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Method for reducing lens hole defects in production of contact lens blanks

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(71) Applicant(s)
Johnson and Johnson Vision Products, Inc.

(72) Inventor(s)
James Jen; Michael Widman; Mehmet Burduroglu

(74) Agent/Attorney
**FREEHILLS CARTER SMITH and BEADLE,Level 47,101 Collins Street,MELBOURNE
VIC 3000**

(56) Related Art
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ABSTRACT

Improved homogeneity and uniformity of surface energy characteristics in a mold surface for hydrophilic contact lens production is achieved with
5 the temporal application of a surface active agent such as Tween 80, to facilitate wetting of the optical surface of the mold, especially the convex mold, with the reactive monomer mix.



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ORIGINAL

Name of Applicant: **JOHNSON & JOHNSON VISION PRODUCTS, INC.**

Actual Inventors: James JEN; Michael WIDMAN; Mehmet BURDUROGLU

Address for service
in Australia: **CARTER SMITH & BEADLE**
2 Railway Parade
Camberwell Victoria 3124
Australia

Invention Title: **METHOD FOR REDUCING LENS HOLE DEFECTS IN
PRODUCTION OF CONTACT LENS BLANKS**

The following statement is a full description of this invention, including the best method of performing it known to us

1 METHOD FOR REDUCING LENS HOLE DEFECTS IN PRODUCTION OF CONTACT LENS BLANKS

This invention relates to methods for reduction of defects in, and an improvement in yield, 5 in the production of contact lens blanks. More particularly, it provides measures to control and minimize lens blank defects known as lens holes.

Contact lens prepared from hydrophilic polymeric materials are now well known, and are 10 prepared commercially in great volume in highly automated manufacturing facilities. As these products are intended for intimate contact with the eye, great care is taken to assure that they meet stringent quality control standards. This can result in a 15 relatively high reject rate, adversely affecting economies in their production.

Accordingly, it is an object of the invention to control and minimize lens blank defects, specifically lens holes. Additionally, it is an 20 object to afford a method operable in high speed automated manufacturing operations to improve yields adversely affected by rejects due to lens holes. Further, it is an object to provide means for reducing lens hole defects originating in the filling operation 25 and attributable to uneven distribution of the reactive monomer mixture forming the lens blank. Finally, it is an object to provide a method for effecting even distribution of reactive monomer mix about and upon the convex or backcurve mold.

30 Processes for preparing hydrophilic hydrogel contact lens blanks have been well documented.

1 Briefly, reactive monomer mix (RMM) for the formation
of hydrophilic contact lenses is dispensed into a
concave or frontcurve mold, formed from a hydrophobic
polymer such as polystyrene, at a filling station. A
5 convex or backcurve mold is then brought into
proximate engagement with the frontcurve mold to form
and shape the lens blank therebetween. Next a
mechanically associated assembly formed from the
frontcurve mold/RMM/backcurve mold is traversed
10 through a UV curing tunnel under conditions to cure
the RMM. The cured lens blank products associated
with the forming molds are then dissociated by
removing the backcurve mold. The cured
lens/frontcurve assembly is then traversed through
15 leaching and hydration tanks, and a contact lens is
thereby produced.

The continuous process implementing the
complete manufacturing process utilizes a lens mold
manufacturing zone, comprising first and second
20 injection molding stations for the formation of
concave and convex lens molds, respectively, and
includes a transport line upon which concave and
convex lens parts may be conveyed from zone to zone;
an enclosed zone ('nitrogen tunnel') maintained under
25 nitrogen for degassing mold halves or sections; a
filling zone for filling concave mold sections with
reactive monomer composition, registering concave and
convex mold sections in aligned relation, and engaging
same in mating molding relation optionally under
30 vacuum conditions, and precuring said reactive monomer
composition with ultraviolet light to a gel-like

1 state, and a curing zone in which the cure is
completed and the finished lens blank readied for
demolding. It will be appreciated that the entire
process is integrated via transport means, generally
5 one or more conveyors upon or in relation to which
lens molds are assembled, arranged or interleaved in
the course of conveyance through the said zones or
stations in operational sequence. The lens molds may
for convenience be situated in or upon mini-pallets
10 (for example, fabricated of cast aluminum, stainless
steel or the like) containing a number of lens molds
(for example eight) arranged regularly thereon in
spatial relation correlated with the treatment
stations and the automated material transfer equipment
15 where employed. All of the conveyance belts or
tunnels are under nitrogen or inert gaseous blankets.

In greater pertinent detail, the concave or
frontcurve mold incorporating an optical molding
surface together with a peripheral zone or flange for
20 interactive engagement with the convex or backcurve
mold is traversed through a stamping station in which
the peripheral flange portion of the mold is treated
with a surfactant material without contact with the
optical surface of the mold. The mold is thereafter
25 filled, sometimes to overflowing with reactive monomer
mix whereupon the frontcurve mold is engaged in mating
relation with the convex or backcurve mold, (the
optical surface of which is typically untreated); the
paired, juxtaposed mold assembly including the RMM
30 molded therebetween, passed to a curing station and
thence to a first demolding station at which the mold

1 sections are disengaged. Facilitated by the presence
of the surfactant upon the peripheral flange of the
frontcurve mold, the excess material is separated from
the remainder of the cured lens blank and retained
5 with the convex or backcurve mold; the optical portion
of the lens then is retained by the frontcurve mold,
whereupon the excess waste material may be removed
from the backcurve mold by any suitable mechanical
means, wherefore the frontcurve mold associated with
10 the retained lens blank free of excess peripheral
material is passed to leaching and hydration stations,
ultimately to be demolded, the contact lenses to be
collected, and prepared for shipment.

As illustrated in Figures 1 and 2 injection
15 molds #1 and #2, shown at steps 101 and 102 in the
flow diagram of Figure 1, mold respectively front
curve and back curve lens mold parts or sections; they
may be located in tandem as shown in Figure 2 or to
shorten exposure to the atmosphere still further, they
20 may be located in a common plane intersecting a
bifurcated transport line, even perpendicularly
oriented thereto in the same plane.

