comprises a multi-colored image.

56. (Amended) The article of manufacture of claim 40, wherein said digitally encoded image is transparent.

57. (Amended) The article of manufacture of claim 40, wherein said digitally encoded image is opaque.

58. (Amended) The article of manufacture of claim 40, wherein said digitally encoded image is partially opaque.

59. (Amended) The article of manufacture of claim 42, wherein said lens is a soft lens.

60. (Amended) The article of manufacture of claim 42, wherein said lens is a hard lens.

61. (Amended) The article of manufacture of claim 42, wherein said lens is a hybrid lens.

62. (Amended) The article of manufacture of claim 45, wherein said polymer is hydrophobic.

63. (Amended) The article of manufacture of claim 45, wherein said polymer is hydrophilic.