Robotic means 103, 104 are provided adjacent
the mold registry and engagement station for receiving
25 concave and convex lens molds, respectively and
transferring said mold part to a low oxygen
environment at a high production cycle rate, as noted
at step 105.

In the course of or following complete
30 degassing of the lens mold sections as indicated at
106 in Figure 1, the pallets containing concave and

1 convex lens mold sections are ordered into interleaved
relation and degassed when enclosed in feed conveyor
such that automated equipment may effect their
operative interengagement into molding relation.

5 The sequencing conveyor 32 including the
interleaving station 40 is enclosed and pressurized
over its entire length with an inert gas, conveniently
nitrogen. The amount of nitrogen is not critical, it
being suitable to use just enough nitrogen pressure to
10 effectively exclude the atmosphere under the operating
conditions experienced. In the nitrogen tunnel
surrounding sequencing conveyor 32 the freshly
prepared lens mold blanks are degassed as indicated at
step 106 in Figure 1.

15 The concave lens molds are filled with the
reactive monomer composition at step 107 and the
concave and convex lens molds are placed into registry
and urged into complementary molding relation. The
filling and assembly zone 50 surrounds a portion of
20 the conveying or transport means 32, which delivers to
the zone pallets concave and convex lens mold
sections, respectively, and at the terminus of the
zone carries pallets of paired and filled molds to the
procure zone. The filling and assembly zone
25 illustrated in Figure 2 at 50 is defined by a
geometrically appropriate, transparent enclosure,
generally of rectangular cross-section, formed of any
suitable thermoplastic or metal and thermoplastic
construction.

30 As illustrated at 107 in Figure 1, the
concave lens mold sections are filled with degassed

1 monomer composition from step 108, and then
transported to an assembly module optionally having a
vacuum chamber formed intermittently within the
nitrogen tunnel in which filled concave lens molds are
5 engaged with convex mold sections in vertical
alignment and in mating relation, such that the
reactive monomer composition is trapped between the
optical surfaces of the respective mold sections and
at least partially sealed by the engagement of the
10 parting edge formed peripherally in each of the lens
mold sections. If present, the vacuum is released.
Then, the mated mold is passed through nitrogen to the
precure station, an integral part of the nitrogen
tunnel.

15 Following assembly of the mold parts, the
incipient lens monomer is precured at step 109 in the
precure module 60 of the present invention. The
process of the procure involves clamping the mold
halves in registration and then precuring the monomer
20 or monomer mixture to a gel like state.

 Following precure, the polymerization of the
monomer or monomer mixture is completed in curing
tunnel 75 as indicated at step 110 with irradiation.

25 In the cure zone (75), the monomer/diluent
mixture is then cured in a UV oven whereby
polymerization is completed in the monomer(s). This
irradiation with actinic visible or ultraviolet
radiation produces a polymer/solvent mixture in the
shape of the final desired hydrogel. In addition, the
30 cure zone also has a source of heat which is effective
to raise the temperature of the polymerizable

1 composition to a temperature sufficient to assist the
propagation of the polymerization and to counteract
the tendency of the polymerizable composition to
shrink during the period that it is exposed to the
5 ultraviolet radiation.

After the polymerization process is
completed, the two halves of the mold are separated
during a demolding step leaving the contact lens in
the first or front curve mold half 10, from which it
10 is subsequently removed. It should be mentioned that
the front and back curve mold halves are used for a
single molding and then discarded or disposed of.

Heating the back curve lens mold creates
differential expansion of the heated mold polymer
15 relative to the cooler lens polymer which shifts one
surface with respect to the other. The resultant
shear force breaks the polymerized lens/polymer mold
adhesion and assists in the separation of mold
portions. The greater the temperature gradient
20 between the surfaces of the mold portions, the greater
the shearing force and the easier the mold portions
separate. This effect is greatest when there is
maximum thermal gradient. As time continues, heat is
lost through conduction from the back mold portion
25 into the lens polymer and the front mold portion, and
then collectively into the surrounding environment.
The heated back mold portion is, therefore, promptly
removed so that very little energy is transferred to
the polymer lens, avoiding the possibility of thermal
30 decomposition of the lens. The heating may be
accomplished by techniques known to one skilled in the

1 art such as by steam, laser and the like. The process
of laser demolding is described in U.S. Patent No.
5,294,379 to Ross et al.

5 If the heating step is hot air or steam,
after the heating step, the back curve is pried from
the front curve and mold in the mold assembly, as
indicated at Step 111. If on the other hand, the
heating is by laser or infrared, no prying is used and
the back curve separates spontaneously from the front
10 curve.

The demolding assemblies of the mold
separation apparatus 90 each physically pry the back
curve mold half 30 from the front curve half 10 of
each contact lens mold to physically expose each
15 contact lens situated in the lens mold for conveyance
to a hydration station for hydration of the lenses.
The prying process occurs under carefully controlled
conditions, so that the back curve half 30 will be
separated from the front curve half 10 without
20 destroying the integrity of the lens formed in the
lens mold.

After the mold assemblies have been
separated in the demold apparatus 90, each pallet
containing the front curve mold halves with an exposed
25 polymerized contact lens therein, is subsequently
transported to a hydration station for hydration and
demolding from the front curve lens mold, inspection
and packaging, as indicated at Step 112.

In the course of commercial operations
30 including high speed production of lenses in volume, a
small member of defects can seriously affect yield,

1 and resultant economics of the process. This is particularly the case where, in consequence of the use of automated manufacturing equipment a defect in a single lens can result in the loss of a larger number
5 of lenses with which it is associated for example in the course of being transferred via integral pallets or frames from one manufacturing station to another.

Lens defects occur for many reasons, including simple misalignment of manufacturing
10 equipment, but as the latter is readily correctable through engineering adjustment, interest is focussed principally on lens holes and puddles formed in the course of filling and curing steps, employing the reactive monomer mix (RMM).

15 Lens holes include voids i.e. areas which contain no monomer, pits i.e. areas of nonuniform thickness, and other similar regularities such as uneven edges, being a function of the efficiency of spreading of the reactive monomer mix on the surface
20 of the convex backcurve mold when the two mold halves are joined.

Puddles, another lens defect, in random or tree branch shapes generally found along the lens edge, are generated during the curing step, and are
25 associated with the concave or frontcurve mold.

High speed photography has demonstrated the formation of lens holes in the filling operation during the spreading of the advancing meniscus of the RMM upon the convex or backcurve mold. However, the
30 occurrence of the defect is apparently indiscriminate, especially considering the number of sound lenses

1 produced in the same manner on the same equipment. It
had already been established that on a macro scale,
RMM wets the polystyrene mold surface well.

5 However, fundamental studies (based upon
work reported by R. H. Dettre and R. E. Johnson Jr. J.
Phys. Chem. 68, 1507 (1096) and in Surface and Colloid
Science, E. Matijevic, Ed., Wiley-Interscience, NY
1969, 161.2 pp. 85 and S.P. Wesson, TRI Progress
10 Report # 49, Textile Research Institute, Princeton
N.J. August 23, 1992) showed that the mold surface,
formed of a hydrophobic polymer such as polystyrene,
was a low energy heterogeneous surface having a small
portion of high energy surface domains. This was
15 consistent with knowledge that the molding resins were
typically fabricated for injection molding purposes to
contain certain additives including mold release
agents, which could provide the high energy domains on
the mold surface.

20 There was in consequence established the
need for means to modify the surface activity at the
interface between the convex or backcurve mold and the
reactive monomer mix, in the context of dynamic lens
formation during molding and in particular, during the
original contact with the RMM, and the advancing
25 meniscus thereof onto and across the convex mold. In
particular, it was desired to establish during molding
an increase in the high energy surface area exhibited
by the convex mold.

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1 In order to implement the high-speed and
mass-production molding of such hydrophilic contact
lenses, there have been developed two-part molds
incorporating pallet-supported mold structures; for
5 example, as disclosed in U.S. Patent No. 4,640,489 to
Larsen, and methods of forming shaped polymeric
hydrogel articles, such as hydrophilic contact lenses,
elucidated in the disclosures of U.S. Patent Nos.
4,680,336 and 5,039,459 to Larsen et al.

10 The release of hydrophilic contact lenses
from adherent mold surfaces subsequent to the
completion of the contact lens molding process can be
facilitated or improved upon, as is set forth in the
disclosure of U.S. Patent 5,264,161 to Druskis et al.
15 In that instance, surfactants are introduced in
solution into a hydration bath employed in the molding
cavities for molding the hydrophilic polymeric
structures or contact lenses. The surfactant which is
dispersed in the hydration bath in concentrations not
20 exceeding 10% by weight aids in facilitating release
of the lenses from adherent contiguous mold surfaces
being separated, the function of such surfactant being
to reduce the surface tension properties of water or
liquids, and to thereby reduce the level of adherence
25 between components consisting, on the one hand, of the
contact lenses and, on the other hand, the mold
surfaces which become adherent during molding.
Numerous types of surfactants are disclosed in this
patent publication, such as polymeric surfactants
30 including polyoxyethylene sorbitan mono-oleates,
which are especially suitable for releasing in an

undamaged state any hydrophilic polymer articles from adherent mold surfaces which are constituted of plastic materials.

U.S. Patent 4,159,292 describes the use of silicone wax, stearic acid and mineral oil as additives for plastic mold compositions to improve the contact lens release from the plastic molds.

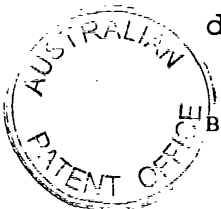
The use of surface applied surfactants as release agents in connection with the manufacturing of hydrogel contact lenses is disclosed and claimed in commonly assigned U.S. Patent 5,542,978. In that patent, a thin layer or film of a surfactant such as Tween 80 is applied via a stamping head to surface regions extending about, i.e., peripherally of the front curve of a mold part for the forming of contact lenses, to facilitate the lens release upon demolding of all or part of the peripheral rings of RMM material expressed externally of the mold by virtue of overrun during filling. In this application, no surface active material is applied to the portion of the mold defining the optical face of the lens.

The present invention is directed to a method for the modification of the surface energy of hydrophobic contact lens molds to improve wettability and release characteristics thereof to reactive monomer mixtures for hydrophilic hydrogel contact lenses, comprising predominantly acrylate monomers, said method comprising coating the surface of each of the mating optical surfaces of said molds with a surfactant in an effective amount of 0.05 to 0.5% by weight of a solution or dispersion, prior to contact of said mold surfaces with said reactive monomer mixture wherein a method for the modification of the surface energy of hydrophobic contact lens molds to improve wettability and release characteristics thereof to reactive monomer mixtures for hydrophilic hydrogel contact lenses, comprising predominantly acrylate monomers,



said method comprising coating the surface of each of the mating optical surfaces of said molds with a surfactant in an effective amount of 0.05 to 0.5% by weight of a solution or dispersion, prior to contact of said mold surfaces with said reactive monomer mixture wherein said surfactant is coated on one of said surfaces in an amount greater than the other of said surfaces such that said one surface has greater wettability and release characteristics than said other surface.

10 The present invention further relates to a method for producing hydrogel contact lens blanks comprising forming a lens blank from a UV curable monomer composition adapted for hydrogel contact lenses between mating concave and convex mold surfaces including the steps of depositing the monomer composition in and upon the concave mold surface and engaging the monomer composition with the mating convex mold surface to thereby conform the monomer mixture into the contact lens shape for UV curing, the improvement which comprises applying to the contact surfaces of each mold a surface active agent, to increase the surface area comprising high surface energy domains, in an amount sufficient to reduce lens hole defects realized in contact lens blanks so produced; wherein a method for producing hydrogel contact lens blanks comprising forming a lens blank from a UV curable monomer composition adapted for hydrogel contact lenses between mating concave and convex mold surfaces including the steps of depositing the monomer composition in and upon the concave mold surface and engaging the monomer composition with the mating convex mold surface to thereby conform the monomer mixture into the contact lens shape for UV curing, the improvement which comprises applying to the contact surfaces of each mold a surface active agent, to increase the surface area comprising high surface energy domains, in an amount sufficient to reduce lens hole defects



realized in contact lens blanks so produced; wherein said surface active agent is applied to said convex mold surface in an amount greater than said concave mold surface such that said convex mold surface has greater wettability and release characteristics than said concave mold surface.

The present invention is still further directed to a method for the modification of the contact surface of only a convex mold comprised of polystyrene for the production of hydrogel contact lens blanks, to increase the surface areas of high energy domains, thereby to increase the wettability of said surface by a hydrophilic monomer composition for the molding of hydrogel contact lens blanks comprising providing to said contact surface in or prior to the molding cycle a uniform application of a surfactant sufficient to reduce lens hole defects in said contact lens blanks.



1 In accordance with the invention, there is
provided a method for minimizing lens hole defects in
the manufacture of hydrogel contact lens comprising
modifying the surface energy characteristics of the
5 convex or backcurve mold surface for contact with the
reactive monomer mixture for said hydrogel contact
lens structures. More specifically, the high energy
surface area in the contact face of the convex or
backcurve mold is modified to enhance its wettability
10 by the reactive monomer mix. In a preferred
embodiment, the convex mold is pretreated by
application of a surface active agent to at least the
contact face of the mold by applying, as by spraying,
dipping or any other suitable means.

15 Such pretreatment may be effected, for
example, by spraying on the contact face of the convex
mold a surfactant such as Tween 80, Glucam P40 or
Glucam DOE 120 appropriately in a solvent vehicle
therefor such as water, alcohol or mixtures thereof,
20 to provide a concentration of 0.05 to 5.0% w/w of
surfactant. The pretreatment may be applied in
conjunction with i.e. to precede each mold cycle or
may be effected intermittently, to maintain the
required surface energy requirements for reduction of
25 lens hole defects. The amount of surfactant to be
employed will also be gauged by a certain balance
between measures taken to ensure desired lens release
preferentially from the convex molding surface at this
stage; and lens demolding from the concave or

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1 frontcurve mold following cure. Thus, in another
embodiment, the concave or frontcurve mold may be
formed from a composition incorporating a compatible
agent such as zinc stearate whereas the surface of the
5 convex or backcurve mold is treated periodically with
a surfactant in accordance with this invention as
aforesaid.

In this manner, it has been shown that lens
hole defects can be reduced by as much as several
10 percent in a high speed automated pilot production
line thereby effecting substantial economic savings
while increasing efficiency of the manufacturing
operation.

Figure 1 is a flow diagram of the continuous
15 process for contact lens production, including
molding, treatment and handling of the molds and
contact lenses in a low oxygen environment.

Figure 2 is a top elevational planar view of
the production line system.

20 In accordance with the invention, the
interfacial tension between the reactive monomer mix,
more specifically the advancing meniscus thereof, and
the optical surface of the convex or backcurve mold is
controlled and minimized by normalizing and extending
25 the surface areas representing high surface energy
domains in the convex mold contact surface. This is
accomplished by the temporal or transient application
of a surfactant to the optical surface of the convex
mold in amount and characteristics effective to
30 increase the population of the high surface energy
areas on the convex mold surface to afford improved

1 wettability by the RMM and effecting a differential in
surface energy as between the respective mold halves,
to overcome the energy required to separate the two
mold halves so to preferentially effect the retention
5 of the optical lens portion on the frontcurve mold.

Thus, it will be appropriate to consider the
surface characteristic expressed in and upon the
frontcurve mold in applying the precepts of this
invention, as it is desired to assure that the lens
10 blank be demolded preferentially from one mold surface
consistently throughout the manufacturing process,
usually (and as described herein) from the convex
mold, thereby permitting the retention of the lens
blank in the concave frontcurve mold for traverse to
15 and through the remaining manufacturing stages. In
consequence, it is necessary to take into account,
relative to the type and amount of surfactant to be
applied to the convex mold surface, whether the
frontcurve or concave mold has itself been pretreated,
20 usually by an internal additive such as zinc stearate
to modify the release characteristics of the mold
surface. More specifically, one implements the
practice of the present invention in such manner as to
assure that, relative to the surface energy retentive
25 characteristics of one mold surface, that a certain
effective differential be induced in the second mold
surface, to effect preferential displacement on a
consistent basis throughout the manufacturing process.
As aforesaid, it is understood that it is preferred
30 that the differential referred to favors release from
the convex surface, especially because the benefits of

1 reduced lens defects arising from poor wetting of the
convex surface with RMM can thereby also be realized.

The nature of the surfactant material
employed herein is not critical, insofar as it is
5 capable in wetting characteristics relative to RMM and
in differential release characteristics relative to
the companion mold surface to which it is not applied
to achieve the benefits of the invention as outlined
herein. Naturally, to the extent that the surfactant
10 is absorbed into the RMM, or remains to a certain
extent on the surface of the lens after hydration, it
will be selected with regard to its physiological or
pharmaceutical acceptability for human use in eye
contact. The surface tension modifying
15 characteristics of the surfactant material in the
circumstances obtaining will be assessed relative to
the desired differential release property; and the
surface energy modifying characteristics will be
assessed relative to the enhanced wettability for the
20 RMM in relation to the mold surface (in particular,
the convex mold surface, as aforesaid) in a manner
well known to the artisan. The surfactant material is
also selected for compatibility with the mold
materials and the reactive monomer mix. While, as a
25 consequence, amounts to be applied may differ in
response to these characteristics, it has been found
that in most cases, a selected application to the mold
surface in the range of 0.05 to 5.0 weight % of a
solution of the surfactant material is sufficient,
30 usually 0.05 to 2.0 weight %.

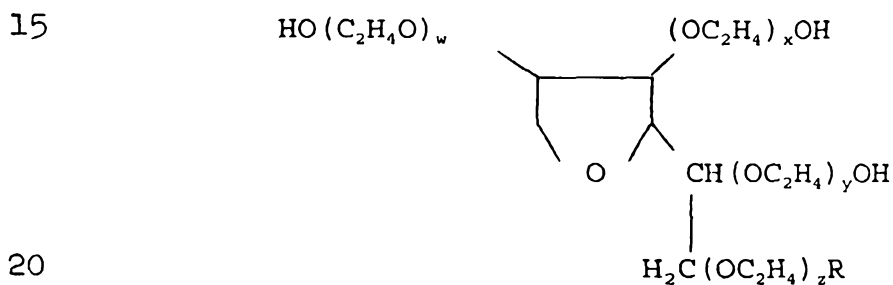
1 In addition to the advantages afforded by
reduced lens hole defects in the differential release
of the mold halves in or following the curing stage,
the application of the surfactant where applied to the
5 frontcurve mold remains effective in facilitating
release of the contact lens blank from the mold
surface after hydration, that is, release from the
concave or frontcurve mold, without application of
heat or special mechanical manipulation.

10 Among otherwise suitable surfactants, anti-
static agents, ionic surfactants, non-ionic
surfactants or lubricant formulations may be employed
in the present invention. Suitably, the surfactant
constitutes a solution or dispersion of the surface
15 active agents in an essentially inert vehicle to
facilitate application to the mold surface by
spraying, wiping, vapor deposition, sponging, dipping
or the like. Thus, water, an alkanol or mixtures
there may be satisfactorily and economically used to
20 constitute a solution or dispersion of the surface
active agent.

 Among the materials found to not only aid in
wettability of the mold surface but also to retain
effective release characteristics for lens demolding
25 from the frontcurve mold (where so applied) after
hydration and equilibration in saline are Tween 80, a
polyethylene oxide sorbitan monooleate, Glucamate DOE-
120, and ethoxylated (120) methyl glucoside dioleate,
and Glucam P-10, a 10 mole propoxylate of
30 methylglucose, available from Amerchol Corporation.
Generally, water soluble or water dispersible

1 materials are preferred for ease of application. As
the mold materials are typically manufactured from
hydrophobic materials such as polypropylene or
polystyrene, the wettability efficiency for these
5 materials is significant .

Preferably, the surfactant is constituted of
Tween 80 (registered trademark); i.e., a Polysorbate
80. This is basically polyethylene oxide sorbitan
mono-oleate or the like equivalent, and consists of an
10 oleate ester of sorbitol and its anhydrides
copolymerized with approximately 20 moles of ethylene
oxide for each mole of sorbitol and sorbitol
anhydrides, of generally the formula:



[Sum of w, x, y, z is 20; R is $(C_{17}H_{33})COO$]

Other materials suitable for use include the
25 pharmaceutically acceptable ethoxylated amines and
quaternary ammonium compounds such as Larostat 264 A
(a soy dimethyl ethyl ammonium ethosulfate sold by
PPG), Armostat 410 (an ethoxylated tertiary amine sold
by Akzo), Cystat SN (3-lauramidopropyl
30 trimethylammonium methyl sulfate sold by Cytec) and
Atmer 163 (N,N-bis (2-hydroxyethyl) alkylamine)).

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1 Other quaternary compounds include the diamidoamines,
the imidazoliniums, the dialkyl dimethyl quaternaries,
the dialkoxy alkyl quaternaries, and the monoalkyl
5 trimethyl quaternaries. Certain of these materials
offer the further advantage of being soluble in RMM
and hence are conveniently resorbed into the lens
material, leaving the mold surface unaffected upon
release and therefore more readily recycled for
10 further use, without cleansing to a base, or neutral
condition.

Generally, suitable surfactant materials may
be selected from those disclosed in Kirk Othmer,
Encyclopedia of Chemical Technology, Vol. 22, p. 379-
384 (1983).

15 The surface active agent may be applied to
the mold surface by spraying or swabbing or dipping,
as aforesaid, such that the surface is evenly coated
therewith. The mold is merely drip-dried with or
without the aid of heat and stockpiled for use in the
20 manufacturing process. The amount of surfactant so
applied is adapted to provide a uniform coating of a
0.05 to 0.5 weight % solution of surfactant on the
surface of the mold, as aforesaid.

The application of the surfactant may
25 alternately be suitably integrated with the
manufacturing process such that the mold may be
treated immediately prior to their interpolation with
the transport mechanism, or just prior to the filling
operation, such that the surface thereof is fully
30 wetted, i.e., undried at the point of contact with the
reactive monomer mixture. In an alternative

1 embodiment, the surfactant material such as Tween 80
may be incorporated in the reactive monomer mix at
concentrations selected to reduce and control lens
hole defects without inducing puddling on the concave
5 mold.

The molds can be made from any thermoplastic
material which is suitable for mass production and can
be molded to an optical quality surface and with
mechanical properties which will allow the mold to
10 maintain its critical dimensions under the process
conditions employed in the process discussed in detail
below, and which will allow polymerization with the
initiator and radiant energy source contemplated. The
concave and convex mold members can thus be made from
15 thermoplastic resins. Examples of suitable materials
include polyolefins such as low, medium, and high
density polyethylene, polypropylene, including
copolymers thereof; poly-4-methylpentene; and
polystyrene. Other suitable materials are polyacetal
20 resins, polyacrylethers, polyarylether sulfones, nylon
6, nylon 66 and nylon 11. Thermoplastic polyesters
and various fluorinated materials such as the
fluorinated ethylene propylene copolymers and ethylene
fluoroethylene copolymers may also be utilized.

25 It has been found that with the need for a
high quality, stable mold and especially for the use
of a plurality of molds in high volume operations the
choice of material for the molds is significant. In
the present invention the quality of production is not
30 assured by individually inspecting and sorting each
lens for power and curvature. Instead the quality is

1 assured by keeping the dimensions of each individual
mold member within very tight tolerances and
processing molds in particular sequential steps to
give all lenses equal treatment. Since polyethylene
5 and polypropylene partly crystallize during cooling
from the melt there is a relatively large shrinkage
giving dimensional changes difficult to control.
Thus, it further has been found that the most
preferred material for the molds used in the present
10 process is polystyrene which does not crystallize, has
low shrinkage, and can be injection molded at
relatively low temperature/to surfaces of optical
quality. It will be understood that other
thermoplastics, including those mentioned above, may
15 be used provided they have these same properties.
Certain copolymers or blends of polyolefins that
exhibit these desirable characteristics are also
suitable for the present purposes as are polystyrene
copolymers and blends having such characteristics, as
20 described more fully in U.S. Patent No. 4,565,348.

The soft contact lens blanks are formed from
a reactive monomer composition which typically
incorporates in addition to the reactive monomer a
water displaceable diluent in the case of the
25 preparation of a hydrophilic lens, a polymerization
catalyst to assist in curing the reactive monomer, a
cross-linking agent and often a surfactant to aid in
mold release.

The curable compositions preferably include
30 copolymers based on 2-hydroxyethyl methacrylate
("HEMA") and one or more comonomers such as 2-

1 hydroxyethyl acrylate, methyl acrylate, methyl
methacrylate, vinyl pyrrolidone, N-vinyl acrylamide,
hydroxypropyl methacrylate, hydroxyethyl acrylate,
hydroxy propyl acrylate, isobutyl methacrylate,
5 styrene, ethoxyethyl methacrylate, methoxy
triethyleneglycol methacrylate, glycidyl methacrylate,
diacetone acrylamide, vinyl acetate, acrylamide,
hydroxytrimethylene acrylate, methoxyethyl
methacrylate, acrylic acid, methacrylic acid,
10 glyceryl methacrylate, and dimethylamino ethyl
acrylate.

Preferred polymerizable compositions are
disclosed in U.S. Patent No. 4,495,313 to Larsen, U.S.
Patent No. 5,039,459 to Larsen et al. and U.S. Patent
15 No. 4,680,336 to Larsen et al. Such compositions
comprise anhydrous mixtures of a polymerizable
hydrophilic hydroxy ester of acrylic acid,
displaceable ester of boric acid and a polyhydroxyl
compound having preferably at least 3 hydroxyl groups.
20 Polymerization of such compositions, followed by
displacement of the boric acid ester with water,
yields a hydrophilic contact lens. The mold assembly
utilized in the present invention may be employed to
make hydrophobic or rigid contact lenses, but the
25 manufacture of hydrophilic lenses is preferred.

The polymerizable compositions preferably
contain a small amount of a cross-linking agent,
usually from 0.05 to 2% and most frequently from 0.05
to 1.0%, of a diester or triester. Examples of
30 representative cross linking agents include: ethylene
glycol diacrylate, ethylene glycol dimethacrylate,

- 1 1,2-butylene dimethacrylate, 1,3-butylene
dimethacrylate, 1,4-butylene dimethacrylate, propylene
glycol diacrylate, propylene glycol dimethacrylate,
diethylglycol dimethacrylate, glycol dimethacrylate,
5 diethylglycol dimethacrylate, dipropylene glycol
dimethacrylate, diethylene glycol diacrylate,
dipropylene glycol diacrylate, glycerine
trimethacrylate, trimethylol propane triacrylate,
trimethylol propane trimethacrylate, and the like.
10 Typical cross-linking agents usually, but not
necessarily have at least two ethylenically
unsaturated double bonds.

The polymerizable compositions generally
also include a catalyst, usually from about 0.05 to 1%
15 of a free radical catalyst. Typical examples of such
catalysts include lauroyl peroxide, benzoyl peroxide,
isopropyl percarbonate, azobisisobutyronitrile and
known redox system such as the ammonium persulfate-
sodium metabisulfite combination and the like.

20 Irradiation by ultraviolet light, electron beam or a
radioactive source may also be employed to catalyze
the polymerization reaction, optionally with the
addition of a polymerization initiator.

Representative initiators include camphorquinone,
25 ethyl-4-(N,N-dimethyl-amino)benzoate, and 4-(2-
hydroxyethoxy)phenyl-2-hydroxyl-2-propyl ketone.

Polymerization of the polymerizable
composition in the mold assembly is preferably carried
out by exposing the composition to polymerization
30 initiating conditions. The preferred technique is to
include in the composition initiators which work upon

1 expose to ultraviolet radiation; and exposing the
composition to ultraviolet radiation of an intensity
and duration effective to initiate polymerization and
to allow it to proceed. For this reason, the mold
5 halves are preferably transparent to ultraviolet
radiation. After the precure step, the monomer is
again exposed to ultraviolet radiation to a cure step
in which the polymerization is permitted to proceed to
completion. The required duration of the remainder of
10 the reaction can readily be ascertained experimentally
for any polymerizable composition.

The mold assembly comprises at least two
pieces, a female concave piece (frontcurve) and a male
convex piece (backcurve), forming a cavity
15 therebetween, and when said pieces are mated, at least
one piece having a flange thereabout. More
particularly, the mold assembly comprises a front mold
half and a back mold half in contact therewith,
thereby defining and enclosing a cavity therebetween ,
20 and a polymerizable composition in said cavity in
contact with said mold halves, the front mold of which
has a central curved section with a concave section
with a concave surface, a convex surface and circular
circumferential edge, wherein the portion of said
25 concave surface in contact with said polymerizable
composition has the curvature of the frontcurve of a
contact lens to be produced in said mold assembly and
is sufficiently smooth that the surface of a contact
lens formed by polymerization of said polymerizable
30 composition in contact with said surface is optically
acceptable, said front mold also having an annular

1 flange integral with and surrounding said circular
circumferential edge and extending therefrom in a
plane normal to the axis and extending from said
flange, while the back mold has a central curved
5 section with a concave surface, convex surface and
circular circumferential edge, wherein the portion of
said convex surface in contact with said polymerizable
composition has the curvature of the backcurve of a
contact lens to be produced in said mold assembly and
10 is sufficiently smooth that the surface of a contact
lens formed by polymerization of the polymerizable
composition in contact with said surface is optically
acceptable, said backcurve also having an annular
flange integral with and surrounding said circular
15 circumferential edge and extending therefrom in a
plane normal to the axis of said convex structure, and
a generally triangular tab situated in a plane normal
to said axis and extending from said flange, wherein
the convex structure of said back mold half contacts
20 the circumferential edge of the front mold half.

The inner concave surface of the front mold
half defines the outer surface of the contact lens,
while the outer convex surface of the base mold half
defines the inner surface of the contact lens which
25 rests upon the edge. Specifics of such constructions
are known having reference to U.S. Patent 4,640,489 to
Larsen.

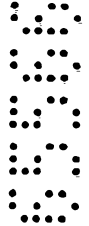
In accordance with the invention, a convex
mold surface which has been pretreated with the
30 surfactant, as aforesaid. is brought into mating
engagement with a frontcurve mold and the reactive

1 monomer mix filling the molding cavity therebetween,
during which process the optical surface of the convex
mold contacts and by reason of its modified surface is
efficiently wetted by the RMM such that the advancing
5 meniscus uniformly coats the mold surface without the
formation of lens hole defects. The convex mold, when
mechanically separated from the concave mold by reason
of its modified surface, efficiently (and consistently
throughout the process, involving an interaction of
10 similarly treated molds) releases the lens blank
(which remains with the concave mold for curing)
without tearing or otherwise damaging the lens blank.

In a preferred embodiment, the frontcurve
mold is formed from a composition which comprises an
15 added mold release agent such as zinc stearate, which
aids in demolding of the lens blank after hydration.
In consequence, its surface energy characteristics
have been modified and an additional level of
surfactant may be required in application to the
20 convex mold surface to balance the release
characteristics in such manner as to assure release of
the lens blank for retention by the concave or
frontcurve mold surface.

It will be understood in connection with the
25 foregoing description that the concepts as well as
theoretical considerations affecting demolding are
entirely distinct from the problem of adequately
wetting the surface of the forming mold with the
monomer composition although each consideration is
30 interrelated to the other in practice, i.e., one may
successfully demold a lens blank which, however, is

1 defective due to one or more lens holes. The contact
portion of the convex lens mold in particular must be
receptive to the monomer composition at the point and
time of application under the conditions then
5 obtaining, in the sense that it requires a critical
wettability controlling efficient spreadability across
the contact surface of the mold to be established, by
increasing the surface area comprising high surface
energy domains in the convex mold contact surface.
10 While the invention has been described with
particular reference to application of the surfactant
to the optical surface of the convex mold in a
particular manufacturing operation, including a
generally vertical disposition of the mating mold
15 elements with the concave member generally supporting
the incipient lens blank in a supine or lower
position, it will be understood that to effect
preferential displacement of the lens blank as, for
example, in other geometric arrangements the
20 surfactant may be applied to the optical surface of
either lens mold surface.



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EXAMPLE 1

Convex molds were immersed in 2% aqueous solutions of Larostat 264 A (PPG), Armostat 410 (Akzo) and Cystat SN (Cytec), respectively, and then dried under ambient conditions for 48 hours. The thus formed coating rendered the surface more wettable by the RMM, a HEMA based composition.

When the treated molds were employed in an automated pilot manufacturing facility, lens mold defects were reduced by about 34.6%.

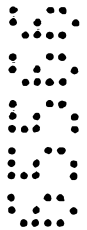
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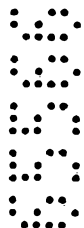


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EXAMPLE 2

Polystyrene contact lens molds were swabbed with Glucam P-10, Tween 80 and an aqueous dispersion of Glucam DOE 120, respectively, and the molds were
5 utilized in molding contact lenses employing a reactive monomer mix comprising 96.8% HEMA, 1.97% methacrylic acid, 0.78% ethylene glycol dimethacrylate, and 0.1% of trimethylolpropane trimethacrylate and 0.34% of Darvocur 1173 dispersed
10 (48% RMM) in glycerin boric acid ester as an inert water displaceable diluent. The mold halves were readily separated without defects.

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EXAMPLE 3

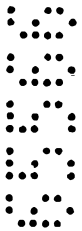
Dimethyl tallow ammonium chloride in solvent/propellant was sprayed onto the optical surface of a backcurve mold. A toner powder test showed that the surfactant actives were well dispersed across the mold surface.

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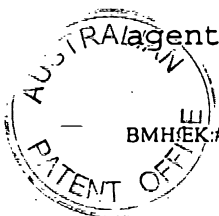
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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A method for the modification of the surface energy of hydrophobic contact lens molds to improve wettability and release characteristics thereof to reactive monomer mixtures for hydrophilic hydrogels contact lenses, comprising predominantly acrylate monomers, said method comprising coating the surface of each of the mating optical surfaces of said molds with a surfactant in an effective amount of 0.05 to 0.5% by weight of a solution or dispersion, prior to contact of said mold surfaces with said reactive monomer mixture wherein said surfactant is coated on one of said surfaces in an amount greater than the other of said surfaces such that said one surface has greater wettability and release characteristics than said other surface.

2. The method of Claim 1 wherein said contact lens molds are consisting essentially of polystyrene.

3. In a method for producing hydrogel contact lens blanks comprising forming a lens blank from a UV curable monomer composition adapted for hydrogel contact lenses between mating concave and convex mold surfaces including the steps of depositing the monomer composition in and upon the concave mold surface and engaging the monomer composition with the mating convex mold surface to thereby conform the monomer mixture into the contact lens shape for UV curing, the improvement which comprises applying to the contact surfaces of each mold a surface active agent, to increase the surface area comprising high surface energy domains, in an amount sufficient to reduce lens hole defects realized in contact lens blanks so produced; wherein said surface active agent is applied to said convex mold surface in an amount



greater than said concave mold surface said that said convex mold surface has greater wettability and release characteristics than said concave mold surface.

5 4. The method of Claim 3, wherein the monomer composition is hydrophilic.

 5. The method of Claim 3, wherein the convex mold is composed of a hydrophobic polymer.

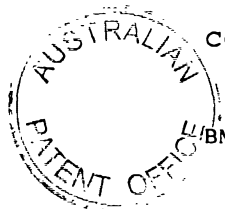
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 6. The method of Claim 5, wherein the hydrophobic polymer is polystyrene.

 7. A method for the modification of the contact surface of only a convex mold comprised of polystyrene for the production of hydrogel contact lens blanks, to increase the surface areas of high energy domains, thereby to increase the wettability of said surface by a hydrophilic monomer composition for the molding of hydrogel contact lens blanks comprising providing to said contact surface in or prior to the molding cycle a uniform application of a surfactant sufficient to reduce lens hole defects in said contact lens blanks.

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25 8. The method of Claim 1 wherein said one surface is convex.

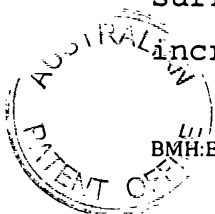
 9. In a method for producing hydrogel contact lens blanks comprising forming a lens blank from a UV curable monomer composition adapted for hydrogel contact lenses between mating concave and convex mold surfaces including the steps of depositing the monomer composition in and upon the concave mold surface and engaging the monomer composition



with the mating convex mold surface to thereby conform the monomer composition into the contact lens shape for UV curing, the improvement which comprises incorporating a surface active agent within the monomer composition prior to the step of depositing, releasing said surface agent from said monomer composition subsequent the step of depositing, said surface agent being released onto contact surfaces of each mold to increase the surface area comprising high surface energy domains in an amount sufficient to reduce lens hole defects realised in contact lens blanks so produced.

10. A method for the modification of the surface energy of a convex hydrophobic contact lens mold to improve wettability and release characteristics thereof to reactive monomer mixtures for hydrophilic hydrogel contact lenses, comprising predominantly acrylate monomers, said method comprising coating the surface of only the convex mating optical surface of said mold with a surfactant in an effective amount of 0.05 to 0.5% by weight of a solution or dispersion, prior to contact of said mold surface with said reactive monomer mixture.

11. In a method for producing hydrogel contact lens blanks comprising forming a lens blank from a UV curable monomer composition adapted for hydrogel contact lenses between mating concave and convex mold surfaces including the steps of depositing the monomer composition in and upon the concave mold surface and engaging the monomer composition with the mating convex mold surface to thereby conform the monomer mixture into the contact lens shape for UV curing, the improvement which comprises applying to the contact surface of only the convex mold a surface active agent, to increase the surface area comprising high surface energy



domains, in an amount sufficient to reduce lens hole defects realized in contact lens blanks so produced.

12. A method of producing hydrogel blanks substantially as hereinbefore described with reference to the examples and drawings.

13. A lens produced by any one of claims 1 to 12.

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DATED: 31 January 2000

CARTER SMITH & BEADLE

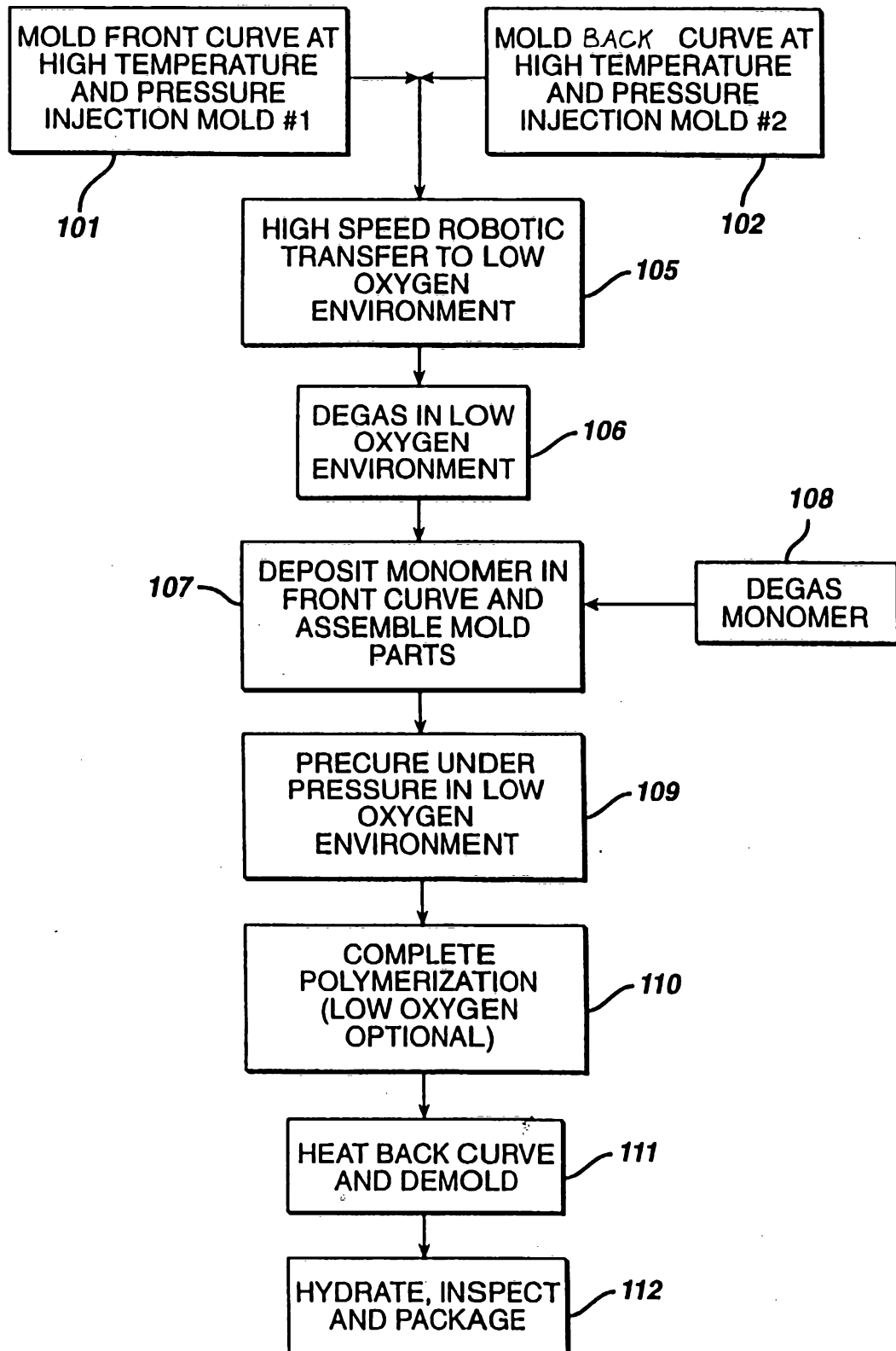
Patent Attorneys for the Applicant:

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JOHNSON & JOHNSON VISION PRODUCTS INC

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FIG. 1

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FIG. 2

